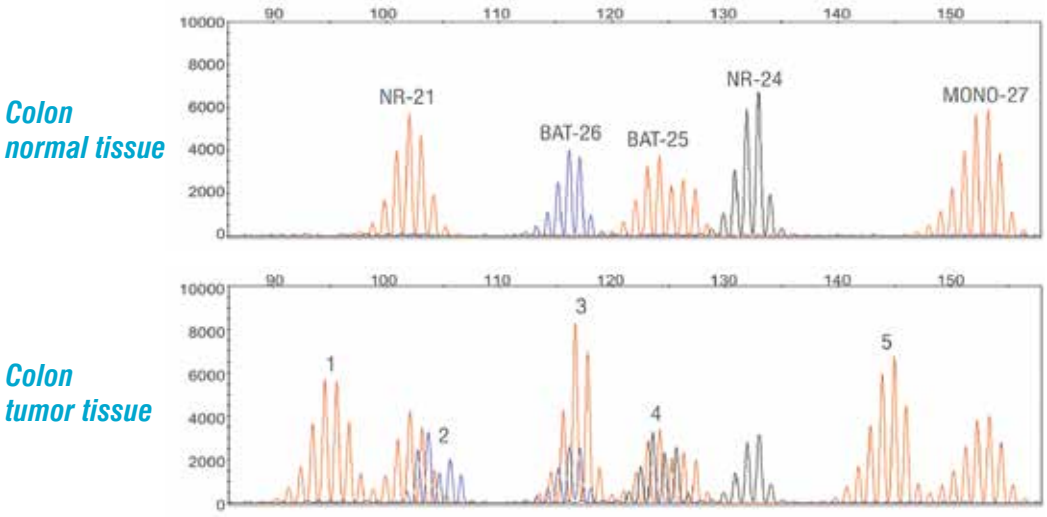
Q² Solutions®

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, Q² Solutions' 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 available for Research Use Only applications.

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: 3 x 5um FFPE tumor slides or 3 curls or FFPE block or DNA. Minimum 20% neoplastic cellularity required. Normal: either whole blood (1-3 mL, K2EDTA) *or* tumor FFPE slides with clearly indicated normal tissue area *or* 3 x 5um normal tissue FFPE slides, curls or block. If H&E stained slide with indicated tumor normal areas is not available, Q² Solutions will perform H&E assessment and determine specimen adequacy.
Assay method	MSI Analysis System (Promega)[2]
System compatibility	Thermo Fisher Scientific SeqStudio
Regulatory tier	RUO, GCP, consult for CLIA availability
Deliverables	MSI Status report. Exact number of MSI markers available as custom report.
TAT	6-8 weeks

[1] Boland et al. *Cancer Res.* 1998;58:5248-5257. [2] Promega MSI assay also available in Q² Solutions' Beijing, China Laboratory facility.

Turning Hope Into Help™

Q² Solutions: Your global laboratory partner

Q² Solutions 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.

Q² Solutions has a global testing footprint

Genomics	Flow cytometry / immunoassays	Anatomical pathology
• TCR immune sequencing • Immune gene signature/epigenetic signatures • Digital spatial profiling (AP-gene & 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 & 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.

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To learn more about our clinical genomic services, please visit **www.Q2LabSolutions.com/genomics-laboratories**

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