

Acute Lymphoblastic Leukemia (ALL) FISH Panel

Methodology: Fluorescence In Situ Hybridization (FISH) Probes: BCR/ABL1 t(9;22), MLL

(11q23), ETV6(TEL)/RUNX1(AML1) t(12;21)

Test Description: The ALL FISH Panel uses probes to detect several translocations seen in B

lymphoblastic leukemia/lymphoma with recurrent genetic abnormalities: BCR/ABL1, MLL, and ETV6(TEL)/RUNX1(AML1). The ETV6/RUNX1 translocation is often undetectable by routine cytogenetics, making FISH a particularly important

tool to exclude this abnormality.

Specimen Requirements: Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or

purple top (EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top

(EDTA) tube.

Storage & Transportation: Store and transport at room temperature.

CPT Code(s): 88377
Level of Service: Global
Turnaround Time: 48-72 hrs

Acute Myeloid Leukemia (AML) FISH Panel

Methodology: FISH

Methodology: Fluorescence In Situ Hybridization (FISH) Probes: RUNX1T1/RUNX1 t(8;21),

PML/RARA t(15;17), inv16 (CBFB), 11q23(MLL)

Test Description: The AML FISH Panel uses probes to detect several abnormalities seen in AML with

recurrent genetic abnormalities: RUNX1T1/RUNX1, PML/RARA, CBFB, and MLL. Abnormalities of CBFB and MLL are often undetectable by routine cytogenetics, making

FISH a particularly important tool for detection.

Specimen Requirements:Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or purple top

(EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top (EDTA) tube.

Storage & Transportation: Store and transport at room temperature.

CPT Code(s): 88377
Level of Service: Global
Turnaround Time: 48-72 hrs

ALK FISH for NSCLC

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: ALK (2p23)

Test Description: This ALK FISH analysis is used to detect ALK rearrangements in non-small cell

lung cancer (NSCLC) to aid in identifying patients eligible for treatment with Xalkori® (crizotinib). See "ALK (2p23) FISH" for ALK testing recommended in

anaplastic large cell lymphoma.

Specimen Requirements: Fresh tissue: 1 cm3 tissue completely immersed in RPMI.

Paraffin block: FFPE block label with patient name & ID number and 1 H&E

stained slide with tumor encircled.

Unstained slides: 3 unstained charged slides and 1 H&E slide cut at 4 microns.

Clearly label with patient name and ID number.

Storage & Transportation:Block or unstained slides: Store and transport at room temperature.

Fresh tissue: Refrigerate until transport; ship with cool pack.

ALK (2p23) FISH

Specimen Requirements:

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: ALK (2p23)

Test Description: The ALK Dual Color, Break Apart Rearrangement Probe is designed to detect the

known ALK (2p23) rearrangements that occur in anaplastic large cell lymphoma

including t(2;5) and its variants.

See "ALK FISH for NSCLC" for ALK testing recommended in non-small cell lung cancer.

Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or

purple top (EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top (EDTA) tube.

Fresh tissue: 1 cm3 tissue completely immersed in RPMI.

Paraffin block: FFPE block label with patient name & ID number and 1 H&E

stained slide with tumor encircled.

Unstained slides: 3 unstained charged slides and 1 H&E slide cut at 4 microns.

Clearly label with patient name and ID number.

Storage & Transportation: BM/PB, block or unstained slides: Store and transport at room temperature.

Fresh tissue: Refrigerate until transport; ship with cool pack.

CPT Code(s): 88377
Level of Service: Global
Turnaround Time: 48-72 hrs

RUNX1/RUNX1T1 (AML1/ETO) t(8;21) FISH

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: RUNX1/RUNX1T1 (AML1/ETO) t(8;21)

Test Description: This test is used to aid in the diagnosis of acute myeloid leukemia with t(8:21

(q22;q22.1);RUNX1-RUNX1T1. This probe is also available as part of the AML FISH Panel.

Specimen Requirements:Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or

purple top (EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top (EDTA) tube.

Storage & Transportation: Store and transport at room temperature.

