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Coagulation Departmental Quality Control Programs-RO

Document Type: Procedure

I. PURPOSE AND OBJECTIVES:

A. The assurance of quality in both the performing and the reporting of all laboratory tests and procedures are fundamental in providing appropriate patient care. The Departmental Quality Control Program has been developed to meet this objective.

B. Quality Control (QC) programs ensure that the information generated Directives by the laboratory is accurate, reliable, and reproducible. This is accomplished by assessing the quality of the specimens; monitoring the performance of test procedures, reagents, media, instrumentation and personnel reviewing test results; and documenting the validity of the test method.

C. Quality control in the laboratory is the systematic assessment of the laboratory work being performed to ensure that the final product has an acceptable degree of conformity within previously established tolerance limits. It is essential to ensure accuracy, reliability, and reproducibility of performance of tests. In this way, it benefits the patients directly and increases the physician confidence in the lab results.

II. SPECIFIC OBJECTIVES:

A. Establish and document minimum performance criteria (tolerance limits) for each laboratory test or procedure.

B. Ensure that established minimum performance criteria meet clinical needs and conform to or exceed local and national standards.

C. Monitor and document performance of all procedures by the use of proper control and survey material to ensure constant compliance with previously established tolerance limits.

D. Identify situations in which tolerance limits are being exceeded and initiate and document the following actions:

1. Immediately suspend reporting of relevant patient data.
2. Investigate and document procedural problems. Resolve problems and document corrective action.
3. Following corrective action, establish and document that the procedure is now within tolerance limits; rerun and report patient data.

4. If the problem is systematic, institute appropriate procedural modifications or in-service training of personnel.

E. Maintain adequate records and documentation to show active and complete compliance with the objectives of the program, to include evidence of periodic review at all levels of administration within the section.

III. PRINCIPLE:

A. "In accordance with CAP accreditation requirements as noted during our recent biennial inspection, we have formulated the attached written description of the Clinical Pathology Department Quality Control Program. It is written in a format that may be applied to any section of the Laboratory. Please read it carefully to ensure that your section is in compliance with the policies specific and that you have the appropriate documentation. A copy of this Departmental Quality Control Program must be inserted into every procedure manual in all sections. All personnel should be made aware of the nature of the program, its description, and its location in their respective work." Memo dated 10/31/1983

B. The Director of Clinical Pathology has overall responsibility for the implementation and administration of the Quality Assurance Program. This responsibility is delegated to the Chief of each laboratory section, who may further delegate components of the program to Supervisors and Technologists.

C. Each Section Chief is responsible for implementing the objectives of the program in his own laboratory area in a way, which is appropriate for the nature of laboratory work performed in that area. The following components of the program must, therefore, be addressed individually by each area, and should be reflected in procedure manuals, maintenance manuals, in-service and new employee education:

1. Establish and document tolerance limits or minimum performance criteria for each test or procedure.
2. Document methodology within each procedure to assure that tolerance limits are not being exceeded, e.g., number, nature and level of controls, positive and negative controls.
3. Within each procedural description, document methodology for systematic trouble-shooting in the event tolerance limits are exceeded, to include a precise method for recording and reviewing corrective action.
4. Document periodic review of Quality Assurance Charts and Corrective Action Reports, in addition to sources and levels of control materials.
5. Participate in appropriate proficiency surveys, with accompanying documentation to indicate review of survey results, documentation of "unacceptable results", educational exercises and review of comparative results from other laboratories using similar and alternate methods.
6. Maintain records of review for an appropriate time period but not less than two years.
7. Maintain procedures manuals, instruments, systems and safety policies within CAP accreditation and applicable local standards with timely correction of any identified deficiency.
8. Provide for continuing education of all personnel and new employees to ensure compliance with all quality assurance policies.
9. Integrate information and studies provided by the Departmental Quality Assurance Committee into active revision and modification of procedures.

