Beaumont

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Key Words:	
Applicability:	*Royal Oak*

Coagulation General Directives-RO

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

A. This document guides employee in multiple sections of coagulation laboratory e.g. specimen collection, specimen handling, quality control, calibration, proficiency testing, and reagents.

B. The hematology and coagulation medical technologist leads may be designated to approve/ sign off on various hematology/coagulation maintenance logs/ quality controls as deemed appropriate by the supervisor.

II. ACRONYMS:

A. Activated Partial Thromboplastin Time (aPTT)

B. Activated Protein C resistance (APCR)

C. Anticoagulation Management Service (AMS)

D. Antithrombin (AT3)

E. College of American Pathologist (CAP)

F. Clinical Laboratory Improvement Amendments (CLIA)

G. Clinical and Laboratory Standards Institute (CLSI)

H. Diluted Russell's Viper Venom Time Confirm (DRVVT C)

I. Diluted Russell's Viper Venom Time Screen (DRVVT S)

J. Extracorporeal membrane oxygenation (ECMO)

K. Fibrin Split Product (FSP)

L. Lab Test Directory (LTD)

M. Laboratory Information System (LIS)

N. Low Molecular Weight Heparin (LMWH)

O. National Institute of Standards and Technology (NIST)

P. North American Specialized Coagulation Laboratory Association (NASCOLA)

Q. Platelet Function Analysis (PFA)

R. Protein C (PC)

S. Protein S (PS)

T. Prothrombin Time (PT)

U. Quality Control (QC)

V. Quality Not Sufficient (QNS)

W. Standard of Practice (SOP)

X. Thrombin Time (TT)

Y. Unfractionated Weight Heparin (UNFH)

Z. Von Willebrand Activity (VWF ACT)

AA. Von Willebrand Antigen (VWFAG)

III. PROCEDURE:

A. **Specimen Collection:**

1. Specimen collection, specimen preservation, transportation and storage before testing for each test are listed in the Coagulation Specimen Collection and Handling (Non-Platelet Function Tests Only) procedure. Special procedures that require special handling are indicated in the individual procedure or LTD.

B. **Vacutainer Technique:**

1. A good venipuncture is essential for a suitable coagulation specimen.
    a. For the appropriate order of draw when collecting multiple specimens refer to the specimen collection guidelines located on Beaumont Health > Document> Policies> Beaumont Health System> Phlebotomy . A minimal volume discard tube must be drawn prior to the blue top for special coagulation studies. This minimizes contamination of specimen by tissue thromboplastin. The discard tube is not required for PT, aPTT, Fibrinogen, TT, FSP, and D- Dimers.
    b. Tubes should be well mixed after collection to verify mixing of blood and anticoagulant.
    c. Tubes must be full.

C. **Specimen Handling:**

1. Refer to the Specimen Collection and Handling (Non – Platelet Function Tests Only) procedure.
2. Based on an in-house study, the centrifugation temperature has been changed from 6°C to room temperature (20° to 25°C). This change complies with the CLSI H21-A5 standard.

    NOTE: All specimens must be visually inspected for hemolysis, high HCT and inadequate filling of the 3.2% sodium citrated tube after centrifugation and before loading onto any coagulation instrument.

D. **Unsuitable Specimens:**

1. Clotted or QNS specimens are not suitable for coagulation studies. These specimens are kept in a designated rack for a week before being discarded. In addition, any sodium citrate specimens suspected of being clotted, (e.g., hemolyzed, abnormally short clotting times, severely depressed or absent fibrinogen, etc.), must be checked for clots with applicator sticks
2. Hemolysis is rated by the posted Specimen Integrity Chart. However, all hemolyzed specimens must still be checked for a clot, regardless of hemolysis index.
3. If no clot is detected during coagulation testing, perform a fibrinogen test. If the fibrinogen result is <35 mg/dL suspect the sample is actually serum. Contact the nursing unit and ask if they were expecting abnormal results before canceling any tests.
4. Red blood cells contain a thromboplastic substance (erythrocytin) which shortens the aPTT. The protime is not affected since tissue thromboplastin is added in the reagent. Any hemolysis should be noted in report. The presence of hemolysis also suggests traumatic venipuncture which may also indicate specimen is unsuitable for testing. Based on in house study, hemolysis <200 is acceptable for testing. See sample integrity chart posted in the laboratory for reference.
5. Lipemic and icteric plasmas are noted on the report.

