Beaumont HEALTH

Beaumont Laboratory
Royal Oak

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Related Documents:
RC.HM.CG.PR.001 Coagulation Tests: Specimen Collection and Handling (Non-Platelet Function Tests Only)

aPTT
START 4 METHOD

RC.HM.CG.PR.071.r03

Principle

This is a mechanical clot detection method

The Activated Partial Thromboplastin Time (aPTT) employs the intrinsic pathway of clotting. A lipid factor, similar to that released by the platelets, and calcium are added to the plasma and the clotting mechanism is initiated. The aPTT will detect significant deficiencies in all of the plasma coagulation factors except factor VII and platelets.

The detection on the START 4 is based on the increase in viscosity of the plasma being tested as a clot is formed. Increases in viscosity are measured through the perpendicular motion of a steel ball. There are two coils on opposite sides of a cuvette that produce an electromagnetic oscillation of the steel ball. When the appropriate start reagent is added, the detection starts immediately. The ball starts oscillating left and right, activating the chronometer. As a clot appears, plasma viscosity increases and the amplitude of the ball's oscillation decreases.

Specimen Collection and Handling

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

Supplies

EQUIPMENT / MATERIALS:

Diagnostica Stago START 4
Cuvettes
Metal balls with dispenser
100mcL pipette
Small pipette tips
Plastic tubes

REAGENTS:

1. **HemosIL SynthASil –** APTT reagent: 5 X 10 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 15-25ºC for at least 15 minutes and mixed thoroughly before. Unopened reagents are stable until the expiration date shown on the vial when stored at 2-8ºC. Opened reagent is stable 30 days at 2-8ºC in the original vial, 10 days at 15°C on the ACL TOP® Family. Do not freeze.

2. **HemosIL SynthASil**- Calcium Chloride: 5 X 10 vials of an aqueous solution of calcium chloride (0.020 Mol/L).The reagent is ready for use. Opened reagent is stable 30 days at 2-30°C.
3. **Distilled Water –** Reagent grade, distilled, deionized water.

CONTROLS:

1. **HemosIL Normal Control 1:** Lyophilized human plasma containing buffer, stabilizers and preservatives. Store unopened vials at 2-8ºC and use by the expiration date printed on the label. Dissolve the contents of each vial with 1 mL of deionized (DI) water or equivalent. Replace the stopper and swirl gently. Complete reconstitution of the product is required. Keep the control at 15-25ºC for 30 minutes and invert to mix before use. Stability after reconstitution is 24 hours at 2-8°C or 15-30°C on board the ACL TOP.
2. **HemosIL Abnormal Control 3:** Lyophilized human plasma containing buffer, stabilizers and preservatives. Store unopened vials at 2-8ºC and use by the expiration date printed on the label. Dissolve the contents of each vial with 1 mL of DI water or equivalent. Replace the stopper and swirl gently. Complete reconstitution of the product is required. Keep the control at 15-25ºC for 30 minutes and invert to mix before use. Stability after reconstitution is 24 hours at 2-8°C or 15-30°C on board the ACL TOP.

Maintenance

Refer to Attachment A.

Quality Control

START 4 QC is required only when patient samples are run on the instrument. Document QC results on START 4 QC log.

HemosIL normal control 1 and HemosIL abnormal control 3 are run once per shift when the instrument is used.

Procedure

1. Label two plastic tubes “APTT reagent” and “CaCl2” with time and date. Pour the amount of APTT reagent and Calcium chloride needed into each plastic tube. (100mcL of each per sample; all samples are run in duplicate) Incubate calcium chloride **only** at 37^{0}C.
2. Place a 4-cuvette strip in incubation column #1. Add a metal ball to each cuvette. Let the cuvettes incubate for at least 3 minutes.
3. From the “main Menu”, select *TEST MODE* by pressing the [1] key and confirm with [ENT] key. Select *APTT* by pressing the [2] key and confirm with the [ENT] key.
4. Enter the patient ID number. Only 2 samples per run. A maximum of 7 digits is allowed for each ID number. Only enter the ID once. The START 4 will display your ID in duplicate. After all the ID numbers have been entered, press [ENT] and a working list will print out and the screen displays the working screen.
5. Pipette 100mcL of sample or control into each cuvette. Then pipette 100mcL of APTT reagent into each cuvette.
6. Immediately press incubation timer key #1 at bottom of incubation column. The column timer #1 starts to run.

