



Technical Bulletin

Oncology Testing Supports QMC Precision Medicine Program

TO: Medical Staff and Clients

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SUBJECT: New oncology sequencing detects five hundred twenty-three (523) cancer related genes

The DLS Central Molecular Laboratory has begun utilizing next-generation sequencing (NGS) to create gene profiles from solid tumor biopsies. This testing is a core component of the Queen’s Medical Center’s Precision Medicine Program, and designed to identify advanced cancer patients who may be eligible for FDA-approved, National Comprehensive Cancer Network (NCCN) guided treatments including molecular targeted and immunotherapies. This comprehensive NGS testing examines the DNA and RNA for variants in 523 cancer relevant genes, and can be used for many solid tumor types.

Tumor tissue is examined for multiple variant types including single nucleotide variants (SNVs), insertions/deletions (INDELS), copy-number alterations (CNAs), splice site variants and gene fusions. Genomic loci are also assessed for tumor mutational burden (TMB) and microsatellite instability (MSI), which can be used to guide immunotherapy. Result reports are designed to be clear and concise.

This test was developed and performance characteristics established by DLS; it has not been reviewed or evaluated by the FDA. It is designed for clinical use in consultation with pathologists and oncologists. Validation testing examined 1060 SNVs, 173 INDELS, 61 amplification targets, 17 splice site variants, 87 fusion alterations, 68 microsatellite comparisons and 105 TMB assessments. When adequate tumor nucleic acid was recovered, the positive predictive values were 99.4% for SNVs, 96.9% for INDELS, 70.5% for amplification targets, 91.7% for splice site variants, 94.1% for fusion alterations and 97.1% for microsatellite comparisons. The Pearson correlation coefficient was 1.00 (p=1.3e-44) for TMB analyses.

Pathology consultation (808-691-4271) is required. Although many plans will cover this testing, clients are encouraged to check with insurers in advance. An Advance Beneficiary Notice (ABN) of non-coverage is required.

<i>Test</i>	<i>Specimen</i>	<i>Unit Code</i>	<i>Collection</i>	<i>Turn-around Time</i>
NGS Oncology Tumor Profile	Formalin fixed paraffin embedded tissue	72060	Weekly	14-days after receipt of sample
NGS Oncology Melanoma Profile	Formalin fixed paraffin embedded tissue	72070	Weekly	14-days after receipt of sample

Optimal specimen stability is 5 years from date of biopsy or surgery post-histology processing.

For interpretive questions, please contact Dr. Christopher Lum, Medical Director of Molecular Diagnostics, at 808-691-4271.

For laboratory questions, contact Dr. Amy Woron, Manager - DLS Molecular Laboratory at 441-5436, or DLS Client Services at 589-5101.

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