HEMATOLOGY AND COAGULATION - SECTION 2
PROPOSED CHECKLIST

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NOTE: Material on Body Fluids (Clinical Microscopy) has been relocated to Urinalysis and Clinical Microscopy Checklist 3A.

NOVEMBER 1999 OUTLINE

PROFICIENCY TESTING
QUALITY CONTROL AND QUALITY IMPROVEMENT
  SUPERVISION
  PROCEDURE MANUAL
  SPECIMEN COLLECTION AND HANDLING
  REPORTING OF RESULTS
  REAGENTS
  INSTRUMENTS AND EQUIPMENT

COMPLETE BLOOD COUNT (CBC) INSTRUMENTS
  CALIBRATION
    Fresh Whole Blood
    Commercial Calibrators
  QUALITY CONTROL
    Stabilized Controls
    Moving Averages
    Retained Patient Specimens
    Interinstrument Comparisons
  ERROR DETECTION AND VERIFICATION
  GENERAL INSTRUMENT ISSUES

MANUAL HEMOGLOBIN DETERMINATION (CYANMETHEMOGLOBIN)
MANUAL HEMATOCRIT (MICROHEMATOCRIT, PACKED CELL VOLUME)
MANUAL (HEMOCYTOMETER) WBC AND PLT COUNTS (BLOOD)
AUTOMATED DIFFERENTIAL COUNTERS
MANUAL BLOOD FILM EXAMINATION (DIFFERENTIAL COUNT)
AUTOMATED RETICULOCYTES
MANUAL RETICULOCYTE COUNTS
BONE MARROW PREPARATIONS
BLOOD COAGULATION STUDIES
  Interinstrument Comparisons
  Photo-Optical Coagulation Systems
  Electromechanical Coagulation Systems
  Manual Coagulation Systems
  Coagulation Factor Assays
ABNORMAL HEMOGLOBIN DETECTION

PERSONNEL
PHYSICAL FACILITIES
LABORATORY SAFETY
PROFICIENCY TESTING

CAP-accredited laboratories must participate in the CAP Surveys or a CAP-approved alternative proficiency testing program. This must include attempted enrollment in programs with graded analytes matching those for which the laboratory performs patient testing.

QUESTION: 02:1015  PHASE: II

Is the laboratory enrolled in the appropriate available graded CAP Surveys or a CAP-approved alternative proficiency testing program for the patient testing performed?

NOTE: For purposes of photomicrograph identification in CAP Surveys, it is strongly recommended that the current CAP Surveys Hematology Glossary (Blood Identification section) be readily available to the bench technologist in the section.

PROFICIENCY TESTING:

THE LABORATORY MUST PARTICIPATE IN AN APPROVED PROGRAM OF GRADED INTERLABORATORY COMPARISON TESTING APPROPRIATE TO THE SCOPE OF THE LABORATORY, IF AVAILABLE. THIS MUST INCLUDE ENROLLMENT IN SURVEYS WITH ANALYTES MATCHING THOSE FOR WHICH THE LABORATORY PERFORMS PATIENT TESTING. LABORATORIES WILL NOT BE PENALIZED IF THEY ARE UNABLE TO PARTICIPATE IN AN OVERSUBSCRIBED SURVEY.


COMMENTARY: 02:1015 PHASE: II

THE LABORATORY MUST BE ENROLLED IN A CAP SURVEY OR A CAP-APPROVED ALTERNATIVE PROFICIENCY TESTING PROGRAM APPROPRIATE FOR THE PATIENT TESTING PERFORMED.

QUESTION: 02:1017 PHASE: II

Does the laboratory integrate the external Surveys samples within the routine laboratory workload, and are those samples analyzed by personnel who routinely test patient samples, using the same primary method systems as for patient samples?

NOTE: Replicate analysis of Surveys samples is acceptable only if patient specimens are routinely analyzed in the same manner. If the laboratory uses multiple methods for an analyte, Surveys samples should be analyzed by the primary method. There must not be any interlaboratory communication on proficiency testing data before results reporting.

COMMENTARY: 02:1017 PHASE: II

EXTERNAL PROFICIENCY TESTING SAMPLES MUST BE INTEGRATED WITHIN THE ROUTINE LABORATORY WORKLOAD, AND ANALYZED BY PERSONNEL WHO ROUTINELY TEST PATIENT SAMPLES, USING PRIMARY METHOD SYSTEMS. THERE MUST NOT BE ANY INTERLABORATORY COMMUNICATION ON PROFICIENCY TESTING DATA BEFORE RESULTS REPORTING. ONE OR MORE OF THESE REQUIREMENTS ARE NOT BEING MET BY THE LABORATORY, AND MUST BE CORRECTED. THE EDUCATIONAL PURPOSES AND DOCUMENTATION OF PROFICIENCY ARE BEST SERVED BY A ROTATION THAT ALLOWS ALL TECHNOLOGISTS TO BE INVOLVED IN THE PROFICIENCY TESTING PROGRAM. RECORDS OF THESE STUDIES MUST BE KEPT AND CAN BE AN IMPORTANT PART OF THE PERSONNEL AND CONTINUING EDUCATION FILES OF THE INDIVIDUALS.

REFERENCE: Department of Health and Human Services, Health Care Financing Adminis-

QUESTION: 02:1020 PHASE: II

Is there documented evidence of active review by the laboratory director or designee of the proficiency testing results?

COMMENTARY: 02:1020 PHASE: II

THERE MUST BE EVIDENCE OF ACTIVE REVIEW BY THE LABORATORY DIRECTOR OR DESIGNEE OF PROFICIENCY TESTING RESULTS.


QUESTION: 02:1025 PHASE: II

Is there evidence of evaluation and, if indicated, corrective action in response to "unacceptable" results on the Surveys report?

COMMENTARY: 02:1025 PHASE: II

THERE IS INSUFFICIENT EVIDENCE OF EVALUATION AND, IF INDICATED, CORRECTIVE ACTION IN RESPONSE TO EACH "UNACCEPTABLE" RESULT ON THE PROFICIENCY SURVEYS REPORT. THE EVALUATION MUST DOCUMENT THE SPECIFIC REASON(S) FOR THE "UNACCEPTABLE" RESULTS AND ACTIONS TAKEN TO REDUCE THE LIKELIHOOD OF RECURRENT. THIS MUST BE DONE WITHIN ONE MONTH AFTER THE LABORATORY RECEIVES ITS SURVEYS EVALUATION.

For analytes where graded proficiency testing is not available, are other procedures used to validate performance at least semi-annually?

NOTE: Other appropriate procedures may include: participation in ungraded proficiency survey programs, split sample analysis with reference or other laboratories, split samples with an established in-house method, assayed material, regional pools, clinical validation by chart review, or other suitable and documented means. It is the responsibility of the laboratory director to define such procedures, as applicable, in accordance with good clinical and scientific laboratory practice.

SUPERVISION

Judgment of the acceptability of quality control (QC) data must be made before patient results are reported. Oversight review must occur at least monthly by the laboratory director or designee. Beyond these specific requirements, a laboratory may (optionally) perform more frequent review at intervals that it determines appropriate for its setting and the assays involved. Because of the many variables, the CAP makes no specific recommendations on the frequency of any additional assessment/review of QC data.

Quality improvement issues are addressed in Laboratory General Checklist 1.

QUESTION: 02:2000 PHASE: II

Is there a document for the design and evaluation of the laboratory quality control (QC) and quality improvement (QI) program?

NOTE: The QC/QI program must provide the system design and evaluation of proper patient identification and preparation; specimen collection, identification, preservation, transportation, and processing; and accurate result reporting. This system must ensure optimum patient specimen and result integrity throughout the pre-analytical, analytical, and post-analytical processes. Opportunities for system improvement are identified and, based on such evaluations, corrective plans are developed and implemented.

QUALITY CONTROL AND QUALITY IMPROVEMENT:

SUPERVISION: THE QC/QI PROGRAM IN HEMATOLOGY SHOULD BE CLEARLY DEFINED AND WELL-ORGANIZED. THE PROGRAM MUST PROVIDE THE SYSTEM DESIGN AND EVALUATION OF PROPER PATIENT IDENTIFICATION AND PREPARATION; SPECIMEN COLLECTION, IDENTIFICATION, PRESERVATION, TRANSPORTATION, AND PROCESSING; AND ACCURATE RESULT REPORTING. THIS SYSTEM MUST ENSURE OPTIMUM PATIENT SPECIMEN AND RESULT INTEGRITY THROUGHOUT THE PREANALYTICAL, ANALYTICAL, AND POST-ANALYTICAL PROCESSES. OPPORTUNITIES FOR SYSTEM IMPROVEMENT ARE IDENTIFIED AND, BASED ON SUCH EVALUATIONS, CORRECTIVE PLANS ARE DEVELOPED AND IMPLEMENTED.

JUDGMENT OF THE ACCEPTABILITY OF QUALITY CONTROL DATA MUST BE MADE BEFORE PATIENT RESULTS ARE REPORTED. OVERSIGHT REVIEW MUST
OCCUR AT LEAST MONTHLY BY THE LABORATORY DIRECTOR OR DESIGNEE. BEYOND THESE SPECIFIC REQUIREMENTS, A LABORATORY MAY (OPTIONALLY) PERFORM MORE FREQUENT REVIEW AT INTERVALS THAT IT DETERMINES APPROPRIATE FOR ITS SETTING AND THE ASSAYS INVOLVED. BECAUSE OF THE MANY VARIABLES, THE CAP MAKES NO SPECIFIC RECOMMENDATIONS ON THE FREQUENCY OF ANY ADDITIONAL ASSESSMENT/REVIEW OF QC DATA.

COMMENTARY: 02:2000  PHASE: II

THE LABORATORY MUST HAVE A COMPREHENSIVE PROGRAM FOR QUALITY CONTROL AND QUALITY IMPROVEMENT IN THE HEMATOLOGY SECTION OF THE LABORATORY.

QUESTION: 02:2002  PHASE: II

Is there a documented procedure(s) describing methods for patient identification, patient preparation, specimen collection and labeling, specimen preservation, and conditions for transportation, and storage before testing, consistent with good laboratory practice?

COMMENTARY: 02:2002  PHASE: II

THE LABORATORY MUST HAVE COMPLETELY DOCUMENTED PROCEDURES DESCRIBING METHODS FOR PATIENT IDENTIFICATION, PATIENT PREPARATION, SPECIMEN COLLECTION AND LABELLING, SPECIMEN PRESERVATION, CONDITIONS FOR TRANSPORTATION, AND STORAGE BEFORE TESTING. SUCH PROTOCOLS MUST BE CONSISTENT WITH GOOD LABORATORY PRACTICE.


QUESTION: 02:2005  PHASE: II

For numeric QC data generated by the hematology laboratory, are Gaussian or other quality control statistics (S.D. and C.V.) calculated at least monthly to define analytic precision?

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.

COMMENTARY: 02:2005  PHASE: II
THE LABORATORY MUST CALCULATE PRECISION STATISTICS (S.D. AND C.V.) AT LEAST MONTHLY FOR NUMERIC HEMATOLOGY QC DATA. 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.


QUESTION: 02:2007 PHASE: II

Does the laboratory have 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 documentation 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 indicated. Finally, if commercially-sponsored interlaboratory QC data for the same control lot and instrument model show SD/CV values markedly smaller or larger than the peer group, an explanation is required.

COMMENTARY: 02:2007 PHASE: II

THE LABORATORY MUST HAVE AN ACTION PROTOCOL WHEN DATA FROM PRECISION STATISTICS CHANGE SIGNIFICANTLY FROM PREVIOUS DATA. 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 DOCUMENTATION 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 INDICATED. FINALLY, IF COMMERCIALL-
SPONSORED INTERLABORATORY QC DATA FOR THE SAME CONTROL LOT AND INSTRUMENT MODEL SHOW SD/CV VALUES MARKEDLY SMALLER OR LARGER THAN THE PEER GROUP, AN EXPLANATION IS REQUIRED.

QUESTION: 02:2010  PHASE: II

Are tolerance limits (numeric and/or non-numeric) fully defined and documented for all hematology and coagulation control procedures?

COMMENTARY: 02:2010  PHASE: II

NUMERIC AND/OR NON-NUMERIC TOLERANCE LIMITS MUST BE FULLY DEFINED AND DOCUMENTED FOR ALL HEMATOLOGY AND COAGULATION CONTROL PROCEDURES. THE GOAL IS TO HAVE SCIENTIFICALLY VALID, LOGICAL "ACTION LIMITS" FOR QUALITY CONTROL PROCEDURES THAT PROMPTLY ALERT THE TECHNOLOGIST OF THE NEED FOR IMMEDIATE EVALUATION OF THE PARTICULAR ASSAY, INCLUDING INITIATION OF CORRECTIVE ACTION, PRIOR TO RELEASE OF PATIENT RESULTS.

QUESTION: 02:2012  PHASE: II

Are control specimens tested in the same manner as patient samples?

COMMENTARY: 02:2012  PHASE: II

IT IS IMPLICIT IN QUALITY CONTROL THAT CONTROL SPECIMENS ARE TESTED IN THE SAME MANNER AS PATIENT SPECIMENS. MOREOVER, QC SPECIMENS MUST BE ANALYZED BY PERSONNEL WHO ROUTINELY PERFORM PATIENT TESTING - THIS DOES NOT IMPLY THAT EACH OPERATOR MUST PERFORM QC DAILY, SO LONG AS EACH INSTRUMENT AND/OR TEST SYSTEM HAS QC PERFORMED AT REQUIRED FREQUENCIES. TO THE EXTENT POSSIBLE, ALL STEPS OF THE TESTING PROCESS MUST BE CONTROLLED, RECOGNIZING THAT PRE-ANALYTIC AND POST-ANALYTIC VARIABLES MAY DIFFER FROM THOSE ENCOUNTERED WITH PATIENTS.


QUESTION: 02:2014  PHASE: II

Are the results of controls verified for acceptability before reporting results?
COMMENTARY: 02:2014 PHASE: II

CONTROLS MUST BE REVIEWED BEFORE REPORTING PATIENT RESULTS. IT IS IMPLICIT IN QUALITY CONTROL THAT PATIENT TEST RESULTS WILL NOT BE REPORTED WHEN CONTROLS DO NOT YIELD ACCEPTABLE RESULTS.


QUESTION: 02:2015 PHASE: II

Is there evidence of active review of results of controls, instrument maintenance and function, etc., for routine procedures on all shifts?

COMMENTARY: 02:2015 PHASE: II

THERE MUST BE ACTIVE REVIEW OF RECORDS OF CONTROLS, INSTRUMENT FUNCTION AND MAINTENANCE, ETC., ON ALL SHIFTS.

QUESTION: 02:2020 PHASE: II

Is there a documented system in operation to detect and correct significant clerical errors that could affect patient management?

COMMENTARY: 02:2020 PHASE: II

THE LABORATORY MUST HAVE A DOCUMENTED SYSTEM IN OPERATION TO DETECT AND CORRECT SIGNIFICANT CLERICAL ERRORS IN THE GENERATION OF PATIENT CARE DATA. ONE COMMON METHOD IS A REVIEW OF RESULTS BY A QUALIFIED PERSON (TECHNOLOGIST, SUPERVISOR, PATHOLOGIST), BUT THERE IS NO REQUIREMENT FOR SUPERVISORY REVIEW OF ALL REPORTED DATA. THE SELECTIVE USE OF DELTA CHECKS MAY ALSO BE USEFUL IN DETECTING CLERICAL ERRORS IN CONSECUTIVE SAMPLES FROM THE SAME PATIENT. IN COMPUTERIZED LABORATORIES, THERE SHOULD BE AUTOMATIC "TRAPS" FOR IMPROBABLE RESULTS.


QUESTION: 02:2025 PHASE: II

Is there a documented system in operation to detect and correct significant analytic errors
or interferences for each laboratory test or instrument?

COMMENTARY: 02:2025  PHASE: II

THE LABORATORY MUST HAVE A DOCUMENTED SYSTEM IN OPERATION TO DETECT AND CORRECT SIGNIFICANT ANALYTICAL ERRORS OR INTERFERENCES FOR EACH TEST OR INSTRUMENT. EACH HEMATOLOGY PROCEDURE MUST INCLUDE A LISTING OF COMMON SITUATIONS THAT MAY CAUSE ANALYTICALLY INACCURATE RESULTS, TOGETHER WITH A DEFINED PROTOCOL FOR DEALING WITH SUCH ANALYTIC ERRORS OR INTERFERENCES. THIS MAY REQUIRE ALTERNATE TESTING METHODS OR AN INABILITY TO REPORT SOME OR ALL DATA.

QUESTION: 02:2030  PHASE: II

Is there a documented system in operation to verify highly unusual results for each laboratory test or instrument?

NOTE:  This does NOT imply that there must be verification of EVERY result outside the reference interval (normal range).

COMMENTARY: 02:2030  PHASE: II

THE LABORATORY MUST HAVE A DOCUMENTED SYSTEM IN OPERATION TO VERIFY HIGHLY UNUSUAL RESULTS FOR EACH TEST OR INSTRUMENT. THERE MUST BE A PROTOCOL FOR REVIEW OF HIGHLY UNUSUAL PATIENT DATA BY A SUPERVISOR OR PATHOLOGIST, PARTICULARLY WHEN SUCH DATA ARE USED FOR IMPORTANT PATIENT MANAGEMENT DECISIONS. THIS DOES NOT IMPLY THAT THERE MUST BE VERIFICATION OF EVERY RESULT OUTSIDE THE REFERENCE INTERVAL (NORMAL RANGE).

QUESTION: 02:2035  PHASE: II

Do the systems for detecting clerical errors, significant analytic errors/interferences, and unusual results provide for timely correction of erroneous results?

COMMENTARY: 02:2035  PHASE: II

THE SYSTEM FOR DETECTING CLERICAL ERRORS, SIGNIFICANT ANALYTICAL ERRORS/INTERFERENCES, AND UNUSUAL LABORATORY RESULTS MUST PROVIDE FOR TIMELY CORRECTION OF ERRONEOUS RESULTS. CORRECTIONS MADE AFTER THE ORIGINAL DATA HAVE BEEN RELEASED AND USED FOR PATIENT CARE DECISIONS ARE CLEARLY OF LIMITED CLINICAL VALUE.
QUESTION: 02:2040  PHASE: II

In the absence of on-site supervisors, are the results of tests performed by personnel reviewed by the laboratory director, hematology section director, general supervisor, or person in charge of hematology on the next routine working shift?

NOTE: The CAP does NOT require supervisory review of all test results before or after reporting to patient records. Rather, this question is intended to address only that situation defined under CLIA-88 for "high complexity testing" performed by trained high school graduates qualified under 42CFR493.1489(b)(5) when a qualified general supervisor is not present.

COMMENTARY: 02:2040  PHASE: II

IN THE ABSENCE OF ON-SITE SUPERVISORS, THE RESULTS OF TESTS PERFORMED BY PERSONNEL MUST BE REVIEWED BY THE LABORATORY DIRECTOR, HEMATOLOGY SECTION DIRECTOR, GENERAL SUPERVISOR, OR PERSON IN CHARGE OF HEMATOLOGY ON THE NEXT ROUTINE WORKING SHIFT. THE CAP DOES NOT REQUIRE SUPERVISORY REVIEW OF ALL TEST RESULTS BEFORE OR AFTER REPORTING TO PATIENT RECORDS. RATHER, THIS QUESTION IS INTENDED TO ADDRESS ONLY THAT SITUATION DEFINED UNDER CLIA-88 FOR "HIGH COMPLEXITY TESTING" PERFORMED BY TRAINED HIGH SCHOOL GRADUATES QUALIFIED UNDER 42CFR493.1489(b)(5) WHEN A QUALIFIED GENERAL SUPERVISOR IS NOT PRESENT.

