

BayCare Laboratories Testing Services

Reference Guide

Table of Contents

Flow Cytometry2

Leukemia/Lymphoma Immunophenotyping.....	2
Lymphocyte Enumeration.....	2
DNA Ploidy and S-Phase Cell Cycle Analysis	2
CD4/CD8 Abbreviated Panel	2
Transfusion-Related Cell Count.....	2
Flow Cytometric Immunophenotyping for Leukemia or Lymphoma	3
Lymphocyte Subset Enumeration.....	3
DNA Ploidy	3

Cytogenetics.....3

Chromosome Oncology Analysis.....	4
Constitutional Chromosome Analysis.....	4
Chromosome POC Analysis.....	4

FISH.....5

ALK by FISH	5
AML Panel by FISH	5
Angelman Syndrome by FISH.....	6
BCR/ABL1 by FISH	6
CCND1/IGH t(11;14) by FISH	6
CLL Panel by FISH.....	6
DiGeorge Syndrome by FISH.....	7
HER2 by FISH.....	7
IGH/BCL2 t(14;18) by FISH.....	7
MDS Panel by FISH.....	7
MLL by FISH.....	8
MYC Breakapart by FISH.....	8
Myeloma Panel by FISH	8
MYC/IGH t(8;14) by FISH.....	8
PML/RARA t(15;17) by FISH	9
Prader-Willi Syndrome by FISH.....	9
ROS1 by FISH	9
UroVysion by FISH	10

Molecular..... 10

Molecular Oncology.....	10
Molecular Genetics.....	10
Molecular Infectious Disease Testing.....	10
B-cell Gene Rearrangement.....	11
BCR/ABL by PCR.....	11
Jak2 exon 12 mutation	11
MPL mutation	11
Bordetella Pertussis/Parapertussis	12
Legionella	12
Atypical pneumonia	12
BRAF V600E Mutation.....	12
Cystic Fibrosis for Carrier	13
Chlamydia Trachomatis/Neisseria Gonorrhoea.....	13
Cytomegalovirus (CMV) Qualitative.....	13
Cytomegalovirus (CMV) Quantitative	13
EGFR Mutation.....	14
Factor II (Prothrombin) Mutation.....	14
Factor V Leiden Mutation	14
Herpes Virus 1/2.....	14
Hepatitis B Virus (HBV).....	15
Hepatitis C Genotype.....	15
Hepatitis C Virus (HCV) Qualitative.....	15
Hepatitis C Virus (HCV) Viral Load.....	15
BK virus Quantitative	16
Epstein-Barr Virus (EBV) Quantitative	16
Human Immunodeficiency Virus (HIV) Viral Load.....	16
Human Papilloma Virus (HPV) High Risk.....	16
Jak2 V617F Mutation	17
KRAS Mutation.....	17
Microsatellite Instability (MSI).....	17
MTHFR Mutation	17
Respiratory Viral Panel.....	18
T-cell Gene Rearrangement	18

For more information: (800) 324-7853



Flow Cytometry

Leukemia/Lymphoma Immunophenotyping

Immunophenotyping can help diagnose and classify blood cell cancers (leukemias and lymphomas). It may be ordered as a follow-up test when a white cell count differential shows an increased number of lymphocytes, the presence of immature white cells, an idiopathic change in the red cell indices or when there is a significant increase or decrease in the number of platelets (thrombocytosis or thrombocytopenia). Testing is most often performed on blood and/or bone marrow samples, but may also be done on body fluids or other biopsy tissue samples.

Immunophenotyping by Flow Cytometry is useful to:

- Evaluate lymphocytoses of unknown etiology
- Identify B- and T-cell lymphoproliferative disorders
- Distinguish acute lymphoblastic leukemia (ALL) from acute myeloid leukemia (AML)
- Subtype ALL
- Distinguish reactive lymphocytes from malignant lymphoma
- Distinguish between malignant lymphoma and acute leukemia
- Phenotype subclassification of B- and T-cell chronic lymphoproliferative disorders
- Recognize AML with minimal morphologic evidence of differentiation

CD4/CD8 Abbreviated Panel

Test name: Abbreviated blood lymphocyte subset enumeration

Order name: CD4/CD8 ABBREVIATED PANEL

Specimen requirements: EDTA peripheral blood

Minimum volume: 0.5 ml

Storage and stability information: Room temperature, 48–72 hours

Test performed: Daily

Methodology: Flow Cytometry

Reference range: See laboratory report

Clinical significance: T-lymphocyte count assists in evaluating cellular immunocompetency.

CPT codes: 86356, 86359, 86360

Lymphocyte Enumeration

The BayCare lymphocyte enumeration panel contains:

- CD3 for the identification of T lymphocytes
- CD19 for the identification of B lymphocytes
- CD16 for the identification of NK lymphocytes
- CD4 for the identification of T helper lymphocytes
- CD56 for the identification of NK lymphocytes
- CD8 for the identification of T suppressor lymphocytes
- An abbreviated CD4/CD8 panel is also available.

DNA Ploidy and S-Phase Cell Cycle Analysis

DNA ploidy and cell cycle analysis is a rapid and efficient way to evaluate the DNA content (ploidy) and proliferative activity (cell cycle/S-phase fraction) of cells. By staining the DNA with a fluorescent dye, flow cytometry can measure the dye fluorescence in many individual cells, and the data can be analyzed for ploidy (diploid/normal content or aneuploid/abnormal content) and proliferative activity.

For more information: (800) 324-7853

Transfusion-Related Cell Count

Test name: Transfusion Related Cell Count

Specimen requirements: RBCs and platelet transfusion products within 48 hours following leuco-reduction

Minimum volume: 400uL

Storage and stability information: Room temperature, 48 hours

Test performed: Daily

Methodology: Flow Cytometry

Reference range: $<5.0 \times 10^6$ cells/ μ L

Clinical significance: This test is performed as a service for blood banks to count and enumerate residual white blood cells (rWBCs) in leuco-reduced blood products.

CPT codes: N/A

Flow Cytometric Immunophenotyping for Leukemia or Lymphoma

Test name: Flow Cytometric Immunophenotyping for Leukemia or Lymphoma

Order name: FLOW LEUK/LYMPH

Specimen requirements: Sodium heparin peripheral blood or bone marrow, fresh tissue in RPMI, Body Fluid, CSF

Minimum volume: 2mL peripheral blood or bone marrow, 5mL preferred. Minimum of 100mg fresh tissue submitted in RPMI. Two 50mL conicals of body fluid, minimum dependent upon cellularity. 5mL CSF submitted in original collection container, minimum dependent upon cellularity.

Storage and stability information: Blood and bone marrow, room temperature, 48–72 hours; fresh tissue, refrigerate, 48–72 hours; body fluid, refrigerate, 48–72 hours; CSF, refrigerate, 48–72 hours

Test performed: Daily

Methodology: Flow Cytometry

Reference range: See laboratory report

Clinical significance: This test is primarily ordered by hematopathologists to help confirm a diagnosis of hematologic malignancy or to classify the tumor.

CPT codes: 88184 for the first marker, 88185 each additional marker, 881867 for 2–8 markers, 88188 for 9–15 markers, 88189 for 16 or more markers

Lymphocyte Subset Enumeration

Test name: Blood lymphocyte Subset Enumeration (T,B and NK cell surface markers)

Order name: T CELL SUBSET

Specimen requirements: EDTA peripheral blood

Minimum volume: 0.5mL

Storage and stability information: Room temperature, 48–72 hours

Test performed: Daily

Methodology: Flow Cytometry

Reference range: See laboratory report

Clinical significance: Lymphocyte enumeration can be used to determine immune status of patients with HIV infection, monitor anti-retroviral and immunosuppressive therapy and is useful for differential diagnosis of congenital and acquired immune deficiencies.