CPT Code(s): 88377
Level of Service: Global
Turnaround Time: 48-72 hrs

MLL (11q23) FISH

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: MLL (11q23)

Test Description: This probe is used to detect abnormalities in MLL (11q23), which are seen

in MDS, AML, and ALL. Translocations involving MLL are often undetectable by routine cytogenetics, making FISH a particularly important tool for detection. This probe is also available as part of the AML, MDS, and ALL FISH Panels.

Specimen Requirements: Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or

purple top (EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top (EDTA) tube.

Store and transport at room temperature.

CPT Code(s): 88377
Level of Service: Global
Turnaround Time: 48-72 hrs

PML/RARA t(15;17) FISH

Storage & Transportation:

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: PML/RARA t(15;17)

Test Description:This test is used to aid in the diagnosis of acute promyelocytic leukemia with PML-RARA.

This probe is also available as part of the AML FISH Panel.

Specimen Requirements: Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or

purple top (EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top (EDTA) tube.

Storage & Transportation: Store and transport at room temperature.

CPT Code(s): 88377 Level of Service: Global

Turnaround Time: Performed as STAT with preliminary results available 24 Hours from receipt in lab.

CBFB inv(16) FISH

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: CBFB inv(16)

Test Description: This test is used to aid in the diagnosis of acute myeloid leukemia with inv(16)

(p13.1q22) or t(16;16)(p13.1;q22);CBFB-MYH11. This probe is also available as

part of the AML FISH Panel.

Specimen Requirements: Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or

purple top (EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top (EDTA) tube.

Storage & Transportation: Store and transport at room temperature.

CPT Code(s): 88377
Level of Service: Global
Turnaround Time: 48-72 Hours

IGH Gene Rearrangement FISH *

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: IGH (14q32)

Test Description: The IGH Dual Color, Break Apart Rearrangement Probe is designed to detect

chromosomal breakage of the immunoglobulin heavy chain (IGH) locus that is

associated with 14q32 translocations involving multiple other loci.

IGH rearrangements are seen in a variety of lymphoid neoplasms of B-cell origin. This probe is also available as part of the Non-Hodgkin Lymphoma, Large B-Cell

Lymphoma, and Multiple Myeloma Panels.

Specimen Requirements:Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or

purple top (EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top (EDTA) tube.

Storage & Transportation: Store and transport at room temperature.

CPT Code(s): 88377
Level of Service: Global
Turnaround Time: 48-72 hrs

Bladder Cancer Profile FISH

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: CEP 3, CEP 7, 9p21, CEP 17 **Test Description:** UroVysion Bladder Cancer FISH Analysis is designed to detect aneuploidy for

UroVysion Bladder Cancer FISH Analysis is designed to detect aneuploidy for chromosomes 3, 7, 17, and/or loss of the 9p21 locus in urine specimens from patients suspected of having bladder cancer. Results from the UroVysion test are intended for use in conjunction with, but not in lieu of, current standard diagnostic procedures for initial diagnosis of bladder carcinoma in patients with

hematuria and for monitoring for tumor recurrence in patients previously

diagnosed with bladder cancer.

Specimen Requirements: ≥33 ml voided urine, fresh or in PreservCyt vial **Storage & Transportation:** Refrigerate until transport. Frozen unacceptable.

CPT Code(s): 88377

Level of Service:Global Tech Only **Turnaround Time:**48-72 Hours

MYC (8q24) FISH

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: MYC (8q24)

Test Description:The MYC Dual Color Break Apart Rearrangement Probe is intended to detect

chromosomal rearrangements involving the MYC gene on chromosome 8q24. Translocations involving MYC have diagnostic and prognostic importance in B-cell lymphomas including Burkitt lymphoma and high-grade B-cell lymphoma, with MYC and BCL2 and/or BCL6 rearrangements (double/triple-hit lymphomas). This probe is also available as part of the Non-Hodgkin Lymphoma and Large B-Cell

Lymphoma Panels.

Specimen Requirements: Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or

purple top (EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top (EDTA) tube.

Fresh tissue: 1 cm3 tissue completely immersed in RPMI.

