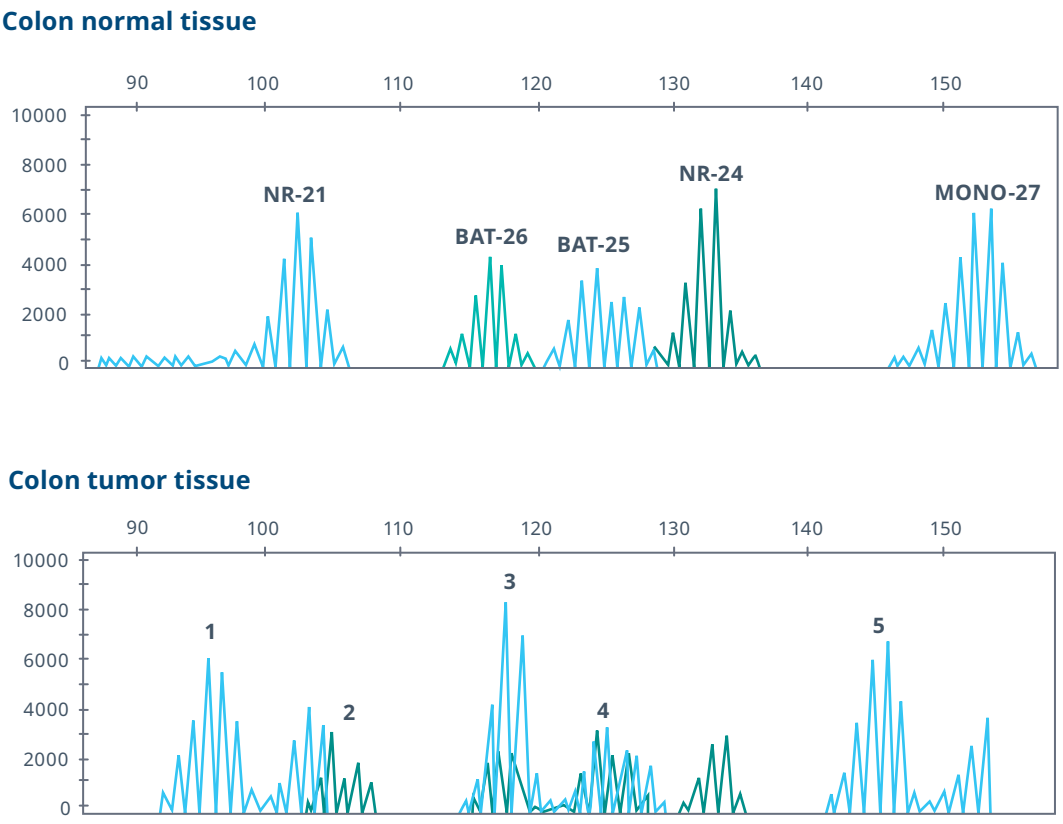
Fact Sheet

Microsatellite Instability Assay for Response to Immunotherapy

Microsatellite instability (MSI) results from an accumulation of insertion or deletion of repeating units during DNA replication in tumor cells with a deficient mismatch repair (MMR) system. MSI status is associated with response/resistance to certain immune checkpoint inhibitors. Available within our comprehensive immuno-oncology assay portfolio, IQVIA Laboratories MSI assay utilizes multiplex, fluorescent PCR and capillary electrophoresis to enable sensitive detection of five mononucleotide repeat markers (BAT-25, BAT-26, NR-21, NR-24 and MONO-27)[1] in tumor FFPE specimens. Microsatellite instability at two or more mononucleotide loci is interpreted as MSI-High; microsatellite instability at a single mononucleotide locus is interpreted as MSI-Low; no instability at any of the loci tested is interpreted as microsatellite stable (MSS). The MSI assay has been analytically validated and is reported under **CAP/CLIA** and is established in support of clinical trial enrollment, primary and secondary endpoints, and research objectives outside of a clinical trial.