REFERENCE: Department of Health and Human Services, Health Care Financing Administration. Clinical laboratory improvement amendments of 1988; final rule. Federal Register. 1992(Feb 28):7182 [42CFR493.1463(a)93) and 42CFR493.1463(c)]: 7183 [42CFR493.1489(b)(1) and 42CFR493.1489(b)(5)].

PROCEDURE MANUAL

The complete procedure manual should be written in substantial compliance and meet the intent of the National Committee for Clinical Laboratory Standards (NCCLS) GP2-A3 (1996) without having to precisely copy it. The procedure manual should be available to, and used by, personnel at the workbench and must include: principle, clinical significance, specimen type, required reagents, calibration, quality control, procedural steps, calculations, reference ranges, and interpretation.
The inspection team should review the procedure manual in detail to understand the laboratory's standard operating procedures, ensure that all significant information and instructions are included, and that actual practice matches the contents of the procedure manuals. Deficiencies detected in the procedure manual should be listed in the Inspection Summation Report.

QUESTION: 02:2100 PHASE: II

Is a complete procedure manual available at the workbench or in the work area?

NOTE 1: The use of inserts provided by manufacturers is not acceptable in place of a procedure manual. However, such inserts may be used as part of a procedure description, if the insert accurately and precisely describes the procedure as performed in the laboratory. Any variation from this printed procedure must be detailed in the procedure manual. In all cases, appropriate reviews must occur.

NOTE 2: A manufacturer's procedure manual for an instrument/reagent system may be acceptable as a component of the overall departmental procedures. Any modification to or deviation from the procedure manual must be clearly documented.

NOTE 3: Card files or similar systems that summarize key information are acceptable for use as quick reference at the workbench provided that:

A. A complete manual is available for reference.
B. The card file or similar system corresponds to the complete manual and is subject to document control.

NOTE 4: Electronic (computerized) manuals are fully acceptable. There is no requirement for paper copies, so long as the electronic versions are readily available to all personnel. Such electronic versions must be subjected to proper document control (i.e., only authorized persons may make changes, changes are dated/signed (manual or electronic), and there is documentation of periodic review). Current paper copies of electronically stored procedures should be available at the time of the CAP inspection, or rapidly generated at the request of the inspector.

PROCEDURE MANUAL:

THERE MUST BE A COMPLETE PROCEDURE MANUAL AVAILABLE AT THE WORKBENCH. THE ELEMENTS SHOULD INCLUDE: PRINCIPLE, CLINICAL SIGNIFICANCE, SPECIMEN TYPE, REQUIRED REAGENTS, CALIBRATION, QUALITY CONTROL, PROCEDURAL STEPS, CALCULATIONS, REFERENCE RANGES, AND INTERPRETATION.

COMMENTARY: 02:2100 PHASE: II
A WRITTEN PROCEDURE MANUAL MUST BE DEVELOPED FOR HEMATOLOGY.

NOTE 1: THE USE OF INSERTS PROVIDED BY MANUFACTURERS IS NOT ACCEPTABLE IN PLACE OF A PROCEDURE MANUAL, HOWEVER, SUCH INSERTS MAY BE USED AS PART OF A PROCEDURE DESCRIPTION IF THE INSERT ACCURATELY AND PRECISELY DESCRIBES THE PROCEDURE AS PERFORMED IN THE LABORATORY. ANY VARIATION FROM THIS PRINTED PROCEDURE MUST BE DETAILED IN THE PROCEDURE MANUAL. IN ALL CASES, APPROPRIATE REVIEWS MUST OCCUR.

NOTE 2: A MANUFACTURER'S PROCEDURE MANUAL FOR AN INSTRUMENT/REAGENT SYSTEM MAY BE ACCEPTABLE AS A COMPONENT OF THE OVERALL DEPARTMENTAL PROCEDURES. ANY MODIFICATION TO OR DEVIATION FROM THE PROCEDURE MANUAL MUST BE CLEARLY DOCUMENTED.

NOTE 3: CARD FILES OF SIMILAR SYSTEMS THAT SUMMARIZE KEY INFORMATION ARE ACCEPTABLE FOR USE AS QUICK REFERENCE AT THE WORKBENCH PROVIDED THAT:

A. A COMPLETE MANUAL IS AVAILABLE FOR REFERENCE
B. THE CARD FILE OR SIMILAR SYSTEM CORRESPONDS TO THE COMPLETE MANUAL AND IS SUBJECT TO DOCUMENT CONTROL.

NOTE 4: ELECTRONIC (COMPUTERIZED) MANUALS ARE FULLY ACCEPTABLE. THERE IS NO REQUIREMENT FOR PAPER COPIES, SO LONG AS THE ELECTRONIC VERSIONS ARE READILY AVAILABLE TO ALL PERSONNEL. SUCH ELECTRONIC VERSIONS MUST BE SUBJECT TO PROPER DOCUMENT CONTROL (i.e., ONLY AUTHORIZED PERSONS MAY MAKE CHANGES, CHANGES ARE DATED/SIGNED (MANUAL OR ELECTRONIC), AND THERE IS DOCUMENTATION OF PERIODIC REVIEW). CURRENT PAPER COPIES OF ELECTRONICALLY STORED PROCEDURES SHOULD BE AVAILABLE AT THE TIME OF THE CAP INSPECTION, OR RAPIDLY GENERATED AT THE REQUEST OF THE INSPECTOR.


QUESTION: 02:2107 PHASE: II
Is there documentation of at least annual review of all policies and procedures in the hematology laboratory section by the current laboratory director or designee?

NOTE: The director must ensure that the collection of policies and technical protocols is complete, current, and has been thoroughly reviewed by a knowledgeable person. Technical approaches must be scientifically valid and clinically relevant. To minimize the burden on the laboratory and reviewer(s), it is suggested that a schedule be developed whereby roughly 1/12 of all procedures are reviewed monthly. Paper/electronic signature review must be at the level of each procedure, or as multiple signatures on a listing of named procedures. A single signature on a Title Page or Index of all procedures is not sufficient documentation that each procedure has been carefully reviewed. Signature or initials on each page of a procedure is not required.

COMMENTARY: 02:2107 PHASE: II

THERE MUST BE DOCUMENTATION OF AT LEAST ANNUAL REVIEW OF ALL POLICIES AND PROCEDURES IN THE HEMATOLOGY LABORATORY SECTION BY THE CURRENT LABORATORY DIRECTOR OR DESIGNEE. THE DIRECTOR IS RESPONSIBLE FOR ENSURING THAT THE COLLECTION OF TECHNICAL PROTOCOLS IS COMPLETE, CURRENT, AND HAS BEEN THOROUGHLY REVIEWED BY A KNOWLEDGEABLE PERSON. TECHNICAL APPROACHES MUST BE SCIENTIFICALLY VALID AND CLINICALLY RELEVANT. TO MINIMIZE THE BURDEN ON THE LABORATORY AND REVIEWER(S), IT IS SUGGESTED THAT A SCHEDULE BE DEVELOPED WHEREBY ROUGHLY 1/12 OF ALL PROCEDURES ARE REVIEWED MONTHLY. PAPER/ELECTRONIC SIGNATURE REVIEW MUST BE AT THE LEVEL OF EACH PROCEDURE, OR AS MULTIPLE SIGNATURES ON A LISTING OF NAMED PROCEDURES. A SINGLE SIGNATURE ON A TITLE PAGE OR INDEX OF ALL PROCEDURES IS NOT SUFFICIENT DOCUMENTATION THAT EACH PROCEDURE HAS BEEN CAREFULLY REVIEWED. SIGNATURE OR INITIALS ON EACH PAGE OF A PROCEDURE IS NOT REQUIRED.


QUESTION: 02:2108 PHASE: II

Does the laboratory have a system documenting that all personnel are knowledgeable about the contents of procedure manuals (including changes) relevant to the scope of their testing activities?

COMMENTARY: 02:2108 PHASE: II
THE LABORATORY MUST HAVE A SYSTEM DOCUMENTING THAT ALL PERSONNEL ARE KNOWLEDGEABLE ABOUT THE CONTENTS OF PROCEDURE MANUALS (INCLUDING CHANGES) RELEVANT TO THE SCOPE OF THEIR TESTING ACTIVITIES. THE FORM OF THIS SYSTEM IS AT THE DISCRETION OF THE LABORATORY DIRECTOR.

QUESTION: 02:2110 PHASE: II

If there is a change in directorship, does the new director ensure (over a reasonable period of time) that laboratory policies and procedures are well-documented and undergo at least annual review?

COMMENTARY: 02:2110 PHASE: II

IF THERE IS A CHANGE IN DIRECTORSHIP OF THE LABORATORY, THE NEW DIRECTOR MUST ENSURE (OVER A REASONABLE PERIOD OF TIME) THAT ALL HEMATOLOGY LABORATORY POLICIES AND PROCEDURES ARE WELL-DOCUMENTED AND UNDERGO AT LEAST ANNUAL REVIEW.


QUESTION: 02:2115 PHASE: II

When a policy or procedure is discontinued, is a copy maintained for at least two years, recording initial date of use and retirement date?

COMMENTARY: 02:2115 PHASE: II

A COPY OF A DISCONTINUED POLICY OR PROCEDURE MUST BE MAINTAINED FOR AT LEAST TWO YEARS, RECORDING INITIAL DATE OF USE AND RETIREMENT DATE.


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SPECIMEN COLLECTION AND HANDLING
QUESTION: 02:2200  PHASE: II

Are all blood specimens collected in anticoagulant for hematology testing mixed thoroughly immediately before analysis?

NOTE: There must be documentation that specimen mixing is sufficient to ensure reproducibility of CBC results. 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. The use of a rotary mixer for at least 5 minutes is recommended. If mixing is manually performed, there must be at least 60 complete inversions. 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.

SPECIMEN COLLECTION AND HANDLING:

COMMENTARY: 02:2200  PHASE: II

SPECIMENS COLLECTED IN ANTICOAGULANTS FOR HEMATOLOGY STUDIES MUST BE MIXED THOROUGHLY IMMEDIATELY BEFORE ANALYSIS. THERE MUST BE DOCUMENTATION THAT SPECIMEN MIXING BY ROTARY MIXER, ROCKER, AUTOMATED SAMPLER, OR MANUAL INVERSIONS IS SUFFICIENT TO ENSURE REPRODUCIBILITY OF CBC RESULTS. 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. THE USE OF A ROTARY MIXER FOR AT LEAST 5 MINUTES IS RECOMMENDED. IF MIXING IS MANUALLY PERFORMED, THERE MUST BE AT LEAST 60 COMPLETE INVERSIONS. 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.


QUESTION: 02:2205  PHASE: II

Are routine samples for complete blood counts and blood film morphology collected in potassium EDTA?
COMMENTARY: 02:2205  PHASE: II

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), PSEUĐOLEUKOCYTOSIS 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.


QUESTION: 02:2207  PHASE: II

Are there documented criteria for the rejection of unacceptable specimens and the special handling of sub-optimal specimens?

NOTE: This question does not imply that all "unsuitable" specimens are discarded or not analyzed. If, for example, a CBC is ordered and there is visible hemolysis, the hemoglobin concentration may still be valid, but other parameters are not. There must be a mechanism to notify the requesting physician, and to note the condition of the sample on the report if the analytically valid incomplete test results are desired by the ordering physician. The laboratory
should record that a dialogue was held with the physician, when such occurs.

COMMENTARY: 02:2207 PHASE: II

DOCUMENTED CRITERIA MUST BE AVAILABLE FOR UNACCEPTABLE SPECIMENS, AND SPECIAL HANDLING OF SUBOPTIMAL SPECIMENS. THIS DOES NOT IMPLY THAT ALL "UNSUITABLE" SPECIMENS ARE DISCARDED OR NOT ANALYZED. IF, FOR EXAMPLE, A CBC IS ORDERED AND THERE IS VISIBLE HEMOLYSIS, THE HEMOGLOBIN CONCENTRATION MAY STILL BE VALID, BUT OTHER PARAMETERS ARE NOT. THERE MUST BE A MECHANISM TO NOTIFY THE REQUESTING PHYSICIAN, AND TO NOTE THE CONDITION OF THE SAMPLE ON THE REPORT IF THE ANALYTICALLY VALID INCOMPLETE TEST RESULTS ARE DESIRED BY THE ORDERING PHYSICIAN. THE LABORATORY SHOULD RECORD THAT A DIALOGUE WAS HELD WITH THE PHYSICIAN, WHEN SUCH OCCURS.


QUESTION: 02:2210 PHASE: II

Are samples collected in capillary tubes for microhematocrits or capillary/dilution systems obtained in duplicate whenever possible and adequately labeled with patient identification information throughout the analytic sequence?

NOTE: Microspecimen containers such as those used for capillary blood CBC parameter determinations need not be collected in duplicate. Because of the risk of injury, the use of plain glass capillary tubes is strongly discouraged.

COMMENTARY: 02:2210 PHASE: II

SAMPLES COLLECTED IN CAPILLARY TUBES MUST BE OBTAINED IN DUPLICATE WHENEVER POSSIBLE AND LABELED WITH ADEQUATE PATIENT IDENTIFICATION THAT IS RETAINED THROUGHOUT THE ANALYTIC SEQUENCE. THIS APPLIES TO CAPILLARY TUBES USED FOR MICROHEMATOCRIT DETERMINATIONS AS WELL AS CAPILLARY/DILUTION SYSTEMS USED IN PROXIMITY TO THE PATIENT. BECAUSE OF THE RISK OF INJURY, THE USE OF PLAIN GLASS CAPILLARY TUBES IS STRONGLY DISCOURAGED.

QUESTION: 02:2215 PHASE: II
Are CBC specimens checked for clots (visual, applicator sticks, or automated analyzer histogram inspection/flags) before reporting results?

COMMENTARY: 02:2215  PHASE: II

CBC SPECIMENS MUST BE CHECKED FOR CLOTS OF ANY SIZE BEFORE REPORTING RESULTS. 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.

QUESTION: 02:2220  PHASE: II

Are CBC specimens checked for significant in vitro hemolysis and possible interfering lipemia before reporting results?

NOTE: 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.

COMMENTARY: 02:2220  PHASE: II

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 COUNT FROM ERYTHROCYTE STROMA. VISSIBLY 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.

QUESTION: 02:2225 PHASE: II

Are special handling requirements for coagulation tests defined and followed (i.e., proper anticoagulant, standardization of tube type/size, storage of specimens and testing with minimum delay) as necessary?

NOTE: If the laboratory does not adhere to NCCLS recommendations, it must have data on file to demonstrate that alternate storage conditions before testing produce accurate and precise results. Blood specimens for prothrombin time may be stored at room temperature (centrifuged in an unopened evacuated venipuncture tube or unspun), but should be processed and tested within 24 hours of venipuncture. These guidelines refer to uncomplicated samples, such as those obtained from patients on oral anticoagulant therapy. The stability of the PT for samples obtained from hospitalized patients with complex coagulopathies has not been established. Thus, date/time of collection information must be provided for samples obtained remotely.

COMMENTARY: 02:2225 PHASE: II

SPECIAL HANDLING REQUIREMENTS FOR COAGULATION STUDIES MUST BE DEFINED AND FOLLOWED. THESE INCLUDE CONSIDERATIONS OF SODIUM CITRATE CONCENTRATION (3.2% vs 3.8%), TUBE SIZE AND DRAW VOLUME, STORAGE BEFORE TESTING, ETC. IF THE LABORATORY DOES NOT ADHERE TO NCCLS RECOMMENDATIONS FOR HANDLING AND DELAY BEFORE TESTING, IT MUST HAVE DATA ON FILE TO DEMONSTRATE THAT ALTERNATE STORAGE CONDITIONS BEFORE TESTING PRODUCE ACCURATE AND PRECISE RESULTS. BLOOD SPECIMENS FOR PROTHROMBIN TIME MAY BE STORED AT ROOM TEMPERATURE (CENTRIFUGED IN AN UNOPENED EVACUATED VENIPUNCTURE TUBE OR UNSPUN), BUT SHOULD BE PROCESSED AND TESTED WITHIN 24 HOURS OF VENIPUNCTURE. THESE GUIDELINES REFER TO UNCOMPLICATED SAMPLES, SUCH AS THOSE OBTAINED FROM PATIENTS ON ORAL ANTICOAGULANT THERAPY. THE STABILITY OF THE PT FOR SAMPLES OBTAINED FROM HOSPITALIZED PATIENTS WITH COMPLEX COAGULOPATHIES HAS NOT BEEN ESTABLISHED. THUS, DATE/TIME OF COLLECTION INFORMATION MUST BE PROVIDED FOR SAMPLES OBTAINED REMOTELY.


QUESTION: 02:AAAE PHASE: I NEW

Has the laboratory clearly defined sample storage conditions and stability for all hematology and coagulation parameters?

COMMENTARY: 02:AAAE PHASE: I

THE LABORATORY SHOULD DEFINE SAMPLE STORAGE CONDITIONS AND STABILITY FOR ALL HEMATOLOGY AND COAGULATION PARAMETERS, AS TIME-AND TEMPERATURE-DEPENDENT ALTERATIONS CAN OCCUR, CREATING SPURIOUS RESULTS.


REPORTING OF RESULTS

QUESTION: 02:2300 PHASE: II

Are reference intervals (normal ranges) established or verified by the laboratory for the population tested?

REPORTING OF RESULTS:
AGE- AND SEX-SPECIFIC REFERENCE INTERVALS (NORMAL VALUES) MUST BE VERIFIED OR DETERMINED BY THE LABORATORY. IF A FORMAL REFERENCE INTERVAL STUDY IS NOT POSSIBLE OR PRACTICAL, THEN THE LABORATORY SHOULD CAREFULLY EVALUATE THE USE OF PUBLISHED DATA FOR ITS OWN REFERENCE INTERVALS, AND RETAIN DOCUMENTATION OF THIS EVALUATION.


QUESTION: 02:2305 PHASE: II

Where possible, are all patient results reported with accompanying reference intervals or interpretive ranges?

NOTE: The results of commercial quality control plasmas are internal data for quality assurance purposes, and must NOT be externally reported; if reported with patient results, they may be confused as normal values.

COMMENTARY: 02:2305 PHASE: II
THE LABORATORY MUST REPORT REFERENCE INTERVALS OR INTERPRETIVE RANGES WITH PATIENT RESULTS. THIS IS IMPORTANT TO ALLOW PROPER INTERPRETATION OF PATIENT DATA. ALSO, THE USE OF HIGH AND LOW FLAGS (GENERALLY AVAILABLE WITH A COMPUTERIZED LABORATORY INFORMATION SYSTEM) IS RECOMMENDED. FOR PROTHROMBIN TIMES AND ACTIVATED PARTIAL THROMBOPLASTIN TIMES, THE RESULTS OF COMMERCIAL QUALITY CONTROL PLASMAS ARE INTERNAL DATA FOR QUALITY ASSURANCE PURPOSES, AND MUST NOT BE EXTERNALLY REPORTED; IF REPORTED WITH PATIENT RESULTS, THEY MAY BE CONFUSED AS NORMAL VALUES.

QUESTION: 02:2310 PHASE: II

Are documented criteria established for immediate notification of a physician or other clinical personnel responsible for patient care when results of certain tests exceed critical limits important for prompt patient management decisions?