Paraffin block: FFPE block labeled with patient name & ID number and 1 H&E stained slide with tumor encircled. Unstained slides: 3 unstained charged slides and 1 H&E Slide cut at 4 microns. Clearly label with patient name and ID number. BM/PB, block or unstained slides: Store and transport at room temperature.

Fresh tissue: Refrigerate until transport; ship with cool pack.

CPT Code(s): 88377
Level of Service: Global
Turnaround Time: 48-72 hrs

Chronic Lymphocytic Leukemia (CLL) FISH Panel

Methodology: Fluorescence In Situ Hybridization (FISH) Probes: 11q22.3 ATM,

Test Description: 13q14.3/D13S25, 17p13.1 P53, CEP12, t(11;14) CCND1/IGH, 6q23.3 MYB
This FISH Panel includes probes to detect various recurrent abnormalities seen in chronic lymphocytic leukemia (CLL) and the CCND1/IGH rearrangement seen

in the vast majority of mantle cell lymphomas. This panel is useful to help establish an initial diagnosis of CLL and exclude mantle cell lymphoma and to assess

important prognostic markers in CLL.

Specimen Requirements: Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or

purple top (EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top (EDTA) tube.

Storage & Transportation: Store and transport at room temperature.

CPT Code(s): 88377, 88367 Level of Service: Global Turnaround Time: 48-72 Hours

BCR/ABL1 t(9;22) FISH

Test Description:

Storage & Transportation:

Methodology: Fluorescence In Situ Hybridization (FISH) Probes: BCR/ABL1/ASS1 t(9;22)

The BCR/ABL1/ASS1 Tri-Color Dual Fusion FISH Probe Kit is used to detect the t(9;22)(q34;q11.2) reciprocal translocation involving the BCR and ABL1 genes . The t(9;22) translocation is the diagnostic hallmark of chronic myeloid leukemia (CML), BCR-ABL1+ but is also seen in a subset of cases of B lymphoblastic leukemia/lymphoma. This analysis includes a probe for the ASS1 gene on chromosome 9, which can help distinguish true rearrangement from random

signal overlap in a subset of cases.

Specimen Requirements: Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or

purple top (EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top (EDTA) tube.

Storage & Transportation: Store and transport at room temperature.

EGFR FISH+

Methodology: Fluorescence In Situ Hybridization (FISH) Probes: EGFR/CEP7

Test Description:This analysis is used to detect abnormalities in the EGFR gene including increased

copy number and amplification, which have been correlated with the development of many solid tumors including non-small cell lung cancer (NSCLC) and colorectal cancers. Assessment of EGFR amplification may be indicated in some tumors to

predict response to anti-EGFR therapy.

Specimen Requirements: Fresh tissue: 1 cm3 tissue completely immersed in RPMI.

Paraffin block: FFPE block labeled with patient name & ID number and 1 H&E

stained slide with tumor encircled.

Unstained slides: 3 unstained charged slides and 1 H&E Slide cut at 4 microns.

Clearly label with patient name and ID number.

Storage & Transportation: BM/PB, block or unstained slides: Store and transport at room temperature.

Fresh tissue: Refrigerate until transport; ship with cool pack.

CPT Code(s): 88377
Level of Service: Global
Turnaround Time: 48-72 hrs

Eosinophilia FISH Panel

Storage & Transportation:

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: PDGFRA, PDGFRB

Test Description: This Panel is used to aid in the diagnosis or exclusion of myeloid and lymphoid

neoplasms with eosinophilia and abnormalities of PDGFRA or PDGFRB. The PDGFRA translocation is often undetectable by routine cytogenetics, making FISH

a particularly important tool to exclude this abnormality.

Specimen Requirements: Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or

purple top (EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top (EDTA) tube.

Store and transport at room temperature.

CPT Code(s): 88374 x 2
Level of Service: Global
Turnaround Time: 48-72 Hours

EWSR1 FISH⁺

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: EWSR1

Test Description: The EWSR1 Dual Color Break Apart Rearrangement Probe is used to aid in the

diagnosis of Ewing sarcoma and other malignancies with EWSR1 rearrangements.

