

South Texas Reference Laboratories

Client Services Room: 344B Medical School Building

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Hours of Operation: Monday-Friday 7:30am to 5:30pm

Clinical and Molecular Cytogenetics Laboratory: The UT Health Clinical and Molecular Cytogenetics Laboratory is a state of art clinical laboratory providing diagnostic testing services to not only the UT Health Physicians but other partners like Baptist Health System, San Antonio Military Medical Center, University of Texas Medical Branch in Galveston, TX and surrounding regional medical centers. The laboratory also provides research testing services to collaborators at the Mays Cancer Center, Greehey Children's Cancer Research Institute, UT Health San Antonio, and collaborators across the United States. The laboratory excels in providing quality service in both clinical and research arenas.

Cytopathology Laboratory: The Cytopathology Laboratory diagnoses malignant and premalignant lesions and diseases on the microscopic level. Our cytology lab currently processes and analyzes specimens submitted for the Thin Prep Pap Test. The Pap Test is one of the most successful cancer-screening tools ever developed, reducing deaths from cervical cancer by about 70 percent. The Cytopathology Laboratory collaborates with the Molecular Diagnostic Laboratory to help manage patient care and achieve precise results. Thin Prep Pap Test samples are shared for a combination of tests performed in both areas.

Electron Microscopy Laboratory: is a full-service facility that provides technical and professional support for patient care and research studies that require transmission and scanning electron microscopy.

Fungus Testing Laboratory: Fungal identification, antifungal susceptibility testing of yeasts and molds, measurement of levels of antifungal agents in biological tissues and fluids, molecular identification and strain relatedness studies, clinical trials, environmental sampling analysis, and drug discovery research.

Flow Cytometry Laboratory: Immunophenotypic analysis by multiparameter flow cytometry which is useful in the diagnosis/classification of acute leukemia, non-Hodgkin's lymphoma and the detection of residual leukemia/lymphoma following therapy. Also, panels for detection of Paroxysmal Nocturnal Hemoglobinuria (PNH) clones and detection of hemoglobin F in feta-maternal hemorrhage are offered.

Histopathology Laboratory: Offers biopsy and consultation services for bone marrow, breast, gynecologic, liver, oral, prostate, renal, skin, and skeletal muscle services utilizing routine, immunofluorescence, immunohistochemistry, in-situ hybridization, special stains, and muscle enzyme studies.

Molecular Diagnostics Laboratory: Molecular diagnostic tests for nucleic acid targets found in hematopathology, solid tumors, genetic disease, and infectious disease. Techniques such as next generation sequencing, real-time quantitative PCR, and capillary electrophoresis are used. Results of PML::RARA can be reported within 24-48 business hours of receiving sample.

Oral and Maxillofacial Pathology Laboratory: We offer a comprehensive, computerized service that processes biopsy and cytology specimens from the oral cavity and head and neck region. The laboratory is staffed by two pathologist board certified by the American Board of Oral and Maxillofacial Pathology. We are also supported by a major health center with a large general and specialty surgical pathology faculty.

Test Name: Routine Chromosome Analysis on Peripheral Blood (RCA-BL)

1. CPT Code(s): 88230, 88262, 88280, 88291
2. Synonym(s): High Resolution Chromosome Analysis / Chromosome Analysis
3. Performed: In-House
4. Methodology: PHA stimulated short-term culture; chromosome preparation and banding; microscopic analysis and karyotype; interpretation and report.
5. Panel/Profile Components: N/A
6. Critical Values: STAT, including infants 6 months or younger: Preliminary results in 24 hours
7. Specimen Collection / Handling Requirements:
 - a. Peripheral blood collected in green top - sodium heparin tube
 - b. Store and ship at room temperature
 - c. Avoid freezing or heating
 - d. Ship within 24 hours
 - e. Delay > 24 hours – Refrigerate the sample
 - f. A complete requisition slip must accompany all specimens and the specimen must be labeled with the patient's name and identification number.
 - g. ANY SPECIMENS RECEIVED WITHOUT A COMPLETE REQUISITION OR AN UNLABELED SPECIMEN WILL BE REJECTED.
 - h. All requisitions must have a valid ICD-10 code/clinical indication and must have the name of an authorized physician. Any sample without this information will be rejected.
8. Minimum Specimen Requirements: Optimal Quantity: 4-5 ml; Minimum Quantity: 1-2 ml
9. Turnaround Time: Total testing time: 10 days
10. Communication:
 - a. Turnaround time non-conformity: Email or call Pathologist on request form to notify them of the delay.
 - b. Technical Updates: Email Applicable Laboratory Director.
11. Quality: QA/Utilization Report

Test Name: Routine Chromosome Analysis on Amniotic Fluid (RCA-AF)

1. **CPT Code(s):** 88235, 88267, 88280, 88291
2. **Synonym(s):** Amniotic Fluid Chromosome Analysis
3. **Performed:** In-House
4. **Methodology:** In Situ long-term culture; chromosome preparation and banding; microscopic analysis and karyotype; interpretation and report.
5. **Panel/Profile Components:** N/A
6. **Critical Values:** N/A
7. **Specimen Collection / Handling Requirements:**
 - a. Amniotic fluid collected in sterile 15 mL tubes (discard first 1 cc of amniotic fluid)
 - b. Store and ship at room temperature
 - c. Avoid freezing or heating
 - d. Ship within 24 hours
 - e. Delay > 24 hours – Refrigerate the sample
 - f. A complete requisition slip must accompany all specimens and the specimen must be labeled with the patient's name and identification number.
 - g. ANY SPECIMENS RECEIVED WITHOUT A COMPLETE REQUISITION OR AN UNLABELED SPECIMEN WILL BE REJECTED.
 - h. All requisition must have a valid ICD-10 code/clinical indication and must have the name of an authorized physician. Any sample without this information will be rejected.
8. **Minimum Specimen Requirements:** Optimal Quantity: > 15 ml; Minimum Quantity: 5 ml
9. **Turnaround time:** Total testing time: **14 days**
10. **Communication:**
 - a. Turnaround time non-conformity: **Email or call Pathologist on request form to notify them of the delay.**
 - b. Technical Updates: **Email Applicable Laboratory Director.**
11. **Quality:** QA/Utilization Report

Test Name: Routine Chromosome Analysis on Products of Conception (RCA-POC)

1. **CPT Code(s):** 88233, 88262, 88280, 88291
2. **Synonym(s):** Chromosome Analysis on Abortus Tissue / Miscarriage / Fetal Tissue
3. **Performed:** In-House
4. **Methodology:** In Situ long-term culture initiated using Collagenase for enzyme digestion; chromosome preparation and banding; microscopic analysis and karyotype; interpretation and report
5. **Panel/Profile Components:** N/A
6. **Critical Values:** N/A
7. **Specimen Collection / Handling Requirements:**
 - a. Chorionic villi preferred
 - b. Collected in sterile specimen cup or sterile 15 mL tube with RPMI or sterile saline
 - c. Fetal tissue may also be sent with the same conditions
 - d. Store and ship at room temperature
 - e. Avoid freezing or heating
 - f. Ship within 24 hours
 - g. Delay > 24 hours – Refrigerate the sample
 - h. A complete requisition slip must accompany all specimens and the specimen must be labeled with the patient's name and identification number.
 - i. ANY SPECIMENS RECEIVED WITHOUT A COMPLETE REQUISITION OR AN UNLABELED SPECIMEN WILL BE REJECTED.
 - j. All requisition must have a valid ICD-10 code/clinical indication and must have the name of an authorized physician. Any sample without this information will be rejected.
8. **Minimum Specimen Requirements:** Optimal Quantity: 2 cm³; Minimum Quantity: 1 cm³
9. **Turnaround time:** Total testing time: **6 weeks**
10. **Communication:**
 - a. Turnaround time non-conformity: **Email or call Pathologist on request form to notify them of the delay.**
 - b. Technical Updates: **Email Applicable Laboratory Director.**
11. **Quality:** QA/Utilization Report

Test Name: Routine Chromosome Analysis on Skin (RCA-SK)

1. **CPT Code(s):** 88233, 88263, 88280, 88291
2. **Synonym(s):** Chromosome Analysis on Skin / Tissues
3. **Performed:** In-House
4. **Methodology:** In Situ long-term culture initiated using Collagenase for enzyme digestion; chromosome preparation and banding; microscopic analysis and karyotype; interpretation and report
5. **Panel/Profile Components:** N/A
6. **Critical Values:** N/A
7. **Specimen Collection / Handling Requirements:**
 - a. Collected in sterile specimen cup or sterile 15 mL tube with RPMI or sterile saline
 - b. Store and ship at room temperature
 - c. Avoid freezing or heating
 - d. Ship within 24 hours
 - e. Delay > 24 hours – Refrigerate the sample
 - f. A complete requisition slip must accompany all specimens and the specimen must be labeled with the patient's name and identification number.
 - g. ANY SPECIMENS RECEIVED WITHOUT A COMPLETE REQUISITION OR AN UNLABELED SPECIMEN WILL BE REJECTED.
 - h. All requisition must have a valid ICD-10 code/clinical indication and must have the name of an authorized physician. Any sample without this information will be rejected.
8. **Minimum Specimen Requirements:** Optimal Quantity: 2 cm³; Minimum Quantity: 1 cm³
9. **Turnaround time:** Results to Client: **6 weeks for 90% cases No Growth in 21 days**
10. **Communication:**
 - a. Turnaround time non-conformity: **Email or call Pathologist on request form to notify them of the delay.**
 - b. Technical Updates: **Email Applicable Laboratory Director.**
11. **Quality:** QA/Utilization Report

Test Name: Chromosome Mosaicism Analysis (RCA-MOS)

1. **CPT Code(s):**
 - a. Peripheral Blood – 88230, 88263, 88280, 88291
 - b. Skin – 88233, 88263, 88280, 88291
2. **Synonym(s):** Mosaicism Study
3. **Performed:** In-House
4. **Methodology:** PHA stimulated short-term culture / In Situ long-term culture initiated using Collagenase for enzyme digestion; chromosome preparation and banding; microscopic analysis of up to 50 cells and karyotype; interpretation and report
5. **Panel/Profile Components:** N/A
6. **Critical Values:** N/A
7. **Specimen Collection / Handling Requirements:**
 - a. Peripheral blood collected in green top - sodium heparin tube (Peripheral Blood)
 - b. Collected in sterile specimen cup or sterile 15 mL tube with RPMI or sterile saline (Skin)
 - c. Store and ship at room temperature
 - d. Avoid freezing or heating
 - e. Ship within 24 hours
 - f. Delay > 24 hours – Refrigerate the sample
 - g. A complete requisition slip must accompany all specimens and the specimen must be labeled with the patient's name and identification number.
 - h. ANY SPECIMENS RECEIVED WITHOUT A COMPLETE REQUISITION OR AN UNLABELED SPECIMEN WILL BE REJECTED.
 - i. All requisition must have a valid ICD-10 code/clinical indication and must have the name of an authorized physician. Any sample without this information will be rejected.
8. **Minimum Specimen Requirements:** Optimal Quantity: 4-5 ml; Minimum Quantity: 1-2 ml (Peripheral Blood); Optimal Quantity: 2 cm³; Minimum Quantity: 1 cm³ (Skin)
9. **Turnaround time:** Total testing time: **10 days (Peripheral Blood)**
6 weeks (Skin)
10. **Communication:**
 - a. Turnaround time non-conformity: **Email or call Pathologist on request form to notify them of the delay.**

b. Technical Updates: **Email Applicable Laboratory Director.**

11. Quality: QA/Utilization Report

Test Name: Routine Chromosome Analysis on Bone Marrow (RCA-BM)

1. **CPT Code(s):** 88237, 88264, 88280, 88291
2. **Synonym(s):** Bone Marrow Chromosome Analysis / Chromosome Analysis for Leukemia
3. **Performed:** In-House
4. **Methodology:** Unstimulated short-term culture; chromosome preparation and banding; microscopic analysis and karyotype; interpretation and report
5. **Panel/Profile Components:** N/A
6. **Critical Values:** STAT (Promyelocytic Leukemia): Preliminary results in 24 hours
7. **Specimen Collection / Handling Requirements:**
 - a. Whole bone marrow collected in green top - sodium heparin tube
 - b. Store and ship at room temperature
 - c. Avoid freezing or heating
 - d. Ship within 24 hours
 - e. Delay > 24 hours – Refrigerate the sample
 - f. A complete requisition slip must accompany all specimens and the specimen must be labeled with the patient's name and identification number.
 - g. ANY SPECIMENS RECEIVED WITHOUT A COMPLETE REQUISITION OR AN UNLABELED SPECIMEN WILL BE REJECTED.
 - h. All requisition must have a valid ICD-10 code/clinical indication and must have the name of an authorized physician. Any sample without this information will be rejected.
8. **Minimum Specimen Requirements:** Optimal Quantity: 3-4 ml; Minimum Quantity: 1-2 ml
9. **Turnaround time:** Total testing time: **10 days**
10. **Communication:**
 - a. Turnaround time non-conformity: **Email or call Pathologist on request form to notify them of the delay.**
 - b. Technical Updates: **Email Applicable Laboratory Director.**
11. **Quality:** QA/Utilization Report

Test Name: Routine Chromosome Analysis on Leukemic Blood (RCA-LB)

1. **CPT Code(s):** 88237, 88264, 88280, 88291
2. **Synonym(s):** Peripheral Blood Chromosome Analysis for Leukemia
3. **Performed:** In-House
4. **Methodology:** Unstimulated short-term culture; chromosome preparation and banding; microscopic analysis and karyotype; interpretation and report
5. **Panel/Profile Components:** N/A
6. **Critical Values:** STAT (Promyelocytic Leukemia): Preliminary results in 24 hours
7. **Specimen Collection / Handling Requirements:**
 - a. Peripheral Blood collected in green top - sodium heparin tube
 - b. Store and ship at room temperature
 - c. Avoid freezing or heating
 - d. Ship within 24 hours
 - e. Delay > 24 hours – Refrigerate the sample
 - f. A complete requisition slip must accompany all specimens and the specimen must be labeled with the patient's name and identification number.
 - g. ANY SPECIMENS RECEIVED WITHOUT A COMPLETE REQUISITION OR AN UNLABELED SPECIMEN WILL BE REJECTED.
 - h. All requisition must have a valid ICD-10 code/clinical indication and must have the name of an authorized physician. Any sample without this information will be rejected.
8. **Minimum Specimen Requirements:** Optimal Quantity: 3-4 ml; Minimum Quantity: 1-2 ml
9. **Turnaround time:** Total testing time: **10 days**
10. **Communication:**
 - a. Turnaround time non-conformity: **Email or call Pathologist on request form to notify them of the delay.**
 - b. Technical Updates: **Email Applicable Laboratory Director.**
11. **Quality:** QA/Utilization Report

Test Name: Routine Chromosome Analysis on Lymph Node (RCA-LN)

1. **CPT Code(s):** 88237, 88264, 88280, 88291
2. **Synonym(s):** Chromosome Analysis for Lymphoma
3. **Performed:** In-House
4. **Methodology:** Unstimulated short-term culture; chromosome preparation and banding; microscopic analysis and karyotype; interpretation and report
5. **Panel/Profile Components:** N/A
6. **Critical Values:** STAT (Burkitt Lymphoma): Preliminary results in 24 hours
7. **Specimen Collection / Handling Requirements:**
 - a. Lymph node biopsy collected in sterile 15 mL tube with RPMI or sterile saline
 - b. Store and ship at room temperature
 - c. Avoid freezing or heating
 - d. Ship within 24 hours
 - e. Delay > 24 hours – Refrigerate the sample
 - f. A complete requisition slip must accompany all specimens and the specimen must be labeled with the patient's name and identification number.
 - g. ANY SPECIMENS RECEIVED WITHOUT A COMPLETE REQUISITION OR AN UNLABELED SPECIMEN WILL BE REJECTED.
 - h. All requisition must have a valid ICD-10 code/clinical indication and must have the name of an authorized physician. Any sample without this information will be rejected.
8. **Minimum Specimen Requirements:** Optimal Quantity: 2 cm³; Minimum Quantity: 1 cm³
9. **Turnaround time:** Total testing time: **10 days**
10. **Communication:**
 - a. Turnaround time non-conformity: **Email or call Pathologist on request form to notify them of the delay.**
 - b. Technical Updates: **Email Applicable Laboratory Director.**
11. **Quality:** QA/Utilization Report

Test Name: Routine Chromosome Analysis on Solid Tumors (RCA-ST)

1. **CPT Code(s):** 88239, 88264, 88280, 88291
2. **Synonym(s):** Tumor Chromosome Analysis
3. **Performed:** In-House
4. **Methodology:** In Situ long-term culture initiated using Collagenase for enzyme digestion; chromosome preparation and banding; microscopic analysis and karyotype; interpretation and report
5. **Panel/Profile Components:** N/A
6. **Critical Values:** N/A
7. **Specimen Collection / Handling Requirements:**
 - a. Lymph node biopsy collected in sterile 15 mL tube with RPMI or sterile saline
 - b. Store and ship at room temperature
 - c. Avoid freezing or heating
 - d. Ship within 24 hours
 - e. Delay > 24 hours – Refrigerate the sample
 - f. A complete requisition slip must accompany all specimens and the specimen must be labeled with the patient's name and identification number.
 - g. ANY SPECIMENS RECEIVED WITHOUT A COMPLETE REQUISITION OR AN UNLABELED SPECIMEN WILL BE REJECTED.
 - h. All requisition must have a valid ICD-10 code/clinical indication and must have the name of an authorized physician. Any sample without this information will be rejected.
8. **Minimum Specimen Requirements:** Optimal Quantity: 2 cm³; Minimum Quantity: 1 cm³
9. **Turnaround time:** Total testing time: **28 days**
10. **Communication:**
 - a. Turnaround time non-conformity: **Email or call Pathologist on request form to notify them of the delay.**
 - b. Technical Updates: **Email Applicable Laboratory Director.**
11. **Quality:** QA/Utilization Report

Test Name: Fluorescence In Situ Hybridization for Microdeletions (FISH-DEL)

1. **CPT Code(s):** 88271x2, 88273, 88291
2. **Synonym(s):** FISH for Prader-Willi Syndrome / FISH for 22q11.2 microdeletion etc.
3. **Performed:** In-House
4. **Methodology:** PHA stimulated short-term culture; metaphase cell slide preparation; DNA denaturation with target probe and hybridization followed by post-hybridization wash; DAPI application for fluorescence microscopic analysis of chromosomes; interpretation and report (Peripheral Blood)
In Situ long-term culture; chromosome preparation; DNA denaturation with target probe and hybridization followed by post-hybridization wash; DAPI application for fluorescence microscopic analysis of chromosomes; interpretation and report (Amniotic Fluid / Products of Conception / Skin)
5. **Panel/Profile Components:** N/A
6. **Critical Values:** N/A
7. **Specimen Collection / Handling Requirements:**
 - a. Peripheral blood collected in green top - sodium heparin tube (Peripheral Blood)
 - b. Collected in sterile specimen cup or sterile 15 mL tube with RPMI or sterile saline (Amniotic Fluid / Products of Conception / Skin)
 - c. Store and ship at room temperature
 - d. Avoid freezing or heating
 - e. Ship within 24 hours
 - f. Delay > 24 hours – Refrigerate the sample
 - g. A complete requisition slip must accompany all specimens and the specimen must be labeled with the patient's name and identification number.
 - h. ANY SPECIMENS RECEIVED WITHOUT A COMPLETE REQUISITION OR AN UNLABELED SPECIMEN WILL BE REJECTED.
 - i. All requisition must have a valid ICD-10 code/clinical indication and must have the name of an authorized physician. Any sample without this information will be rejected.
8. **Minimum Specimen Requirements:**
 - a. Optimal Quantity: 4-5 ml; Minimum Quantity: 1-2 ml (Peripheral Blood)
 - b. Optimal Quantity: 2 cm³; Minimum Quantity: 1 cm³ (Skin)

9. Turnaround time: Total testing time: **7 days**

10. Communication:

- a. Turnaround time non-conformity: **Email or call Pathologist on request form to notify them of the delay.**
- b. Technical Updates: **Email Applicable Laboratory Director.**

11. Quality: QA/Utilization Report

Test Name: Fluorescence In Situ Hybridization on Amniotic Fluid (FISH-ANU)

1. **CPT Code(s):** 88271x3, 88273, 88291
2. **Synonym(s):** Rapid FISH / Rapid Prenatal FISH / Rapid FISH Screen for Aneuploidies
3. **Performed:** In-House
4. **Methodology:** Direct harvest of amniocytes; interphase cell slide preparation; DNA denaturation with target probe and hybridization followed by post-hybridization wash; DAPI application for fluorescence microscopic analysis of nuclei; interpretation and report
5. **Panel/Profile Components:** N/A
6. **Critical Values:** N/A
7. **Specimen Collection / Handling Requirements:**
 - a. Amniotic fluid collected in sterile 15 mL tubes (discard first 1 cc of amniotic fluid)
 - b. Store and ship at room temperature
 - c. Avoid freezing or heating
 - d. Ship within 24 hours
 - e. Delay > 24 hours – Refrigerate the sample
 - f. A complete requisition slip must accompany all specimens and the specimen must be labeled with the patient's name and identification number.
 - g. ANY SPECIMENS RECEIVED WITHOUT A COMPLETE REQUISITION OR AN UNLABELED SPECIMEN WILL BE REJECTED.
 - h. All requisition must have a valid ICD-10 code/clinical indication and must have the name of an authorized physician. Any sample without this information will be rejected.
8. **Minimum Specimen Requirements:** Optimal Quantity: > 15 ml; Minimum Quantity: 5 ml
9. **Turnaround time:** Total testing time: **7 days**
10. **Communication:**
 - a. Turnaround time non-conformity: **Email or call Pathologist on request form to notify them of the delay.**
 - b. Technical Updates: **Email Applicable Laboratory Director.**
11. **Quality:** QA/Utilization Report

Test Name: Fluorescence In Situ Hybridization on Products of Conception (FISH-POC)

1. **CPT Code(s):** 88271x3, 88273, 88291
2. **Synonym(s):** Rapid FISH
3. **Performed:** In-House
4. **Methodology:** Direct harvest of fibroblast cells; interphase cell slide preparation; DNA denaturation with target probe and hybridization followed by post-hybridization wash; DAPI application for fluorescence microscopic analysis of nuclei; interpretation and report
5. **Panel/Profile Components:** N/A
6. **Critical Values:** N/A
7. **Specimen Collection / Handling Requirements:**
 - a. Chorionic villi preferred
 - b. Collected in sterile specimen cup or sterile 15 mL tube with RPMI or sterile saline
 - c. Fetal tissue may also be sent with the same conditions
 - d. Store and ship at room temperature
 - e. Avoid freezing or heating
 - f. Ship within 24 hours
 - g. Delay > 24 hours – Refrigerate the sample
 - h. A complete requisition slip must accompany all specimens and the specimen must be labeled with the patient's name and identification number.
 - i. ANY SPECIMENS RECEIVED WITHOUT A COMPLETE REQUISITION OR AN UNLABELED SPECIMEN WILL BE REJECTED.
 - j. All requisition must have a valid ICD-10 code/clinical indication and must have the name of an authorized physician. Any sample without this information will be rejected.
8. **Minimum Specimen Requirements:** Optimal Quantity: 2 cm³; Minimum Quantity: 1 cm³
9. **Turnaround time:** Total testing time: **7 days**
10. **Communication:**
 - a. Turnaround time non-conformity: **Email or call Pathologist on request form to notify them of the delay.**
 - b. Technical Updates: **Email Applicable Laboratory Director.**
11. **Quality:** QA/Utilization Report