NOTE: May be indicated either in the procedure manual and/or in a separate manual. The bench technologists must be familiar with critical limits for procedures that they perform.

COMMENTARY: 02:2310 PHASE: II

THE HEMATOLOGY/COAGULATION LABORATORY MUST HAVE DOCUMENTED CRITERIA FOR THE IMMEDIATE NOTIFICATION OF A PHYSICIAN OR OTHER CLINICAL PERSONNEL WHEN RESULTS OF CERTAIN TESTS EXCEED CRITICAL LIMITS. WHILE SOMETIMES INFORMALLY KNOWN AS "PANIC VALUES," THESE ARE BETTER DESCRIBED AS "ALERT," "CRITICAL" OR "LIFE-THREATENING" DATA THAT USUALLY REQUIRE PROMPT PATIENT MANAGEMENT ACTION BY A CLINICIAN. THESE ARE BEST DEVELOPED BY THE LABORATORY IN CONSULTATION WITH USER CLINICIANS, AND MUST BE PUBLISHED. THESE MAY BE INDICATED IN THE PROCEDURE MANUAL AND/OR IN A SEPARATE MANUAL OR POLICY. THE BENCH TECHNOLOGISTS MUST BE FAMILIAR WITH CRITICAL LIMITS FOR PROCEDURES THAT THEY PERFORM.

QUESTION: 02:2312  PHASE: II

Is there documentation of prompt notification of the physician (or other clinical personnel responsible for patient care) of results of all critical values?

NOTE: In addition, the laboratory should document any failure of attempts to notify the appropriate person of critical results, and document the action taken to prevent recurrence of this problem.

COMMENTARY: 02:2312  PHASE: II

RECORDS MUST BE MAINTAINED INDICATING THE NOTIFICATION OF THE APPROPRIATE CLINICAL INDIVIDUAL PROMPTLY AFTER OBSERVING RESULTS IN CRITICAL RANGE. THESE RECORDS SHOULD INCLUDE: DATE, TIME, RESPONSIBLE LABORATORY INDIVIDUAL, PERSON NOTIFIED AND TEST RESULTS. IN ADDITION, THE LABORATORY SHOULD DOCUMENT ANY FAILURE OF ATTEMPTS TO NOTIFY THE APPROPRIATE PERSON OF CRITICAL RESULTS, AND DOCUMENT THE ACTION TAKEN TO PREVENT RECURRENCE OF THIS PROBLEM.


QUESTION: 02:2315  PHASE: II

Are routine and STAT results available within a reasonable time?

NOTE: A reasonable time for routine daily service, assuming receipt or collection of specimen in the morning, is 4 to 8 hours. For common hematology and coagulation tests, emergency or STAT results that do not require special additional verification procedures should be reported within 1 hour after specimen receipt in the laboratory.

COMMENTARY: 02:2315  PHASE: II

TIMELINESS OF SERVICE MUST BE IMPROVED. A REASONABLE TIME FOR SAME-DAY SERVICE, ASSUMING RECEIPT OR COLLECTION OF THE ROUTINE HEMATOLOGY OR COAGULATION SPECIMEN IN THE MORNING, IS 4 TO 8 HOURS. EMERGENCY OR STAT RESULTS THAT DO NOT REQUIRE ADDITIONAL
VERIFICATION PROCEDURES (e.g., MANUAL VERIFICATION OF AN AUTOMATED CBC INSTRUMENT RESULT) SHOULD BE REPORTED WITHIN 1 HOUR AFTER SPECIMEN RECEIPT IN THE LABORATORY.


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REAGENTS

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The verification of reagent performance is required and must be documented. Any of several methods may be appropriate, such as direct analysis with reference materials, parallel testing of old vs. new reagents, or checking against routine controls. The intent of the questions are for new reagents to be checked by an appropriate method and the results recorded before being placed in service.

QUESTION: 02:2400  PHASE: II

Are all reagents properly labeled, as applicable and appropriate, with the following elements:

1. content and quantity, concentration or titer,
2. storage requirements,
3. date prepared or received,
4. date placed in service,
5. expiration date?

NOTE: The inspector will describe specific issues of non-compliance in the Inspector's Summation Report. Sublots of some materials, such as separate vials of control substances shipped in a single primary container, do not have to be individually labeled if the original primary container was properly labeled, and the vials are maintained in the primary container.

REAGENTS:

REAGENT PERFORMANCE AND ADEQUACY MUST BE VERIFIED BEFORE PLACING THE MATERIAL IN SERVICE. VARIOUS METHODS, SUCH AS DIRECT ANALYSIS, USE OF REFERENCE MATERIALS, OR PARALLEL TESTING OF OLD VERSUS NEW REAGENTS, ARE ACCEPTABLE. THE RESULTS OF VERIFICATION CHECKS MUST
BE RECORDED. WHERE INDIVIDUALLY PACKAGED REAGENTS/KITS ARE USED, THERE SHOULD BE CRITERIA ESTABLISHED FOR MONITORING REAGENT QUALITY AND STABILITY, BASED ON VOLUME OF USAGE AND STORAGE REQUIREMENTS. PROCESSING OF PERIODIC "WET CONTROLS" TO VALIDATE REAGENT QUALITY AND OPERATOR TECHNIQUE IS A TYPICAL COMPONENT OF SUCH A SYSTEM.

COMMENTARY: 02:2400  PHASE: II

ALL REAGENTS MUST BE PROPERLY LABELED, AS APPLICABLE AND APPROPRIATE, WITH THE FOLLOWING ELEMENTS:

1. CONTENT AND QUANTITY, CONCENTRATION OR TITER,
2. STORAGE REQUIREMENTS,
3. DATE PREPARED OR RECEIVED,
4. DATE PLACED IN SERVICE,
5. EXPIRATION DATE.

ONE OR MORE OF THE ABOVE ELEMENTS WERE ABSENT DURING THE ON-SITE INSPECTION. DETAILS ARE PROVIDED IN THE INSPECTOR'S SUMMATION REPORT.

QUESTION: 02:2410  PHASE: II

Are all reagents used within their indicated expiration date?

COMMENTARY: 02:2410  PHASE: II

HEMATOLOGY OR COAGULATION REAGENTS MUST NOT BE USED BEYOND THEIR STATED OR ASSIGNED EXPIRATION DATE.

QUESTION: 02:2415  PHASE: II

Are reagents for functional clotting assays (e.g., PT, aPTT, fibrinogen) prepared, stored, and discarded as recommended by the manufacturer?

COMMENTARY: 02:2415  PHASE: II

REAGENTS FOR FUNCTIONAL CLOT-BASED ASSAYS (e.g., PT, aPTT, FIBRINOGEN) MUST BE PREPARED, STORED, AND DISCARDED AS RECOMMENDED BY THE MANUFACTURER.

REFERENCE: National Committee for Clinical Laboratory Standards. One-stage prothrombin time (PT) test and activated partial thromboplastin time (aPTT) test; approved guideline H47-A.
QUESTION: 02:2500  PHASE: II

Is the temperature of water baths and/or heat blocks, refrigerators and other temperature-dependent equipment checked and recorded daily (or on each day of use)?

INSTRUMENTS AND EQUIPMENT:

COMMENTARY: 02:2500  PHASE: II

THE TEMPERATURE OF WATER BATHS AND/OR HEATING BLOCKS, REFRIGERATORS, FREEZERS AND OTHER TEMPERATURE-DEPENDENT EQUIPMENT MUST BERecorded daily, or on each day of use.


QUESTION: 02:2510  PHASE: II

Are mechanical timers in the hematology section checked at least semi-annually for accuracy?

NOTE: Not applicable to electronic timers.

COMMENTARY: 02:2510  PHASE: II

MECHANICAL TIMERS USED IN THE HEMATOLOGY SECTION MUST BE CHECKED FOR ACCURACY AT LEAST SEMI-ANNUALLY. THIS DOES NOT APPLY TO ELECTRONIC TIMERS.

QUESTION: 02:2515  PHASE: II

Are pipettors and dilutors (fixed volume or adjustable) checked at specific defined intervals for accuracy and reproducibility, and results recorded?
COMMENTARY: 02:2515  PHASE: II

PIPETTORS AND DILUTORS (FIXED VOLUME OR ADJUSTABLE) MUST BE CHECKED FOR VOLUMETRIC ACCURACY AND REPRODUCIBILITY AT SPECIFIC DEFINED INTERVALS AND THE RESULTS OF SUCH TESTING DOCUMENTED.

QUESTION: 02:2525  PHASE: II

Is volumetric glassware of certified accuracy (Class A), or checked by the laboratory to verify accuracy?

COMMENTARY: 02:2525  PHASE: II

VOLUMETRIC GLASSWARE MUST BE CERTIFIED FOR ACCURACY (CLASS A) OR CHECKED FOR ACCURACY BEFORE BEING PLACED IN SERVICE. DISPOSABLE MICROPIPETS MUST BE EXAMINED VISUALLY FOR UNIFORMITY OF LENGTH OF COLUMN AND A REPRESENTATIVE SAMPLE CHECKED BEFORE THE BOX IS PLACED IN SERVICE.

QUESTION: 02:2530  PHASE: II

Are microscopes clean, adequate (i.e., low, high dry and oil immersion lenses), optically aligned, and properly maintained with documentation of preventive maintenance?

COMMENTARY: 02:2530  PHASE: II

MICROSCOPES MUST BE CLEAN, OPTICALLY ALIGNED, HAVE AN ADEQUATE SELECTION OF OBJECTIVE LENSES (e.g., LOW (X10 OR X20), HIGH DRY (X25 OR X40), AND OIL IMMERSION (X63-65 OR X100)) AND PROPERLY MAINTAINED WITH DOCUMENTATION OF PREVENTIVE MAINTENANCE. KOEHLER ILLUMINATION MUST BE MAINTAINED FOR OPTIMAL RESOLUTION. FOR MANUAL PLATELET COUNTING, A PHASE CONTRAST MICROSCOPE IS RECOMMENDED.


QUESTION: 02:2535  PHASE: II

Are instrument maintenance, service and repair records (or copies) promptly available to, and usable by, the technical staff operating the equipment?

COMMENTARY: 02:2535  PHASE: II
THE EFFECTIVE UTILIZATION OF INSTRUMENTS BY THE TECHNICAL STAFF DEPENDS UPON THE PROMPT AVAILABILITY OF MAINTENANCE, REPAIR AND SERVICE DOCUMENTATION (COPIES ACCEPTABLE). THE LABORATORY PERSONNEL ARE RESPONSIBLE FOR THE RELIABILITY AND PROPER FUNCTION OF THEIR INSTRUMENTS AND MUST HAVE ACCESS TO THE INFORMATION.

COMPLETE BLOOD COUNT (CBC) INSTRUMENTS

CALIBRATION

Several different methods may be used for calibration of an automated Complete Blood Count (CBC) instrument. The laboratory should have a document that provides the design and detailed procedural steps for calibration and calibration verification.

Calibration techniques include: A) the use of multiple analyzed fresh whole blood specimens, and B) the use of manufactured, stabilized preparations of red cells, white cells (or white cell surrogates) and platelets (or platelet surrogates). Typically, a laboratory uses one of these two approaches as their primary calibration technique, with the other for backup, or for verification of the primary method, or on an emergency basis. All calibration techniques should include periodic verifications of analyzer hemoglobin measurements against a certified hemoglobin preparation (ICSH/WHO international haemoglobincyanide standard), or material that has been certified by its manufacturer as being derived from the certified international haemoglobincyanide standard using reference procedures. Ordinary commercial control materials are not suitable for instrument calibration.

QUESTION: 02:2540  PHASE: II

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

NOTE: This question does not apply to CBC instruments that can be calibrated by the laboratory.

CBC INSTRUMENT CALIBRATION:
SEVERAL DIFFERENT METHODS MAY BE USED FOR CALIBRATION AND CALIBRATION VERIFICATION OF AUTOMATED HEMATOLOGY ANALYZERS. CALIBRATION TECHNIQUES INCLUDE: A) THE USE OF MULTIPLE ANALYZED FRESH WHOLE BLOOD SPECIMENS, AND B) THE USE OF MANUFACTURED, STABILIZED PREPARATIONS OF RED CELLS, WHITE CELLS (OR WHITE CELL SURROGATES) AND PLATELETS (OR PLATELET SURROGATES). TYPICALLY, A LABORATORY USES ONE OF THESE TWO APPROACHES AS THEIR PRIMARY CALIBRATION TECHNIQUE, WITH THE OTHER FOR BACKUP, OR FOR VERIFICATION OF THE PRIMARY METHOD, OR ON AN EMERGENCY BASIS. ALL CALIBRATION TECHNIQUES SHOULD INCLUDE PERIODIC VERIFICATIONS OF ANALYZER HEMOGLOBIN MEASUREMENTS AGAINST A CERTIFIED HEMOGLOBIN PREPARATION (ICSH/WHO INTERNATIONAL HAEMIGLOBINCYANIDE STANDARDS), OR MATERIAL THAT HAS BEEN CERTIFIED BY ITS MANUFACTURER AS BEING DERIVED FROM THE CERTIFIED INTERNATIONAL HAEMIGLOBINCYANIDE STANDARD USING REFERENCE PROCEDURES.


COMMENTARY: 02:2540 PHASE: II

SINCE PRECALIBRATED INSTRUMENTS MAY NOT BE ADJUSTABLE BY THE LABORATORY, VERIFICATION OF THE CALIBRATION STATUS MUST BE PERFORMED WITH CONTROL MATERIALS APPROPRIATE FOR THE SYSTEM.

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Fresh Whole Blood

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QUESTION: 02:2545 PHASE: 0

Are automated instruments calibrated using multiple analyzed fresh whole blood specimens?

NOTE: If not, omit this subsection and continue with Commercial Calibrators.

QUESTION: 02:2550 PHASE: II

Is there a document defining the specific procedural steps for the periodic calibration of the analyzer with fresh whole blood specimens?
FRESH WHOLE BLOOD CALIBRATION:

COMMENTARY: 02:2550 PHASE: II

WHEN MULTIPLE ANALYZED WHOLE BLOOD SPECIMENS ARE USED FOR CALIBRATING AUTOMATED INSTRUMENTS, A DETAILED DOCUMENTED CALIBRATION PROCEDURE, WITH SPECIFIC STEPS, MUST BE MAINTAINED AND FOLLOWED BY THE LABORATORY. OF CENTRAL IMPORTANCE IS A CLEAR INDICATION OF THE NEED FOR RECALIBRATION, BASED UPON THE DATA FROM THE DAILY QUALITY CONTROL SYSTEM.

QUESTION: 02:2555 PHASE: II

Does the initial or primary instrument calibration include duplicate analysis of at least 10 fresh whole blood samples that have been analyzed by reference methods?

NOTE: The exact number of whole blood samples and number of replicates may not be as specified above for all instruments. Manufacturers' instructions should be followed.

COMMENTARY: 02:2555 PHASE: II

THE PRIMARY (INITIAL) INSTRUMENT CALIBRATION MUST INCLUDE DUPLICATE ANALYSIS OF AT LEAST 10 FRESH WHOLE BLOOD SAMPLES WHICH HAVE BEEN ANALYZED BY REFERENCE METHODS. THE EXACT NUMBER OF WHOLE BLOOD SAMPLES AND NUMBER OF REPLICATES MAY NOT BE AS SPECIFIED ABOVE FOR ALL INSTRUMENTS. MANUFACTURERS' INSTRUCTIONS SHOULD BE FOLLOWED.


QUESTION: 02:2557 PHASE: II
Are criteria established for calibration verification?

NOTE: Criteria must be established for calibration verification. Criteria include:

1. at complete changes of reagents (i.e., change in type of reagent from same vendor, or change to a different vendor),
2. when indicated by quality control data,
3. after major maintenance or service,
4. when recommended by the manufacturer,
5. at least every six months.

One common method of calibration verification involves processing a commercial calibrator and comparing results to those published by the manufacturer. Linearity studies are not required.

COMMENTARY: 02:2557  PHASE: II

CRITERIA MUST BE ESTABLISHED FOR CBC INSTRUMENT CALIBRATION VERIFICATION. CRITERIA INCLUDE:

1. AT COMPLETE CHANGES OF REAGENTS, i.e., CHANGE IN TYPE OF REAGENT FROM SAME VENDOR, OR CHANGE TO A DIFFERENT VENDOR,
2. WHEN INDICATED BY QUALITY CONTROL DATA,
3. AFTER MAJOR MAINTENANCE OR SERVICE,
4. WHEN RECOMMENDED BY THE MANUFACTURER,
5. AT LEAST EVERY SIX MONTHS.

ONE COMMON METHOD OF CALIBRATION VERIFICATION INVOLVES PROCESSING A COMMERCIAL CALIBRATOR AND COMPARING RESULTS TO THOSE PUBLISHED BY THE MANUFACTURER. LINEARITY STUDIES ARE NOT REQUIRED. WHEN CALIBRATION VERIFICATION CRITERIA ARE EXCEEDED, THE LABORATORY MUST RECALIBRATE.


QUESTION: 02:2560  PHASE: II

Does the laboratory's procedure for recalibration of CBC instrument parameter(s) require one of the following approaches:
1. comparison to at least 10 fresh whole blood samples whose values have been determined by duplicate analysis in another instrument known to be accurately calibrated, or

2. duplicate analysis of at least 10 fresh whole blood specimens by reference methods?

NOTE: The selection of 10 different blood samples (or alternate protocol recommended by the instrument manufacturer) is needed to accommodate a diversity of matrices, and to have the absolute minimum sample size on which to perform statistical calculations. Such fresh samples must have values within the instrument's operating ranges, and must not generate flags indicative of possible abnormalities.

COMMENTARY: 02:2560  PHASE: II

THE FRESH WHOLE BLOOD RECALIBRATION PROCEDURE FOR CBC INSTRUMENTS MUST REQUIRE ONE OF THE FOLLOWING APPROACHES:

1. COMPARISON TO AT LEAST 10 FRESH WHOLE BLOOD SAMPLES WHOSE VALUES HAVE BEEN DETERMINED BY DUPLICATE ANALYSIS IN ANOTHER INSTRUMENT KNOWN TO BE ACCURATELY CALIBRATED, OR

2. DUPLICATE ANALYSIS OF AT LEAST 10 FRESH WHOLE BLOOD SPECIMENS BY REFERENCE METHODS.

THE SELECTION OF 10 DIFFERENT BLOOD SAMPLES (OR ALTERNATE PROTOCOL RECOMMENDED BY THE INSTRUMENT MANUFACTURER) IS NEEDED TO ACCOMMODATE A DIVERSITY OF MATRICES, AND TO HAVE THE ABSOLUTE MINIMUM SAMPLE SIZE ON WHICH TO PERFORM STATISTICAL CALCULATIONS. SUCH FRESH SAMPLES MUST HAVE VALUES WITHIN THE INSTRUMENT'S OPERATING RANGES, AND MUST NOT GENERATE INSTRUMENT FLAGS INDICATIVE OF POSSIBLE ABNORMALITIES.

QUESTION: 02:AAAM  PHASE: I NEW

Following whole blood calibration, is there a documented procedure for calibration verification?

COMMENTARY: 02:AAAM  PHASE: I

FOLLOWING WHOLE BLOOD CALIBRATION, THE LABORATORY SHOULD HAVE A DETAILED DOCUMENT THAT DESCRIBES THE SEQUENTIAL STEPS FOR VERIFYING
THAT WHOLE BLOOD CALIBRATION HAS BEEN SUCCESSFUL, i.e., THAT RESULTS ACCURACY IS ESTABLISHED.

