Cancer Microarray Analysis
also known as: Cancer Array

TEST DESCRIPTION:
The current Cancer Microarray is a high density single nucleotide polymorphism (SNP) platform designed to interrogate the whole genome at resolution much higher than is possible using traditional karyotyping or fluorescence in situ hybridization (FISH) methodologies. Our High Density SNP array contains a total of 2.6 million markers distributed throughout the genome for the detection of both genomic dosage anomalies (deletions and duplications) and regions of homozygosity (ROH; regions lacking typical amounts of genetic variation). This marker density provides a global resolution of 10 Kb to 20 Kb for copy number changes and 5 Mb resolution for ROH. This microarray is designed to identify two types of genetic changes associated with neoplasm: copy number changes associated with chromosomal deletions and duplications and copy neutral loss of heterozygosity (LOH) associated with loss of genetic variation in the absence of a net loss of genetic material. Detection of LOH is particularly useful in regions of the genome that contain oncogenes and tumor suppressor genes.

TEST DETAILS and COMPLEMENTARY TESTING:
- Cancer Microarray is a test following (or used in conjunction with) Chromosome Analysis and/or FISH of diagnostic bone marrow, cancer blood, lymph node, or tumor tissue specimens.
- Cancer Microarray testing is available for all hematologic malignancies. It can provide both diagnostic and prognostic information. At this time, we are recommending a diagnosis-specific approach to testing.
  - We recommend cancer microarray testing be performed upon initial receipt of the specimen when the testing indication is ALL. We make this testing recommendation for the following reasons:
    - This disease largely affects the pediatric population.
    - This technology identifies prognostically important genetic changes, including hypodiploid clones and deletions/duplications at the breakpoints of chromosomal rearrangements.
    - The hyperdiploid abnormalities identified in the diagnostic specimen by routine cytogenetics and FISH are often absent in follow-up specimens.
  - We recommend cancer microarray testing be performed in a reflex manner for cases with a testing indication of CLL, CML, AML, or NHL. The following scenarios would warrant this reflex testing:
    - Normal routine cytogenetic analysis for any of the above described testing indications.
    - Identification of a sole abnormality routine cytogenetic analysis in cases of AML.

ADVANTAGES:
- Circumvents the limitations of routine cytogenetics and selective FISH panel analyses.
- Using only one methodology, this assay provides genome-wide assessment of copy number changes and LOH frequently observed in cancer.
- Provides potentially diagnostic and prognostic information, including cases with low mitotic indexes.
- Interrogates known and novel disease-associated regions of the genome at a higher resolution than routine cytogenetics and FISH testing and is often useful for cases with normal findings by these traditional methodologies.
- Identifies loss of heterozygosity (LOH) in regions of the genome that contain tumor suppressor genes.
- Able to detect low-level mosaicism (>10%) in dividing and non-dividing cells.

LIMITATIONS:
- This platform is unable to detect balanced translocations or the location of duplicated or rearranged segments.
- This platform cannot identify sequence-based mutations.
- The improved resolution of this assay may generate information about copy number changes or LOH in regions of the genome that are not currently well understood. Therefore, some of the aberrations identified with this assay may not be useful in medical management at this time.
INDICATIONS FOR TESTING:
- Hematologic malignancies, specifically AML, ALL, CLL, CML, and NHL

SPECIMEN COLLECTION & TRANSPORT:
Complimentary test kits are available upon request, but are not required.

SAMPLE TYPES and REQUIREMENTS:
FRESH
- **blood [cancer]**: 3-5 ml whole blood in a sodium heparin tube (green top)
- **bone marrow**: 1.5-3 ml bone marrow in a sodium heparin tube (green top)
  - Collect marrow from 1st or 2nd aspirate using a sodium-heparinized syringe
- **lymphatic tissue/node**: ≥5 mm³ collect, store, and transport in tissue culture media – room temperature
- **solid tumor tissue**: ≥5 mm³ representative tumor tissue / collect, store, and transport in tissue culture media – room temperature

FIXED (any specimen type)
- **tissue, paraffin embedded**: 5-10 dissected cores from selected malignant region

SHIPPING:
- Maintain and ship samples at room temperature.
- Coordinate transport for sample to be received in our laboratory within 24-48 hours of collection.
  - **LOCAL**: Call 402-559-5070 (option 1)
  - **OUT OF AREA**: Prior to shipment, please fax the completed test request form to 402-559-7248, including the FedEx® airbill tracking number.
    - Saturday delivery MUST be checked when sending FedEx® on Friday.
    - Please include Internal Billing Reference # 3155070600 on the FedEx® airbill.
    - **Ship To**: Human Genetics Laboratory – Zip 5440
      UNMC Shipping & Receiving Dock
      601 S. Saddle Creek Road
      Omaha, NE 68106

FORMS FOR TESTING: The following forms can be downloaded via our website.
- **Required**: Oncology Test Request Form
- **Optional**: Informed Consent for Genetic Testing

POTENTIAL TEST RESULTS:
For either type of genetic change observed (copy number change or LOH), the following designation will be made:

NORMAL:
- A normal or negative result indicates that no potentially pathogenic copy number changes or regions of LOH were identified.

ABNORMAL:
- An abnormal / pathogenic or positive result indicates that microarray identified one or more clinically-significant copy number change or region of LOH. In most cases, these abnormalities will include aberrations in known oncogenes or tumor suppressor genes.
- In some cases, the clinical significance of a copy number change or regions of LOH which were identified in areas of the genome that may have well-characterized roles in pathogenesis. These anomalies will be reported as variants of uncertain clinical significance. As the number of cases studied by microarray increases over time, these uncertain results may be better classified as normal or abnormal.
- In some cases, microarray may identify non-neoplastic genetic changes that may have consequences for the patient and his/her medical management. These unexpected results will be reported.
- In some circumstances, a sample may not contain sufficient DNA and a result will be unavailable.
TURNAROUND TIMES: Results are typically available in 1-2 weeks when performed on bone marrow; 7-10 days when performed on cancer blood, lymphatic tissue/node, and solid tumor tissue; and 2-3 weeks when performed on paraffin embedded tissue.

BILLING: Our laboratory offers patient/self-pay, insurance (including Medicare/Medicaid), and client/institution billing options. Verifying coverage requirements or obtaining preauthorization PRIOR TO OR AT THE TIME OF SPECIMEN COLLECTION is often necessary. We provide preauthorization services upon request by calling 402-559-5070 (option 3); the following form is helpful for obtaining the information required by insurance providers and can be downloaded via our website.

- Request for Pre-Authorization

In some circumstances, a test may be warranted even though insurance coverage is denied or not guaranteed. For these situations, we request the following form be signed by the patient and submitted with the sample. This helps inform patients of their potential financial responsibility, should the costs of genetic testing not be paid by their insurance provider.

- Advanced Beneficiary Notice of Noncoverage (ABN) – required when billing Medicare

CPT CODES:

- blood [cancer], bone marrow, and core: 81406, 88237
- lymph node / solid tumor tissue: 81406, 88239
- tissue, paraffin embedded: 81406

PRICING: For current costs contact the laboratory billing staff at 402-559-5070 (option 3).

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