COLLEGE of AMERICAN PATHOLOGISTS

Master

# Hematology and Coagulation Checklist

CAP Accreditation Program



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## INTRODUCTION

*This checklist is used in conjunction with the All Common and Laboratory General Checklists to inspect a hematology laboratory section or department.*

*Certain requirements are different for waived versus nonwaived tests. Refer to the checklist headings and explanatory text to determine applicability based on test complexity. The current list of tests waived under CLIA may be found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm.*

*Policy/Procedure icon - The placement of this icon next to a checklist requirement indicates that a written policy or procedure is required to demonstrate compliance with the requirement. The icon is not intended to imply that a separate policy or procedure is required to address individual requirements. A single policy or procedure may cover multiple checklist requirements.*

***Laboratories not subject to US regulations:*** *Checklist requirements apply to all laboratories unless a specific disclaimer of exclusion is stated in the checklist. When the phrase "FDA-cleared/approved test (or assay)" is used within the checklist, it also applies to tests approved by an internationally recognized regulatory authority (eg, CE-marking).*

# HEMATOLOGY

# SPECIMEN COLLECTION AND HANDLING

## Inspector Instructions:

| | |
|---|---|
| READ | • Sampling of hematology specimen collection and handling policies and procedures |
| OBSERVE | • Sampling of patient CBC specimens (anticoagulant, labeling, storage) |
| ASK | • How do you know if the CBC specimen is clotted, lipemic, or hemolyzed?<br>• How do you ensure the CBC sample is thoroughly mixed before analysis?<br>• What is your course of action when you receive unacceptable hematology specimens? |

**HEM.22000 Collection in Anticoagulant** **Phase II**

**All blood specimens collected in anticoagulant for hematology testing are mixed thoroughly immediately before analysis.**

*NOTE: Some rocking platforms may be adequate to maintain even cellular distribution of previously well-mixed specimens, but are incapable of fully mixing a settled specimen. For instruments with automated samplers, the laboratory must ensure that the automated mixing time is sufficient to homogeneously disperse the cells in a settled specimen.*

**Evidence of Compliance:**

✓ Records of evaluation of each specimen mixing method (eg, rotary mixer, rocker, automated sampler, or manual inversions) for reproducibility of results, as applicable

REFERENCES
1) Clinical and Laboratory Standards Institute. *Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens.* 7th ed. CLSI standard GP42. Clinical and Laboratory Standards Institute, Wayne, PA, 2020.
2) Clinical and Laboratory Standards Institute. *Collection of Diagnostic Venous Blood Specimens;* 7th ed. CLSI standard GP41-ED7. Clinical and Laboratory Standards Institute, Wayne, PA, 2017.

**HEM.22050 CBC Anticoagulant** **Phase II**

**Samples for complete blood counts and blood film morphology are collected in potassium EDTA.**

*NOTE: Blood specimens for routine hematology tests (eg, CBC, leukocyte differential) must be collected in potassium EDTA to minimize changes in cell characteristics. Laboratories must follow manufacturer's recommendations for use of alternative anticoagulants.*

REFERENCES
1) Cohle SD, *et al*. Effects of storage of blood on stability of hematologic parameters. *Am J Clin Pathol.* 1981;76:67-79
2) Savage RA. Pseudoleukocytosis due to EDTA-induced platelet clumping. *Am J Clin Pathol.* 1984;82:132-133
3) Rabinovitch A. Anticoagulants, platelets and instrument problems. *Am J Clin Pathol.* 1984;82:132
4) Clinical and Laboratory Standards Institute. *Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens.* 7th ed. CLSI standard GP42. Clinical and Laboratory Standards Institute, Wayne, PA, 2020.