    NOTE: If a PT-AMS specimen needs to be redrawn, add a follow up to the patient chart, so the Outreach Customer Service will notify the Anticoagulant Management Service.

E. **Specimen Identification:**

1. All specimens are barcode labeled with the patient's first and last name, middle initial, birth date, hospital number, room number, date, wrist band "B" number, phlebotomist number, test(s) ordered and time of collection. Refer to the Specimen Collection Manual for further information.
2. In addition, good laboratory practice dictates that all secondary specimens (e.g. aliquot tubes, dilution tubes, etc.) be properly labeled as to patient identity.

F. **Special Requirements for Specimen Preparation:** Elevated hematocrits may be noticed when examining the specimen. If there appears to be an elevated hematocrit, a chart review should be performed to see if a hematocrit has been ordered. Patients with a hematocrit greater than 55% must be drawn according to instructions below:

1. **Anticoagulant Adjustment of Blood**
    a. Remove 0.1 mL of the NA citrate from the 3.2% NA Citrate tube using a tuberculin syringe so that the vacuum will not be "diminished".
    b. Write on NA citrate tube, "sodium citrate has been adjusted for high Hct". Highlight this statement on the tube.
    c. Phlebotomist/Nurse will add 2.7 mL whole blood to the indicated reduced amount of sodium citrate.
    d. Add the following comment, "Sodium citrate adjusted in 3.2% sodium citrate tube because patient has a high Hematocrit".

G. **Universal precautions:**

1. All specimens are handled according to the Universal Precautions and Infection Control policies stated in the Clinical Pathology Safety Manual. Specifically that means:
    a. Disposable gloves and impervious gowns are to be worn for all specimen-related procedures (e.g. venipuncture, specimen analysis). Technologists who have allergies to gloves are directed to Employee Health Services who will determine if the employee needs an alternate glove type. In addition, an appropriate splash shield (which may be worn or fixed in position at the bench) must be used when handling an open blood. Face shields should also be engaged while working with reagents, including pipetting of reagents).
    b. Hands are to be washed after handling specimens or removing gloves. Hands should be washed upon leaving the lab.
    c. Specimen bags must be disposed of with biohazard materials. Specimen bags must be placed in red biohazard bagged containers with "Biohazard Bags" green label.
    d. Specimens are to be discarded into double-thickness red biohazard bagged containers with "Biohazard" yellow label for autoclaving prior to disposal.
    e. *Grossly* contaminated paper, gauze and disposable plastic transfer pipettes are to be discarded into red biohazard bagged containers with "Biohazard" yellow label. Slightly contaminated items may be disposed of in the regular trash.
    f. Specimen contaminated glass, needles, wood sticks and items with sharp or pointed edges are to be discarded into red Sharp safe Biohazard Waste containers.
    g. Serological pipettes (plastic) are to be disposed of in red bins with snap-close lids with "Serological Pipette" pink label, due to the ability to puncture red biohazard and trash bags. Serological pipettes will be disposed of with regular biohazard materials.
    h. Decontaminate laboratory bench work surfaces with a hospital/ laboratory approved disinfectant before beginning work, after a spill of blood and when work activities are complete. Verify that manufacturer's instructions for contact time {10 minutes for Encompass (30 mL/ 1 gallon H_2O) or 1:10 bleach solution} are followed as well as allowance to air-dry. Cleaning is documented on the appropriate Maintenance Log.
    i. A specimen visibly contaminated with blood or other body fluid should be cleaned with appropriate disinfectant before sending it for further testing.
2. **Potential Creutzfeldt-Jakob Disease (CJD):** Follow guidelines as stated in Clinical Pathology Specimen Handling and Precautions for Potential CJD Specimens. Note that masks and protective eyewear MUST be worn. Specimens

must be handled in a laminar flow class II or higher biological safety cabinet or behind a protective splash shield when specimen containers are opened. Because CSF specimens from CJD patients are considered low risk for transmission of CJD, instruments should be cleaned and disinfected by conventional protocols. Clean environmental surfaces with a hospital/ laboratory approved disinfectant. Specimens may be discarded by conventional methods.