CPT codes: 86355, 86356, 86357, 86359, 86360

DNA Ploidy

Test name: DNA Ploidy and S-phase analysis

Order name: DNA PLOIDY

Specimen requirements: Formalin fixed paraffin-embedded block with representative H&E slide with tumor clearly marked. Please provide pathology report with specimen. Please provide a normal control tissue block to be run in parallel.

Minimum volume: N/A

Storage and stability information: Room temperature

Test performed: Daily

Methodology: Flow cytometry

Reference range: See laboratory report

Clinical significance: The analyses of DNA ploidy and cell cycle are a rapid and efficient way to evaluate the DNA content (ploidy) and proliferative activity (cell cycle/S-phase fraction) of cells. By staining the DNA with a fluorescent dye, flow cytometry can measure the dye fluorescence in many individual cells, and the data can be analyzed for ploidy (diploid/normal content or aneuploid/abnormal content) and proliferative activity.

CPT codes: 86355, 86356, 86357, 86359, 86360

Cytogenetics

The BayCare Cytogenetics Laboratory is a full-service laboratory offering high-quality chromosome and fluorescence in situ hybridization (FISH) analyses for oncology and clinical genetic conditions on peripheral blood specimens, bone marrow aspirates, skin biopsies, and products of conception. These technologies allow for the detection of aneuploidy, translocations, microdeletions, microduplications and other chromosomal rearrangements.

For more information: (800) 324-7853

FISH probes and Cytogenetic Testing Available	
Cytogenetics: <ul style="list-style-type: none"> Chromosome analysis for oncology Chromosome analysis for constitutional abnormalities Chromosome analysis for products of conception 	Genetic Conditions <ul style="list-style-type: none"> Angelman syndrome Prader-Willi syndrome DiGeorge syndrome/22q11.2 deletion syndrome
Myeloid Disorders <ul style="list-style-type: none"> MDS Panel (5q/5p, 7q/7p, 8, 20) BCR/ABL1 t(9;22) AML Panel (MLL, t(8;21), t(15;17), inv16) PML/RARA t(15;17) 	Lymphoid Disorders <ul style="list-style-type: none"> BCR/ABL1 t(9;22) MLL
Myeloma/MGUS <ul style="list-style-type: none"> Myeloma Panel (13q14, IGH, TP53, CEP 5/9/15, t(11;14))* 	CLL <ul style="list-style-type: none"> CLL Panel (ATM, 12, 13q, TP53)*
Lymphoma Panel <ul style="list-style-type: none"> CCND1/IGH t(11;14) IGH/BCL2 t(14;18) MYC/IGH t(8;14) MYC 8q24 	Solid Tumors (Breast, Gastric Cancer) <ul style="list-style-type: none"> Her2
Bladder Cancer <ul style="list-style-type: none"> UroVysion 	Lung Cancer <ul style="list-style-type: none"> ALK ROS1

*Available Spring 2012

Chromosome Oncology Analysis

Test name: Chromosome oncology analysis

Order name: Chromosome oncology request

Specimen requirements: Sodium heparin peripheral blood or bone marrow

Minimum volume: 0.5mL minimum, 3mL bone marrow preferred, 5mL blood preferred

Storage and stability information: Room temperature. Transport to lab within one day of collection.

Test performed: Turnaround time 7–10 days

Methodology: Microscopy, karyotype analysis

Reference range: See lab report

Clinical significance: In hematological malignant diseases, recurrent chromosomal abnormalities often correlate with particular types of leukemia and give information on diagnosis, staging of the disease, remission and relapse status and transplant status.

CPT codes: 88237 x 2, 88262

Constitutional Chromosome Analysis

Test name: Constitutional Chromosome Analysis

Order name: Chromosome constitutional request

Specimen requirements: Sodium heparin peripheral blood

Minimum volume: 1ml, 4mL preferred

Storage and stability information: Room temperature. Transport to lab within one day of collection.

Test performed: Turnaround time 7–10 days

Methodology: Microscopy, karyotype analysis

Reference range: See report

Clinical significance: Cytogenetic analysis of peripheral blood lymphocytes is performed to detect numerical or structural chromosome abnormalities. Indications include multiple congenital anomalies, mental retardation of unknown etiology, abnormalities of growth or sexual development and features of a recognized genetic syndrome. Chromosome analysis may also be warranted in individuals with infertility or recurrent pregnancy loss.

CPT codes: 88237 x 2, 88262

Chromosome POC Analysis

Test name: Chromosomes POC

Order name: CHR M POC

Specimen requirements: Tissue from spontaneous abortions (miscarriages), stillborns, or autopsy specimens

Minimum volume: 3–10 mm³ of tissue, collected aseptically, placed in tissue transport media. May use any type of sterile media in a sterile container.

Storage and stability information: Room temperature or refrigerate if overnight

Test performed: Turnaround time 14–21 days

Methodology: Microscopy, karyotype analysis

Reference range: See lab report

Clinical significance: Chromosome abnormalities are observed in ~60% of miscarriage specimens and 5 to 10% of stillborns. Analysis of these abnormalities can help determine the cause of the miscarriage and the probability of recurrence due to a chromosome abnormality.

CPT codes: 88233x2, 88262

FISH

The BayCare Cytogenetics Laboratory is a full service laboratory offering high quality chromosome and fluorescence in situ hybridization (FISH) analyses for oncology and clinical genetic conditions on peripheral blood specimens, bone marrow aspirates, skin biopsies, and products of conception. These technologies allow for the detection of aneuploidy, translocations, microdeletions, microduplications and other chromosomal rearrangements.

For more information: (800) 324-7853

FISH probes and Cytogenetic Testing Available	
Cytogenetics: <ul style="list-style-type: none"> Chromosome analysis for oncology Chromosome analysis for constitutional abnormalities Chromosome analysis for products of conception 	Genetic Conditions <ul style="list-style-type: none"> Angelman syndrome Prader-Willi syndrome DiGeorge syndrome/22q11.2 deletion syndrome
Myeloid Disorders <ul style="list-style-type: none"> MDS Panel (5q/5p, 7q/7p, 8, 20) BCR/ABL1 t(9;22) AML Panel (MLL, t(8;21), t(15;17), inv16) PML/RARA t(15;17) 	Lymphoid Disorders <ul style="list-style-type: none"> BCR/ABL1 t(9;22) MLL
Myeloma/MGUS <ul style="list-style-type: none"> Myeloma Panel (13q14, IGH, TP53, CEP 5/9/15, t(11;14)*) 	CLL <ul style="list-style-type: none"> CLL Panel (ATM, 12, 13q, TP53)*
Lymphoma Panel <ul style="list-style-type: none"> CCND1/IGH t(11;14) IGH/BCL2 t(14;18) MYC/IGH t(8;14) MYC 8q24 	Solid Tumors (Breast, Gastric Cancer) <ul style="list-style-type: none"> Her2
Bladder Cancer <ul style="list-style-type: none"> UroVysion 	Lung Cancer <ul style="list-style-type: none"> ALK ROS1

*Available Spring 2012

ALK by FISH

Test name: ALK by FISH

Order name: ALK by FISH request

Specimen requirements: Formalin fixed paraffin-embedded tissue (FFPE)

Minimum volume: FFPE – two unstained 4µm thick sections on positively charged slides plus one stained H&E slide of the same block

Storage and stability information: Room temperature

Test performed: Twice per week

Methodology: Fluorescence in situ hybridization

Reference range: See lab report

Clinical significance: Abnormalities of ALK are present in 2 to 7% of non-small-cell lung cancers. Patients with rearrangements of ALK are eligible for treatment with the ALK inhibitor, XALKORI® (crizotinib).

