





## Test Name: **Constitutional Chromosome Analysis – Blood**

1. **CPT Code(s):** 88230, 88262
2. **Synonym(s):** Chromosome Analysis, Chromosome Analysis – Blood, RCA-BL
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 - 48 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 cytogenetics test requisition 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 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: **7 - 10 days**
10. **Communication:** Final reports faxed or emailed based on provider's preference
11. **Quality:** QA/Utilization Report

**Test Name: Constitutional Chromosome Analysis, Non-Blood – Amniotic Fluid**

1. **CPT Code(s):** 88235, 88269
2. **Synonym(s):** Amniotic Fluid Chromosome Analysis, RCA-AF
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 cytogenetics test requisition 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 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: **8 - 14 days**
10. **Communication:** Final reports faxed or emailed based on provider's preference
11. **Quality:** QA/Utilization Report

**Test Name: Constitutional Chromosome Analysis, Non-Blood – Products of Conception**

1. **CPT Code(s):** 88233, 88262
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 cytogenetics test requisition 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 requisitions must have a 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 cm<sup>3</sup>; Minimum Quantity: 1 cm<sup>3</sup>
9. **Turnaround time:** Total testing time: **6 weeks**
10. **Communication:** Final reports faxed or emailed based on provider's preference
11. **Quality:** QA/Utilization Report

**Test Name: Constitutional Chromosome Analysis, Non-Blood – Skin**

1. **CPT Code(s):** 88233, 88263
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 cytogenetics test requisition 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 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 cm<sup>3</sup>; Minimum Quantity: 1 cm<sup>3</sup>
9. **Turnaround time:** Results to Client: **6 weeks for 90% cases**
10. **Communication:** Final reports faxed or emailed based on provider's preference
11. **Quality:** QA/Utilization Report

**Test Name: Oncologic Chromosome Analysis - Blood**

**CPT Code(s):** 88237, 88264, 88280

- 1. Synonym(s):** Peripheral Blood Chromosome Analysis for Leukemia, Leukemic Blood Chromosome
- 2. Performed:** In-House
- 3. Methodology:** Unstimulated short-term culture; chromosome preparation and banding; microscopic analysis and karyotype; interpretation and report
- 4. Panel/Profile Components:** N/A
- 5. Critical Values:** STAT (Promyelocytic Leukemia): Preliminary results in 24-48 hours
- 6. 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 cytogenetics test requisition 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 clinical indication and must have the name of an authorized physician.  
Any sample without this information will be rejected.
- 7. Minimum Specimen Requirements:** Optimal Quantity: 3-4 ml; Minimum Quantity: 1-2 ml
- 8. Turnaround time:** Total testing time: **7-10 days**
- 9. Communication:** Final reports faxed or emailed based on provider's preference
- 10. Quality:** QA/Utilization Report

## Test Name: **Oncologic Chromosome Analysis, Non-Blood - Bone Marrow**

1. **CPT Code(s):** 88237, 88264, 88280
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 24-48 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 cytogenetics test requisition 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 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: **7-10 days**
10. **Communication:** Final reports faxed or emailed based on provider's preference
11. **Quality:** QA/Utilization Report

## Test Name: **Oncologic Chromosome Analysis, Non-Blood – Lymph Node**

1. **CPT Code(s):** 88237, 88264, 88280
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 24-48 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 cytogenetics test requisition 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 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 cm<sup>3</sup>; Minimum Quantity: 1 cm<sup>3</sup>
9. **Turnaround time:** Total testing time: **7-10 days**
10. **Communication:** Final reports faxed or emailed based on provider's preference
11. **Quality:** QA/Utilization Report

## Test Name: **Oncologic Chromosome Analysis, Non-Blood – Solid Tumors**

**CPT Code(s):** 88239, 88264, 88280

1. **Synonym(s):** Tumor Chromosome Analysis
2. **Performed:** In-House
3. **Methodology:** In Situ long-term culture initiated using Collagenase for enzyme digestion; chromosome preparation and banding; microscopic analysis and karyotype; interpretation and report
4. **Panel/Profile Components:** N/A
5. **Critical Values:** N/A
6. **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 cytogenetics test requisition 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 clinical indication and must have the name of an authorized physician.  
Any sample without this information will be rejected.
7. **Minimum Specimen Requirements:** Optimal Quantity: 2 cm<sup>3</sup>; Minimum Quantity: 1 cm<sup>3</sup>
8. **Turnaround time:** Total testing time: **10-14 days**
9. **Communication:** Final reports faxed or emailed based on provider's preference
10. **Quality:** QA/Utilization Report

**Test Name: Oncologic Fluorescence In Situ Hybridization, Blood, and Non-Blood (Bone Marrow, Lymph Node, Touch Prep Slides) – Only Fresh Tissue**

**Not performed on Formalin Fixed Paraffin Embedded (FFPE) Tissue**

**ALL Panels – COG Panel**

<b>ALL - COG</b>		
<b>Probe Name</b>	<b>Locus/CHR</b>	<b>Catalogue #</b>
<b>ASS1/ABL1/BCR</b>	9q34/22q11.2	Cytocell LPH038
<b>D10Z1/D17Z1</b>	Chromosomes 10/17	Cytocell LPE010G/LPE017R
<b>KMT2A</b>	11q23.3	Cytocell LPH013
<b>ETV6/RUNX1</b>	12p13.2/21q22.12	Cytocell LPH012

**ALL Panels – Extended Panel**

<b>ALL - Extended</b>		
<b>Probe Name</b>	<b>Locus/CHR</b>	<b>Catalogue #</b>
<b>FIP1L1/CHIC2/PDGFR</b>	4q12	Cytocell LPH032
<b>MYC</b>	8q24.21	Cytocell LPH010
<b>CDKN2A/D9Z3</b>	9p21.3/9q12	Cytocell LPH009
<b>ASS1/ABL1/BCR</b>	9q34/22q11.2	Cytocell LPH038
<b>D10Z1/D17Z1</b>	Chromosomes 10/17	Cytocell LPE010G/LPE017R
<b>KMT2A</b>	11q23.3	Cytocell LPH013
<b>ETV6/RUNX1</b>	12p13.2/21q22.12	Cytocell LPH012
<b>IGH</b>	14q32.33	Cytocell LPH014
<b>TCF3</b>	19p13.3	Cytocell LPH019

**ALL Panels – Ph-Like Reflex Panel**

<b>ALL - Ph Like Reflex</b>		
<b>Probe Name</b>	<b>Locus/CHR</b>	<b>Catalogue #</b>
<b>CHIC2</b>	4q12	Cytocell LPH032
<b>BCR/ABL1/ASS1</b>	9q34/22q11.2	Cytocell LPH038
<b>D10Z1/D17Z1</b>	Chromosomes 10/17	Cytocell LPE010G/LPE017R
<b>KMT2A</b>	11q23.3	Cytocell LPH013
<b>ETV6/RUNX1</b>	12p13.2/21q22.12	Cytocell LPH012
<b>CRLF2</b>	Xp22.33/Yp11.32	Cytocell LPH511/512

<b>ABL2</b>	1q25.2	Cytocell MPD2671/2672
<b>CSF1R</b>	5q32	Cytocell MPD2751/2752
<b>PDGFRB</b>	5q32	Cytocell LPH031
<b>JAK2</b>	9p24.1	Cytocell MPD2681/2682
<b>EPOR</b>	19p13.2	Cytocell MPH2741/2742

