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Applicability	Royal Oak

Activated Partial Thromboplastin Time (aPTT) on the IL ACL TOP -RO

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

The purpose of this procedure is to give the steps on how to perform the Activated Partial Thromboplastin Time (aPTT) test on the IL ACL TOP.

II. PRINCIPLE:

A. The Activated Partial Thromboplastin Time (aPTT) employs the intrinsic pathway of clotting. In the aPTT test, the plasma sample is incubated with an optimal quantity of phospholipids, a negatively charged contact activator, and buffer activating the intrinsic coagulation pathway. Calcium is added after incubating at 37°C for a specific period of time, and the time for clot formation is measured. The aPTT included in the SynthASil kit is a liquid buffered reagent which contains synthetic phospholipid for optimal platelet–like activity and a highly defined non–setting colloidal silica for optimal activation of the contact phase of coagulation.

B. SynthASil is sensitive to decreased concentrations of contact factors, factors in the intrinsic and common pathway, the anticoagulant effect of heparin and to the presence of inhibitors, particularly to the lupus-like anticoagulant.

C. Prolonged clotting times may be observed in the following situations: deficiency of Factors XII, XI, X, IX, VIII, V, II or fibrinogen, liver diseases, Vitamin K deficiency, presence of heparin, lupus anticoagulant or other inhibitors.

III. ACRONYMS:

A. Activated Partial Thromboplastin Time (aPTT)

B. Coagulation Error (CE)

C. Coagulation Warning (CW)

D. Instrumentation Laboratory (IL)

E. Laboratory Information System (LIS)

F. Quality Control (QC)

G. StarT4 (ST4)

IV. SPECIMEN COLLECTION AND HANDLING:

Refer to Coagulation Test: Specimen Collection and Handling (Non - Platelet Function Test Only) procedure.

V. SUPPLIES:

A. **Equipment**:

1. IL Coagulation Analyzer
2. Cuvette
3. IL reagent racks and sample racks
4. Cleaning and Rinse solutions
5. Serological and automatic pipettes

B. **Reagents:**

1. **HemosIL SynthASil Kit Contains**:
    a. **APTT SynthASil Reagent**: 5 vials of a buffered synthetic phospholipid reagent containing a colloidal silica activator, stabilizers and a preservative**. Each vial of APTT reagent must be equilibrated at 15-25˚C for at least 15 minutes and mixed thoroughly before use**. Opened reagents are stable 30 days at 2-8°C in the original vial and 10 days at 15°C on the ACL TOP® Family. Do not freeze. **Must be changed on ACL TOP at same time as Calcium Chloride.**
    b. **Calcium Chloride**: 5 vials of an aqueous solution of calcium chloride (0.020 Mol/L) and a preservative. Ready for use. Opened reagent is stable 30 days at 2-30°C, 10 days at 15°C on the ACL TOP® Family. Do not freeze. **Must be changed on ACL TOP at same time as SynthASil.**

C. **Controls**:

1. **HemosIL Normal Control 1**: 10 vials of lyophilized human plasma containing buffer, stabilizers and preservatives. Dissolve the contents of each vial with 1mL of deionized (DI) water or equivalent. Replace the stopper and swirl gently. Completed reconstitution of the product is required. Keep the control at 15-25°C for 30 minutes and invert to mix before use. Do not shake. Avoid foam formation. Control is stable after reconstitution for 24 hours at 2-8°C or 15-25°C onboard the ACL TOP® Family.
2. **HemosIL Abnormal Control 3**: 10 vials of lyophilized human plasma containing buffer, stabilizers and preservatives. Dissolve the contents of each vial with 1mL of DI water or equivalent. Replace the stopper and swirl gently. Completed reconstitution of the product is required. Keep the control at 15-25°C for 30 minutes and invert to mix before use. Do not shake. Avoid foam formation. Control is stable after reconstitution for 24 hours at 2-8°C or 15-25°C onboard the ACL TOP® Family.

VI. QUALITY CONTROL:

A. Quality control consists of: HemosIL Normal Control 1 and HemosIL Abnormal Control 3

B. Frequency of Control Use:

1. Controls should be run at least once every 8 hours.
2. On each shift.
3. Whenever there is a reagent change.

VII. PROCEDURE:

A. Gently invert vials of reagents and QC. Calcium chloride and aPTT reagents come as a set and must be loaded/removed **together**. Check for bubbles before loading aPTT reagents and controls on IL ACL TOP.

B. Load Calcium chloride in R3-R6 lane.

C. Load aPTT reagent in D3, R1-R4 lane.

D. Run both levels of QC for aPTT

E. Verify that all levels of QC are within acceptable range before running patients.
Note: If you run a capped sample in the Yellow sample rack, you will crash the Probe. If you run an uncapped sample in the Blue sample rack, the alignment of the probe and its coordinates will be affected.