IV. ACRONYMS:

A. Activated Partial Thromboplastin Time (aPTT)

B. Coefficient of variation (CV)
C. Collage of American Pathologist (CAP)
D. Factor IX Activity (FIX)
E. Factor VIII Activity (FVIII)
F. Instrumentaion Laboratory (IL)
G. Low Molecular Weight Heparin (LMWH)
H. North American Specialized Coagulation Association (NACOLA)
I. Prothrombin Time (PT)
J. Quality Control (QC)
K. Standard Deviation (SD)
L. Thrombin Time (TT)
M. Unfractionated Weight Heparin (UNFH)
N. Von Willebrand Activity (VWF ACT)
O. Von Willebrand Antigen (VWFAG)

V. PROCEDURE:

A. **Implementation and Responsibility:**

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    b. Document methodology within each procedure to assure that tolerance limits are not being exceeded, e.g., number, nature and level of controls, positive and negative controls.
    c. Within each procedural description, document methodology for systematic trouble-shooting in the event tolerance limits are exceeded, to include a precise method for recording and reviewing corrective action.
    d. Document periodic review of Quality Assurance Charts and Corrective Action Reports, in addition to sources and levels of control materials.
    e. Participate in appropriate proficiency surveys, with accompanying documentation to indicate review of survey results, documentation of "unacceptable results", educational exercises and review of comparative results from other laboratories using similar and alternate methods.
    f. Maintain records of review for an appropriate time period but not less than two years.
    g. Maintain procedures manuals, instruments, systems and safety policies within CAP

accreditation and applicable local standards with timely correction of any identified deficiency. Provide for continuing education of all personnel and new employees to ensure compliance with all quality assurance policies.

h. Integrate information and studies provided by the Departmental Quality Assurance Committee into active revision and modification of procedures.

B. **Quality Control Parameters:**

1. **Specimen Collection and Transport:**
   a. Provides procedures for patient identification, specimen collection and transport.
   b. Establishes criteria for acceptable specimens.
   c. Provides rejection criteria for unacceptable specimens.
   d. Specific information is provided in the Coagulation tests: Specimen collection and handling procedure.
2. **Procedure Manual:**
   a. Review and approve in policy management system.
   b. Make available in work areas.
   c. Retain obsolete procedures for 2 years and Include retirement date.
   d. Procedures are reviewed and re-approved if there is a change in directorship.
3. **Personnel:**
   a. Document continuing education activities.
   b. Provide employees with written performance standards.
   c. Evaluate employees annually.
   d. Document competency assessments.
   e. Document participation in proficiency testing programs.
4. **QC Records:**
   a. Record all QC results on appropriate QC forms.
   b. Document all out-of-control results and report to hematology management.
   c. Monthly review of QC records by hematology management and Medical Director to detect unusual errors or trends (i.e. CV, SD variation). Investigate variations.
   d. Retain QC records for at least 2 years.
   e. Record all lot numbers and expiration dates of materials received and retain them for 2 years.
5. **Patient Reports:**
   a. Report only to authorize personnel.
   b. Notify test requester of "Critical Values" immediately.
   c. Provide normal ranges where appropriate.
   d. Mark abnormal results where appropriate.
   e. Correct errors in patient reports in a timely fashion. Notify test requester and/or appropriate house staff of corrected value.

f. Retain records for at least 2 years in an easily accessible location.

6. **Referral Specimens:**
    a. Use only accredited or licensed reference laboratories
7. **Proficiency Testing:**
    a. Participate in an external proficiency testing program (CAP, NASCOLA) at the appropriate level.
    b. Participate in an internal competency testing program.
    c. Integrate samples within the routine laboratory workload and analyze by personnel who routinely test patient samples, using the same methods as for patient samples.
    d. Survey review is by hematology management and director.
    e. Document evaluation and corrective action, if indicated, in response to "unacceptable" results. Evaluate “lack of consensus” challenges.
    f. Provide feedback to the tech who officially reported the CAP survey (or equivalent).
8. **Instrument / Equipment Performance:**
    a. Document function checks of equipment.
    b. Document routine preventative maintenance.
    c. Document required temperatures (e.g. refrigerators, freezers, water baths).
    d. See specific instrument / equipment procedures for detailed QC information.
9. **Critical Value List:**
    a. Define testing procedures whose critical limits have been established by the Hematopathology / Coagulation Division as being considered "Stat" for prompt patient management decisions.
    b. Define level of abnormality for each procedure that is considered a critical value.
    c. Define procedures for notification of physicians and/or appropriate hospital staff of critical values. REFERENCES:
10. **Materials (Reagents, Supplies, Etc.)**
    a. Label containers to include the following:
        i. Contents.
        ii. Concentration.
        iii. Date prepared/ validated
        iv. Validation tech.
        v. Lot Number.
        vi. Date received.
        vii. Date placed into service.
        viii. Hazard designation.
        ix. Storage temp.
        x. Expiration date (note open-vial stability dates). Use “O” for opened date and “E” for expiration date.