7. Ten seconds before the 180 second incubation time is reached, the instrument starts to beep. At this sound, quickly transfer the cuvette strip from incubation column to test column. Exactly when the incubation timer #1 reaches the 180 seconds mark, dispense 100mcL of the calcium chloride into cuvette channel #1and press the PIP key; repeat into the successive cuvette channels #2, #3, and #4. Each time calcium chloride is added, press the PIP key simultaneously.
8. When a test in a cuvette channel has reached its end-point, the clotting time is displayed on the screen.
9. When all the tests in the 4-cuvette channels have reached their end-points, their respective clotting times are displayed and the results are printed out. If there is an "*" next to the result, repeat the sample due to a >5%CV.
10. Duplicates for aPTT should agree within 5% 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.
11. **Multiply the aPTT result by .85**. Record the control results on the QC log and the patient results on the START 4 report form. Record the control results on the QC log and the patient results on the START 4 report form.
12. Enter the results in LIS. If the test performed by START 4 confirms a questionable result from an automated instrument, then enter the result from the automated instrument and add the comment "verified by alternate method". If the result from the START 4 does not match the result from the automated instrument within 10%, then enter the result from the START 4 and add the comment "performed by alternate method". Enter START 4 as the instrument code.

Expected Values

REPORTABLE RANGE:

<21 - >125 seconds

TAT:

Routine aPTT	2 hours
STAT aPTT	30 minutes

References

1. Start 4 Operator's Manual, Diagnostica Stago, France, June 2002.
2. Palkuti, HS: *Clinical Hemostasis Review,* Coagulation Questions and Comments, January 1993.
3. Palkuti, HS and Jensen R: *Clinical Hemostasis Review,* Coagulation Questions and Comments, February 1993.

Authorized Reviewers

Chair, Pathology and Laboratory Medicine
Medical Director, Coagulation

Attachments

ATTACHMENT A – DIAGNOSTICA STAGO START 4 / PREVENTATIVE MAINTENANCE

MONTHLY:

1. Clean the work-surface and the reagent storage wells with absorbent paper soaked with deionized water.
2. Use cotton-tips soaked in deionized water to clean the incubation and test wells.

SIX-MONTHS:

System Check

1. From the “Main Menu” display, press the [4] key and confirm with [ENT]. Then from the “System check” display, select “Diagnostic Tests” by pressing the [2] key and confirm with [ENT]. Press [ENT] to initiate the Self-Check.
2. Follow the instructions displayed on the screen. If any of the tests do not check out notify hematology management.
   a. When the “Self Test” is completed, the “System check” Menu is displayed again.
   b. Press the [ESC] key to go back to the “Main Menu”.

APTT – START 4 METHOD

Document Control

Location of Master: Coagulation Procedure Manual
Master electronic file stored on the Beaumont Laboratory server under:
S:\HEMACOAG\Document Control\Coagulation\Procedure\Master Documents\aPTT Start4.doc
Number of Controlled Copies posted for educational purposes: 0
Number of circulating Controlled Copies: 0
Location of circulating Controlled Copies: NA

Document History

Signature	Date	Revision #		Related Documents Reviewed/ Updated
Prepared by: Karri Henderson MT(ASCP)	04/30/2012			
Approved by: Marc Smith, MD	12/11/2012			
Reviewed by: (Signature)	**Date**	**Revision #**	**Modification**	**Related Documents Reviewed/ Updated**
Marc D. Smith, MD	12/11/2012	00	New Procedure.	OK
Mark D. Kolins, MD	12/12/2012			
Marc Smith, MD	12/22/2014		No change	OK
Marc Smith, MD	06/06/2016		No change	OK
Elizabeth Sykes, MD	02/22/2018			
Marc Smith, MD	10/02/2018	**01**	Updated logo. Changed the reagents and controls used.	OK
Peter Millward, MD	09/27/2018			
Marc Smith, MD	09/06/2019	02	Multiplying aPTT result by 0.85	
Marc Smith, MD	11/18/2019	03	Added normal ranges and therapeutic range	