Specimen Requirements: Fresh tissue: 1 cm3 tissue completely immersed in RPMI.

Paraffin block: FFPE block labeled with patient name & ID number and 1 H&E stained slide with tumor encircled. Unstained slides: 3 unstained charged slides and 1 H&E Slide cut at 4 microns. Clearly label with patient name and ID number.

Storage & Transportation: BM/PB, block or unstained slides: Store and transport at room temperature.

Fresh tissue: Refrigerate until transport; ship with cool pack.

IGH/BCL2 t(14;18) FISH

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: IGH/BCL2, t(14;18)

Test Description: The IGH/BCL2 Dual Color, Dual Fusion Translocation Probe is designed to detect

the translocation involving IGH at 14q32 and BCL2 at 18q21, t(14;18)(q32;q21). This rearrangement is found in the majority of follicular lymphomas and in a subset of diffuse large B-cell lymphomas and high-grade B-cell lymphomas, with MYC and BCL2 and/or BCL6 rearrangements (double/triple-hit lymphomas). This probe

is also available as part of the Non-Hodgkin Lymphoma and Large B-Cell

Lymphoma Panels.

Specimen Requirements:Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or

purple top (EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top (EDTA) tube.

Fresh tissue: 1 cm3 tissue completely immersed in RPMI.

Paraffin block: FFPE block labeled with patient name & ID number and 1 H&E

stained slide with tumor encircled.

Unstained slides: 3 unstained charged slides and 1 H&E Slide cut at 4 microns.

Clearly label with patient name and ID number.

Storage & Transportation: BM/PB, block or unstained slides: Store and transport at room temperature.

Fresh tissue: Refrigerate until transport; ship with cool pack.

CPT Code(s): 88377
Level of Service: Global
Turnaround Time: 48-72 hrs

FOXO1 FISH⁺

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: FOX01 (13q14)

Test Description: The FOX01 Dual Color Break Apart Rearrangement Probe is intended to

detect chromosomal rearrangements involving the FOX01 gene on chromosome

13q14, which are characteristic of alveolar rhabdomyosarcoma.

Specimen Requirements: Fresh tissue: 1 cm3 tissue completely immersed in RPMI.

Paraffin block: FFPE block labeled with patient name & ID number and 1 H&E

stained slide with tumor encircled.

Unstained slides: 3 unstained charged slides and 1 H&E Slide cut at 4 microns.

Clearly label with patient name and ID number.

Storage & Transportation:Block or unstained slides: Store and transport at room temperature.

Fresh tissue: Refrigerate until transport; ship with cool pack.

CPT Code(s): 88377
Level of Service: Global
Turnaround Time: 48-72 hrs

HER2 FISH

Methodology: Fluorescence In Situ Hybridization (FISH) Probes: CEP 17, HER2

Test Description: HER2 testing in breast cancer is used to assess prognosis and eligibility for

trastuzumab (Herceptin®) treatment. In gastric cases, it is also used to determine

eligibility for anti-HER2 treatments.

Specimen Requirements: Fresh tissue: 1 cm3 tissue completely immersed in RPMI.

Paraffin block: FFPE block labeled with patient name & ID number and 1 H&E

stained slide with tumor encircled.

Unstained slides: 3 unstained charged slides and 1 H&E Slide cut at 4 microns

Clearly label with patient name and ID number.

Storage & Transportation:Block or unstained slides: Store and transport at room temperature.

Fresh tissue: Refrigerate until transport; ship with cool pack.

HER2 Equivocal FISH

Methodology: Fluorescence In Situ Hybridization (FISH) Probes: CEP 17, RARA, TP53

Test Description: The HER2 Equivocal FISH test is a reflex test utilized when a patient has double

equivocal HER2 results (IHC and FISH). Following current CAP HER2 Testing guidelines, this test uses alternative chromosome 17 probes to recalculate the

HER2 ratio.

Specimen Requirements: Fresh tissue: 1 cm3 tissue completely immersed in RPMI.

Paraffin block: FFPE block labeled with patient name & ID number and 1 H&E

stained slide with tumor encircled.