Commercial Calibrators

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, and the latter must not be used for routine instrument calibration.

QUESTION: 02:2565 PHASE: 0

Are automated instruments calibrated using a commercial preparation marketed by a manufacturer for calibration?

NOTE: If not, omit this subsection and continue with Quality Control.

QUESTION: 02:2570 PHASE: II

Is there a document defining the specific procedural steps for the periodic calibration of the analyzer with stabilized materials whose target values have been certified by the manufacturer using primary reference procedures?

COMMERCIAL CALIBRATORS:

COMMENTARY: 02:2570 PHASE: II

WHEN STABILIZED WHOLE BLOOD OR OTHER COMMERCIAL PREPARATIONS ARE USED FOR THE PERIODIC RECALIBRATION OF AUTOMATED INSTRUMENTS, THE TARGET VALUES FOR THE MEASURED PARAMETERS MUST HAVE BEEN ASSIGNED BY USING PRIMARY REFERENCE PROCEDURES. THE LABORATORY MAY ASSIGN SUCH VALUES OR THE MANUFACTURER MAY CERTIFY THAT THE TARGET VALUES WERE DERIVED THROUGH PRIMARY REFERENCE PROCEDURES. A DETAILED DOCUMENTED RECALIBRATION PROCEDURE, WITH DEFINED STEPS, MUST BE MAINTAINED AND FOLLOWED BY THE LABORATORY. OF CENTRAL IMPORTANCE IS A CLEAR INDICATION OF THE NEEDS FOR RECALIBRATION, BASED UPON THE DATA FROM THE QUALITY CONTROL SYSTEM.
QUESTIONS: 02:2576 PHASE: II

Are criteria established for calibration verification?

NOTE: Criteria must be established for calibration verification. Criteria include:

1. at complete changes of reagents (i.e., change in type of reagent from same vendor, or change to a different vendor),
2. when indicated by quality control data,
3. after major maintenance or service,
4. when recommended by the manufacturer,
5. at least every six months.

One common method of calibration verification involves processing a commercial calibrator and comparing results to those published by the manufacturer. Linearity studies are not required.

COMMENTARY: 02:2576 PHASE: II

CRITERIA MUST BE ESTABLISHED FOR CBC INSTRUMENT CALIBRATION VERIFICATION. CRITERIA INCLUDE:

1. AT COMPLETE CHANGES OF REAGENTS (i.e., CHANGE IN TYPE OF REAGENT FROM SAME VENDOR, OR CHANGE TO A DIFFERENT VENDOR),
2. WHEN INDICATED BY QUALITY CONTROL DATA,
3. AFTER MAJOR MAINTENANCE OR SERVICE,
4. WHEN RECOMMENDED BY THE MANUFACTURER,
5. AT LEAST EVERY SIX MONTHS.

These are criteria mandated under CLIA-88. One common method of calibration verification involves processing a commercial calibrator and comparing results to those published by the manufacturer. Linearity studies are not required.

QUESTION: 02:2578 PHASE: II

Does the laboratory's procedure for recalibration of a parameter(s) require analysis of stabilized whole blood or other commercial preparations, the parameters of which have been certified by the manufacturer?

COMMENTARY: 02:2578 PHASE: II

THE PROCEDURE FOR CBC INSTRUMENT RECALIBRATION MUST REQUIRE ANALYSIS OF STABILIZED WHOLE BLOOD OR OTHER COMMERCIAL PREPARATIONS (COMMERCIAL "CALIBRATOR"), THE PARAMETERS OF WHICH HAVE BEEN CERTIFIED BY THE MANUFACTURER

QUESTION: 02:AAAQ PHASE: I NEW

Following calibration with commercial calibrators, is there a documented procedure for calibration verification?

COMMENTARY: 02:AAAQ PHASE: I

FOLLOWING CALIBRATION WITH COMMERCIAL CALIBRATORS, THE LABORATORY SHOULD HAVE A DETAILED DOCUMENT THAT DESCRIBES THE SEQUENTIAL STEPS FOR VERIFYING THAT CALIBRATION HAS BEEN SUCCESSFUL, i.e., THAT RESULTS ACCURACY IS ESTABLISHED.

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CBC INSTRUMENT QUALITY CONTROL

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Longitudinal process quality control (QC) procedures for individual instruments or inter-instrument comparisons 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.

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.

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Stabilized Controls

QUESTION: 02:2580  PHASE: 0

Does the laboratory use preserved or stabilized whole blood preparations for quality control of CBC analyses?

NOTE: If not, omit this subsection and continue with Moving Averages.

QUESTION: 02:2585  PHASE: II

Are 2 different stabilized control specimens analyzed and results recorded during each 8-hours of analyzer use?

NOTE: Stabilized control materials must be at 2 different analytic levels (i.e., "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" (e.g., 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.

CBC INSTRUMENT QUALITY CONTROL - STABILIZED CONTROLS:

COMMENTARY: 02:2585  PHASE: II

THE LABORATORY MUST PERFORM AN APPROPRIATE NUMBER OF ANALYSES OF 2 DIFFERENT LEVELS (i.e., "NORMAL" AND "HIGH") OF STABILIZED CONTROL MATERIAL DURING EACH 8-HOURS THAT THE AUTOMATED ANALYZER IS USED. THREE LEVELS OF CONTROL IS A CONCEPTUAL CARRYOVER FROM CLINICAL CHEMISTRY, AND DOES NOT APPLY TO HEMATOLOGY PARTICLE COUNTING. THERE SHOULD BE SOME RELATIONSHIP BETWEEN THE FREQUENCY OF CONTROL RUNS AND THE NUMBERS OF PATIENT SPECIMENS PROCESSED. COMMERCIAL CONTROLS SHOULD BE AT MORE THAN ONE LEVEL (i.e., NORMAL AND HIGH). DILUTE, "LOW-LEVEL" (e.g., LEUKOPENIC AND
"Thrombocytopenic) "Oncology" Controls are less Informative Indicators of Instrument 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.


QUESTION: 02:2587 PHASE: II

If commercially assayed controls are used for CBC instruments, do control values correspond to the methodology and have target values (mean and QC ranges) been verified or established by the laboratory?

NOTE: Most commercial controls have expected recovery ranges for each parameter, provided by the manufacturer. The mean of such ranges may not be the exact target value in a given laboratory. Each laboratory should assign its own initial target value, based on initial analysis of the material; this target value should fall within the recovery range supplied by the manufacturer, but need not exactly match the package insert mean. The laboratory should establish specific recovery ranges that accommodate known changes in product attributes, assuming that calibration status has not changed.

COMMENTARY: 02:2587 PHASE: II

For assayed controls used on CBC instruments, control values must correspond to the methodology and target values (mean and QC ranges) must be verified or established by the laboratory. Most commercial controls have expected recovery ranges for each parameter, provided by the manufacturer. The mean of such ranges
MAY NOT BE THE EXACT TARGET VALUE IN A GIVEN LABORATORY. EACH LABORATORY SHOULD ASSIGN ITS OWN INITIAL TARGET VALUE, BASED ON INITIAL ANALYSIS OF THE MATERIAL; THIS TARGET VALUE SHOULD FALL WITHIN THE RECOVERY RANGE SUPPLIED BY THE MANUFACTURER, BUT NEED NOT EXACTLY MATCH THE PACKAGE INSERT MEAN. THE LABORATORY SHOULD ESTABLISH SPECIFIC RECOVERY RANGES THAT ACCOMMODATE KNOWN CHANGES IN PRODUCT ATTRIBUTES, ASSUMING THAT CALIBRATION STATUS HAS NOT CHANGED.

**QUESTION: 02:2588  PHASE: II**

If UNASSAYED controls are used, has a statistically valid target mean and range been established for each lot by repetitive analysis in runs that include previously tested control materials?

**COMMENTARY: 02:2588  PHASE: II**

FOR UNASSAYED CONTROLS, THE LABORATORY MUST ESTABLISH A STATISTICALLY VALID MEAN AND TARGET RANGE FOR EACH LOT BY REPETITIVE ANALYSIS IN RUNS THAT INCLUDE PREVIOUSLY TESTED CONTROL MATERIALS.


**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.

QUESTION: 02:2590  PHASE: 0

Does the laboratory use "moving averages" of data from patient specimens for quality control of CBC analyses?

NOTE: If not, omit this subsection and continue with Retained Patient Specimens.

QUESTION: 02:2592  PHASE: II

Are control limits for moving averages appropriately sensitive?

NOTE: There must be documentation of the method used to establish the moving average, the frequency of calculation (batch size), and a definition of the basis for selection of upper and lower limits.

CBC INSTRUMENT QUALITY CONTROL - MOVING AVERAGES:

COMMENTARY: 02:2592  PHASE: II

CONTROL LIMITS FOR MOVING AVERAGES MUST BE APPROPRIATELY SENSITIVE SUCH THAT SIGNIFICANT CALIBRATION ALTERATIONS ARE ALWAYS DETECTED. 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. DOCUMENTATION MUST INCLUDE THE METHOD USED TO ESTABLISH THE MOVING AVERAGE, THE FREQUENCY OF CALCULATION (BATCH SIZE), AND A DEFINITION OF THE BASIS FOR SELECTION OF UPPER AND LOWER LIMITS.


**QUESTION: 02:2599 PHASE: II**

If a "moving averages" system is combined with another control system, is the process well-defined and appropriately sensitive to drift in analyzer calibration?

**COMMENTARY: 02:2599 PHASE: II**

IF A "MOVING AVERAGES" SYSTEM IS COMBINED WITH THE USE OF COMMERCIAL CONTROLS AND/OR RETAINED PATIENT SPECIMENS AS ANOTHER CONTROL SYSTEM(S), THE OVERALL PROCESS MUST BE CLEARLY DEFINED, DOCUMENTED AND APPROPRIATELY SENSITIVE TO DETECT SIGNIFICANT ALTERATIONS IN ANALYZER CALIBRATION STATUS.


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**Retained Patient Specimens**

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Use of retained patient specimens alone is inadequate for routine QC, 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.

**QUESTION: 02:2582  PHASE: 0**

Does the laboratory use retained, previously analyzed patient whole blood samples for quality control of CBC analyses?

**NOTE:** If not, omit this subsection and continue with Interinstrument Comparisons.

**QUESTION: 02:AAAZ  PHASE: I** **NEW**

When the laboratory uses retained patient samples, are limits quantitatively defined for results agreement of sequential assays of a given sample?

**INSTRUMENT QUALITY CONTROL - RETAINED PATIENT SPECIMENS:**

**COMMENTARY: 02:AAAZ  PHASE: I**

THE LABORATORY SHOULD CLEARLY DEFINE NUMERIC RANGES OF AGREEMENT BETWEEN SEQUENTIAL ASSAYS OF RETAINED PATIENT SPECIMENS USED FOR QUALITY CONTROL PURPOSES. THESE RANGES MUST BE STATISTICALLY DEFINED, AND NOT SIMPLY QUALITATIVE. ALLOWANCE MUST BE MADE FOR TIME-DEPENDENT ALTERATIONS IN DATA FROM SUCH LABILE SAMPLES.

**QUESTION: 02:BAAB  PHASE: I** **NEW**

Is there a defined range of CBC values for which these limits are applicable?

**COMMENTARY: 02:BAAB  PHASE: I**

BECAUSE IMPRECISION (STANDARD DEVIATION, COEFFICIENT OF VARIATION) IS DEPENDENT UPON THE HEMATOLOGIC TARGET VALUE, THE LABORATORY SHOULD HAVE DEFINED RANGES OF CBC VALUES WHEN USING RETAINED PATIENT SPECIMENS FOR QC PURPOSES.

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Interinstrument Comparisons
The laboratory may use fresh patient or donor specimens analyzed on a primary instrument for daily QC of a secondary instrument. The selection of these materials (rather than simply stabilized commercial controls) is important to directly address the issue of whether a patient sample yields the same results on all of the laboratory's instruments. If the laboratory has only one instrument for patient testing, this section does not apply.

**QUESTION: 02:2800 PHASE: II**

If the laboratory has more than one instrument (same or different makes/models) for performing CBCs, are they checked against each other at least twice a year for correlation of patient results?

**INSTRUMENT QUALITY CONTROL - INTERINSTRUMENT COMPARISONS:**

**COMMENTARY: 02:2800 PHASE: II**

When more than one CBC instrument is used to generate patient-reportable results, it is important that the laboratory verify comparable performance across instruments. Checks for correlation of patient results must be done at least twice a year. The selection of fresh blood samples (rather than simply stabilized commercial controls) is important to directly address the issue of whether a patient sample yields the same results on all of the laboratory's instruments. Statistical agreement of commercial control materials across instruments does not guarantee comparability of patient specimen results.

**REFERENCE:** Department of Health and Human Services, Health Care Financing Administration. Medicare, Medicaid and CLIA programs; CLIA fee collection; correction and final rule. Federal register. 1993(Jan 19):5236 [42CFR493.1709(a)].

**QUESTION: 02:BAAD PHASE: I NEW**

Are there precisely defined tolerance limits for results agreement of interinstrument assays?

**COMMENTARY: 02:BAAD PHASE: I**

The laboratory should clearly define numeric ranges of agreement between multiple CBC instruments used by the laboratory. These ranges must be statistically defined, and not simply qualitative.
QUESTION: 02:BAAE PHASE: I NEW

Is there a defined range of CBC values for which these limits are applicable?

COMMENTARY: 02:BAAE PHASE: I

BECAUSE IMPRECISION (STANDARD DEVIATION, COEFFICIENT OF VARIATION) IS DEPENDENT UPON THE HEMATOLOGIC TARGET VALUE, THE LABORATORY SHOULD HAVE DEFINED RANGES OF CBC VALUES WHEN COMPARING RESULTS ACROSS MULTIPLE INSTRUMENTS.

QUESTION: 02:3007 PHASE: I

Are there data that periodically compare results obtained for patient specimens analyzed in the multiple sampling modes of the blood analyzer (e.g., "open" and "closed" modes) to ensure that they are in agreement?

COMMENTARY: 02:3007 PHASE: I

THE LABORATORY SHOULD HAVE DATA THAT PERIODICALLY COMPARE CBC RESULTS ACROSS DIFFERENT INSTRUMENT SAMPLING MODES. DIFFERENT MODES MAY INVOLVE DILUTION OR 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 SHOULD BE PERFORMED IN THE ALTERNATE MODE(S), AND RESULTS SHOULD 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.

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ERROR DETECTION AND VERIFICATION

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QUESTION: 02:3010 PHASE: II

Is there a documented procedure available and in use for detecting and correcting 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 lab should evaluate its system(s) and develop appropriate detection and correction procedures.

CBC INSTRUMENT ERROR DETECTION AND VERIFICATION:

COMMENTARY: 02:3010 PHASE: II

AUTOMATED PARTICLE COUNTERS MAY INCLUDE SOME NUCLEATED NON-LEUKOCYTES IN THE "LEUKOCYTE" COUNT. THERE MUST BE A DOCUMENTED PROCEDURE AVAILABLE AND USED FOR CORRECTING AUTOMATED WBC COUNTS FOR THE PRESENCE OF NUCLEATED RED CELLS OR MEGAKARYOCYTES. THIS IS IMPORTANT TO PREVENT REPORTING A FALSELY HIGH WBC COUNT. WITH SOME AUTOMATED CBC INSTRUMENTS, NUCLEATED ERYTHROCYTES OR MEGAKARYOCYTES MAY PRESENT THEMSELVES HISTOGRAPHICALLY OR CYTOGRAPHICALLY, AND THIS CAN SERVE AS A CLUE FOR CAREFUL STAINED BLOOD FILM INSPECTION. THE LABORATORY MUST ESTABLISH IF ITS PARTICULAR INSTRUMENT(S) INCLUDES SOME OR ALL NUCLEATED NON-LEUKOCYTES IN ITS APPARENT WBC COUNT.


QUESTION: 02:3015 PHASE: II

Is there a documented procedure available and in use to detect other spurious CBC instrument results that may be clinically significant (e.g., pseudomacrocytosis from rouleaux or agglutinates; pseudoleukocytosis with erroneous hemoglobin, falsely low erythrocyte count and hematocrit; hyperlipemias)?

COMMENTARY: 02:3015 PHASE: II

A DOCUMENTED PROCEDURE MUST BE AVAILABLE AND IN USE TO DETECT SPURIOUS CBC INSTRUMENT RESULTS THAT MAY BE CLINICALLY SIGNIFICANT. ANALYTIC SOURCES OF ERROR WITH AUTOMATED INSTRUMENTS DEPEND ON THE TYPE OF INSTRUMENT AND REAGENTS USED BY THE LABORATORY. COMMON POTENTIAL ERRORS FOR THE HEMOGRAM (WITHOUT PLATELETS) INCLUDE PSEUDOMACROCYTOSIS (DUE TO MICROCLOTS, COLD AGGLUTININS, ROULEAUX, OR OSMOTIC MATRIX EFFECTS), PSEUDOLEUKOCYTOSIS (DUE TO PLATELET AGGLUTINATION, GIANT PLATELETS, UNLYSED ERYTHROCYTES, NUCLEATED ERYTHROCYTES, MEGAKARYOCYTES, RED CELL INCLUSIONS, CRYOPROTEINS, CIRCULATING MUCIN), ERRONEOUS HEMOGLOBIN AND INDICES (DUE TO LIPEMIA OR LEUKOCYTOSIS), FALSELY LOW RED CELL COUNT AND
HEMATOCRIT (DUE TO IN VITRO HEMOLYSIS OR EXTREME MICROCYTOSIS), AND FALSELY DEPRESSED RESULTS FOR ALL PARAMETERS (DUE TO CLOTS).


QUESTION: 02:3020 PHASE: I

Are red cell indices (MCV, MCH, MCHC) monitored routinely to detect random errors?

COMMENTARY: 02:3020 PHASE: I

PATIENT SAMPLE RED CELL INDICES (WINTROBE INDICES OR MCV, MCH, MCHC) SHOULD BE MONITORED ROUTINELY TO DETECT RANDOM ERRORS, INSTRUMENT MALFUNCTION, OR SPURIOUS RESULTS. IF SEMIAUTOMATED METHODS ARE USED, INDICES SHOULD BE CALCULATED. ON MANY AUTOMATED INSTRUMENTS, THE MCHC IS THE MOST USEFUL PARAMETER TO ENSURE ACCURACY OF THE RED CELL PARAMETERS IN INDIVIDUAL PATIENTS SAMPLES. SINCE MCHC VARIES OVER A NARROW RANGE, AN ABNORMAL MCHC WILL OFTEN FLAG POTENTIALLY SPURIOUS RED CELL PARAMETERS. TRULY ELEVATED MCHCs MAY BE SEEN WITH SPHEROCYTOSIS, WHILE DECREASED MCHCs CAN ACCOMPANY A LOW MCV IN SEVERE IRON DEFICIENCY ANEMIA. IF SUCH RBC ABNORMALITIES ARE NOT PRESENT ON THE BLOOD FILM, ONE OR MORE OF THE MEASURED RBC PARAMETERS IS LIKELY ERRONEOUS. INCORRECT DATA MAY BE DUE TO THE INSTRUMENT MALFUNCTION OR TO PROBLEMS WITH THE BLOOD SAMPLE ITSELF. SOME EXAMPLES INCLUDE: SPURIOUSLY ELEVATED MCVs AND MCHCs WITH COLD AGGLUTININS, FALSELY ELEVATED MCHCs WITH LIPEMIA AND PLASMA PARAPROTEINS, SPURIOUSLY LOW MCHCs WITH LEUKOCYTOSIS AND OSMOTIC EFFECTS SUCH AS HYPERGLYCEMIA ALTERING MCV. MCV AND MCH ARE FAIRLY CONSTANT FOR EACH PATIENT, AND MONITORING THESE INDICES IN A DELTA CHECK ERROR DETECTION PROGRAM MAY PROVIDE RAPID PATIENT-BASED DETECTION OF
INSTRUMENT MALFUNCTION OR SPECIMEN MISIDENTIFICATION.


