

## Laboratory:

DermPath Molecular Diagnostic Laboratory

## Referral Laboratory:

## Soft Order Code:

MDPAT

**CPT Code:** 81406

## Synonyms:

Chromosomal Microarray Analysis, Tumor; Microarray CGH, Tumor

## Offsite Collection:

1. **Tissue rolls:** If examination of a representative H&E tissue section reveals that more than 50% of the cells are tumor cells, 10 FFPE tissue rolls cut at 10-micron thickness in a clean 1.5 ul tube are required. If the surface of the tissue section is above 0.5 cm<sup>2</sup>, 5 tissue rolls at 10-micron thickness are sufficient. For cases with very small amounts of tissue, it may be necessary to cut more than ten 10-micron sections to ensure the presence of sufficient material from which to extract DNA. Avoid exhausting the FFPE block whenever possible. One serial H&E is also obtained to assess specimen adequacy. Cases in which the percentage of tumor cells is less than 30% or the tumor area is less than 1mm<sup>2</sup> are not suitable for CGH.

2. **Unstained slides:** If examination of a representative H&E tissue section reveals that more than 50% of the cells are tumor cells, 10 FFPE serial unstained sections at 10-microns thickness on regular slides and one H&E slide are required. The tumor area is marked by a certified pathologist to ensure a minimum of 30% tumor purity in the sample. While 10-micron thick sections are preferred, 4-micron sections are acceptable. The tissue in the marked area is micro-dissected from the slide with a sterile scalpel and placed in a 1.5 ml tube. Cases in which the

percentage of tumor cells is less than 30% in the area to be micro-dissected or the tumor area is less than 1mm<sup>2</sup> are not suitable for CGH.

**3. DNA yield:** Samples with total DNA yield and concentration above 80ng and 12ng/ul, respectively, are acceptable. Samples with total DNA yield less than 80ng and concentration less than 12ng/ul will be rejected due to the minimum DNA sample input and volume requirements of CGH. For those samples with total DNA yield below 80ng but with concentration less than 12ng/ul, a concentration step is included in the protocol.

### **Onsite Collection (UMHS Hospitals Only):**

**1. Tissue rolls:** If examination of a representative H&E tissue section reveals that more than 50% of the cells are tumor cells, 10 FFPE tissue rolls cut at 10-micron thickness in a clean 1.5 ul tube are required. If the surface of the tissue section is above 0.5 cm<sup>2</sup>, 5 tissue rolls at 10-micron thickness are sufficient. For cases with very small amounts of tissue, it may be necessary to cut more than ten 10-micron sections to ensure the presence of sufficient material from which to extract DNA. Avoid exhausting the FFPE block whenever possible. One serial H&E is also obtained to assess specimen adequacy. Cases in which the percentage of tumor cells is less than 30% or the tumor area is less than 1mm<sup>2</sup> are not suitable for CGH.

**2. Unstained slides:** If examination of a representative H&E tissue section reveals that more than 50% of the cells are tumor cells, 10 FFPE serial unstained sections at 10-microns thickness on regular slides and one H&E slide are required. The tumor area is marked by a certified pathologist to ensure a minimum of 30% tumor purity in the sample. While 10-micron thick sections are preferred, 4-micron sections are acceptable. The tissue in the marked area is micro-dissected from the slide with a sterile scalpel and placed in a 1.5 ml tube. Cases in which the percentage of tumor cells is less than 30% in the area to be micro-dissected or the tumor area is less than 1mm<sup>2</sup> are not suitable for CGH.

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sample input and volume requirements of CGH. For those samples with total DNA yield below 80ng but with concentration less than 12ng/ul, a concentration step is included in the protocol.

**Days Set Up:**

Monday – Friday , 8:30am - 5:30pm

**Analytic Time:**

3 weeks

**Test Methodology:**

SNP microarray analysis is performed using the Affymetrix OncoScan (TM) FFPE Assay Kit for the sole purpose of identifying DNA copy number gains and losses and regions of loss of heterozygosity. The assay utilizes Molecular Inversion Probe (MIP) technology, which is optimized for highly degraded FFPE samples (probe interrogation site of just 40 base pairs). For copy numbers the assay has a resolution of 50-100 kb copy in selected 900 cancer genes and of 300 kb outside of the cancer genes. The detection threshold for mosaicism is variable, depending on the size of the segment. CNV cited in the Database of Genomic Variants are not reported. Gains and losses that include a known clinically significant cancer gene, or are greater than 3Mb outside clinical oncology significant regions, and loss of heterozygosity greater than 10Mb are reported. The analysis is based on the GRCh37 assembly.

**Reference Range:**

\*Reference ranges may change over time. Please refer to the original patient report when evaluating results.

Interpretive report provided.

**Test Usage:**

This microarray assay detects DNA copy number gains (including amplification) and losses as well as regions of copy neutral loss of heterozygosity (CN-LOH) by SNP analysis. This assay is particularly useful for detecting malignant conditions in FFPE tissues which usually generate degraded DNA and low DNA yield. At least 30% malignant cells must be present in the sample submitted for Chromosomal Microarray Analysis for Tumor assay.

**Contraindications:**

Chromosomal Microarray Analysis for Tumor assay should not be ordered for follow-up studies to determine remission status or presence of minimal residual disease.

**Test Limitations:**

Although SNP Array is a powerful diagnostic tool for the evaluation of chromosomal copy number changes, this assay will not detect balanced chromosomal aberrations, imbalance of regions not represented on the microarray. Although copy number changes present at 20% of cells can generally be detected using a SNP array, the quality of solid tumor specimens is very variable. Therefore, this test requires 30% or greater tumor burden in the specimen. Interpretation of the results can be complicated by the detection of mosaic changes that due to mixture of tumor cells with normal cells, which will decrease the copy number aberration density. In some cases, results may suggest that the patient may benefit from referral to a clinical geneticist for further evaluation and counseling.

**Additional Information:**

Concurrent chromosome analysis should be sent for all the samples requesting Chromosomal Microarray Analysis for Tumor.

**CPT Code:**

81406

**Inpatient Fee Code:**

EA002

**Outpatient Fee Code:**

EA002

**MLabs Fee Code:**

EA002

**Rejection Criteria:**

Small samples with insufficient amount of DNA are not acceptable. At least 30% malignant cells must be present in the sample submitted for Chromosomal Microarray Analysis for Tumor assay.