H. **Test Status:** The LIS lets the requester know the status of the test at all times (e.g., ordered, collected, received, pending). Results must be verified for calls to route to the Customer Service call queue.

1. **Delay in Testing:** If a significant delay in testing has occurred notify the Coagulation Medical Technologist Lead. If the Medical Technologist Lead is unavailable notify the Hematology Supervisor. If both are not available notify the Medical Laboratory Director.
    a. Notify the Outreach Operations Manager.
    b. Notify the Stat Lab that the stat specimens will be routed to the stat lab for testing.
    c. Notify the Processing Supervisor. If the supervisor is unavailable notify the processors.
    d. See the Disaster Laboratory calling list for the phone numbers located on the Hematology and Coagulation bulletin boards.

I. **Centrifuges:** All specimens must be capped prior to centrifugation to eliminate generation of infectious aerosols. Hazardous aerosols may be produced by many solutions (organic solvents, carcinogens, radionuclides, etc.). In case of breakage of glassware during the centrifuge run, turn the centrifuge power off. When the centrifuge rotor has stopped, clean the spill according to the procedure cited in "Clinical Pathology Laboratory Procedures for Spill Clean Up." The hospital maintenance department performs safety and electrical checks on the centrifuges twice a year. If a procedure requires a specific gravitational force (G-force), the centrifuge must be recalibrate by a Jaquet Speed indicator or Standco Tachometer. The hospital maintenance department also performs quarterly RPM checks on the centrifuges.

J. **Calibration:**

1. Calibration is performed if:
    a. There has been a change in reagent lots.
    b. Major maintenance or service is performed.
    c. QC fails to meet established criteria and when recommended by the manufacturer.
2. Calibration is verified by using reference materials with matrix characteristics and target values appropriated for the method. All coagulation tests that require a calibration must be calibrated every 6 months or as needed.

K. **Analytic Measurement Range (AMR):** It is the range of analyte values for which a linear relationship has been established. For several assays in the coagulation laboratory at Royal Oak, the following rules apply:

1. **Q.F.A., Dimer HS 500 and Anti Xa:**
    a. AMR verification is accomplished through the calibration process. It includes calibrators that span the full range of the AMR, including low, midpoint, and high values. Calibration is performed at least every 6 months or with each new lot.
2. **Von Willebrand antigen and von Willebrand activity:**
    a. AMR verification is accomplished by an on-board dilution threshold. For any sample greater than 120%, the acceptable highest range of the linearity based on the calibration, undergoes an on-board dilution whose final value will fall within the full range of the AMR. Calibration is performed at least every 6 months or with each new lot.
3. **Antithrombin activity, Plasminogen, and Plasmin Inhibitor**:
    a. AMR verification for the highest point of calibration is performed on a sample that is +/-10% of the highest point. This sample may be obtained from a patient sample, or hyper concentrated calibrator, or quality control, and will be serial diluted to test the full range of the AMR. Acceptable values will fall within +/-10% of the target value. Calibration is performed at least every 6 months or with each new lot.

L. **Temperatures:**

1. An appropriate thermometric standard device of known accuracy (guaranteed by manufacturer to meet NIST

Standards or traceable to NIST Standards) is available from the Chemistry department. This thermometer is used to check all non-certified thermometers in use before initial use and annually. Verification records are kept. Thermometers failing to fall within acceptable limits are removed from service.

2. Temperatures are taken daily. If temperature exceeds established limits, all refrigerator/ freezer contents are moved to an alternate cooling system that is known to be in control.

