COLA Clinical Laboratory Accreditation

COLA Primers Accreditation

COLA PRIMER 21

Automated Hematology

•Overview •

Many clinical laboratories use automated hematology analyzers to perform Complete Blood Counts (CBC). Depending on the patient volume and patient specialty, this usually determines the type of analyzer that best fits your clinical setting. This primer will discuss specimen collection and handling, maintenance, calibration, quality control, patient testing, automated differentials, and quality assessment.

• Specimen Collection and Handling •

Venous blood collection in EDTA (lavender top) tubes is the specimen of choice for CBCs. Capillary punctures, either finger or heel, can be used for some analyzers. Follow all manufacturer requirements regarding what type of specimens can be used.

In addition, the following are important tips:

- Follow venous specimen collection guidelines set up by the laboratory with proper patient identification, as well as finger sticks when performed for microtainer collection tubes.
- Proper specimen mixing following collection- gently invert the EDTA tube to mix the anticoagulant with the whole blood, and microtainer tubes.
- Perform clot inspections visually by inverting the tube looking for clots, OR by using a wooden applicator stick to rim the blood, and inspecting the stick for clots.
- Use tube rockers or rotators to mix the EDTA tubes if the manufacturer recommends this. NOTE: Check the operator's manual for mixing instructions, as some manufacturers do NOT recommend use of mechanical rockers or rotators.

• Instrument Maintenance •

Each instrument comes with an operating manual that will include a section on maintenance. Vendors usually provide a log with daily, weekly, monthly, six-month and annual maintenance checks. Some or all maintenance frequencies may apply depending on the instrument.
Record all maintenance activities on the log according to the frequency. This includes:

- Date performed,
- Daily-function checks, weekly, monthly, six month, annual,
- Tech initials,
- Lot numbers and expiration dates, if applicable,
- Stain checks-if performing in house manual differentials, and
- Reviewed by Supervisor/date.

Remember to rotate all maintenance activities among the laboratory personnel who perform patient testing. This ensures laboratory personnel are competent in instrument activities. Keep all maintenance records at least two years.

• Calibration •

Instrument calibration is one of the primary processes used to maintain instrument accuracy. Automated hematology analyzers must be calibrated at least every six months. Calibration verification is met when the lab follows manufacturer's instruction for instrument operation and performs a minimum of two (2) levels of QC each day of testing.
Calibration is also performed at other times:

- Quality control shows shifts and trends, or is out of limits.
- All other corrective actions have failed.

Operating manuals include step-by-step instructions on performing calibration. Each manufacturer will recommend the type of calibrator material for use with the instrument.
Keep records, at least two years, of all calibration activities including the calibrator data analysis sheets (the number, type and concentration of materials used), results obtained, and any adjustments to the calibration.

• Quality Control •

Quality control is defined as a system of maintaining standards in manufactured products by testing a sample of the output against the specification.
Prior to running quality control samples, laboratory personnel should follow manufacturer's handling instructions:

- Consult the package insert to determine how long the control material must sit out at room temperature prior to testing.
- Mixing controls properly prior to testing ensures controls give accurate results. Standard mixing is by gentle inversion using the 8 x 8 mixing method. Gently roll the tube 8 times between your hands; invert the tube and gently roll the tube 8 times between your hands.
- Controls must be stored properly. Consult the package insert to determine the open expiration of controls, AND record on the vial the OPEN expiration date.

At least two levels of controls must be run each day of patient testing. Most hematology controls come in a set of three: Low, Normal, and High. The laboratory personnel should follow procedures for accepting two of three controls prior to patient testing. Keep in mind the following when running controls:

- Ensure open controls are not expired prior to testing.
- Run three levels each day of patient testing assures two levels will be acceptable prior to patient testing.

- Laboratory personnel should review the results for each control level; document any corrective action, and initial control results for acceptability.
- Run controls in the same manner as patients; therefore, all laboratory personnel performing patient testing should rotate performing quality control.

Troubleshooting unacceptable controls:

- Repeat the controls ONE time. Prior to repeating the controls, ensure proper mixing took place, AND the length of time the controls sat at room temperature.
- If a control is unacceptable after the first repeat, open a fresh control vial, leaving it at room temperature for the appropriate amount of time and mixing properly.
- If the fresh control is still unacceptable, then consult the operator's manual for additional troubleshooting measures OR contact the manufacturer.
- Document all troubleshooting on a corrective action log.
- Do not run patients until two levels of controls are within acceptable limits.

**Controls should not be run multiple times to get acceptable results.

A ***Levey-Jennings*** chart is a graph that quality control data is plotted on to give a visual indication whether a laboratory test is working well. To determine shifts or trends in quality control, review Levey-Jennings charts every 5-7 days. Reviews can be done visually on the analyzer screen or by printing the charts. Either way, the laboratory needs to document weekly review. If any shifts and trends are observed, corrective action or calibration can then be done.

• Patient Testing •

Once controls are acceptable, patient testing can begin.

- Ensure proper mixing of samples
- Follow procedures for flags, repeat samples when necessary
- Report patient results accurately and document critical values
- Follow the procedure for verifying automated differentials

• Automated WBC Differentials •

Instrument manufacturers will provide the user with specific criteria for when the automated differential must be reflexed to a manual differential to verify the results. These instructions must be followed by the user. The user must be aware of these warning codes and symbols that may generate on the reports and their corresponding significance. Check the operator's manual for this information. If there are no specific manufacturer instructions, the Laboratory Director must establish criteria for performing an "in house" manual differential or referring to a reference laboratory.

If manual differentials are performed “in house”, significant abnormal RBC morphology and immature WBC cells are considered **high** complexity.

Laboratory personnel performing manual differentials need to review and record that the smears are checked regularly for appropriateness of staining. This can be included in the records of your hematology instrument’s daily, weekly, or monthly maintenance.

• Quality Assessment •

Regular reviews in the quality assessment program for hematology should include:

- Review of maintenance logs.
- Review of calibration due dates and results.
- Review quality control records monthly to ensure acceptability of daily controls.
- Review Levey-Jennings graphs monthly to check for shifts and trends in quality control.
- Review corrective action logs.
- Review documentation of critical value reporting.
- If hematology analyzers are interfaced with an LIS, periodic review of data transmission from the instrument to the LIS to the EMR.