Global testing will be performed unless otherwise noted

Billings, MT 59101

Solid Tumor Test Menu

Breast Carcinoma

- Basic Breast Panel (ER, PR, HER2 (ISH))
- Extended Breast Panel
  (ER, PR, HER2 (ISH), p53, Ki-67)
- HER2 (ISH)
  - Reflex to HER2 (IHC) if results is ◦ Non-Amplified ◦ Equivocal.
  - ER/PR
  - Breast Tumor Profile
    (BRAF, c-KIT, EGFR, PIK3CA, TP53, HER2 (ISH))

Colorectal Carcinoma

- MSI Evaluation (Comprehensive Guideline Based Algorithm)
- KRAS Mutation Analysis
  - Reflex to BRAF if KRAS is negative
  - BRAF Mutation Analysis
  - Mismatch Repair/MMR (HIC)

- Reflex to MS (PCR) if any marker in panel is not expressed
- Reflex to BRAF if MLH-1 is not expressed
- MLH1-Methylation (PCR)
- Colorectal Tumor Profile
  (BRAF, c-KIT, DNM3, EGFR, IDH1, IDH2, KRAS, NRAS, PIK3CA, TP53, MSI)

All Cancer Types:

- NeoARRAY™ SNP/Cytogenetic Profile
- NeoTYPE™ Solid Tumor (Other) Profile
  - BRAF, c-KIT, EGFR, KRAS, NRAS, PIK3CA, TP53, Other Tests (please specify)
  - NeoARRAY™ SNP/Cytogenetic Profile
  - NeoTYPE™ Solid Tumor (Other) Profile

Gastric Carcinoma

- HER2 (ISH)
  - Reflex to HER2 (IHC) if results is ◦ Non-Amplified ◦ Equivocal.
  - Gastric Tumor Profile
    (BRAIN, c-KIT, DNM3, EGFR, IDH1, IDH2, KRAS, NRAS, PIK3CA, TP53, HER2 (ISH))

Lung Cancer

- Lung Tumor Reflex Profile
  (KRAS with reflex to EGFR and ALK, if indicated)
- EGFR Mutation (PCR)
  - Reflex to ALK (FISH) if KRAS is negative
- ALK (FISH)
  - Reflex to ROS1 (FISH) if ALK is negative
- ROS1 (FISH)
  - Extended Lung Tumor Profile
    (BRAIN, c-KIT, DNM3, EGFR, IDH1, IDH2, KRAS, NRAS, PIK3CA, TP53, ALK (ISH))
Specimen Requirements

- Bone Marrow Core / 1-2 cm Minimum core length in 10% Neutral Buffered Formalin or FFPE Block Cassette.
- Bone Marrow Aspirate / clot / placed in 10% Neutral Buffered Formalin or FFPE Block Cassette.

Flow Cytometry (Please provide recent CBC)

- Bone Marrow Aspirate / 1-2 mL minimum in EDTA (purple top) tube preferred. 2-5 mL minimum in Sodium Heparin tube (green top) or ACDA (pale yellow / no gel separator) is acceptable. Please provide recent CBC report.
- Peripheral Blood / 1-2 mL minimum in EDTA (purple top) tube preferred. 2-5 mL minimum in Sodium Heparin tube (green top) or ACDA (pale yellow / no gel separator) is acceptable. Please provide recent CBC report.
- Bone Marrow Core / 1-2 cm Minimum core length in RPMI.
- Fresh Tissue / Two pieces tissue 0.2 cm3 minimum in RPMI.
- Fluids / FNAs / Equal parts RPMI and specimen volume.

Cytogenetics

- Bone Marrow Aspirate / 1-2 mL Minimum in Sodium Heparin tube (green top).
- Must provide EDTA tube (purple top) in addition to Sodium Heparin tube (green top) when ordering AML Reflex.*
- Peripheral Blood / 2-5 mL Minimum in Sodium Heparin (green top) tube preferred. 1-2 mL minimum in EDTA tube (purple top) is acceptable.
- Bone Marrow Core / 1-2 cm Minimum core length in RPMI.
- Fresh Tissue / Two pieces tissue 0.2 cm3 Minimum in RPMI.
- Fluids / Equal parts RPMI and specimen volume; FNAs / Minimum 5 mL RPMI with specimen.

Molecular Genetics

- BCR-ABL1 Reflex to ABL1 / ABL1 Kinase Domain Mutation will be run when BCR-ABL1 is positive.
- JAK2 Exon 12 (Ref. to JAK2 exon 12:14) will be run when V617F is negative.
- MPN Standard Reflex Panel: JAK2 V617F is run first. JAK2 Exon 12:14 will be run when V617F is negative. MPL will be run when JAK2 exon 12:14 is negative.