CPT codes: 88368 x 2

AML Panel by FISH

Test name: AML panel by FISH (inv16, t(15;17), t(8;21), MLL)

Order name: AML panel by FISH request

Specimen requirements: Sodium heparin peripheral blood or bone marrow

Minimum volume: 1mL

Storage and stability information: Room temperature three days

Test performed: Twice per week

Methodology: Fluorescence in situ hybridization

Reference range: See lab report

Clinical significance: The t(8;21) translocation is found in 7–8% of patients with cytogenetically abnormal acute myelogenous leukemia (AML) and in adults usually predicts good response to chemotherapy with a high remission rate and a relatively long median survival. Abnormalities of 11q23 are found in 2% of cytogenetically abnormal adult AML cases and 10% of pediatric AML cases and are generally associated with a poor prognosis. The t(15;17) translocation has been described in almost 100% of Acute Promyelocytic Leukemia (APL) cases. This subtype of AML is sensitive to all-trans retinoic acid (ATRA) has the highest complete remission rate, and the longest median survivals for patients with AML. Inversion of chromosome 16 is seen in 4% of cytogenetically abnormal AML cases and has a very high complete remission rate and long median survival.

CPT codes: 88368 x 8

Angelman Syndrome by FISH

Test name: FISH, Angelman syndrome

Order name: Angelman syndrome by FISH request

Specimen requirements: Sodium heparin peripheral blood

Minimum volume: 1mL. 4mL preferred

Storage and stability information: Room temperature three days

Test performed: Once per week

Methodology: Fluorescence in situ hybridization

Reference range: See lab report

Clinical significance: Seventy percent of patients with Angelman syndrome have an interstitial deletion of chromosome 15. Approximately 7% of patients with Angelman syndrome do not have the deletion, but instead have two copies of the 15q11.2q13 critical region that are inherited from the father. This form of inheritance is known as paternal uniparental disomy. Another 3% have evidence of normal biparental inheritance of chromosome 15, but have an imprinting mutation. DNA methylation studies can be performed to detect these abnormalities. Eleven percent of patients have a mutation in the UBE3A gene and are detected by sequence analysis. In the remaining patients, the genetic mutation has not been identified.

CPT codes: 88368 x 3

BCR/ABL1 by FISH

Test name: BCR/ABL1, t(9;22) by FISH

Order name: BCR/ABL1 by FISH request

Specimen requirements: Sodium heparin peripheral blood or bone marrow

Minimum volume: 1mL

Storage and stability information: Room temperature three days

Test performed: Twice per week

Methodology: Fluorescence in situ hybridization

Reference range: See lab report

Clinical significance: The abnormality, t(9;22)(q34;q11.2) has been identified in 90% of cases of chronic myeloid leukemia (CML). The remaining cases of CML have other variant translocations that create the BCR/ABL1 fusion and that can also be detected by this assay. The t(9;22)(q34;q11.2) translocation can also be detected in 20% of adult cases and 3% of pediatric cases of B acute lymphoblastic leukemia (B-ALL). The t(9;22)(q34;q11.2) translocation can also be present in mixed phenotype acute leukemia (MPAL), which accounts for <1% of acute leukemias.

CPT codes: 88368 x 2

CCND1/IGH t(11;14) by FISH

Test name: FISH, CCND1/IGH t(11;14)

Order name: t(11;14) by FISH request

Specimen requirements: Sodium heparin peripheral blood or bone marrow. Formalin fixed paraffin-embedded tissue (FFPE).

Minimum volume: 1mL blood or bone marrow. FFPE — two unstained 4µm thick sections on positively charged slides plus one stained H&E slide of the same block.

Storage and stability information: Room temperature three days for blood and bone marrow. FFPE at room temperature indefinitely.

Test performed: Twice per week

Methodology: Fluorescence in situ hybridization

Reference range: See lab report

Clinical significance: The t(11;14) translocation leads to juxtaposition of the Immunoglobulin Heavy Chain loci with the CCND1 (Cyclin D1) gene and is found in almost all cases of mantle cell lymphoma. The t(11;14) is not specific for mantle cell lymphoma however, as it can be identified in other B-cell neoplasms, including plasma cell myeloma.

CPT codes: 88368 x 2

CLL Panel by FISH

Test name: CLL panel by FISH (del(13)(q14.3), trisomy12, del(11)(q22.3), del(17)(p13.1))

Order name: CLL panel by FISH request

Specimen requirements: Sodium heparin peripheral blood or bone marrow

Minimum volume: 1mL

Storage and Stability information: Room temperature three days

Test performed: Twice per week

Methodology: Fluorescence in situ hybridization

Reference range: See lab report

Clinical significance: Chromosome abnormalities are found in about 50% of cases by chromosome analysis and in about 80% of chronic lymphocytic leukemia (CLL) cases by fluorescence in situ hybridization (FISH) of interphase cells. The most frequent changes are deletion 13q (55%), deletion 11q (18%), trisomy 12 (16%), and deletion 17p (7%).

CPT codes: 88368 x 5

DiGeorge Syndrome by FISH

Test name: FISH, 22q11.2 deletion syndrome, DiGeorge syndrome

Order name: DiGeorge syndrome by FISH

Specimen requirements: Sodium heparin peripheral blood

Minimum volume: 1mL. 4mL preferred

Storage and stability information: Room temperature three days

Test performed: Once per week

Methodology: Fluorescence in situ hybridization

Reference range: See lab report

Clinical significance: Deletions in 22q11.2 have been associated with several disorders including DiGeorge syndrome (DGS) and Velocardiofacial syndrome (VCFS). These syndromes are now officially known as 22q11.2 deletion syndrome, but many clinicians still refer to the syndromes by their individual names. Greater than 90% of DGS and VCFS are associated with a deletion of this region. In addition, a proportion of isolated conotruncal cardiac malformations have been associated with a deletion of the same region.

CPT codes: 88368 x 2

HER2 by FISH

Test name: FISH, HER2 amplification

Order name: HER2 by FISH request

Specimen requirements: Formalin fixed paraffin-embedded tissue (FFPE)

Minimum volume: FFPE – two unstained 4µm thick sections on positively charged slides plus one stained H&E slide of the same block

Storage and stability information: FFPE at room temperature indefinitely

Test performed: Twice per week

Methodology: Fluorescence in situ hybridization

Reference range: See lab report

Clinical significance: This test can be used as a prognostic indicator for patients with both node-positive or node-negative breast cancer; to guide therapy, as patients with HER2 amplification may be candidates for Herceptin therapy; and to confirm the presence of HER2 amplification in cases with 2+ (low-level) or 3+ (high-level) HER2 overexpression by immunohistochemistry.

CPT codes: 88368 x 2

IGH/BCL2 t(14;18) by FISH

Test name: FISH, IGH/BCL2 t(14;18)

Order name: t(14;18) by FISH request

Specimen requirements: Sodium heparin peripheral blood or bone marrow. Formalin fixed paraffin-embedded tissue (FFPE).

Minimum volume: 1mL blood or bone marrow. FFPE — two unstained 4µm thick sections on positively charged slides plus one stained H&E slide of the same block.

Storage and stability information: Room temperature three days for blood and bone marrow. FFPE at room temperature indefinitely.

Test performed: Twice per week

Methodology: Fluorescence in situ hybridization

Reference range: See lab report

Clinical significance: The t(14;18) translocation is found in 80 to 90% of follicular lymphomas, 30% of diffuse large B-cell lymphomas, and 15% of non-Hodgkin lymphomas.

CPT codes: 88368 x 2

MDS Panel by FISH

Test name: MDS panel by FISH (-5, del5q, -7 del7q, trisomy 8, deletion 20q12)

Order name: MDS panel by FISH request

Specimen requirements: Sodium heparin peripheral blood or bone marrow

Minimum volume: 1mL

Storage and stability information: Room temperature three days

Test performed: Twice per week

Methodology: Fluorescence in situ hybridization (FISH)

Reference range: See lab report

Clinical significance: Chromosome abnormalities are found at diagnosis in about 60% of patients with de novo myelodysplastic syndrome (MDS) and almost 85% of those with secondary MDS. Abnormalities involving chromosome 5 or 7 are poor prognostic findings. Trisomy 8 has an intermediate prognosis dependent on other cytogenetic abnormalities. Deletion of the long arm of chromosome 20, as the sole cytogenetic abnormality, confers a favorable prognosis.