Unstained slides: 3 unstained charged slides and 1 H&E Slide cut at 4 microns. Clearly label with patient name and ID number. If sending solely as a reflex test, please provide original HER2 FISH results with corresponding H&E to ensure the

analysis is performed on the same tumor area.

Fixation Requirements: 6-72 Hours fixation recommended as per CAP-ASCO guidelines.

Block or unstained slides: Store and transport at room temperature.

Fresh tissue: Refrigerate until transport; ship with cool pack.

CPT Code(s): 88377
Level of Service: Global
Turnaround Time: 48-72 hrs

BIRC3/MALT1 t(11;18) FISH

Storage & Transportation:

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: BIRC3/MALT1, t(11:18)

The API2(BIRC3)/MALT1 Dual Color, Dual Fusion Translocation Probe is designed to detect the translocation involving API2(BIRC3) at 11q21 and MALT1 at 18q21, t(11;18)(q21;q21). This translocation is seen in a subset of extranodal marginal zone lymphomas of mucosa-associated lymphoid tissue (MALT lymphomas) and has been associated with advanced-stage disease and lack of response to H.

pylori eradication in gastric MALT lymphoma. This probe is also available as part of the Non-Hodgkin Lymphoma Panel.

Specimen Requirements: Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or

purple top (EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top (EDTA) tube.

Fresh tissue: 1 cm3 tissue completely immersed in RPMI.

Paraffin block: FFPE block labeled with patient name & ID number and 1 H&E

stained slide with tumor encircled.

Unstained slides: 3 unstained charged slides and 1 H&E Slide cut at 4 microns.

Clearly label with patient name and ID number.

Storage & Transportation: BM/PB, block or unstained slides: Store and transport at room temperature.

Fresh tissue: Refrigerate until transport; ship with cool pack.

CPT Code(s): 88377
Level of Service: Global
Turnaround Time: 48-72 hrs

IGH/MALT1 t(14;18) FISH

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: IGH/MALT1, t(14;18)

Test Description: The IGH/MALT1 Dual Color, Dual Fusion Translocation Probe is designed to

detect the translocation involving IGH at 14q32 and MALT1 at 18q21, t(14;18) (q32;q21). This translocation is seen in a subset of extranodal marginal zone lymphomas of mucosa-associated lymphoid tissue (MALT lymphomas). This probe is also available as part of the Non-Hodgkin Lymphoma Panel.

Specimen Requirements: Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or

purple top (EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top (EDTA) tube.

Fresh tissue: 1 cm3 tissue completely immersed in RPMI.

Paraffin block: FFPE block labeled with patient name & ID number and 1 H&E

stained slide with tumor encircled.

Unstained slides: 3 unstained charged slides and 1 H&E Slide cut at 4 microns.

Clearly label with patient name and ID number.

Storage & Transportation: BM/PB, block or unstained slides: Store and transport at room temperature.

Fresh tissue: Refrigerate until transport; ship with cool pack.

CCND1 (BCL1)/IGH t(11;14) FISH

Test Description:

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: CCND1 (BCL1)/IGH t(11;14)

The CCND1(BCL1)/IGH Dual Color, Dual Fusion Translocation Probe is designed to detect the translocation involving CCND1(BCL1) at 11q13 and IGH at 14q32, t(11;14)(q13;q32). This translocation is seen in the vast majority of mantle cell lymphomas but is generally not seen in other B-cell lymphomas. This translocation is also seen in a subset of plasma cell myelomas. This probe is also available as

part of the CLL and Non-Hodgkin Lymphoma Panels.

Specimen Requirements: Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or

purple top (EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top (EDTA) tube.

Fresh tissue: 1 cm3 tissue completely immersed in RPMI.

Paraffin block: FFPE block labeled with patient name & ID number and 1 H&E

stained slide with tumor encircled.

Unstained slides: 3 unstained charged slides and 1 H&E Slide cut at 4 microns.

Clearly label with patient name and ID number.

Storage & Transportation: BM/PB, block or unstained slides: Store and transport at room temperature.