5) Clinical and Laboratory Standards Institute. *Collection of Diagnostic Venous Blood Specimens;* 7th ed. CLSI standard GP41-ED7. Clinical and Laboratory Standards Institute, Wayne, PA, 2017.
6) Doeleman MJH, Esseveld A, Huisman A, de Roock S, Tiel Goenestege WM. Stability and comparison of complete blood count parameters between capillary and venous blood samples. *Int J Lab Hematol.* 2023;45(5):659-667.
7) Brunson D, *et al*. Comparing hematology anticoagulants: K2EDTA vs K3EDTA. *Lab Hematol.* 1995;1:112-119
8) Boos MS, *et al*. Temperature- and storage-dependent changes in hematologic variable and peripheral blood morphology. *Am J Clin Pathol*. 1998;110:537
9) Wood BL, *et al*. Refrigerated storage improves the stability of the complete blood cell count and automated differential. *Am J Clin Pathol*. 1999;112:687-695

**HEM.22100 Capillary Tube Collection Criteria** **Phase II**

**Samples collected in capillary tubes for microhematocrits or capillary/dilution systems are obtained in duplicate whenever possible.**

*NOTE: Microspecimen containers such as those used for other capillary blood CBC parameter determinations need not be collected in duplicate. Because of the risk of injury, the use of glass capillary tubes is discouraged; if glass capillary tubes are used, measures have been implemented to reduce risk or injury.*

REFERENCES
1) Clinical and Laboratory Standards Institute. *Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens.* 7th ed. CLSI standard GP42. Clinical and Laboratory Standards Institute, Wayne, PA, 2020.
2) Occupational Safety and Health Administration. Toxic and hazardous substances. Bloodborne pathogens. Washington, DC: US Government Printing Office, 1999(Jul 1): [29CFR1910.1030].

# COMPLETE BLOOD COUNT (CBC) INSTRUMENTS

## CALIBRATION

*Commercially available calibrator materials represent a convenient way to ensure that CBC instruments yield accurate results. Because of differences in technology, such calibrators are typically instrument-specific, and are cleared by the Food and Drug Administration for such use. These calibrators have more rigorous assignment of target values than ordinary commercial QC materials. Commercial control materials are not suitable for routine instrument calibration.*

## Inspector Instructions:

| | |
|---|---|
| READ | • Sampling of CBC calibration policies and procedures<br>• Sampling of CBC calibration records |
| ASK | • What is your course of action if the CBC instrument fails to pass all calibration parameters?<br>• When was the last time you performed a calibration procedure and how did you verify the calibration? |

**HEM.25400 Precalibrated Instrument Verification** **Phase II**

**If precalibrated instruments are used, the manufacturer's calibrations are verified with appropriate control materials for the system.**

*NOTE: This requirement does not apply to CBC instruments that can be calibrated by the*

*laboratory.*

**Evidence of Compliance:**

✓ Records of calibration verification following manufacturer's instructions

REFERENCES
1) Whitehead RD Jr, Mei Z, Mapango C, Jefferds MED. Methods and analyzers for hemoglobin measurement in clinical laboratories and field settings. *Ann N Y Acad Sci*. 2019;1450(1):147-171.
2) Department of Health and Human Services, Centers for Medicare & Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24): [42CFR493.1255]
3) McCafferty R, Cembrowski G, de la Salle B, Peng M, Urrechaga E. ICSH guidance for internal quality control policy for blood cell counters. *Int J Lab Hematol*. 2024;46(2):227-233.

**HEM.25700 Calibration** **Phase II**

**The laboratory follows defined criteria for periodic analyzer calibration using stabilized materials with target values certified by the manufacturer using primary reference procedures.**

REFERENCES
1) McCafferty R, Cembrowski G, de la Salle B, Peng M, Urrechaga E. ICSH guidance for internal quality control policy for blood cell counters. *Int J Lab Hematol*. 2024;46(2):227-233.
2) Clinical and Laboratory Standards Institute (CLSI). Validation, Verification, and Quality Assurance of Automated Hematology Analyzers; Approved Standard—Second Edition. CLSI document H26-A2 (ISBN 1-56238-728-6). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2010.
3) Department of Health and Human Services, Centers for Medicare & Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24): [42CFR493.1255]