11. **Commercially Prepared Reagents:**
    a. Retain copy of manufacturer's assurance standards that their production follows CLSI guidelines.
    b. Commercial Kits:
        i. Test each new lot number upon arrival.
        ii. Validate kit with appropriate QC prior to reporting patient results. When in service, use the positive and negative controls included in the kit.
        iii. Document QC on appropriate forms and place sticker on box indicating it is ready for use.
        iv. Document any problems and notify hematology management.
        v. Do not interchange reagents between different lot numbered kits.
        vi. Discard outdated materials.
        vii. Do not report patient results until problems with QC are resolved.

C. **EXCEPTION:** Analyzers which automatically track expiration dates when reagent is loaded onto analyzer.
    1. Store materials under appropriate conditions (temperature, light exposure, etc).
    2. Perform QC and document on appropriate forms for non-IL reagent.
        a. Reagents lot number and expiration date.
        b. When in use.
        c. Control lot number, normal ranges
        d. Report any problems to hematology management.
        e. Discard outdated materials.
        f. Establish performance standard

D. **Coagulation Quality control Program**
    1. Commercial Controls
        a. INSTRUMENTS TESTED: IL ACL-TOP 750 LAS; IL ACL-TOP 700 CTS; IL ACL-TOP 550 CTS.
        b. MATERIALS: refer to IL ACL TOP Operation procedure Attachment A
        c. FREQUENCY: HemosIL normal control 1, abnormal control 3, low abnormal fibrinogen, and Dimer HS 500 controls run every 8 hours on each instrument used.
        d. CONTROL (TOLERANCE) LIMITS: See Attachment A.
        e. ACTION IF RESULT EXCEEDS CONTROL LIMITS:
            i. Rerun control.
            ii. If value is within control limits, accept values.
            iii. If value is outside of control limits, ensure that the instrument is taken out of service until QC is acceptable.Perform maintenance and troubleshooting as required and rerun control. Re-calibrate if applicable.
            iv. If instrument is taken out of service, note the time when the QC was last run and acceptable.

v. Retrieve three specimens and printouts that were run on the same analyzer. **Do not use specimens which contain heparin or direct thrombin inhibitors.**

vi. One specimen must be shortly after the last QC on that test was found to be acceptable.

vii. One specimen must be midway between the two acceptable QC values.

viii. One specimen must be right before the QC was found to be unacceptable.

ix. Refer to the correlation tolerance limits to see if the repeat test results are acceptable.

x. If the repeat test results are not acceptable contact the instrument vendors' customer service and correct the patients' results.

2. Instrument to instrument Correlation Controls (Patient Plasma)

a. Instrument Correlation

IL ACL TOP 1	IL ACL TOP 2
IL ACL TOP 1	IL ACL TOP 3
IL ACL TOP 1	IL ACL TOP 4

b. Select 5 patient samples. These samples will be used as correlation controls between instruments.

c. FREQUENCY: Correlations are performed twice a year.

d. RECORDING DATA: Record differences between instruments for each of the following parameters: PT, APTT, D-Dimer, Fibrinogen (except IL ACL TOP 550 TOP 4), and TT (except IL ACL TOP 550 TOP 4).

e. Verify that the results are within the tolerance limits for the IL ACL-TOP's for the the following parameters:

Assays	Tolerance Limits
PT (N)	± 0.5 sec
PT (ABN)	± 2.7 sec
INR (N)	± 0.2
INR (ABN)	± 0.4
PTT (N)	± 3.5 sec
PTT (ABN)	± 6.5 sec
Fibrinogen (<400)	± 30 mg/dL
Fibrinogen (300-400)	± 45 mg/dL
Fibrinogen (>400)	± 60 mg/dL
DDimer HS 500 (<500)	±100 ng/mL FEU
DDimer HS 500 (500-1000)	±150 ng/mL FEU
DDimer HS 500 (>1000)	±250 ng/mL FEU
TT (N)	± 3.5 sec
TT(ABN)	± 15 sec

f. Verify that the results are within the tolerance limits for the following parameters for the IL ACL

TOP 1 and 3

Assays	Tolerance Limits
FVIII	20%
FIX	20%
UNFH	20%
LMWH	20%
VWFACT	20%
VWFAG	20%

3. Tolerance limits for each of the parameters were determined according to criteria established by manufacturer recommendations. (See Attachment A.)
4. ACTION TAKEN IF RESULTS EXCEED TOLERANCE LIMITS: No action unless one parameter has exceeded the limits two or more times.
5. IF ANY ONE PARAMETER HAS EXCEEDED THE LIMITS two or more times, a corrective action form must be filled out explaining why they were out and what corrective measures were taken.

E. **IL AccuTrak Data Entry QC PROGRAM**

1. Monthly QC data is due by the 10th of the month, QC data is printed from the instruments. The mean, SD and number of points are submitted electronically to IL AccuTrack. IL then compares us to other laboratories using the same instrumentation and lot number of controls. This report is sent back to us, reviewed by the hematology management and section chief, and becomes a permanent record of QC data.

F. **Proficiency Testing**

1. Throughout the year, we receive proficiency testing surveys (i.e. CAP or equivalent) containing unknown samples. The specimens are run on our instruments and the data is submitted to the proficiency survey organization.
2. The proficiency survey organization compiles the data and compares us to all other laboratories that are using the same instrumentation. Means, SDs and CVs are also shown for all other instrumentation data submitted. This report is sent back to us, reviewed by hematology management and medical director, and becomes a permanent record of QC data.
3. Any values outside of acceptable range that we reported must be accounted for in a written response. Feedback is given to the techs who participated in the survey. Unacceptable results are also reviewed with the employee who participated in the survey. Unacceptable results that were not graded (due to lack of consensus, results submitted after the cut-off date, no submission of results or no submission of an appropriate method code) are still assessed for good performance and followed up on accordingly. (This does not apply to those surveys which were pre-determined to be ungraded or educational samples.)

VI. REFERENCES:

A. Bull, B.S. and Korpman, R. "Interlaboratory Quality Control Using Patients' Data", Cavill, I.: Quality Control, Churchill Livingston, 1982.

B. ACL TOP Family Series Operator's Manual 2015

C. Isenberg, H. Clinical Microbiology Procedures Handbook. 1992. ASM Washington D.C.

D. HemosIL Normal Control 1 package insert, September 2016

E. HemosIL Abnormal Control 3 package insert, September 2016

F. HemosIL Low Fibrinogen Control package insert, June 2017

G. HemosIL D-Dimer HS 500 Control package insert, February 2017

H. Weisbrot, Irwin M.: "Details of Quality Control in Hematology", Barnett RM: Clinical Laboratory Statistics, Second Edition. Little, Brown and Company; Boston: 1979, pp 101-105.

I. Laboratory Quality Policy

J. Royal Oak Laboratory Individualized Quality Control Plan (IQCP)

Attachments

ATTACHMENT A

Approval Signatures

Step Description	Approver	Date
CP Chief Medical Director	Peter Millward: Chief, Pathology Service Line	5/1/2021
Coagulation Medical Director Designee	Marc Smith: System Med Dir, Coagulation	4/30/2021
Policy and Forms Steering Committee Approval (if needed)	Tamara Sabih: Medical Technologist Lead	4/22/2021
Policy and Forms Steering Committee Approval (if needed)	Gail Juleff: Project Mgr Policy	4/22/2021
System Manager	Rebecca Bacarella: Mgr Laboratory	4/22/2021
	Tamara Sabih: Medical Technologist Lead	4/22/2021

Applicability

Royal Oak