### ALL Panels – Ph-Like Panel

<b>ALL - Ph Like</b>		
<b>Probe Name</b>	<b>Locus/CHR</b>	<b>Catalogue #</b>
<b>CRLF2</b>	Xp22.33/Yp11.32	Cytocell LPH511/512
<b>ABL2</b>	1q25.2	Cytocell MPD2671/2672
<b>CSF1R</b>	5q32	Cytocell MPD2751/2752
<b>PDGFRB</b>	5q32	Cytocell LPH031
<b>JAK2</b>	9p24.1	Cytocell MPD2681/2682
<b>EPOR</b>	19p13.2	Cytocell MPH2741/2742

### Myeloid Panels – AML Panel

<b>AML Panel</b>		
<b>Probe Name</b>	<b>Locus/CHR</b>	<b>Catalogue #</b>
<b>RUNX1T1/RUNX1</b>	8q21.3/21q22.1	Cytocell LPH026
<b>KMT2A</b>	11q23.3	Cytocell LPH013
<b>PML/RARA</b>	15q24.1/17q21.1-q21.2	Cytocell LPH023
<b>MYH11/CBFB</b>	16p13.1/16q22	Cytocell LPH022

### Myeloid Panels – MDS Panel

<b>MDS</b>		
<b>Probe Name</b>	<b>Locus/CHR</b>	<b>Catalogue #</b>
<b>EGR1/TAS2R1</b>	5p15.3/5q31.2	Cytocell LPH024
<b>TES/RELN</b>	7q22/7q31.2	Cytocell LPH025
<b>KMT2A</b>	11q23.3	Cytocell LPH013
<b>PTPRT/MYBL2</b>	20q12/20q13.1	Cytocell LPH020
<b>TP53/D17Z1</b>	17p13.1/17p11.1-q11.1	Cytocell LPH017

### Myeloid Panels – AML/MDS Panel

<b>AML / MDS</b>		
<b>Probe Name</b>	<b>Locus/CHR</b>	<b>Catalogue #</b>
<b>TAS2R1/EGR1</b>	5p15.3/5q31.2	Cytocell LPH024
<b>TES/RELN</b>	7q22/7q31.2	Cytocell LPH025
<b>RUNX1T1/RUNX1</b>	8q21.3/21q22.1	Cytocell LPH026
<b>KMT2A</b>	11q23.3	Cytocell LPH013
<b>PML/RARA</b>	15q24.1/17q21.1-q21.2	Cytocell LPH023
<b>MYH11/CBFB</b>	16p13.1/16q22	Cytocell LPH022
<b>TP53/D17Z1</b>	17p13.1/17p11.1-q11.1	Cytocell LPH017
<b>PTPRT/MYBL2</b>	20q12/20q13.1	Cytocell LPH020

### B-cell Lymphoma Panels – B-cell Aggressive Panel

<b>B-cell Aggressive Panel</b>		
<b>Probe Name</b>	<b>Locus/CHR</b>	<b>Catalogue #</b>
<b>BCL6</b>	3q27.3	Cytocell LPH035
<b>MYC</b>	8q24.21	Cytocell LPS027
<b>IGH/BCL2</b>	14q32.33/18q21.33	Cytocell LPH018

### B-cell Lymphoma Panels – B-cell Lymphoma Panel

<b>B-cell Lymphoma Panel</b>		
<b>Probe Name</b>	<b>Locus/CHR</b>	<b>Catalogue #</b>
<b>BCL6</b>	3q27.3	Cytocell LPH035
<b>MYC</b>	8q24.21	Cytocell LPS027
<b>IGH</b>	14q32.33	Cytocell LPH014

### CLL Panels – CLL Panel

<b>CLL</b>		
<b>Probe Name</b>	<b>Locus/CHR</b>	<b>Catalogue #</b>
<b>D6Z1/MYB</b>	6q23.3/6p11.1-q11.1	Cytocell LPH016
<b>D11Z1/ATM</b>	11q22.3/11p11.1-q11.1	Cytocell LPH011
<b>D12Z1</b>	12p11.1-q11.1	Cytocell LPH069

<b>D13S319/D13S828/D13S293</b>	13q14.2-q14.3/13q34	Cytocell LPH068
<b>IGH</b>	14q32.33	Cytocell LPH014
<b>TP53/D17Z1</b>	17p13.1/17p11.1-q11.1	Cytocell LPH017

### CLL Panels – CLL Extended Panel

<b>CLL Extended</b>		
<b>Probe Name</b>	<b>Locus/CHR</b>	<b>Catalogue #</b>
<b>MYB/D6Z1</b>	6q23.3/6p11.1-q11.1	Cytocell LPH016
<b>ATM/D11Z1</b>	11q22.3/11p11.1-q11.1	Cytocell LPH011
<b>CCND1/IGH</b>	11q13.3/14q32.33	Cytocell LPH021
<b>D12Z1</b>	12p11.1-q11.1	Cytocell LPH069
<b>D13S319</b>	13q14.2-q14.3/13q34	Cytocell LPH068
<b>TP53/D17Z1</b>	17p13.1/17p11.1-q11.1	Cytocell LPH017
<b>IGH/BCL2</b>	14q32.33/18q21.33	Cytocell LPH018
<b>IGH/BCL3</b>	14q32.33/19q13.31-q13.32	Cytocell MPD10590

### CLL Panels – CLL IGH Reflex Panel

<b>CLL IGH Reflex Panel</b>		
<b>Probe Name</b>	<b>Locus/CHR</b>	<b>Catalogue #</b>
<b>CCND1/IGH</b>	11q13.3/14q32.33	Cytocell LPH021
<b>IGH/BCL2</b>	14q32.33/18q21.33	Cytocell LPH018
<b>IGH/BCL3</b>	14q32.33/19q13.31-q13.32	Cytocell MPD10590

### Multiple Myeloma Panel

<b>Multiple Myeloma</b>		
<b>Probe Name</b>	<b>Locus/CHR</b>	<b>Catalogue #</b>
CKS1B/CDKN2C	1q21-q22/1932.3	CytoCELL LPH039
FGFR3/IGH	4p16.3/14q32.33	CytoCELL LPH030
IGH/MAF v2	14q32.33/16q23	CytoCELL LPH101
TP53/D17Z1	17p13.1/17p11.1-q11.1	CytoCELL LPH017
IGH/MAFB	14q32.33/20q12	CytoCELL LPH044

### Myeloproliferative Neoplasms / Myeloproliferative Disease Panels – MPN/MPD Panel

<b>MPN/MPD Panel</b>		
<b>Probe Name</b>	<b>Locus/CHR</b>	<b>Catalogue #</b>
FIP1L1,CHIC2,PDGFRA	4q12	CytoCELL LPH032
PDGFRB	5q32	CytoCELL LPH031
FGFR1/D8Z2	8p11.23-p11.22/8p11.1-q11.1	CytoCELL LPS018
ASS1/ABL1/BCR	9q34/22q11.2	CytoCELL LPH038

### T-cell Lymphoma Panels – ALCL Panel

<b>T-cell ALCL Panel</b>		
<b>Probe Name</b>	<b>Locus/CHR</b>	<b>Catalogue #</b>
ALK	2p23.2-p23.1	CytoCELL LPS019
DUSP22/IRF4	6p25.3/6p11.1	CytoCELL MPP5610