QUESTION: 02:3025  PHASE: II

Are upper and lower limits of all reportable parameters on the CBC instrument defined, so results that fall outside these limits are verified before reporting?

NOTE: Apparent analyte concentrations that are lower or higher than the reportable range may be reported as "less than" the lower limit or "greater than" the higher limit. Alternatively, when clinically appropriate, samples with results exceeding the higher limit may be diluted so that the value falls within the established analytic range, and appropriate multipliers applied.

COMMENTARY: 02:3025  PHASE: II

THE LABORATORY MUST INITIALLY ESTABLISH OR VERIFY THE REPORTABLE RANGE FOR EACH PARAMETER OF ITS AUTOMATED OR SEMI-AUTOMATED CBC INSTRUMENT. IN PARTICULAR, THE LABORATORY MUST HAVE DATA ON ITS INSTRUMENT'S ACCURACY WITH THROMBOCYTOPENIC AND LEUKOPENIC SAMPLES. PLATELET CONCENTRATIONS BELOW THE ESTABLISHED LOWER LIMITS MUST BE REANALYZED BY ANOTHER METHOD (e.g., MANUAL HEMOCYTOMETRY, OR SEMIQUANTITATIVE BLOOD FILM ESTIMATES, OR FLUORESCENCE FLOW CYTOMETRY USING SPECIFIC PLATELET MONOCLONAL ANTIBODIES). PARTICLE (WBC, RBC, PLT) CONCENTRATIONS ABOVE THE ESTABLISHED UPPER LIMITS MUST, AS CLINICALLY NEEDED, BE REANALYZED BY DOING THE MINIMUM DILUTION NECESSARY TO BRING THE COUNTS INTO THE INSTRUMENT'S LINEAR RANGE. ALTERNATIVELY, WHEN CLINICALLY APPROPRIATE, APPARENT ANALYTE CONCENTRATIONS THAT ARE LOWER OR HIGHER THAN THE REPORTABLE RANGE MAY BE REPORTED AS "LESS THAN" THE LOWER LIMIT OR "GREATER THAN" THE HIGHER LIMIT.

QUESTION: 02:3030 PHASE: II

Is there an adequate system (such as microscopic correlation with the blood film) to prevent reporting of spurious thrombocytopenia when platelet clumps, giant platelets, or platelet satellitism are present?

COMMENTARY: 02:3030 PHASE: II

WHEN PLATELET SATELLITOSIS (SATELLITISM), SIGNIFICANT NUMBERS OF GIANT PLATELETS AND/OR PLATELET CLUMPS ARE SUSPECTED/DETECTED BY CYTO/HISTOGRAPHIC ABNORMALITIES OR INSTRUMENT REJECTION OF A PLATELET COUNT, THE PLATELET COUNT MUST BE INDEPENDENTLY VERIFIED. CORRELATION WITH A WELL-PREPARED BLOOD FILM MUST BE MADE. IF PLATELETS ARE CLUMPED AFTER COLLECTION IN AN EDTA-ANTICOAGULATED TUBE THAT WAS WELL-MIXED AT THE TIME OF COLLECTION, THIS MAY REPRESENT IN VITRO EDTA-INDUCED CHANGES; PLATELETS SHOULD BE QUANTITATED FROM BLOOD COLLECTED DIRECTLY INTO A COUNTING DILUENT, OR BY USE OF A DIFFERENT ANTICOAGULANT (e.g., LIQUID SODIUM CITRATE WITH SUBSEQUENT ADJUSTMENT FOR DILUTION) OR BY ESTIMATION FROM A NON-ANTICOAGULATED BLOOD FILM.


QUESTION: 02:3035 PHASE: II

If significant numbers of unlysed RBC, giant platelets and/or platelet clumps are suspected/detected, is the white count rechecked by another method or are blood films examined to prevent reporting spuriously high white cell counts?

COMMENTARY: 02:3035 PHASE: II

WHEN UNLYSED RBC, SIGNIFICANT NUMBERS OF GIANT PLATELETS AND/OR PLATELET CLUMPS ARE SUSPECTED/DETECTED BY HISTOGRAPHIC ABNORMALITIES OR INSTRUMENT REJECTION OF A PLATELET COUNT, THE WHITE COUNT MUST BE VERIFIED MANUALLY, BY AUTOMATED COUNTING AFTER COLLECTION INTO A DIFFERENT ANTICOAGULANT, BY AUTOMATED COUNTING...
IN A LYSE-RESISTANT MODE, OR BY SEMIQUANTITATIVE BLOOD FILM EVALUATION TO PREVENT REPORTING SPURIOUSLY HIGH WHITE CELL COUNTS.


QUESTION: 02:3040 PHASE: II

If significant numbers of microcytic erythrocytes and/or small cell fragments are detected/suspected, is the platelet count determined or verified using an alternate method?

COMMENTARY: 02:3040 PHASE: II

WHEN A SIGNIFICANT NUMBER OF INTERFERING PARTICLES ARE IDENTIFIED AT THE UPPER OR LOWER PLATELET COUNTING THRESHOLD (BY INSPECTION OF THE PLATELET HISTOGRAM OR INSTRUMENT FLAG), THE PLATELET COUNT MUST BE DETERMINED OR VERIFIED BY AN ALTERNATE METHOD. SUCH METHODS COULD INCLUDE ALTERNATE INSTRUMENTATION, HEMOCYTOMETRY, OR BLOOD FILM ESTIMATE, DEPENDING UPON THE PLATELET CONCENTRATION AND THE DEGREE OF CLINICAL ACCURACY THAT IS REQUIRED.


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GENERAL INSTRUMENT ISSUES

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QUESTION: 02:3050 PHASE: II

If manual methods are used as system controls for automated procedures, is their accuracy verified and documented periodically?
GENERAL INSTRUMENT ISSUES:

COMMENTARY: 02:3050 PHASE: II

IF MANUAL METHODS ARE USED AS SYSTEM CONTROLS FOR AUTOMATED PROCEDURES, THEIR ACCURACY MUST BE VERIFIED PERIODICALLY AND THE RESULTS DOCUMENTED. VERIFICATION MAY BE ADAPTED FROM THE SYSTEMS USED WHEN MANUAL TESTING IS DONE AS A DAILY ROUTINE, INCLUDING USE OF REFERENCE MATERIALS AND CHECKING OF INSTRUMENTS.

QUESTION: 02:3055 PHASE: II

Is there a regular schedule for routine function checks and maintenance procedures?

COMMENTARY: 02:3055 PHASE: II

THERE MUST BE A SCHEDULE FOR ROUTINE FUNCTION CHECKS OR MAINTENANCE OF THE CELL COUNTING SYSTEM.

QUESTION: 02:3060 PHASE: II

Are function checks conveniently recorded or plotted to readily detect instrument malfunction?

COMMENTARY: 02:3060 PHASE: II

FUNCTION CHECKS MUST BE CONVENIENTLY RECORDED OR DISPLAYED TO READILY DETECT INSTRUMENT MALFUNCTION.

QUESTION: 02:3065 PHASE: II

Are performance or tolerance limits defined for each instrument, component or procedure in the system?

COMMENTARY: 02:3065 PHASE: II

TOLERANCE LIMITS FOR ACCEPTABLE PERFORMANCE MUST BE ESTABLISHED FOR ALL INSTRUMENTS, COMPONENTS OR PROCEDURES IN THE SYSTEM.

QUESTION: 02:3070 PHASE: II

If semi-automated methods are used with manual dilutions, are there appropriate documented time limits for assay after dilution?
COMMENTARY: 02:3070  PHASE: II

IF SEMI-AUTOMATED METHODS ARE USED WITH MANUAL DILUTIONS, THERE MUST BE DOCUMENTED TIME LIMITS FOR ASSAY AFTER DILUTION. MINIMUM TIME LIMITS FOR READING WHITE CELLS AND HEMOGLOBIN ARE NECESSARY TO ENSURE COMPLETE LYSIS OF RED CELLS. MAXIMUM TIME LIMITS FOR RED CELL AND WHITE CELL COUNTING AFTER DILUTION SHOULD BE SET SO LYSIS OF THE CELLS WILL NOT SPURIOUSLY LOWER THE COUNTS. TIME LIMITATIONS ESTABLISHED FOR FRESH HUMAN BLOOD SAMPLES MAY NOT APPLY TO PRESERVED COMMERCIAL CONTROL MATERIALS.

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MANUAL HEMOGLOBIN DETERMINATION (CYANMETHEMOGLOBIN)

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This section is intended for laboratories performing reference measurements of hemoglobin by use of a general-purpose spectrophotometer. It does not apply to instruments whose function is to yield a hemoglobin concentration directly from a clinical sample (i.e., hemoglobinometers).

QUESTION: 02:3100  PHASE: 0

Are hemoglobin tests performed manually for routine patient services, backup, or for calibration of automated methods?

(If "NO," mark all questions in this subsection "N/A" and continue with MANUAL HEMATO-CRIT.)

QUESTION: 02:3105  PHASE: II

Is the procedure standardized with reference materials of known, certified values?

MANUAL HEMOGLOBIN DETERMINATION (CYANMETHEMOGLOBIN):

IF MANUAL HEMOGLOBIN DETERMINATIONS ARE DONE, THEY SHOULD FOLLOW ROUTINE QUALITY CONTROL PROCEDURES INCLUDING USE OF REFERENCE MATERIALS AND CHECKING OF INSTRUMENTS.

COMMENTARY: 02:3105  PHASE: II

FOR CYANMETHEMOGLOBIN METHODS, THE PROCEDURE MUST BE PERFORMED
WITH HEMOGLOBIN CYANIDE CALIBRATION STANDARDS MEETING THE INTERNATIONAL COMMITTEE FOR STANDARDIZATION IN HEMATOLOGY (ICSH) SPECIFICATIONS.


QUESTION: 02:3110 PHASE: II

Are at least four different hemoglobin concentrations used to prepare the calibration curve or to calibrate the readout instruments?

NOTE: This requirement relates to the generation of a calibration curve of hemoglobin concentration versus absorbance, and NOT to the number of controls used in the longitudinal process control system.

COMMENTARY: 02:3110 PHASE: II

CALIBRATION OF THE INSTRUMENT OR PREPARATION OF A CALIBRATION CURVE MUST CHECK AT LEAST FOUR DIFFERENT CONCENTRATIONS THAT ARE WITHIN, ABOVE AND BELOW THE CONCENTRATIONS ENCOUNTERED IN PATIENT SAMPLES. THIS SHOULD NOT BE TAKEN TO MEAN THAT AT LEAST FOUR DIFFERENT CONCENTRATIONS OF HEMIGLOBIN ARE REQUIRED AS PART OF THE LONGITUDINAL PROCESS CONTROL SYSTEM.


QUESTION: 02:3115 PHASE: II

For procedures using calibration curves, are all curves repeated regularly and verified
after servicing or recalibration of instruments?

COMMENTARY: 02:3115  PHASE: II

CALIBRATION CURVES MUST BE CHECKED PERIODICALLY AND REGULARLY VERIFIED AFTER SERVICING OR RECALIBRATION OF INSTRUMENTS.

QUESTION: 02:3120  PHASE: II

Are photometer function checks run and recorded daily?

COMMENTARY: 02:3120  PHASE: II

ROUTINE PHOTOMETER FUNCTION CHECKS MUST BE DEFINED, RUN DAILY AND RESULTS RECORDED.

QUESTION: 02:3130  PHASE: II

Are photometers checked for linearity periodically and when instrument adjustments have been made with appropriate filters or solutions?

NOTE: Spectrophotometers also should be checked for wavelength calibration and stray light.

COMMENTARY: 02:3130  PHASE: II

PHOTOMETER ABSORBANCE AND LINEARITY MUST BE CHECKED PERIODICALLY AND WHEN INSTRUMENT ADJUSTMENTS HAVE BEEN MADE WITH FILTERS OR REFERENCE SOLUTIONS. IF A SPECTROPHOTOMETER IS USED, IT MUST BE PERIODICALLY CHECKED FOR WAVE LENGTH CALIBRATION AND STRAY LIGHT.

QUESTION: 02:3135  PHASE: II

Are photometer sample wells and exterior and interior parts clean and well-maintained?

COMMENTARY: 02:3135  PHASE: II

SAMPLE WELLS AND INTERIOR AND EXTERIOR PARTS MUST BE CLEAN AND WELL-MAINTAINED AT ALL TIMES.

QUESTION: 02:3140  PHASE: II

Are manual or semiautomated hemoglobin dilutions checked for turbidity, and clarified (if necessary) before determining the absorbance?
COMMENTARY: 02:3140 PHASE: II

DILUTIONS FOR HEMOGLOBINOMETRY MUST BE CHECKED FOR TURBIDITY, AND CLARIFIED, IF NECESSARY, BEFORE DETERMINING THE ABSORBANCE. INCREASED TURBIDITY WILL LEAD TO FALSELY ELEVATED HEMOGLOBIN CONCENTRATIONS. CAUSES OF TURBIDITY INCLUDE HYPERLIPIDEMIA, LEUKOCYTOSIS, PRECIPITABLE MONOCLONAL PROTEINS, AND UNLYSED ERYTHROCYTES. TURBIDITY DUE TO LEUKOCYTOSIS CAN BE ELIMINATED BY CENTRIFUGATION, WHILE TURBIDITY DUE TO UNLYSED RED CELLS MAY BE REMOVED THROUGH USE OF ADDITIONAL LYSENG AGENT. CORRECTED HEMOGLOBIN MEASUREMENTS IN HYPERLIPIDEMIC STATES CAN BE OBTAINED BY REPLACING THE LIPEMIC PLASMA WITH SALINE OR BY SUBTRACTION OF THE APPARENT "PLASMA HEMOGLOBIN."


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MANUAL HEMATOCRIT (MICROHEMATOCRIT, PACKED CELL VOLUME)

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QUESTION: 02:3200 PHASE: 0

Are microhematocrits (packed cell volumes) performed for routine patient services, backup, or for calibration of automated methods?

(If "NO," mark all questions in this subsection "N/A" and continue with MANUAL (HEMOCYTOMETER) WBC, RBC, AND PLT COUNTS (BLOOD).)

QUESTION: 02:3205 PHASE: II

Is the speed of the microhematocrit centrifuge checked at specific intervals?

NOTE: Relative centrifugal field (RCF) should be sufficient to achieve maximum packing of cells. In most microhematocrit centrifuges with fixed speed, the RCF will exceed a value of 10,000.

MANUAL HEMATOCRIT (MICROHEMATOCRIT, PACKED CELL VOLUME):
COMMENTARY: 02:3205  PHASE: II

THE MICROHEMATOCRIT CENTRIFUGE MUST BE CHECKED AT SPECIFIC, DEFINED INTERVALS WITH A TACHOMETER. THE CENTRIFUGE MUST BE CAPABLE OF SUSTAINING A RELATIVE CENTRIFUGAL FIELD (RCF) OF 10,000 TO 15,000 AT THE PERIPHERY FOR 5 MINUTES WITHOUT EXCEEDING A TEMPERATURE OF 45 DEGREES CELSIUS.


QUESTION: 02:3210  PHASE: II

If a mechanical timer is used, is it checked at specified intervals?

NOTE: Not applicable to electronic timers.

COMMENTARY: 02:3210  PHASE: II

THE ACCURACY OF MECHANICAL CENTRIFUGE TIMER MUST BE CHECKED AND RECORDED PERIODICALLY. THIS IS NOT APPLICABLE TO ELECTRONIC TIMERS.

QUESTION: 02:3215  PHASE: II

Is the constant packing time (minimum spin to reach maximum packing of cells) reassessed when there has been a change in either the speed or time?

COMMENTARY: 02:3215  PHASE: II

THE CONSTANT PACKING TIME (MINIMUM TIME OF SPIN REQUIRED TO REACH MAXIMUM PACKING OF CELLS) MUST BE ESTABLISHED AND POSTED SO THAT PROPER TIME IS USED BY ALL OPERATORS. THE CONSTANT PACKING TIME MUST BE RECHECKED AFTER ANY CHANGES IN SPEED OR TIME.


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MANUAL (HEMOCYTOMETER) LEUKOCYTE (WBC) AND
PLATELET (PLT) COUNTS (BLOOD)

QUESTION: 02:3300  PHASE: 0

Does the laboratory perform platelet or leukocyte counts by manual (hemocytometer) methods for routine patient services, backup, or calibration of automated methods?

NOTE: Hemocytometry RBC counts are not recommended because of the level of imprecision and inability to verify results against a stained blood film.

(If "NO," mark all questions in the subsection "N/A" and continue with AUTOMATED DIFFERENTIAL COUNTERS.)

QUESTION: 02:3320  PHASE: II

If WBC or PLT counts are performed manually by pipet dilution and chamber count, is each sample diluted in duplicate and each dilution counted in duplicate, plating two hemocytometer chambers?

NOTE: If the sample is diluted in a standard volume reservoir, the leukocyte or platelet count may be performed on a single dilution, provided that the results are verified against a semi-quantitative estimate of WBC or PLT count from an adequately made blood film.

MANUAL (HEMOCYTOMETER) LEUKOCYTE (WBC) AND PLATELET (PLT) COUNTS (BLOOD):

COMMENTARY: 02:3320  PHASE: II

WHEN MANUAL (HEMOCYTOMETER) WHITE CELL COUNTS ARE PERFORMED BY PIPETTE DILUTION AND CHAMBER COUNT, EACH SAMPLE MUST BE DILUTED IN DUPLICATE AND EACH DILUTION COUNTED IN DUPLICATE, PLATING TWO HEMOCYTOMETER CHAMBERS. IF THE SAMPLE IS DILUTED IN A STANDARD VOLUME RESERVOIR, THE WBC COUNT MAY BE PERFORMED ON A SINGLE DILUTION PROVIDED THAT RESULTS ARE VERIFIED AGAINST A SEMIQUANTITATIVE ESTIMATE FROM AN ADEQUATELY MADE BLOOD FILM. DUE TO A HIGH LEVEL OF IMPRECISION, HEMOCYTOMETRY IS NOT RECOMMENDED FOR RED CELL ENUMERATION IN BLOOD SAMPLES.

QUESTION: 02:3325  PHASE: II

When there is leukopenia or thrombocytopenia, does the manual hemocytometer
procedure require a technique to offset the increased error associated with counting smaller numbers of cells in the hemocytometer?

NOTE: Typical techniques involve counting the cells in an increased number of hemocytometer squares, or using a lesser dilution of the specimen.

COMMENTARY: 02:3325  PHASE: II

THE LABORATORY PROTOCOL MUST SPECIFY AN INCREASED NUMBER OF CELLS COUNTED (e.g., INCREASED NUMBER OF HEMOCYTOMETER SQUARES ENUMERATED, OR A LESSER SPECIMEN DILUTION) WHEN THERE IS LEUKOPENIA OR THROMBOCYTOPENIA, IN ORDER TO AVOID INCREASING THE IMPRECISION OF PARTICLE COUNTING, WHICH IS GOVERNED BY BINOMIAL DISTRIBUTIONS AND POISSON STATISTICS.


