Every patient
Deserves the
Gold Standard…

Hematology and Coagulation
Checklist

SAMPLE
UNDERSTANDING THE CAP ACCREDITATION CHECKLIST COMPONENTS

To provide laboratories with a better means to engage in and meet their accreditation requirements, the CAP has enhanced the checklist content and updated its design. New components containing additional information for both the laboratory and inspectors include Subject Headers, Declarative Statements and Evidence of Compliance. See below for a definition of each new feature as an example of how they appear in the checklists.

**Subject Header**
A phrase that provides the key concept of the requirement.

**Declarative Statement**
Checklist questions are reworded as declarative statements to better convey the regulatory nature of requirements.

**Using Evidence of Compliance (EOC)**

This component, which appears with several checklist requirements, is intended to:

1. Assist a laboratory in preparing for an inspection and managing ongoing compliance
2. Drive consistent understanding of requirements between the laboratory and the inspector
3. Provide specific examples of acceptable documentation (policies, procedures, records, reports, charts, etc.)

In addition to the Evidence of Compliance listed in the checklist, other types of documentation may be acceptable. Whenever a policy/procedure/process is referenced within a requirement, it is only repeated in the Evidence of Compliance if such statement adds clarity. All policies/procedures/processes covered in the CAP checklists must be documented. A separate policy is not needed for each item listed in EOC as it may be referenced in an overarching policy.
HOW TO INSPECT USING R.O.A.D INSPECTION TECHNIQUES  
(Read, Observe, Ask, Discover)

CAP has streamlined the inspection approach used during onsite inspections and is now offering guidance to inspectors by providing assessment techniques to facilitate a more efficient, consistent, and effective inspection process. Specific inspector instructions are listed at the beginning of a grouping of related requirements.

Rather than reviewing each individual requirement, CAP inspectors are encouraged to focus on the Inspector Instructions for a grouping of related requirements. Once an area of concern has been identified through "Read," "Observe," "Ask," "Discover," or a combination thereof, inspectors are encouraged to "drill down" to more specific requirements, when necessary and review more details outlined in the Evidence of Compliance statements. If a requirement is non-compliant, circle the requirement number to later list on the Inspector Summation Report. Inspectors may also make notes in the margins of the checklist document.

Inspector Instructions and Icons used to evaluate a laboratory’s performance now appear in several areas throughout the Inspector Checklists. Please note that all four R.O.A.D elements are not always applicable for each grouping, or sections of related requirements.

**Inspector Instructions:**

| **READ** | review a sampling of laboratory documents. Information obtained from this review will be useful as you observe processes and engage in dialogue with the laboratory staff.  
*(Example of the complimentary inspector instructions for Quality Management/Quality Control General Issues section appearing across checklists):*  
- Sampling of QM/QC policies and procedures  
- Incident/error log and corrective action |
|---|---|
| **OBSERVE** | laboratory practices by looking at what the laboratory personnel are actually doing and note if practice deviates from the documented policies/procedures.  
*(Example)*  
- Observe the settings/QC range limits established in the laboratory LIS/HIS to ensure that the laboratory's stated ranges are accurately reflected |
| **ASK** | open-ended, probing questions that start with phrases such as "tell me about..." or "what would you do if..." This approach can be a means to corroborate inspection findings that were examined by other techniques, such as Read & Observe. Ask follow-up questions for clarification. Include a variety of staff levels in your communication process.  
*(Example)*  
- As a staff member, what is your involvement with quality management?  
- How do you detect and correct laboratory errors? |
DISCOVER is a technique that can be used to "drill down" or further evaluate areas of concern uncovered by the inspector. "Follow the specimen" and "teach me" are two examples of Discovery. Utilizing this technique will allow for the discovery of pre-analytic, analytic, and post-analytic processes while reviewing multiple requirements simultaneously.

