COLLEGE of AMERICAN PATHOLOGISTS

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Hematology and Coagulation Checklist

CAP Accreditation Program

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Hematology and Coagulation Checklist

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ON-LINE CHECKLIST DOWNLOAD OPTIONS

Participants of the CAP accreditation programs may download the checklists by logging into cap.org and going to e-LAB Solutions Suite - Accreditation Checklists. They are available in different checklist types and formatting options, including:

- Master — contains ALL of the requirements and instructions available in PDF, Word/XML or Excel formats
- Custom — customized based on the laboratory's activity (test) menu; available in PDF, Word/XML or Excel formats
- Changes Only — contains only those requirements with significant changes since the previous checklist edition in a track changes format to show the differences; in PDF version only. Requirements that have been moved or merged appear in a table at the end of the file.

CHECKLIST ACCREDITATION RESOURCES

CAP accredited laboratories have access to additional checklist accreditation tools and resources found on the CAP website (cap.org) by logging into e-LAB Solutions Suite - Accreditation Resources. Content found in Accreditation Resources includes:

- A library of past Focus on Compliance webinars and laboratory inspection preparation videos
- Answers to the most common checklist questions
- Customizable templates and forms (eg, competency assessment, personnel, validation/verification, quality management)
- Proficiency testing (PT) frequently asked questions, forms, and troubleshooting guides
- IQCP eligibility, frequently asked questions, forms, templates, and examples
- Laboratory director education and resources
- Quality management resources
- Inspector training and inspection tip sheets
- Self and post inspection toolbox

SUMMARY OF CHECKLIST EDITION CHANGES
Hematology and Coagulation Checklist
12/26/2024 Edition

The information below includes a listing of checklist requirements with significant changes in the current edition and previous edition of this checklist. The list is separated into three categories:

1. New
2. Revised:
   - Modifications that may require a change in policy, procedure, or process for continued compliance; or
   - A change to the Phase
3. Deleted/Moved/Merged**:**
   - Deleted
   - Moved — Relocation of a requirement into a different checklist (requirements that have been resequenced within the same checklist are not listed)
   - Merged — The combining of similar requirements

NOTE: The requirements listed below are from the Master version of the checklist. The customized checklist version created for inspections and self-evaluations may not list all of these requirements.

Previously Cited Checklist Requirements

- The **inspector's version** of the checklist contains a listing of previously cited checklist requirements. Specific information on those citations, including the inspection date and inspector comments, is included following each related requirement within the checklist.
- Laboratories can access data on previously cited deficiencies by logging into e-LAB Solutions Suite on cap.org and going to Accreditation Reports - Inspection Summation Report.

NEW Checklist Requirements
None

REVISED Checklist Requirements

Requirement	Effective Date
HEM.35762	08/24/2023
HEM.36820	12/26/2024

DELETED/MOVED/MERGED Checklist Requirements
None

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).*

QUALITY CONTROL

NONWAIVED TESTS - GENERAL

The following group of requirements is applicable to nonwaived manual, automated, and semi-automated testing, unless a separate checklist requirement exists in another checklist section that defines a specific QC frequency (eg, CBC instrument, coagulation testing, manual cell counts).

HEM.19360 Daily QC - Nonwaived Tests **Phase II**

The laboratory performs controls for quantitative and qualitative tests each day of testing, or more frequently if specified in manufacturer's instructions, laboratory procedure, or the CAP Checklist, and when changes occur that may impact patient results.

NOTE: The laboratory must define the number and type of quality control used and the frequency of testing in its quality control procedures. Control testing is not required on days when patient testing is not performed.

Controls must be run prior to resuming patient testing when changes occur that may impact patient results, including after a change of analytically critical reagents, major preventive maintenance, change of a critical instrument component, or with software changes, as appropriate.