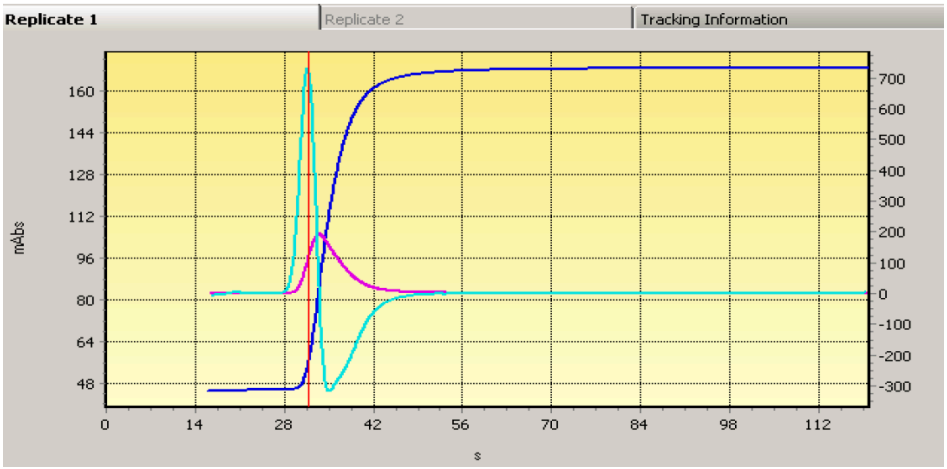
F. Document any troubleshooting performed if QC fails.

G. Refer to IL Operations Procedure for any instrumentation details.

VIII. RESULTING:

A. **Resulting Patient Samples: Results may be verified in the LIS. Refer to Coagulation Autoverification procedure except for the following**:.

1. FAILED result: **see Attachment A- ACL TOP Family Reaction (Clot) Curve**.
    a. Examine the Derivative Curve. APTT utilizes the 2nd Derivative Curve which is indicated in aqua on the instrument.
    b. If there is a distinctive peak and trough for the 2nd derivative curve, then a numerical result can be reported.
    c. Use the mouse to navigate the arrow to the peak of the 2nd derivative curve and the instrument will display the PTT result.

d. 

2. **aPTT results >200 or < 21 seconds:**
    a. **If aPTT results >200 seconds**:
        i. Check samples for a clot. If the sample is not clotted and there are no other flags, verify the patient 's medication list. If that can not be confirmed and IL graph is unacceptable, verify the result by the backup method ST4.
    b. **If aPTT results <21 seconds**:
        i. All aPTT results < 21 seconds must be checked for a clot. Cancel if a clot is present, or the sample integrity is compromised. Otherwise, report the result with the comment " Shortened aPTT may be secondary to acute phase response. Consider redraw if not compatible with the clinical picture."

IX. EXPECTED VALUES:

A. **Any unreasonable result is to be repeated.**
B. All aPTTs >110 seconds are automatically repeated by the ACL TOP.
C. **Normal Ranges:**
    1. Refer to Coagulation Tests: Reportable Limits and Normal / Therapeutic Values procedure.
D. **Reportable Ranges**:
    1. Refer to Coagulation Tests: Reportable Limits and Normal / Therapeutic Values procedure.
E. **Turn Around Time**:
    1. Routine aPTT - 90 minutes
    2. STAT aPTT - 30 minutes

X. LIMITATION:

A. HemosIL SynthASil results are not affected by:

1. Hemoglobin up to 500 mg/dL
2. Bilirubin up to 26 mg/ dL
3. Triglycerides up to 1000 mg/dL

XI. PROCEDURE:

A. ACL TOP Online Operator's Manual, Version 2.2, June 2017.
B. Advanced Operator Training Manual, 2018.
C. HemosIL SynthASil package insert, June 2017.
D. HemosIL Normal 1 Control package insert, 04/2018.
E. HemosIL Abnormal Control 2 package insert, September 2016.

Attachments

ATTACHMENT A- ACL TOP Family Reaction (Clot) Curve

Approval Signatures

Step Description	Approver	Date
	Ann Marie Blenc: System Med Dir, Hematopath	1/13/2023
Coagulation Medical Director Designee	Marc Smith: System Med Dir, Coagulation	1/12/2023
Policy and Forms Steering Committee Approval (if needed)	Gail Juleff: Project Mgr Policy	12/29/2022
Policy and Forms Steering Committee Approval (if needed)	Tamara Sabih: Medical Technologist Lead	12/29/2022
System Manager	Megan Masakowski: Mgr, Division Laboratory	12/29/2022
	Tamara Sabih: Medical Technologist Lead	11/3/2022