Fresh tissue: Refrigerate until transport; ship with cool pack.

CPT Code(s): 88377
Level of Service: Global
Turnaround Time: 48-72 hrs

Large B-Cell Lymphoma FISH Panel

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: MYC (8q24), IGH/BCL2 t(14;18),

BCL6 (3q27), IGH (14q32)

Test Description: This panel can detect several common translocations seen in large B-cell

lymphomas and is useful to evaluate for high-grade B-cell lymphoma, with MYC

and BCL2 and/or BCL6 rearrangements (double/triple-hit lymphomas),

Specimen Requirements: Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or

purple top (EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top (EDTA) tube.

Fresh tissue: 1 cm3 tissue completely immersed in RPMI.

Paraffin block: FFPE block labeled with patient name & ID number and 1 H&E

stained slide with tumor encircled.

Unstained slides: 3 unstained charged slides and 1 H&E Slide cut at 4 microns

Clearly label with patient name and ID number.

Storage & Transportation: BM/PB, block or unstained slides: Store and transport at room temperature.

Fresh tissue: Refrigerate until transport; ship with cool pack.

CPT Code(s): 88377
Level of Service: Global
Turnaround Time: 48-72 hrs

Melanocytic Differentiation FISH Panel

Methodology: Fluorescence In Situ Hybridization (FISH) Probes: RREB1, CEP 6, MYB, CCND1

Test Description:This panel is used to detect copy number gains of the RREB1 (6p region) and CCND1 (11q region) genes as well as copy number loss of the MYB (6q region).

Detection of these abnormalities can help distinguish melanomas from nevi.

Specimen Requirements: Fresh tissue: 1 cm3 tissue completely immersed in RPMI.

Paraffin block: FFPE block labeled with patient name & ID number and 1 H&E

stained slide with tumor encircled.

Unstained slides: 3 unstained charged slides and 1 H&E Slide cut at 4 microns.

Clearly label with patient name and ID number.

Storage & Transportation: BM/PB, block or unstained slides: Store and transport at room temperature.

Fresh tissue: Refrigerate until transport; ship with cool pack.

Multiple Myeloma FISH Panel

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: D5S23, CEP 9, CEP 15,

CEP11, TP53, 13q14.3/D13S25, IGH

Test Description: This panel is used to detect common abnormalities seen in multiple myeloma

(plasma cell myeloma), which are often undetectable by routine cytogenetics. Detection of one or more of these abnormalities can help to establish a diagnosis of myeloma and provide prognostic information. The Multiple Myeloma Reflex Panel is recommended when IGH rearrangement is detected to determine the

specific fusion partner and prognostic implications.

Specimen Requirements: Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or

purple top (EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top (EDTA) tube.

Storage & Transportation: Store and transport at room temperature.

CPT Code(s): 88377
Level of Service: Global
Turnaround Time: 48-72 hrs

Multiple Myeloma Reflex FISH Panel (IGH Fusions)

Methodology: Fluorescence In Situ Hybridization (FISH)

Probe: CCND1 (BCL1)/IGH, FGFR3/IGH, IGH/MAF

Test Description: This panel is mainly used to help determine the specific fusion partner and

prognostic implications when an IGH rearrangement is detected in the Multiple Myeloma FISH Panel, although the panel can also be ordered as a stand-alone test if clinically indicated. The common IGH fusion partners that can be detected

include CCND1 (11q13), FGFR3 (4p16.3), and C-MAF (16q23).

Specimen Requirements:Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or

purple top (EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top (EDTA) tube.

Storage & Transportation: Store and transport at room temperature.

CPT Code(s): 88377
Level of Service: Global
Turnaround Time: 48-72 hrs

Myelodysplastic Syndrome (MDS) FISH Panel

Methodology: Fluorescence In Situ Hybridization (FISH)

Probes: EGR1, 7q31/del7q, CEP8, 20q12, MLL

Test Description: This panel is used to detect common abnormalities seen in myelodysplastic

syndromes (MDS) and other myeloid neoplasms, including gain of chromosome 8, deletion of chromosome 7/7q, deletion of chromosome 5/5q, deletion of chromosome 20q, and deletion of chromosome 11q. Detection of one or more of

these abnormalities can help to establish a diagnosis of MDS and provide

prognostic information.