CPT codes: 88368 x 6

MLL by FISH

Test name: MLL by FISH

Order name: MLL by FISH request

Specimen requirements: Sodium heparin peripheral blood or bone marrow

Minimum volume: 1mL

Storage and stability information: Room temperature three days

Test performed: Twice per week

Methodology: Fluorescence in situ hybridization

Reference range: See lab report

Clinical significance: Abnormalities of 11q23 involving the MLL gene are found in 7% of cytogenetically abnormal acute myelogenous leukemia (AML) cases and approximately 1/3 of those cases are treatment-related due to prior chemotherapy with epipodophyllotoxins and doxorubicin. MLL is known to have multiple different translocation partners and most cases respond poorly to treatment and have a poor prognosis. Cytogenetic analysis is required to identify specific MLL translocation partners. MLL rearrangements can also be identified in a subtype of B-acute lymphoblastic leukemias, particularly in neonates, and also in a subtype of mixed phenotypic acute leukemias.

CPT codes: 88368 x 2

MYC Breakapart by FISH

Test name: FISH, MYC breakapart by FISH

Order name: MYC breakapart by FISH request

Specimen requirements: Sodium heparin peripheral blood or bone marrow. Formalin fixed paraffin-embedded tissue (FFPE).

Minimum volume: 1mL blood or bone marrow. FFPE — two unstained 4µm thick sections on positively charged slides plus one stained H&E slide of the same block.

Storage and stability information: Room temperature three days for blood and bone marrow. FFPE at room temperature indefinitely.

Test performed: Twice per week

Methodology: Fluorescence in situ hybridization

Reference range: See lab report

Clinical significance: Rearrangements of MYC are associated with B-cell neoplasms and are found in both Burkitt lymphoma/leukemia and B-cell lymphoma, unclassifiable, with features intermediate between diffuse large B-cell lymphoma and Burkitt lymphoma. Translocation of the MYC 8q24 region may be to the Immunoglobulin heavy chain locus (14q32), either the kappa or lambda immunoglobulin light chain loci (2p12 and 22q11, respectively) as well as to non-immunoglobulin loci.

CPT codes: 88368 x 3

Myeloma Panel by FISH

Test name: Myeloma panel by FISH (CEP 5/9/15, del13q14, IGH, t(11;14), TP53)

Order name: Myeloma panel by FISH request

Specimen requirements: Sodium heparin peripheral blood or bone marrow

Minimum volume: 1mL

Storage and stability information: Room temperature three days

Test performed: Twice per week

Methodology: Fluorescence in situ hybridization

Reference range: See lab report

Clinical significance: Chromosomal abnormalities are found in 30–50% of patients with multiple myeloma. The abnormality detection rate is greatly increased by FISH analysis. Using FISH, aneuploidy is detected in 67–90% of cases, while rearrangements of IGH translocations are found in at least 65–70% of patients with the t(11;14) translocation representing 10%. Deletions of 13q or loss of chromosome 13 are found by FISH in 20–30% of patients. These abnormalities are associated with a significant lower rate of response to conventional chemotherapy and to a shorter survival. Deletions of TP53 are also known to have a poor prognosis.

CPT codes: 88368 x 11

MYC/IGH t(8;14) by FISH

Test name: FISH, MYC/IGH t(8;14)

Order name: t(8;14) by FISH request

Specimen requirements: Sodium heparin peripheral blood or bone marrow. Formalin fixed paraffin-embedded tissue (FFPE)

Minimum volume: 1mL blood or bone marrow. FFPE — two unstained 4µm thick sections on positively charged slides plus one stained H&E slide of the same block.

Storage and stability information: Room temperature three days for blood and bone marrow. FFPE at room temperature indefinitely.

Test performed: Twice per week

Methodology: Fluorescence in situ hybridization

Reference range: See lab report

Clinical significance: The t(8;14) translocation leads to juxtaposition of the Immunoglobulin Heavy Chain loci with the MYC gene. The t(8;14) is associated with B-cell neoplasms, particularly Burkitt lymphoma/leukemia, although it is not specific for this neoplasm. In addition, as the MYC gene can rearrange with other loci, the absence of the t(8;14) does not exclude the diagnosis of Burkitt lymphoma.

CPT codes: 88368 x 2

PML/RARA t(15;17) by FISH

Test name: t(15;17) by FISH (or PML/RARA)

Order name: t(15;17) by FISH request

Specimen requirements: Sodium heparin peripheral blood or bone marrow

Minimum volume: 1mL

Storage and stability information: Room temperature three days

Test performed: Twice per week

Methodology: Fluorescence in situ hybridization

Reference range: See lab report

Clinical significance: The t(15;17) translocation has been described in almost 100% of APL cases, has the highest complete remission rate, and the longest median survivals for patients with AML. Most cases are de novo, but approximately 5% occur after previous chemotherapy, mainly drugs targeting topoisomerase II. Although the outcome of APL is favorable, the high tendency for disseminated intravascular coagulation (DIC) is a serious threat.

CPT codes: 88368 x 2

Prader-Willi Syndrome by FISH

Test name: FISH, Prader-Willi syndrome

Order name: Prader-Willi by FISH request

Specimen requirements: Sodium heparin peripheral blood

Minimum volume: 1mL. 4mL preferred

Storage and stability information: Room temperature three days

Test performed: Once per week

Methodology: Fluorescence in situ hybridization

Reference range: See lab report

Clinical significance: Seventy percent of patients with Prader-Willi syndrome have an interstitial deletion of chromosome 15. Twenty to 30% of patients with Prader-Willi syndrome have been described who do not have the cytogenetic deletion, but instead have two copies of the 15q11.2q13 critical region that are inherited from the mother. This form of inheritance is known as maternal uniparental disomy. The remaining 2 to 5% of patients have evidence of normal biparental inheritance of chromosome 15, but with an imprinting mutation. DNA methylation studies can be performed to detect these defects.

CPT codes: 88368 x 4

ROS1 by FISH

Test name: ROS1 by FISH

Order name: ROS1 by FISH request

Specimen requirements: Formalin fixed paraffin-embedded tissue (FFPE)

Minimum volume: FFPE – two unstained 4µm thick sections on positively charged slides plus 1 stained H&E slide of the same block

Storage and stability information: Room temperature

Test performed: Twice per week

Methodology: Fluorescence *in situ* hybridization

Reference range: See lab report

Clinical significance: Gene fusions involving ROS1 are present in 1-2% of non-small cell lung carcinomas, primarily adenocarcinomas. Several partner genes (FIG, SLC34A2, CD74) have been identified. Resulting activation of ROS1 kinase activity appears to be a principal growth driver in these tumors. This kinase is sensitive to crizotinib, and patients with ROS1-fusion positive tumors have shown responses to this inhibitor. This test utilizes a break-apart FISH probe to the ROS1 locus to screen for these gene fusions by FISH.

CPT codes: 88368 x 2

UroVysion by FISH

Test name: UroVysion (CEP 3/7/17 and 9p21)

Order name: UroVysion by FISH request

Specimen requirements: Urine, bladder washing, urethral washing

Minimum volume: 50mL of neat urine. Any volume of bladder and urethral washing will be attempted if cells are present.

Storage and stability information: Refrigerated. Transport to lab within 1 day of collection.

Test performed: Twice per week

Methodology: Fluorescence in situ hybridization

Reference range: See lab report

Clinical significance: The UroVysion assay is designed to detect aneuploidy for chromosomes 3, 7, 17, and loss of the 9p21 locus via fluorescence in situ hybridization (FISH) in urine specimens from persons with hematuria suspected of having bladder cancer. Results from this assay are intended for use, in conjunction with current standard diagnostic procedures, as an aid for initial diagnosis of bladder carcinoma in patients with hematuria, and subsequent monitoring for tumor recurrence in patients previously diagnosed with bladder cancer.