(Example)
- Select several occurrences in which QC is out of range and follow documentation to determine if the steps taken follow the laboratory policy for corrective action
INTRODUCTION

An inspection of a laboratory section, or department will include the discipline-specific checklist(s), the Laboratory General Checklist, and the All Common Checklist.

In response to the ongoing request to reduce the redundancy within the Accreditation Checklists, the CAP accreditation program is introducing the All Common Checklist (COM).

The purpose of the All Common Checklist is to group together those requirements that were redundant in Laboratory General and the discipline-specific checklists. Therefore, the CAP centralized all requirements regarding: proficiency testing, procedure manuals, test method validations, and critical results into one checklist, the COM checklist.

Note for non-US laboratories: Checklist requirements apply to non-US laboratories unless the checklist items contain a specific disclaimer of exclusion.

For this sample checklist, the following are requirements taken from the Hematology Checklist to illustrate the scope covered under the discipline of Hematology.

SPECIMEN COLLECTION AND HANDLING – HEMATOLOGY

Inspector Instructions:

- Sampling of hematology specimen collection and handling policies and procedures
- Sampling of specimen rejection records/log

- Sampling of patient CBC specimens (anticoagulant, labeling, storage)

- How do you know if the CBC specimen is clotted, lipemic, or hemolyzed?
- How do you ensure the CBC sample is thoroughly mixed before analysis?
- 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.

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 (e.g. CBC, leukocyte differential) must be collected in potassium EDTA to minimize changes in cell characteristics. Oxalate can cause unsuitable morphologic changes such as cytoplasmic vacuoles, cytoplasmic crystals, and irregular nuclear lobulation. Heparin can cause cellular clumping (especially of platelets), pseudo-leukocytosis with pseudo-thrombocytopenia in some particle counters, and troublesome blue background in Wright-stained blood films. Citrate may be useful in some cases of platelet agglutination due to EDTA, but those CBC data will require adjustment for the effects of dilution.

HEM.22150  Specimen Quality Assessment – CBC  Phase II
CBC specimens are checked for clots (visual, applicator sticks, or automated analyzer histogram inspection/flags) before reporting results.

NOTE: This may be done visually or with applicator sticks before testing. Additionally, microclots will often present themselves histographically on automated and semi-automated particle counters or by flagging, and the laboratory must become familiar with such patterns. Finally, platelet clumps or fibrin may be microscopically detected if a blood film is prepared on the same sample.

HEM.22200  Hemolyzed or Lipemic Specimens – CBC  Phase II
CBC specimens are checked for significant in vitro hemolysis and possible interfering lipemia before reporting results.

NOTE: Specimens for complete blood counts must be checked for in vitro hemolysis that may falsely lower the erythrocyte count and the hematocrit, as well as falsely increase the platelet concentration from erythrocyte stroma. Visibly red plasma in a tube of EDTA-anticoagulated settled or centrifuged blood should trigger an investigation of in vivo hemolysis (in which case the CBC data are valid) versus in vitro hemolysis (in which case some or all of the CBC data are not valid and should not be reported). Lipemia may adversely affect the hemoglobin concentration and the leukocyte count. This does not imply that every CBC specimen must be subjected to centrifugation with visual inspection of the plasma supernatant, particularly if this would significantly impair the laboratory’s turnaround time. An acceptable alternative for high volume laboratories with automated instrumentation is to examine the numeric data for anomalous results (especially indices), as well as particle histogram inspection.

Evidence of Compliance:
✓ Written procedure defining method for checking specimens for in vitro hemolysis and lipemia
SPECIMEN COLLECTION AND HANDLING – COAGULATION

Inspector Instructions:

- Sampling of coagulation specimen collection and handling policies and procedures
- Sampling of specimen rejection records/log

- Sampling of patient coagulation specimens (anticoagulant, labeling)

- How do you know if the specimen is clotted?
- What further actions are necessary if the specimen has a hematocrit of 60%?
- What is your course of action when you receive unacceptable coagulation specimens?