Specimen Requirements:Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or

purple top (EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top (EDTA) tube.

Storage & Transportation: Store and transport at room temperature.

BCL6 (3q27) FISH

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: BCL6

Test Description: The BCL6 Dual Color, Break Apart Rearrangement Probe is used to detect

translocations involving the BCL6 gene. BCL6 translocations are seen in

diffuse large B-cell lymphoma; high-grade B-cell lymphoma, with MYC and BCL2 and/or BCL6 rearrangements; and other B-cell lymphoproliferative disorders. This probe is also available as part of the Non-Hodgkin Lymphoma and Large B-Cell

Lymphoma Panels.

Specimen Requirements: Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or

purple top (EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top (EDTA) tube.

Fresh tissue: 1 cm3 tissue completely immersed in RPMI.

Paraffin block: FFPE block labeled with patient name & ID number and 1 H&E stained slide with tumor encircled. Unstained slides: 3 unstained charged slides and 1 H&E Slide cut at 4 microns. Clearly label with patient name and ID number. BM/PB, block or unstained slides: Store and transport at room temperature.

Storage & Transportation:BM/PB, block or unstained slides: Store and transport at room Fresh tissue: Refrigerate until transport; ship with cool pack.

CPT Code(s): 88377
Level of Service: Global
Turnaround Time: 48-72 hrs

Non-Hodgkin Lymphoma FISH Panel

Methodology: Fluorescence In Situ Hybridization (FISH)

Probes: ALK, IGH, BCL6, MYC, CCND1/IGH, IGH/BCL2, BIRC3/MALT1, IGH/MALT1, Test Description:

The Non-Hodgkin Lymphoma FISH Panel includes probes to detect a range of

The Non-Hodgkin Lymphoma FISH Panel includes probes to detect a range of recurrent genetic abnormalities seen in non-Hodgkin lymphoma that are useful for

diagnosis and subclassification.

Specimen Requirements: Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or

purple top (EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top (EDTA) tube.

Fresh tissue: 1 cm3 tissue completely immersed in RPMI.

Paraffin block: FFPE block labeled with patient name & ID number and 1 H&E

stained slide with tumor encircled.

Unstained slides: Min14 unstained charged slides and 1 H&E Slide cut at 4 microns.

Clearly label with patient name and ID number.

Storage & Transportation: BM/PB, block or unstained slides: Store and transport at room temperature.

Fresh tissue: Refrigerate until transport; ship with cool pack.

CPT Code(s): 88377
Level of Service: Global
Turnaround Time: 48-72 hrs

PDGFRA FISH

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: FIP1L1/CHIC2/PDGFRA

Test Description: The FIP1L1/CHIC2/PDGFRA FISH Deletion/Fusion Probe is used to aid in the

diagnosis or exclusion of myeloid and lymphoid neoplasms with PDGFRA rearrangement, which are associated with eosinophilia. The PDGFRA rearrangement is often undetectable by routine cytogenetics, making FISH a particularly important tool for detection. This probe is also available as part of the

Eosinophilia Panel.

Specimen Requirements: Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or

purple top (EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top (EDTA) tube.

Storage & Transportation: Store and transport at room temperature.

PDGFRB FISH

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: PDGFRB

Test Description: This analysis is used to aid in the diagnosis or exclusion of myeloid neoplasms

with PDGFRB rearrangement, which are associated with eosinophilia. This probe

is also available as part of the Eosinophilia Panel.

Specimen Requirements: Bone marrow aspirate: Minimum 2 ml in green top (sodium heparin) tube or

purple top (EDTA) tube.

Peripheral blood: Minimum 5 ml in green top (sodium heparin) or purple top (EDTA) tube.

Storage & Transportation: Store and transport at room temperature.