CPT codes: 88368 x 4

Molecular

Molecular Oncology

As a hospital-based laboratory, BayCare Laboratories knows the importance of personalized health care. BayCare Laboratories provides a wide range of molecular oncology testing to help our physicians make the most educated treatment decisions for their cancer patients.

Molecular Genetics

BayCare Laboratories offers the most frequently ordered and useful molecular genetic tests on the market. Our molecular genetics menu helps physicians and their patients make important and informed decisions regarding their risk of inherited disease.

Molecular Infectious Disease Testing

BayCare Laboratories offers an infectious disease menu including FDA-approved and laboratory-developed tests, with high sensitivity and specificity for the detection of infectious disease pathogens. We understand that the speed and quality of diagnostic service is essential to physician practices and that is why most of our infectious disease tests are performed daily. (See page 10)

For more information: (800) 324-7853

Molecular Testing Available		
Molecular Oncology		Molecular Genetics
Hematopoietic Diseases <ul style="list-style-type: none"> • Jak2 V617F mutation • B cell gene rearrangement • T cell gene rearrangement • BCR/ABL Quantitative PCR • Jak2 exon 12 mutation* • MPL mutation* 		Solid Tumor <ul style="list-style-type: none"> • KRAS mutation • EGFR mutation • BRAF V600E mutation • Microsatellite Instability • Factor V Leiden mutation • Factor II (Prothrombin G20210A) mutation • MTHR (677 and 1298) mutations • Cystic fibrosis 60-mutation panel
Molecular Infectious Disease		
Sexually Transmitted Disease <ul style="list-style-type: none"> • Chlamydia trachomatis/Neisseria gonorrhoea • Human Papilloma Virus (HPV), including HPV 16,18 genotyping • Herpes Virus 1/2 • Bacterial Vaginosis, Trichomoniasis, and Candidiasis (Affirm) 	Viral Load Testing <ul style="list-style-type: none"> • BK virus Quantitative (BKV) • Epstein-Barr Virus (EBV) Quantitative • Human Immunodeficiency Virus (HIV) • Hepatitis B Virus (HBV) • Hepatitis C Virus (HCV) • Cytomegalovirus (CMV) • HCV Qualitative • Hepatitis C Genotype 	Respiratory Disease <ul style="list-style-type: none"> • Respiratory Viral Panel • Bordetella pertussis/parapertussis • Legionella • Atypical Pneumonia • Cytomegalovirus (CMV)

*Available Fall 2013

B-cell Gene Rearrangement

Test name: B-cell receptor gene rearrangement, PCR, cell-based

Order name: B-CELL GENE RR

Specimen requirements: EDTA peripheral blood and bone marrow, fresh tissue in RPMI, Formalin-fixed paraffin embedded tissue (FFPE)

Minimum volume: 0.5mL peripheral blood or bone marrow. FFPE: 5–10 10µm thickness curls submitted in a sterile cup along with stained H&E of same block). If tumor percentage is less than 10% of total nuclei, macrodissection is required, send 5–10 10µm thickness unstained slides with stained H&E of same block.

Storage and stability information: Blood and bone marrow (room temperature, one week), fresh tissue (refrigerated, one week), FFPE (room temperature)

Test performed: Once per week

Methodology: Polymerase Chain Reaction (PCR), Capillary Electrophoresis

Reference range: No clonal population detected

Clinical significance: This test is used to aid in the diagnosis of B-cell malignancies, to determine lineage of leukemias and lymphomas for prognosis and treatment selection, and to detect minimal residual disease or recurrent disease.

CPT codes: 81261, 81264

BCR/ABL by PCR

Test name: BCR/ABL1 by PCR

Order name: BCR/ABL1 BY PCR REQUEST

Specimen requirements: EDTA peripheral blood or bone marrow

Minimum volume: 3mL peripheral blood, 1mL bone marrow

Storage and stability information: Refrigerated, three days (transport to lab within one day of collection)

Test performed: Once per week

Methodology: Real-time Polymerase Chain Reaction (PCR)

Reference range: Negative for the BCR/ABL1 translocation

Clinical significance: The BCR/ABL1 fusion gene is formed by the translocation involving chromosomes 9 and 22, t(9;22)(q34;q11) and is the initiating event in chronic myeloid leukemia (CML) and Ph+ acute lymphoblastic leukemia (ALL). The quantitative detection of the BCR/ABL1 fusion gene is useful to monitor patients' response to imatinib and/or 2nd generation tyrosine kinase inhibitors (TKI). Serial reporting of patients' quantitative results is provided for both major and minor translocation fusion genes.

CPT codes: 81206, 81207

Jak2 exon 12 mutation

Order name: Jak2 Exon 12

Specimen requirements: Peripheral blood or bone marrow

Minimum volume: 0.5mL

Storage and stability information: Refrigerated, one week

Test performed: Once per week

Methodology: Sequencing

Reference range: No Jak2 Exon 12 Mutations detected

Clinical significance: The Jak2 V617F mutation is the most common mutation present in several of the myeloproliferative neoplasms: 96% of patients with Polycythemia vera (PV); 33-57% of patients with Essential thrombocythemia (ET); 35-50% of patients with Primary myelofibrosis (PMF). In 2007, mutations discovered in exon 12 of the Jak2 gene were reported in PV patients lacking the Jak2 V617F mutation. Therefore, almost all cases of PV have either the exon 14 V617F mutation or an exon 12 mutation. At least 27 different exon 12 mutations have been reported in PV and include substitutions, deletions and insertions. This test sequences the entire length of exon 12 of the Jak2 gene.

CPT code: 81403

MPL mutation

Order name: MPL mutation

Specimen requirements: Peripheral blood or bone marrow

Minimum volume: 0.5mL

Storage and stability information: Refrigerated, one week

Test performed: Once per week

Methodology: PCR followed by fragment analysis

Reference range: No MPL mutations detected

Clinical significance: Patients with Jak2 V617F negative essential thrombocythemia (ET) or primary myelofibrosis (PMF) may have a mutation of the MPL gene; presence of an MPL mutation can help confirm diagnosis of a myeloproliferative neoplasm (MPN). An MPL mutation is present in 3-5% of ET cases and 5-10% of PMF cases. MPL mutations have not been detected in polycythemia vera (PV), and therefore can help distinguish ET and PMF from PV. This test detects the most common MPL mutations, accounting for approximately 98% of MPL mutations; W515K, W515L, W515A and S505N.

Bordetella Pertussis/Parapertussis

Test name: Bordetella pertussis/parapertussis PCR

Order name: BORD PERT/PARA PCR

Specimen requirements: Nasopharyngeal swab or nasal wash

Minimum volume: One Nasopharyngeal swab, red or blue top
Storage and stability information: Room temperature, one day; refrigerated, five days

Test performed: Daily

Methodology: Real-time Polymerase Chain Reaction (PCR)

Reference range: Bordetella pertussis/parapertussis not detected

Clinical significance: B. pertussis is the causative agent of whooping cough, while B. parapertussis can cause non-specific bronchitis. While the presence of Bordetella pertussis DNA suggests active infection, the results should be used in conjunction with clinical presentation, patient history and other diagnostic tests.

CPT codes: 87798 x2

Legionella

Order name: Legionella PCR

Specimen requirements: Nasopharyngeal swab placed into viral transport media or nasal washing; sputum; plasma

Minimum volume: 0.5mL

Storage and stability information: Refrigerated five days, frozen longer

Test performed: Daily

Methodology: Real-time Polymerase Chain Reaction (PCR)

Reference range: NEGATIVE for the presence of Legionella pneumophila DNA

Clinical significance: *Legionella pneumophila* are Gram-negative aerobic coccobacilli, isolated from surface water, mud, or thermally polluted lakes or streams. It is pathogenic for man and it has no known soil or animal sources. *Legionella pneumophila* is a main causative agent of Legionnaires' Disease. It has been isolated from numerous environmental sites as well as from human lung tissue, respiratory secretions, and blood.