Fluorescence In Situ Hybridization Panels (FISH-PL)**Acute Myeloid Leukemia/Myelodysplastic Syndrome (AML/MDS)****Synonym(s):** FISH, MDS/Myeloid Panel, -5/5q-, -7/7q-, +8, 20q-**Panel/Profile Components:**

- 5q deletion / monosomy 5
- 7q deletion / monosomy 7
- 20q deletion / monosomy 20
- t(8;21) – RUNX1T1 (ETO) / RUNX1 (AMML1) gene rearrangement
- t(15;17) – PML / RARA gene rearrangement inv(16)
- 11q – MLL gene rearrangement
- 17p – p53 gene deletion

Acute Lymphocytic Leukemia (ALL)**Synonym(s):** FISH, ALL, Extended Panel / FISH, ALL, Pre-B Panel**Panel/Profile Components:**

- hyperdiploidy – chromosomes 4, 10, 17
- t(9;22) – BCR / ABL1 gene rearrangement
- t(12;21)– TEL (ETV6) / RUNX1 (AML1) gene rearrangement
- t(1;19) – E2A gene rearrangement
- 9p – p16 deletion
- 8q – cMYC gene rearrangement / copy number changes
- 11q – MLL gene rearrangement
- 14q – IGH gene rearrangement

Chronic Lymphocytic Leukemia (CLL)**Synonym(s):** FISH, B-Cell Chronic Lymphocytic Leukemia Panel**Panel/Profile Components:**

- Trisomy 12
- 13q deletion 11q
- ATM deletion 6q deletion
- t(14;18) – IGH / BCL2 gene rearrangement
- t(11;14) – CCND1 / IGH gene rearrangement
- 14q – IGH gene rearrangement

17p – p53 gene deletion

Multiple Myeloma (on Isolated Plasma Cells)

Synonym(s): FISH, Multiple Myeloma, Chromosomes 5, 9, 15 / FISH, Myeloma, 13q, 14q, 17p / FISH Myeloma, 17p-, rea 14q32 / FISH Myeloma, IGH Panel (MAFB, MAF, FGFR3, CCND1) / FISH, Myeloma, Risk Assessment Panel/ Plasma Cell Neoplasia Follow-Up Panel

Panel/Profile Components:

t(11;14) – CCND1/IGH gene rearrangement
t(4;14) – FGFR3 / IGH gene rearrangement
t(14;16) – IGH / MAF gene rearrangement
hyperdiploidy
11q – ATM deletion
13q deletion

Synonym(s): FISH, MDS/Myeloid Panel, -5/5q-, -7/7q-, +8, 20q-

Panel/Profile Components:

5q deletion / monosomy 5
7q deletion / monosomy 7
20q deletion / monosomy 20
t(8;21) – RUNX1T1 (ETO) / RUNX1 (AMML1) gene rearrangement
t(15;17) – PML / RARA gene rearrangement inv(16)
11q – MLL gene rearrangement
17p – p53 gene deletion

Acute Lymphocytic Leukemia (ALL)

Synonym(s): FISH, ALL, Extended Panel / FISH, ALL, Pre-B Panel

Panel/Profile Components:

hyperdiploidy – chromosomes 4, 10, 17
t(9;22) – BCR / ABL1 gene rearrangement
t(12;21)– TEL (ETV6) /RUNX1 (AML1) gene rearrangement
t(1;19) – E2A gene rearrangement
9p – p16 deletion
8q – cMYC gene rearrangement / copy number changes
11q – MLL gene rearrangement

14q – IGH gene rearrangement

Chronic Lymphocytic Leukemia (CLL)

Synonym(s): FISH, B-Cell Chronic Lymphocytic Leukemia Panel

Panel/Profile Components:

Trisomy 12

13q deletion 11q

– ATM deletion 6q deletion

t(14;18) – IGH / BCL2 gene rearrangement

t(11;14) – CCND1 / IGH gene rearrangement

14q – IGH gene rearrangement

17p – p53 gene deletion

Multiple Myeloma (on Isolated Plasma Cells)

Synonym(s): FISH, Multiple Myeloma, Chromosomes 5, 9, 15 / FISH, Myeloma, 13q, 14q, 17p / FISH

Myeloma, 17p-, rea 14q32 / FISH Myeloma, IGH Panel (MAFB, MAF, FGFR3, CCND1) / FISH, Myeloma, Risk Assessment Panel / Plasma Cell Neoplasia Follow-Up Panel

Panel/Profile Components:

t(11;14) – CCND1/IGH gene rearrangement

t(4;14) – FGFR3 / IGH gene rearrangement

t(14;16) – IGH / MAF gene rearrangement hyperdiploidy

11q – ATM deletion 13q deletion

17p – p53 gene deletion

Myeloproliferative Disease (MPD)

Synonym(s): FISH, Myeloproliferative Neoplasms (Eosinophilia)

Panel/Profile Components:

t(9;22) – BCR / ABL1 gene rearrangement

4q – CHIC2 gene deletion (PDGFRA gene rearrangement)

t(5;12) – PDGFRB gene rearrangement

8p – FGFR1 gene rearrangement

B-cell Lymphoma

Synonym(s): FISH, High-Grade Lymphoma Panel

Panel/Profile Components:

- 8q – cMYC gene rearrangement [t(8;14)]
- 3q – BCL6 gene rearrangement t(11;14)
- CCND1 / IGH gene rearrangement t(14;18)
- IGH / BCL2 gene rearrangement

T-cell Lymphoma

Panel/Profile Components:

- 7 / 7q – TCRB gene rearrangement
- 14q – TCRAD gene rearrangement
- t(2;5) – ALK gene rearrangement

Test Name: Microarray Testing – SNP Oligo

1. **CPT Code(s):** 81229
2. **Synonym(s):**
3. **Performed:** In-House
4. **Methodology:** DNA extraction / Hybridization / Data Analysis
5. **Panel/Profile Components:**
6. **Critical Values:**
7. **Specimen Collection / Handling Requirements:**
 - a. Peripheral blood collected in green top - sodium heparin tube / purple top EDTA tube
 - b. Store and ship at room temperature
 - c. Avoid freezing or heating
 - d. Ship within 24 hours
 - e. Refrigerate the sample after 8 hours of collection
 - f. A complete requisition slip must accompany all specimens and the specimen must be labeled with the patient's name and identification number.
 - g. ANY SPECIMENS RECEIVED WITHOUT A COMPLETE REQUISITION OR AN UNLABELED SPECIMEN WILL BE REJECTED.
 - h. All requisition must have a valid ICD-10 code/clinical indication and must have the name of an authorized physician. Any sample without this information will be rejected.
8. **Minimum Specimen Requirements:** Optimal Quantity: 3-5 ml; Minimum Quantity: 2 ml
9. **Turnaround Time:** Total testing time: **28 days**
10. **Communication:**
 - a. Turnaround time non-conformity: **Email or call Ordering physician on request form to notify them of the delay when possible.**
 - b. Technical Updates: **Email Applicable Laboratory Director.**
11. **Quality:** QA/Utilization Report

Test Name: Fluorescence In Situ Hybridization for Leukemia / Lymphoma Panels (FISH-PL)

1. **CPT Code(s):** 88271x5, 88275, 88291
2. **Synonym(s):** SEE under each Panel
3. **Performed:** In-House
4. **Methodology:** Unstimulated short-term culture; interphase cell slide preparation; DNA denaturation with target probes and hybridization followed by post-hybridization wash; DAPI application for fluorescence microscopic analysis of nuclei; interpretation and report
5. **Panel/Profile Components:** SEE under each panel
6. **Critical Values:** STAT (Promyelocytic Leukemia / Burkitt Lymphoma): Preliminary results in 24 hours
7. **Specimen Collection / Handling Requirements:**
 - a. Whole bone marrow collected in green top - sodium heparin tube
 - b. Lymph node biopsy collected in sterile 15 mL tube with RPMI or sterile saline
 - c. Store and ship at room temperature
 - d. Avoid freezing or heating
 - e. Ship within 24 hours
 - f. Delay > 24 hours – Refrigerate the sample
 - g. A complete requisition slip must accompany all specimens and the specimen must be labeled with the patient's name and identification number.
 - h. ANY SPECIMENS RECEIVED WITHOUT A COMPLETE REQUISTION OR AN UNLABELED SPECIMEN WILL BE REJECTED.
 - i. All requisition must have a valid ICD-10 code/clinical indication and must have the name of an authorized physician. Any sample without this information will be rejected.
8. **Minimum Specimen Requirements:**

Optimal Quantity: 3-4 ml; Minimum Quantity: 1-2 ml (Bone Marrow & Leukemic Blood)

Optimal Quantity: 2 cm³; Minimum Quantity: 1 cm³ (Lymph Node & Tissues)
9. **Transportation to STRL:** Pick up by STRL Lab Personnel
10. **Turnaround time:** Total testing time: **7 days**
11. **Communication:**

- a. Turnaround time non-conformity: **Email or call Pathologist on request form to notify them of the delay.**
- b. Specimen rejection: **Most causes for specimen rejection are noted at pick- up, prior to the sample leaving UHS premises, communicated verbally, and corrected immediately. In rare cases where cause for specimen rejection is noted after the sample has arrived at UT Health San Antonio, the Pathologist on the request form will be contacted by email or phone.**
- c. Technical Updates: **Email Applicable Laboratory Director.**

12. Quality: QA/Utilization Report

Fluorescence In Situ Hybridization Single Probes (FISH-SGL)

All probes used on the panels may be requested as single studies. For a listing of target probes available as single studies, refer to the laboratory website, (<http://pathology.uthscsa.edu/str/cytogenics/index.shtml>).

Test Name: Fluorescence In Situ Hybridization for Leukemia / Lymphoma single probes (FISH-SGL)

1. **CPT Code(s):** 88271x2, 88275, 88291
2. **Synonym(s):** FISH, NHL, MYC-BA, 8q24 Rearrangement / FISH, Follicular Lymphoma, IGH/BCL2, t(14;18) / FISH, High-Grade Lymphoma Panel / FISH, Mantle Cell Lymphoma, IGH/CCND1, t(11;14) / FISH, Multiple Myeloma, IGH/FGFR3, t(4;14) / FISH, Multiple Myeloma, IGH/MAF, t(14;16) / FISH, AML M3, PML/RARA Translocation 15,17 / FISH, AML, AML1/ETO Translocation 8,21 / FISH, MLL (11q23) Gene Rearrangement / FISH, ALL, MYC-BA, 8q24 Rearrangement / FISH, ALL, bcr/abl translocation 9,22 / FISH, MLL (11q23) Gene Rearrangement / FISH, Multiple Myeloma, IGH/FGFR3, t(4;14) / FISH, Multiple Myeloma, IGH/MAF, t(14;16) / FISH, NHL, MYC-BA, 8q24 Rearrangement / FISH, Follicular Lymphoma, IGH/BCL2, t(14;18) / FISH, Mantle Cell Lymphoma, IGH/CCND1, t(11;14)
3. **Performed:** In-House
4. **Methodology:** Unstimulated short-term culture; interphase cell slide preparation; DNA denaturation with target probes and hybridization followed by post-hybridization wash; DAPI application for fluorescence microscopic analysis of nuclei; interpretation and report
5. **Panel/Profile Components:** N/A
6. **Critical Values:** STAT (Promyelocytic Leukemia / Burkitt Lymphoma): Preliminary results in 24 hours
7. **Specimen Collection / Handling Requirements:**
 - a. Whole bone marrow collected in green top - sodium heparin tube
 - b. Lymph node biopsy collected in sterile 15 mL tube with RPMI or sterile saline
 - c. Store and ship at room temperature
 - d. Avoid freezing or heating
 - e. Ship within 24 hours
 - f. Delay > 24 hours – Refrigerate the sample
 - g. A complete requisition slip must accompany all specimens and the specimen must be labeled with the patient's name and identification number.

- h. ANY SPECIMENS RECEIVED WITHOUT A COMPLETE REQUISITION OR AN UNLABELED SPECIMEN WILL BE REJECTED.
- i. All requisition must have a valid ICD-10 code/clinical indication and must have the name of an authorized physician. Any sample without this information will be rejected.

8. Minimum Specimen Requirements:

Optimal Quantity: 3-4 ml; Minimum Quantity: 1-2 ml (Bone Marrow & Leukemic Blood)

Optimal Quantity: 2 cm³; Minimum Quantity: 1 cm³ (Lymph Node & Tissues)

9. Turnaround time: Total testing time: **7 days**

10. Communication:

- a. Turnaround time non-conformity: **Email or call Pathologist on request form to notify them of the delay.**
- b. Specimen rejection: **Most causes for specimen rejection are noted at pick- up, prior to the sample leaving UHS premises, communicated verbally, and corrected immediately. In rare cases where cause for specimen rejection is noted after the sample has arrived at UT Health San Antonio, the Pathologist on the request form will be contacted by email or phone.**
- c. Technical Updates: **Email Applicable Laboratory Director.**

11. Quality: QA/Utilization Report

Test Name: Pap Test, Liquid Based Thin Prep

1. **CPT Code(s):** 88142, 88141
2. **Synonym(s):** Thin Prep PAP, PAP Smear
3. **Performed:** In-House
4. **Methodology:** Liquid-based Thin Prep
5. **Panel/Profile Components:**
 - a. Thin Prep Pap Test and HPV Test Request: Includes the PAP and HPV tests.
 - b. Thin Prep Pap Test w/Reflex HPV Test Request: Includes the PAP test. The HPV test will only be performed when the Pap Test interpretation is either ASC-US, ASC-H, or LSIL.
 - c. Thin Prep Pap Test: includes Pap Test only

NOTE: Thin Prep Pap aliquot specimens are held 60 days for add-on HPV testing.

Please call the Cytology Lab at 210-567-2827 to request add on HPV.

There is an additional charge for HPV testing.

6. **Critical Values:** N/A
7. **Specimen Collection / Handling Requirements:**
 - a. Complete the GYN cytology order in EPIC and include all pertinent information to ensure a thorough and complete interpretation:
 - Specimen source
 - Birthdate
 - Date of last menstrual period
 - Whether patient is pregnant or postpartum
 - Presence of an IUD
 - Abnormal cervix
 - Previous gynecological surgery and procedures
 - Previous abnormal Pap smear(s) (specify previous abnormality)
 - Current hormonal therapy
 - Chemotherapy
 - Radiation therapy
 - Past or present history of cancer

Any other relevant clinical history such as abnormal bleeding

NOTE: All test requisitions must have a valid ICD-10 code/clinical indication and must have the name of an authorized physician. Any sample without this information will be rejected.

All specimens received without a complete requisition, mismatched requisition/specimen vial, or an unlabeled thin prep vial will be rejected.

- b. Obtain an adequate sample from the source using a plastic spatula. If desired, use lukewarm water to warm and lubricate the speculum. Apply water-soluble, carbomer-free gel lubricant sparingly to the posterior blade of the speculum if necessary.

Select the contoured end of the plastic spatula and rotate it 360 degrees around the entire ectocervix, while maintaining tight contact with ectocervical surface.

Rinse the spatula as quickly as possible into the PreservCyt® Solution vial by swirling the spatula vigorously in the vial 10 times. Discard the spatula.

Obtain an adequate sampling from the endocervix using an endocervical brush device. Insert the brush into the cervix until only the bottom-most fibers are exposed. Slowly rotate 1/4 or 1/2 turn in one direction. **DO NOT OVER-ROTATE THE BRUSH.**

Rinse the brush as soon as possible in the same PreservCyt

Solution by rotating the device in the solution 10 times while pushing it against the PreservCyt vial wall. Swirl the brush vigorously to further release material. Discard the brush.

Tighten the cap so that the torque line on the cap passes the torque line on the vial.

- c. Place the patient label vertical on the body of the PreservCyt vial.

Verify the labeled specimen vial and test requisition match prior to placing vial in a biohazard bag for transport to the laboratory.

For optimal results, transport the labeled specimen to the laboratory as soon as possible after collection.

Keep the preserved specimen at room temperature or refrigerated (2-8 °C).

8. Minimum Specimen Requirements:

Mid-cycle smears are optimal for cytological evaluation.

Patient has not douched the vagina for 48 hours prior to examination.

Patient has avoided the use of contraceptive creams or jellies for 48 hours prior to examination.

9. Turnaround time:

- a. Results to Client: < **7 working days**

- b. Turnaround time non-conformity: **Please call the cytology laboratory at 210-567-2827 to inquire on cytology results.**

9. Communication:

- a. Clinician will be notified of significant PAP Test results that require patient follow-up.
- b. Specimen rejection: **The provider listed on the request form or appropriate clinic personnel will be contacted by email or phone. Cause for specimen rejection is noted in the Harvest LIS.**
- c. Technical Updates: **Please call the cytology laboratory at 210-567-2827 to obtain educational information on the thin Prep Pap Test.**
- d. Education Materials offered:
- Hologic Patient Education Annual Exam
 - Hologic Protocol: Endocervical Brush/Spatula Collection Guide
 - Hologic Thin Prep Pap Test Specimen Collection
 - Thin Prep Customer Letter: Pap Collection and Lubricant Compatibility
 - Thin Prep Pap Lubricant Compatibility Memo
 - Thin Prep Pap Lubricant Compatibility List

10. Supply Request: Email: strlclientservices@uthscsa.edu to request Supply Request Form.

11. Quality:

- a. Thin Prep PAP Test slides will undergo an additional review when the patient has documented significant clinical history.
- b. Pap Test specimens that require a pathologist review may have delayed reporting to client.

Test Name: Electron Microscopy

1. **CPT Code:** 88348
2. **Synonym(s):** EM
3. **Performed:** In-House
4. **Methodology:** Transmission Electron Microscopy (TEM)
5. **Panel/Profile Components:** N/A
6. **Critical Values:** N/A
7. **Specimen Collection / Handling Requirements:**
 - a. Immediately place specimen for TEM in 4CF1G (EM fixative) provided by STRL EM Laboratory. Specimen must be fixed for 2 hours and can remain at room temperature.
 - b. A complete requisition slip must accompany all specimens and the specimen must be labeled with the patient's name and identification number.

ANY SPECIMENS RECEIVED WITHOUT A COMPLETE REQUISITION OR AN UNLABELED SPECIMEN WILL BE RETURNED IMMEDIATELY

- c. Patient information must include:
 - Name, address, date of birth of patient
 - Hospital identification number
 - Insurance information (hospital admission form)
 - Pathology accession number where applicable
 - Requesting physicians name and address
 - Test requested
 - d. Shipping Information (address all specimens to):
 - Department of Pathology – Client Services Center MC 7750
 - The University of Texas Health Science Center at San Antonio
 - 7703 Floyd Curl Drive
 - San Antonio, Texas 78229-3900
8. **Minimum Specimen Requirements:** One needle core (1mm cube) placed in 4CF1G (EM fixative).
9. **Turnaround Times:** Total testing time: **3 days**
Results to Client: **14 days**

10. Communication:

- a. Turnaround time non-conformity: **Email or call Pathologist on request form to notify them of the delay.**
- b. Specimen rejection: **Most causes for specimen rejection are noted at pick- up, prior to the sample leaving UHS premises, communicated verbally, and corrected immediately. In rare cases where cause for specimen rejection is noted after the sample has arrived at UT Health San Antonio, the Pathologist on the request form will be contacted by email or phone.**
- c. Technical Updates: **Email Applicable Laboratory Director.**

11. Quality: A quality assurance report is sent out to the pathologist with every case for them to evaluate the slides and images.

Test Name: Electron Microscopy-Whole Blood

1. **CPT Code:** 88348
2. **Synonym(s):** EM
3. **Performed:** In-House
4. **Methodology:** Transmission Electron Microscope
5. **Panel/Profile Components:** N/A
6. **Critical Values:** N/A
7. **Specimen Collection / Handling Requirements:**
 - a. Whole blood drawn in a purple-top tube (EDTA)
 - b. A complete requisition slip must accompany all specimens and the specimen must be labeled with the patient's name and identification number.

ANY SPECIMENS RECEIVED WITHOUT A COMPLETE REQUISITION OR AN UNLABELED SPECIMEN WILL BE RETURNED IMMEDIATELY

- c. Patient information must include:
 - Name, address, date of birth of patient
 - Hospital identification number
 - Insurance information (hospital admission form)
 - Pathology accession number where applicable
 - Requesting physicians name and address
 - Test requested
 - d. Shipping Information (address all specimens to):
 - Department of Pathology – Client Services Center MC 7750
 - The University of Texas Health Science Center at San Antonio
 - 7703 Floyd Curl Drive
 - San Antonio, Texas 78229-3900
8. **Minimum Specimen Requirements:** 3ml
9. **Total testing time:** **3 days**
Results to Client: **14 days**
10. **Communication:**
 - a. Turnaround time non-conformity: **Email or call Pathologist on request form to notify them of the delay.**

- b. Specimen rejection: **Most causes for specimen rejection are noted at pick- up, prior to the sample leaving UHS premises, communicated verbally, and corrected immediately. In rare cases where cause for specimen rejection is noted after the sample has arrived at UT Health San Antonio, the Pathologist on the request form will be contacted by email or phone.**
 - c. Technical Updates: **Email Applicable Laboratory Director**
- 11. Quality:** A quality assurance report is sent out to the pathologist with every case for them to evaluate the slides and images.

Test Name: Electron Microscopy, Platelet Study

1. **CPT Code:** 88348
2. **Synonym(s):** EM
3. **Performed:** In-House
4. **Methodology:** Blood Platelet Preparation for TEM
5. **Panel/Profile Components:** N/A
6. **Critical Values:** N/A
7. **Specimen Collection / Handling Requirements:**
 - a. Platelet rich plasma prepared from citrate tube (0.109M NaCitrate). Send sample at room temperature.
 - b. A complete requisition slip must accompany all specimens and the specimen must be labeled with the patient's name and identification number.