QUESTION: 02:3330  PHASE: II

Is a system defined and documented for assuring that dilution fluids are free of contaminants that may spuriously change the true cell counts?

COMMENTARY: 02:3330  PHASE: II

THE LABORATORY MUST HAVE A DEFINED SYSTEM TO ENSURE THAT DILUTING FLUIDS AND REAGENTS USED IN MANUAL CELL COUNTING DO NOT ACQUIRE PARTICULATES OR HAVE AN ALTERED COMPOSITION THAT MIGHT RENDER CELL CONCENTRATIONS INACCURATE. SUGGESTED CHECKS INCLUDE pH, OSMOLALITY AND BACKGROUND COUNTS.

QUESTION: 02:3333  PHASE: I

Is at least one cell count control specimen analyzed, or a procedural control employed for each 8 hours of patient testing?

NOTE: For leukocytes and platelets, this requirement can be met with assayed liquid control material, a previously assayed patient sample, or comparison with a visual blood film concentration estimate. Visual estimates are not appropriate for erythrocyte hemocytometry.
AT LEAST ONE CELL COUNT CONTROL SPECIMEN SHOULD BE ANALYZED DURING EACH 8 HOURS OF PATIENT TESTING WITH HEMOCYTOMETRY. ALTERNATIVELY, A PROCEDURAL CONTROL IS SUITABLE FOR LEUKOCYTES AND PLATELETS, USING A PREVIOUSLY ASSAYED PATIENT SAMPLE OR COMPARISON WITH A VISUAL BLOOD FILM CONCENTRATION ESTIMATE. VISUAL ESTIMATES ARE NOT APPROPRIATE FOR ERYTHROCYTE HEMOCYTOMETRY.


QUESTION: 02:3335 PHASE: II

For hemocytometry platelets, is the manual count correlated with a platelet estimate from a properly prepared blood film?

COMMENTARY: 02:3335 PHASE: II

THE MANUAL PLATELET COUNT MUST BE CORRELATED WITH A SEMIQUANTITATIVE ESTIMATE FROM A PROPERLY PREPARED AND WELL-STAINED BLOOD FILM.


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AUTOMATED DIFFERENTIAL COUNTERS

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QUESTION: 02:3400 PHASE: 0

Does the laboratory use an automated leukocyte differential counter (flow-through or pattern recognition type)?

(If "NO," mark all questions in this subsection "N/A" and continue with MANUAL BLOOD...
QUESTION: 02:3405 PHASE: II

Is there documentation to indicate that the automated method was carefully evaluated in the laboratory against previous leukocyte differential methods before it was placed into routine use?

NOTE: The laboratory should have the results of its evaluation studies, either in summary form or actual data, available to the inspector for review.

AUTOMATED DIFFERENTIAL COUNTERS:

COMMENTARY: 02:3405 PHASE: II

A NEW AUTOMATED DIFFERENTIAL COUNTER (PATTERN RECOGNITION OR FLOW-THROUGH TYPE) MUST BE EVALUATED BY THE HEMATOLOGY LABORATORY AGAINST REFERENCE/MANUAL METHODS BEFORE BEING PLACED IN SERVICE. THE LABORATORY IS NOT REQUIRED TO VERIFY THE MANUFACTURER'S STUDIES ON FLAGGING OF ABNORMAL CELLS, ALTHOUGH STUDIES OF THE LOCAL PATIENT POPULATION ARE RECOMMENDED. THE FOLLOWING REFERENCES MAY BE CONSULTED FOR EXAMPLES OF SPECIFIC EVALUATION Protocols.

QUESTION: 02:3410 PHASE: II

Does the quality control procedure include defined limits of agreement with WBC subclasses from manually counted blood films or commercially available material containing at least two classes of white cells and/or surrogate particles?

NOTE: For commercial controls, mixed leukocyte subclasses (e.g., "mononuclear" or "large unclassified cells") or "remainder" fractions do not need to be assessed with QC procedures. The commercial material should contain surrogate particles to measure total neutrophils, total granulocytes, total lymphoid cells, monocytes, eosinophils, and basophils, if these subtypes are enumerated by the instrument and reported by the laboratory. If discrete populations of abnormal cells are identified and enumerated by the instrument (e.g., nucleated RBC, blasts), then the QC material must contain surrogate particles to evaluate accuracy.

COMMENTARY: 02:3410 PHASE: II

THERE MUST BE DEFINED, DOCUMENTED LONGITUDINAL PROCESS CONTROL SYSTEMS TO MONITOR THE PERFORMANCE OF THE AUTOMATED DIFFERENTIAL COUNTER. FOR PATTERN RECOGNITION MICROSCOPY SYSTEMS (e.g., HEMATRAK), THIS CAN BE DONE BY PERIODIC PROCESSING OF PREPARED CONTROL SLIDES AND MAINTENANCE/ANALYSIS OF LEVEY-JENNINGS CHARTS. FOR FLOW-THROUGH SYSTEMS (e.g., ABBOTT, COULTER, SYSMEX, TECHNICON, ETC.), AT LEAST TWO APPROACHES ARE REASONABLE: 1) COMPARISON OF INSTRUMENT DIFFERENTIALS ON FRESH BLOOD SAMPLES WITH A CONVENTIONAL MANUAL DIFFERENTIAL COUNT, AND/OR 2) USE OF COMMERCIALY AVAILABLE STABILIZED LEUKOCYTES AND/OR PARTICLE SURROGATE CONTROL MATERIAL. THE AUTOMATED INSTRUMENT AND REFERENCE DETERMINATIONS SHOULD BE TREATED AS REPLICATE MANUAL DIFFERENTIALS AND EVALUATED USING THE +/- 2 OR 3 S.D. AGREEMENT LIMITS OF RUMKE.

FOR COMMERCIAL CONTROLS, MIXED LEUKOCYTE SUBCLASSES (e.g., "MONONUCLEAR" OR "LARGE UNCLASSIFIED CELLS") OR "REMAINDEIR" FRACTIONS DO NOT NEED TO BE ASSESSED WITH QC PROCEDURES. THE COMMERCIAL MATERIAL SHOULD CONTAIN SURROGATE PARTICLES TO MEASURE TOTAL NEUTROPHILS, TOTAL GRANULOCYTES, TOTAL LYMPHOID CELLS, MONOCYTES, EOSINOPHILS, AND BASOPHILS, IF THESE SUBTYPES ARE ENUMERATED BY THE INSTRUMENT AND REPORTED BY THE LABORATORY. IF DISCRETE POPULATIONS OF ABNORMAL CELLS ARE IDENTIFIED AND ENUMERATED BY THE INSTRUMENT (e.g., NUCLEATED RBC, BLASTS), THEN THE QC MATERIAL MUST CONTAIN SURROGATE PARTICLES TO EVALUATE ACCURACY.

QUESTION: 02:3415 PHASE: II

Is there evidence of corrective action where tolerance limits for control slides or specimens are exceeded?

COMMENTARY: 02:3415 PHASE: II

WHEN DEFINED TOLERANCE LIMITS FOR ACCURACY AND/OR PRECISION OF THE AUTOMATED DIFFERENTIAL COUNTER ARE EXCEEDED, THERE MUST BE DOCUMENTATION OF CORRECTIVE ACTION. THIS SHOULD INCLUDE A DESCRIPTION OF THE PROBLEM, THE PRESUMED CAUSE, AND SPECIMEN REANALYSES THAT INDICATE ACCEPTABLE AGREEMENT BETWEEN REFERENCE AND TEST METHODS.

QUESTION: 02:3420 PHASE: II

Has the laboratory established criteria for checking and reviewing leukocyte differential counter data, histograms, and/or blood films for clinically important results flagged by the automated differential counter?

COMMENTARY: 02:3420 PHASE: II
THE LABORATORY MUST HAVE DEFINED PROTOCOLS FOR VALIDATION AND REVIEW OF AUTOMATED DIFFERENTIAL COUNTER RESULTS FOR CLINICALLY SIGNIFICANT FINDINGS. THESE INCLUDE PATHOLOGIC QUANTITIES OF NORMAL CELL TYPES AND ABNORMAL CELLS. FLAGGING MECHANISMS INCLUDE THOSE WITHIN THE PARTICULAR INSTRUMENT, INSPECTION OF HISTOGRAPHIC/CYTOGRAPHIC DISPLAYS, LABORATORY CRITERIA BASED UPON LOCAL EXPERIENCE, AND AWARENESS OF PUBLISHED EVALUATIONS.


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MANUAL BLOOD FILM EXAMINATION (DIFFERENTIAL COUNT)
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QUESTION: 02:3425  PHASE: 0

Are manual differential cell counts performed on blood films?

(If "NO," mark all questions in this subsection "N/A" and continue with AUTOMATED RETICULOCYTES.)
QUESTION: 02:3430  PHASE: II

Is the quality of blood films satisfactory (properly stained, free of precipitate, good cell distribution)?

MANUAL BLOOD FILM EXAMINATION (DIFFERENTIAL COUNT):

COMMENTARY: 02:3430  PHASE: II

HIGH QUALITY BLOOD FILMS ARE ESSENTIAL FOR PROPER MORPHOLOGIC EVALUATION. FILMS EXAMINED BY THE INSPECTOR WERE TECHNICALLY UNACCEPTABLE FOR PROPER EVALUATION OF THE CELLULAR ELEMENTS OF BLOOD (ERYTHROCYTES, LEUKOCYTES, AND/OR PLATELETS).


QUESTION: 02:3435  PHASE: II

Are slides uniquely identified?

COMMENTARY: 02:3435  PHASE: II

BLOOD FILM IDENTIFICATION MUST BE ADEQUATE. SLIDE OR COVERSLEIP IDENTIFICATION MUST INCLUDE UNIQUE ELEMENTS, SUCH AS SPECIMEN OR ACCESSION NUMBER, PATIENT NAME AND/OR NUMBER, AND DATE.

QUESTION: 02:3440  PHASE: II

Does the hematology laboratory have a defined, documented system to ensure consistency of morphologic observations among all personnel performing blood cell microscopy?

Suggested methods to accomplish this include:

1. Circulation of blood films with defined leukocyte differential distributions and specific qualitative abnormalities of each class of cells (WBC, RBC, PLT), and/or
2. Multi-headed microscopy, and/or

3. Use of blood or marrow photomicrographs with referee and consensus identifications (e.g., former CAP surveys photomicrographs).


COMMENTARY: 02:3440 PHASE: II

THE HEMATOLOGY LABORATORY MUST HAVE A DOCUMENTED SYSTEM THAT ENSURES THAT ALL PERSONNEL REPORT MICROSCOPIC MORPHOLOGIC DATA ON PATIENT SAMPLES IN A SIMILAR FASHION. FOR SERIAL SAMPLES FROM THE SAME PATIENT, THE LABORATORY MUST BE ABLE TO DOCUMENT THAT ALL OF ITS STAFF ARE CONSISTENT WITH RESPECT TO MORPHOLOGIC CLASSIFICATION. SUGGESTED METHODS TO ACCOMPLISH THIS INCLUDE:

1. CIRCULATION OF BLOOD FILMS WITH DEFINED LEUKOCYTE DIFFERENTIAL DISTRIBUTIONS AND SPECIFIC QUALITATIVE ABNORMALITIES OF EACH CLASS OF CELLS (WBC, RBC, PLT), AND/OR

2. MULTI-HEADED MICROSCOPY, AND/OR

3. USE OF BLOOD OR MARROW PHOTOMICROGRAPHS WITH REFEREE AND CONSENSUS IDENTIFICATIONS (e.g., FORMER CAP SURVEYS PHOTOMICROGRAPHS).

IN THE CASE OF COMPARATIVE BLOOD FILM WBC DIFFERENTIALS, THE METHOD OF RUMKE IS RECOMMENDED TO DEFINE STATISTICAL AGREEMENT BETWEEN OBSERVERS.


QUESTION: 02:3445 PHASE: II
Are blood films retained for at least one week for possible review and/or reference?

COMMENTARY: 02:3445  PHASE: II

BLOOD FILMS MUST BE RETAINED FOR AT LEAST ONE WEEK FOR REFERRAL AND REVIEW BEFORE DISCARDING. IT MAY BE DESIRABLE TO RETAIN OUTPATIENT FILMS FOR A LONGER PERIOD AND SIGNIFICANTLY ABNORMAL FILMS INDEFINITELY FOR TEACHING PURPOSES.

QUESTION: 02:3450  PHASE: II

Do the laboratory staff fully assess, and accurately report, RBC and PLT morphology as part of the performance of a WBC differential?

NOTE: Each laboratory Director should, in consultation with its medical staff, determine what qualitative morphologic findings are reportable to the patient chart. For example, minor degrees of anisocytosis and poikilocytosis without specific types of RBC abnormalities may be considered within the normal spectrum and not necessarily reportable to the chart, where such information may not be clinically meaningful. However, the laboratory must have a system to ensure that technical personnel have fully assessed all morphologic findings in each patient film.

COMMENTARY: 02:3450  PHASE: II

THE EVALUATION OF RBC AND PLT MORPHOLOGY MUST ACCOMPANY THE BLOOD FILM WBC DIFFERENTIAL "COUNT". EACH LABORATORY DIRECTOR SHOULD, IN CONSULTATION WITH ITS MEDICAL STAFF, DETERMINE WHAT MORPHOLOGIC FINDINGS ARE REPORTABLE. FOR EXAMPLE, MINOR DEGREES OF ANISOCYTOSIS AND POIKILOCYTOSIS WITHOUT SPECIFIC TYPES OF RBC ABNORMALITIES MAY BE CONSIDERED WITHIN THE NORMAL SPECTRUM AND NOT NECESSARILY REPORTABLE TO THE CHART. THERE MUST BE A DEFINED QUALITATIVE OR SEMIQUANTITATIVE GRADING SYSTEM FOR REPORTING THE DEGREE OF DESCRIBED ERYTHROCYTE ABNORMALITIES. WHERE DEFINED ABNORMALITIES (e.g., SPHEROCYTES, TARGET CELLS, FRAGMENTS, ETC.) ARE PRESENT, NON-SPECIFIC LISTINGS OF "ANISOCYTOSIS" AND/OR "POIKILOCYTOSIS" MAY NOT PROVIDE ADDITIONAL CLINICALLY USEFUL INFORMATION. THE LABORATORY MUST HAVE A SYSTEM TO ENSURE THAT TECHNICAL PERSONNEL HAVE FULLY ASSESSED ALL MORPHOLOGIC FINDINGS IN EACH PATIENT FILM.


**QUESTION: 02:3455  PHASE: II**

Is an estimate of platelet sufficiency made from the blood film if a quantitative result is not reported from an instrumental or hemocytometer method?

*NOTE: Examination of a blood film includes evaluation of platelets. There is NO requirement for all numeric platelet counts to be verified against a blood film.*

**COMMENTARY: 02:3455  PHASE: II**

AN ESTIMATE OF PLATELET CONCENTRATION MUST BE MADE WHEN BLOOD FILMS ARE PREPARED FOR ANY MORPHOLOGIC EVALUATION, AND A QUANTITATIVE RESULT IS NOT REPORTED FROM AN INSTRUMENTAL OR HEMOCYTOMETER METHOD. IT IS NOT REQUIRED TO VERIFY ALL NUMERIC PLATELET COUNTS WITH A BLOOD FILM.


**QUESTION: 02:3460  PHASE: II**

Are there documented criteria with specified findings for blood films that must be reviewed by the pathologist, supervisor or other technologist qualified in hematomorphology, and is there evidence of such review?

**COMMENTARY: 02:3460  PHASE: II**

THERE MUST BE DOCUMENTED CRITERIA FOR REVIEW OF SELECTED BLOOD FILMS BY A PATHOLOGIST, SUPERVISOR OR OTHER TECHNOLOGIST QUALIFIED IN HEMATOMORPHOLOGY, AS WELL AS EVIDENCE THAT SUCH CRITERIA WERE ACTUALLY IMPLEMENTED.

**QUESTION: 02:3465  PHASE: I**

Is there a file of unusual slides?

**COMMENTARY: 02:3465  PHASE: I**

THE MAINTENANCE OF A FILE FOR SLIDES OF UNUSUAL AND/OR SIGNIFICANT BLOOD DISEASES IS RECOMMENDED.
AUTOMATED RETICULOCYTES

QUESTION: 02:3500 PHASE: 0

Is automated reticulocyte quantification performed by flow cytometry or instrument pattern recognition technology?

(If "NO," mark all questions in this subsection "N/A" and continue with MANUAL RETICULOCYTE COUNTS.)

QUESTION: 02:3502 PHASE: I

Is there documentation to indicate that the automated method was carefully evaluated in the laboratory against previous manual reticulocyte methods before it was placed into routine use?

AUTOMATED RETICULOCYTES:

COMMENTARY: 02:3502 PHASE: I

A NEW AUTOMATED RETICULOCYTE METHOD SHOULD BE EVALUATED BY THE LABORATORY AGAINST REFERENCE/MANUAL METHODS BEFORE BEING PLACED IN SERVICE.


QUESTION: 02:3505 PHASE: I

Is there a procedure in place to determine the strength and stability of the detection dye used for flow-through instrument quantification of reticulocytes?

NOTE: Not applicable to commercial kits approved or cleared by the Food and Drug Administration (FDA) and used according to manufacturer's instructions.

COMMENTARY: 02:3505 PHASE: I

THE LABORATORY MUST HAVE A PROCEDURE TO DETERMINE THE STRENGTH AND STABILITY OF THE DETECTION DYE FOR RETICULOCYTES. AUTOMATED RETICULOCYTE ENUMERATION DEPENDS UPON FLUORESCENT RNA (OR DNA-RNA)-BINDING DYSES SUCH AS ACRIDINE ORANGE, PYRONINE Y, PROPIDUM IODINE, THIOFLAVIN T, AURAMINE O, ETC., AS THE DETECTION AGENT. ACCURATE DETERMINATION OF THE RNA (OR DNA-RNA) BINDING DEPENDS ON THE STOICHIOMETRIC PROPERTIES OF EACH DYE. THE DYE SHOULD BE AT SATURATING CONCENTRATION, AND THE CONCENTRATION OF THE DYE IN ITS BUFFER SHOULD BE NOTED ON THE REAGENT CONTAINER. DETERMINATION OF THE SATURATING CONCENTRATION OF THE DYE MUST BE PERFORMED BY CORRELATIVE STUDY OF AUTOMATED RESULTS WITH A MANUAL METHOD ON A SERIES OF SAMPLES OF LOW, NORMAL, AND HIGH RETICULOCYTE CONCENTRATIONS, WITH PREFERENCE GIVEN TO DETECTION OF LOW RETICULOCYTE COUNTS. THESE PROCEDURES ARE NOT REQUIRED OF COMMERCIAL KITS APPROVED OR CLEARED BY THE FOOD AND DRUG ADMINISTRATION (FDA) AND USED ACCORDING TO MANUFACTURER'S INSTRUCTIONS.

QUESTION: 02:3510  PHASE: I

Is there a quality control program in place to determine the reproducibility (precision) of reticulocyte quantification?