Temperature Range	°C	°F
Room Temperature	20-25^{o}C	68-77^{o} F
Refrigerated Temperature	2-8^{o}C	36-46^{o} F
Frozen Temperature	- 20^{o}C or colder	- 4^{o}F or colder

M. **Specimen Tracking:** Tracking provides a more accurate time line for specimen processing. Specimens are tracked throughout the lab, from receipt through resulting. Coag specimens must be tracked:

1. When referring samples to Send outs
2. When storing (i.e. freezer) samples for later testing
3. When sample for D dimer is received
4. **Specimen Retention:** Refer to Specimen Retention Procedure.

IV. QUALITY CONTROL:

A. **Frequency of QC Testing:** Controls must fall within ranges established for that lot number. These ranges are in the instrument QC program and out-of-control conditions are identified. The IL ACL TOP(s) store quality control data. Control data for the routine tests are printed and reviewed by the supervisor and medical director. A monthly report of the IL ACL TOP for special coagulation is reviewed by hematology management and the medical director.

B. **Daily QC Testing:**

1. A= Daily quality control for routine test is performed every 8 hours.
2. C= Control to be run with every batch of samples.

HemosIL Control	PT ACL TOP	aPTT ACL TOP	D-Dimer HS 500 ACL TOP	Fibrinogen ACL TOP	TT ACL TOP	PT ST4	APTT ST4	Fibrinogen ST4
Normal 1	A	A		A	C	C	C	C
Abnormal 3	A	A				C	C	C
Low Fibrinogen								
Low Abnormal Assayed				A	C			
Low and and High Dimer HS-500 liquid controls			A					

HomosIL Control	AT3	PC	PS	DRVVTS/ DRVVTC	APCR	VWFACT	VWFAG	Factors	LMWH	UNFH	Plasminogen	Plasmin Inhibitor
Normal Assayed	C	C	C			C	C	C			C	C
Abnormal Assayed	C	C	C									
Special Test 1						C						
Special							C	C			C	C

Test 2												
APC level 1 and 2					C							
LA Positive and Negative				C								
Low and High LMWH									C			
Low and High UNFH										C		

C. **Troubleshooting QC:**

1. If both PT and aPTT on the same level of control are outside of control range, suspect control problem.
2. If either PT or aPTT on both levels of control are outside of control range, suspect reagent or instrument problem.
3. If Fibrinogen or D-Dimer HS 500 QC is out of control, rule out control and reagent problem, then consider loading a new bottle of factor diluent.

NOTE: Using 2 standard deviations gives only 95% confidence limits and one out of every 20 determinations can be expected to fall outside 2SD. It is very unlikely that a control will fall outside 2SD on consecutive days on the same side of the mean and any such pattern should be considered an out of control situation. For the same reason, both normal and abnormal controls should not be out of control on the same day. ANY OUT OF CONTROL SITUATION THAT CANNOT BE RESOLVED MUST BE BROUGHT TO THE ATTENTION OF SHIFT SUPERVISOR **IMMEDIATELY**. IF SHIFT SUPERVISOR IS NOT AVAILABLE CALL TECHNICAL SERVICES. NO PATIENT RESULTS ARE TO BE REPORTED UNTIL CONTROL VALUES ARE WITHIN ACCEPTABLE LIMITS..

V. CHECKING AND REPORTING OF RESULTS:

A. Patient specimens are received into the computer either by the automated laboratory sorter, or manually.

B. All hemolyzed specimens must be checked for a clot, regardless of the hemolysis index.

C. Two patient identifiers are always used for identification purposes, including manual specimen processing and resulting.

D. Entry of test results into the computer requires entering the patient specimen number, either manually, barcode scanned, or as part of an instrument on-line batch. The patient name, ID number and specimen number will appear on LIS screen. The technologist then verifies the patient's identity before entering or accepting the results. Non-autoverified results must be reviewed and accepted by the technologist before they are transmitted.
Copies of printouts from interfaced instruments are not saved within the Coagulation laboratory. Worksheets are retained according to the Document Management Procedure for miscellaneous tests and instruments not interfaced to the LIS/HIS. (Printouts from interfaced instruments must be retained only when LIS is down.)

E. If a transcription error is made reports can be corrected or additional comments can be made by correcting the report. All corrected reports must be called to nursing unit as soon as possible.