### T-cell Lymphoma Panels – T-cell Panel

<b>T-Cell Lymphoma</b>		
<b>Probe Name</b>	<b>Locus/CHR</b>	<b>Catalogue #</b>
<i>TCRB</i>	7q34	CytoCELL LPS048

<b>TCRAD</b>	14q11.2	Cytocell LPH047
<b>TCL1</b>	14q32.13-q32.2	Cytocell LPH046

**CPT Code(s):** 88271, 88275 each unit multiplied with number of probes used in the panel

1. **Synonym(s):** SEE under each Panel
2. **Performed:** In-House
3. **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
4. **Panel/Profile Components:** SEE under each panel
5. **Critical Values:** STAT (Promyelocytic Leukemia / Burkitt Lymphoma): Preliminary results in 24-48 hours
6. **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 cytogenetics test requisition 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 requisitions must have a clinical indication and must have the name of an authorized physician. Any sample without this information will be rejected.
7. **Minimum Specimen Requirements:**

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

Optimal Quantity: 2 cm<sup>3</sup>; Minimum Quantity: 1 cm<sup>3</sup> (Lymph Node & Tissues)
8. **Turnaround time:** Total testing time: **7-10 days**
9. **Communication:** Final reports faxed or emailed based on provider's preference
10. **Quality:** QA/Utilization Report

**Test Name: Fluorescence In Situ Hybridization – FISH Single Probe**

**Any probes in the listed panels can be ordered as single FISH probe test. For list of probes, see the FISH-Panel List above.**

**CPT Code(s):** 88271x1, 88275x1

1. **Synonym(s):** FISH, single probe
2. **Performed:** In-House
3. **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
4. **Panel/Profile Components:** N/A
5. **Critical Values:** STAT (Promyelocytic Leukemia / Burkitt Lymphoma): Preliminary results in 24-48 hours
6. **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 cytogenetics test requisition 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 requisitions must have a clinical indication and must have the name of an authorized physician. Any sample without this information will be rejected.
7. **Minimum Specimen Requirements:**

Optimal Quantity: 3-4 ml; Minimum Quantity: 1-2 ml (Bone Marrow & Leukemic Blood)  
Optimal Quantity: 2 cm<sup>3</sup>; Minimum Quantity: 1 cm<sup>3</sup> (Lymph Node & Tissues)
8. **Turnaround time:** Total testing time: **7-10 days**
9. **Communication:** Final reports faxed or emailed based on provider's preference



**10. Quality:** QA/Utilization Report

**Test Name: Constitutional Microarray - Tissue**
**CPT Code(s):** 81229

1. **Synonym(s):**
2. **Performed:** In-House
3. **Methodology:** DNA extraction / Hybridization / Data Analysis
4. **Panel/Profile Components:** N/A
5. **Critical Values:** N/A
6. **Specimen Collection / Handling Requirements:**

	<b>Amniotic Fluid</b>	<b>Products of Conception</b>	<b>Skin</b>
<b>Container</b>	Two 15 mL Sterile leak proof conical tubes (Discard first 1 mL of fluid to avoid maternal cell contamination)	Sterile leak proof container with Saline or Transport Media <b>Never place in Formalin</b>	Sterile leak proof container with Saline or Transport Media <b>Never place in Formalin</b>
<b>Optimum Quantity</b>	20 - 25 mL	2x2x2 cM, villi preferred or fetal tissue	2x2x2 cM, villi preferred or fetal tissue
<b>Minimum Quantity</b>	10 mL	1x1x1 cM	1x1x1 cM
<b>Storage</b>	Room Temperature	Room Temperature	Room Temperature
<b>Stability</b>	Stable for 8 hours at room temperature, then refrigerate	Stable for 8 hours at room temperature, then refrigerate	Stable for 8 hours at room temperature, then refrigerate
<b>Transportation</b>	Avoid freezing or heating above 35°C	Avoid freezing or heating above 35°C	Avoid freezing or heating above 35°C

- a. A complete cytogenetics test requisition must accompany all specimens, and the specimen must be labeled with the patient's name and identification number.
- b. ANY SPECIMENS RECEIVED WITHOUT A COMPLETE REQUISITION OR AN UNLABELED SPECIMEN WILL BE REJECTED.
- c. All requisitions must have a clinical indication and must have the name of an authorized physician.  
Any sample without this information will be rejected.

7. **Minimum Specimen Requirements:** See the table above
8. **Turnaround Time:** Total testing time: **14-28 days**
9. **Communication:** Final reports faxed or emailed based on provider's preference
10. **Quality:** QA/Utilization Report

## Test Name: **Microarray - Blood**

**CPT Code(s):** 81229

1. **Synonym(s):**
2. **Performed:** In-House
3. **Methodology:** DNA extraction / Hybridization / Data Analysis
4. **Panel/Profile Components:** N/A
5. **Critical Values:** N/A
6. **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 cytogenetics test requisition 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 clinical indication and must have the name of an authorized physician.  
Any sample without this information will be rejected.
12. **Minimum Specimen Requirements:** Optimal Quantity: 4-5 ml; Minimum Quantity: 1-2 ml
13. **Turnaround Time:** Total testing time: **14-28 days**
14. **Communication:** Final reports faxed or emailed based on provider's preference
15. **Quality:** QA/Utilization Report

## 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: 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:**
  - HPLC: voriconazole, amphotericin B, posaconazole;
  - LC/MS-MS: fluconazole, itraconazole, isavuconazole
- 5. Panel/Profile Components:** N/A
- 6. Critical Values:** N/A
- 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:**
  - Minimum plasma/serum volume requirements:
  - Voriconazole - 0.5 ml
  - Amphotericin B - 0.5 ml
  - Fluconazole - 0.25 ml
  - Itraconazole - 0.5 ml
  - Posaconazole - 0.5 ml
  - Isavuconazole – 0.5 ml
- 9. Turnaround Times:**
  - Total testing time: **6 hours**
  - Results to Client: **72 hours**
- 10. Communication:**
  - Turnaround time non-conformity: **Email or call Pathologist on request form to notify them of the delay.**
  - Specimen rejection: **Most causes for specimen rejection are noted at receipt. These are communicated verbally, with the client. In 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, Rezafungin)

- CPT:** 87188 (mould), 87186 (yeast)
- 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)
- Performed:** In-House
- 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 for filamentous fungi, and by broth microdilution or macrodilution susceptibility testing against yeasts according to the CLSI M27 reference standard.
- Panel/Profile Components:** Testing tailored to requests for submitting laboratory/physician. Individual drugs or groups of agents tested per request.
- Critical Values:** N/A
- 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.
- Minimum Specimen Requirements:**