CPT code: 87541

Atypical pneumonia

Order name: Atypical pneumonia PCR

Specimen requirements: Nasopharyngeal swab placed into viral transport media or nasal washing; sputum

Minimum volume: 0.5mL

Storage and stability information: Refrigerated five days, frozen longer

Test performed: Daily

Methodology: Real-time Polymerase Chain Reaction (PCR)

Reference range: NEGATIVE for the presence of both Mycoplasma pneumonia and Chlamydia pneumonia DNA

Clinical significance: *Mycoplasma pneumoniae* is a frequent causative agent of community-acquired pneumonia. This agent may be responsible for epidemics that spread slowly because it requires a 10 to 14-day incubation period. Growth in culture is slow and insensitive; therefore infection is diagnosed primarily by serology and PCR. *Chlamydia pneumoniae*, formerly known as Chlamydia pneumonia, infects humans and is a major cause of pneumonia. *C. pneumoniae* has a complex life cycle and must infect another cell in order to reproduce and thus is classified as an obligate intracellular pathogen.

CPT codes: 87486, 87581

BRAF V600E Mutation

Test name: BRAF mutation

Order name: BRAF

Specimen requirements: Formalin-fixed paraffin embedded tissue (FFPE)

Minimum volume: 5–10 10µm sections of FFPE tissue in a sterile cup with stained H&E of same block. If tumor percentage is less than 10% of total nuclei, macrodissection is required, send 5–10 10µm thickness unstained slides with stained H&E of same block.

Storage and stability information: Room temperature

Test performed: Once per week

Methodology: Real-time Polymerase Chain Reaction (PCR)

Reference range: No BRAF V600 mutation detected

Clinical significance: BRAF is found in approximately 15% of colon tumors that do not contain a KRAS mutation. Patients whose colon cancer is positive for the BRAF mutation have poor response to anti-EGFR therapy and a worse prognosis based on time to progression and survival data, especially when the cancer is microsatellite stable. Detection of the BRAF mutation is also useful in aiding the diagnosis of papillary thyroid carcinoma or anaplastic thyroid carcinoma, and in the identification of melanoma tumors that may respond to BRAF-targeted therapies. This test detects BRAF mutations V600E, V600D, V600K, V600R, V600M, V600A, and V600G. However, the assay cannot distinguish between V600E and D and among V600K, R and M.

CPT code: 81210

Cystic Fibrosis for Carrier

Test name: Cystic fibrosis (CF) for carrier screening

Order name: CF Carrier

Specimen requirements: EDTA peripheral blood

Minimum volume: 0.5mL

Storage and stability information: Room temperature, one week

Test performed: Once per week

Methodology: PCR, Bead array

Reference range: Negative for mutations analyzed.

Clinical significance: The clinical indication for this test is to screen for CF carrier status in individuals during the preconception or prenatal period. This assay is performed with the Luminex IVD CF60 bead array method; the assay detects 60 clinically relevant mutations, which include the mutation panel recommended by ACMG/ACOG, and additional mutations allowing improved carrier detection among the African American and Hispanic populations.

CPT codes: 81220

Chlamydia Trachomatis/Neisseria Gonorrhoea

Test name: Chlamydia trachomatis, Neisseria gonorrhoea

Order name: CT NG AMP PRB

Specimen requirements: BD Qx cervical swab (pink) or BD Qx male urethral swab (blue), Urine (dirty catch) ; Thin prep sample

Minimum volume: One swab, 5mL urine, 2mL Thin prep

Storage and stability information: BD Qx swab – room temperature, five days; urine – refrigerated, seven days; thin prep – room temperature, two weeks

Test performed: Daily

Methodology: Strand Displacement Amplification

Reference range: Negative for Chlamydia trachomatis and Neisseria gonorrhoea

Clinical significance: C. trachomatis infections are the leading cause of sexually transmitted diseases in the United States. C. trachomatis is known to cause cervicitis, pelvic inflammatory disease (PID), infant conjunctivitis, infant pneumonia, urethritis, epididymitis and proctitis. It is also the most frequent cause of non-gonococcal urethritis in men. Neisseria gonorrhoea (gonococci) is the causative agent of gonorrhoea.

CPT codes: 87491, 87591

Cytomegalovirus (CMV) Qualitative

Test name: CytoMegalovirus (CMV) Qualitative PCR

Order name: CMV PCR QUAL

Specimen requirements: Urine, CSF, Respiratory samples

Minimum volume: 0.5mL

Storage and stability information: Refrigerated or frozen at -20°C, one week

Test performed: Once per week

Methodology: Real-time Polymerase chain reaction

Reference range: CMV DNA not detected

Limit of detection: 200 copies/mL

Clinical significance: Infection with cytomegalovirus (CMV) is a significant cause of morbidity and mortality in transplant recipients and other immunocompromised hosts, as well as neonates. Infection may involve multiple organs including the brain, lung, liver and gastrointestinal tract.

CPT codes: 87497

Cytomegalovirus (CMV) Quantitative

Test name: CytoMegalovirus (CMV) Quantitative PCR

Order name: CMV PCR Quant.

Specimen requirements: EDTA Peripheral blood or plasma

Minimum volume: 0.5mL

Storage and stability information: Peripheral blood (refrigerated, one week); plasma (refrigerated or frozen at -20°C, one week)

Test performed: Once per week

Methodology: Real-time Polymerase Chain Reaction (PCR)

Reference range: CMV DNA not detected

Clinical significance: Infection with cytomegalovirus (CMV) is a significant cause of morbidity and mortality in transplant recipients and other immunocompromised hosts, as well as neonates. Infection may involve multiple organs including the brain, lung, liver, and gastrointestinal tract. In plasma, the detection of CMV is more indicative of an active CMV infection. Assays performed on whole blood can potentially detect latent virus.

Linear range: 500–500,000 copies/mL

Limit of detection: 200 copies/mL

CPT code: 87497

EGFR Mutation

Test name: EGFR mutation

Order name: EGFR

Specimen requirements: Formalin-fixed paraffin embedded tissue (FFPE)

Minimum volume: 5–10 10µm sections of FFPE tissue in a sterile cup with stained H&E of same block. If tumor percentage is less than 10% of total nuclei, macrodissection is required, send 5–10 10µm thickness unstained slides with stained H&E of same block.

Storage and stability information: Room temperature

Test performed: Once per week

Methodology: Real-time Polymerase Chain Reaction (PCR)

Reference range: No EGFR mutation detected

Clinical significance: Somatic mutations in the epidermal growth factor receptor (EGFR) gene have been associated with non-small cell lung cancer (NSCLC) patients' responsiveness to tyrosine kinase inhibitors (TKI) (gefitinib, erlotinib). However, while some mutations have a sensitizing effect, other mutations are linked to TKI resistance. This test detects the following mutations: T790M, exon 19 deletions, L858R, G719X, exon 20 insertions, S768I, and L861Q.

CPT code: 81401

Factor II (Prothrombin) Mutation

Test name: Factor II (Prothrombin) mutation

Order name: FII MUT

Specimen requirements: EDTA Peripheral blood

Minimum volume: 0.5mL

Storage and stability information: Room temperature, one week

Test performed: Once per week

Methodology: PCR, Invader assay

Reference range: Negative for the Factor II Prothrombin G20210A mutation

Clinical significance: Factor II Mutation (G20210A) is a most common cause of venous thrombosis. Assessment of Factor II (Prothrombin) G20210A is useful in patients with thromboembolism, deep vein thrombosis or pulmonary embolism. Carriers of the mutation have a three-fold increased risk. Other mutations and other risk factors (ex. contraceptive use) compound the risk for venous thrombosis.