F. Approximately 100 random PFA and platelet aggregation printouts are monitored yearly for clerical errors. Corrections are made if necessary and the nurse (inpatient) or physician (outpatient) is notified.

G. Abnormalities that are deemed critical (see Critical Values and Response for Coagulation Results procedure) are immediately communicated by the coagulation staff (EC patients) or Customer Service (non-EC patients) to the appropriate physician or nursing staff and documented in the LIS. Personnel receiving verbal or phone orders must read back the entire order to verify accuracy of transcription. All non-EC critical values can be accepted by the coag technologist and Customer Services will notify the appropriate physician or nursing staff.

H. **Delta Checks:** The laboratory computer alerts the technologist whenever a patient's INR varies more than + 2.0. When this occurs, the department protocol is to:

1. Perform a trend of the patient's results.
2. Check specimen adequacy (clot, QNS, heparin contamination, etc.)
3. If any question, request a redraw, notify nursing unit and complete an internal quality improvement workform.

I. **Autoverification of Results:** Results within established ranges tested on Coagulation instruments are autoverified by the LIS. See Autoverification Policy.

J. **Stat Turnaround Times (TAT):** Occasions may arise when a special coagulation test is ordered STAT with the expectation that it be run and resulted ASAP (i.e. Anti-Xa from ECMO). In these instances, the expectation is to run and report this test within 4 hours of collection. Every effort will be made to communicate this request to coagulation lab ahead of time.

1. The expected TAT of STAT:

Assays	TAT
PT	30 Minutes
aPTT	30 Minutes
Fibrinogen	30 Minutes
D-Dimer	30 Minutes
Anti Xa	4 Hours

K. **Test Cancellation:**

1. Canceling a verified test can only be done due for few reasons: incorrect test ordered, incorrect patient tested, or add-on testing to verified tests that are part of the add-on panel. For more information refer to tip sheets "Cancel a Verified Test" in Laboratory Learning Home Dashboard.
2. Specimens which are QNS to repeat after an instrument malfunction SHOULD NOT be canceled as “QNS”. They should be canceled with the comment “INSTRUMENT MALFUNCTION”.
3. A specimen should only be considered QNS if it arrives in the lab and has insufficient volume BEFORE being run.

L. ***Computer Calculation Verification:*** LIS computer calculation verification is performed annually.

VI. LIS/HIS COMPUTER DOWNTIME:

A. Refer to Coagulation Computer Downtime procedure.

VII. PROFICIENCY TESTING / CAP (or EQUILIVANT) SURVEYS:

The laboratory follows the Clinical Pathology Proficiency Testing Procedure.

A. Specimens received for analysis are assayed in a manner identical to routine patient samples.

B. Specimens are given to the techs on the associated workstation for that day.

C. The technologists performing the assay sign the survey report. When the results of our performance are returned, they are reviewed by the supervisor and section medical director. Feedback is given to the techs who participated in the survey. For unacceptable results, quality control is reviewed for the day that the survey was run as well as any unusual circumstances that may have been documented.

D. Unacceptable results are 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).

E. All information is passed on to the participating employee, then placed in a designated binder for one year. The original

survey report is retained in a permanent file in the QA coordinator's office for two years, then sent to off-site storage for an additional ten years.

F. Per Centers for Medicare and Medicaid Services (CMS) requirements and College of American Pathologists (CAP) directives regarding secondary instrument proficiency testing, Coagulation runs and reports results from only one designated coagulation analyzer (including STAT lab).

G. Biannual correlation studies are performed for the remaining coagulation analyzers. Proficiency testing for backup coagulation procedures is demonstrated by comparison to the primary methodology. There are no current coagulation tests performed in our lab that are not covered by CAP or equivalent proficiency programs. Under CLIA-88 regulations, there is a strict prohibition against inter- laboratory communication about proficiency testing samples until after the deadline for submission of data to the proficiency testing provider. It is also prohibitive to refer (external) proficiency testing specimens to an outside laboratory.