**ANY SPECIMENS RECEIVED WITHOUT A COMPLETE REQUISITION OR AN UNLABELED SPECIMEN
WILL BE RETURNED IMMEDIATELY**

- c. Patient information must include:
 - Name, address, date of birth of patient
 - Hospital identification number
 - Insurance information (hospital admission form)
 - Pathology accession number where applicable
 - Requesting physicians name and address
 - Test requested
 - d. Shipping Information (address all specimens to):
 - Department of Pathology – Client Services Center MC 7750
 - The University of Texas Health Science Center at San Antonio
 - 7703 Floyd Curl Drive
 - San Antonio, Texas 78229-3900
8. **Minimum Specimen Requirements:** 1ml
9. **Turnaround Times:**
 - a. Total testing time: **3 days**
 - b. Results to Client: **14 days**

10. Communication:

- a. Turnaround time non-conformity: **Email or call Pathologist on request form to notify them of the delay.**
- b. Specimen rejection: **Most causes for specimen rejection are noted at pick- up, prior to the sample leaving UHS premises, communicated verbally, and corrected immediately. In rare cases where cause for specimen rejection is noted after the sample has arrived at UT Health San Antonio, the Pathologist on the request form will be contacted by email or phone.**
- c. Technical Updates: **Email Applicable Laboratory Director.**

11. Quality: A quality assurance report is sent out to the pathologist with every case for them to evaluate the slides and images.

Test Name: Leukemia Immunophenotyping

1. **CPT:** 88184, 88185 x 30, 88189
2. **Synonym(s):** Leukemia Panel
3. **Performed:** In-House
4. **Methodology:** Flow Cytometry Immunophenotyping
5. **Panel/Profile Components:**
CD2, CD3, CD4, CD5, CD7, CD8, CD10, CD11b, CD11c, CD13, CD14, CD15, CD16, CD19, CD20, CD22, CD23, CD25, CD33, CD34, CD41a, CD45, CD56, CD57, CD71, CD117, CD138, FMC-7, HLA-Dr, Kappa, Lambda.
6. **Critical Values:** N/A
7. **Specimen Collection / Handling Requirements:**
See Minimum Specimen Requirements.
8. **Minimum Specimen Requirements:**
For Blood and Bone Marrow Aspirates
 1. Collection:
 - a. Collect bone marrow or blood aseptically into a sterile K₃EDTA (lavender top) blood collection tube. (ACD or heparin is acceptable anticoagulants if K₃EDTA is not available.)
 - b. The primary specimen container must be labeled with at least two patient identifiers.
 - If fewer than two identifiers are visible then request the sending facility to recollect the specimen.
 - If recollection is not possible, document how the labeling error is addressed in the electronic QA log.
 2. Requirements:
 - a. A minimum of 1ml of bone marrow or blood is required.
 - b. The sample must come with a request specifying the test required, the requesting doctor and facility, and appropriate patient demographic information (name, date of birth or age, identification number, specimen source, and provisional diagnosis). If the test was ordered verbally, additional tests are needed, or if the requisition does not accompany the specimen, the Flow lab will contact the facility immediately and request that the documentation be electronically sent or faxed as soon as possible.

- The laboratory personnel receiving the verbal or phone orders must read back the entire order to verify accuracy of transcription. Document who placed the order and the date the order was placed followed by the initials and date of the lab personnel performing the read back.
 - If the accompanying requisition is unclear, for whatever reason, contact the requesting facility upon receipt of the specimen for further clarification
3. Handling:
- a. The anticoagulated bone marrow must be stored at room temperature (20°C to 25°C), no longer than 24 hours prior to staining.
4. Transportation:
- a. Maintain and transport bone marrow samples at room temperature (20^o to 25^o C)
 - b. Transport samples in a reseal-able plastic biohazard bag.
 - c. Place the biohazard bag(s) containing the samples in a padded carrying case or a Styrofoam box. Do not place biohazard bags in a garment pocket for transport.
 - d. Avoid drastic temperature changes, such as <10°C or >37°C.
 - In hot weather, pack specimens in a container which has insulating material around it and place this container inside another that contains a cold pack (ice pack) and some type of absorbent material. This will help maintain the specimen at ambient temperature. **NOTE: DO NOT PLACE BONE MARROW SPECIMENS (OR BLOOD) DIRECTLY ON ICE OR REFRIGERATE. DO NOT FREEZE.**

For Tissue

1. Collection:
- a. Place the lymphoid tissue in a conical tube with RPMI medium. Tissue for flow cytometry should only be collected after tissue has been submitted for histology in formalin or BS fixative. The tissue sample that will be submitted to the flow lab must not be fixed in formalin or similar fixative.
 - b. The primary specimen container must be labeled with at least two patient identifiers.
 - If fewer than two identifiers are visible then request the sending facility to recollect the specimen.
 - If recollection is not possible, document how the labeling error is addressed in the electronic QA log.

2. Requirements:

- a. A minimum of 0.5 cm³ of tissue is required. If less tissue is available, consider freezing it for frozen section immunostains or molecular studies. Refer any questions to the Supervisor.
- b. The sample must be accompanied by a request specifying the test needed, the requesting doctor and facility, and appropriate patient demographic information (name, date of birth or age, identification number, specimen source, and provisional diagnosis). If the test was ordered verbally or if additional tests are needed, or if the requisition does not accompany the specimen, the lab will contact the facility and request that documentation be sent or faxed as soon as possible.
 - The laboratory personnel receiving the verbal or phone orders must read back the entire order to verify accuracy of transcription. Document who placed the order and the date the order was placed followed by the initials and date of the lab personnel performing the read back.
 - If the accompanying requisition is unclear, for whatever reason, contact the requesting facility upon receipt of the specimen for further clarification.

3. Handling:

- a. The lymphoid tissue is usually at room temperature and brought immediately to the lab for processing.
- b. If there is a delay in sending the lymph tissue, it must be stored at 4°C in RPMI, no longer than 24 hours before staining.

4. Transportation:

- a. Maintain and transport lymphoid tissue samples at room temperature (20° to 25°C) stored in a conical tube containing RPMI.
- b. Transport samples in a sealed plastic biohazard bag.
- c. Place the biohazard bags containing the samples in a padded carrying case or a Styrofoam box. Do not place biohazard bags in a garment pocket for transport.
- d. If samples cannot be immediately delivered to the lab for processing, place tissue in RPMI and place on wet ice or in the refrigerator.
- e. **NOTE: DO NOT FREEZE OR FIX LYMPH TISSUE.**
- f. Samples from University Hospital:
 - Samples are picked up from Histology along with a request for lymphocyte studies.

- Ensure the surgery number is correct when signing sample out on Histology Log before leaving.
- Initial for the sample being picked up.
- Place samples in small carrying case and transport to flow lab.

For All Body Fluids and Fine Needle Aspirates (FNA)

1. Collection:

- a. Collect spinal fluid (CSF) in a sterile container.
- b. Collect pleural fluid/ascitic fluid in a ratio of 1 ml of sodium heparin or ACD to 100 ml of fluid.
- c. Collect FNA specimens in a sterile container that contains RPMI.
- d. The primary specimen container must be labeled with at least two patient identifiers.
 - If fewer than two identifiers are visible then request the sending facility to recollect the specimen.
 - If recollection is not possible, document how the labeling error is addressed in the electronic QA log.

2. Requirements:

- a. CSF, Body fluid, and FNA samples must have an adequate amount of cellularity present in order for proper flow cytometric analysis. Minimum acceptable volumes are dependent on the overall cellularity of the available specimen.
- b. The sample must be accompanied by a request specifying the test needed, the requesting doctor and facility, and appropriate patient demographic information (name, date of birth or age, identification number, specimen source, and provisional diagnosis). If the test was ordered verbally or if additional tests are needed, or if the requisition does not accompany the specimen, the lab will contact the requesting facility and request that documentation be sent or faxed as soon as possible.
 - The laboratory personnel receiving the verbal or phone orders must read back the entire order to verify accuracy of transcription. Document who placed the order and the date the order was placed followed by the initials and date of the lab personnel performing the read back.
 - If the accompanying requisition is unclear, for whatever reason, contact the requesting facility upon receipt of the specimen for further clarification.

3. Handling:

- a. The freshly collected body fluid or FNA is brought immediately to the lab for processing.
- b. If there is a delay in sending the specimen, it must be stored at 4° C, for no longer than 24 hours before staining.

4. Transportation:

- a. Maintain and transport the body fluid at room temperature (20°C to 25° C) if delivery will take less than 1 hour. Transport on ice if further delay is expected.
- b. Transport samples in a re-sealable plastic biohazard bag.
- c. Place the biohazard bag(s) containing the sample(s) in a padded carrying case or a Styrofoam box. Do not place biohazard bags in a garment pocket for transport.
- d. If samples cannot be immediately delivered to the lab for processing, store the tube on wet ice or in the refrigerator. **NOTE: DO NOT FREEZE OR FIX FLUID.**

9. Turnaround Times:

- a. Results to Client: **5 business days**

10. Communication:

- a. Turnaround time non-conformity: **Email or call Pathologist on request form to notify them of the delay.**
- b. Specimen rejection: **Most causes for specimen rejection are noted at pick- up, prior to the sample leaving UHS premises, communicated verbally, and corrected immediately. In rare cases where cause for specimen rejection is noted after the sample has arrived at UT Health San Antonio, the Pathologist on the request form will be contacted by email or phone.**
- c. Technical Updates: **Email Applicable Laboratory Director.**

11. Quality:**For all specimens**

- a. The diagnosis of malignant lymphoma or leukemia is made on the identification of an abnormal population of cells, i.e., an aberrant phenotype or monoclonality. This is done by comparison of the staining of different markers in the same specimen. Therefore, normal values are not used in the interpretation.

- b. The patient's name and number are verified on the receiving system by two persons.
- c. Notify signing pathologist of specimens that have a viability of 50% or less.
- d. All new monoclonal antibody lot numbers are verified with previous lot numbers.
- e. Reactivity of the Lyse is assessed daily by visually inspecting each tube for clear supernatant without sediment of intact RBC after centrifugation.
- f. If supernatant remains red, a fresh new batch of lysing solution may be required to re-lyse the patient sample.
- g. Reagent-grade water and de-ionized water free of extraneous contamination.
- h. T & B cell comparisons:
 - i. Normal lymphocytes are marked with T cell, B cell or LG/NK cell markers.
 - j. The total T cell population should compare with the total for all subsets of T (i.e., T cytotoxic/suppressor plus T helper/inducer should be equal to the total T).
 - k. Compare all Pan T-cell markers (CD3, CD2, CD5, and CD7) and Pan B-cell markers (CD19, CD20, and KAPPA/LAMBDA).
- l. CAP Survey: Performed the same way as patient samples.

Test Name: Lymphoma Immunophenotyping

1. **CPT:** 88184, 88185 x 22, 88189
2. **Synonym(s):** Leukemia Panel
3. **Performed:** In-House
4. **Methodology:** Flow Cytometry Immunophenotyping
5. **Panel/Profile Components:**
CD2, CD3, CD4, CD5, CD7, CD8, CD10, CD11c, CD16, CD19, CD20, CD22, CD23, CD25, CD34, CD45, CD56, CD57, CD138, FMC-7, HLA-Dr, Kappa, Lambda.
6. **Critical Values:** N/A
7. **Specimen Collection / Handling Requirements:** See Minimum Specimen Requirements.
8. **Minimum Specimen Requirements:**

For Blood and Bone Marrow Aspirates

1. Collection:
 - a. Collect bone marrow or blood aseptically into a sterile K₃EDTA (lavender top) blood collection tube. (ACD or heparin is acceptable anticoagulants if K₃EDTA is not available.)
 - b. The primary specimen container must be labeled with at least two patient identifiers.
 - If fewer than two identifiers are visible then request the sending facility to recollect the specimen.
 - If recollection is not possible, document how the labeling error is addressed in the electronic QA log.
2. Requirements:
 - a. A minimum of 1ml of bone marrow or blood is required.
 - b. The sample must come with a request specifying the test required, the requesting doctor and facility, and appropriate patient demographic information (name, date of birth or age, identification number, specimen source, and provisional diagnosis). If the test was ordered verbally, additional tests are needed, or if the requisition does not accompany the specimen, the Flow lab will contact the facility immediately and request that the documentation be electronically sent or faxed as soon as possible.

- The laboratory personnel receiving the verbal or phone orders must read back the entire order to verify accuracy of transcription. Document who placed the order and the date the order was placed followed by the initials and date of the lab personnel performing the read back.
 - If the accompanying requisition is unclear, for whatever reason, contact the requesting facility upon receipt of the specimen for further clarification.
3. Handling:
 - a. The anticoagulated bone marrow must be stored at room temperature (20°C to 25°C), no longer than 24 hours prior to staining
 4. Transportation:
 - a. Maintain and transport bone marrow samples at room temperature (20°C to 25°C)
 - b. Transport samples in a reseal-able plastic biohazard bag
 - c. Place the biohazard bag(s) containing the samples in a padded carrying case or a Styrofoam box. Do not place biohazard bags in a garment pocket for transport
 - d. Avoid drastic temperature changes, such as <10°C or >37°C
 - In hot weather, pack specimens in a container which has insulating material around it and place this container inside another that contains a cold pack (ice pack) and some type of absorbent material. This will help maintain the specimen at ambient temperature. **NOTE: DO NOT PLACE BONE MARROW SPECIMENS (OR BLOOD) DIRECTLY ON ICE OR REFRIGERATE. DO NOT FREEZE.**

For Tissue

1. Collection:
 - a. Place the lymphoid tissue in a conical tube with RPMI medium. Tissue for flow cytometry should only be collected after tissue has been submitted for histology in formalin or BS fixative. The tissue sample that will be submitted to the flow lab must not be fixed in formalin or similar fixative.
 - b. The primary specimen container must be labeled with at least two patient identifiers.
 - If fewer than two identifiers are visible then request the sending facility to recollect the specimen.
 - If recollection is not possible, document how the labeling error is addressed in the electronic QA log.
2. Requirements:

- a. A minimum of 0.5 cm³ of tissue is required. If less tissue is available, consider freezing it for frozen section immunostains or molecular studies. Refer any questions to the Supervisor.
 - b. The sample must be accompanied by a request specifying the test needed, the requesting doctor and facility, and appropriate patient demographic information (name, date of birth or age, identification number, specimen source, and provisional diagnosis). If the test was ordered verbally or if additional tests are needed, or if the requisition does not accompany the specimen, the lab will contact the facility and request that documentation be sent or faxed as soon as possible.
 - The laboratory personnel receiving the verbal or phone orders must read back the entire order to verify accuracy of transcription. Document who placed the order and the date the order was placed followed by the initials and date of the lab personnel performing the read back.
 - If the accompanying requisition is unclear, for whatever reason, contact the requesting facility upon receipt of the specimen for further clarification.
3. Handling:
- a. The lymphoid tissue is usually at room temperature and brought immediately to the lab for processing.
 - b. If there is a delay in sending the lymph tissue, it must be stored at 4^o C in RPMI, no longer than 24 hours before staining.
4. Transportation:
- a. Maintain and transport lymphoid tissue samples at room temperature (20^oC to 25^oC) stored in a conical tube containing RPMI.
 - b. Transport samples in a sealed plastic biohazard bag.
 - c. Place the biohazard bags containing the samples in a padded carrying case or a Styrofoam box. Do not place biohazard bags in a garment pocket for transport.
 - d. If samples cannot be immediately delivered to the lab for processing, place tissue in RPMI and place on wet ice or in the refrigerator.
 - e. **NOTE: DO NOT FREEZE OR FIX LYMPH TISSUE.**
 - f. Samples from University Hospital:
 - Samples are picked up from Histology along with a request for lymphocyte studies.
 - Ensure the surgery number is correct when signing sample out on Histology Log before leaving.
 - Initial for the sample being picked up.
 - Place samples in small carrying case and transport to flow lab.

For All Body Fluids and Fine Needle Aspirates (FNA)

1. Collection:
 - a. Collect spinal fluid (CSF) in a sterile container.
 - b. Collect pleural fluid/ascitic fluid in a ratio of 1 ml of sodium heparin or ACD to 100 ml of fluid.
 - c. Collect FNA specimens in a sterile container that contains RPMI
 - d. The primary specimen container must be labeled with at least two patient identifiers.
 - If fewer than two identifiers are visible then request the sending facility to recollect the specimen.
 - If recollection is not possible, document how the labeling error is addressed in the electronic QA log.
2. Requirements:
 - a. CSF, Body fluid, and FNA samples must have an adequate amount of cellularity present in order for proper flow cytometric analysis. Minimum acceptable volumes are dependent on the overall cellularity of the available specimen.
 - b. The sample must be accompanied by a request specifying the test needed, the requesting doctor and facility, and appropriate patient demographic information (name, date of birth or age, identification number, specimen source, and provisional diagnosis). If the test was ordered verbally or if additional tests are needed, or if the requisition does not accompany the specimen, the lab will contact the requesting facility and request that documentation be sent or faxed as soon as possible.
 - The laboratory personnel receiving the verbal or phone orders must read back the entire order to verify accuracy of transcription. Document who placed the order and the date the order was placed followed by the initials and date of the lab personnel performing the read back.
 - If the accompanying requisition is unclear, for whatever reason, contact the requesting facility upon receipt of the specimen for further clarification.
3. Handling:
 - a. The freshly collected body fluid or FNA is brought immediately to the lab for processing.
 - b. If there is a delay in sending the specimen, it must be stored at 4^o C, for no longer than 24 hours before staining.
4. Transportation:
 - a. Maintain and transport the body fluid at room temperature (20^oC to 25^o C) if delivery will take less than 1 hour. Transport on ice if further delay is expected.

- b. Transport samples in a re-sealable plastic biohazard bag.
- c. Place the biohazard bag(s) containing the sample(s) in a padded carrying case or a Styrofoam box.
Do not place biohazard bags in a garment pocket for transport.
- d. If samples cannot be immediately delivered to the lab for processing, store the tube on wet ice or in the refrigerator. **NOTE: DO NOT FREEZE OR FIX FLUID.**

9. Turnaround Times

- a. Results to Client: **5 business days**

10. Communication

- a. Turnaround time non-conformity: **Email or call Pathologist on request form to notify them of the delay.**
- b. Specimen rejection: **Most causes for specimen rejection are noted at pick-up, prior to the sample leaving UHS premises, communicated verbally, and corrected immediately. In rare cases where cause for specimen rejection is noted after the sample has arrived at UT Health San Antonio, the Pathologist on the request form will be contacted by email or phone.**
- c. Technical Updates: **Email Applicable Laboratory Director.**

11. Quality

For all specimens:

- a. The diagnosis of malignant lymphoma or leukemia is made on the identification of an abnormal population of cells, i.e., an aberrant phenotype or monoclonality. This is done by comparison of the staining of different markers in the same specimen. Therefore, normal values are not used in the interpretation.
- b. The patient's name and number are verified on the receiving system by two persons.
- c. Notify signing pathologist of specimens that have a viability of 50% or less.
- d. All new monoclonal antibody lot numbers are verified with previous lot numbers.
- e. Reactivity of the Lyse is assessed daily by visually inspecting each tube for clear supernatant without sediment of intact RBC after centrifugation.
- f. If supernatant remains red, a fresh new batch of lysing solution may be required to re-lyse the patient sample.
- g. Reagent-grade water and de-ionized water free of extraneous contamination.
- h. T & B cell comparisons:

- Normal lymphocytes are marked with T cell, B cell or LG/NK cell markers.
 - The total T cell population should compare with the total for all subsets of T (i.e., T cytotoxic/suppressor plus T helper/inducer should be equal to the total T).
 - Compare all Pan T-cell markers (CD3, CD2, CD5, and CD7) and Pan B-cell markers (CD19, CD20, and KAPPA/LAMBDA).
- i. CAP Survey: Performed the same way as patient samples.

Test Name: Limited Panel Immunophenotyping

1. **CPT:** 88184, 88185 x (varies based on number of antibodies used), 88189
2. **Synonym(s):** Myeloma Panel, Fine Needle Aspirate Panel, & Intracytoplasmic panel
3. **Performed:** In-House
4. **Methodology:** Flow Cytometry Immunophenotyping
5. **Panel/Profile Components may contain the following:**
CD3, CD4, CD5, CD8, CD10, CD16, CD19, CD34, CD45, CD56, CD138, HLA-Dr, Kappa, Lambda, MPO, TdT, cKappa, cLambda,
6. **Critical Values:** N/A
7. **Specimen Collection / Handling Requirements: See Minimum Specimen Requirements**
8. **Minimum Specimen Requirements:**

For Blood and Bone Marrow Aspirates:

1. Collection:
 - a. Collect bone marrow or blood aseptically into a sterile K₃EDTA (lavender top) blood collection tube. (ACD or heparin is acceptable anticoagulants if K₃EDTA is not available.)
 - b. The primary specimen container must be labeled with at least two patient identifiers.
 - If fewer than two identifiers are visible then request the sending facility to recollect the specimen.
 - If recollection is not possible, document how the labeling error is addressed in the electronic QA log.
2. Requirements:
 - a. A minimum of 1ml of bone marrow or blood is required.
 - b. The sample must come with a request specifying the test required, the requesting doctor and facility, and appropriate patient demographic information (name, date of birth or age, identification number, specimen source, and provisional diagnosis). If the test was ordered verbally, additional tests are needed, or if the requisition does not accompany the specimen, the Flow lab will contact the facility immediately and request that the documentation be electronically sent or faxed as soon as possible.

- The laboratory personnel receiving the verbal or phone orders must read back the entire order to verify accuracy of transcription. Document who placed the order and the date the order was placed followed by the initials and date of the lab personnel performing the read back.
 - If the accompanying requisition is unclear, for whatever reason, contact the requesting facility upon receipt of the specimen for further clarification.
3. Handling:
 - a. The anticoagulated bone marrow must be stored at room temperature (20°C to 25°C), no longer than 24 hours prior to staining.
 4. Transportation:
 - a. Maintain and transport bone marrow samples at room temperature (20°C to 25°C)
 - b. Transport samples in a reseal-able plastic biohazard bag.
 - c. Place the biohazard bag(s) containing the samples in a padded carrying case or a Styrofoam box. Do not place biohazard bags in a garment pocket for transport.
 - d. Avoid drastic temperature changes, such as <10°C or >37°C.
 - In hot weather, pack specimens in a container which has insulating material around it and place this container inside another that contains a cold pack (ice pack) and some type of absorbent material. This will help maintain the specimen at ambient temperature. NOTE: DO NOT PLACE BONE MARROW SPECIMENS (OR BLOOD) DIRECTLY ON ICE OR REFRIGERATE. DO NOT FREEZE.

For Tissue:

1. Collection:
 - a. Place the lymphoid tissue in a conical tube with RPMI medium. Tissue for flow cytometry should only be collected after tissue has been submitted for histology in formalin or BS fixative. The tissue sample that will be submitted to the flow lab must not be fixed in formalin or similar fixative.
 - b. The primary specimen container must be labeled with at least two patient identifiers.
 - If fewer than two identifiers are visible, then request the sending facility to recollect the specimen.
 - If recollection is not possible, document how the labeling error is addressed in the electronic QA log.
2. Requirements:
 - a. A minimum of 0.5 cm³ of tissue is required. If less tissue is available, consider freezing it for frozen section immunostains or molecular studies. Refer any questions to the Supervisor.