HEM.22707 Specimen Collection - Intravenous Lines Phase II
There is a documented procedure regarding clearing (flushing) of the volume of intravenous lines before drawing samples for hemostasis testing.

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 should 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 discarded before the coagulation tube is filled. For those samples collected from a normal saline lock (capped off venous port) twice the dead space volume of the catheter and extension set should be discarded.

HEM.22748 Anticoagulant – Coagulation Phase II
All coagulation specimens should be 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 Na3C6H5O7·2H2O) is the recommended anticoagulant for coagulation testing. Reference intervals for clot-based assays should 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 (i.e. PT and aPTT) performed on slightly underfilled samples and samples with high hematocrits. Coagulation testing cannot be performed in samples collected in EDTA due to the more potent calcium chelation. Heparinized tubes are not appropriate due to the inhibitory effect of heparin on multiple coagulation proteins. Testing for platelet function can be performed on 3.2% or 3.8% sodium citrate.

**Evidence of Compliance:**
✓ Written procedure defining the use of 3.2% buffered sodium citrate for coagulation specimen collection OR procedure with an alternative anticoagulant defined with validation data

**HEM.22789 Specimen Rejection Criteria – Coagulation Phase II**

There are documented guidelines for rejection of under- or overfilled collection tubes.

NOTE: The recommended proportion of blood to the sodium citrate anticoagulant volume is 9:1. Inadequate filling of the collection device will decrease this ratio, and may lead to inaccurate results for calcium-dependent clotting tests, such as the PT and aPTT. The effect on clotting time from under-filled tubes is more pronounced when samples are collected in 3.8% rather than 3.2% sodium citrate. The effect of fill volume on coagulation results also depends on the reagent used for testing, size of the evacuated collection tube, and citrate concentration. A minimum of 90% fill is recommended; testing on samples with less than 90% fill should be validated by the laboratory.

**Evidence of Compliance:**
✓ Records of rejected specimens

**HEM.22871 Specimen Quality Assessment - Coagulation Phase II**

Coagulation specimens are checked for clots (visual, applicator sticks, or by analysis of testing results) before testing or reporting results.

NOTE: Specimens with grossly visible clots may have extremely low levels of fibrinogen and variably decreased levels of other coagulation proteins, so that results of the PT, aPTT, fibrinogen and other coagulation assays will be inaccurate or unobtainable. Checking for clots may be done with applicator sticks or by visual inspection of centrifuged plasma for small clots. This may also be performed by analysis of results (waveform analysis or delta checks). Additionally, when a clot is not detected during PT and aPTT testing and, where the fibrinogen level is <25 mg/dL, it should be suspected that the sample is actually serum. This may be important when coagulation specimens are received as centrifuged, frozen “plasma”. Centrifuged plasma and serum cannot be distinguished by visual inspection alone. There should be a mechanism in place to identify these specimens appropriately and/or to reject the sample as a probable serum sample. Laboratories should be encouraged to work with their clients that perform sample processing to ensure that they practice appropriate specimen handling for coagulation specimens.
ABNORMAL HEMOGLOBIN DETECTION

Inspector Instructions:

- Sampling of abnormal hemoglobin policies or procedures
- Sampling of patient reports (confirmatory testing, comments)
- Sampling of QC records

- Hemoglobin electrophoretic patterns (appropriate separations and controls)
- Examine a sampling of medium (media) used to identify hemoglobin variants including alkaline/acid electrophoresis, isoelectric focusing, HPLC, or other methods
- Hemoglobin electrophoretic patterns (appropriate separations and controls)

- What is your course of action when the primary screening method appears to show Hb S?
- What is your course of action when the primary Hb electrophoresis method shows Hb variants migrating in nonA/nonS positions?

HEM.35925 Hb S Primary Screen Phase II
For patient samples that appear to have Hb S in the primary screening (by any method), the laboratory either 1) performs a second procedure (solubility testing, or other acceptable method) to confirm the presence of Hb S, or 2) includes a comment in the patient report recommending that confirmatory testing be performed.