H. We are enrolled in CAP and/or NASCOLA surveys. These provide proficiency testing for the following tests:

PT	Protein S Functional
aPTT	Protein C Functional
Fibrinogen	vWF Antigen
Factor Assays	DRVVT
D-Dimer	Argatroban
FSP	Ristocetin Cofactor
Thrombin Time	APCR
AT III UNFH	Plasminogen Plasmin Inhibitor
Anti -Xa LMWH	Heparin / anti-Xa Unfractionated
PFA	Platelet aggregation
Inhibitor Screen	Bethesda Inhibitor
PNP	Quantitative D-Dimer

VIII. TRAINING:

A. Coagulation training is approximately five days for each bench rotation.Training checklists are provided to each new employee on their first day in the hematology/ coagulation department. The technologist assigned to a bench for that day is responsible for training new employees as identified in the Clinical Pathology Training and Competency Assessment Program procedure.

B. All checklist items will be covered with the new employee during the training process through discussion and performance. The goal is to perform all listed tasks during the training period. However, because it may not be possible to perform all listed tasks prior to completion of training due to test availability, discussion of those items will serve as an acceptable method of training. Oral Query by hematology/coagulation management at the end of each bench rotation serves as the Second Level Review of the training checklist.

C. Employee must be able to answer questions from management staff to indicate awareness of the Standard of Practice (SOP) for each designated item listed in the training checklist. After this management review, the employee will be considered competent and be responsible for defining, performing, calibrating (when necessary) and reporting results per SOP for each procedure/process without supervision and within acceptable limits.

D. Training methods which may be used for bench training include hands-on practice, unknowns, Computer Based Modules (CBTs), self-study, reading SOPs and observation/performance of daily work. Training materials which may be used for bench training include workflows, flowcharts and tables, written procedures, operator's manual for instrument/equipment, product inserts.

IX. COMPETENCY TESTING:

A. To comply with CLIA '88 regulations, all technologists working in hematology/coagulation undergo competency assessment for test procedure performance and test result reporting. This competency evaluation is performed and documented biannually for new employees during their first year of employment and annually for employees employed for more than one year

B. Employees are assessed on each Test System for hematology/coagulation. Employees are to complete each Competency Assessment Checklist Form and submit indicated documentation to hematology management by designated date (preferably July 1st) of each calendar year. All CLIA elements identified in the Clinical Pathology Training and Competency Assessment Program procedure will be assessed for the competency of each employee.

C. Employees failing competency assessment are retrained and reassessed. If unable to satisfactorily pass the assessment, then further action will be taken, including but not limited to, supervisory review of work or other action deemed appropriate by the Laboratory Director. Documentation of retraining and reassessment of employees who initially fail competency assessment will be kept on file for a minimum of seven years.

D. As a follow-up to PSQIs or pathologist findings, a review of protocol or specific morphologic findings may be conducted with the employee. These reviews are considered to be an inservice (documented as Inservice Documentation) and do not require retraining or reassessment of the employee unless such reviews become more than an occasional occurrence. If such inservices become more than an occasional occurrence, as deemed by hematology management, then Human Resources may become involved and an appropriate Action Plan may ensue due to Poor Job Performance.

X. CORRELATION TESTING:

Refer to Coagulation Correlations.

XI. EQUIPMENT QUALITY CONTROL:

Refer to Equipment Quality Control procedure.

XII. NORMAL / THERAPEUTIC VALUES:

Refer to procedure “Coagulation Test: Reportable Limits and Normal / Therapeutic Values.

XIII. COAGULATION QC INFORMATION:

See Attachment B.

XIV. WATER:

The Coagulation laboratory utilizes water supplied from the U.S. Filter PURELAB PLUS system. (Type I). Records for the quality control of this water are kept in the Chemistry department.

XV. REAGENTS:

A. Newly delivered reagents and/or reagent kits must be dated by the individual who accepted and signed the delivery slip. The reagents must be stored immediately according to manufacturer's specifications. All lyophilized reagents and controls are reconstituted with distilled deionized water. All bottles are dated at time of reconstitution. No reagent or control is to be used beyond its established expiration date.