Daily quality control must be run as follows:

- *Quantitative tests - two controls at different concentrations at least daily, except for coagulation tests (two controls every eight hours), or unless otherwise required elsewhere in this checklist*
- *Qualitative tests - a negative control and a positive control (when applicable) at least daily*

Controls should verify assay performance at relevant decision points. The selection of these points may be based on clinical or analytical criteria.

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 procedures **AND**
- ✓ Manufacturer product insert or manual

HEM.19380 Control Range Establishment or Verification **Phase II**

The laboratory establishes or verifies an acceptable control range for each lot of control material.

NOTE: For unassayed control materials, the laboratory must establish an acceptable control range by repetitive analysis in runs that include previously tested control material. For assayed control materials, the laboratory must verify control ranges supplied by the manufacturer.

Control values supplied by the manufacturer may be used without verification for qualitative (eg, positive or negative) testing.

Evidence of Compliance:
- ✓ Records for control range establishment or verification of each lot

HEM.20050 Numeric QC Data **Phase II**

For numeric QC data, quality control statistics (eg, SD and CV) are calculated monthly to define and monitor analytic imprecision.

NOTE: For CBC data where stabilized whole blood is not used for quality control, such statistics may be generated from previous patient samples using the standard deviation of duplicate pairs.

Evidence of Compliance:
- ✓ QC records showing monthly monitoring of imprecision

HEM.20070 Precision Statistics **Phase I**

The laboratory has an action protocol when data from precision statistics change significantly from previous data.

NOTE: As an example, if the laboratory's normal-level commercial control usually yields a monthly CV of 2% for WBC, but the most recent month shows a 4% CV, then something has caused increased imprecision, and investigation with records is required. Similarly, if the monthly SD for MCV by moving averages is typically around 1.8 fL, but now is at 3.1 fL, the laboratory must find a cause for this shift and take action. If commercially sponsored interlaboratory QC data for the same control lot and instrument model show SD/CV values outside those of the peer group, an explanation is required.

Evidence of Compliance:
- ✓ Records of investigation and corrective actions taken

HEM.20090 Alternative Control Procedures **Phase II**

If the laboratory performs test procedures for which control materials are not commercially available, the laboratory performs and records alternative control procedures to detect immediate errors and monitor test system performance over time.

NOTE: "Performance" includes elements of accuracy, precision, and clinical discriminating power. The following are examples of alternative procedures: split sample testing with another method or with another laboratory, the testing of previously tested patient specimens in duplicate, testing of patient specimens in duplicate, or other defined processes approved by the laboratory director.

Evidence of Compliance:
- ✓ Records of alternative control procedures

HEM.20120 QC Handling **Phase II**

The laboratory tests control specimens in the same manner and by the same personnel as patient samples.

NOTE: Personnel who routinely perform patient testing must analyze QC specimens; however, this does not imply that each operator must perform QC daily. Personnel must participate in QC on a regular basis. To the extent possible, all steps of the testing process must be controlled.

Evidence of Compliance:
- ✓ Records reflecting that QC is performed by the same personnel performing patient testing

HEM.20140 QC Confirmation of Acceptability **Phase II**

Personnel review control results for acceptability before reporting patient/client results.

Evidence of Compliance:
- ✓ Records of control result approval

HEM.20143 QC Corrective Action **Phase II**

The laboratory performs and records corrective action when control results exceed defined acceptability limits.

NOTE: The actions taken must be consistent with the laboratory's quality control program (GEN.30000). Patient test results obtained in an analytically unacceptable test run or since the last acceptable test run must be re-evaluated to determine if there is a significant clinical difference in patient/client results. Re-evaluation may or may not include re-testing patient samples, depending on the circumstances.

Even if patient samples are no longer available, test results can be re-evaluated to search for evidence of an out-of-control condition that might have affected patient results. For example, evaluation could include comparison of patient means for the run in question to historical patient means, and/or review of selected patient results against previous results to see if there are consistent biases (all results higher or lower currently than previously) for the test(s) in question.