- b. The sample must be accompanied by a request specifying the test needed, the requesting doctor and facility, and appropriate patient demographic information (name, date of birth or age, identification number, specimen source, and provisional diagnosis). If the test was ordered verbally or if additional tests are needed, or if the requisition does not accompany the specimen, the lab will contact the facility and request that documentation be sent or faxed as soon as possible.
 - The laboratory personnel receiving the verbal or phone orders must read back the entire order to verify accuracy of transcription. Document who placed the order and the date the order was placed followed by the initials and date of the lab personnel performing the read back.
 - If the accompanying requisition is unclear, for whatever reason, contact the requesting facility upon receipt of the specimen for further clarification.
3. Handling:
 - a. The lymphoid tissue is usually at room temperature and brought immediately to the lab for processing.
 - b. If there is a delay in sending the lymph tissue, it must be stored at 4^o C in RPMI, no longer than 24 hours before staining.
4. Transportation:
 - a. Maintain and transport lymphoid tissue samples at room temperature (20^o to 25^oC) stored in a conical tube containing RPMI.
 - b. Transport samples in a sealed plastic biohazard bag.
 - c. Place the biohazard bags containing the samples in a padded carrying case or a Styrofoam box. Do not place biohazard bags in a garment pocket for transport.
 - d. If samples cannot be immediately delivered to the lab for processing, place tissue in RPMI and place on wet ice or in the refrigerator.
 - e. **NOTE: DO NOT FREEZE OR FIX LYMPH TISSUE.**
 - f. Samples from University Hospital:
 - Samples are picked up from Histology along with a request for lymphocyte studies.
 - Ensure the surgery number is correct when signing sample out on Histology Log before leaving.
 - Initial for the sample being picked up.
 - Place samples in small carrying case and transport to flow lab.

For All Body Fluids and Fine Needle Aspirates (FNA):

1. Collection:

- a. Collect spinal fluid (CSF) in a sterile container.
 - b. Collect pleural fluid/ascitic fluid in a ratio of 1 ml of sodium heparin or ACD to 100 ml of fluid.
 - c. Collect FNA specimens in a sterile container that contains RPMI
 - d. The primary specimen container must be labeled with at least two patient identifiers.
 - If fewer than two identifiers are visible, then request the sending facility to recollect the specimen.
 - If recollection is not possible, document how the labeling error is addressed in the electronic QA log.
2. Requirements:
- a. CSF, Body fluid, and FNA samples must have an adequate amount of cellularity present in order for proper flow cytometric analysis. Minimum acceptable volumes are dependent on the overall cellularity of the available specimen.
 - b. The sample must be accompanied by a request specifying the test needed, the requesting doctor and facility, and appropriate patient demographic information (name, date of birth or age, identification number, specimen source, and provisional diagnosis). If the test was ordered verbally or if additional tests are needed, or if the requisition does not accompany the specimen, the lab will contact the requesting facility and request that documentation be sent or faxed as soon as possible.
 - The laboratory personnel receiving the verbal or phone orders must read back the entire order to verify accuracy of transcription. Document who placed the order and the date the order was placed followed by the initials and date of the lab personnel performing the read back.
 - If the accompanying requisition is unclear, for whatever reason, contact the requesting facility upon receipt of the specimen for further clarification.
3. Handling:
- a. The freshly collected body fluid or FNA is brought immediately to the lab for processing.
 - b. If there is a delay in sending the specimen, it must be stored at 4°C, for no longer than 24 hours before staining.
4. Transportation:
- a. Maintain and transport the body fluid at room temperature (20°C to 25°C) if delivery will take less than 1 hour. Transport on ice if further delay is expected.
 - b. Transport samples in a re-sealable plastic biohazard bag.

- c. Place the biohazard bag(s) containing the sample(s) in a padded carrying case or a Styrofoam box. Do not place biohazard bags in a garment pocket for transport.
- d. If samples cannot be immediately delivered to the lab for processing, store the tube on wet ice or in the refrigerator. **NOTE: DO NOT FREEZE OR FIX FLUID.**

9. Turnaround Times:

- a. Results to Client: **5 business days**

10. Communication:

- a. Turnaround time non-conformity: **Email or call Pathologist on request form to notify them of the delay.**
- b. Specimen rejection: **Most causes for specimen rejection are noted at pick-up, prior to the sample leaving UHS premises, communicated verbally, and corrected immediately. In rare cases where cause for specimen rejection is noted after the sample has arrived at UT Health San Antonio, the Pathologist on the request form will be contacted by email or phone.**
- c. Technical Updates: **Email Applicable Laboratory Director.**

11. Quality:

For all specimens

- a. The diagnosis of malignant lymphoma or leukemia is made on the identification of an abnormal population of cells, i.e., an aberrant phenotype or monoclonality. This is done by comparison of the staining of different markers in the same specimen. Therefore, normal values are not used in the interpretation.
- b. The patient's name and number are verified on the receiving system by two persons.
- c. Notify signing pathologist of specimens that have a viability of 50% or less.
- d. All new monoclonal antibody lot numbers are verified with previous lot numbers.
- e. Reactivity of the Lyse is assessed daily by visually inspecting each tube for clear supernatant without sediment of intact RBC after centrifugation.
- f. If supernatant remains red, a fresh new batch of lysing solution may be required to re-lyse the patient sample.
- g. Reagent-grade water and de-ionized water free of extraneous contamination.
- h. T & B cell comparisons:
 - Normal lymphocytes are marked with T cell, B cell or LG/NK cell markers.

- The total T cell population should compare with the total for all subsets of T (i.e., T cytotoxic/suppressor plus T helper/inducer should be equal to the total T).
 - Compare all Pan T-cell markers (CD3, CD2, CD5, and CD7) and Pan B-cell markers (CD19, CD20, and KAPPA/LAMBDA).
- i. CAP Survey: Performed the same way as patient samples.

Test Name: Paroxysmal Nocturnal Hemoglobinuria (PNH)

1. **CPT:** 88184, 88185 x 7, 88189
2. **Synonym(s):** PNH
3. **Performed:** In-House
4. **Methodology:** Flow Cytometry Immunophenotyping
5. **Panel/Profile Components may contain the following:**
CD14, CD15, CD24, CD33, CD45, CD59, CD235a, & FLAER
6. **Critical Values:** N/A
7. **Specimen Collection / Handling Requirements:** See Minimum Specimen Requirements.
8. **Minimum Specimen Requirements:**
 1. Collection:
 - a. Collect peripheral blood aseptically into a sterile K₃EDTA (lavender top) blood collection tube.
 - b. The primary specimen container must be labeled with at least two patient identifiers.
 - If fewer than two identifiers are visible then request the sending facility to recollect the specimen.
 2. Requirements for peripheral blood:
 - a. A minimum of 5ml of whole blood for adults.
 - b. A minimum of 1ml of whole blood for small children.
 - c. For peripheral blood a white cell count, and a differential count should be performed on the same day by the requesting institution. NOTE: A second EDTA tube of blood is required if the ordering institution is from out of town; this is used to perform the white cell count and differential. (The white cell count is known before staining the cells.)
 - d. The sample must come with a request specifying the requested test, the requesting doctor and facility, and appropriate patient demographic information (name, date of birth or age), identification number, specimen source, and provisional diagnosis). If the test was ordered verbally, or additional tests are needed, or if the requisition does not accompany the specimen, the lab will contact the facility and request that documentation be sent or faxed as soon as possible.
 - The laboratory personnel receiving the verbal or phone orders must read back the entire order to verify accuracy of transcription. Document who placed the order and the date the order was placed followed by the initials and date of the lab personnel performing the read back.

- If the accompanying requisition is unclear, for whatever reason, contact the requesting facility upon receipt of the specimen for further clarification.

3. Handling:

- a. The anticoagulated blood must be stored at room temperature (20^o to 25^o C), for no longer than 24 hours before staining.

4. Transportation:

- a. Maintain and transport peripheral blood samples at room temperature (2^oc to 25^oC).
- b. Transport samples in a seal-able plastic biohazard bag.
- c. As needed place the samples in a secondary container that will maintain the appropriate transport temperature.
- d. Samples from University Hospital:
 - Samples are picked up directly from the Hematology lab.
 - Write names and hospital accession numbers on pad in the Hematology section; initial for those samples being picked up.
 - Place samples in a small carrying case, if necessary, and transport to the flow lab.

9. Turnaround Times:

- a. Results to Client: **5 business days**

10. Communication:

- a. Turnaround time non-conformity: **Email or call Pathologist on request form to notify them of the delay.**
- b. Specimen rejection: **Most causes for specimen rejection are noted at pick- up, prior to the sample leaving UHS premises, communicated verbally, and corrected immediately. In rare cases where cause for specimen rejection is noted after the sample has arrived at UT Health San Antonio, the Pathologist on the request form will be contacted by email or phone.**
- c. Technical Updates: **Email Applicable Laboratory Director.**

11. Quality:

For all specimens

Peripheral Blood Sample:

- a. The patient's name and number are verified on the receiving system by two technologists.
- b. Cells must be greater than 50% viable and sufficient in number to perform analysis by flow cytometry; if not, notify Medical Director

- c. All new monoclonal antibody lot numbers are verified with previous lot numbers.
- d. Reactivity of the Lysing solution is assessed by visually inspecting each tube for clear supernatant without sediment of intact RBC after centrifugation.
- e. If supernatant remains red, a fresh new batch of lysing solution may be diluted and relyse the sample.
- f. Reagent-grade de-ionized water free of extraneous contamination.
- g. Neutrophils, monocytes and erythrocytes comparisons:
 - Normal neutrophils express intermediate intensity CD45 with strong intensity CD15/FLAER/CD24.
 - Normal monocytes express intermediate to strong intensity CD45 with strong intensity CD33/FLAER/CD14.
 - Normal erythrocytes express CD235a with intermediate intensity CD59.
- h. Control with unremarkable CBC: stain with the same antibody panel as test.
- i. CAP Survey: Performed twice a year and handled exactly like a patient sample.

Test Name: Quantitation of Red Blood Cells Containing Fetal Hemoglobin

1. **CPT:** 88184, 88189
2. **Synonym(s):** Hemoglobin F Quantitation, Fetal Hemoglobin
3. **Performed:** In-House
4. **Methodology:** Flow Cytometry cytoplasmic Immunophenotyping
5. **Panel/Profile Components:** Anti-Hemoglobin F
6. **Critical Values:** N/A
7. **Specimen Collection / Handling Requirements:** See Minimum Specimen Requirements.
8. **Minimum Specimen Requirements:**
 1. Collection:
 - a. Collect aseptically by venipuncture into a sterile K₃EDTA (lavender top) blood collection tube.
 - b. The primary specimen container must be labeled with at least two patient identifiers.
 - If fewer than two identifiers are visible then request the sending facility to recollect the specimen.
 - If recollection is not possible, document how the labeling error is addressed in the electronic QA log.
 2. Requirements:
 - a. A minimum of 1ml of whole blood.
 - b. The sample must come with a request specifying the test needed the requesting doctor and facility, and appropriate patient demographic information (name, date of birth or age, identification number, specimen source, phone number, fax number, and provisional diagnosis). If the test was ordered verbally, additional tests are needed, or if the requisition does not accompany the specimen, the lab will contact the facility and request that documentation be sent or faxed as soon as possible.
 - The laboratory personnel receiving the verbal or phone orders must read back the entire order to verify accuracy of transcription. Document who placed the order and the date the order was placed followed by the initials and date of the lab personnel performing the read back.
 - If the accompanying requisition is unclear, for whatever reason, contact the requesting facility upon receipt of the specimen for further clarification.

3. Handling:

- a. The anti-coagulated specimen must be stored at room temperature (20^o – 25^o C) and testing should be performed within 6 hours post collection but not longer than 30 hours.

4. Transportation:

- a. Maintain and transport peripheral blood samples at room temperature (20^o to 25^oC).
- b. Transport samples in a seal-able plastic biohazard bag.
- c. Place the biohazard bags containing the samples in a padded carrying case or a Styrofoam box. Do not place biohazard bags in a garment pocket for transport.
- d. Avoid drastic temperature changes, such as <10^o C or >37^o C. It may be necessary, in hot weather, to pack the specimens in a container which has insulating material around it and place this container inside another that contains a cold pack (ice pack) and some type of absorbent material. This will help maintain the specimen at the appropriate temperature. **NOTE: DO NOT PLACE BLOOD SPECIMENS DIRECTLY ON ICE OR REFRIGERATE. DO NOT FREEZE.**

9. Turnaround Times:

- a. Results to Client:
 - Weekdays Monday – Friday: **24 hours from receipt**
 - Weekends: **48 hours from receipt**

10. Communication:

- a. Turnaround time non-conformity: **Email or call Pathologist on request form to notify them of the delay.**
- b. Specimen rejection: **Most causes for specimen rejection are noted at pick-up, prior to the sample leaving UHS premises, communicated verbally, and corrected immediately. In rare cases where cause for specimen rejection is noted after the sample has arrived at UT Health San Antonio, the Pathologist on the request form will be contacted by email or phone.**
- c. Technical Updates: **Email Applicable Laboratory Director.**

11. Quality:**For all specimens**

- a. Controls have been established in the Lymphocytic Laboratory as being run once a day.
- b. Three levels of controls (Normal-Level 1, Low positive – Level 2, High positive- Level 3). ALL three controls are analyzed with each day's first run of samples.
- c. Store mixtures in the refrigerator when not in use.

- d. FETALTROL< controls are stable for 25 thermal cycles.
- e. Allow the three levels of controls to warm to ambient temperature for 10 min – DO NOT MIX during this period. PRE-mix by rolling vials horizontally between palms of hands 10-20 times. Gently invert vials 10 times – Continue in this manner until the cells are completely mixed. DO NOT USE MECHANICAL MIXER.
- f. Three levels of FETALTROL< controls should be included with each test sample or group of test samples analyzed to ensure proper laboratory working conditions and to establish that all reagents are performing consistently. In this manner, the positive fluorescence attributed to antibody-stained fetal red cell is differentiated from unstained normal red blood cell leucocytes and any cellular debris. The FETALTROL control samples consist of a Negative control and Low and High Positive Controls.

**Test: Antifungal Drug Levels/Therapeutic Drug Monitoring
(Fluconazole, Itraconazole, Posaconazole, Voriconazole, Amphotericin)**

1. **CPT:** 80187 Posaconazole; 80285 Voriconazole, 80189 Itraconazole; 80299 Others
2. **Synonym(s):** N/A
3. **Performed:** In-House
4. **Methodology:**
 - a. HPLC: voriconazole, amphotericin B, posaconazole;
 - b. UPLC/MS: fluconazole, itraconazole, isavuconazole
5. **Panel/Profile Components:** N/A
6. **Critical Values:** Voriconazole level <1.0 mcg/ml; Voriconazole level >6.0 mcg/ml
7. **Specimen Collection / Handling Requirements:**

Serum or plasma separated from whole blood is required. Samples must remain frozen if the time from separation to delivery to our laboratory exceeds 24 hours. Samples for measurement of amphotericin B or concentrations must be protected from light, as these agents are light sensitive.
8. **Minimum Specimen Requirements:**
 - a. Minimum plasma/serum volume requirements:
 - b. Voriconazole - 0.5 ml
 - c. Amphotericin B - 0.5 ml
 - d. Fluconazole - 0.25 ml
 - e. Itraconazole - 0.5 ml
 - f. Posaconazole - 0.5 ml
 - g. Isavuconazole – 0.5 ml
9. **Turnaround Times:**
 - a. Total testing time: **6 hours**
 - b. Results to Client: **72 hours**
10. **Communication:**
 - a. Turnaround time non-conformity: **Email or call Pathologist on request form to notify them of the delay.**
 - b. Specimen rejection: **Most causes for specimen rejection are noted at pick-up, prior to the sample leaving UHS premises, communicated verbally, and corrected immediately. In rare cases where cause**

for specimen rejection is noted after the sample has arrived at UT Health San Antonio, the Pathologist on the request form will be contacted by email or phone.

c. Technical Updates: **Email Applicable Laboratory Director.**

11. Quality: Three control concentrations along with standard curve are performed for each assay at the time of each run. Suitability of control concentrations (within + 2 SD from mean concentration of each control) assessed by technologist and director before results are released.

Test: Antifungal Susceptibility Testing – Moulds and Yeasts

(Amphotericin B, Nystatin, Natamycin, 5-Fluorocytosine, Caspofungin, Anidulafungin, Micafungin, Fluconazole, Itraconazole, Miconazole, Clotrimazole, Terconazole, Voriconazole, Posaconazole, Isavuconazole, Terbinafine, Griseofulvin, Ibrexafungin, Rezafungin)

1. **CPT:** 87188 (mould), 87186 (yeast)
2. **Synonym(s):** Mould MIC (Amphotericin B = AMB, Nystatin = NYS, Natamycin = NAT, 5-Fluorocytosine = 5-FC, Caspofungin = CAS, Anidulafungin = ANID, Micafungin = MICA, Fluconazole = FLU, Itraconazole = ITRA, Miconazole = MON, Clotrimazole = CLOT, Terconazole = TERC, Voriconazole = VORI, Posaconazole = POS, Isavuconazole = ISA, Terbinafine = TERB, Griseofulvin = GRIS, Rezafungin = REZA, Ibrexafungin = IBX))
3. **Performed:** In-House
4. **Methodology:** Antifungal susceptibility testing is performed by microdilution or macrodilution susceptibility testing according to the methods set forth in the Clinical and Laboratory Standards Institute (CLSI) M38 reference standard filamentous fungi, and by broth microdilution or macrodilution susceptibility testing against yeasts according to the CLSI M27 reference standard.
5. **Panel/Profile Components:** Testing tailored to requests for submitting laboratory/physician. Azole panel (fluconazole, voriconazole, itraconazole, posaconazole) and amphotericin/echinocandin panel (amphotericin B, anidulafungin, caspofungin, micafungin) available if requested. Otherwise, individual drugs or combinations of agents tested per request.
6. **Critical Values:** N/A
7. **Specimen Collection / Handling Requirements:**

A pure culture of organism on solid agar (plate or slant) at room temperature is required. Universal precautions should be used for handling fungal cultures.
8. **Minimum Specimen Requirements:**

A pure culture of organism on solid agar (plate or slant) is required.
9. **Turnaround Times:**
 - a. Total testing time: **1 to 10 days from receipt of culture (species dependent)**
 - b. Results to Client: **<10 business days from receipt of culture**
10. **Communication:**

- a. Turnaround time non-conformity: **Email or call Pathologist on request form to notify them of the delay.**
 - b. Specimen rejection: **Most causes for specimen rejection are noted at pick-up, prior to the sample leaving UHS premises, communicated verbally, and corrected immediately. In rare cases where cause for specimen rejection is noted after the sample has arrived at UT Health San Antonio, the Pathologist on the request form will be contacted by email or phone.**
 - c. Technical Updates: **Email Applicable Laboratory Director.**
- 11. Quality:** Quality controls run for each drug at each set-up of assay according to CLSI M38- A2 and M27-A3 reference standard recommendations. QC MICs reviewed by medical technologist before release of results and reviewed once weekly by director.

Test: Fungal Species Identification by Morphology and Molecular Sequencing/MALDI-TOF MS

1. **CPT:** 87107 and 87153 (moulds), 87106 and 87153 (yeasts)
2. **Synonym(s):** N/A
3. **Performed:** In-House
4. **Methodology:**

Both microscopic and macroscopic characteristics of fungal isolates are evaluated to characterize the morphology. Various phenotypic and physiologic characteristics are also evaluated in order to determine the species identification. These include, but are not limited to:

- a. Growth at various temperatures (10°C to 50°C)
- b. Compounds susceptibility or resistance to various substances (e.g., cycloheximide, benomyl)

The species identification of fungal isolates is also determined by the DNA sequence at various targets (loci). The methods used are consistent with set forth in CLSI document MM18A. Two DNA targets are sequenced for each isolate, and these targets include, but may not be limited to the following:

Abbreviation	Target
ITS	Internal transcribed spacer region
D1/D2	28S rDNA large subunit
TUB	Beta-tubulin
CAL	Calmodulin
TEF	Translation elongation factor
RPB1/RPB2	RNA polymerase
GPD	Glyceraldehyde-3-phosphate dehydrogenase

Sequences are then compared to those within GenBank and with smaller validated databases available through the CBS-KNAW Fungal Biodiversity Center. Species identification may also be made by MALDI-TOF MS. If species identification cannot be made by MALDI-TOF MS, reflex testing to DNA sequence analysis occurs.

5. **Panel/Profile Components:** N/A
6. **Critical Values:** Preliminary identifications to the genus level are provided when available. However, no critical exist.
7. **Specimen Collection / Handling Requirements:**

A pure culture of organism on solid agar (plate or slant) at room temperature is required. Universal precautions should be used for handling fungal cultures.

8. Minimum Specimen Requirements:

A pure culture of organism on solid agar (plate or slant) is required.

9. Turnaround Times:

- a. Total testing time: **< 14 days from receipt of culture (species dependent)**
- b. Results to Client: **< 14 business days from receipt of culture**

10. Communication:

- a. Turnaround time non-conformity: **Email or call Pathologist on request form to notify them of the delay.**
- b. Specimen rejection: **Most causes for specimen rejection are noted at pick-up, prior to the sample leaving UHS premises, communicated verbally, and corrected immediately. In rare cases where cause for specimen rejection is noted after the sample has arrived at UT Health San Antonio, the Pathologist on the request form will be contacted by email or phone.**
- c. Technical Updates: **Email Applicable Laboratory Director.**

11. Quality: Quality controls (both negative and positive controls) are run at each set up of the molecular assays to assess for both contamination of the reagents as well as appropriate amplification, sequencing, and BLAST analysis of the DNA targets.

