HEMATOLOGY / URINALYSIS REAGENT VERIFICATION

☒ St. Joseph Medical Center, Tacoma, WA	☒ St. Anthony Hospital Gig Harbor, WA	☐ Harrison Medical Center, Bremerton, WA
☒ St. Francis Hospital, Federal Way, WA	☒ St. Elizabeth Hospital Enumclaw, WA	☐ Harrison Medical Center, Silverdale, WA
☒ St. Clare Hospital Lakewood, WA	☐ Highline Medical Center Burien, WA	☐ PSC

PURPOSE

To provide instructions for verifying and documenting the performance of reagents and quality control materials in Hematology and Urinalysis.

VERIFYING AND DOCUMENTING REAGENT PERFORMANCE

Procedural Steps	Additional Information
1. Handle reagents according to manufacturer's instructions.	• All containers labeled by the manufacturer or in the laboratory must contain: Content, quantity, concentration, storage requirements, date of preparation or reconstitution, and expiration date. • This information may be recorded in a log (paper or electronic), providing the container is traceable to the appropriate data in the log. • A new expiration date must be recorded if opening the container changes the expiration date.
2. Calibrate the new reagent, if applicable.	• New shipments may not require calibration. • Write the calibrator lot number, calibrator open expiration, Tech ID and date on the calibration report, if applicable.
3. Monitor reagent performance after loading. Note: The hematology/urinalysis analyzers contain reagent reservoirs, making it difficult to assess when the old lot has been purged from the system.	• Monitor for inadequate priming. • Monitor increased specimen flagging or system errors at the middleware. • Monitor XB batches, when possible, for shifts in %Diff from the time the new reagent was loaded. • Monitor specimen results by comparing microscopic and chemistry results in UA. • If necessary, previously reported patient samples may be used for the comparison.
4. Perform shift QC materials at the regularly scheduled time period for your shift unless performance issues are found.	• If reagent issues are found, take the analyzer off-line and do not report patients. • Immediately perform all levels of QC material.
5. Review QC for acceptability	• Analyzer may be placed On-Line if QC is acceptable within 2 SD of the mean and/or reacts as described in the manufacturer's instructions. • If QC fails, results are not reported until the issue is resolved. • A look-back is required for failed QC (unless it is due to the QC material itself).

6. Compare QC results with current lot data and /or pool member data.	• Notify the MT-Coordinator, or Lead Tech, if results appear to be trending or not acceptable.
7. Start Lot to Lot Correlations, if indicated.	
8. Document the new reagent in-use date on the appropriate log, i.e. Critical Supply Log.	
9. Review the package/ kit insert for changes, if applicable.	• Note changes on the printout and notify the MT-Coordinator.
10. For ALL QC NL/NS: Notify MT-Coordinator to update ranges in LIS, or on the analyzer.	• Give QC insert with QC ranges to MT-Coordinator. Write date in use, expiration date, received date, and tech ID on the insert.
11. For all sites using stickers to mark New Lots or Shipments: Fill in date tested for the specific analyzer which has the new reagent loaded, date started, and Tech ID.	• Reagent lots/shipments with documented NL/NS stickers are considered verified and ready for use.