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Leaders in Laboratory Medicine

Laboratory Bulletin

DATE:	2021 December 29
TO:	Strathcona Community Hospital Laboratory – Physicians, Nurses, Pharmacists, and Managers
FROM:	Alberta Precision Laboratories
RE:	**New Coagulation Analyzer Implementation at Strathcona Community Hospital Laboratory**

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Key Message

- New ACL TOP coagulation analyzer is going live **January 11, 2022** at Strathcona Community Hospital Laboratory**.**
- These new analyzers are being implemented in a staggered fashion across the entire Edmonton Zone over the span of a few weeks. As this platform is already in use everywhere else in Alberta, implementation also allows for provincial standardization of coagulation testing.

Background

- The coagulation lab at Strathcona Community Hospital Laboratory already performs the following tests: PTT, INR, and D-Dimer.
- The new coagulation analyzers will continue to perform all the same tests. However, the new coagulation analyzers, from Instrumentation Laboratories (aka Werfen), utilize a different clot detection method (optical) than the retiring Stago brand of analyzers (mechanical). Consequently, significant changes to how results are reported will occur.
- Additional changes will also be occurring as a result of provincial standardization.

How this will impact you

1. **Interfering Substances:**
   - Thresholds for interfering substances will change (see Appendix Table 1). Comments will continue to be appended if results may be affected by interfering substances.
   - Thrombin Time is particularly sensitive to interfering substances and the test will be cancelled if there is visible lipemia or hemolysis.

2. **Reference Ranges:**
   - Regional Thrombin Time reference range changing: 10.3-16.6 seconds (previously 14.3-19.7s)
   - No impact to other reference ranges.

3. **Heparin Monitoring:**
   - PTT Nomogram ranges will be updated in Epic.

4. **Turnaround Times:**
   - On-instrument analysis time may be prolonged in the setting of significantly abnormal INR, PTT and Fibrinogens. This may lead to extended turnaround time for critical results.
   - The *maximum* differences from our previous analyzers have been estimated as follows:
     - INR (when >5): +3 minutes.
     - PTT (when >120 s): +7 minutes
     - Fibrinogen (when <1.5 g/L): +4 minutes

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5. **D-Dimer Assay Changes:**
   - The new D-Dimer assay (HemosIL D-Dimer HS500) maintains the same clinical cut-off for exclusion of venous thromboembolism as the previous assay (Stago STA-Liatest D-Di) of 0.50 mg/L FEU.
   - Otherwise, however, the assays are by no means equivalent. The incoming HemosIL HS-500 assay reactivity is progressively higher than the retiring Stago assay for values >0.50 mg/L.
   - This stems from a lack of an international standard for D-Dimer calibration.
   - For example, for a sample run in parallel on both analyzers:
     - Stago STA-Liatest D-Di result: 5.0 mg/L
     - HemosIL HS-500 result: 7.5 mg/L
   - Thus, we advise AGAINST adjusting the cut-off for venous thromboembolism exclusion based on patient age.
   - **Note:** Most widely available age-adjustment calculators online do not account for differences between assay types/manufacturers.

6. **Critical Results - Preliminary Reporting and Reflex Testing:**
   - Provincial standardization initiatives coincide with the new analyzer implementation and necessitate changes to the process for laboratory handling of critical results.
   - Previously, critical PTTs, INRs, and fibrinogens were *Preliminarily* reported while the laboratory confirmed their validity, and then were *Final Verified*.
   - Going forward, only critical Fibrinogen assay results will be *Preliminarily* reported. The lab will then investigate for possible interferences and if none are found, the Fibrinogen result will be *Final Verified*. INR and PTT results will only be available at the *Final Verified* result stage.
   - Under some circumstances, a critical INR or PTT result may cause reflex Fibrinogen testing to be suggested. Because fibrinogens are not performed on-site, a comment will be appended to the INR/PTT result indicating that testing may be of value, and to contact the lab if required.

7. **Critical Results – Contacting Collectors:**
   - The new critical handling process also acknowledges the risk of specimen collection issues causing expectedly grossly abnormal (critical) results.
   - Laboratory technical staff may attempt to contact the specimen collector (nursing, allied health, lab phlebotomist, etc.) to inquire regarding the collection if the results were not previously critical.
   - Comments may be appended to the results if the lab suspects or cannot determine if there was specimen interference/compromise.

Action Required

- Be aware of limitations and changes associated with incoming coagulation analyzers relevant to your practice.

Effective **January 11, 2022**

Questions/Concerns

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Approved by

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APPENDIX

Table 1: Tests on the ACL TOP instruments are accurate up to (and including) the tabulated levels of the interfering substance

	Interfering Substance			
Test	Triglycerides (mmol/L)	Bilirubin (umol/L)	Free Hemoglobin (mg/L hemolysis)	Heparin (U/mL)
INR	10	510	5000	1.0
PTT	10	425	5000	N/A – sensitive to heparin
Fibrinogen	8	350	3750	1.0
D-Dimer	15	305	5000	10
Thrombin Time	N/A – sensitive to lipemia	410	N/A – sensitive to hemolysis	N/A – sensitive to heparin
Anti-Xa Heparin	10	480	5000	N/A – sensitive
Antithrombin 3	26	680	5000	4.0

Table 1: Tests on the ACL ELITE PRO instruments are accurate up to (and including) the tabulated levels of the interfering substance

	Interfering Substance			
Test	Triglycerides (mmol/L)	Bilirubin (umol/L)	Free Hemoglobin (mg/L hemolysis)	Heparin (U/mL)
INR	8	250	5000	1.0
PTT	10	510	4000	N/A – sensitive to heparin