Test: Special Stains

1. **CPT:** 88312,88313,88314
2. **Synonym(s):** Acid Fast Bacilli Stain; Alcian Blue Stain; Auramine Rhodamine Stain; Bile Stain; Colloidal Iron Stain; Congo Red Stain; Copper Stain; Elastic Stain; Iron Stain; Fite Stain; Fontana Masson Stain; Giemsa Stain; Grocott Methenamine Silver Stain; Gram Stain; Luxol Fast Blue Stain; Luxol Fast Blue/ PAS Stain ; Masson's Trichrome Stain; Mucicarmine Stain; Periodic Acid Methanimine Stain; Periodic Acid Schiffs Stain; PAS Fungal Stain; PAS w/Diastase Stain; Post B5 H&E; Post B5 PASH; PTAH Stain; Retic Stain; Steiner Stain; Toluidine Blue Stain; Von Kossa Stain; Wright Stain
3. **Performed:** In-House
4. **Methodology:** Special Stain Procedure (Bench)
5. **Panel/Profile Components:** N/A
6. **Critical Values:** N/A
7. **Specimen Collection / Handling Requirements:**

PROTOCOL FOR Special Stain:

1. A complete requisition slip must accompany all specimens and the specimen must be labeled with the patient's name and identification number.
ANY SPECIMENS RECEIVED WITHOUT A COMPLETE REQUISITION OR AN UNLABELED SPECIMEN WILL BE RETURNED IMMEDIATELY
2. Patient information must include:
 - a. Name, address, date of birth of patient
 - b. Hospital identification number
 - c. Insurance information (hospital admission form)
 - d. Pathology accession number where applicable
 - e. Requesting physicians name and address
 - f. Test requested
3. Shipping Information (address all specimens to):

Department of Pathology – Client Services Center MC 7750
The University of Texas Health Science Center at San Antonio
7703 Floyd Curl Drive
San Antonio, Texas 78229-3900

8. Minimum Specimen Requirements: PARAFFIN BLOCKS PREFERRED SLIDES

- a. Cut sections at 4-5 microns
- b. Sections must be on Plus Coated slides.
- c. Slides must have the accession number clearly written
- d. Slides must have the type of fixation written on the slide if other than formalin.
- e. Submit two (2) slides for each antibody ordered. Do not heat dry slides in oven

9. Tech only Turnaround Times:

- a. Results to Client: **24 hours**

10. Communication:

- a. Turnaround time non-conformity: **Email or call client contact on request form to notify them of the delay.**
- b. Specimen rejection: **In rare cases where cause for specimen rejection is noted after the sample has arrived at UT Health San Antonio, the client contact information on the request form will be notified by email or phone.**
- c. Technical Updates: **Email Applicable Laboratory Director.**

11. Quality: Appropriate + Control Tissue is run with the patient specimen for Quality Control. The patient and control tissues are evaluated every day by the technologist before the slides are released to the client.

Test: Immunofluorescence

1. **CPT:** 88346
2. **Synonym(s):** IF
3. **Performed: In-House:** Yes
4. **Methodology:** Direct Immunofluorescence and Indirect (C4d) Immunofluorescence
5. **Panel/Profile Components: IMMUNOFLUORESCENCE PANELS:**

Renal Panel	Skin & Conjunctiva Panel	Oral Panel	Lung Panel
H&E	H&E	H&E	H&E
IgG	IgG	IgG	C4d
IgA	IgA	IgA	Negative
IgM	IgM	IgM	
C3	C3	C3	
C1Q	C1Q	Fibrinogen	
Fibrinogen	Fibrinogen	Negative	
Kappa	Negative	H&E	
Lambda	H&E		
Negative			
H&E			
C4d (transplants)			

6. **Critical Values:** N/A
7. **Specimen Collection / Handling Requirements:**
Procedure:
 - a. Immediately place specimen for immunofluorescent studies in Michel's IF Transport Media. (Provided by STRL Histology/Immunohistochemistry Laboratory)
 - b. Label specimen container with patient name, specimen type, and identification number.
 - c. Include completed laboratory requisition, patient report and send to laboratory.

Shipping Information (address all specimens to):

Department of Pathology – Client Services Center MC 7750
 The University of Texas Health Science Center at San Antonio
 7703 Floyd Curl Drive
 San Antonio, Texas 78229-3900

(210) 567-6599

8. **Minimum Specimen Requirements:** 1 to 2 core biopsies
9. **Tech only Turnaround Times:**
 - a. Results to Client: **72 hours**
10. **Communication:**
 - a. Turnaround time non-conformity: **Email Applicable Laboratory Director.**
 - b. Specimen rejection: **In rare cases where cause for specimen rejection is noted after the sample has arrived at UT Health San Antonio, the client contact information on the request form will be notified by email or phone.**
 - c. Technical Updates: **Email Applicable Laboratory Director.**
11. **Quality: Staining** - All routine H&E's, Special Stains, Immunofluorescence, and Immunohistochemistry stains performed are run with positive tissue controls (and negative tissue controls for IF and IHC's) to ensure a quality stain has been achieved. The controls and patient tissues are reviewed and checked for quality and accuracy by the histologist and again by the pathologist. Staining results are recorded by the technologist daily and initialed by the pathologists on the QA form. Muscle biopsies contain internal controls which are evaluated by our neuropathologist. Any variability in staining is documented in the quality control/quality assurance report that accompanies each case. Periodically normal skeletal muscle controls are used to test the quality of unexpired reagents.

Test: In-Situ Hybridization

- a. EBER
1. **CPT:** 88365
2. **Synonym(s):** ISH
3. **Performed: In-House**
 - a. EBER-Yes
4. **Methodology:** ISH I-View Blue Plus (Ventana)
5. **Panel/Profile Components:**
 - a. EBER, U6 RNA +Control, ISH –Control
6. **Critical Values:** N/A
7. **Specimen Collection / Handling Requirements:**
 1. A complete requisition slip must accompany all specimens and the specimen must be labeled with the patient's name and identification number.
ANY SPECIMENS RECEIVED WITHOUT A COMPLETE REQUISITION OR AN UNLABELED SPECIMEN WILL BE RETURNED IMMEDIATELY
 2. Patient information must include:
 - a. Name, address, date of birth of patient
 - b. Hospital identification number
 - c. Insurance information (hospital admission form)
 - d. Pathology accession number where applicable
 - e. Requesting physicians name and address
 3. Shipping Information (address all specimens to):
Department of Pathology – Client Services Center MC 7750
The University of Texas Health Science Center at San Antonio
7703 Floyd Curl Drive
San Antonio, Texas 78229-3900
(210) 567-6599

8. Minimum Specimen Requirements:

1. Paraffin Block Preferred
2. Slides
 - a. Cut sections at 3-4 microns
 - b. Sections must be on Plus Coated slides (only certain slides work on Ventana IHC stainers please call the Histology/Immunohistochemistry laboratory before cutting sections).
 - c. Slides must have the accession number and patient name clearly written
 - d. Slides must have the type of fixation written on the slide if other than formalin.
 - e. Submit two (3) slides.
 - f. **Do not** heat dry slides in oven.

9. Tech only Turnaround Times:

- a. Results to Client: **48 hours**

10. Communication:

- a. Turnaround time non-conformity: **Email Applicable Laboratory Director.**
- b. Specimen rejection: **In rare cases where cause for specimen rejection is noted after the sample has arrived at UT Health San Antonio, the client contact information on the request form will be notified by email or phone.**
- c. Technical Updates: **Email Applicable Laboratory Director.**

11. Quality: All routine H&E's, Special Stains, Immunofluorescence and Immunohistochemistry stains performed are run with positive tissue controls (and negative tissue controls for IF and IHC's) to ensure a quality stain has been achieved. The controls and patient tissues are reviewed and checked for quality and accuracy by the histologist and again by the pathologist. Staining results are recorded by the technologist daily and initialed by the pathologists on the QA form. Muscle biopsies contain internal controls which are evaluated by our neuropathologist. Any variability in staining is documented on the quality control/quality assurance report that accompanies each case. Periodically normal skeletal muscle controls are used to test the quality of unexpired reagents.

Test: Immunohistochemistry

1. **CPT:** 88342
2. **Synonym(s):** IHC
3. **Performed:** In-House: Yes
4. **Methodology:** Avidin-Biotin I-View DAB (Ventana), Ultra-View, DAB or Alkaline Phosphatase (Ventana), Opti-View DAB (Ventana)
5. **Panel/Profile Components:** The following IHC tests all without interpretation: A-1 ACT; ACTH; AFP; ALK-1; B72.3; BCL2; BCL6; Ber-EP4; BOB 1; Beta-Catenin; CA19-9; CA-125; Calcitonin; Calponin-1; Calretinin; Cam 5.2; CA9; CD1a; CD2; CD3; CD4; CD5; CD7; CD8; CD10; CD15; CD20; CD21; CD23; CD25; CD30; CD31; CD33; CD34; CD43; CD45RB; CD45RO; CD56; CD57; CD61; CD68; CD71; CD79a; CD99; CD117; CD123; CD138; CD207; CDK4; CDX-2; CEA; Chromogranin; CK5/6; CK7; CK20; CLA; Clusterin; CMV; CXCL13; Cyclin-D1; D2-40; Desmin; EBV-LMP; E-Cadherin; EGFR; ER; Factor VIII; Factor XIIIa; Fascin; FSH; Gastrin; GATA-3; GCDFP-15; GFAP; GH; Glucagon; Glycophorin A; Glypican-3; HBME; HCG-Beta; Hemoglobin A; Hepar; Her2; HHV-8; HMB-45; H.pylori; HSV 1; HSV 2; IDH1; IgA; IgD; IgG; IgG4; IgM; Inhibin A; Insulin; Kappa; Keratin AE1/3; Keratin 903; Ki67; Lambda; Laminin; LH; Lysozyme; Mart 1; Mammaglobin; Mast Cell Tryptase; MDM2; MLH-1; MSH-2; MSH-6; MUM-1; Myeloperoxidase; Myogenin; Neurofilament; NSE; OCT 2; OCT ¾; P 16; P40 (P63); P53 (D07); Pan-Actin; Pan Melanoma; Pax5; Pax8; PD1; PHH3; PIN 4; PLAP; PMS 2; Polyomavirus(SV40); PR; Prolactin; PSA; PSMA; PTH; S100; SMA; Sox 11; Spirochete; Synaptophysin; TCL-1a; TCRbf1; TCR gamma; TDT; Thyroglobulin; TIA-1; TSH; TTF-1; Vimentin; WT-1
6. **Critical Values:** N/A
7. **Specimen Collection / Handling Requirements:**
 - a. A complete requisition slip must accompany all specimens and the specimen must be labeled with the patient's name and identification number.
ANY SPECIMENS RECEIVED WITHOUT A COMPLETE REQUISITION OR AN UNLABELED SPECIMEN WILL BE RETURNED IMMEDIATELY
 - b. Patient information must include:
 - Name, address, date of birth of patient
 - Hospital identification number
 - Insurance information (hospital admission form)
 - Pathology accession number where applicable

- Requesting physicians name and address
 - Test requested
- c. Shipping Information (address all specimens to):
- Department of Pathology – Client Services Center MC 7750
The University of Texas Health Science Center at San Antonio
7703 Floyd Curl Drive
San Antonio, Texas 78229-3900
- 8. Minimum Specimen Requirements:**
- PARAFFIN BLOCKS PREFERRED SLIDES:**
- a. Cut sections at 3-4 microns
 - b. Sections must be on Plus Coated slides
 - c. Slides must have the accession number clearly written
 - d. Slides must have the type of fixation written on the slide if other than formalin
 - e. Submit two (2) slides for each antibody ordered. Do not heat dry slides in oven
- 9. Tech only Turnaround Times:**
- a. Results to Client: **24 hours**
- 10. Communication:**
- a. Turnaround time non-conformity: **Email Applicable Laboratory Director.**
 - b. Specimen rejection: **In rare cases where cause for specimen rejection is noted after the sample has arrived at UT Health San Antonio, the client contact information on the request form will be notified by email or phone.**
 - c. Technical Updates: **Email Applicable Laboratory Director.**

11. Quality:

There are two sets of patient slides run through the assay. One set receives the appropriate primary antibody and the other remains in primary diluent during primary incubation: as the negative control. The control tissue which is placed on top of each patient test slide are known positive tissues that have been previously tested and have good-excellent results. Therefore, by evaluating these slides which have predictable results the quality of the procedure is closely monitored. The patient and control tissues are evaluated and graded from 1-4+ every day by the technologist and the pathologist before the slides are released to the doctors or residents.

Test: **Histochemistry Muscle Enzyme**

1. **CPT:** 88314
2. **Synonym(s):** N/A
3. **Performed:** In-House: Yes
4. **Methodology:** Enzyme Histochemistry
5. **Panel/Profile Components:**
 - a. H&E –Snap Frozen
 - b. H&E –Snap Frozen
 - c. Gomori Trichrome – Snap Frozen
 - d. NADH
 - e. Esterase
 - f. ATPase 10.4
 - g. ATPase 4.5
 - h. PAS w/o Digestion- Snap Frozen
 - i. PAS w/Digestion Snap Frozen
 - j. Alkaline Phosphatase
 - k. Oil Red O- Snap Frozen
 - l. Phosphorylase

6. **Critical Values:** N/A

7. **Specimen Collection / Handling Requirements:**

PROCEDURE:

- a. Please notify the Histology/Immunohistochemistry Laboratory at UTHSCSA one day in advance that a muscle specimen will be arriving.

**MUSCLE BIOSPIES ARE RECEIVED IN THE STRL HISTOLOGY LABORATORY
MONDAY- FRIDAY (EXCEPT HOLIDAYS) 8:00AM TO 4:00PM.**

Contact Histology Lab at (210)567-6599.

- b. A complete requisition slip must accompany all specimens and the specimen must be labeled with the patient's name and identification number.
ANY SPECIMENS RECEIVED WITHOUT A COMPLETE REQUISITION OR AN UNLABELED SPECIMEN WILL BE RETURNED IMMEDIATELY. THE CLINICAL HISTORY OF THE PATIENT IS ALSO REQUIRED.
- c. Patient information must include:

- Name, address, date of birth of patient (If patient is 2yrs old or younger EM will automatically be performed by the laboratory)
 - Hospital identification number
 - Insurance information (hospital admission form)
 - Pathology accession number where applicable
 - Requesting physicians name and address
 - A brief, concise, pertinent clinical history of patient's neurological, laboratory, and EMG/Nerve conduction studies. Also advise surgeons of requirement of patient history.
- d. Shipping Information (address all specimens to):
- Department of Pathology – Client Services Center MC 7750
The University of Texas Health Science Center at San Antonio
7703 Floyd Curl Drive
San Antonio, Texas 78229-3900
(210) 567-6599

MATERIALS:

- a. STRL/UTHSCSA Histology/Immunohistochemistry Laboratory Request Form
- b. Glutaraldehyde. (One source: Poly Sciences, Inc. #216, 8% aqueous in sealed ampoules)
- c. 10% Neutral Buffered Formalin (One source: Stat Lab)
- d. Phosphate Buffer solutions as specified below
- e. Isopentane (2-methylbutane) (One source: Fisher Scientific)
- f. Two isometric muscle clamps. Source: Baxter v. Mueller, 1500 Waukegan Rd, McGaw Park, IL 60085, Phone: 1-800-323-9088. 8mm clamp #SU209- 10(Pediatric Clamp) ; 15mm clamp, #SU209-12(Adult Clamp)
- g. Insulated shipping container adequate to hold dry ice for 4 days. (11x9x12inches or similar dimensions)
- h. Liquid nitrogen and dry ice are needed at the time of the biopsy, in addition to dry ice to pack inside insulated box above

Note: Local Contributors with immediate access can omit items 5, 7, & 8 above and bring specimen for freezing on saline dampened gauze in a labeled (patient name and surgical #) container placed in a cooler with crushed ice. This specimen needs to be received within 1 hour of the surgery by the UTHSCS/STRL Histology Lab.

FIXATIVES:

- a. 10% Neutral Buffered Formalin
- b. Glutaraldehyde Fixative (EM Testing)

***Can be obtained from the UTHSCSA Histology Lab (210)567-6599 OBTAINING AND**

HANDLING MUSCLE BIOPSY SPECIMENS:

NOTE: Coordinate with UTHSCSA/STRL Histology Laboratory before obtaining or sending the muscle biopsy. Phone number is (210) 567-6599 or (210)567-4056.

ADVANCE SURGICAL PREPARATION:

- a. Two labeled vials, with openings big enough for clamps, one containing enough EM glutaraldehyde fix and one containing enough 10% neutral buffered formalin fix to fully cover the end of the clamp and contained muscle. Since the clamps must remain in the fixatives for 1 hour, use tall vials that can be closed, or plastic specimen bags. Fix at room temperature.
- b. Two isometric muscle biopsy clamps (8mm-Pediatric and 15mm-Adult if possible, but length of specimen is not highly critical) wrapped and sterilized. Other surgical implements are not listed, but curved Metzenbaum scissors are good to free and gently elevate muscle cord for clamping.
- c. Specimen bottle containing gauze dampened with balanced salt solution, physiologic saline, or mammalian Ringer's (**NOTE: DAMP, NOT FULLY WET. IT IS ABOUT RIGHT IF A CORNER OF 4X4 GAUZE SQUARE IS STILL DRY.**) Place the sealed labeled specimen bottle in crushed ice. Enzyme activity will be stable for about 1hour, after which time a rapidly declining course will follow.
- d. Liquid nitrogen, isopentane, dry ice and shipping container for frozen specimen should be available. Isopentane cannot be precooled as it will solidify.

HANDLING SPECIMENS:

Three cylindrical specimens are needed, all about 5 mm in diameter and 8 to 16mm long. For each of the 2 specimens to be fixed, the surgeon should gently blunt- dissect a cord of muscle free, lift the cord slightly on open scissors, clamp and then cut free the ends of the muscle cord to obtain a roughly cylindrical piece of

muscle, held at rest length in the clamp. As noted below, a piece for freezing may be taken with that in a clamp.

Please be advised that the specimen for freezing should be approximately 1-2 cm in length X 0.5-0.8 cm in thickness. Also note that crushed muscle in the teeth area of the clamp is not suitable for interpretation.

Clamped specimens should be fixed immediately at room temperature. Do not unclamp for 1 hour.

Place one clamped specimen in 10% neutral buffered formalin. Leave clamped and see "B."

Place second clamped specimen in EM glutaraldehyde fix. Leave clamped. After 1 hour of fixation, open clamps and seal specimens into fully labeled (include patient name, surgical pathology number, site of biopsy, date, fixative) vials for shipment. The specimens should remain in the same fixative solutions for shipment.

SHIP SEPARATELY FROM FROZEN SPECIMEN. DO NOT FREEZE.

SPECIMEN TO BE FROZEN:

A cylinder of muscle about 10mm long and 5 mm in diameter is obtained and kept on damp gauze in a cold sealed specimen vial until frozen. If the clamp was placed toward one end of the dissected cord or bundle of fibers, the specimen for freezing can be the other end of the same cord. This free end can be left and cut off into the specimen bottle containing the damp gauze before the clamp is put into fixative (glutaraldehyde). The specimen for freezing should be handled, if necessary, by gently holding the extreme end only with tweezers. The use of one cord for two specimens minimizes the amount of muscle lost by the patient and increases the probability of correlating electron microscopy features with those seen with histochemical stains.

FREEZING SPECIMEN FOR HISTOCHEMICAL STUDY:

Successful histochemical tests require muscle that has been very rapidly frozen, uncovered, without excess liquid and without matrix. It must remain frozen until sectioned.

Put some crushed dry ice into the insulated shipping container and precool the shipping tube or vial for the frozen specimen. You can use screw cap plastic centrifuge tubes (falcon) 15 to 50 ml size.

Put about 2 inches (height) of isopentane into a Pyrex beaker with a collar of Styrofoam or cork so that it can be put into a Dewar flask of liquid nitrogen for cooling.

Cool isopentane to between minus 130 and minus 150. If you have no thermometer which registers that low, cool until isopentane becomes syrupy and white lumps start to form at the bottom and sides of the beaker.

Handling gently by the very end with tweezers, place the muscle tissue into the cooled isopentatane for about 10 seconds. Remove from the isopentane and immediately blot or drain off any excess isopentatane and place the tissue in the precooled specimen tube on dry ice. **DO NOT ALLOW SPECIMEN TO THAW.** Close the tube securely and place in a shipping container filled with dry ice.

8. SHIPPING

Mail fixed specimens, in fixative, unfrozen to:

Department of Pathology – Client Services Center MC 7750 The University of Texas Health Science Center at San Antonio 7703 Floyd Curl Drive
San Antonio, Texas 78229 (210) 567-6599

Ship frozen specimens in insulated box with enough dry ice for 4 days.

Ship: Monday through Thursday only, laboratory hours are 7:30am -4:30pm.

Specimens obtained Thursday or Friday can be held in an ultralow freezer (-70 C or less) for shipment on the following Monday.

Ship to the same address as above.

Add to address on shipping label:

NOTE: RUSH-FROZEN TISSUE – DO NOT ALLOW TO THAW.

Notify the UTHSCSA Histology Lab at (210) 567-6599.

SHIP BY EXPRESS MAIL OR OVERNIGHT PRIORITY MAIL.

Address To:

Department of Pathology – Client Services Center MC 7750
The University of Texas Health Science Center at San Antonio
7703 Floyd Curl Drive
San Antonio, Texas 78229-3900 (210) 567-6599

CONTRIBUTORS ARE RESPONSIBLE FOR IDENTIFYING (POTENTIALLY) INFECTIOUS MATERIAL.

9. Minimum Specimen Requirements: Three cylindrical specimens are needed, all about 5 mm in diameter and 8 to 16mm long

10. Tech only Turnaround Times: Results to Client: **72 hours**

11. Communication:

a. Turnaround time non-conformity: **Email Applicable Laboratory Director.**

- b. Specimen rejection: **In rare cases where cause for specimen rejection is noted after the sample has arrived at UT Health San Antonio, the client contact information on the request form will be notified by email or phone.**
- c. Technical Updates: **Email Applicable Laboratory Director.**

12. Quality: Staining –

All routine H&E's, Special Stains, Immunofluorescence, and Immunohistochemistry stains performed are run with positive tissue controls (and negative tissue controls for IF and IHC's) to ensure a quality stain has been achieved. The controls and patient tissues are reviewed and checked for quality and accuracy by the histologist and again by the pathologist. Staining results are recorded by the technologist daily and initialed by the pathologists on the QA form. Muscle biopsies contain internal controls which are evaluated by our neuropathologist. Any variability in staining is documented in the quality control/quality assurance report that accompanies each case. Periodically normal skeletal muscle controls are used to test the quality of unexpired reagents.

Test: Quantitative BCR-ABL1 (p210) by RT-PCR

1. **CPT:** 81206 (BCR/ABL1 (t(9;22))translocation analysis; major breakpoint, qualitative or quantitative)
2. **Synonym(s):** BCR-ABL1/ABL1; Quantitative p210 BCR-ABL
3. **Performed:** In-House

4. Methodology:

RNA is isolated, reverse transcribed and amplified by real-time PCR using specific primers targeting the p210 BCR-ABL and ABL genes. Quantitative results are obtained by comparing relative levels of p210 BCR-ABL and ABL transcripts to standard curves. P210 BCR-ABL results are reported as a percentage based on an international scale (IS).

5. Panel/Profile Components: N/A**6. Critical Values:** N/A**7. Specimen Collection / Handling Requirements:****Specimen Labeling**

- a. The specimen must be labeled with two identifiers at the time of collection. Examples of acceptable identifiers include but are not limited to: patient name, date of birth, hospital number, requisition number, accession number, and unique random number. A location (e.g., hospital room number) is not an acceptable identifier. Collection date and collector's identifier are required.
- b. A completed requisition form should be submitted with every sample, and, at minimum, the following is required: ordering physician name, phone number, fax number, and patient's name, identifying number of patient, patient sex, patient date of birth or age, specimen type, collection date, tests requested, provisional diagnosis or clinical rationale for test, and billing information.

Specimen Type

- a. Peripheral blood (PB): 2-5mL, in purple top (sodium EDTA) tube; yellow top tube (ACD) acceptable.
- b. Bone marrow (BM): 1-3mL, drawn into a syringe containing anticoagulant and then delivered in a purple top tube.