The corrective action for tests that have an IQCP approved by the laboratory director must include an assessment of whether further evaluation of the risk assessment and quality control plan is needed based on the problems identified (eg, trending for repeat failures, etc.).

Evidence of Compliance:
- ✓ Records of corrective action for unacceptable control results

HEM.20146 Monthly QC Review **Phase II**

The laboratory director or designee reviews and assesses quality control data at least monthly.

NOTE: The reviewer must record follow-up for outliers, trends, or omissions that were not previously addressed.

The QC data for tests performed less frequently than once per month may be reviewed when the tests are performed.

The review of quality control data for tests that have an IQCP approved by the laboratory director must include an assessment of whether further evaluation of the risk assessment and quality control plan is needed based on problems identified (eg, trending for repeat failures, etc.).

Evidence of Compliance:
- ✓ Records of QC review **AND**
- ✓ Records of corrective action taken when acceptability criteria are not met

HEMATOLOGY

BODY FLUIDS

RESULT REPORTING - BODY FLUID

HEM.35650 Body Fluid Result Reporting of Nucleated Cells **Phase I**

When absolute total cell counting methods cannot reliably distinguish white blood cells from other nucleated cells, body fluid cell counts and differential results are reported with the total nucleated cell count and a differential with all nucleated cell types observed.

NOTE: If the absolute total cell counting method in the laboratory cannot reliably distinguish white blood cells from other nucleated cells (eg, unstained bright-field visualization of cells in a hemocytometer chamber and certain automated counting technologies), the laboratory must report the absolute total cell count (cells/µL) as TNC (total nucleated cells) not WBC (total white blood cells). The relative differential (% of total cells counted) performed on a stained cytocentrifuge slide, which can reliably distinguish white blood cells from other nucleated cells, must include the percentage of all nucleated cell types (eg, lymphocyte, neutrophil, monocyte/macrophage, basophils, eosinophil, plasma cell, mesothelial cell, bronchial lining cell, synovial lining cell, ventricular lining cell, endothelial cell, squamous epithelial, and other) when TNC is reported for the absolute total cell count.

Evidence of Compliance:
- ✓ Patient report with body fluid cell count and differential results

SEMEN ANALYSIS

The preceding items in the Body Fluid Cell Counting and Body Fluid Nucleated Cell Differentials are generally applicable to semen analysis. Additional items of importance to this specialized area are identified in this section.

REQUISITIONS, SPECIMEN RECEIPT AND RESULTS REPORTING

HEM.35661 Azoospermic Specimen Result Reporting **Phase I**

For azoospermic and post-vasectomy seminal fluid specimens, the laboratory clearly communicates the findings of the assay and either employs a concentrating technique on seminal fluid or includes a comment in the patient report indicating that a concentrating technique was not performed.

NOTE 1: Without a concentration technique, the presence of both motile and non-motile sperm may not be detected. The method for detection of motile and non-motile sperm and the laboratory findings must be clearly communicated on the patient report so that the clinician can interpret the results in context to the method performed. The decision on the method used and extent of testing to be performed should be made in consultation with the medical staff served.

The American Urological Association (AUA) Vasectomy Guideline recommends a careful evaluation of an uncentrifuged specimen, and does not recommend centrifugation of the specimen for further assessment. The AUA Guideline also recommends reporting both the presence and absence of sperm and presence or absence of sperm motility on the patient report. If no sperm are seen in the uncentrifuged specimen, the guideline recommends reporting that the presence of sperm is below the limit of detection.

NOTE 2: If the laboratory only performs post-vasectomy checks for presence or absence of sperm, HEM.35661 is the only applicable requirement in this section.

Evidence of Compliance:

- ✓ Patient report with concentration findings or appropriate comment indicating that concentration was not performed

HEM.35680 Specimen Collection/Handling **Phase I**

There are written patient instructions for collection and prompt delivery of a semen sample to the laboratory.