CPT Code(s): 88377 Level of Service: Global **Turnaround Time:** 48-72 hrs

Prostate FISH Panel (PROSTACOMP)

Methodology: Fluorescence In Situ Hybridization (FISH)

Probes: PTEN, TMPRSS2/ERG

Test Description: This analysis is used to detect PTEN deletion and TMPRSS2:ERG rearrangement,

which have been associated with adverse prognosis in prostate cancer...

Fresh tissue: 1 cm3 tissue completely immersed in RPMI. **Specimen Requirements:**

> Paraffin block: FFPE block labeled with patient name & ID number and 1 H&E stained slide with tumor encircled. Unstained slides: Minimum 4 unstained charged slides and 1 H&E Slide cut at 4 microns. Clearly label with patient name

and ID number.

Storage & Transportation: Block or unstained slides: Store and transport at room temperature.

Fresh tissue: Refrigerate until transport; ship with cool pack.

CPT Code(s): 88377 Level of Service: Global **Turnaround Time:** 48-72 hrs

ROS1 FISH

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: ROS1

Test Description: This analysis is used to detect rearrangement of the ROS1 gene, which occurs in

1-2% of non-small cell lung cancer and is associated with responsiveness to

treatment with Xalkori® (crizotinib).

Specimen Requirements: Fresh tissue: 1 cm3 tissue completely immersed in RPMI.

> Paraffin block: FFPE block labeled with patient name & ID number and 1 H&E stained slide with tumor encircled. Unstained slides: 3 unstained charged slides and 1 H&E Slide cut at 4 microns. Clearly label with patient name and ID number.

Storage & Transportation: Block or unstained slides: Store and transport at room temperature.

Fresh tissue: Refrigerate until transport; ship with cool pack.

CPT Code(s): 88377 Level of Service: Global **Turnaround Time:** 48-72 hrs

Synovial Sarcoma SS18 (SYT) FISH+

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: SS18 (SYT)

Test Description: The SS18 Dual Color Break Apart Rearrangement Probe is intended to detect

chromosomal rearrangements involving the SS18 (SYT) gene on chromosome

18g11.2, which are characteristic of synovial sarcoma. Fresh tissue: 1 cm3 tissue completely immersed in RPMI.

Specimen Requirements: Paraffin block: FFPE block labeled with patient name & ID number and

1 H&E stained slide with tumor encircled.

Unstained slides: 3 unstained charged slides and 1 H&E Slide cut at 4 microns.

Clearly label with patient name and ID number.

Storage & Transportation: Block or unstained slides: Store and transport at room temperature.

Fresh tissue: Refrigerate until transport; ship with cool pack.

Cervical Cancer TERC FISH

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: TERC/CEN3

Test Description:This analysis is used to detect increases in the copy number of the telomerase

component gene (TERC) in cervical cytology specimens. Detection of such abnormalities can help determine which patients with low-grade or atypical Pap test results have an increased risk of high-grade cervical intraepithelial neoplasia

or invasive carcinoma.

Specimen Requirements: Cervical brushing: Submit sample in Thinprep Cytolyt collection container.

Unstained slides: Minimum 2 ThinPrep slides.

Storage & Transportation: Cervical brushing: Store refrigerated, and ship with cool pack .Unstained slides:

Store and transport at room temperature.

CPT Code(s): 88377
Level of Service: Global
Turnaround Time: 48-72 hrs

TOP2A FISH (Breast Carcinoma) +

Methodology: Fluorescence In Situ Hybridization (FISH) Probe: TOP2A

Test Description: The topoisomerase II-α (TOP2A) FISH test is used to detect amplifications and

deletions of the TOP2A gene. These abnormalities have been associated with responsiveness to anthracycline-based chemotherapy in breast carcinoma.

Specimen Requirements: Fresh tissue: 1 cm3 tissue completely immersed in RPMI.

Paraffin block: FFPE block labeled with patient name & ID number and 1 H&E

stained slide with tumor encircled.

Unstained slides: 3 unstained charged slides and 1 H&E

Storage & Transportation:
Slide cut at 4 microns. Clearly label with patient name and ID number.
Block or unstained slides: Store and transport at room temperature.

Fresh tissue: Refrigerate until transport; ship with cool pack.