Handling

- a. Specimens requiring RNA isolation required special handling to preserve the integrity of the RNA.

- b. PB and BM should be transported to the laboratory within 4 hours of collection
- c. If necessary, blood or bone marrow samples may be refrigerated for up to 24 hours
- d. Do not freeze whole blood or bone marrow

Unacceptable Conditions

- a. Serum or plasma; frozen PB or BM; clotted blood; severely hemolyzed samples

8. Minimum Specimen Requirements:

Peripheral blood (PB): 2mL, in purple top (sodium EDTA) tube; yellow top tube (ACD) acceptable.

Bone marrow (BM): 1mL, drawn into a syringe containing anticoagulant and then delivered in a purple top tube.

9. Turnaround Times:

Total testing time: **8 hours/Wednesday**

Results to Client: **6 working days**

10. Communication:

- a. Turnaround time non-conformity: **Email or call Pathologist on request form to notify them of the delay.**
- b. Specimen rejection: **Most causes for specimen rejection are noted at pick-up, prior to the sample leaving UHS premises, communicated verbally, and corrected immediately. In rare cases where cause for specimen rejection is noted after the sample has arrived at UT Health San Antonio, the Pathologist on the request form will be contacted by email or phone.**
- c. Technical Updates: **Email Applicable Laboratory Director.**

11. Quality:

- a. RNA quality and quantity will be checked by control gene amplification.
- b. Clinical relevance: all samples analyzed for this assay will be screened by a hematologist/oncologist or pathologist to ensure that the test is appropriate for the patient in question. All samples analyzed should have other clinical assays performed (cytogenetics, blood/bone marrow morphologic examination, flow cytometry, etc.) for correlation purposes.
- c. Reports assay sensitivity for patients in whom p210 BCR-ABL is undetectable.
- d. Patient results are reported by the international scale (IS).
- e. Composes the report in the context of patient history and clinical information such as whether the patient has known CML, has been treated, bone marrow findings, and results of karyotype, FISH and prior molecular results.

- f. Cite literature references as appropriate.
- g. All reports include methodology, interpretation, clinical comments, references, and an FDA disclaimer.
- h. For all specimens sent to MDL, when previous samples have been tested and reported by MDL on the same patient, current results are compared to previous results.
- i. MDL takes part in the College of American Pathologist (CAP) bi-annual survey of minimal residual disease (MRD) program for this assay.
- j. If the assay is **inoperable** due to shortage of reagents or instrument malfunction, efforts will be made immediately to recruit reagents or repair instruments. Meanwhile, STRL send out samples to another accredited lab if the turn-around time is critical.

Test: Quantitative BCR-ABL1 (p190) by RT-PCR

1. **CPT:** 81207 (BCR/ABL1 (t(9;22)) translocation analysis; minor breakpoint, qualitative or quantitative)
2. **Synonym(s):** Quantitative p190 BCR-ABL, BCR/ABL1 t(9;22) translocation analysis; minor breakpoint.
3. **Performed:** In-House

4. Methodology:

RNA is isolated, reverse transcribed and amplified by real-time PCR using specific primers targeting the p190 BCR-ABL and ABL genes. Quantitative results are obtained by comparing relative levels of p190 BCR-ABL and ABL transcripts to standard curves. Results are reported as a p190 BCR-ABL to ABL ratio after calibration with a p190 BCR-ABL positive tumor cell line.

5. **Panel/Profile Components:** N/A
6. **Critical Values:** N/A
7. **Specimen Collection / Handling Requirements:**

Specimen Labeling

- a. The specimen must be labeled with two identifiers at the time of collection. Examples of acceptable identifiers include but are not limited to: patient name, date of birth, hospital number, requisition number, accession number, and unique random number. A location (e.g., hospital room number) is not an acceptable identifier. Collection date and collector's identifier are required.
- b. A completed requisition form should be submitted with every sample, and, at minimum, the following is required: ordering physician name, phone number, fax number, and patient's name, identifying number of patient, patient sex, patient date of birth or age, specimen type, collection date, tests requested, provisional diagnosis or clinical rationale for test, and billing information.

Specimen Type

- a. Peripheral blood (PB): 2-5mL, in purple top (sodium EDTA) tube; yellow top tube (ACD) acceptable.
- b. Bone marrow (BM): 1-3mL, drawn into a syringe containing anticoagulant and then delivered in a purple top tube.

Handling

- a. Specimens requiring RNA isolation required special handling to preserve the integrity of the RNA.
- b. PB and BM should be transported to the laboratory within 4 hours of collection
- c. If necessary, blood or bone marrow samples may be refrigerated for up to 24 hours
- d. Do not freeze whole blood or bone marrow

Unacceptable Conditions

- a. Serum or plasma; frozen PB or BM; clotted blood; severely hemolyzed samples

8. Minimum Specimen Requirements:

Peripheral blood (PB): 2mL, in purple top (sodium EDTA) tube; yellow top tube (ACD) acceptable.

Bone marrow (BM): 1mL, drawn into a syringe containing anticoagulant and then delivered in a purple top tube.

9. Turnaround Times:

- a. Total testing time: **8 hours/Wednesday**
- b. Results to Client: **6 working days**

10. Communication:

- a. Turnaround time non-conformity: **phone or e-mail**
- b. Specimen rejection: **phone or e-mail**
- c. Technical Updates: **seminar, handouts or e-mail**

11. Quality:

- a. RNA quality and quantity will be checked by control gene amplification.
- b. Clinical relevance: all samples analyzed for this assay will be screened by a hematologist/oncologist or pathologist to ensure that the test is appropriate for the patient in question. All samples analyzed should have other clinical assays performed (cytogenetics, blood/bone marrow morphologic examination, flow cytometry, etc.) for correlation purposes.
- c. Reports assay sensitivity for patients in whom p190 BCR-ABL is undetectable.
- d. Composes the report in the context of patient history and clinical information such as whether the patient has known CML or ALL, has been treated, bone marrow findings, and results of karyotype, FISH and prior molecular results.
- e. MDL takes part in the College of American Pathologist (CAP) bi-annual survey of minimal residual disease (MRD) program for this assay.
- f. Cite literature references as appropriate.
- g. All reports include methodology, interpretation, clinical comments, references, and an FDA disclaimer.
- h. For all specimens sent to MDL, when previous samples have been tested and reported by MDL on the same patient, current results are compared to previous results.

- i. If the assay is **inoperable** due to shortage of reagents or instrument malfunction, efforts will be made immediately to recruit reagents or repair instruments. Meanwhile, STRL send out samples to another accredited lab if the turn-around time is critical.

Test: Quantitative JAK2 (V617F) Mutation

1. **CPT:** 81270 (JAK2 (Janus kinase 2) gene analysis, p.Val617Phe (V617F) variant

2. **Synonym(s):** JAK2 (Janus kinase 2) gene analysis

3. **Performed:** In-House

4. **Methodology:**

Genomic DNA is isolated and amplified by allelic discrimination/quantitative real-time PCR targeting the JAK2 gene. Results are reported as percentage of JAK2 V617F mutant allele relative to the amount of wild type allele.

5. **Panel/Profile Components:** N/A

6. **Critical Values:** N/A

7. **Specimen Collection / Handling Requirements:**

Specimen Labeling

- a. The specimen must be labeled with two identifiers at the time of collection. Examples of acceptable identifiers include but are not limited to: patient name, date of birth, hospital number, requisition number, accession number, and unique random number. A location (e.g., hospital room number) is not an acceptable identifier. Collection date and collector's identifier are required.
- b. A completed requisition form should be submitted with every sample, and, at minimum, the following is required: ordering physician name, phone number, fax number, and patient's name, identifying number of patient, patient sex, patient date of birth or age, specimen type, collection date, tests requested, provisional diagnosis or clinical rationale for test, and billing information.

Specimen Type

- a. Peripheral blood (PB): 1-5mL, in purple top (sodium EDTA) tube; yellow top tube (ACD) acceptable.
- b. Bone marrow (BM): 0.5-3mL, drawn into a syringe containing anticoagulant and then delivered in a purple top tube.

Handling

- a. PB and BM can be delivered at room temperature within 4 hours of collection
- b. If necessary, blood or bone marrow samples may be refrigerated for up to 48 hours
- c. Do not freeze whole blood or bone marrow

Unacceptable Conditions

- a. Serum or plasma; frozen PB or BM; clotted blood; severely hemolyzed samples.

8. Minimum Specimen Requirements:

Peripheral blood (PB): 1mL, in purple top (sodium EDTA) tube; yellow top tube (ACD) acceptable.

Bone marrow (BM): 0.5mL, drawn into a syringe containing anticoagulant and then delivered in a purple top tube.

9. Turnaround Times:

Total testing time: **8 hours/Thursday**

Results to Client: **6 working days**

10. Communication:

- a. Turnaround time non-conformity: **Email or call Pathologist on request form to notify them of the delay.**
- b. Specimen rejection: **Most causes for specimen rejection are noted at pick-up, prior to the sample leaving UHS premises, communicated verbally, and corrected immediately. In rare cases where cause for specimen rejection is noted after the sample has arrived at UT Health San Antonio, the Pathologist on the request form will be contacted by email or phone.**
- c. Technical Updates: **Email Applicable Laboratory Director.**

11. Quality:

- a. DNA quality and quantity will be checked by spectrophotometer and control gene amplification.
- b. Clinical relevance: all samples analyzed for this assay will be screened by a hematologist/oncologist or pathologist to ensure that the test is appropriate for the patient in question.
- c. Reports assay sensitivity for patients in whom JAK2 MT is undetectable.
- d. MDL takes part in the College of American Pathologist (CAP) bi-annual survey of molecular hematological oncology (MHO) program for this assay.
- e. Cite literature references as appropriate.
- f. All reports include methodology, interpretation, clinical comments, references, and an FDA disclaimer.
- g. For all specimens sent to MDL, when previous samples have been tested and reported by MDL on the same patient, current results are compared to previous results.

- h. If the assay is **inoperable** due to shortage of reagents or instrument malfunction, efforts will be made immediately to recruit reagents or repair instruments. Meanwhile, STRL send out samples to another accredited lab if the turn-around time is critical.

Test: B-cell Receptor IGH Gene Rearrangement

1. **CPT:** 81261 (IGH@ (Immunoglobulin heavy chain locus), gene rearrangement analysis to detect abnormal clonal population(s); amplified methodology)
2. **Synonym(s):** IGH Gene Clonality Detection
3. **Performed:** In-House
4. **Methodology:**
DNA is isolated and amplified by PCR using BIOMED-2 primers targeting the VH framework 1, 2, 3, DH and JH sequences of the IGH gene. The gene rearrangements are detected by analyzing the PCR products by capillary gel electrophoresis.
5. **Panel/Profile Components:** N/A
6. **Critical Values:** N/A
7. **Specimen Collection / Handling Requirements:**

Specimen Labeling

- a. The specimen must be labeled with two identifiers at the time of collection. Examples of acceptable identifiers include but are not limited to: patient name, date of birth, hospital number, requisition number, accession number, and unique random number. A location (e.g., hospital room number) is not an acceptable identifier. Collection date and collector's identifier are required.
- b. A completed requisition form should be submitted with every sample and, at minimum, the following is required: ordering physician name, phone number, fax number, and patient's name, identifying number of patient, patient sex, patient date of birth or age, specimen type, collection date, tests requested, provisional diagnosis or clinical rationale for test, and billing information.

Specimen Type

- a. Peripheral blood (PB): 2-5mL, in purple top (sodium EDTA) tube; yellow top tube (ACD) acceptable.
- b. Bone marrow (BM): 1-3mL, drawn into a syringe containing anticoagulant and then delivered in a purple top tube.
- c. Fresh or frozen tissue: fresh tissue should be obtained in a sterile manner, and a minimum of 3 mm³ of tissue is required. Put fresh tissues in culture medium or snap freeze
- d. Formalin-fixed paraffin-embedded (FFPE) tissue blocks: send FFPE tissue blocks to the lab or contact lab for instructions about cutting sections for molecular studies.

Handling

- a. PB and BM can be delivered at room temperature within 4 hours of collection
- b. If necessary, blood or bone marrow samples may be refrigerated for up to 48 hours.
- c. Fresh tissue samples should be delivered at room temperature in RPMI culture medium to the lab within 3 hours of collection, or snap frozen in liquid nitrogen at - 70°C and packed in dry ice for delivery. Please do not allow frozen tissues to thaw.
- d. Formalin-fixed paraffin embedded (FFPE) tissue blocks can be delivered at room temperature.
- e. Do not freeze whole blood or bone marrow.

Unacceptable Conditions

- a. Serum or plasma; frozen PB or BM; clotted blood; severely hemolyzed samples.
- b. **Unacceptable fixed paraffin tissue samples:** block fixed in Zenker's, B5, or Bouin's fixatives; decalcified paraffin-embedded bone marrow biopsy sample.

8. Minimum Specimen Requirements:

- a. Peripheral blood (PB): 2mL, in purple top (sodium EDTA) tube; yellow top tube (ACD) acceptable.
- b. Bone marrow (BM): 1mL, drawn into a syringe containing anticoagulant and then delivered in a purple top tube.
- c. Fresh or frozen tissue: a minimum of 3 mm³ of tissue is required.
- d. FFPE tissue: 5 ten micron tissue sections

9. Turnaround Times:

Total testing time: **4 days/sample has to be received by Friday 3pm to meet TAT**

Results to Client: **7 working days**

10. Communication:

- a. Turnaround time non-conformity: **Email or call Pathologist on request form to notify them of the delay.**
- b. Specimen rejection: **Most causes for specimen rejection are noted at pick-up, prior to the sample leaving UHS premises, communicated verbally, and corrected immediately. In rare cases where cause for specimen rejection is noted after the sample has arrived at UT Health San Antonio, the Pathologist on the request form will be contacted by email or phone.**
- c. Technical Updates: **Email Applicable Laboratory Director.**

11. Quality:

- a. Reports for IGH gene rearrangement assays always include PCR product size(s) and involved segments.
- b. When molecular results are ready, MDL staff or faculty always communicate with ordering physicians and compare molecular results to morphological and historical findings.
- c. For all specimens sent to MDL, when previous samples have been tested and reported by MDL on the same patient, current results are compared to previous results for peak size to differentiate if the same clonality is observed in a given patient.
- d. DNA quality and quantity will be checked by spectrophotometer and control gene amplification.
- e. MDL takes part in the College of American Pathologist (CAP) bi-annual survey of molecular hematological oncology (MHO) program for this assay.
- f. Cite literature references as appropriate.
- g. All reports include methodology, interpretation, clinical comments, references, and an FDA disclaimer.
- h. If the assay is **inoperable** due to shortage of reagents or instrument malfunction, efforts will be made immediately to recruit reagents or repair instruments. Meanwhile, STRL send out samples to another accredited lab if the turn-around time is critical.

Test: B-cell Receptor IGK Gene Rearrangement

1. CPT: 81264 IGK@ (Immunoglobulin kappa light chain locus) (e.g., leukemia and lymphoma, B- Cell) gene rearrangement analysis, evaluation to detect abnormal clonal population(s)

2. Synonym(s): IG-Kappa Gene Clonality Detection

3. Performed: In-House

4. Methodology:

The assay is performed on isolated DNA with BIOMED-2 primers amplifying the VK, JK as well as intragenic and Kde region of the IG kappa gene. The gene rearrangements are detected by analyzing the PCR products using capillary gel electrophoresis.

5. Panel/Profile Components: N/A

6. Critical Values: N/A

7. Specimen Collection / Handling Requirements:

Specimen Labeling

- a. The specimen must be labeled with two identifiers at the time of collection. Examples of acceptable identifiers include but are not limited to: patient name, date of birth, hospital number, requisition number, accession number, and unique random number. A location (e.g., hospital room number) is not an acceptable identifier. Collection date and collector's identifier are required.
- b. A completed requisition form should be submitted with every sample and, at minimum, the following is required: ordering physician name, phone number, fax number, and patient's name, identifying number of patient, patient sex, patient date of birth or age, specimen type, collection date, tests requested, provisional diagnosis or clinical rationale for test, and billing information.

Specimen Type

- a. Peripheral blood (PB): 2-5mL, in purple top (sodium EDTA) tube; yellow top tube (ACD) acceptable.
- b. Bone marrow (BM): 1-3mL, drawn into a syringe containing anticoagulant and then delivered in a purple top tube.
- c. Fresh or frozen tissue: fresh tissue should be obtained in a sterile manner, and a minimum of 3 mm³ of tissue is required. Put fresh tissues in culture medium or snap freeze
- d. Formalin-fixed paraffin-embedded (FFPE) tissue blocks: send FFPE tissue blocks to the lab or contact lab for instructions about cutting sections for molecular studies.

Handling

- a. PB and BM can be delivered at room temperature within 4 hours of collection
- b. If necessary, blood or bone marrow samples may be refrigerated for up to 48 hours.
- c. Fresh tissue samples should be delivered at room temperature in RPMI culture medium to the lab within 3 hours of collection, or snap frozen in liquid nitrogen at - 70°C and packed in dry ice for delivery. Please do not allow frozen tissues to thaw.
- d. Formalin-fixed paraffin embedded (FFPE) tissue blocks can be delivered at room temperature.
- e. Do not freeze whole blood or bone marrow.

Unacceptable Conditions

- a. Serum or plasma; frozen PB or BM; clotted blood; severely hemolyzed samples.
- b. **Unacceptable fixed paraffin tissue samples:** block fixed in Zenker's, B5, or Bouin's fixatives; decalcified paraffin-embedded bone marrow biopsy sample.

8. Minimum Specimen Requirements:

- a. Peripheral blood (PB): 2mL, in purple top (sodium EDTA) tube; yellow top tube (ACD) acceptable.
- b. Bone marrow (BM): 1mL, drawn into a syringe containing anticoagulant and then delivered in a purple top tube.
- c. Fresh or frozen tissue: a minimum of 3 mm³ of tissue is required.
- d. FFPE tissue: 5 ten micron tissue sections

9. Turnaround Times:

- a. Total testing time: **4 days/sample has to be received by Friday 3pm to meet TAT**
- b. Results to Client: **7 working days**

10. Communication:

- a. Turnaround time non-conformity: **Email or call Pathologist on request form to notify them of the delay.**
- b. Specimen rejection: **Most causes for specimen rejection are noted at pick-up, prior to the sample leaving UHS premises, communicated verbally, and corrected immediately. In rare cases where cause for specimen rejection is noted after the sample has arrived at UT Health San Antonio, the Pathologist on the request form will be contacted by email or phone.**
- c. Technical Updates: **Email Applicable Laboratory Director.**

11. Quality:

- a. Reports for all IG-kappa gene rearrangement assays always include PCR product size(s) and involved segments.
- b. When molecular results are ready, MDL staff or faculty always communicate with ordering physicians and compare molecular results to morphological and historical findings.
- c. For all specimens sent to MDL, when previous samples have been tested and reported by MDL on the same patient, current results are compared to previous results for peak size to differentiate if the same clonality is observed in a given patient.
- d. DNA quality and quantity will be checked by spectrophotometers and control gene amplification.
- e. MDL takes part in the College of American Pathologist (CAP) bi-annual survey of molecular hematological oncology (MHO) program for this assay.
- f. All reports include methodology, interpretation, clinical comments, references, and an FDA disclaimer.
- g. If the assay is **inoperable** due to shortage of reagents or instrument malfunction, efforts will be made immediately to recruit reagents or repair instruments. Meanwhile, STRL send out samples to another accredited lab if the turn-around time is critical.

Test: B-cell Clonality Panel (IGH, IGK), PCR

1. **CPT:** 81261 (IGH@ (Immunoglobulin heavy chain locus), gene rearrangement analysis to detect abnormal clonal population(s); amplified methodology), 81264 IGK@ (Immunoglobulin kappa light chain locus) (e.g., leukemia and lymphoma, B-Cell) gene rearrangement analysis, evaluation to detect abnormal clonal population(s)
2. **Synonym(s):** IGH Gene Clonality Detection; IG-Kappa Gene Clonality Detection
3. **Performed:** In-House
4. **Methodology:**
 - a. DNA is isolated and amplified by PCR using BIOMED-2 primers targeting the VH framework 1, 2, 3, DH and JH sequences of the IGH gene. The gene rearrangements are detected by analyzing the PCR products by capillary gel electrophoresis.
 - b. The assay is performed on isolated DNA with BIOMED-2 primers amplifying the VK, JK as well as intragenic and Kde region of the IG kappa gene. The gene rearrangements are detected by analyzing the PCR products using capillary gel electrophoresis.
5. **Panel/Profile Components:** IGH & IGK
6. **Critical Values:** N/A
7. **Specimen Collection / Handling Requirements:**

Specimen Labeling

- a. The specimen must be labeled with two identifiers at the time of collection. Examples of acceptable identifiers include but are not limited to: patient name, date of birth, hospital number, requisition number, accession number, and unique random number. A location (e.g., hospital room number) is not an acceptable identifier. Collection date and collector's identifier are required.
- b. A completed requisition form should be submitted with every sample and, at minimum, the following is required: ordering physician name, phone number, fax number, and patient's name, identifying number of patient, patient sex, patient date of birth or age, specimen type, collection date, tests requested, provisional diagnosis or clinical rationale for test, and billing information.

Specimen Type

- a. Peripheral blood (PB): 2-5mL, in purple top (sodium EDTA) tube; yellow top tube (ACD) acceptable.

- b. Bone marrow (BM): 1-3mL, drawn into a syringe containing anticoagulant and then delivered in a purple top tube.
- c. Fresh or frozen tissue: fresh tissue should be obtained in a sterile manner, and a minimum of 3 mm³ of tissue is required. Put fresh tissues in culture medium or snap freeze.
- d. Formalin-fixed paraffin-embedded (FFPE) tissue blocks: send FFPE tissue blocks to the lab or contact lab for instructions about cutting sections for molecular studies.

Handling

- a. PB and BM can be delivered at room temperature within 4 hours of collection.
- b. If necessary, blood or bone marrow samples may be refrigerated for up to 48 hours.
- c. Fresh tissue samples should be delivered at room temperature in RPMI culture medium to the lab within 3 hours of collection, or snap frozen in liquid nitrogen at - 70°C and packed in dry ice for delivery. Please do not allow frozen tissues to thaw.
- d. Formalin-fixed paraffin embedded (FFPE) tissue blocks can be delivered at room temperature.
- e. Do not freeze whole blood or bone marrow.

Unacceptable Conditions

- a. Serum or plasma; frozen PB or BM; clotted blood; severely hemolyzed samples.
- b. Unacceptable fixed paraffin tissue samples: block fixed in Zenker's, B5, or Bouin's fixatives; decalcified paraffin-embedded bone marrow biopsy sample.