## CBC INSTRUMENT QUALITY CONTROL

*Longitudinal process quality control (QC) procedures for individual instruments may include:*

1. *Use of preserved or stabilized whole blood controls*
2. *"Moving average" monitoring*
3. *Retained patient specimens, or*
4. *Some combination of the above*

*At least two different controls must be assayed and evaluated every 24 hours. For each QC procedure employed, the laboratory must have appropriate QC ranges. For example, expected recovery ranges for commercial control materials are NOT the same as between-run SD ranges, and are probably too wide for daily QC of a single instrument. The laboratory should calculate its own imprecision statistics for each instrument.*

## Inspector Instructions:

| | |
|---|---|
| READ | • Sampling of QC policies and procedures<br>• Sampling of QC records from the previous two-year period<br>• Sampling of CBC error detection policies and procedures |
| ASK | • How do you determine when QC is unacceptable and when corrective actions are needed?<br>• How does your laboratory establish or verify acceptable QC ranges?<br>• How do you ensure results from CBC specimens with cold agglutinins, nucleated RBCs and lipemia are reported accurately? |
| | • Review a sampling of QC data over the previous two-year period. Select several occurrences |

| | |
|---|---|
| DISCOVER | in which QC is out of range and follow records to determine if the steps taken follow the laboratory procedure for corrective action<br>• Select a spurious result example and follow the process used to ensure the correct results are reported |

## Stabilized Controls

**HEM.25850** **QC - Stabilized Controls** **Phase II**

**The laboratory analyzes two different stabilized control specimens during each 24-hours of analyzer use.**

*NOTE: Stabilized control materials must be at two different analytic levels (ie, "normal" and "high"). Three levels of control is a conceptual carryover from clinical chemistry, and does not apply to hematology particle counting. Dilute, "low-level" (eg, leukopenic and thrombocytopenic) "oncology" controls are less informative indicators of calibration status and are neither required nor recommended. For example, a 10% calibration bias will be numerically most apparent in a high-level control, less apparent in a normal-level control, and perhaps inapparent in a low-level control; it would be quite extraordinary for a low-level control to indicate a calibration problem that is not revealed by the other controls. There should be some relationship between the frequency of control runs and the numbers of patient specimens processed. If the frequency of commercial control use is less than two control specimens per 24 hours, one or more of the additional approaches to QC must be employed to produce a total of at least two different data points per 24 hours.*

**Evidence of Compliance:**
✓ Records of QC results

REFERENCES
1) McCafferty R, Cembrowski G, de la Salle B, Peng M, Urrechaga E. ICSH guidance for internal quality control policy for blood cell counters. *Int J Lab Hematol*. 2024;46(2):227-233.
2) Department of Health and Human Services, Centers for Medicare & Medicaid Services. Clinical laboratory improvement amendments of 1988: final rule. *Fed Register*. 2003(Jan 24):[42CFR493.1256(d)]

## Moving Averages

*The technique of weighted moving averages (derived from multiple batch analysis of patient samples) is acceptably sensitive to drifts or shifts in analyzer calibration if a supplemental QC routine (stabilized control material or retained patient specimens) is employed. The latter is needed to detect random error and to avoid bias due to masking of drift by characteristics of the subpopulations within each individual batch.*

*Laboratories analyzing fewer than 100 CBC specimens daily (long term average) should not use moving averages as the primary method for process control, as this would not generate sufficient data within a day to be of value.*

*Depending on the particular instrument, there may be "on-board" moving average analyses for RBC indices only. In such cases, additional QC techniques are required for WBC, PLT and WBC differential parameters. However, some laboratories have found the mathematical logic of moving averages, modified average of normals, etc., applicable to other CBC parameters, and some instruments have these capabilities built into their software. Or, such calculations may be performed with an associated computer.*

**HEM.25920 QC - Moving Averages** **Phase II**

**Control limits for moving averages are appropriately sensitive.**

*NOTE: Control limits for moving averages must be appropriately sensitive such that significant calibration alterations are always detected. The written procedures must define the method used to establish the moving average, the frequency of calculation (batch size), and criteria for selection of upper and lower limits.*