B. Reagents are dated when placed into service. Reagents are acceptable for use through the date of expiration. (An expiration date of April 30, 2017, is good until May 1, 2017.) Reagent label bears expiration date. All reagents are logged onto the TOPs when in use.

C. For those reagents where there is no manufacturer-provided expiration date, expiry is determined by reagent stability and frequency of use as well as reagent deterioration (i.e. cloudiness, color change, lack of QC recovery). See respective procedure for directives.

D. Solutions and buffers must be properly labeled, dated when made up and signed by the technologist. An expiration date and any special instructions for storage (i.e., at 4^{o}C or in the dark) must also be placed on the label.

E. *All reagents must be labeled with potential hazards according to the Clinical Pathology Chemical Hygiene Plan.*

XVI. INSTRUMENT VERIFICATION:

Some instruments are swapped out for preventative maintenance and or repair. When this occurs, it is imperative that a verification of the analyzer be performed prior to reporting patient results. At a minimum, the following must be done: instrument maintenance, 2 levels of control, minimum of 5 patient correlations (at discretion of supervisor, depending upon the specific test/instrument).

XVII. GLASSWARE:

A. Glassware with cracks or chips must be discarded. Glassware or plastic-ware with no volume markings or markings difficult to read are also discarded. Manufacturer's instructions for reagent and control reconstitution are followed.

B. Specimen-contaminated, broken or discarded glass is discarded in red Sharpsafe Biohazard Waste containers that have a biohazard label on them. All biohazard waste is disposed of in the designated large biohazard red buckets. This waste is picked up by an outside company, incinerated and disposed of. Glass slides and glass/plastic serologic pipettes are discarded in large red or clear biohazard containers.

XVIII. PATIENT CONFIDENTIALITY AND RELEASE OF INFORMATION:

Refer to Information Security and Governance Policy for more information.

XIX. COMPLIANCE:

The Coagulation Laboratory follows all hospital and department guidelines for compliance.

XX. SPECIAL HANDLING OF HAZARDOUS SUBSTANCES:

All hazardous substances should be handled according to their respective SDS sheets. If exposure occurs, fill out electronic Employee Injury/ Illness Form. Contact Beaumont- Occupational Health 248-733-7300 ext: 37324 for an appointment.

XXI. LASER SAFETY:

A. Some LIS printers and LIS barcode readers employ lasers. Employees must:

1. Never operate the laser without the internal cover installed.
2. Never look directly into the laser light source or at scattered laser light from any reflective surface (e.g., jewelry or tools) - this can severely damage the eyes.
3. Never use flammables or explosives in the presence of the laser. All service and maintenance must be performed by qualified service personnel. Employees may perform maintenance only as instructed in product reference manual.

XXII. GROOMING POLICY:

The laboratory follows hospital policy regarding grooming: Dress and Grooming Policy

XXIII. PHONE CALLS:

In accordance with hospital policy, lab phones are not to be routinely used for personal business. Incoming personal calls should be of an emergency nature only. In addition, all phone calls should be picked up by the third ring.

XXIV. REFERENCES:

A. ACL TOP Family 50 Series Operator's Manual, Version 6.1, January 2015.

B. HemosIL Normal control 1, 3 package insert, June 2017

C. Jacob Shanberge, MD, WBH Pathologist, Personal Communication, 1995

D. H21-A5: Collection, Transport, Process Blood for Plasma-Based Coag Assays_Jan,

Attachments

Attachment B - Coagulation QC Information
Attachment A - Coagulation Factors at Birth

Approval Signatures

Step Description	Approver	Date
CP Chief Medical Director	Peter Millward: Chief, Pathology Service Line	4/28/2021
Coagulation Medical Director Designee	Marc Smith: System Med Dir, Coagulation	4/28/2021
Policy and Forms Steering Committee Approval (if needed)	Tamara Sabih: Medical Technologist Lead	4/23/2021
Policy and Forms Steering Committee Approval (if needed)	Gail Juleff: Project Mgr Policy	4/23/2021
System Manager	Rebecca Bacarella: Mgr Laboratory	4/22/2021
	Tamara Sabih: Medical Technologist Lead	4/22/2021

Applicability

Royal Oak