

<b>DATE:</b>	4 March 2024
<b>TO:</b>	All Healthcare Providers
<b>FROM:</b>	Alberta Precision Laboratories (APL) – Public Health Laboratory
<b>RE:</b>	New BK Virus Nucleic Acid Test

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## PLEASE POST OR DISTRIBUTE AS WIDELY AS APPROPRIATE

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### Key Message

- On March 13, 2024, the AltoStar BKV PCR Kit (Altona Diagnostics) will be implemented by APL – Public Health Laboratory (ProvLab) to measure BK viral load.
- The current laboratory-developed test (LDT) and the new assay will be run concurrently for a transition period of two months after which the LDT will be discontinued. Results for both tests will be reported during this time.

### Background

- BK virus is a polyomavirus routinely monitored in kidney transplant patients due to its propensity to cause BK polyomavirus-associated nephropathy in this population. It sometimes also causes hemorrhagic cystitis in bone marrow transplant recipients.
- The AltoStar BKV PCR Kit is a Health Canada approved test with increased automation and testing capacity and has comparable diagnostic characteristics to the currently used LDT. It has enhanced sensitivity and so some discordant results between the old and new assay are expected.
- This new assay is calibrated in International Units (IU) and will be reported in IU/mL rather than copies/mL which are currently reported with the LDT.
- Both assays show a strong correlation with viral loads typically being within 1 log IU/mL or copies/mL of each other, though exceptions occasionally occur. There may be greater disparity between the two assays at low viral loads.
- The upper limit of quantitation is  $10^6$  IU/mL for blood and  $10^9$  IU/mL for urine. Viral loads above these cannot be accurately determined.
- Parallel testing using the old and new assays is being done to allow time for the clinical teams to acclimate to the new assay.

### Action Required

- No changes in BK virus nucleic acid test (NAT) ordering or collections will be required. Continue to submit urine and, if indicated, a dedicated EDTA blood tube for testing (ensure that one full EDTA tube is collected for testing in blood; low volumes run the risk of requiring a recollection if test failures occur).
- Be aware that the results of both the old and new assays will be reported for the two-month transition period. The old assay (current state) will be reported as **BK Virus (DNA) LDT NAT** and the new assay will be reported as **BK Virus (DNA) NAT**. Both results will be in the same lab report.



- If a sample has a viral load above the new assay's upper limit of quantitation and an exact viral load is required for patient management, contact the ProvLab Microbiologist on-call at 780-407-8822 (Edmonton) or 403-944-1110 (Calgary).

**Inquiries and feedback may be directed to**

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- Dr. Hong Yuan Zhou, Medical Microbiologist, Public Health Laboratory, APL ([hong.zhou@albertahealthservices.ca](mailto:hong.zhou@albertahealthservices.ca))

**Approved by**

- Dr. Graham Tipples, Medical/Scientific Director, Public Health Laboratory, APL

*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.*