General Hematology Calibration Procedure Guideline

Cal-Chex, Cal-Chex A Plus

Streck provides this template for laboratories to incorporate into their internal protocol.

Streck assumes no responsibility for protocols generated from this template.

Principle

Multi-parameter hematology analyzers require routine calibration checks and/or adjustments in order to produce accurate results. Calibration can be accomplished with the use of fresh whole blood samples which have been assayed by reference methods. A more direct and convenient approach is to use a calibrator material assayed with system specific values traceable to a reference method. Streck calibrators are stable suspensions of erythrocytes, leukocytes, and platelets. Assigned values are derived from replicate analysis on whole blood-calibrated hematology analyzers.

Clinical Laboratory Standards Institute (CLSI) defines calibration as the process of testing and adjusting the instrument or test system readout to establish a correlation between the instrument's measurement of the substance being tested and the actual concentration of the substance.

Calibration verification is the testing of materials of known concentration in the same manner as patient specimens to assure the test system is accurately measuring samples throughout the reportable range.

When to Calibrate

Calibration should take place in accordance with the recommendations outlined in the instrument operator manual, typically once every 6 months or whenever any of the following occur:

- All of the reagents used for a test procedure are changed to new lot numbers, **unless** the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, **and** control values are not adversely affected by reagent lot number changes.
- Following a major preventive maintenance or repair/replacement of critical parts that may influence the test's performance. This includes sending a test system to the manufacturer for repairs.
- Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other troubleshooting means of correcting the unacceptable control values fail to identify and resolve the problem.
- The laboratory has determined that the test system's reportable range for patient test results should be checked more frequently.

Calibration must be considered the last step in a troubleshooting sequence. Frequent unnecessary recalibrations can mask an underlying problem with the instrument's performance.

Safety

Standard Universal Precautions apply.

Calibrator Storage and Stability

Refer to product IFU (Instructions For Use)

Pre-Calibration Procedure Checklist

Date_____
Operator_____
Instrument_____
Serial Number & Software Version_____

1. ☐ Perform all required maintenance.
2. ☐ Verify all reagents have not reached the expiration date and there is ample volume to complete the precision and calibration procedures.
3. ☐ Record calibration information:
   Lot #_____
   Exp. date_____
4. ☐ Verify that background counts are within the acceptable limits.
5. ☐ Print current calibration factors from the instrument.

Precision Check

Prior to calibration, it is prudent to ensure proper instrument performance through a precision check. It is recommended to use a normal patient sample less than 4 hours old for the purpose of this check.

Precision Procedure:

- Run the sample consecutively in a replicate file, at a minimum 11 times.
- Discard the first run and obtain a mean, SD and CV for all parameters that can be calibrated.
- Evaluate the results. The CV% should fall within the acceptable limits of your specific analyzer; limits can be referenced in the Performance Characteristics/Specifications section of the instrument operator manual.
- If any parameter's CV% exceeds the limits, refer to the troubleshooting or diagnostics section of the operator's manual as necessary. Repeat the precision check.
- **Do not proceed with calibration if the precision study does not pass.** If troubleshooting does not bring the CV% to within acceptable limits, you may need to contact service for your analyzer.

Note: The differential parameters are not calibrated and any differential adjustments are made by the instrument field service representative.

Calibration

- Remove vials of calibrator from refrigeration and warm to room temperature (18 °C to 30 °C) for 15 minutes before use.
- Refer to Mixing Procedure in IFU and for a video demonstration, visit www.streck.com/mixing.
- Prime the instrument by aspirating 2 normal blood samples. Disregard results.
- Follow the instructions for calibration in the instrument operator manual. Each instrument has specific requirements for the file to use and number of runs to be performed.
- Calculate the mean for each parameter.
- Compare the results from your instrument to the assay targets:
  a. If the recovered mean values are within the system specific assayed tolerance limits, and your control data does not indicate a change is warranted, the instrument does not require calibration. It may be helpful to correlate your lab control means with a peer group for this assessment.
  b. If the recovered mean values are close to the system specific tolerance limits and your control data indicates an adjustment is warranted, proceed with accepting the new calibration factors.
- Calibration of the specific parameter(s) should be done in accordance with the procedure in your instrument manual. Calibration may not be required for all parameters.
- Once calibration is complete, verify calibration by analyzing the calibrator 3 times in the patient mode. Compare the means of the results to the ranges on the calibrator assay sheet to verify the adjustment is appropriate.
- Print the new calibration factors and retain with your instrument records as documentation along with the calibration verification runs.

Quality Control Verification

Following calibration, it is recommended to run controls and verify results are within range prior to performing patient testing. Print the post-QC results for your records.

Best Practices

It is good laboratory practice to review QC data and correlate the individual lab results to an interlaboratory peer group prior to calibration. Determine the percent deviation from assay and/or the peer group. Verify any differences in calibrator recovery mirror the differences observed in QC data for each parameter being adjusted. Monitor proficiency testing results for ongoing calibration verification as well.

References

Clinical Laboratory Standards Institute, H26-A2, Validation, verification and quality assurance of automated hematology analyzers. Approved Standard - Second Edition.

Clinical Laboratory Standards Institute, H15-A3, Reference and selected procedures for the quantitative determination of hemoglobin in blood. Approved Standard - Third Edition.

Clinical Laboratory Standards Institute, H07-A3, Procedure for determining packed cell volume by the microhematocrit method. Approved Standard - Third Edition.