A pure culture of organism on solid agar (plate or slant) is required.
- Turnaround Times:**
  - Total testing time: **1 to 10 business days from receipt of culture (species dependent)**
  - Results to Client: **<10 business days from receipt of culture**
- Communication:**
  - Turnaround time non-conformity: **Email or call Pathologist on request form to notify them of the delay.**
  - Specimen rejection: **Most causes for specimen rejection are noted at receipt. These are communicated verbally with the client. In 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: **< 21 business days from receipt of culture (species dependent)**
- b. Results to Client: **< 21 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 (88300, 88304, 88305, 88307, 88321, or 88323) could be added as case is worked on
2. **Synonym(s):** Acid Fast Bacilli Stain; Alcian Blue Stain 2.5; Alcian Blue 2.5/PASH, Bile Stain; Colloidal Iron Stain; Congo Red Stain; Copper Stain; Elastic Stain; Iron Stain; Fite Stain; Fontana Masson Stain; Giemsa Stain; Grocott Methanamine 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; Pentachrome, Post B5 H&E; Post B5 PASH; PTAH Stain; Retic Stain; Steiner Stain; Tri-elastic 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 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 accepted
  - 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, 88350 (second test) (88300, 88304, 88305, 88307, 88321, or 88323) could be added as test is worked on
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 & Heart Panel
H&E	H&E	H&E	H&E
IgG	IgG	IgG	C4d
IgA	IgA	IgA	Negative
IgM	IgM	IgM	
C1q	C3	C3	
C3	Fibrinogen	Fibrinogen	
Albumin	Negative	Negative	
Fibrinogen	H&E	H&E	
Kappa			
Lambda			
H&E			
C4d (transplants)			
Negative			

6. **Critical Values:** N/A
7. **Specimen Collection / Handling Requirements:**
  - a. Immediately place specimen for immunofluorescent studies in Michel’s IF Transport Media.
  - 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 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, 88300, 88304, 88305, 88307, 88321, or 88323) could be added as case is worked on
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
    - f. Cold ischemia time and fixation time if available
  3. Shipping Information (address all specimens to):  
Department of Pathology – Client Services 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 (2) 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, 88341 (second test) 88300, 88304, 88305, 88307, 88321, or 88323) could be added as case is worked on
2. **Synonym(s):** IHC
3. **Performed:** In-House: Yes
4. **Methodology:** Ultra-View, DAB or Alkaline Phosphatase (Ventana), Opti-View DAB (Ventana)
5. **Panel/Profile Components:** The following IHC tests all without interpretation: ACTH; AFP; ALK-1; Alpha Synuclein; ATRX, BCL2; BCL6; Ber-EP4; BOB 1; Beta Amyloid; Beta-Catenin; CA-125; Calcitonin; Calponin-1; Cam 5.2; CA9; CD1a; CD2; CD3; CD4; CD5; CD7; CD8; CD10; CD15; CD20; CD21; CD23; CD25; CD30; CD31; CD33; CD34; CD43; CD 44; CD45RB; CD56; CD57; CD61; CD68; CD71; CD79a; CD99; CD117; CD123; CD138; CD207; CDK4; CDX-2; CEA; Chromogranin; CK5/6; CK7; CK20; Clusterin; CMV; CXCL13; Cyclin-D1; Desmin; EBV-LMP; E-Cadherin; EMA; EGFR; ER; Factor VIII; Factor XIIIa; FSH; Gastrin; GATA-3; GCDFP-15; GFAP; GH; 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; Kappa; Keratin AE1/3; Ki67; Lambda; LH; Lysozyme; Mart 1; Mammaglobin; Mast Cell Tryptase; MDM2; Merosin; MHC-1; MUM-1; Myeloperoxidase; Myogenin; Napsin; Neurofilament; OCT 2; OCT ¾; P 16; P40; P53; P62, Pan-Actin; Pan Melanoma; Pax5; Pax8; PD1; PHH3; PIN 4; Polyomavirus(SV40); PR; Prolactin; PTH; S100; SMA; Sox 10; Sox 11; Spirochete; Synaptophysin; TCRbf1; TCR delta; TDT; Thyroglobulin; TIA-1; TSH; TTF-1; Uroplakin II; 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
  - Cold ischemia time and fixation time if available
- c. Shipping Information (address all specimens to):
- Department of Pathology – Client Services 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 the slides in the 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, 88300, 88304, 88305, 88307, 88321, or 88323) could be added as case is worked on
2. **Synonym(s):** N/A
3. **Performed:** In-House: Yes
4. **Methodology:** Enzyme Histochemistry
5. **Panel/Profile Components:**

1. H&E –Snap Frozen
2. H&E –Snap Frozen
3. Gomori Trichrome – Snap Frozen
4. NADH
5. Esterase
6. ATPase 4.3
7. ATPase 4.6
8. ATPase 10.4
9. PAS w/o Digestion- Snap Frozen
10. PAS w/Digestion Snap Frozen
11. Alkaline Phosphatase
12. Oil Red O- Snap Frozen
13. Myophosphorylase
14. MHC-1
15. MAC

Add on testing available:

COX

SDH

COX/SDH Combined

Dysferlin 1

Dysferlin 2

Dystrophin 1

Dystrophin 2

Dystrophin 3

SARC Alpha

SARC Beta

SARC Delta

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 Client Services 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 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. \*For EM sample (One source: Poly Sciences, Inc. #216, 8% aqueous in sealed ampoules)
- c. 10% Neutral Buffered Formalin \* for paraffin sample (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 a saline dampened gauze in a labeled (patient name and surgical #) container placed in a cooler with crushed ice. Do not submerge specimen in saline. This specimen needs to be received within 1 hour of the surgery by the UTHSCS/STRL Histology Lab.**

FIXATIVES:

- a. 10% Neutral Buffered Formalin (for paraffin portion of specimen)
- b. Glutaraldehyde Fixative (EM Testing)
- c. Flash Frozen for Enzyme testing / no fixation

**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 for EM and routine paraffin sectioning:

- a. Two labeled vials, with openings big enough for clamps, one containing enough EM glutaraldehyde fixative to cover specimen and one vial containing enough 10% neutral buffered formalin fixative 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 or 16mm-Adult) 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 the specimen will rapidly decline.
- d. **At no point should the portion of the muscle for enzyme testing be placed in fixative.**
- e. Liquid nitrogen, isopentane, dry ice and shipping containers 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 muscle cord 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 elongated in the clamp. As noted below, a piece for freezing may be taken from the clamp before placing in 10% neutral buffered formalin.

**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.**

Place one clamped specimen in 10% neutral buffered formalin for paraffin processing. Leave the rest of the specimen 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 a damp gauze in a pre-chilled 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 designated from 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 by gently holding the extreme end only with tweezers without teeth. 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.

Place 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 (depth) 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°C and minus 150°C. If you have no thermometer which registers that low, cool isopentane until it 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 isopentane for about 10 seconds. Remove from the isopentane and immediately blot or drain off any excess isopentane and place the tissue in the precooled specimen tube on dry ice. **DO NOT ALLOW SPECIMEN TO THAW.** Close the tube securely and place it in a shipping container filled with dry ice.

## **8. SHIPPING**

Mail fixed specimens, in fixative, unfrozen to:

Department of Pathology – Client Services 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 UTHSCSA Client Services at (210) 567-6599.

SHIP BY EXPRESS MAIL OR OVERNIGHT PRIORITY MAIL.

Address To:

Department of Pathology – Client Services 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: BCR::ABL1 p210 Translocation by Real-Time PCR, Quantitative Report

1. **CPT:** 81206 (BCR/ABL1 (t(9;22))translocation analysis; major breakpoint, qualitative or quantitative), G0452 (Molecular pathology procedure; physician interpretation and report)

1. **Synonym(s):** BCR-ABL1/ABL1; Quantitative p210 BCR-ABL

2. **Performed:** Molecular Diagnostics Laboratory

3. **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).

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

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

6. **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

**7. 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.

**8. Turnaround Times:**

- a. Total testing time: **8 hours**
- b. Results to Client: **6 working days**
- c. STAT Requests: **24-48 hour turn-around time may be requested for an extra fee.**

**9. 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 the collection site 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.