NOTE: This should be written in simple terms in a language readily understood by the patient. Elements should include the need to abstain from ejaculation for 2-7 days before collection of the specimen, avoidance of lubricants and other contamination, completeness of collection, use of the supplied container, maintenance of sample temperature, and prompt delivery. Instructions must be readily available and distributed to patients and to off-site physician offices that refer specimens.

HEM.35699 Specimen Collection/Handling **Phase I**

Semen specimens are accompanied by the following collection information, and records are retained on the following.

1. **Method of collection**
2. **Type of specimen container**
3. **Days of abstinence**
4. **Collection or transport problems (eg, incomplete specimen, exposure to temperature extremes)**
5. **Time of specimen receipt and analysis**

HEM.35718 Liquefaction **Phase I**

All semen specimens are given sufficient time for liquefaction before testing.

HEM.35737 Specimen Handling - Pre-analytic **Phase I**

Semen specimens are mixed thoroughly before testing.

HEM.35756 Specimen Characteristics - Analytic **Phase I**

All characteristics of the semen specimens are noted and reported (eg, gelatinous clumps, viscosity, contaminants, erythrocytes, and abnormalities of liquefaction).

NOTE: Macroscopic and microscopic characteristics of the semen specimens must be noted and reported, in accordance with the WHO laboratory manual for the examination of human semen (ie, fifth or sixth edition).

Evidence of Compliance:
- ✓ Patient reports

SPERM MOTILITY

***REVISED** 08/24/2023*
HEM.35762 Motility Method Verification **Phase I**

The laboratory verifies the sperm motility method used (eg, video tapes/digital images of specimens with known percent motility and/or specific motion quality) at least semiannually.

NOTE: This requirement applies to both automated and manual sperm motility methods.

Evidence of Compliance:
- ✓ Records of method verification

HEM.35765 Motility Quantification **Phase II**

Manual measures of percent sperm motility are quantified in a standardized manner.

NOTE: The laboratory must have a written method for determining and reporting sperm motility that describes how sperm are assessed and counted (percent motility) and is based on a reference method, such as the World Health Organization (WHO) Standards (ie, fifth or sixth edition).

HEM.35768 Forward Progression **Phase II**

Forward progression of sperm is evaluated.

Evidence of Compliance:
- ✓ Patient reports or worksheets with results of forward progression

HEM.35775 Motility/Progression Evaluation **Phase II**

Sperm motility percent and progression are routinely evaluated within one hour of collection.

Evidence of Compliance:
- ✓ Records indicating time of collection and evaluation **AND**
- ✓ Patient reports noting exceptions, when appropriate

HEM.35794 Standard Temperature Range **Phase II**

The laboratory has established a standard temperature range for semen analysis assessment, and deviations from this temperature are noted on the report.

NOTE: Sperm motility is temperature-dependent. Temperature ranges must be defined.

Evidence of Compliance:
- ✓ Records showing monitoring of temperatures

HEM.35813 Motility Microscopic Examination **Phase II**

The laboratory has written instructions for evaluating a sufficient number of separate and randomly chosen microscopic fields and sperm cells.

HEM.35822 Viability Testing Criteria **Phase I**

The laboratory performs viability testing on specimens with low percent motility (eg, less than 30%), or includes a comment that the decreased motility may be the result of non-viable or non-motile sperm.

NOTE: Non-motile sperm may represent forms that were originally non-viable in the ejaculate, or previously motile forms that have subsequently lost motility. Thus, viability assessment is useful in making the distinction, and is commonly performed with a dye-exclusion method such as eosin-nigrosin.

Evidence of Compliance:
- ✓ Patient records or worksheet with results of viability testing **OR** patient report with cautionary verbiage

STAINED SMEAR - SPERM DIFFERENTIAL

HEM.35832 Sperm Morphology Classification **Phase I**

The sperm morphology classification method used is indicated on the report.