8. Minimum Specimen Requirements:

- a. Peripheral blood (PB): 2mL, in purple top (sodium EDTA) tube; yellow top tube (ACD) acceptable.
- b. Bone marrow (BM): 1mL, drawn into a syringe containing anticoagulant and then delivered in a purple top tube.
- c. Fresh or frozen tissue: a minimum of 3 mm³ of tissue is required.
- d. FFPE tissue: 5 ten-micron tissue sections

9. Turnaround Times:

Total testing time: **4 days/sample has to be received by Friday 3pm to meet TAT**

Results to Client: **7 working days**

10. Communication:

- a. Turnaround time non-conformity: **Email or call Pathologist on request form to notify them of the delay.**

- b. Specimen rejection: **Most causes for specimen rejection are noted at pick-up, prior to the sample leaving UHS premises, communicated verbally, and corrected immediately. In rare cases where cause for specimen rejection is noted after the sample has arrived at UT Health San Antonio, the Pathologist on the request form will be contacted by email or phone.**
- c. Technical Updates: **Email Applicable Laboratory Director.**

11. Quality:

- a. Reports for all IGH and IG-kappa gene rearrangement assays always include PCR product size(s) and involved segments.
- b. When molecular results are ready, MDL staff or faculty always communicate with ordering physicians and compare molecular results to morphological and historical findings.
- c. For all specimens sent to MDL, when previous samples have been tested and reported by MDL on the same patient, current results are compared to previous results for peak size to differentiate if the same clonality is observed in a given patient.
- d. DNA quality and quantity will be checked by spectrophotometers and control gene amplification.
- e. MDL takes part in the College of American Pathologist (CAP) bi-annual survey of molecular hematological oncology (MHO) program for this assay.
- f. All reports include methodology, interpretation, clinical comments, references, and an FDA disclaimer.
- g. If the assay is **inoperable** due to shortage of reagents or instrument malfunction, efforts will be made immediately to recruit reagents or repair instruments. Meanwhile, STRL send out samples to another accredited lab if the turn-around time is critical.

Test: Chlamydia trachomatis by Transcription Mediated Amplification (TMA)

1. **CPT Code(s):** 87491
2. **Synonym(s):** Chlamydia, CT
3. **Performed:** In-House
4. **Clinical Indication and Relevance:** The assay is useful to detect Chlamydia trachomatis from vaginal, penile meatal, rectal, throat (pharyngeal), endocervical, male urethral and urine samples.
5. **Methodology:** The assay uses transcription mediated amplification (TMA) on the Hologic Panther System.
6. **Panel/Profile Components:** N/A
7. **Critical Values:** N/A
8. **Sample Type:**
 - a. Aptima Multitest Swab Specimen Collection kit for vaginal, penile meatal, rectal, throat (pharyngeal) swabs.
 - b. Aptima Unisex Swab Specimen Collection Kit for endocervical and male urethral swabs.
 - c. Aptima Urine Specimen Collection Kit for male and female urine.
9. **Specimen Labeling:**
 - a. The specimen must be labeled with two identifiers at the time of collection.
 - b. Examples of acceptable identifiers include but are not limited to patient name, date of birth, hospital medical record number, accession number.
 - c. A location (e.g., hospital room number) is not an acceptable identifier. Collection date and collector's identifier are required.
 - d. A completed requisition form should be submitted with every sample, and at minimum, the following is required: ordering physician name, phone number, fax number, and patient's name, identifying number of patients, patient sex, patient date of birth specimen type, collection date, tests requested, provisional diagnosis or clinical rationale for test, and billing information.
10. **Transport:**
 - a. Specimens can contain high levels of organisms. Specimens must be shipped and transported in accordance with applicable local, national, and international transportation regulations. Maintain proper storage conditions of 2-8°C during shipping to ensure integrity of the specimen.
 - b. Stability:

- Swab specimens: After collection, transport and store the swab in the swab specimen transport tube at 2-30°C up to 60 days after collection.
- Urine Specimens: transport to the lab at 2-30°C where it should be transferred to the Aptima urine specimen transport tube within 24 hours of collection. Store Aptima urine specimen transport tube at 2-30°C and test within 30 days of collection.
- Unacceptable Samples: Improperly labeled or incorrect patient identification, specimen leaked, or incorrect media, specimen transport tube with no swab or two swabs, a cleaning swab or a swab not supplied by Hologic. The Aptima Specimen Transfer Tube will not contain a swab.
- For Urine Transport Tubes, the liquid must fall between the two black indicator lines on the tube label. Specimen does not meet transport, storage, or date of collection requirements.

11. Turnaround time: 1-3 Business Days.

12. Technical Updates: Email Applicable Laboratory Director.

13. Quality: QA/Utilization Report

Test: COVID-19 (SARS-CoV-2) Nucleic Acid Test, Nasopharyngeal

1. **CPT Code(s):** 87635
2. **Synonym(s):** COVID-19; SARS-COV-2
3. **Performed:** Molecular Diagnostics Laboratory
4. **Clinical Indication and Relevance:** The assay is useful to confirm the diagnosis of SARS-CoV-2 (COVID-19).
5. **Methodology:** The assay uses transcription-mediated amplification on the Hologic Panther System.
6. **Minimum Specimen Requirements:**
Sample type: Collect a nasopharyngeal (NP) swab according to instructions provided with the kit in either viral transport media (VTM) or universal transport media (UTM).
7. **Transport:**
 - a. Specimens can contain extremely high levels of virus or other organisms. Specimens must be shipped and transported in accordance with applicable local, national, and international transportation regulations. Maintain proper storage conditions during shipping to ensure integrity of the specimen.
 - b. **Stability:** After collection, store samples at 2-8°C up to 4 days before testing.
 - c. **Unacceptable Samples:** Improperly labeled or incorrect patient identification, specimen leaked, incorrect media, insufficient volume (less than 700 ul), no swab, bloody or grossly mucoid, specimen does not meet transport, storage, or date of collection requirements.
8. **Turnaround time:** 1-2 business days.
9. [View Requisition Sheet](#)

Test: COVID-19 (SARS-CoV-2)/FLU/RSV Nucleic Acid Test, Nasopharyngeal

1. **CPT Code(s):** CPT 87637
2. **Synonym(s):** COVID-19; SARS-COV-2, FLU A, FLU B, Respiratory Syncytial Virus, Influenza
3. **Performed:** Molecular Diagnostics Laboratory
4. **Clinical Indication and Relevance:** The assay is useful to detect SARS-CoV-2 (COVID-19), Influenza A (Flu A), Influenza B (Flu B) and/or Respiratory Syncytial Virus.”
5. **Methodology:** The assay uses polymerase chain reaction (PCR) on the GeneXpert Xpress System.
6. **Minimum Specimen Requirements:**
 - a. Sample type: Collect a nasopharyngeal (NP) swab according to instructions provided with the kit in either viral transport media (VTM) or universal transport media (UTM).
 - b. Specimen Labeling: The specimen must be labeled with two identifiers at the time of collection. Examples of acceptable identifiers include but are not limited to: patient name, date of birth, hospital medical record number, accession number. A location (e.g., hospital room number) is not an acceptable identifier. Collection date and collector’s identifier are required.
 - c. A completed requisition form should be submitted with every sample, and at minimum, the following is required: ordering physician name, phone number, fax number, and patient’s name, identifying number of patients, patient sex, patient date of birth specimen type, collection date, tests requested, provisional diagnosis or clinical rationale for test, and billing information.
7. **Transport:**
 - a. Specimens can contain extremely high levels of virus or other organisms. Specimens must be shipped and transported in accordance with applicable local, national, and international transportation regulations. Maintain proper storage conditions of 2-8°C during shipping to ensure integrity of the specimen.
 - b. Stability: After collection, store samples at 2-8°C up to 7 days before testing.
 - c. Unacceptable Samples: Improperly labeled or incorrect patient identification, specimen leaked, incorrect media, insufficient volume (less than 700 ul), no swab, bloody or grossly mucoid, specimen does not meet transport, storage, or date of collection requirements.
8. **Turnaround time:** 1-2 business days.

Test: Gastrointestinal Pathogen Panel molecular assay with 22 pathogens

1. **CPT Code(s):** CPT 87507
2. **Synonym(s):** Adenovirus, Astrovirus, Norovirus, Rotavirus, Sapovirus, Campylobacter, Clostridium difficile, Plesiomonas shigelloides, Salmonella, Vibrio, Yersinia enterocolitica, Enteroaggregative E. coli, EAEC, Enteropathogenic E. coli, EPEC, Enterotoxigenic E. coli, ETEC, Shiga-like toxin-producing E. coli, STEC, E. coli O157, Shigella/Enteroinvasive E. coli, EIEC, Cryptosporidium, Cyclospora cayetanensis, Entamoeba histolytica, Giardia lamblia.
3. **Performed:** Molecular Diagnostics Laboratory
4. **Clinical Indication and Relevance:** The assay is useful to detect adenovirus F40/41, astrovirus, norovirus GI/GII, rotavirus A, sapovirus (genogroups I, II, IV and V), Campylobacter (*C. jejuni*/*C. coli*/*C. upsaliensis*), Clostridium difficile (toxin A/B), Plesiomonas shigelloides, Salmonella, Vibrio (*V. parahaemolyticus*/*V. vulnificus*/*V. cholerae*), Yersinia enterocolitica, Enteroaggregative E. coli (EAEC), Enteropathogenic E. coli (EPEC), Enterotoxigenic E. coli (ETEC), Shiga-like toxin-producing E. coli (STEC) stx1/stx2 including E. coli O157, Shigella/Enteroinvasive E. coli (EIEC), Cryptosporidium, Cyclospora cayetanensis, Entamoeba histolytica and/or Giardia lamblia.
5. **Methodology:** The assay uses polymerase chain reaction (PCR) on the BioFire FilmArray Torch System.
6. **Minimum Specimen Requirements:**

Sample type:

- a. Collect liquid to soft stool specimen in a sterile cup.
- b. Liquid to soft stool specimen transferred to Cary Blair or FecalSwab (modified Cary-Blair) transport medium.
- c. Minimum sample volume of 0.2 mL

Specimen Labeling:

- a. The specimen must be labeled with two identifiers at the time of collection. Examples of acceptable identifiers include but are not limited to patient name, date of birth, hospital medical record number, accession number. A location (e.g., hospital room number) is not an acceptable identifier. Collection date and collector's identifier are required.
- b. A completed requisition form should be submitted with every sample and, at minimum, the following is required: ordering physician name, phone number, fax number, and patient's name,

identifying number of patients, patient sex, patient date of birth specimen type, collection date, tests requested, provisional diagnosis or clinical rationale for test, and billing information.

7. Transport:

- a. Specimens can contain extremely high levels of virus or other organisms. Specimens must be shipped and transported in accordance with applicable local, national, and international transportation regulations. Maintain proper storage conditions of 2-8°C during shipping to ensure integrity of the specimen.
- b. **Stability:** After collection, transfer to Cary Blair immediately. Sample can be stored at 2-8°C up to 24 hours before transferring to Cary Blair medium.
Once in Cary Blair medium, transport to the lab immediately for testing. Store at 2-8°C up to 72 hours.
- c. **Unacceptable Samples:** Improperly labeled or incorrect patient identification, specimen leaked, incorrect media, insufficient volume (less than 200 ul), rectal swabs, endoscopy stool aspirates, gastrointestinal contents or vomitus, stool sample in fixative, hard stools which rattle inside the container, specimen does not meet transport, storage, or date of collection requirements.

8. Turnaround time: 1-2 business days

Test: Neisseria gonorrhoeae by Transcription Mediated Amplification (TMA)

1. **CPT Code(s):** CPT 87591
2. **Synonym(s):** Neisseria gonorrhoeae, NG
3. **Performed:** Molecular Diagnostics Laboratory
4. **Clinical Indication and Relevance:** The assay is useful to detect Neisseria gonorrhoeae from vaginal, penile meatal, rectal, throat (pharyngeal), endocervical, male urethral, and urine samples.
5. **Methodology:** The assay uses transcription mediated amplification (TMA) on the Hologic Panther system.
6. **Minimum Specimen Requirements:**

Sample type:

- a. Aptima Multitest Swab Specimen Collection Kit for vaginal, penile meatal, rectal, throat (pharyngeal) swabs
- b. Aptima Unisex Swab Specimen Collection Kit for endocervical and male urethral swabs
- c. Aptima Urine Specimen Collection Kit for male and female urine

Specimen Labeling:

- a. The specimen must be labeled with two identifiers at the time of collection. Examples of acceptable identifiers include but are not limited to: patient name, date of birth, hospital medical record number, accession number. A location (e.g., hospital room number) is not an acceptable identifier. Collection date and collector's identifier are required.
- b. A completed requisition form should be submitted with every sample, and, at minimum, the following is required: ordering physician name, phone number, fax number, and patient's name, identifying number of patients, patient sex, patient date of birth specimen type, collection date, tests requested, provisional diagnosis or clinical rationale for test, and billing information.

7. Transport:

- a. Specimens can contain high levels of organisms. Specimens must be shipped and transported in accordance with applicable local, national, and international transportation regulations. Maintain proper storage conditions of 2-8°C during shipping to ensure integrity of the specimen.

- b. **Stability:** Swab specimens: After collection, transport and store the swab in the swab specimen transport tube at 2-30°C up to 60 days after collection.

Urine specimens: Transport to the lab at 2-30°C where it should be transferred to the Aptima urine specimen transport tube within 24 hours of collection. Store Aptima urine specimen transport tube at 2-30°C and test within 30 days of collection.

- c. **Unacceptable Samples:** Improperly labeled or incorrect patient identification, specimen leaked, incorrect media, specimen transport tube with no swab or two swabs, a cleaning swab or a swab not supplied by Hologic. The Aptima Specimen Transfer Tube will not contain a swab. For urine transport tubes, the liquid level must fall between the two black indicator lines on the tube label.

Specimen does not meet transport, storage, or date of collection requirements.

- 8. Turnaround time:** 1-2 business days.

Test: Respiratory Pathogen Panel (RP2.1) molecular assay with 22 pathogens, including SARS-CoV-2, Nasopharyngeal

1. **CPT Code(s):** CPT 87633
2. **Synonym(s):** Adenovirus, Coronavirus, Metapneumovirus, Rhinovirus, Enterovirus, Influenza A, H1N1, H3, H1, Influenza B, Parainfluenza, Bordetella parapertussis, Bordetella pertussis, Chlamydia pneumoniae, Mycoplasma pneumoniae, COVID-19, SARS-COV-2, FLU A, FLU B, Respiratory Syncytial Virus, Influenza
3. **Performed:** Molecular Diagnostics Laboratory
4. **Clinical Indication and Relevance:** The assay is useful to detect adenovirus, coronavirus 229E or HKU1 or NL63 or OC43, human metapneumovirus, human rhinovirus/enterovirus, influenza A including subtypes H1 or H3 or H1-2009, influenza B, parainfluenza virus 1 or 2 or 3 or 4, COVID-19/SARS-COV-2, respiratory syncytial virus, Bordetella parapertussis, Bordetella pertussis, Chlamydia pneumoniae, and/or Mycoplasma pneumoniae.
5. **Methodology:** The assay uses polymerase chain reaction (PCR) on the BioFire FilmArray Torch System RP 2.1.
6. **Minimum Specimen Requirements:**
 - a. **Sample type:** Collect a nasopharyngeal (NP) swab according to instructions provided with the kit in either viral transport media (VTM) or universal transport media (UTM).
 - b. **Specimen Labeling:** The specimen must be labeled with two identifiers at the time of collection. Examples of acceptable identifiers include but are not limited to: patient name, date of birth, hospital medical record number, accession number. A location (e.g., hospital room number) is not an acceptable identifier. Collection date and collector's identifier are required.
 - c. A completed requisition form should be submitted with every sample, and, at minimum, the following is required: ordering physician name, phone number, fax number, and patient's name, identifying number of patient, patient sex, patient date of birth specimen type, collection date, tests requested, provisional diagnosis or clinical rationale for test, and billing information.
7. **Transport:**
 - a. Specimens can contain extremely high levels of virus or other organisms. Specimens must be shipped and transported in accordance with applicable local, national, and international

transportation regulations. Maintain proper storage conditions of 2-8°C during shipping to ensure integrity of the specimen.

- b. **Stability:** After collection, store samples at 2-8°C up to 7 days before testing.
- c. **Unacceptable Samples:** Improperly labeled or incorrect patient identification, specimen leaked, incorrect media, insufficient volume (less than 700 ul), no swab, bloody or grossly mucoid, specimen does not meet transport, storage, or date of collection requirements.

8. Turnaround time: 1-2 business days.

Test: Solid Tumor OncoPanel Hotspot and Fusion on RNA by NGS

1. **CPT Code(s):** 81455, G0452
2. **Synonym(s):** Solid tumor, NGS, next generation sequencing, fusion, translocation, RNA, single nucleotide variant, SNV, hotspot
3. **Performed:** Molecular Diagnostics Laboratory
4. **Clinical Indication and Relevance:** The assay can identify molecular genomic alterations that may help provide a diagnosis and/or therapeutic information. Genomic alterations that can be identified include gene fusions, hotspot single nucleotide variants, small indels (<20bp), and a select number of oncogenic splicing variants.
5. **Methodology:** The Solid Tumor HotSpot and Fusion OncoPanel is a custom-designed targeted RNA sequencing assay, created to detect gene fusions, exon skipping events, and select expressed hotspot mutations in solid tumors (see table 1 and 2 for gene lists). Selected gene targets represent recurrently altered genes expressed in solid tumors. Anchored Multiplex PCR chemistry is used for Archer FusionPlex library preparation with molecular barcoding from specimen RNA or total nucleic acid (TNA) targeting regions of interest in the Solid Tumor HotSpot and Fusion OncoPanel. After sequencing on the Illumina MiSeq, the Archer Analysis Bioinformatics Pipeline is used to detect relevant alterations and uses the molecular barcodes for read deduplication and error correction.

Alterations are assessed as Tier I, Tier II, Tier III or Tier IV (benign or likely benign) based on professional guidelines (Li M et. al, 2017, PMID 27993330), and Tier I-III alterations are reported here after being assessed using public databases (such as COSMIC, OncoKB, Quiver Fusion Database, CIViC, and others).

TABLE 1: LIST OF GENES WITH HOTSPOTS TARGETED BY TEST

AKT1	BCOR	BRAF	CCND1	CIC	CTNNB1
DICER1	EGFR	ERBB2	FGFR1	FGFR2	FGFR3
GNA11	GNAQ	GNAS	H3F3A	HIST1H3B	HRAS
IDH1	IDH2	KIT	KRAS	MAP2K1	MED12
MET	MTOR	NFE2L2	NRAS	NTRK1	NTRK3
PDGFRA	PPP2R1A	RAC1	RAF1	RET	SF3B1
SMO	TP53				

TABLE 2: LIST OF GENES INVOLVED IN FUSIONS TARGETED BY TEST

AKT1	AKT3	ALK	AR	ARHGAP26	ATRX
AXL	BCAR4	BCL2	BCL2L1	BCOR	BRAF
CAMTA1	CCND1	CD274	CDK6	CDKN2B-AS1	CIC
CTNNB1	DNAJB1	EGFR	ERBB3	ERBB4	ERG
ESR1	ETV1	ETV4	ETV5	ETV6	EWSR1
FGFR1	FGFR2	FGFR3	FGFR4	FLI1	FOS
FOSB	FOXA1	FOXO1	FUS	GLI1	HMGA2
JAZF1	KIT	MAML2	MAML3	MAST1	MAST2
MET	MRTFB	MN1	MYB	MYBL1	NCOA1
NCOA2	NDRG1	NOTCH1	NOTCH2	NR4A3	NRG1
NTRK1	NTRK2	NTRK3	NUMB	NUTM1	PAX3
PDGFD	PDGFB	PDGFRA	PHF1	PIK3CA	PLAG1
PPARG	PRKCA	RAF1	RELA	RET	ROS1
RSPO2	RSPO3	SLC45A3	SS18	SS18L1	STAT6
TAF15	TCF12	TCF7L1	TCF7L2	TERT	TFE3
TFEB	TFG	THADA	TMPRSS2	TP53	TRIO
USP6	VGLL2	YWHAE	WWTR1	YAP1	

[SNV Hotspot Regions](#)

[Fusion and Oncogenic Isoform Targets](#)

6. Minimum Specimen Requirements:

Preferred:

- a. Formalin Fixed Paraffin Embedded (FFPE) tissue; should not be more than 5 years old. Tumor percentage should be 40% in one area.
- b. Tissue blocks, including core needle biopsies. The Histology lab will cut 10 unstained slides at 5-10 microns and 1 H&E.
- c. Unstained FFPE tissue slides (10 slides at 5-10 microns thickness). And 1 H&E.
- d. Fine needle aspirate (FNA) processed as FFPE cell block (cytospin). The Histology lab will cut 10 unstained slides at 5-10 microns and 1 H&E.

Less desired:

- a. Cells grown in tissue culture or cells preserved by Cytogenetics. A corresponding H&E from the submitted sample is desired.
- b. Fresh or frozen tissue, at least 0.5 x 0.5 cm. Frozen tissue should be stored at -80°C. An H&E slide is also required.
- c. Frozen tissue preserved in OCT (Optimal Cutting Temperature) and stored at -80C. An H&E slide is also required.

7. Transport:

- a. Formalin-fixed paraffin embedded (FFPE) tissue blocks and slides can be delivered at controlled temperatures, not to exceed 30C.
- b. Fresh tissue samples should be delivered at room temperature in RPMI culture medium to the lab within 3 hours of collection, or snap frozen in liquid nitrogen at -70°C and packed in dry ice for delivery. Please do not allow frozen tissues to thaw.

Unacceptable Samples:

- a. Tissue samples fixed in Zenker's, B5, or Bouin's fixatives
- b. Samples decalcified with strong acids
- c. Hematopathologic samples
- d. FFPE tissue scrolls are not desired, as they cannot be macrodissected. They require pathologist approval.
- e. Tumor percentage less than 40% in one area is not ideal. Tumor content between 5-40% in one area may be approved by a pathologist on a case-by-case basis.
- f. Frozen or fresh tissue samples or samples from cytogenetics must be accompanied by an H&E. In special situations, this may be approved by a pathologist.

8. Turnaround time: Seven to 15 working days.

9. [View Requisition Sheet](#)

Test: T-cell Receptor (TCR) Beta Gene Rearrangement, PCR

1. **CPT:** 81340: TRB@ (T cell antigen receptor, beta) gene rearrangement analysis to detect abnormal clonal population(s); using amplification methodology
2. **Synonym(s):** TCR Beta Gene Clonality Detection
3. **Performed:** In-House
4. **Methodology:**

DNA is isolated and amplified by PCR using BIOMED-2 primers targeting V β , D β and J β sequences. The gene rearrangements are detected by analyzing the PCR products by capillary gel electrophoresis.
5. **Panel/Profile Components:** N/A
6. **Critical Values:** N/A
7. **Specimen Collection / Handling Requirements:**

Specimen Labeling

- a. The specimen must be labeled with two identifiers at the time of collection. Examples of acceptable identifiers include but are not limited to: patient name, date of birth, hospital number, requisition number, accession number, and unique random number. A location (e.g., hospital room number) is not an acceptable identifier. Collection date and collector's identifier are required.
- b. A completed requisition form should be submitted with every sample, and, at minimum, the following is required: ordering physician name, phone number, fax number, and patient's name, identifying number of patient, patient sex, patient date of birth or age, specimen type, collection date, tests requested, provisional diagnosis or clinical rationale for test, and billing information.