CPT code: 81240

Factor V Leiden Mutation

Test name: Factor V Leiden mutation

Order name: FV MUT or FV/FII panel

Specimen requirements: EDTA peripheral blood

Minimum volume: 0.5mL

Storage and stability information: Room temperature, one week

Test performed: Once per week

Methodology: PCR, Invader assay

Reference range: Negative for the Factor V Leiden R506Q mutation

Clinical significance: Factor V (Leiden) Mutation mutation analysis is useful for patients with suspected thrombophilia and for those with a family history. Screening may be appropriate for decisions on oral contraceptive use. Carriers of FV Leiden mutation may require prophylaxes for some situations (ex. prevention of venous thrombosis during pregnancy or postpartum).

CPT codes: 81241

Herpes Virus 1/2

Test name: Herpes Virus (HSV) 1 and 2 PCR

Order name: CSF HSV 1 + 2 PCR

Specimen requirements: Cerebral Spinal Fluid

Minimum volume: 0.5mL

Storage and stability information: Refrigerated, one week. Frozen at -20° seven days.

Test performed: Daily

Methodology: Real-time Polymerase Chain Reaction (PCR)

Reference range: Negative for Herpes Simplex Virus 1 and 2 DNA

Clinical significance: HSV is a virus that is an important cause of encephalitis and meningitis in both adults and children. Untreated HSV encephalitis is associated with high mortality (~70%) and neurologic sequelae in survivors.

CPT codes: 87529 x 2

Hepatitis B Virus (HBV)

Test name: Hepatitis B Virus viral load

Order name: HBV DNA QUANT

Specimen requirements: Serum or plasma separated from peripheral blood within 24 hours of collection

Minimum volume: 0.5mL minimum serum or plasma, 1mL preferred

Storage and stability information: Peripheral blood (refrigerated, 24 hours), serum or plasma (refrigerated, seven days or frozen at -20°C less than one week)

Test performed: Once per week

Methodology: Real-time Polymerase Chain Reaction (PCR)

Reference range: HBV target DNA not detected

Linear range: 20 to 170,000,000 IU/mL. (1.3–8.2 log IU/mL)

Limit of detection: 20 IU/mL (1.3 log)

Clinical significance: This test is intended for use as an aid in the management of patients with chronic HBV infection undergoing anti-viral therapy. The assay can be used to measure HBV DNA levels at baseline and during treatment to aid in assessing response to treatment.

CPT codes: 87517

Hepatitis C Genotype

Test name: Hepatitis C Virus (HCV) Genotype, HCV viral load plus genotype

Order name: HCV Geno, HCV VL U + GENO

Specimen requirements: Plasma or serum separated from peripheral blood less than six hours from collection

Minimum volume: 2mL plasma or serum

Storage and stability information: Peripheral blood (refrigerated, six hours), plasma or serum (refrigerated, three days, or frozen at -20°C less than six days)

Test performed: Once per week

Methodology: Polymerase chain reaction and line-probe assay

Reference range: HCV genotypes 1–6

Clinical significance: Hepatitis C genotype is a predictor of response to interferon alfa-2b (non-type 1 are better responders) and to combination therapy with interferon and ribavirin (all types respond but dosage and duration of treatment is dependent on genotype).

CPT codes: 87902

Hepatitis C Virus (HCV) Qualitative

Test name: Hepatitis C Virus (HCV) Qualitative PCR

Order name: HCV PCR QUAL

Specimen requirements: Plasma or serum separated from peripheral blood less than 6 hours from collection

Minimum volume: 2mL plasma or serum

Storage and stability information: Peripheral blood (refrigerated, six hours), plasma or serum (refrigerated, three days, or frozen at -20°C less than six days)

Test performed: Twice per week

Methodology: Real-time Polymerase Chain Reaction (PCR)

Reference range: No HCV target detected

Limit of detection: The Limit of Detection (LOD) of the assay is 18 IU/mL across HCV genotypes 1–6 [7.1 IU/mL for HCV genotype 1; 15.3 IU/mL for HCV genotype 2; 9.8 IU/mL for HCV genotype 3; 5.6 IU/mL for HCV genotype 4; 18.3 IU/mL for HCV genotype 5; 9.7 IU/mL for HCV genotype 6

Clinical significance: The qualitative assessment of HCV RNA is useful in confirming HCV infection and to assess response to therapy.

CPT codes: 87521

Hepatitis C Virus (HCV) Viral Load

Test name: Hepatitis C Virus (HCV) Viral Load

Order name: HCV VL U

Specimen requirements: Serum or plasma separated from peripheral blood less than six hours from collection

Minimum volume: 2mL serum or plasma

Storage and stability information: Peripheral blood (refrigerated, six hours), serum or plasma (refrigerated, three days, or frozen at -20°C less than six days)

Test performed: Twice per week

Methodology: Real-time Polymerase chain reaction (PCR)

Reference range: No HCV target detected

Linear range: 43 to 69,000,000 IU/mL (1.6 – 7.8 log IU/mL)

Limit of detection: The Limit of Detection (LOD) of the assay is 18 IU/mL across HCV genotypes 1–6 [7.1 IU/mL for HCV genotype 1; 15.3 IU/mL for HCV genotype 2; 9.8 IU/mL for HCV genotype 3; 5.6 IU/mL for HCV genotype 4; 18.3 IU/mL for HCV genotype 5; 9.7 IU/mL for HCV genotype 6

Clinical significance: HCV viral load predicts likelihood of treatment response. Lower viral load at therapy initiation suggests better therapeutic response. The test is useful in monitoring therapy and disease progression.

CPT codes: 87522

BK virus Quantitative

Order name: BKV PCR Quant

Specimen requirements: EDTA plasma, urine

Minimum volume: 0.5mL

Storage and stability information: Plasma (refrigerated or frozen at -20°C, one week), urine (refrigerated, 72 hours)

Test performed: Once per week

Methodology: Real-time Polymerase Chain Reaction (PCR)

Reference range: BK virus DNA not detected

Linear range: 500–5,000,000 copies/mL

Limit of detection: 250 copies/mL in plasma, 500 copies/mL in urine

Clinical significance: BK virus (BKV) is a double-stranded DNA virus and a member of the polyomavirus family. The virus is ubiquitous, having a worldwide seropositivity around 75%, and generally has very mild pathogenicity in healthy individuals. BKV establishes lifelong latency in the urinary epithelium with often no debilitating effects. However BKV can cause clinical disease in immunocompromised patients.

CPT codes: 87799

Epstein-Barr Virus (EBV) Quantitative

Order name: EBV PCR Quant

Specimen requirements: EDTA Peripheral blood, EDTA plasma, CSF

Minimum volume: 0.5mL

Storage and stability information: Peripheral blood (refrigerated, one week), plasma (refrigerated or frozen at -20°C, one week), CSF (refrigerated or frozen at -20°, one week)

Test performed: Once per week

Methodology: Real-time Polymerase Chain Reaction (PCR)

Reference range: EBV DNA not detected

Linear range: 500–9,850,000 copies/mL

Limit of detection: 246 copies/mL in plasma and CSF, 500 copies/mL in whole blood

Clinical significance: Many people become infected with EBV in childhood. EBV infections in children usually do not cause symptoms, or the symptoms are not distinguishable from other mild, brief childhood illnesses. People who get symptoms from EBV infection, usually teenagers or adults, get better in two to four weeks. However some people feel fatigued for as long as several months. After an EBV infection, the virus becomes latent in the body. In some cases, the virus may reactivate. This does not always cause disease but people with compromised immune systems are more likely to develop serious symptoms.