COMMENTARY: 02:3510  PHASE: I

THE LABORATORY MUST HAVE COMPLETE DOCUMENTATION OF DATA TO DOCUMENT REPRODUCIBILITY (PRECISION) OF RETICULOCYTE QUANTIFICATION. THIS MAY BE ACCOMPLISHED BY COMPARING AUTOMATED RESULTS WITH MANUAL METHODS, OR BY USING STABILIZED RED CELLS WITH NORMAL, LOW AND/OR HIGH RETICULOCYTE CONCENTRATIONS. AN ACCEPTABLE QUALITY CONTROL PROGRAM INCLUDES DEFINITION OF TOLERANCE LIMITS FOR ALL CONTROLS AND DOCUMENTATION OF CORRECTIVE ACTION WHEN CONTROLS EXCEED THESE LIMITS. ALTHOUGH THE DIFFICULTIES ASSOCIATED WITH ACCURACY AND REPRODUCIBILITY IN MANUAL RETICULOCYTE COUNTING ARE WELL-KNOWN, A VERIFICATION METHOD NEEDS TO BE IN PLACE.


QUESTION: 02:3515  PHASE: I

Are there documented criteria for identifying samples that may give spurious reticulocyte results by the automated method?

COMMENTARY: 02:3515  PHASE: I

THE LABORATORY LACKS DOCUMENTED CRITERIA FOR IDENTIFYING SAMPLES THAT MAY GIVE SPURIOUS RETICULOCYTE RESULTS BY THE AUTOMATED
METHOD. SINCE ALL DNA- AND RNA-CONTAINING CELLS WILL STAIN WITH THE DNA-RNA FLUORESCENT DYES, A PROCEDURE MUST BE IN PLACE TO IDENTIFY WHEN THE INSTRUMENT CANNOT DISCRIMINATE SUCH STAINED PARTICLES FROM TRUE RETICULOCYTES. POTENTIAL INTERFERENCES INCLUDE HOWELL-JOLLY BODIES, NUCLEATED ERYTHROCYTES, HEINZ BODIES, BASOPHILIC STIPPLING OF RED CELLS, MACROTHROMBOCYTES, MEGAKARYOCYTE FRAGMENTS, PLATELET CLUMPS, AND MALARIA OR OTHER INTRACELLULAR ORGANISMS. ERYTHROCYTE AGGLUTINATION ALSO MAY GIVE SPURIOUSLY HIGH RESULTS, AS MAY VERY HIGH LEUKOCYTOSIS OR THROMBOCYTOSIS. INTERFERING PARTICLES MAY VARY, DEPENDING ON INSTRUMENTATION, DYE, AND REACTION CONDITIONS. BASED UPON INITIAL EVALUATION OF THE INSTRUMENT BY THE LABORATORY, CRITERIA MUST BE DEVELOPED TO DETECT SAMPLES WITH POTENTIALLY ERRONEOUS RESULTS. THIS MAY BE ACCOMPLISHED THROUGH FLAGGING ALGORITHMS INCORPORATED IN THE INSTRUMENT AND BY EXAMINATION OF A BLOOD FILM FROM EVERY SAMPLE TO ENSURE ABSENCE OF RELEVANT INTERFERENCES.


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MANUAL RETICULOCYTES
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QUESTION: 02:3520  PHASE: 0

Are reticulocyte concentrations ("counts") obtained by manual microscopy, either as a primary technique or with automated reticulocyte quantification?
(If "NO," mark all questions in this subsection "N/A" and continue with BONE MARROW PREPARATIONS.)

QUESTION: 02:3525 PHASE: II

Examine a blood film stained for reticulocytes. Is it satisfactory?

MANUAL RETICULOCYTES:

COMMENTARY: 02:3525 PHASE: II

A SLIDE StAINED FOR RETICULOCYTES WAS FOUND TO BE TECHNICALLY UNSATISFACTORY.


QUESTION: 02:3530 PHASE: II

Is the reported reticulocyte concentration based on a minimum sample size of 1,000 RBC?

NOTE: The greatest cause of analytical error in manual reticulocyte counting is interobserver error or at least variation in what to call a reticulocyte (especially the so-called type IV cells of Heilmeyer). The second most common contribution to analytical error is the size of the sample counted. If one counts 100 cells, even with a Miller disk, the chance of error will be greater than if one counts 1000 RBC. The Miller disk is simply a counting aid to create a standard area, not a way to decrease work or decrease the number of cells counted.

COMMENTARY: 02:3530 PHASE: II

THE RETICULOCYTE COUNT MUST BE BASED ON A TOTAL ERYTHROCYTE COUNT OF AT LEAST 1000 RBC, AS RETICULOCYTES ARE STATISTICALLY RARE EVENTS IN COMPARISON WITH THE NUMBER OF MATURE ERYTHROCYTES. THE GREATEST CAUSE OF ANALYTICAL ERROR IN MANUAL RETICULOCYTE COUNTING IS INTEROBSERVER ERROR OR AT LEAST VARIATION IN WHAT TO CALL A RETICULOCYTE (ESPECIALLY THE SO CALLED TYPE IV CELLS OF HEILMEYER). THE SECOND MOST COMMON CONTRIBUTION TO ANALYTICAL ERROR IS THE SIZE OF THE SAMPLE COUNTED. IF ONE COUNTS 100 CELLS, EVEN WITH A MILLER DISK, THE CHANCE OF ERROR WILL BE GREATER THAN IF ONE COUNTS 1000 RBC. THE MILLER DISK IS SIMPLY A COUNTING AID TO CREATE A STANDARD AREA, NOT A WAY TO DECREASE WORK OR DECREASE THE NUMBER OF CELLS COUNTED.

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BONE MARROW PREPARATIONS

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QUESTION: 02:3600  PHASE: 0

Are bone marrow slides prepared and examined on site?

(If "NO," mark all questions in this subsection "N/A" and continue with BLOOD COAGULATION STUDIES.)

QUESTION: 02:3605  PHASE: II

Are bone marrow slides uniquely identified?

BONE MARROW PREPARATIONS:

COMMENTARY: 02:3605  PHASE: II

BONE MARROW SMEAR IDENTIFICATION MUST BE ADEQUATE. SLIDE OR COVERSLEEPM IDENTIFICATION MUST INCLUDE UNIQUE ELEMENTS, SUCH AS SPECIMEN OR ACCESSION NUMBER, PATIENT NAME AND/OR NUMBER, AND DATE.

QUESTION: 02:3610  PHASE: II

Examine a slide prepared by the laboratory. Is the preparation and staining satisfactory for interpretation?

COMMENTARY: 02:3610  PHASE: II

BONE MARROW SLIDES PREPARED BY THE LABORATORY MUST BE TECHNI-
CALLY SATISFACTORY FOR PROPER EVALUATION. THE INSPECTOR NOTED SOME UNACCEPTABLE PREPARATIONS.

QUESTION: 02:3615 PHASE: I

Are fixed sections (marrow biopsy or particle sections) used as a diagnostic aid to the smear aspirate, as appropriate for the clinical situation?

COMMENTARY: 02:3615 PHASE: I

AS CLINICALLY APPROPRIATE, FIXED AND EMBEDDED SECTIONS (MARROW BIOPSY OR CLOTTED ASPIRATE) SHOULD BE USED AS A DIAGNOSTIC AID TO THE SMEAR ASPIRATE.


QUESTION: 02:3620 PHASE: II

Is the quality of fixed tissue sections of bone marrow conducive to a reliable diagnosis?

COMMENTARY: 02:3620 PHASE: II

THE QUALITY OF THE FIXED TISSUE SECTIONS WAS NOT SATISFACTORY FOR PROPER DIAGNOSIS. IMPROVEMENTS MUST BE INSTITUTED.

QUESTION: 02:3625 PHASE: II

If fixed tissue sections and bone marrow aspirate smears are evaluated in different sections of the laboratory, is there a mechanism to compare the data and interpretations from these different areas before reports are released?

COMMENTARY: 02:3625 PHASE: II

FIXED TISSUE SECTIONS AND BONE MARROW ASPIRATE SMEARS THAT ARE EVALUATED IN DIFFERENT SECTIONS OF THE LABORATORY MUST HAVE A DEFINED MECHANISM TO COMPARE THE DATA AND INTERPRETATIONS FROM
THESE DIFFERENT AREAS BEFORE REPORTS ARE RELEASED. SUCH DATA CORRELATION IS ESSENTIAL FOR DIAGNOSTIC CONSISTENCY AND EFFECTIVE PATIENT MANAGEMENT.

QUESTION: 02:3627 PHASE: II

Are bone marrow reports and smears retained for 10 years?

COMMENTARY: 02:3627 PHASE: II

BONE MARROW REPORTS AND/OR SMEARS MUST BE RETAINED FOR AT LEAST 10 YEARS. THE LABORATORY'S CURRENT RETENTION PERIOD MUST BE EXTENDED TO PROVIDE DOCUMENTATION FOR ADEQUATE QUALITY CONTROL AND MEDICAL CARE. IN ESTABLISHING RETENTION REQUIREMENTS, CARE SHOULD BE TAKEN TO COMPLY WITH STATE AND FEDERAL REGULATION.

QUESTION: 02:3630 PHASE: II

Are bone marrow specimens evaluated by a pathologist or qualified hematologist and written reports prepared?

COMMENTARY: 02:3630 PHASE: II

BONE MARROW SPECIMENS MUST BE REVIEWED BY A PATHOLOGIST OR QUALIFIED HEMATOLOGIST, AND WRITTEN REPORTS PREPARED.

QUESTION: 02:3635 PHASE: II

Is an iron stain prepared for bone marrow evaluations of anemia where indicated?

COMMENTARY: 02:3635 PHASE: II

IRON STAINS MUST BE PREPARED TO EVALUATE ANEMIAS WHENEVER INDICATED OR REQUESTED.

QUESTION: 02:BAAP PHASE: II

Are the following special stains used of high quality and do they demonstrate the cellular characteristics for which they were designed:

1. acid phosphatase,
2. ASD chloracetate esterase (Leder),
3. Giemsa,
4. non-specific esterase, 
5. PAS (periodic acid Schiff),
6. sudan black,
7. myeloperoxidase,
8. TdT (terminal deoxynucleotidyl transferase)?

NOTE: This listing is not intended to be all-inclusive nor exclusive of other special stains. For purposes of accreditation, there is no requirement for use of all of these in every bone marrow. For applicable stains, the inspector must provide specific details of any deficiencies in Part B (Deficiency Summary) of the Inspector's Summation Report.

COMMENTARY: 02:BAAP PHASE: II

ONE OR MORE OF THE FOLLOWING SPECIAL STAINING TECHNIQUES MUST BE IMPROVED TO DEMONSTRATE THE CELLULAR CHARACTERISTICS FOR WHICH THEY WERE DESIGNED:

1. ACID PHOSPHATASE, 
2. ASD CHLORACETATE ESTERASE (LEDER),
3. GIEMSA, 
4. NON-SPECIFIC ESTERASE, 
5. PAS (PERIODIC ACID SCHIFF),
6. SUDAN BLACK, 
7. MYELOPEROXIDASE, 
8. TdT (TERM NAL DEOXYNUCLEOTIDYL TRANSFERASE)?

SPECIFIC DETAILS ARE IDENTIFIED IN PART B (DEFICIENCY SUMMARY) OF THE INSPECTOR'S SUMMATION REPORT. THIS LISTING IS NOT INTENDED TO BE ALL-INCLUSIVE NOR EXCLUSIVE OF OTHER SPECIAL STAINS. FOR PURPOSES OF ACCREDITATION, THERE IS NO REQUIREMENT FOR USE OF ALL OF THESE IN EVERY BONE MARROW.

QUESTION: 02:3680 PHASE: II

Are all stains checked for intended reactivity each day of use?

NOTE: Cytochemical reactions should be assessed using both a normal blood film and an evaluation of the staining of residual apparently normal blood cells on the smears being tested. Rarely, the normal control may react, but the expected staining of normal cells on the test smear may be absent for technical reasons. Failure to evaluate the expected reactions of normal cells may cause diagnostic errors.

COMMENTARY: 02:3680 PHASE: II
WHERE AVAILABLE, CONTROLS MUST BE PROCESSED IN PARALLEL WITH ALL SPECIAL STAINS. THE PROCEDURE MANUAL SHOULD REQUIRE AN ASSESSMENT OF STAINING OF THE REMAINING APPARENTLY NORMAL CELLS ON THE TEST SMEAR, AS WELL AS THE STAINING OF CELLS ON A NORMAL CONTROL SMEAR. FAILURE TO EVALUATE THE EXPECTED REACTIONS OF NORMAL CELLS MAY CAUSE DIAGNOSTIC ERRORS.

BLOOD COAGULATION STUDIES

Laboratories serving acute care hospitals should be able to perform a sufficient variety of coagulation tests to evaluate common coagulation disorders. This may not apply to independent laboratories and, if so, questions should be marked "N/A."

QUESTION: 02:3700 PHASE: 0

Are routine and emergency services provided for coagulation studies?

(If "NO," mark all questions in this subsection "N/A" and continue with ABNORMAL HEMOGLOBIN DETECTION.)

QUESTION: 02:3705 PHASE: II

Are tests for common coagulation problems available (prothrombin time, activated partial thromboplastin time, bleeding time or others)?

BLOOD COAGULATION STUDIES:

LABORATORIES SERVING ACUTE CARE HOSPITALS SHOULD PERFORM A SUFFICIENT VARIETY OF COAGULATION TESTS TO EVALUATE COMMON COAGULATION DISORDERS.

PROCEDURES PROVIDED SHOULD INCLUDE:

COMMENTARY: 02:3705 PHASE: II

TESTS FOR COMMON COAGULATION PROBLEMS OF BOTH AN ACQUIRED AND CONGENITAL NATURE, (SUCH AS: PLATELET COUNT; PROTHROMBIN TIME, ACTIVATED PARTIAL THROMBOPLASTIN TIME; FIBRINOGEN ASSAY;
FIBRIN(OGEN) DEGRADATION PRODUCTS OR D-DIMER).

REFERENCE: National Committee for Clinical Laboratory Standards. One-stage prothrombin time (PT) test and activated partial thromboplastin time (aPTT) test; approved guideline H47-A. Wayne, PA: NCCLS, 1996.

QUESTION: 02:3710 PHASE: II

Are tests for monitoring the effects of anticoagulation agents available (whole blood clotting time, plasma recalcification time, prothrombin time or aPTT or others)?

COMMENTARY: 02:3710 PHASE: II

TESTS FOR ANTICOAGULATION EFFECTS (SUCH AS: PLASMA RECALCIFICATION TIME, ACTIVATED PARTIAL THROMBOPLASTIN TIME, ACTIVATED CLOTTING TIME, THROMBIN TIME, HEPARIN ASSAY, PROTHROMBIN TIME).


QUESTION: 02:3712 PHASE: I

Are recommendations provided to clinicians concerning which laboratory tests to use for monitoring heparin and/or oral anticoagulant therapy, and the therapeutic range for the tests?

NOTE: Although the International Normalized Ratio (INR) is recommended for monitoring of oral anticoagulants, many methods are still commonly in use. In addition, more than a dozen methods are in use for monitoring heparin therapy. Most of these methods are widely variable in response to anticoagulation because of patient, reagent, and instrument variability. For this reason, the laboratory should provide the clinician with information concerning which tests are recommended for monitoring anticoagulation, and the values for the tests that indicate that the anticoagulant is in a therapeutic range.
LABORATORY TESTS ARE COMMONLY USED TO MONITOR ANTICOAGULANT THERAPY. THE LABORATORY SHOULD PROVIDE RECOMMENDATIONS CONCERNING WHICH TEST(S) TO USE AND THE THERAPEUTIC RANGE OF TEST RESULTS THAT INDICATE THE INTENDED CLINICAL EFFECT.


QUESTION: 02:3715 PHASE: II

Are tests for defining or monitoring disseminated intravascular coagulation (DIC) problems available, if applicable to the patient population served?

COMMENTARY: 02:3715 PHASE: II

IF APPLICABLE TO THE PATIENT POPULATION SERVED, TESTS FOR DEFINING OR MONITORING DISSEMINATED INTRAVASCULAR COAGULATION (DIC), SUCH AS FIBRINOGEN, FIBRIN(ogen) DEGRADATION PRODUCTS OR D-DIMER, AND PLATELET CONCENTRATION MUST BE AVAILABLE.

QUESTION: 02:3720 PHASE: II

Are PTs and aPTTs performed at 37 degrees Celsius?

COMMENTARY: 02:3720 PHASE: II

PTs AND APTTs MUST BE PERFORMED AT 37 DEGREES CELSIUS.

REFERENCE: National Committee for Clinical Laboratory Standards. One-stage prothrombin time (PT) test and activated partial thromboplastin time (aPTT) test; approved guideline H47-A. Wayne, PA: NCCLS, 1996.

Interinstrument Comparisons (all methods)

The laboratory may use fresh patient or donor specimens analyzed on a primary instrument for daily QC of a secondary instrument. The selection of these materials (rather than commercial controls) is important to directly address the issue of whether a patient sample yields the same results on all of the laboratory's instruments. If the laboratory has only one instrument for patient testing, this section does not apply.

QUESTION: 02:BAAS PHASE: II NEW

If the laboratory has more than one instrument (same or different makes/models) for performing coagulation assays, are they checked against each other at least twice a year for correlation of patient results?

INTERINSTRUMENT COMPARISONS (COAGULATION):

COMMENTARY: 02:BAAS PHASE: II

WHEN MORE THAN ONE COAGULATION INSTRUMENT IS USED TO GENERATE PATIENT-REPORTABLE RESULTS, IT IS IMPORTANT THAT THE LABORATORY
VERIFY COMPARABLE PERFORMANCE ACROSS INSTRUMENTS. CHECKS FOR CORRELATION OF PATIENT RESULTS MUST BE DONE AT LEAST TWICE A YEAR. THE SELECTION OF FRESH BLOOD/PLASMA SAMPLES (RATHER THAN COMMERCIAL CONTROLS) IS IMPORTANT TO DIRECTLY ADDRESS THE ISSUE OF WHETHER A PATIENT SAMPLE YIELDS THE SAME RESULTS ON ALL OF THE LABORATORY'S INSTRUMENTS. STATISTICAL AGREEMENT OF COMMERCIAL CONTROL MATERIALS ACROSS INSTRUMENTS DOES NOT GUARANTEE COMPARA-
RABILITY OF PATIENT SPECIMEN RESULTS.

REFERENCE: Department of Health and Human Services, Health Care Financing Administra-

QUESTION: 02:BAAU PHASE: I NEW

Are there precisely defined tolerance limits for results agreement of interinstrument assays?

COMMENTARY: 02:BAAU PHASE: I

THE LABORATORY SHOULD CLEARLY DEFINE NUMERIC RANGES OF AGREEMENT BETWEEN MULTIPLE CBC INSTRUMENTS USED BY THE LABORATORY. THESE RANGES MUST BE STATISTICALLY DEFINED, AND NOT SIMPLY QUALITATIVE.

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Photo-Optical Coagulation Systems

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QUESTION: 02:3725 PHASE: 0

Is a photo-optical coagulation instrument used for routine coagulation studies (e.g., PT, aPTT)?

(If "NO," mark next three questions "N/A" and continue with Electromechanical Coagulation Systems.)

QUESTION: 02:3730 PHASE: II

Is the automated system checked with 2 different levels of control material during each 8 hour period of patient testing, and each time there is a change in reagents?
PHOTO-OPTICAL COAGULATION SYSTEMS:

COMMENTARY: 02:3730 PHASE: II

THE AUTOMATED SYSTEM MUST BE CHECKED WITH TWO DIFFERENT LEVELS OF CONTROL MATERIAL DURING EACH 8 HOUR PERIOD OF PATIENT TESTING AND EACH TIME THERE IS A CHANGE IN REAGENTS.