NeoTYPE™ Profiles

- NeoTYPE™ AML Prognostic Profile: CEBPA, DNMT3A, F3L1, IDH1 & IDH2, NPM1, RUNX1, WT1
- NeoTYPE™ Breast Tumor Profile: BRAF, c-KIT, EGFR, PIK3CA, PTK7, PTOC, FISH, PTOC Molecular, TP53, HER2 FISH
- NeoTYPE™ CLL Prognostic Profile: CLL FISH Panel, IgVH, NOTCH1, SF3B1, ZAP-70 (FLOW)
- NeoTYPE™ Gastric Tumor Profile: BRAF, c-KIT, DNMT3A, EGFR, IDH1, IDH2, KRAS, NRAS, PIK3CA, PTK7, PTOC, FISH, PTOC Molecular, TP53, MSI
- NeoTYPE™ Lymphoma Profile: BCL2, BCL3, BCL6, BCL11B, CD79A, CD79B, CD10, CD20, CD22, CD70, CD270, CEP150, CEP170, CEP171, FISH
- NeoTYPE™ Myelodysplastic Syndrome Profile: SF3B1, SRSF2, TET2, TP53, U2AF, SRSF2
- NeoTYPE™ Solid Tumor (Other) Profile: BRAF, DNMT3A, EGFR, IDH1, IDH2, KIT, KRAS, NRAS, PIK3CA, PTK7, PTOC, FISH, PTOC Molecular, TP53

Test Descriptions and Notations

Flow Cytometry

- *YHI offers an adaptive and inclusive menu of markers which are selected for use depending on the sample type, sample volume, and clinical information provided.
- *ZIP-70 performed by HC (soon to be performed by flow cytometry).

Cytogenetics

- *Reflex to NeoTYPE Concise AML Prognostic Profile: Intermediate risk cytogenetics in AML, defined by SWOG/ECOG criteria as normal cytogenetics, 6q- or del(6q) will automatically refer to molecular testing. Must provide EDTA tube (purple top) in addition to Sodium Heparin tube (green top) when ordering AML Reflex.
- NeoTYPE AML Prognostic: CEBPA, DNMT3A, F3L1, IDH1, IDH2, NPM1, NRAS, interpretation.

FISH

- MM/MGSUS & High Risk MM Panels: May include plasma cell enrichment on specimens of sufficient cellularity. Sample should be received at NeoGenomics Laboratories within 48 hours of collection.

Common ICD-9 Codes

- 203.00 Multiple Myeloma
- 204.00 Primary Lymphoid Leukemia (AL)
- 204.10 Chronic Lymphocytic Leukemia (CLL)
- 205.00 Acute Myeloid Leukemia (AML)
- 205.10 Chronic Myeloid Leukemia (CML)
- 205.80 Other Myeloid Leukemia
- 205.90 Myelodysplastic Syndrome, Unspecified
- 208.00 Leukemia, Acute NEC
- 208.10 Leukemia, Chronic NEC
- 208.20 Leukemia, Chronic/Unspecified
- 237.31 Monoclonal Gammopathy
- 238.41 Plasma Cell Leukemia
- 238.80 Leukemia, Acute NEC
- 238.90 Leukemia, Chronic NEC
- 243.71 Chronic Lymphocytic Leukemia
- 243.72 Chronic Myelogenous Leukemia
- 243.73 Myelodysplastic Syndrome
- 243.74 Myeloblastic Leukemia
- 243.75 Myelogenous Leukemia
- 243.76 Myeloproliferative Disease
- 243.77 Myeloproliferative Neoplasm
- 243.78 Myeloproliferative Disorder
- 243.79 Myeloproliferative Syndrome
- 243.80 Myeloproliferative Neoplasm
- 243.81 Myeloproliferative Neoplasm
- 243.82 Myeloproliferative Neoplasm
- 243.83 Myeloproliferative Neoplasm
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- 243.97 Myeloproliferative Neoplasm
- 243.98 Myeloproliferative Neoplasm
- 243.99 Myeloproliferative Neoplasm

Additional Billing Information

- Any organization referring specimens for testing services pursuant to this Requisition form ("Client") expressly agrees to the following terms and conditions.
- Third Party Billing by NeoGenomics and Yellowstone Pathology Institute, Inc. for Tests, NeoGenomics and Yellowstone Pathology Institute, Inc. shall, whenever possible and permitted by law, directly bill and collect from all insurers, health care services plans (e.g., health maintenance organizations), federal or state health programs (including Medicare and Medicaid), and other third party payers (collectively, the "Third Party Payers"), for all testing services ordered from NeoGenomics and Yellowstone Pathology Institute, Inc pursuant to this Requisition Form ("Services"). Client agrees that NeoGenomics and Yellowstone Pathology Institute, Inc shall be responsible for billing (i) the professional component of all Services to Medicare, and (ii) global Services to any and all commercial insurance payers unless NeoGenomics and Yellowstone Pathology Institute, Inc and Client agree otherwise for certain insurance payers due to contractual limitations or in other mutually agreed upon special situations. Client further agrees that, except for those tests or portions of tests which should be billed back to Client as described below (Client Billing for Certain Tests), Client will indicate on the Requisition Form that NeoGenomics and Yellowstone Pathology Institute, Inc should bill the appropriate Third Party Payer directly for any such tests or portions of tests, and will provide NeoGenomics and Yellowstone Pathology Institute, Inc all Billing information necessary to bill Third Party Payers for the professional component Services ordered even if the technical component Services are to be billed back to the Client.
- Right to Bill Client in the Event that Billing Information is Not Provided or in the Case of Uninsured Patients. In the event NeoGenomics does not receive the Billing Information requested for it to bill any Third Party-Billed Tests within ten (10) days of the date that any such test is reported by NeoGenomics or the tests were performed for patients that have no Third Party Payer coverage arrangements, NeoGenomics shall have the right to bill such tests to Client. In the event that Client subsequently provides NeoGenomics with Billing Information for such tests before paying the related invoice, then Client may pay the invoiced amount less any amounts for tests in which Billing Information was subsequently provided.