**10. 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: BCR::ABL1 p190 Translocation by Real-Time PCR, Quantitative**

2. **CPT:** 81207 (BCR/ABL1 (t(9;22)) translocation analysis; minor breakpoint, qualitative or quantitative), G0452 (Molecular pathology procedure; physician interpretation and report)
3. **Synonym(s):** Quantitative p190 BCR-ABL, BCR/ABL1 t(9;22) translocation analysis; minor breakpoint, P190, ABL1 Translocation, AML
4. **Performed:** Molecular Diagnostics Laboratory
5. **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.
6. **Panel/Profile Components:** N/A
7. **Critical Values:** N/A
8. **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

**9. 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.

**10. Turnaround Times:**

- a. Total testing time: **8 hours**
- b. Results to Client: **6 working days**
- c. STAT Requests: **24-48 hour turn-around time may be requested for an extra fee.**

**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 the collection site 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:**

- 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: PML::RARA Translocation t(15;17) by Real-Time PCR Qualitative

- 1. CPT:** 81315 (PML::RARA (t(15;17)) genetic analysis), G0452 (Molecular pathology procedure; physician interpretation and report)
- 2. Synonym(s):** PML, RARA, PML::RARA, PML-RARA, Acute Promyelocytic Leukemia, APL
- 3. Performed:** Molecular Diagnostics Laboratory
- 4. Methodology:**

RNA is isolated, reverse transcribed and amplified by real-time PCR using specific primers targeting the *PML-RARa* and *ABL* genes. Qualitative results (positive or negative only) are obtained in a two-step RT-PCR approach on a QuantStudio 3 instrument. In a separate well, a segment of *ABL* gene is amplified from the same cDNA sample which serves as a control for monitoring RT-PCR Performance and efficiency.
- 5. Panel/Profile Components:** N/A
- 6. Critical Values:** N/A
- 7. Specimen Collection / Handling Requirements:**

### 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 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.
- 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

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

### Handling

- Specimens requiring RNA isolation required special handling to preserve the integrity of the RNA.
- PB and BM should be transported to the laboratory within 4 hours of collection
- 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**
- b. Results to Client: **6 working days**
- c. STAT Requests: **24-48 hour turn-around time may be requested for an extra fee**

**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 the collection site 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. Composes the report in the context of patient history and clinical information such as whether the patient has known APL, has been treated, bone marrow findings, and results of karyotype, FISH and prior molecular results.
- 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: JAK2 p.V617F Variant Analysis by Real-Time PCR Quantitative

**12. CPT:** 81270 (JAK2 (Janus kinase 2) gene analysis, p.Val617Phe (V617F) variant, G0452 (Molecular pathology procedure; physician interpretation and report)

**1. Synonym(s):** JAK2 (Janus kinase 2) gene analysis, JAK2 (p.V617)

**2. Performed:** Molecular Diagnostics Laboratory

**3. 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.

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

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

**6. 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.

#### 7. 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.

#### 8. Turnaround Times:

Total testing time: **8 hours**

Results to Client: **6 working days**

#### 9. 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 the collection site 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.

#### 10. 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: Immunoglobulin Heavy Chain (IGH) Clonality Detection by PCR and Capillary Electrophoresis

**13. CPT:** 81261 (IGH@ (Immunoglobulin heavy chain locus), gene rearrangement analysis to detect abnormal clonal population(s); amplified methodology), G0452 (Molecular pathology procedure; physician interpretation and report)

**1. Synonym(s):** IGH, Molecular, Immunoglobulin Heavy Chain (IGH) Clonality Detection

**2. Performed:** Molecular Diagnostics Laboratory

**3. 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.

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

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

**6. 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 mm<sup>3</sup> 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.

### 7. 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 mm<sup>3</sup> of tissue is required.
- d. FFPE tissue: 5 ten micron tissue sections

### 8. Turnaround Times:

Total testing time: **4 days/sample must be received by Thursday 5 pm to meet TAT**

Results to Client: **7 working days**

### 9. 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 the collection site 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.

#### 10. 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: Immunoglobulin Kappa (IGK) Clonality Detection by PCR and Capillary

### Electrophoresis

- 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), G0452 (Molecular pathology procedure; physician interpretation and report)
- 2. Synonym(s):** Molecular, Immunoglobulin Kappa (IGK) Clonality Detection, IGK
- 3. Performed:** Molecular Diagnostics Laboratory
- 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

- 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.
- 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

- Peripheral blood (PB): 2-5mL, in purple top (sodium EDTA) tube; yellow top tube (ACD) acceptable.
- 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 mm<sup>3</sup> 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 mm<sup>3</sup> of tissue is required.
- d. FFPE tissue: 5 ten micron tissue sections

### 9. Turnaround Times:

- a. Total testing time: **4 days/sample must be received by Thursday 5pm 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 the collection site 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: T-cell Receptor Beta (TCB) Clonality Detection by PCR and Capillary Electrophoresis

- CPT:** 81340: TRB@ (T cell antigen receptor, beta) gene rearrangement analysis to detect abnormal clonal population(s); using amplification methodology, G0452 (Molecular pathology procedure; physician interpretation and report)
- Synonym(s):** TCR Beta Gene Clonality Detection, T-Cell Receptor (TCR) Beta Gene Rearrangement, PCR, TCRB, Molecular, T-Cell Receptor Beta (TRB) Clonality Detection
- Performed:** Molecular Diagnostics Laboratory
- Methodology:**  
DNA is isolated and amplified by PCR using BIOMED-2 primers targeting V $\beta$ , D $\beta$  and J $\beta$  sequences. The gene rearrangements are detected by analyzing the PCR products by capillary gel electrophoresis.
- Panel/Profile Components:** N/A
- Critical Values:** N/A
- Specimen Collection / Handling Requirements:**

### 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 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.
- 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

- Peripheral blood (PB): 2-5mL, in purple top (sodium EDTA) tube; yellow top tube (ACD) acceptable.
- Bone marrow (BM): 1-3mL, drawn into a syringe containing anticoagulant and then delivered in a purple top tube.
- Fresh or frozen tissue: fresh tissue should be obtained in a sterile manner, and a minimum of 3 mm<sup>3</sup> 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 mm<sup>3</sup> of tissue is required.
- d. FFPE tissue: 5 ten micron tissue sections

**9. Turnaround Times:**

- a. Total testing time: 4 days/sample must be received by Thursday 5pm 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 the collection site 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 Gamma (TRG) Clonality Detection by PCR and Capillary Electrophoresis

- CPT:** 81342: TRG@ (T cell antigen receptor, gamma) gene rearrangement analysis, evaluation to detect abnormal clonal population(s), G0452 (Molecular pathology procedure; physician interpretation and report)
- Synonym(s):** TCRG, Molecular, T-Cell Receptor Gamma (TRG) Clonality Detection
- Performed:** Molecular Diagnostics Laboratory
- Methodology:**

DNA is isolated and amplified by PCR using BIOMED-2 primers targeting the V $\gamma$ 1-8, V $\gamma$ 9, V $\gamma$ 10, V $\gamma$ 11 and J $\gamma$ 1.1/2.1, J $\gamma$ 1.3/2.3 sequences. The gene rearrangements are detected by analyzing the PCR products by capillary gel electrophoresis.
- Panel/Profile Components:** N/A
- Critical Values:** N/A
- Specimen Collection / Handling Requirements:**