*Recalibration is not required for minor calibration variations of no clinical consequence. In other words, there should be a high probability for error detection and a low probability for false rejection.*

REFERENCES
1) Cembrowski GS, Smith B, Tung D. Rationale for using insensitive quality control rules for today's hematology analyzers. Int J Lab Hematol. 2010:32(6 Pt 2):606-615.
2) McCafferty R, Cembrowski G, de la Salle B, Peng M, Urrechaga E. ICSH guidance for internal quality control policy for blood cell counters. *Int J Lab Hematol*. 2024;46(2):227-233.
3) Lukic V, Ignjatovic S. Moving average procedures as an additional tool for real-time analytical quality control: challenges and opportunities of implementation in small-volume medical laboratories. *Biochem Med (Zagreb)*. 2022;32(1):010705.
4) Clinical and Laboratory Standards Institute (CLSI). Validation, Verification, and Quality Assurance of Automated Hematology Analyzers; Approved Standard—Second Edition. CLSI document H26-A2 (ISBN 1-56238-728-6). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2010.

## Retained Patient Specimens

*Use of retained patient specimens alone is inadequate for routine QC of the primary CBC instrument, and must be considered as a supplemental procedure, in combination with another QC system. Retained patient specimens, while conveniently available, present some difficulties in mathematically defining "agreement" between CBC results separated in time, as these are not stabilized samples. This is in contrast to commercial control materials that have been treated to reduce time-dependent degradation.*

**HEM.26660 QC - Retained Patient Specimens** **Phase I**

**When the laboratory uses retained patient specimens, statistically defined limits are used to determine agreement of sequential assays of a given specimen.**

*NOTE: Allowance should be made for time-dependent alterations in data from such labile specimens.*

**Evidence of Compliance:**
✓ QC records for retained patient specimens

## Error Detection and Verification

**HEM.30070 Sampling Mode Comparison** **Phase I**

**The laboratory compares all results obtained for patient specimens analyzed in the multiple sampling modes of the CBC analyzer (eg, "primary" and "secondary" modes) at least annually to ensure that they are in agreement.**

*NOTE: Different modes may involve a different sample path before analysis. When samples are analyzed in more than one mode, it is important to ensure that all modes function properly. Re-analysis of a previously analyzed sample must be performed in the alternate mode(s), and results must agree with the initial mode within the tolerance limits established for agreement by the hematology laboratory's quality control program, and any recommendations by the instrument*

*manufacturer. Mode-to-mode correlation is not necessary for those analyzers that use the same pathway for all modes.*

**Evidence of Compliance:**
✓ Records of sampling mode comparison studies

**HEM.30100 Detection/Correction Procedure - WBC** **Phase II**

**The laboratory has a process to detect and correct automated WBC counts for the presence of nucleated red cells or megakaryocytes.**

*NOTE: The effect of nucleated erythrocytes and blood megakaryocytes on the apparent WBC count varies with the system used for analysis. Each laboratory must evaluate its system(s) and develop appropriate detection and correction procedures. This is important to prevent reporting a falsely high WBC concentration. With some automated CBC instruments, nucleated erythrocytes or megakaryocytes may present themselves histographically or cytographically, and this can serve as an indicator for careful inspection of a stained blood film. The laboratory must establish if its particular instrument(s) includes some or all nucleated non-leukocytes in its apparent WBC "count".*

**Evidence of Compliance:**
✓ Records showing actions taken to verify WBC concentration prior to reporting

REFERENCES
1) Zandecki M, Genevieve F, Gerard J, Gordon A. Spurious counts and spurious results on haematology analysers: a review. Part II: white blood cell, red blood cells, haemaglobin, red cell indices and reticulocytes. *Int J Lab Hematol.* 2007;29(1):21-41.
2) Barnes PW, McFadden SL, Machin SJ, Simson E. The international consensus group for hematology review: suggested criteria for action following automated CBC and WBC differential analysis. *Lab Hematol.* 2005;11(2):83-90.
3) Gulati G, Uppal G, Gong J. Unreliable automated complete blood count results: causes, recognition, and resolution. *Ann Lab Med.* 2022;42(5):515-530.



