Document History:

Title: **i-STAT® POCT INR Mini Verification Protocol**

Site(s): **Sites Approved by Shared Health Hematology Medical Director**

Document #:	**140-170-09**	**Version #:**	**02**
Section:	**Hematology**	**Subsection:**	**POCT Laboratory**

Approved by: **Signature:**	Dr. Ping Sun *(signature on file)*	**Date:**	28-SEPT-2021
		Effective Date:	11-NOV-2021

Details of Recent Revision

- Updated process states that a patient consent is not required if a physician orders a PT/INR test (page 2)
- Correct ISTAT SOP (page 2 & 3)
- Changed # of times controls required to be processed from two to one

i-STAT® POCT INR Mini Verification Protocol

Purpose:

This verification protocol provides instructions to verify that the INR results obtained by each handheld device and the i-STAT® PT/INR cartridge are comparable to the INR results obtained from a venous citrated specimen processed on the coagulation analyzer in a Hematology Laboratory.

The verification of performance should provide evidence that the accuracy, precision, and reportable range are adequate to meet the needs of the patient population and clinicians as determined by the Medical Director.

The mini verification protocol is used when a replacement unit is received for the initial unit.

Policy:

Each handheld is a test system and must be verified before use.
The i-STAT® PT/INR cartridge is intended for the monitoring of oral anticoagulant therapy (OAT).

Materials:

Reagents:	Supplies:	Equipment:
• i-STAT® PT/INR Level 1 (normal) and Level 2 (abnormal) controls	• PT/INR Cartridges, (catalogue #03P89-24) • Lancets • Plastic syringes • Tubes with no additive (Stevens - #333-366703-X, BD - B366703-BD) • Gauze • Alcohol swab • Plastic transfer devices • Plastic pipette (used for red plastic tube from VWR, catalogue #70250015 400/box)	• I-STAT ® Handheld device

Sample:

L1 and L2 controls performed.

Special Safety Precautions:

Follow Routine Practices. Mandatory use of gloves and safety glasses required.

Process:

Follow the activities in the table below to perform the verification study.

Collection method must be established prior to start of verification. Collection methods include capillary (finger puncture), venous via plastic syringe or venous into red plastic tube with no additive present.

Note: Patient consent is not required if the physician/healthcare practitioner has ordered a PT/INR test.

Testing Familiarity

Step:	Action:
1	The individuals performing the tests should be thoroughly familiar with the operation, maintenance and quality control procedures as well as storage conditions and preparation of consumables for the test and comparative methods before starting the protocol.

	• See i-STAT® System, 100-10-02. • All individuals must have completed initial training and be signed off prior to performing any testing. • A variation of operators is required.
2	A precision study must be performed. See Procedure A: Precision Study. The values are inserted into F140-170-01C and submitted to the Hematology Technical Director by fax (204-787-4030) or e-mail.
3	An i-STAT® Verification Summary report F140-170-01D will be issued to the Laboratory. The specific INR result that requires a venous sample to be sent to the Laboratory for confirmation will be included in the report.

Handheld Device Preparation: Handhelds should be on a level surface and should not be moved during the PT/INR test cycle. Before starting this verification, ensure that the clock in each Handheld is correct for your time zone.

Procedure A: Precision Study Perform as per Procedure for Testing PT/INR Controls with i-STAT® PT/INR Level 1 (normal) and Level 2 (abnormal) control. See i-STAT® System, 100-10-02.

Step:	Action:
1	Test the PT/INR Level 1 and Level 2 Controls.
2	Insert values into F140-170-01C – i-STAT® INR Precision Study Log
3	Submit to Hematology Technical Director.
4	It is important to follow the instructions exactly for handling the controls. • Only one vial should be reconstituted at a time. A reconstituted control must be used in less than 30 seconds.

Controls:

If:	Then:
An out-of-range result is obtained and it can be verified that the cause was operator error,	The result can be discarded and replaced with a result from a new cartridge.
More than one out-of-range result is obtained,	The operator should review the test procedure, practice the test procedure, and re-start the Precision Study

Related Procedures:
Procedure: Specimen Acceptance Policy [10-50-03]
Procedure: i-STAT® System [100-10-02]

Related Documents:
Form: i-STAT® POCT INR Precision Study (F140-170-01C)
Form: i-STAT® Verification Summary Report (F140-170-01D)

References:
1. i-STAT® - Prothombin Time/(PT/INR) – 715236-01G
2. i-STAT® - System Performance Verification Protocol
3. i-STAT® - PT Control Insert