Specimen Type

- a. Peripheral blood (PB): 2-5mL, in purple top (sodium EDTA) tube; yellow top tube (ACD) acceptable.
- b. Bone marrow (BM): 1-3mL, drawn into a syringe containing anticoagulant and then delivered in a purple top tube.
- c. Fresh or frozen tissue: fresh tissue should be obtained in a sterile manner, and a minimum of 3 mm³ of tissue is required. Put fresh tissues in culture medium or snap freeze
- d. Formalin-fixed paraffin-embedded (FFPE) tissue blocks: send FFPE tissue blocks to the lab or contact lab for instructions about cutting sections for molecular studies.

Handling

- a. PB and BM can be delivered at room temperature within 4 hours of collection
- b. If necessary, blood or bone marrow samples may be refrigerated for up to 48 hours.
- c. Fresh tissue samples should be delivered at room temperature in RPMI culture medium to the lab within 3 hours of collection, or snap frozen in liquid nitrogen at - 70°C and packed in dry ice for delivery. Please do not allow frozen tissues to thaw.
- d. Formalin-fixed paraffin embedded (FFPE) tissue blocks can be delivered at room temperature.
- e. Do not freeze whole blood or bone marrow.

Unacceptable Conditions

- a. Serum or plasma; frozen PB or BM; clotted blood; severely hemolyzed samples.

Unacceptable fixed paraffin tissue samples:

- a. Block fixed in Zenker's, B5, or Bouin's fixatives; decalcified paraffin-embedded bone marrow biopsy sample.

8. Minimum Specimen Requirements:

- a. Peripheral blood (PB): 2mL, in purple top (sodium EDTA) tube; yellow top tube (ACD) acceptable.
- b. Bone marrow (BM): 1mL, drawn into a syringe containing anticoagulant and then delivered in a purple top tube.
- c. Fresh or frozen tissue: a minimum of 3 mm³ of tissue is required.
- d. FFPE tissue: 5 ten micron tissue sections

9. Turnaround Times:

- a. Total testing time: 4 days/sample has to be received by Friday 3pm to meet TAT
- b. Results to Client: 7 working days

10. Communication:

- a. Turnaround time non-conformity: **Email or call Pathologist on request form to notify them of the delay.**
- b. Specimen rejection: **Most causes for specimen rejection are noted at pick-up, prior to the sample leaving UHS premises, communicated verbally, and corrected immediately. In rare cases where cause for specimen rejection is noted after the sample has arrived at UT Health San Antonio, the Pathologist on the request form will be contacted by email or phone.**
- c. Technical Updates: **Email Applicable Laboratory Director.**

11. Quality:

- a. Reports for TCR beta gene rearrangement assays always include PCR product size(s) and involved segments.
- b. When molecular results are ready, MDL staff or faculty always communicate with ordering physicians and compare molecular results to morphological and historical findings.
- c. For all specimens sent to MDL, when previous samples have been tested and reported by MDL on the same patient, current results are compared to previous results for peak size to differentiate if the same clonality is observed in a given patient.
- d. DNA quality and quantity will be checked by spectrophotometers and control gene amplification.
- e. MDL takes part in the College of American Pathologist (CAP) bi-annual survey of molecular hematological oncology (MHO) program for this assay.
- f. Cite literature references as appropriate.
- g. All reports include methodology, interpretation, clinical comments, references, and an FDA disclaimer.
- h. If the assay is **inoperable** due to shortage of reagents or instrument malfunction, efforts will be made immediately to recruit reagents or repair instruments. Meanwhile, STRL send out samples to another accredited lab if the turn-around time is critical.

Test: T-cell Receptor (TCR) Gamma Gene Rearrangement, PCR

1. **CPT:** 81342: TRG@ (T cell antigen receptor, gamma) gene rearrangement analysis, evaluation to detect abnormal clonal population(s)
2. **Synonym(s):** TCR-gamma Gene Clonality Detection
3. **Performed:** In-House
4. **Methodology:**
DNA is isolated and amplified by PCR using BIOMED-2 primers targeting the V γ 1-8, V γ 9, V γ 10, V γ 11 and J γ 1.1/2.1, J γ 1.3/2.3 sequences. The gene rearrangements are detected by analyzing the PCR products by capillary gel electrophoresis.
5. **Panel/Profile Components:** N/A
6. **Critical Values:** N/A
7. **Specimen Collection / Handling Requirements:**

Specimen Labeling

- a. The specimen must be labeled with two identifiers at the time of collection. Examples of acceptable identifiers include but are not limited to patient name, date of birth, hospital number, requisition number, accession number, and unique random number. A location (e.g., hospital room number) is not an acceptable identifier. Collection date and collector's identifier are required.
- b. A completed requisition form should be submitted with every sample, and, at minimum, the following is required: ordering physician name, phone number, fax number, and patient's name, identifying number of patient, patient sex, patient date of birth or age, specimen type, collection date, tests requested, provisional diagnosis or clinical rationale for test, and billing information.

Specimen Type

- a. Peripheral blood (PB): 2-5mL, in purple top (sodium EDTA) tube; yellow top tube (ACD) acceptable.
- b. Bone marrow (BM): 1-3mL, drawn into a syringe containing anticoagulant and then delivered in a purple top tube.
- c. Fresh or frozen tissue: fresh tissue should be obtained in a sterile manner, and a minimum of 3 mm³ of tissue is required. Put fresh tissues in culture medium or snap freeze.
- d. Formalin-fixed paraffin-embedded (FFPE) tissue blocks: send FFPE tissue blocks to the lab or contact lab for instructions about cutting sections for molecular studies.

Handling

- a. PB and BM can be delivered at room temperature within 4 hours of collection.
- b. If necessary, blood or bone marrow samples may be refrigerated for up to 48 hours.
- c. Fresh tissue samples should be delivered at room temperature in RPMI culture medium to the lab within 3 hours of collection, or snap frozen in liquid nitrogen at - 70°C and packed in dry ice for delivery. Please do not allow frozen tissues to thaw.
- d. Formalin-fixed paraffin embedded (FFPE) tissue blocks can be delivered at room temperature.
- e. Do not freeze whole blood or bone marrow.

Unacceptable Conditions

- a. Serum or plasma; frozen PB or BM; clotted blood; severely hemolyzed samples.

Unacceptable fixed paraffin tissue samples

- a. Block fixed in Zenker's, B5, or Bouin's fixatives; decalcified paraffin-embedded bone marrow biopsy sample.

8. Minimum Specimen Requirements:

- a. Peripheral blood (PB): 2mL, in purple top (sodium EDTA) tube; yellow top tube (ACD) acceptable.
- b. Bone marrow (BM): 1mL, drawn into a syringe containing anticoagulant and then delivered in a purple top tube.
- c. Fresh or frozen tissue: a minimum of 3 mm³ of tissue is required.
- d. FFPE tissue: 5 ten-micron tissue sections

9. Turnaround Times:

Total testing time: **4 days/sample has to be received by Friday 3pm to meet TAT**

Results to Client: **7 working days**

10. Communication:

- a. Turnaround time non-conformity: **Email or call Pathologist on request form to notify them of the delay.**
- b. Specimen rejection: **Most causes for specimen rejection are noted at pick-up, prior to the sample leaving UHS premises, communicated verbally, and corrected immediately. In rare cases where cause for specimen rejection is noted after the sample has arrived at UT Health San Antonio, the Pathologist on the request form will be contacted by email or phone.**
- c. Technical Updates: **Email Applicable Laboratory Director.**

11. Quality:

- a. Reports for all TCR gamma gene rearrangement assays always include PCR product size(s) and involved segments.
- b. When molecular results are ready, MDL staff or faculty always communicate with ordering physicians and compare molecular results to morphological and historical findings.
- c. For all specimens sent to MDL, when previous samples have been tested and reported by MDL on the same patient, current results are compared to previous results for peak size to differentiate if the same clonality is observed in a given patient.
- d. DNA quality and quantity will be checked by spectrophotometers and control gene amplification.
- e. MDL takes part in the College of American Pathologist (CAP) bi-annual survey of molecular hematological oncology (MHO) program for this assay.
- f. Cite literature references as appropriate.
- g. All reports include methodology, interpretation, clinical comments, references, and an FDA disclaimer.
- h. If the assay is **inoperable** due to shortage of reagents or instrument malfunction, efforts will be made immediately to recruit reagents or repair instruments. Meanwhile, STRL send out samples to another accredited lab if the turn-around time is critical.

Test: T-cell Clonality Panel (TCRB, TCRG), PCR

1. **CPT: 81340:** TRB@ (T cell antigen receptor, beta) gene rearrangement analysis to detect abnormal clonal population(s); using amplification methodology, 81342 TRG@ (T cell antigen receptor, gamma) gene rearrangement analysis, evaluation to detect abnormal clonal population(s)
2. **Synonym(s):** TCR-beta and gamma Gene Clonality Detection
3. **Performed:** In-House
4. **Methodology:**
 - a. DNA is isolated and amplified by PCR using BIOMED-2 primers targeting V β , D β and J β sequences. The gene rearrangements are detected by analyzing the PCR products by capillary gel electrophoresis.
 - b. DNA is isolated and amplified by PCR using BIOMED-2 primers targeting the V γ 1-8, V γ 9, V γ 10, V γ 11 and J γ 1.1/2.1, J γ 1.3/2.3 sequences. The gene rearrangements are detected by analyzing the PCR products by capillary gel electrophoresis.
5. **Panel/Profile Components:** TCR-beta and TCR-gamma
6. **Critical Values:** N/A
7. **Specimen Collection / Handling Requirements:**

Specimen Labeling

- a. The specimen must be labeled with two identifiers at the time of collection. Examples of acceptable identifiers include but are not limited to: patient name, date of birth, hospital number, requisition number, accession number, and unique random number. A location (e.g., hospital room number) is not an acceptable identifier. Collection date and collector's identifier are required.
- b. A completed requisition form should be submitted with every sample, and, at minimum, the following is required: ordering physician name, phone number, fax number, and patient's name, identifying number of patient, patient sex, patient date of birth or age, specimen type, collection date, tests requested, provisional diagnosis or clinical rationale for test, and billing information.

Specimen Type

- a. Peripheral blood (PB): 2-5mL, in purple top (sodium EDTA) tube; yellow top tube (ACD) acceptable.
- b. Bone marrow (BM): 1-3mL, drawn into a syringe containing anticoagulant and then delivered in a purple top tube.

- c. Fresh or frozen tissue: fresh tissue should be obtained in a sterile manner, and a minimum of 3 mm³ of tissue is required. Put fresh tissues in culture medium or snap freeze
- d. Formalin-fixed paraffin-embedded (FFPE) tissue blocks: send FFPE tissue blocks to the lab or contact lab for instructions about cutting sections for molecular studies.

Handling

- a. PB and BM can be delivered at room temperature within 4 hours of collection.
- b. If necessary, blood or bone marrow samples may be refrigerated for up to 48 hours.
- c. Fresh tissue samples should be delivered at room temperature in RPMI culture medium to the lab within 3 hours of collection, or snap frozen in liquid nitrogen at - 70°C and packed in dry ice for delivery. Please do not allow frozen tissues to thaw.
- d. Formalin-fixed paraffin embedded (FFPE) tissue blocks can be delivered at room temperature.
- e. Do not freeze whole blood or bone marrow.

Unacceptable Conditions

- a. Serum or plasma; frozen PB or BM; clotted blood; severely hemolyzed samples.

Unacceptable fixed paraffin tissue samples:

- a. Block fixed in Zenker's, B5, or Bouin's fixatives; decalcified paraffin-embedded bone marrow biopsy sample.

8. Minimum Specimen Requirements:

- a. Peripheral blood (PB): 2mL, in purple top (sodium EDTA) tube; yellow top tube (ACD) acceptable.
- b. Bone marrow (BM): 1mL, drawn into a syringe containing anticoagulant and then delivered in a purple top tube.
- c. Fresh or frozen tissue: a minimum of 3 mm³ of tissue is required.
- d. FFPE tissue: 5 ten-micron tissue sections

9. Turnaround Times:

Total testing time: **4 days/sample has to be received by Friday 3pm to meet TAT**

Results to Client: **7 working days**

10. Communication:

- a. Turnaround time non-conformity: **Email or call Pathologist on request form to notify them of the delay.**
- b. Specimen rejection: **Most causes for specimen rejection are noted at pick-up, prior to the sample leaving UHS premises, communicated verbally, and corrected immediately. In rare cases where**

cause for specimen rejection is noted after the sample has arrived at UT Health San Antonio, the Pathologist on the request form will be contacted by email or phone.

- c. Technical Updates: **Email Applicable Laboratory Director.**

11. Quality:

- a. Reports for all TCR-beta and gamma gene rearrangement assays always include PCR product size(s) and involved segments.
- b. When molecular results are ready, MDL staff or faculty always communicate with ordering physicians and compare molecular results to morphological and historical findings.
- c. For all specimens sent to MDL, when previous samples have been tested and reported by MDL on the same patient, current results are compared to previous results for peak size to differentiate if the same clonality is observed in a given patient.
- d. DNA quality and quantity will be checked by spectrophotometers and control gene amplification.
- e. MDL takes part in the College of American Pathologist (CAP) bi-annual survey of molecular hematological oncology (MHO) program for this assay.
- f. Cite literature references as appropriate.
- g. All reports include methodology, interpretation, clinical comments, references, and an FDA disclaimer.
- h. If the assay is **inoperable** due to shortage of reagents or instrument malfunction, efforts will be made immediately to recruit reagents or repair instruments. Meanwhile, STRL send out samples to another accredited lab if the turn-around time is critical.

Test: Factor V (Leiden) Mutation Analysis

1. **CPT: 81241:** F5 (coagulation Factor V) gene analysis, Leiden variant
2. **Synonym(s):** Factor V (F5) Leiden (R506Q) Mutation by Real-Time PCR
3. **Performed:** In-House
4. **Methodology:** DNA is isolated from the patient sample and the Factor V gene containing the Leiden mutation site is PCR-amplified and analyzed using an allelic discrimination assay employing primers and TaqMan probes. Results are reported as normal, heterozygous or homozygous for the factor V Leiden mutation.
5. **Panel/Profile Components:** N/A
6. **Critical Values:** N/A
7. **Specimen Collection / Handling Requirements:**

Specimen Labeling

- a. The specimen must be labeled with two identifiers at the time of collection. Examples of acceptable identifiers include but are not limited to: patient name, date of birth, hospital number, requisition number, accession number, and unique random number. A location (e.g., hospital room number) is not an acceptable identifier. Collection date and collector's identifier are required.
- b. A completed requisition form should be submitted with every sample and, at minimum, the following is required: ordering physician name, phone number, fax number, and patient's name, identifying number of patient, patient sex, patient date of birth or age, specimen type, collection date, tests requested, provisional diagnosis or clinical rationale for test, and billing information.

Specimen Type

- a. Peripheral blood (PB): 1-3mL, in purple top (sodium EDTA) tube; yellow top tube (ACD) acceptable.

Handling

- a. PB can be delivered at room temperature within 8 hours of collection
- b. If necessary, blood or bone marrow samples may be refrigerated for up to 48 hours
- c. Do not freeze whole blood

Unacceptable Conditions

- a. Serum or plasma; frozen PB or BM; clotted blood; severely hemolyzed samples.

8. **Minimum Specimen Requirements:** Peripheral blood (PB): 1mL, in purple top (sodium EDTA) tube; yellow top tube (ACD) acceptable.

9. Turnaround Times:

Total testing time: **8 hours/Friday**

Results to Client: **6 working days**

10. Communication:

- a. Turnaround time non-conformity: **Email or call Pathologist on request form to notify them of the delay.**
- b. Specimen rejection: **Most causes for specimen rejection are noted at pick-up, prior to the sample leaving UHS premises, communicated verbally, and corrected immediately. In rare cases where cause for specimen rejection is noted after the sample has arrived at UT Health San Antonio, the Pathologist on the request form will be contacted by email or phone.**
- c. Technical Updates: **Email Applicable Laboratory Director.**

11. Quality:

- a. DNA quality will be checked by control gene amplification.
- b. MDL takes part in the College of American Pathologist (CAP) bi-annual survey of molecular genetics (MGL) program for this assay.
- c. Cite literature references as appropriate.
- d. All reports include methodology, interpretation, clinical comments, references, and an FDA disclaimer.
- e. If the assay is **inoperable** due to shortage of reagents or instrument malfunction, efforts will be made immediately to recruit reagents or repair instruments. Meanwhile, STRL send out samples to another accredited lab if the turn-around time is critical.

Test: Prothrombin (Factor II) 20210G>A Mutation Analysis

1. **CPT:** 81240: F2 (prothrombin, coagulation factor II) gene analysis, 20210 G>A variant
2. **Synonym(s):** Prothrombin (F2) G20210A Mutation Analysis by Real-Time PCR
3. **Performed:** In-House
4. **Methodology:** DNA is isolated from the patient sample and the prothrombin gene containing the 20210 mutation site is PCR-amplified and analyzed using an allelic discrimination assay employing primers and TaqMan probes. Results are reported as normal, heterozygous or homozygous for the G20210A mutation.
5. **Panel/Profile Components:** N/A
6. **Critical Values:** N/A
7. **Specimen Collection / Handling Requirements:**

Specimen Labeling

- a. The specimen must be labeled with two identifiers at the time of collection. Examples of acceptable identifiers include but are not limited to: patient name, date of birth, hospital number, requisition number, accession number, and unique random number. A location (e.g., hospital room number) is not an acceptable identifier. Collection date and collector's identifier are required.
- b. A completed requisition form should be submitted with every sample and, at minimum, the following is required: ordering physician name, phone number, fax number, and patient's name, identifying number of patient, patient sex, patient date of birth or age, specimen type, collection date, tests requested, provisional diagnosis or clinical rationale for test, and billing information.

Specimen Type

- a. Peripheral blood (PB): 1-3mL, in purple top (sodium EDTA) tube; yellow top tube (ACD) acceptable.

Handling

- a. PB can be delivered at room temperature within 8 hours of collection
- b. If necessary, blood or bone marrow samples may be refrigerated for up to 48 hours
- c. Do not freeze whole blood

Unacceptable Conditions

- a. Serum or plasma; frozen PB or BM; clotted blood; severely hemolyzed samples.

8. Minimum Specimen Requirements:

Peripheral blood (PB): 1mL, in purple top (sodium EDTA) tube; yellow top tube (ACD) acceptable.

9. Turnaround Times:

Total testing time: **8 hours/Friday**

Results to Client: **6 working days**

10. Communication:

- a. Turnaround time non-conformity: **Email or call Pathologist on request form to notify them of the delay.**
- b. Specimen rejection: **Most causes for specimen rejection are noted at pick-up, prior to the sample leaving UHS premises, communicated verbally, and corrected immediately. In rare cases where cause for specimen rejection is noted after the sample has arrived at UT Health San Antonio, the Pathologist on the request form will be contacted by email or phone.**
- c. Technical Updates: **Email Applicable Laboratory Director.**

11. Quality:

- a. DNA quality will be checked by control gene amplification.
- b. MDL takes part in the College of American Pathologist (CAP) bi-annual survey of molecular genetics (MGL) program for this assay.
- c. Cite literature references as appropriate.
- d. All reports include methodology, interpretation, clinical comments, references, and an FDA disclaimer.
- e. If the assay is **inoperable** due to shortage of reagents or instrument malfunction, efforts will be made immediately to recruit reagents or repair instruments. Meanwhile, STRL send out samples to another accredited lab if the turn-around time is critical.

Test: Hereditary Hemochromatosis DNA Mutation Analysis (10249)

1. **CPT:** 81256: HFE (hemochromatosis) gene analysis, common variants (e.g., C282Y, H63D)
2. **Synonym(s):** HFE Gene Analysis; Hereditary Hemochromatosis (C282Y and H63D mutation) by PCR and RFLP
3. **Performed:** In-House
4. **Methodology:** DNA is isolated from the patient sample and the HFE gene containing C282Y and H63D mutation sites is PCR-amplified, digested with restriction endonucleases, separated by gel electrophoresis, and analyzed by restriction fragment length polymorphisms (RFLP). Results are reported as normal, heterozygous or homozygous for C282Y and/or H63D mutation.
5. **Panel/Profile Components:** N/A
6. **Critical Values:** N/A
7. **Specimen Collection / Handling Requirements:**

Specimen Labeling

- a. The specimen must be labeled with two identifiers at the time of collection. Examples of acceptable identifiers include but are not limited to: patient name, date of birth, hospital number, requisition number, accession number, and unique random number. A location (e.g., hospital room number) is not an acceptable identifier. Collection date and collector's identifier are required.
- b. A completed requisition form should be submitted with every sample, and, at minimum, the following is required: ordering physician name, phone number, fax number, and patient's name, identifying number of patient, patient sex, patient date of birth or age, specimen type, collection date, tests requested, provisional diagnosis or clinical rationale for test, and billing information.

Specimen Type

- a. Peripheral blood (PB): 1-3mL, in purple top (sodium EDTA) tube; yellow top tube (ACD) acceptable.

Handling

- a. PB can be delivered at room temperature within 8 hours of collection
- b. If necessary, blood or bone marrow samples may be refrigerated for up to 48 hours
- c. Do not freeze whole blood

Unacceptable Conditions

- a. Serum or plasma; frozen PB or BM; clotted blood; severely hemolyzed samples.

8. **Minimum Specimen Requirements:**

- a. Peripheral blood (PB): 1mL, in purple top (sodium EDTA) tube; yellow top tube (ACD) acceptable.

9. Turnaround Times:

Total testing time: **8 hours/Wednesday**

Results to Client: **6 working days**

10. Communication:

- a. Turnaround time non-conformity: **Email or call Pathologist on request form to notify them of the delay.**
- b. Specimen rejection: **Most causes for specimen rejection are noted at pick-up, prior to the sample leaving UHS premises, communicated verbally, and corrected immediately. In rare cases where cause for specimen rejection is noted after the sample has arrived at UT Health San Antonio, the Pathologist on the request form will be contacted by email or phone.**
- c. Technical Updates: **Email Applicable Laboratory Director.**

11. Quality:

- a. DNA quality will be checked by control gene amplification.
- b. MDL takes part in the College of American Pathologist (CAP) bi-annual survey of molecular genetics (MGL) program for this assay.
- c. Cite literature references as appropriate.
- d. All reports include methodology, interpretation, clinical comments, references, and an FDA disclaimer.
- e. If the assay is **inoperable** due to shortage of reagents or instrument malfunction, efforts will be made immediately to recruit reagents or repair instruments. Meanwhile, STRL send out samples to another accredited lab if the turn-around time is critical.