# COAGULATION

## SPECIMEN COLLECTION AND HANDLING - COAGULATION

### Inspector Instructions:

| | |
|---|---|
| READ | • Sampling of coagulation specimen collection and handling policies and procedures<br>• Sampling of specimen rejection records/log |
| OBSERVE | • Sampling of patient coagulation specimens (anticoagulant, labeling, fill volume) |
| ASK | • How do you know if the specimen is clotted?<br>• What further actions are necessary if the specimen has a hematocrit of 60%?<br>• What is your course of action when you receive unacceptable coagulation specimens?<br>• How do you ensure that platelet-poor plasma is used for testing? |

## HEM.36840 Specimen Collection - Intravenous Lines — Phase I

**Instructions for the clearing (flushing) of intravenous lines before drawing specimens for hemostasis testing are defined and followed.**

*NOTE: Collection of blood for coagulation testing through intravenous lines that have been previously flushed with heparin should be avoided, if possible. If the blood must be drawn through an indwelling catheter, possible heparin contamination and specimen dilution must be considered. When obtaining specimens from indwelling lines that may contain heparin, the line should be flushed with 5 mL of saline, and the first 5 mL of blood or 6-times the line volume (dead space volume of the catheter) be drawn off and not used for coagulation testing. For those specimens collected from a normal saline lock (capped off venous port) twice the dead space volume of the catheter and extension set should be discarded.*

REFERENCES
1) Lew JKL, *et al*. Intra-arterial blood sampling for clotting studies. Effects of heparin contamination. *Anesthesia.* 1991;46:719-721
2) Konopad E, *et al*. Comparison of PT and aPTT values drawn by venipuncture and arterial line using three discard volumes. *Am J Crit Care.* 1992;3:94-101
3) Laxson CJ, Titler MG. Drawing coagulation studies from arterial lines; an integrative literature review. *Am J Critical Care*. 1994; 1:16-24
4) Adcock DM, *et al*. Are discard tubes necessary in coagulation studies? *Lab Med.* 1997;28:530-533
5) Brigden ML, *et al*. Prothrombin time determination. The lack of need for a discard tube and 24-hour stability. *Lab Med.* 1997;108:422-426
6) Clinical and Laboratory Standards Institute (CLSI). *Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays*. 6th ed. CLSI guideline H21. Clinical and Laboratory Standards Institute; 2024.
7) Clinical and Laboratory Standards Institute. *Collection of Diagnostic Venous Blood Specimens*; 7th ed. CLSI standard GP41-ED7. Clinical and Laboratory Standards Institute, Wayne, PA, 2017.

## HEM.36860 Anticoagulant - Coagulation — Phase I

**Routine coagulation specimens are collected into 3.2% buffered sodium citrate.**

*NOTE: Sodium citrate is effective as an anticoagulant due to its mild calcium-chelating properties. Of the 2 commercially available forms of citrate, 3.2% buffered sodium citrate (105-109 mmol/L of the dihydrate form of trisodium citrate $Na_3C_6H_5O_7 \cdot 2H_2O$) is the recommended anticoagulant for coagulation testing. Reference intervals for clot-based assays must be determined using the same concentration of sodium citrate that the laboratory uses for patient testing. The higher citrate concentration in 3.8% sodium citrate, may result in falsely lengthened clotting times (more so than 3.2% sodium citrate) for calcium-dependent coagulation tests (ie, PT and aPTT) performed on slightly underfilled samples and samples with high hematocrits. The prolonged results are also more pronounced when the clotting time is abnormal, such as in samples from patients on warfarin therapy. Both the World Health Organization and CLSI recommend utilizing 3.2% sodium citrate (105-109 nm/L), as the thromboplastin International Sensitivity Index (ISI) values applied in the INR calculations are based on specimens collected in 3.2% sodium citrate. Coagulation testing cannot be performed in samples collected in EDTA due to the more potent calcium chelation. While certain assay systems, such as platelet mapping via thromboelastography require heparin, heparinized tubes are not appropriate for clot-based plasma assays due to the inhibitory effect of heparin on multiple coagulation proteins. Other testing for platelet function, such as light transmission platelet aggregation assay can be performed on 3.2% or 3.8% sodium citrate.*