NOTE: For primary definitive diagnosis screening by electrophoresis or other separation methods, all samples with hemoglobins migrating in the “S” positions or peak must be tested for solubility or by other acceptable confirmatory testing for sickling hemoglobin(s). Known sickling and non-sickling controls both must be included with each run of patient specimens tested.

Evidence of Compliance:
✓ Written procedure defining criteria for follow-up when Hb S appears in the primary screen

HEM.35927 Daily QC - Hgb Electrophoresis Phase II
Controls containing at least three known major hemoglobins, including both a sickling and a non-sickling hemoglobin (e.g. A, F, and S) are applied with the patient specimen(s) and separations are satisfactory.
Evidence of Compliance:
✓ Written procedure defining QC requirements for hemoglobin electrophoresis AND
✓ QC records reflecting the use of appropriate controls AND
✓ Electrophoresis gels demonstrating appropriate controls and separation

HEM.35984 Hb S Predominant Band Phase II
All samples that appear to have Hb S as the predominant band by the primary screening (by whatever method) and that are confirmed as sickling by appropriate methods are further examined to ascertain whether the "Hb S" band or peak contains solely Hb S or both Hb S and Hb D, Hb G or other variant hemoglobins.

NOTE: When the predominant hemoglobin component appears to be Hb S, it is necessary to determine whether this represents homozygous Hb S or a heterozygote for Hb S and another variant such as Hb D, Hb G, Hb Lepore, or other hemoglobin variant(s). Given the clinical implications of homozygous Hb S (or Hb S/ß-zero thalassemia) it is imperative to exclude other hemoglobin variants, however rare. Referral of these specimens to a reference laboratory for further workup is acceptable.

Evidence of Compliance:
✓ Written procedure defining criteria for determination of homozygous versus heterozygous Hb S AND
✓ Patient records or worksheets showing exclusion of hemoglobin variants OR documentation of referral for further work-up

BONE MARROW PREPARATIONS

Inspector Instructions:

- Bone marrow policy and procedure
- Sampling of stain QC records
- Bone Marrow slide (uniquely identified, satisfactory staining and cell distribution)
- How do you reconcile clinically significant discrepancies between the bone marrow morphologic diagnosis and the results of ancillary studies?
**HEM.36050 Slide Labeling**  
**Phase II**  
Bone marrow slides are uniquely identified.  

NOTE: Slide or coverslip identification must include a unique identifier(s), such as specimen or accession number, patient name and/or number, and date. The ability to identify the patient as well as the date the specimen was obtained applies to all parts of the bone marrow case, which may include blood films, bone marrow aspirate, marrow clot and core biopsy specimens.

**Evidence of Compliance:**
✓ Written procedure for slide labeling

**HEM.36150 Fixed Sections**  
**Phase I**  
Fixed sections (marrow biopsy or particle sections) are used as a diagnostic aid to the smear aspirate, as appropriate for the clinical situation.

**Evidence of Compliance:**
✓ Patient reports with documentation of aspirate and fixed section review, as applicable

**HEM.36250 Fixed Tissue Correlation**  
**Phase II**  
If fixed tissue sections and bone marrow aspirate smears are evaluated in different sections of the laboratory, or if separate reports are released at different times, there is a mechanism to compare the data and interpretations from these different sections.

NOTE: Unified reporting of bone marrow aspirates and biopsies is strongly recommended. If aspirate smears and biopsy reports are released by different sections of the laboratory, or at different times, a mechanism must be in place to comment upon the existing report and interpretation when the subsequent report is released. Any conflicting data should be commented upon. Such data correlation is essential for diagnostic consistency and effective patient management.

**Evidence of Compliance:**
✓ Written procedure defining process for review/correlation of fixed tissue sections and bone marrow aspiration smear results/interpretations AND  
✓ Records of review/correlation with follow-up reporting if a discrepancy is identified