### 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 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.
- 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

- Peripheral blood (PB): 2-5mL, in purple top (sodium EDTA) tube; yellow top tube (ACD) acceptable.
- Bone marrow (BM): 1-3mL, drawn into a syringe containing anticoagulant and then delivered in a purple top tube.
- Fresh or frozen tissue: fresh tissue should be obtained in a sterile manner, and a minimum of 3 mm<sup>3</sup> 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 mm<sup>3</sup> of tissue is required.
- d. FFPE tissue: 5 ten-micron tissue sections

**9. Turnaround Times:**

Total testing time: **4 days/sample must be received by Thursday 5pm 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 the collection site 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: F5 Leiden (p.R506Q) Variant Analysis by Real-Time PCR**

- 1. CPT:** 81241 F5 (coagulation Factor V) gene analysis, Leiden variant, G0452 (Molecular pathology procedure; physician interpretation and report)
- 2. Synonym(s):** F5, Factor V, R506Q Hypercoagulability, Coagulation Factor V, Molecular, Factor V Leiden Variant
- 3. Performed:** Molecular Diagnostics Laboratory
- 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 variant not detected, 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**

- 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.
- 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**

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

**Handling**

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

**Unacceptable Conditions**

- Serum or plasma; frozen PB; 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**

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 the collection site 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, F2) c.\*97G>A or 20210G>A Variant Analysis**

- 1. CPT:** 81240: F2 (prothrombin, coagulation factor II) gene analysis, 20210 G>A variant, G0452 (Molecular pathology procedure; physician interpretation and report)
- 2. Synonym(s):** Prothrombin, F2, Factor II, G20210A, C.\*97G.A
- 3. Performed:** Molecular Diagnostics Laboratory
- 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 variant not detected, 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**

- 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.
- 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**

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

**Handling**

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

**Unacceptable Conditions**

- Serum or plasma; frozen PB; 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**

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 the collection site 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: Hemochromatosis (HFE) 2 Variants Analysis by Real-Time PCR**

- 1. CPT:** 81256: HFE (hemochromatosis) gene analysis, common variants (e.g., C282Y, H63D), G0452 (Molecular pathology procedure; physician interpretation and report)
- 2. Synonym(s):** HFE Gene Analysis; Hereditary Hemochromatosis (C282Y and H63D mutation), Hereditary Hemochromatosis DNA Mutation Analysis, Molecular, Hemochromatosis Variants
- 3. Performed:** Molecular Diagnostics Laboratory
- 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 variants not detected, 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**

- 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.
- 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**

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

**Handling**

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

**Unacceptable Conditions**

- Serum or plasma; frozen PB; 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**

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: Chlamydia trachomatis by Transcription Mediated Amplification (TMA)**

1. **CPT Code(s):** 87491 *Chlamydia trachomatis* DNA, AMP Probe
2. **Synonym(s):** Chlamydia, CT
3. **Performed:** Molecular Diagnostics Laboratory
4. **Clinical Indication and Relevance:** The assay is useful to detect *Chlamydia trachomatis* from vaginal, penile meatal, rectal, throat (pharyngeal), 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:** Positive results for either *Chlamydia trachomatis* in a patient **under the age of 13**
8. **Sample Type:**
  - a. Aptima Multitest Swab Specimen Collection kit for vaginal, penile meatal, rectal, throat (pharyngeal) swabs.
  - b. 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. 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.
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.

- c. **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: *Neisseria gonorrhoeae* by Transcription Mediated Amplification (TMA)**

1. **CPT Code(s):** CPT 87591 *Neisseria gonorrhoeae* DNA, AMP Probe
1. **Synonym(s):** *Neisseria gonorrhoeae*, NG
2. **Performed:** Molecular Diagnostics Laboratory
3. **Clinical Indication and Relevance:** The assay is useful to detect *Neisseria gonorrhoeae* from vaginal, penile meatal, rectal, throat (pharyngeal), and urine samples.
4. **Methodology:** The assay uses transcription mediated amplification (TMA) on the Hologic Panther system.
5. **Panel/Profile Components:** N/A
6. **Critical Values:** Positive results for *Neisseria gonorrhoeae* in a patient **under the age of 13**
7. **Sample Type:**
  - a. Aptima Multitest Swab Specimen Collection Kit for vaginal, penile meatal, rectal, throat (pharyngeal) swabs
  - b. Aptima Urine Specimen Collection Kit for male and female urine
8. **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.
9. **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.

**10. Turnaround time:** 1-3 business days.

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

**12. Quality:** QA/Utilization Report

## Test: **Chlamydia trachomatis and Neisseria gonorrhoeae by Transcription Mediated Amplification (TMA)**

- 1. CPT Code(s):** 87491 *Chlamydia trachomatis* DNA, AMP Probe, CPT 87591 *Neisseria gonorrhoeae* DNA, AMP Probe
- 2. Synonym(s):** CT,GC, CT/GC, Neisseria GO
- 3. Performed:** Molecular Diagnostics Laboratory
- 4. Clinical Indication and Relevance:** The assay is useful to detect *Chlamydia trachomatis* from vaginal, penile meatal, rectal, throat (pharyngeal), and urine samples.
- 5. Methodology:** The assay uses transcription mediated amplification (TMA) on the Hologic Panther System.
- 6. Panel/Profile Components:** *Chlamydia trachomatis* by TMA and *Neisseria gonorrhoeae* by TMA
- 7. Critical Values:** Positive results for either *Chlamydia trachomatis* or *Neisseria gonorrhoeae* in a patient under the age of 13
- 8. Sample Type:**
  - Aptima Multitest Swab Specimen Collection kit for vaginal, penile meatal, rectal, throat (pharyngeal) swabs.
  - Aptima Urine Specimen Collection Kit for male and female urine.
- 9. 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.
  - 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:**
  - 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, 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: Human papillomavirus (HPV) by Transcription Mediated Amplification (TMA)**

1. **CPT Code(s):** 87624 Human Papillomavirus High-Risk Types
2. **Synonym(s):** HPV, high-risk HPV
3. **Performed:** Molecular Diagnostics Laboratory
4. **Clinical Indication and Relevance:** The assay is useful to detect 14 high-risk types of Human papillomavirus from cervical specimens collected in ThinPrep Pap Test vials and transferred into the Aptima Specimen transfer tube.
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 Specimen Transport Tube
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:** Aptima Transport tubes: After collection, transport and store the transport tube at 2-30°C up to 60 days after collection.

- c. Unacceptable Samples: Improperly labeled or incorrect patient identification, specimen leaked, or incorrect media. ThinPrep liquid cytology specimens containing less than 1 mL after ThinPrep Pap Test slide preparation are considered inadequate for the Aptima HPV assay.

**11. Turnaround time:** 1-3 Business Days.

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

**13. Quality:** QA/Utilization Report

**Test: *Mycoplasma genitalium*, (TMA)**

1. **CPT Code(s):** 87563 *Mycoplasma genitalium* amplified probe
2. **Synonym(s):** M. gen, MG
3. **Performed:** Molecular Diagnostics Laboratory
4. **Clinical Indication and Relevance:** The assay is useful to aid in the diagnosis of *M. genitalium* urogenital infections in male and female patients. This assay can be used to test the following specimens: clinician and self-collected vaginal swabs (in a clinical setting), clinician-collected endocervical swabs, female and male urine, clinician-collected male urethral swabs, and self-collected penile meatal swabs (in a clinical setting).
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 and penile meatal swabs
  - b. Aptima Urine Specimen Collection Kit for male and female urine specimens
9. **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.
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.
- 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. 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.

