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OncoMate™ MSI

OncoMate™ MSI Dx Analysis System

Diagnostic Testing for Microsatellite Instability

The OncoMate™ MSI Dx Analysis System is a PCR-based fragment sizing test used to determine microsatellite instability (MSI) status of solid tumors. The system generates allelic profiles with tumor and non-tumor formalin-fixed paraffin-embedded (FFPE) tissue samples from the same patient through polymerase chain reaction (PCR) amplification of DNA microsatellite markers. The amplified products are then separated using capillary electrophoresis and the allelic profiles for normal and tumor samples are compared.

Clinical Use

The OncoMate™ MSI Dx Analysis System is a CE-Marked IVD Medical Device for the characterization of a tumor's MSI status. The system offers physicians a functional molecular measurement of the level of DNA mismatch repair deficiency present in their patient's sample by leveraging the five mononucleotide repeat markers in the NCI recommended, revised Bethesda panel[1]. The system offers actionable results that can be used to better inform potential immunotherapy decisions and assist in the diagnosis of hereditary cancer syndromes such as Lynch syndrome.

Materials Required

- Less than one section each of normal and tumor FFPE tissue samples from the same individual
- A DNA extraction method *(e.g., Maxwell® CSC Instrument and Kits)*
- Double-stranded dye-based DNA quantitation method *(e.g., QuantiFluor® dsDNA System)*
- Thermocycler
- Capillary electrophoresis instrument
- OncoMate™ MSI Dx Analysis System
- OncoMate™ 5C Matrix Standard
- Fragment analysis software *(e.g., GeneMapper® Software)*

Workflow

Isolate DNA

from FFPE samples.

Quantitate DNA

using fluorescent DNA quantitation reagents and instruments.

Amplify DNA

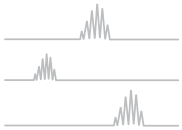
using the OncoMate™ MSI Dx Analysis System.

Calibrate the Dye Spectrum

using the OncoMate™ 5C Matrix Standard.

Separate and Detect Fragments

using a capillary electrophoresis instrument capable of fluorescent detection.



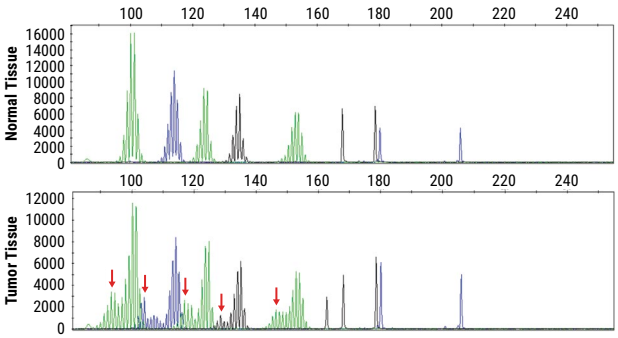
Data Analysis and Reporting

using fragment analysis software.

Turnaround Time: In as little as 10 hours or overnight

Assay Specifications

Assay Type

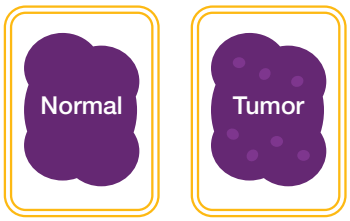


Instability is determined by fragment size analysis on a capillary electrophoresis instrument following PCR amplification of DNA from a patient's normal and tumor tissue samples. Unstable loci in the tumor tissue are indicated by red arrows.

DNA Input Required

Uses only 1ng of amplification-quality DNA per reaction.

Tissue Requirement



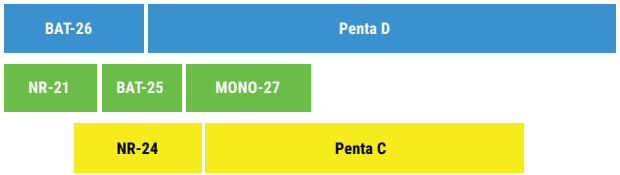
Normal and tumor FFPE samples with tissue volume of 0.1mm^3 to 2.0mm^3. Tumor sample should contain at least 20% viable tumor cells.

Assay Time

Quick, multiplexed reaction, balanced for accuracy and efficiency, goes from DNA to answer in as little as 2.5 hours.

Biomarker and Loci Information

The OncoMate™ MSI Dx Analysis System includes fluorophore-labeled primers for co-amplification of seven microsatellite markers: five mononucleotide repeat markers (BAT-25, BAT-26, NR-21, NR-24 and MONO-27) and two pentanucleotide repeat markers (Penta C and Penta D). The mononucleotide-repeat markers are analyzed to determine MSI status and were selected for high sensitivity and specificity to alterations in repeat lengths in samples containing mismatch repair defects. The pentanucleotide-repeat markers were selected for their high level of polymorphism and are included as an identity check between individual normal and tumor sample pairs to confirm that the sample pairs were derived from the same individual.



Assay Design

MSI status is determined by comparing the allelic profiles. An expansion or reduction in the length of repetitive DNA sequences in the tumor cell DNA when compared to the normal cell DNA from the same patient indicates MSI. Normal and tumor tissue from the same patient must be tested at the same time and data from both samples must be available for comparison for results to be valid.

If you have any questions, contact our Technical Services Team at:
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To learn more, visit:
promega.com/OncoMateInfo

Intended Use: The OncoMate™ MSI Dx Analysis System is not intended to diagnose a specific disease. It is intended for use with patients already diagnosed with cancer who may benefit from additional genetic testing. Test results using the product must be interpreted by healthcare professionals in conjunction with other clinical findings, family history and laboratory data. This product is intended for professional use only.

[1]Umar *et al.* (2004) Revised Bethesda Guidelines for hereditary nonpolyposis colorectal cancer (Lynch syndrome) and microsatellite instability. *J. Natl. Cancer Inst.* **96**, 261–8.

The OncoMate™ MSI Dx Analysis System and OncoMate™ 5C Matrix Standard are currently only available in the United Kingdom and select European countries.