CPT codes: 87497

Human Immunodeficiency Virus (HIV) Viral Load

Test name: Human Immunodeficiency Virus (HIV) Viral Load

Order name: HIV PCR ULTRA

Specimen requirements: Plasma separated from EDTA peripheral blood within 24 hours from collection

Minimum volume: 1mL minimum plasma, 2mL preferred

Storage and stability information: Peripheral blood (refrigerated, 24 hours), plasma (refrigerated, six days, or frozen at -20°C less than six days)

Test performed: Three times per week

Methodology: Real-time Polymerase Chain Reaction (PCR)

Reference range: No HIV target detected

Linear range: 20 copies/mL (1.3 log) – 10,000,000 copies/mL (7.0 log).

Limit of detection: 20 copies/mL (1.3 log)

Clinical significance: The quantitative measurement of HIV-1 RNA (viral load) can be used to assess patients' prognosis at baseline and to monitor the effects of antiretroviral therapy during the course of antiretroviral treatment. This test is not intended for use as a screening test for the presence of HIV-1 in blood or as a diagnostic test to confirm the presence of HIV-1 infection.

CPT codes: 87536

Human Papilloma Virus (HPV) High Risk

Test name: Human Papilloma Virus (HPV) High Risk

Order name: HPV HR

Specimen requirements: Thin Prep

Minimum volume: 1mL Thin Prep

Storage and stability information: Room temperature, two weeks; refrigerated, one month

Test performed: Twice per week

Methodology: Real-time Polymerase Chain Reaction (PCR)

Reference range: Negative for HPV high-risk types

Clinical significance: Persistent infection with human papillomavirus (HPV) is the principal cause of cervical cancer and its precursor cervical intraepithelial neoplasia (CIN) 1–3. The presence of HPV has been implicated in greater than 99% of cervical cancers, worldwide. This test can specifically identify HPV types 16 and 18, while concurrently detecting the rest of the high-risk types (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68).

CPT codes: 83891, 83900, 83912

Jak2 V617F Mutation

Test name: Jak2 V617F mutation

Order name: JAK2

Specimen requirements: EDTA peripheral blood or bone marrow

Minimum volume: 0.5mL

Storage and stability information: Room temperature, one week

Test performed: Once per week

Methodology: Real-time Polymerase Chain Reaction (PCR)

Reference range: Negative for the Jak2 V617F mutation

Clinical significance: The mutation affecting the Janus Tyrosine Kinase 2 (JAK2 V617F) is the most common molecular abnormality in chronic Myeloproliferative Disorders (MPD). The highest mutation frequency occurs in patients with PV (Polycythemia Vera, >90%) or ET (Essential Thrombocythemia, 35% to 70%); the lowest frequency is in PMF patients (Primary Myelofibrosis, 50%).

CPT codes: 81270

KRAS Mutation

Test name: KRAS mutation

Order name: KRAS

Specimen requirements: Formalin-fixed paraffin embedded tissue (FFPE)

Minimum volume: 5–10 10µm sections of FFPE tissue in a sterile cup with stained H&E of same block. If tumor percentage is less than 10% of total nuclei, macrodissection is required, send 5–10 10µm thickness unstained slides with stained H&E of same block.

Storage and stability information: Room temperature

Test performed: Once per week

Methodology: Real-time Polymerase Chain Reaction (PCR)

Reference range: No KRAS mutation detected

Clinical significance: Mutations in the K-RAS oncogene are frequently found in human cancers. The presence of these mutations has been shown to correlate with a lack of response to certain EGFR inhibitor therapies, such as cetuximab and panitumumab, in metastatic colorectal cancer patients. Screening for the K-RAS mutations aids doctors in selecting appropriate therapies for patients. This test detects the seven most common KRAS mutations: Gly12 Ala, Gly12Asp, Gly12Arg, Gly12Cys, Gly12Ser, Gly12Val, and Gly13Asp.

CPT code: 81275

Microsatellite Instability (MSI)

Test name: MSI – Microsatellite Instability

Order name: MSI

Specimen requirements: Formalin-fixed paraffin embedded tissue (FFPE)

Minimum volume: This test compares tumor DNA to normal DNA. Therefore, two tissue types must be submitted; slides containing tumor in addition to slides with normal tissue. Tumor containing block: 5–10 10µm thickness unstained slides with stained H&E of same block. Normal tissue block: 5–10 10µm thickness unstained slides with stained H&E of same block.

Storage and stability information: Room temperature

Test performed: Once per week

Methodology: Polymerase Chain Reaction (PCR), Capillary Electrophoresis

Reference range: MSI stable

Clinical significance: The Microsatellite Instability assay is used to evaluate tumor tissue to identify patients at high risk for having HNPCC/Lynch syndrome. Tumor tissue is indirectly evaluated for the presence of defective DNA Mismatch repair by analyzing MSI (Microsatellite instability) patterns.

CPT codes: 81301

MTHFR Mutation

Test name: Methylene tetrahydrofolatereductase (MTHFR) mutation

Order name: MTHFR RFLX

Specimen requirements: EDTA Peripheral blood

Minimum volume: 0.5mL

Storage and stability information: Room temperature, one week

Test performed: Once per week

Methodology: PCR, Invader assay

Reference range: NEGATIVE for the MTHFR C677T mutation

Clinical significance: The MTHFR gene is involved in the regulation of methylenetetrahydrofolate metabolism and mutations within this gene are associated with reduced enzyme activity. This assay detects the MTHFR C677T and A1298C mutations. Carriers of two copies of the C677T mutation or carriers of one copy of the C677T and one copy of the A1298C mutation have significantly elevated homocysteine levels and increased risk of cardiovascular disease; however mutation status is not an independent risk factor.

CPT codes: 81291

Respiratory Viral Panel

Test name: Respiratory viral panel by PCR

Order name: RVP BY PCR

Specimen requirements: Nasopharyngeal swab or nasal wash

Minimum volume: 0.5mL nasal wash, NP swab in viral transport media

Storage and stability information: Refrigerated, five days

Test performed: Daily

Methodology: Polymerase Chain Reaction (PCR), Bead array

Reference range: Negative for the respiratory viruses tested

Clinical significance: Respiratory viruses cause acute local and systemic illnesses that range in severity, with the potential to cause severe disease especially in the young and elderly. Respiratory viruses are highly prevalent and are the most common cause of acute illness in the U.S. Viruses tested in this assay include:

- Influenza A – H3 Seasonal Strain
- Influenza A – H1 Seasonal Strain
- Influenza A – No Subtype
- Influenza B
- Respiratory Syncytial Virus Type A
- Respiratory Syncytial Virus Type B
- Parainfluenza 1
- Parainfluenza 2
- Parainfluenza 3
- Rhinovirus
- Adenovirus
- Human Metapneumovirus

CPT codes: 87502, 87503, 87798 x 8

T-cell Gene Rearrangement

Test name: T-cell receptor gene rearrangement, PCR, cell-based

Order name: T-CELL GENE RR

Specimen requirements: EDTA peripheral blood and bone marrow, fresh tissue in RPMI, Formalin-fixed paraffin embedded tissue (FFPE)

Minimum volume: 0.5mL peripheral blood or bone marrow. FFPE: 5–10 10µm thick curls submitted in a clean cup along with stained H&E of same block). If tumor percentage is less than 10% of total nuclei, macrodissection is required, send 5–10 10µm thick unstained slides with stained H&E of same block.

Storage and stability information: Blood and bone marrow (room temperature, one week), fresh tissue (refrigerated, one week), FFPE (room temperature)

Test performed: Once per week

Methodology: Polymerase Chain Reaction (PCR), Capillary Electrophoresis

Reference range: No clonal population detected

Clinical significance: This test is used to aid in the diagnosis of T-cell malignancies, to determine lineage of leukemias and lymphomas for prognosis and treatment selection, and to detect minimal residual disease or recurrent disease.

CPT codes: 81340, 81342

For more information: (800) 324-7853