**11. Turnaround time:** 1-3 Business Days.

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

**13. Quality:** QA/Utilization Report

**Test: Vaginitis/Vaginosis (TMA)**

1. **CPT Code(s):** 87481 Candida, DNA PCR (x2), 81513 DS Bacterial Vaginosis RNA, 87661 Trichomonas Vaginalis Amplified Probe
2. **Synonym(s):** Sureswab Advanced Vaginitis, TMA, VAG
3. **Performed:** Molecular Diagnostics Laboratory
4. **Clinical Indication and Relevance:**
  - a. Bacterial vaginosis (BV): The assay is useful to detect bacteria that have been associated with bacterial vaginosis (BV), including *Lactobacillus* (*L. gasseri*, *L. crispatus*, and *L. jensenii*) from clinician or patient-collected vaginal swab specimens in an Aptima Multitest Transport Swab.
  - b. *Candida* Vaginitis (CV)/ *Trichomonas vaginalis* (TV): The assay is useful to detect microorganisms that have been associated with vulvovaginal candidiasis (candida vaginitis CV) and trichomoniasis (*Trichomonas vaginalis*, TV), including *Candida* species group (*C. albicans*, *C. tropicalis*, *C. parapsilosis*, *C. dubliniensis*), *Candida glabrata*, *Trichomonas vaginalis* from clinician or patient-collected vaginal swab specimens in an Aptima Multitest Transport Swab.
5. **Methodology:** The assay uses transcription mediated amplification (TMA) on the Hologic Panther System.
6. **Panel/Profile Components:** Bacterial Vaginosis (BV), *Candida* Vaginitis (CV)/ *Trichomonas vaginalis* (TV)
7. **Critical Values:** N/A
8. **Sample Type:**
  - a. Aptima Multitest Swab Collection Kit
9. **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.
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: Aptima Multitest Swab Collection Kit: After collection, transport and store the transport tube at 2-30°C up to 60 days after 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.

**11. Turnaround time:** 1-3 Business Days.

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

**13. Quality:** QA/Utilization Report

**Test: Vaginitis and Vaginosis Plus Chlamydia and Gonorrhoeae, (TMA)**

1. **CPT Code(s):** 87481 Candida, DNA PCR (x2), 81513 DS Bacterial Vaginosis RNA, 87661 Trichomonas Vaginalis Amplified Probe, 87491 Chlamydia DNA PCR, 87591 GC DNA PCR
2. **Synonym(s):** CT-GC-VAG
3. **Performed:** Molecular Diagnostics Laboratory
4. **Clinical Indication and Relevance:**
  - a. Bacterial vaginosis (BV): The assay is useful to detect bacteria that have been associated with bacterial vaginosis (BV), including *Lactobacillus* (*L. gasseri*, *L. crispatus*, and *L. jensenii*) from clinician or patient-collected vaginal swab specimens in an Aptima Multitest Transport Swab.
  - b. *Candida* Vaginitis (CV)/ *Trichomonas vaginalis* (TV): The assay is useful to detect microorganisms that have been associated with vulvovaginal candidiasis (candida vaginitis CV) and trichomoniasis (*Trichomonas vaginalis*, TV), including *Candida* species group (*C. albicans*, *C. tropicalis*, *C. parapsilosis*, *C. dubliniensis*), *Candida glabrata*, *Trichomonas vaginalis* from clinician or patient-collected vaginal swab specimens in an Aptima Multitest Transport Swab.
  - c. The assay is useful to detect *Chlamydia trachomatis* from vaginal, penile meatal, rectal, throat (pharyngeal), endocervical, male urethral and urine samples.
  - d. 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. **Panel/Profile Components:** Bacterial Vaginosis (BV), *Candida* Vaginitis (CV)/ *Trichomonas vaginalis* (TV), *Chlamydia trachomatis* (CT)/ *Neisseria gonorrhoeae* (GC).
7. **Critical Values:** Positive results for either *Chlamydia trachomatis* or *Neisseria gonorrhoeae* in a patient under the age of 13
8. **Sample Type:**
  - a. Aptima Multitest Swab Collection Kit
9. **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.

**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: Aptima Multitest Swab Collection Kit: After collection, transport and store the transport tube at 2-30°C up to 60 days after 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.

**11. Turnaround time:** 1-3 Business Days.

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

**13. Quality:** QA/Utilization Report

**Test: Vaginitis and Vaginosis Plus Chlamydia and Gonorrhoeae with M Gen, (TMA)**

1. **CPT Code(s):** 87481 Candida, DNA PCR (x2), 81513 DS Bacterial Vaginosis RNA, 87661 Trichomonas Vaginalis Amplified Probe, 87491 Chlamydia DNA PCR, 87591 GC DNA PCR, 87563 Mycoplasma genitalium amplified probe
2. **Synonym(s):** CT-GC-MG-VAG
3. **Performed:** Molecular Diagnostics Laboratory
4. **Clinical Indication and Relevance:**
  - a. Bacterial vaginosis (BV): The assay is useful to detect bacteria that have been associated with bacterial vaginosis (BV), including *Lactobacillus* (*L. gasseri*, *L. crispatus*, and *L. jensenii*) from clinician or patient-collected vaginal swab specimens in an Aptima Multitest Transport Swab.
  - b. *Candida* Vaginitis (CV)/ *Trichomonas vaginalis* (TV): The assay is useful to detect microorganisms that have been associated with vulvovaginal candidiasis (candida vaginitis CV) and trichomoniasis (*Trichomonas vaginalis*, TV), including *Candida* species group (*C. albicans*, *C. tropicalis*, *C. parapsilosis*, *C. dubliniensis*), *Candida glabrata*, *Trichomonas vaginalis* from clinician or patient-collected vaginal swab specimens in an Aptima Multitest Transport Swab.
  - c. The assay is useful to detect *Chlamydia trachomatis* from vaginal, penile meatal, rectal, throat (pharyngeal), endocervical, male urethral and urine samples.
  - d. The assay is useful to detect *Neisseria gonorrhoeae* from vaginal, penile meatal, rectal, throat (pharyngeal), endocervical, male urethral, and urine samples.
  - e. The assay is useful to aid in the diagnosis of *M. genitalium* urogenital infections in male and female patients. This assay can be used to test the following specimens: clinician and self-collected vaginal swabs (in a clinical setting), clinician-collected endocervical swabs, female and male urine, clinician-collected male urethral swabs, and self-collected penile meatal swabs (in a clinical setting).
5. **Methodology:** The assay uses transcription mediated amplification (TMA) on the Hologic Panther System.
6. **Panel/Profile Components:** Bacterial Vaginosis (BV), *Candida* Vaginitis (CV)/ *Trichomonas vaginalis* (TV), *Chlamydia trachomatis* (CT)/ *Neisseria gonorrhoeae* (GC), *Mycoplasma genitalium* (M gen)
7. **Critical Values:** Positive results for either *Chlamydia trachomatis* or *Neisseria gonorrhoeae* in a patient under the age of 13

**8. Sample Type:**

- a. Aptima Multitest Swab Collection Kit

**9. 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.

**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: Aptima Multitest Swab Collection Kit: After collection, transport and store the transport tube at 2-30°C up to 60 days after 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.