REFERENCES
1) Adcock DM, *et al*. Effect of 3.2% *vs* 3.8% sodium citrate concentration on routine coagulation testing. *Am J Clin Pathol.* 1997;107:105-110
2) Reneke, J *et al.* Prolonged prothrombin time and activated partial thromboplastin time due to underfilled specimen tubes with 109 mmol/L (3.2%) citrate anticoagulant. *Am J Clin Pathol.* 1998;109:754-757
3) Clinical and Laboratory Standards Institute (CLSI). *Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays*. 6th ed. CLSI guideline H21. Clinical and Laboratory Standards Institute; 2024.

# QUALITY CONTROL - COAGULATION

## Inspector Instructions:

| | |
|---|---|
| READ | • Sampling of quality control policies and procedures<br>• Sampling of QC records |
| ASK | • How do you determine when QC is unacceptable and when corrective actions are needed? |
| DISCOVER | • Review a sampling of QC data over the previous two-year period. Select several occurrences in which QC is out of range and follow records to determine if the steps taken follow the laboratory procedure for corrective action |



**HEM.37300 Coagulation Quality Control** **Phase II**

**The laboratory performs controls using two different levels of control material each eight hours of patient testing and each time there is a change in reagents, or more frequently if specified in manufacturer's instructions, or the CAP Checklist.**

*NOTE: For manual methods (ie, tilt tube method), controls must be performed by each individual who performs the tilt tube test in the same eight hour period.*

*If an internal quality control process (eg, electronic/procedural/built-in) is used instead of an external control material to meet daily quality control requirements, the laboratory must have an individualized quality control plan (IQCP) approved by the laboratory director defining the control process, including the frequency and use of external and internal controls. At a minimum, external control materials must be analyzed with new lots and shipments of reagents or more frequently if indicated in the manufacturer's instructions. Please refer to the IQCP section of the All Common Checklist for the eligibility of tests for IQCP and requirements for implementation and ongoing monitoring of an IQCP.*

**Evidence of Compliance:**

✓ Records of QC results including external and internal control processes **AND**
✓ Manufacturer product insert or manual

REFERENCES
1) Steindel SJ, Tetrault G. Quality control practices for calcium, cholesterol, digoxin, and hemoglobin. A College of American Pathologists Q-Probes study in 505 hospital laboratories. *Arch Pathol Lab Med* 1998;122:401-408
2) Voss EM, *et al.* Determining acceptability of blood glucose meters. Statistical methods of determining error. *Lab Med.* 1996;27:601-606
3) Clinical and Laboratory Standards Institute (CLSI). *Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions.* 4th ed. CLSI guideline C24. Clinical and Laboratory Standards Institute, Wayne, PA, 2016.
4) Ye JJ, *et al.* Performance evaluation and planning for patient/client-based quality control procedures. *Am J Clin Pathol.*2000;113:240-248
5) LaBeau KM, *et al.* Quality control of test systems waived by the clinical laboratory improvement amendments of 1988. Perceptions and practices. *Arch Pathol Lab Med.* 2000;124:1122-1127
6) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2003(Jan 24): [42CFR493.1269(b) & 42CFR.493.1269(c)(2)]
7) Department of Health and Human Services, Centers for Medicare and Medicaid Services. S & C: 16-20-CLIA: Policy Clarification on Acceptable Control Materials Used when Quality Control (QC) is Performed in Laboratories. April 8, 2016.