NOTE: Different classification systems have different reference intervals for normality. To improve the consistency and usefulness of reporting, CAP recommends the use of the WHO Standards (ie, fourth, fifth, or sixth edition), and the Kruger classification system, and discontinuing the use of older classification systems.

HEM.35851 Morphologic Observation Evaluation - Sperm **Phase II**

The laboratory evaluates consistency of morphologic observation among personnel performing microscopic morphologic classification of sperm and other cells at least annually.

NOTE: The laboratory must ensure the identification of sperm and other cells is reported consistently amongst all personnel performing the microscopic analysis.

Suggested methods to accomplish this include:

1. *Circulation of a pre-graded set of stained semen smears with defined specific qualitative abnormalities of sperm*
2. *Multi-headed microscopy*
3. *Use of current published references*
4. *Digital images*
5. *Enrollment and participation of all personnel in an external assessment program for morphologic observation of semen smears.*

The laboratory director or designee must determine acceptability criteria for agreement. The laboratory must maintain records of performance and record corrective actions taken for personnel demonstrating significant discrepancies from the group consensus.

Evidence of Compliance:

- ✓ Records of evaluation **AND/OR**
- ✓ Records of enrollment/participation of staff in an external assessment program

HEM.35870 Consultation **Phase II**

An individual with expertise in sperm morphology (the pathologist, laboratory director, supervisor, or other technologist) is available for consultation, when needed.

HEM.35889 Sperm Morphology Reference **Phase I**

There is a file of unusual slides or current atlas of sperm morphology, available for training and reference.

HEM.35892 Stain Usage **Phase I**

Stains are used to facilitate morphologic classification of cell types in semen (as opposed to performing differentials of unstained preparations).

HEM.35893 Leukocyte Confirmation Techniques **Phase I**

There is an additional procedure beyond unstained bright-field microscopy to ensure the accurate distinction of leukocytes from other round cells (eg, Wright's, leukocyte alkaline phosphatase, or myeloperoxidase stains).

NOTE: This requirement only applies to laboratories that differentiate leukocytes from other round cells on the patient report.

Evidence of Compliance:

- ✓ Patient records or worksheets indicating use of additional procedure

HEM.35895 Stain QC **Phase II**

Quality control of all stains is performed and recorded to check for contamination and intended reactivity each day of use.

Evidence of Compliance:
- ✓ Records of stain QC

HEM.35902 Stain Quality **Phase II**

The stains used (Wright's, Papanicolaou, eosin-nigrosin, peroxidase, etc.) and slide preparations are of sufficient quality to demonstrate the cellular characteristics for which they are designed.

Evidence of Compliance:
- ✓ Examples of each type of stained slide available for microscopic review by inspector, as applicable

RESULTS REPORTING - HEMATOLOGY

***REVISED** 12/26/2024*
HEM.36820 Reference Intervals **Phase II**

Patient results are reported with accompanying reference intervals or interpretive ranges.

NOTE: For WBC differential counts, the CAP recommends that laboratories report absolute cell counts, along with their corresponding reference intervals. The CAP discourages the reporting of percent cell counts without absolute counts on WBC differentials. Laboratories reporting only percent cell counts must provide laboratory established reference intervals.

Under some circumstances it may be appropriate to distribute lists or tables of reference intervals (printed copies or electronic data) to users and sites where reports are received. The laboratory must ensure that such data is up to date.

Reference interval citations from the manufacturer's insert or published literature citations may be used to determine the reference interval. However, reference intervals have not been published for many body fluid analytes and obtaining normal fluids to establish reference intervals may not be feasible. If reference intervals are not available, results must be accompanied by an appropriate comment such as, "The reference interval(s) and other method performance specifications are unavailable for this body fluid. Comparison of the result with concentration in the blood, serum, or plasma is recommended."

Evidence of Compliance:
- ✓ Patient reports