Example of colon cancer FFPE tissue specimen demonstrating MSI-high status



Example capillary electropherogram demonstrating reference, normal profile in normal tissue (upper panel) and MSI-High profile in tumor FFPE tissue (lower panel). New MSI events labeled 1 — 5 are detected in tumor tissue.

MSI assay specifications

Markers	BAT-25, BAT-26, MONO-27, NR-21, and NR-24 microsatellite loci
Specimen requirements	Tumor: 4-8 x 5um FFPE tumor slides or 3 curls or FFPE block or DNA. Minimum 30% neoplastic cellularity required. Normal: either whole blood (2 mL, K2EDTA) *or* tumor FFPE slides with clearly indicated normal tissue area *or* 4-8 x 5um normal tissue FFPE slides, curls or block. If H&E stained slide with indicated tumor normal areas is not available, IQVIA Laboratories will perform H&E assessment and determine specimen adequacy
Assay method	OncoMateTM MSI Dx Analysis System (Promega)[2]
System compatibility	SeqStudio Flex
Regulatory tier	RUO, GCP, CAP/CLIA
Deliverables	MSI Status report. Exact number of MSI markers available as custom report
TAT	10 BD for small batch fast TAT testing, custom for larger batch retrospective testing

[1] Boland et al. Cancer Res. 1998;58:5248-5257.
[2] Promega MSI assay also available in IQVIA Laboratories China and Edinborough Laboratory facilities.

IQVIA Laboratories: Your global laboratory partner

IQVIA Laboratories is committed to providing customers an innovative, progressive and responsive partner with the quality focus, global experience and deep medical expertise integral to drug, medical device and diagnostic development. We work collaboratively with our customers, business partners and colleagues to lead the industry and live our customer promise of *Turning Hope Into Help*.

Our deep scientific and medical expertise, coupled with our strategic operating models, enables an impressive range of end-to-end lab solutions and one of the most robust test menus in the industry, including genomic and esoteric tests, fit-for-purpose biomarkers and companion diagnostics to support precision medicine.

IQVIA Laboratories has a global testing footprint

GENOMICS	FLOW CYTOMETRY/IMMUNOASSAYS	ANATOMICAL PATHOLOGY
• TCR immune sequencing • Immune gene signature/ epigenetic signatures • Digital spatial profiling (AP-gene and protein expression) • Minimal residual disease (MRD) • Tumor mutation burden (TMB) • DNA-mismatch repair (MMR) deficiency/ microsatellite instability (MSI) • HLA and KIR typing • Whole exome sequencing • Neoantigen discovery • Microbiome 16S rRNA	• Immuno-phenotyping • CAR-T tracking • Receptor occupancy (mono/bispecific mAbs) • Tumor infiltrating lymphocytes (TILs) • Intracellular cytokine survey • Minimal residual disease (MRD) • Circulating soluble proteins • PBMC processing • ELISpot • Pembrolizumab PK and anti-pembrolizumab antibody	• IHC (single and multiplex) • Tumor infiltrating lymphocytes (TILs) • Digital pathology • FISH

Focus on quality

Our quality management system (QMS) follows CLSI guidelines and our laboratories are CAP accredited. Additionally, all of our CLIA validated assays are supported by bioinformatics and electronic systems that meet HIPAA, GAMP5, ICH Q9, and 21 CFR Part 11 standards.

Global consistency
Harmonized assay testing on **3 continents** for consistent results.

Personalized service
Custom turnaround times for **delivery and analysis.**

Massive data delivery
1.2+ petabytes of genomic data globally in 2024.

Decades of Expertise
Over 20 years in genomics testing.

Industry leader
Leading in genomic testing **since 2001.**

Extensive experience working with the **top 10 pharmaceutical companies.**

IQVIA Genomics has partnered with **> 125 leading/top biotech companies.**

To learn more about our clinical genomic services, please visit
www.lab.iqvia.com/genomics-laboratories

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