**11. Turnaround time:** 1-3 Business Days.

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

**13. Quality:** QA/Utilization Report

## Test: UT Health Oncopanel NGS

- CPT Code(s):** 81455, G0452
- Synonym(s):** Solid tumor, NGS, next generation sequencing, fusion, translocation, RNA, single nucleotide variant, SNV, hotspot
- Performed:** Molecular Diagnostics Laboratory
- 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.
- 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:

- Formalin Fixed Paraffin Embedded (FFPE) tissue; should not be more than 5 years old. Tumor percentage should be 40% in one area.
- Tissue blocks, including core needle biopsies. The Histology lab will cut 10 unstained slides at 5-10 microns and 1 H&E.
- Unstained FFPE tissue slides (10 slides at 5-10 microns thickness). And 1 H&E.
- 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 -80 °C. 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 macro dissected. They require a pathologist's 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:** 7 to 15 working days.

**9. [View Requisition Sheet](#)**

**Test: UT Health San Antonio Heme Oncor DNA Panel by NGS**

- 1. CPT Code(s):** 81455, G0452
- 2. Synonym(s):** NGS, Next generation sequencing, Heme Panel, Myeloid, Lymphoid, Hematologic neoplasms, Oncor, Heme, Sequencing, Leukemia, Lymphoma, DNA, Molecular, Panel, AML, MDS, MPN, ALL, myelodysplastic syndrome, myeloproliferative disorders, clonal hematopoiesis of indeterminate potential, clonal cytopenia of undetermined significance
- 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 single nucleotide variants (SNVs) and small indels from the coding regions of 129 genes, FLT3 ITDs and presence of EBV & HHV8 viruses in hematologic samples.
- 5. Methodology:** The UT Health San Antonio Heme Oncor DNA Panel by NGS is a targeted sequencing assay, created to detect genomic alterations found in hematological malignancies including myelodysplastic syndrome, myeloproliferative disorders, leukemia, lymphoma, clonal hematopoiesis of indeterminate potential (VAF limit of 2.5%) and other hematologic neoplasms, as clinically indicated. The UTHSA Heme Panel NGS assay is custom designed to detect single nucleotide variants (SNVs) and small indels of <91bp from the coding regions of 129 genes (see Table 1 for gene list), FLT3 ITDs and EBV and HHV8 presence in hematologic samples. This test allows capture-based enrichment of a custom set of genes from whole genome using IDT xGen Lockdown hybridization probes. High quality libraries are generated using UMIs for sequencing on the Illumina next-generation sequencing (NGS) platform, MiSeq. After sequencing, the data is UMI extracted, FASTQ demultiplexed and then processed using the ICA DRAGEN Somatic Enrichment pipeline. An in-house secondary pipeline analyzes the FLT3 ITDs, oncogenic virus presence, region of interest coverage and other metrics. Variant and quality files are passed to GenomOncology (GO) variant reporting system for variant interpretation and reporting. 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). Tier I and Tier II will be reported clinically with information on variant significance, targeted therapy and available clinical trials after being assessed using public databases (such as OncoKB, dbSNP, GNOMAD, Genie, PubMed and others). Tier III alteration will be reported separately in a list format and Tier IV alterations will not be reported clinically.

**TABLE 1: Genes with coding region targeted by test**

ABL1	BIRC3	CEBPA	ETV6	IDH2	KMT2A	NOTCH1	PPM1D	SF3A1	TCF3
ANKRD26	BRAF	CHEK2	EZH2	IKZF1	KMT2D	NOTCH2	PRPF8	SF3B1	TERT
ARAF	BRCA1	CREBBP	FBXW7	IKZF3	KRAS	NPM1	PTEN	SH2B3	TET2
ARID1A	BRCA2	CSF3R	FLT3	IL7R	LUC7L2	NRAS	PTPN11	SMARCA4	TNFAIP3
ASXL1	BTK	CUX1	GATA1	IRF4	MAP2K1	NTRK1	RAD21	SMARCB1	TNFRSF14
ASXL2	CALR	CXCR4	GATA2	IRF8	MAPK1	PAX5	RB1	SMC1A	TP53
ATM	CARD11	DDX3X	GATA3	JAK1	MEF2B	PDGFRA	RHOA	SMC3	U2AF1
ATRX	CBL	DDX41	GNA13	JAK2	MIR142	PHF6	RUNX1	SOCS1	U2AF2
B2M	CBLB	DNMT1	GNAS	JAK3	MPL	PIGA	SAMD9	SRSF2	UBA1
BCL2	CD79A	DNMT3A	HNRNPCK	KDM6A	MYC	PIK3CA	SAMD9L	STAG2	WT1
BCL6	CD79B	ELANE	HRAS	KIT	MYD88	PLCG1	SETBP1	STAT3	XPO1
BCOR	CDKN2A	EP300	ID3	KLF2	NF1	PLCG2	SETD2	STAT5B	ZRSR2
BCORL1	CDKN2B	ETNK1	IDH1	KLHL6	NFKBIE	POT1	SF1	SUZ12	

## 6. Minimum Specimen Requirements:

### Preferred:

- a. Peripheral blood (PB): 3-5mL EDTA tube (lavender top), ACD (yellow top) also acceptable, store and transport at 2-8°C (wet ice or cold packs), collected within 72 hours (if exceeds, call Lab Manager as samples >7 days old were tested in validation)
- b. Bone marrow (BM): 3-5 EDTA tube (minimum 1 mL), ACD (yellow top) also acceptable, store and transport at 2-8°C (wet ice or cold packs), collected within 72 hours (if exceeds, call Lab Manager as samples >7 days old were tested in validation)
- c. Fresh or frozen tissue: At least 0.3x0.3 cm tissue. Flash frozen tissue stored at -80 °C or fresh tissue in RPMI collected within 72 hours. Store and transport fresh tissue at 2-8°C (wet ice or cold packs).
- d. Select tissue from hematopathologic neoplasm/suspected neoplasm, ideally with more than 500 neoplastic cells. A H&E slide is also requested:

- e. Formalin Fixed Paraffin Embedded (FFPE) tissue blocks, including core needle biopsies. The Histology lab will cut 10 unstained slides at 5-10 microns and 1 H&E.
- f. Unstained FFPE tissue slides (10 slides at 5-10 microns size) and 1 H&E. o Fine needle aspirate (FNA) processed as FFPE cell blocks (cytospin). The Histology lab will cut 10 unstained slides at 5-10 microns and 1 H&E.

**7. Transport:**

- a. FFPE should be transported to the laboratory at controlled temperatures. Sample temperature should not exceed 30°C.
- b. Peripheral blood or bone marrow or fresh tissue should be delivered immediately at 2-8°C (wet ice or cold packs). Do not freeze.

**8. Unacceptable Samples:**

- a. FFPE samples fixed in Zenker's B5 or Bouin's fixatives.
- b. FFPE samples decalcified with strong acids.
- c. PB and BM samples less than 2 mL require pathologist approval
- d. Serum or plasma, frozen peripheral blood or bone marrow, clotted blood, severely hemolyzed samples.
- e. FFPE tissue scrolls are not desired, as they cannot be macro dissected. They require a pathologist's approval. Unstained tissue slides should be accompanied by an H&E slide.

**9. Turnaround time:** 7 to 15 working days.

**10. [View Requisition Sheet](#)**