

<b>DATE:</b>	20 March 2024
<b>TO:</b>	All Pathologists and Hematologists/Oncologists
<b>FROM:</b>	Molecular Pathology, Alberta Precision Laboratories
<b>RE:</b>	<b>NGS Testing Delays</b>

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### Key Message

- The Molecular Pathology South Sector laboratory is experiencing an instrument failure affecting Next-Generation Sequencing (NGS) capabilities. There is currently no projected timeline for the instrument repair and alternative testing pathways are being initiated.
- This impacts the South Sector Myeloid NGS testing, South Sector lung RNA (not DNA) biomarker testing, provincial Pan-Solid Tumor Fusion Panel and Kinase Fusion Panel
- Result delivery delays are expected.

### Background

- As of March 13<sup>th</sup>, the Molecular Pathology South Sector laboratory has been experiencing intermittent downtime on its NGS instrument. Repairs have been unsuccessful to date and the vendor is unable to provide a reliable timeline for completion of repairs.
- The instrument has been placed out of service until repairs are completed and functionality has been verified and restored.
- The Pan-Solid Tumor Fusion Panel and Lung RNA Fusion Panel (Kinase Fusion Panel) are custom panels designed to cover a broad range of test indications. On a review of available sendout options, no single direct substitute exists that can cover the full breadth of testing with adequate turnaround time and sufficient throughput for the volume of Alberta cases. Therefore, multiple different sendout assays will be utilized on a case-by-case basis depending on the clinicopathologic context.

### How this will impact you

- All myeloid testing is currently being sent to Edmonton for testing. Reporting of the results will be unchanged.
- Triaging of urgent lung testing will occur and testing to be sent to Edmonton. Reporting of these results into EPIC will be unchanged.
- Sendout test strategies include the following:
  - **Lung adenocarcinoma, predictive fusions:** MayoComplete Lung Rearrangements, Rapid, Tumor (MCLNR) – Mayo Clinic Laboratories (turnaround time (TAT): 4 to 8 days)
    - <https://www.mayocliniclabs.com/test-catalog/Overview/616488>
  - **Bone/soft tissue tumor / gynecologic mesenchymal tumors, diagnostic fusions:** Sarcoma Targeted Gene Fusion/Rearrangement Panel, Next-Generation Sequencing, Tumor (SARCP) – Mayo Clinic Laboratories (TAT: 14 to 21 days)
    - <https://www.mayocliniclabs.com/test-catalog/overview/606427>
    - See Appendix A for panel content comparison



- **Central nervous system tumor, diagnostic fusions:** Neuro-Oncology Expanded Gene Panel with Rearrangement, Tumor (NONCP) – Mayo Clinic Laboratories (TAT: 12 to 20 days)
  - <https://www.mayocliniclabs.com/test-catalog/overview/603047>
  - See Appendix B for panel content comparison
- **Melanocytic lesion, diagnostic fusions:** FusionPlex® Solid Tumor Panel – University of Washington Laboratory for Precision Diagnostics (TAT: 7-14 days)
  - <http://uwcpdx.org/fusionplex-solid-tumor-panel/>
- **Thyroid carcinoma, predictive fusions:** FusionPlex® Solid Tumor Panel – University of Washington Laboratory for Precision Diagnostics (TAT: 7-14 days)
  - <http://uwcpdx.org/fusionplex-solid-tumor-panel/>
- **NTRK fusions (FastTRK program):** Oncomine Focus Assay performed in Edmonton.
- **Salivary gland, head/neck, kidney, and other tumors, diagnostic fusions:** In-house options include MAML2 FISH and TFE3 FISH in the Calgary Cancer Cytogenetics Laboratory. The above listed sendout options are also available if they are of utility on a case-by-case basis.

## Action Required

**Pathologists:** Please continue to submit requests in the same way. Incoming test requests will be reviewed by the molecular pathologist on service in the North / South sectors, who will assess and initiate the appropriate sendout strategy as per the above list. Please feel free to discuss the test strategy with the molecular pathologist on service, who can also aid in considering other sendout options if needed for unusual cases. External test results will be received by the molecular pathology laboratories and PDF copies of the results will be populated into EPIC Chart review “labs” tab as “miscellaneous external sendout”.

**Oncologists:** Please continue to submit requests in the same way. Predictive fusion testing (lung adenocarcinoma, thyroid carcinoma, FastTRK program) will be arranged by the molecular pathology laboratory. External test results will be received by the molecular pathology laboratories and PDF copies of the results will be populated into EPIC Chart review “labs” tab as “miscellaneous external sendout”.

**Effective      March 19, 2024**

## Questions/Concerns

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- Dr. Cheryl Mather, Medical Lead, Molecular Pathology North [cheryl.mather@albertaprecisionlabs.ca](mailto:cheryl.mather@albertaprecisionlabs.ca)

## Approved by

- Dr. Adrian Box, Medical/Scientific Director, Molecular Pathology Program
- Mark Douesnard, Operations Director, Molecular Pathology Program
- Dr. Carolyn O’Hara, Chief Medical Laboratory Officer (Interim), Alberta Precision Laboratories

*Effective September 1, 2023, APL has become the sole provider of all public lab services in Alberta. As a result, community lab services formally provided by DynaLIFE Medical Labs will become the responsibility of Alberta Precision Labs (APL). This change impacts all zones.*