QUESTION: 02:3735 PHASE: II

Are tolerance limits defined for each instrument, component or procedure in the system?

COMMENTARY: 02:3735 PHASE: II

TOLERANCE LIMITS MUST BE DEFINED FOR EACH INSTRUMENT, COMPONENT OR PROCEDURE IN THE SYSTEM.

QUESTION: 02:3740 PHASE: I

Are guidelines established for determining when alternative procedures should be performed (e.g., lipemia, hyperbilirubinemia, turbidity, etc.)?

COMMENTARY: 02:3740 PHASE: I

VERY LONG CLOTTING TIMES MAY NOT BE REPRODUCIBLE ON AN AUTOMATED COAGULATION INSTRUMENT. CRITERIA SHOULD BE ESTABLISHED BY EACH LABORATORY FOR PERFORMANCE OF THE PT OR APTT BY AN ALTERNATE TECHNIQUE (e.g., MANUAL METHOD) WHEN THE READABLE RANGE OF THE INSTRUMENT IS EXCEEDED. IN ADDITION, CRITERIA SHOULD BE PROVIDED FOR PERFORMANCE OF ALTERNATE PROCEDURES IN THE PRESENCE OF SIGNIFICANT HYPERBILIRUBINEMIA OR LIPEMIA, PARADOXICALLY SHORT APTTs AND NONDUPLICATING APTTs.

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Electromechanical Coagulation Systems

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QUESTION: 02:3745 PHASE: 0

Is an electromechanical system used for routine coagulation studies (e.g., PT, aPTT)?
(If "NO," mark next three questions "N/A" and continue with Manual Coagulation Systems.)

**QUESTION: 02:3750  PHASE: II**

Is the system checked with two different levels of control material during each 8 hour period of patient testing and each time there is a change in reagents?

**ELECTROMECHANICAL COAGULATIONS SYSTEMS:**

**COMMENTARY: 02:3750  PHASE: II**

THE ELECTROMECHANICAL COAGULATION SYSTEM MUST BE CHECKED AT LEAST EVERY SHIFT WITH APPROPRIATE CONTROLS.

**QUESTION: 02:3755  PHASE: II**

Are tolerance limits defined for each instrument, component or procedure in the system?

**COMMENTARY: 02:3755  PHASE: II**

TOLERANCE LIMITS MUST BE DEFINED FOR EACH INSTRUMENT, COMPONENT OR PROCEDURE IN THE ELECTROMECHANICAL COAGULATION SYSTEM.

**QUESTION: 02:3760  PHASE: II**

Are documented guidelines for cleaning the probes available?

**COMMENTARY: 02:3760  PHASE: II**

THE PROBES ON ELECTROMECHANICAL CLOT TIMERS CAN DEVELOP SIGNIFICANT PROTEIN BUILD-UP OVER A SHORT PERIOD OF TIME. SUCH PROTEIN BUILD-UP INTERFERES WITH SENSING OF CLOT FORMATION. ROUTINE CLEANING OF THE PROBES IS THEREFORE NECESSARY TO ENSURE ACCURATE COAGULATION TESTING.

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**Manual Coagulation Systems**

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**QUESTION: 02:3765  PHASE: 0**
Are routine coagulation studies (e.g., PT, aPTT) performed by manual, tilt-tube technique?

(If "NO," mark all questions under this Manual Coagulation Systems subsection "N/A" and continue with Coagulation Factor Assay.)

QUESTION: 02:3770  PHASE: II

Is the manual coagulation system checked by each individual with two different levels of control material in duplicate during each 8 hour period of patient testing, and each time there is a change of reagents?

MANUAL COAGULATION SYSTEMS:

COMMENTARY: 02:3770  PHASE: II

THE MANUAL COAGULATION SYSTEM MUST BE CHECKED BY EACH INDIVIDUAL WITH TWO DIFFERENT LEVELS OF CONTROL MATERIAL IN DUPLICATE DURING EACH 8 HOUR PERIOD OF PATIENT TESTING AND EACH TIME THERE IS A CHANGE OF REAGENTS.

QUESTION: 02:3775  PHASE: II

Are tolerance limits defined for each component or procedure in the system?

COMMENTARY: 02:3775  PHASE: II

TOLERANCE LIMITS MUST BE DEFINED FOR EACH COMPONENT OR PROCEDURE IN THE SYSTEM.

QUESTION: 02:3780  PHASE: II

Are determinations performed in duplicate?

COMMENTARY: 02:3780  PHASE: II

MANUAL CLOTTING ASSAYS MUST ALWAYS BE PERFORMED IN DUPLICATE TO VERIFY RESULTS.

QUESTION: 02:3785 PHASE: II

Are criteria for acceptable duplication of values available?

COMMENTARY: 02:3785 PHASE: II

THE DUPLICATES MUST AGREE WITHIN 10% OF THE SHORTER CLOTTING TIME. IF DUPLICATES DO NOT AGREE WITHIN THESE CRITERIA, THE TEST MUST BE REPEATED. THREE OF THE FOUR TIMES SHOULD THEN AGREE WITHIN 10% OF THE SHORTEST CLOTTING TIME OBSERVED.


QUESTION: 02:3790 PHASE: II

Is the temperature of the water bath or incubator verified with a certified thermometer or equivalent technique?

COMMENTARY: 02:3790 PHASE: II

COAGULATION ASSAYS MUST BE PERFORMED AT 37 DEGREES CELSIUS. STANDARD LABORATORY PRACTICE INCLUDES CONFIRMATION OF OPERATING TEMPERATURE USING STANDARDIZED THERMOMETERS.


Coagulation Factor Assays

QUESTION: 02:3792 PHASE: 0

Are factor assays performed?
QUESTION: 02:3794  PHASE: II

Are three or more points plotted for the standard curve?

COAGULATION FACTOR ASSAYS:

COMMENTARY: 02:3794  PHASE: II

AT LEAST THREE POINTS ARE NECESSARY TO ENSURE LINEARITY OF THE CURVE OVER THE RANGE TESTED. PLOTTING LESS THAN THREE POINTS MAY GENERATE AN ERRONEOUS LINE.


QUESTION: 02:3796  PHASE: I

Are the standard curves validated with at least two reference points each time a factor assay is determined?

COMMENTARY: 02:3796  PHASE: I

THE Y INTERCEPT OF THE STANDARD CURVE VARIES ACCORDING TO THE REAGENT AND ENVIRONMENTAL OR INSTRUMENT CONDITIONS. VALIDATING THE CURVE (e.g., TWO OR MORE POINTS WITH ASSAYED REFERENCE PLASMA) EACH TIME ENSURES ACCURACY OF THE RESULT.


QUESTION: 02:3798  PHASE: II

Are two or more points plotted for the patient's factor assay?

COMMENTARY: 02:3798  PHASE: II
PLOTTING AT LEAST TWO PATIENT POINTS DILUTIONS ENHANCES ACCURACY BY MINIMIZING DILUTOR ERROR, AND ALLOWS FOR DETECTION OF INHIBITORS OR ANTICOAGULANTS. TO BE VALID, ALL PATIENT POINTS MUST FALL WITHIN THE UPPER AND LOWER LIMITS OF THE STANDARD CURVE USED FOR THE CALCULATION OF THE RESULT.

REFERENCES:  
1) National Committee for Clinical Laboratory Standards. Determination of Factor VIII coagulant activity (VIII:C); proposed guideline H34-P. Wayne, PA: NCCLS, 1986;  
2) National Committee for Clinical Laboratory Standards. Determination of Factor IX coagulant activity (VIII:C); proposed guideline H40-P. Wayne, PA: NCCLS, 1986;  
3) National Committee for Clinical Laboratory Standards. Procedure for the determination of fibrinogen in plasma; tentative guideline H30-T. Wayne, PA: NCCLS, 1993;  

ABNORMAL HEMOGLOBIN DETECTION

Hemoglobin solubility testing alone is NOT sufficient for detecting or confirming the presence of sickling hemoglobins in all situations. For purposes of diagnosing hemoglobinopathies, additional tests are required.

QUESTION: 02:3800 PHASE: 0

Does the laboratory perform hemoglobin phenotyping by techniques such as alkaline and acid electrophoresis, isoelectric focusing, or high-performance liquid chromatography (HPLC)?

(If "NO," mark all questions in this subsection "N/A" and continue with PERSONNEL.)

NOTE: The inspector will examine an example of the medium (media) used to identify hemoglobin variants. These may include alkaline and/or acid electrophoresis, isoelectric focusing, high performance liquid chromatography, or other methods.

QUESTION: 02:3805 PHASE: II

Are controls containing at least three known major hemoglobins, including both a sickling and a non-sickling hemoglobin (e.g., A, F, and S) applied with the patient specimen(s) and are separations satisfactory?
ABNORMAL HEMOGLOBIN DETECTION:

COMMENTARY: 02:3805  PHASE: II

CONTROLS CONTAINING AT LEAST THREE KNOWN MAJOR HEMOGLOBINS INCLUDING BOTH A KNOWN POSITIVE (SICKLING) AND NEGATIVE (NON-SICKLING) HEMOGLOBIN (e.g., A, F, AND S) MUST BE APPLIED ON THE ELECTROPHORETIC OR CHROMATOGRAPHIC MEDIUM TOGETHER WITH THE PATIENT SPECIMEN(S). THE VARIOUS HEMOGLOBIN SPECIES MUST BE SATISFACTORILY SEPARATED.


QUESTION: 02:3810  PHASE: II
Are all samples with hemoglobin variants migrating in "non-A, non-S" positions on alkaline electrophoresis, isoelectric focusing, or HPLC further defined with electrophoresis at acid pH or other acceptable methods where clinically and technically appropriate?

COMMENTARY: 02:3810  PHASE: II

ELECTROPHORESIS AT ACID pH IS USEFUL TO FURTHER CHARACTERIZE HEMOGLOBIN VARIANTS MIGRATING IN THE Hb A2 POSITION, IF ALL VARIANTS ARE NOT CLEARLY SEPARATED BY THE PRIMARY METHOD. THIS METHOD WILL DIFFERENTIATE THE THREE MAJOR HEMOGLOBINS THAT MIGRATE IN THIS POSITION, NAMELY Hb C, Hb E, AND Hb O-ARAB, AS WELL AS GIVE INFORMATION ON RARE VARIANTS SUCH AS Hb C-HARLEM. HOWEVER, FOR HEMOGLOBIN VARIANTS THAT MIGRATE IN OTHER "NON-A, NON-S" POSITIONS, SUCH AS FAST HEMOGLOBIN VARIANTS, ELECTROPHORESIS AT ACID pH IS GENERALLY NOT INFORMATIVE. FURTHER WORKUP OF SUCH VARIANTS, INCLUDING REFERRAL TO A REFERENCE LABORATORY, IS DEPENDENT UPON THE PATIENT'S OVERALL CLINICAL SITUATION, SUCH AS FINDINGS OF ERYTHROCYTOSIS OR A HEMOLYTIC ANEMIA.


**QUESTION: 02:BAAV PHASE: II**

Are all samples that appear to have Hb S in the primary screening (by whatever method) further examined to confirm the presence of Hb S by solubility testing or other acceptable methods?

**NOTE:** Solubility testing alone is NOT sufficient for detecting or confirming the presence of sickling hemoglobins.

**COMMENTARY: 02:BAAV PHASE: II**

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 SERIES OF PATIENT SPECIMENS TESTED. SOLUBILITY TESTING ALONE IS NOT SUFFICIENT FOR DETECTING OR CONFIRMING THE PRESENCE OF SICKLING HEMOGLOBINS.

**QUESTION: 02:3812 PHASE: II**

Are 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 further examined to ascertain whether the "Hb S" band or peak contains solely Hb S or both Hb S and Hb D or Hb G?

**COMMENTARY: 02:3812 PHASE: II**

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/B-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.

QUESTION: 02:3815 PHASE: II

Does the method protocol include adequate controls, normal ranges, and proper reporting procedures?

COMMENTARY: 02:3815 PHASE: II

THE METHOD PROTOCOL MUST INCLUDE ADEQUATE CONTROLS, NORMAL RANGES, AND PROPER REPORTING PROCEDURES.


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PERSONNEL

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QUESTION: 02:4000  PHASE: II

Does the person in charge of hematology have education and experience equivalent to an MT (ASCP) and at least four years experience (one of which is in clinical hematology) under a qualified director?

PERSONNEL:

COMMENTARY: 02:4000  PHASE: II

THE TECHNOLOGIST IN CHARGE OF THE HEMATOLOGY SECTION MUST HAVE EDUCATION AND EXPERIENCE EQUIVALENT TO THAT OF AN MT(ASCP) AND AT LEAST FOUR YEARS EXPERIENCE IN A CLINICAL LABORATORY (ONE OF WHICH IS IN HEMATOLOGY) UNDER A QUALIFIED DIRECTOR.

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PHYSICAL FACILITIES

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Sufficient space and utilities need to be provided for the workload of the department, and to meet all safety requirements.

QUESTION: 02:5000  PHASE: I

Is there adequate space for administrative functions?

PHYSICAL FACILITIES:

COMMENTARY: 02:5000  PHASE: I

ADDITIONAL SPACE SHOULD BE PROVIDED FOR ADMINISTRATIVE FUNCTIONS.

QUESTION: 02:5005  PHASE: I

Is there adequate space for clerical work?

COMMENTARY: 02:5005  PHASE: I

ADDITIONAL SPACE SHOULD BE PROVIDED FOR CLERICAL WORK.
QUESTION: 02:5010  PHASE: I

Is there adequate space for technical work (bench space)?

COMMENTARY: 02:5010  PHASE: I

ADDITIONAL SPACE SHOULD BE PROVIDED FOR TECHNICAL WORK (BENCH).

QUESTION: 02:5015  PHASE: I

Is there adequate space for instruments?

COMMENTARY: 02:5015  PHASE: I

ADDITIONAL SPACE SHOULD BE PROVIDED FOR INSTRUMENTS.

QUESTION: 02:5020  PHASE: I

Is there adequate space for shelf storage?

COMMENTARY: 02:5020  PHASE: I

ADDITIONAL SPACE SHOULD BE PROVIDED FOR SHELF STORAGE FOR REAGENTS AND SUPPLIES.

QUESTION: 02:5025  PHASE: I

Is there adequate space for refrigerated/freezer storage?

COMMENTARY: 02:5025  PHASE: I

ADDITIONAL SPACE SHOULD BE PROVIDED FOR REFRIGERATED/FREEZER STORAGE.

QUESTION: 02:5030  PHASE: I

Is the space available efficiently utilized?

COMMENTARY: 02:5030  PHASE: I

EXISTING SPACE SHOULD BE USED MORE EFFICIENTLY.

REFERENCE: College of American Pathologists. Medical laboratory planning and design.
QUESTION: 02:5035  PHASE: II

Is the space available so there is no compromise of the quality of work, safety of personnel, or limitation of quality control activities?

COMMENTARY: 02:5035  PHASE: II

THE INSPECTOR FELT THAT EXISTING SPACE LIMITATIONS WERE SO SEVERE AS TO INTERFERE WITH THE QUALITY OF WORK, THE SAFETY OF PERSONNEL, AND/OR THE ABILITY OF PERSONNEL TO CARRY OUT ADEQUATE QUALITY CONTROL PROCEDURES WITH APPROPRIATE DOCUMENTATION.


QUESTION: 02:5040  PHASE: I

Are floors and benches clean, free of clutter and well-maintained?

COMMENTARY: 02:5040  PHASE: I

THE MAINTENANCE OF FLOORS AND BENCHES MUST BE IMPROVED.

QUESTION: 02:5045  PHASE: I

Are water taps, sinks and drains adequate?

COMMENTARY: 02:5045  PHASE: I

WATER TAPS, SINKS AND DRAINS SHOULD BE IMPROVED TO SUPPORT THE TYPES OF PROCEDURES AND WORKLOAD OF THE LABORATORY.

QUESTION: 02:5050  PHASE: I

Are electrical outlets adequate?

COMMENTARY: 02:5050  PHASE: I

ELECTRICAL OUTLETS SHOULD BE IMPROVED TO SUPPORT THE TYPES OF PROCEDURES AND WORKLOAD OF THE LABORATORY.
QUESTION: 02:5055  PHASE: I

Is emergency power adequate?

COMMENTARY: 02:5055  PHASE: I

EMERGENCY POWER SHOULD BE IMPROVED TO SUPPORT THE TYPES OF PROCEDURES AND WORKLOAD OF THE LABORATORY.

QUESTION: 02:5060  PHASE: I

Is lighting adequate?

NOTE: A minimum average illumination of 40-foot candles measured at 30 inches above the floor should be maintained in any area where printed material must be read by employees in the customary performance of their normal function. Direct sunlight should be avoided because of its extreme variability and the need for low light levels necessary to observe various computer console lights, etc. Lighting control should be sectionalized so general levels of illumination can be controlled in areas of the room if desired.

COMMENTARY: 02:5060  PHASE: I

LIGHTING SHOULD BE IMPROVED. A MINIMUM AVERAGE ILLUMINATION OF 40-FOOT CANDLES MEASURED AT 30 INCHES ABOVE THE FLOOR SHOULD BE MAINTAINED IN ANY AREA WHERE PRINTED MATERIAL MUST BE READ BY EMPLOYEES IN THE CUSTOMARY PERFORMANCE OF THEIR NORMAL FUNCTION. DIRECT SUNLIGHT SHOULD BE AVOIDED BECAUSE OF ITS EXTREME VARIABILITY AND THE NEED FOR LOW LIGHT LEVELS NECESSARY TO OBSERVE VARIOUS COMPUTER CONSOLE LIGHTS, ETC. LIGHTING CONTROL SHOULD BE SECTIONALIZED SO GENERAL LEVELS OF ILLUMINATION CAN BE CONTROLLED IN AREAS OF THE ROOM IF DESIRED.


QUESTION: 02:5065  PHASE: I

Is ventilation adequate?

COMMENTARY: 02:5065  PHASE: I

VENTILATION SHOULD BE IMPROVED TO SUPPORT THE TYPES OF PROCEDURES
AND WORKLOAD OF THE LABORATORY.

QUESTION: 02:5070  PHASE: I

Is temperature control adequate?

COMMENTARY: 02:5070  PHASE: I

TEMPERATURE CONTROL SHOULD BE IMPROVED TO SUPPORT THE TYPES OF PROCEDURES AND WORKLOAD OF THE LABORATORY.

QUESTION: 02:5080  PHASE: I

Are telephones conveniently located and are calls easily transferred?

COMMENTARY: 02:5080  PHASE: I

TELEPHONES - NUMBER AND/OR LOCATION SHOULD BE IMPROVED TO SUPPORT THE TYPES OF PROCEDURES AND WORKLOAD OF THE LABORATORY.

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LABORATORY SAFETY

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NOTE TO THE INSPECTOR: Please review ALL safety questions in the Laboratory General checklist. These questions have been omitted from this checklist to avoid repetition. Deficiencies should be marked in the Laboratory General checklist. Please elaborate upon the location and the details of each deficiency in the Summation Report.

QUESTION: 02:6000  PHASE: I

Is the hematology laboratory in compliance with all safety requirements as identified in the Laboratory General checklist?

LABORATORY SAFETY:

COMMENTARY: 02:6000  PHASE: I

ONE OR MORE SAFETY DEFICIENCIES FOR THE HEMATOLOGY CHECKLIST ARE ITEMIZED IN THE LABORATORY GENERAL CHECKLIST.