

Molecular Diagnostics Oncology Laboratory (MODL) – Biomarkers

Background and Context:

As part of the OH-CCO (Ontario Health-Cancer Care Ontario) program to provide expanded NGS (Next Generation Sequencing) for solid tumors, MODL is licensed to perform the OncoPrint Comprehensive Assay v3 (OCAv3).

OCAv3 is a targeted NGS assay that allows for the simultaneous detection of genomic variants.

- OCAv3 is an amplicon based NGS assay that analyzes DNA and RNA extracted from FFPE (formalin fixed paraffin embedded) specimens.
- The RNA portion of OCAv3 is performed only if gene fusion and/or exon skipping detection is desired.
- Sequencing is performed on an Ion Torrent S5 system.
- Bioinformatic analysis is performed on the Ion Reporter (version 5.16) using the hg19 reference genome.
- Variant filtering is performed to exclude germline variants and artifacts of sequencing.
- Variants are only reviewed for the subset of genes listed in the table below (note that the gene list is dependent on the tumor site).
- Variants are reported into templates based on CAP (College of American Pathologists) worksheets.

Panels of Biomarkers:

The following panels are part of the “Molecular Diagnostics for Solid Tumors” order set which can be found in the EPIC health information system (HIS).

| Panel | OH- CCO Testing Indication | PowerPath Order Code | Mandatory Biomarkers | Testing Method | Additional Comments |
|----------------------|---|----------------------|---|----------------|-------------------------------------|
| Bladder NGS Panel | Reflex testing on newly diagnosed tumours with advanced/metastatic bladder carcinoma. | MOLBLADDER | FGFR1, FGFR2, FGFR3 (gene fusions) | NGS | |
| Breast NGS Panel | Testing on advanced/metastatic breast cancer where PIK3CA directed therapy is being considered. | MOLBREAST | PIK3CA (DNA variants) | NGS | |
| Colorectal NGS Panel | Reflex testing on newly diagnosed cases advanced*/metastatic colorectal or small bowel carcinoma. <i>*For biomarker testing purposes, advanced is considered CRC/Small Bowel tumours Stage III and above</i> | MOLCOLORECTAL | BRAF, KRAS, NRAS, PIK3CA (DNA variants) | NGS | |
| ctDNA NGS Panel | N/A | N/A | Biomarkers on Canexia Follow-It assay | NGS | This is a send out test to Canexia. |

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| Endometrial NSG Panel | Reflex testing on newly diagnosed tumours with invasive endometrial carcinoma. | MOLENDOMETRIAL | POLE (DNA variants) | NGS | |
| Glial Tumor NGS Panel | TBA | MOLCNSNGS | TBA | NGS | |
| Lung NGS Panel | Reflex testing on newly diagnosed cases of NSCLC (adenocarcinoma/non-squamous). | MOLLUNGNGS | EGFR, KRAS, BRAF, HER2 (ERBB2), KRAS, PIK3CA (DNA variants) ALK, ROS1, RET, NTRK1, NTRK2, NTRK3 (gene fusions) MET (exon 14 skipping) | NGS | |
| Melanoma NGS Panel | Reflex testing on newly diagnosed cases of advanced*/metastatic Melanoma <i>*For biomarker testing purposes, advanced is considered any melanoma >2mm in depth (pT3)</i> | MOLMELANOMA | BRAF, NRAS, KIT (DNA variants) | NGS | |
| Ovarian NGS Panel | High grade serous ovarian carcinoma, fallopian tube, primary peritoneal carcinoma | N/A | BRCA1, BRCA2 (DNA variants) | NGS | This is a send out test – not performed at EORLA. |
| Prostate NGS Panel | Reflex testing on newly diagnosed tumours with advanced/metastatic prostate carcinoma. | MOLPROSTATE | BRCA1, BRCA2, ATM, PALB2 (DNA variants) | NGS | |
| Thyroid NGS Panel | Reflex testing on all metastatic thyroid cancer, including sporadic medullary and radio-iodine refractory well differentiated thyroid cancer. | MOLTHYROID | BRAF, HRAS, KRAS, NRAS, RET (DNA variants) NTRK1, NTRK2, NTRK3, PPARG, RET (gene fusions) | NGS | |
| Other NGS Panel | This will require justification and prior approval | N/A | As needed | NGS | |

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