KAISER PERMANENTE®

DOCUMENT NUMBER:	RIV-PPP-1166
DOCUMENT TITLE:	Performing Pipette Carryover Study on Stago Analyzers
DOCUMENT NOTES:	

LOCATION:	RIV-rel	**VERSION:**	01
DOC TYPE:	RIV PPP	**STATUS:**	Release

EFFECTIVE DATE:	02 May 2024	**NEXT REVIEW DATE:**	02 May 2026
RELEASE DATE:	02 May 2024	**EXPIRATION DATE:**	

AUTHOR:		**PREVIOUS NUMBER:**	
OWNER:		**CHANGE NUMBER:**	RIV-CR-0391

Kaiser Permanente Medical Care Program California Division - South	SCPMG Laboratory Systems Coagulation Procedure

Performing Pipette Carryover Study on Stago Analyzers

Introduction

Carryover is the contamination of a sample by the sample or reagent used in the analysis immediately before it. This is most often due to contamination by the sampling syringe pipette. This happens and becomes a problem for consecutive analytes with a wide clinical range of analyte concentration. Errors due to carryover of analyte from a sample with a high level of analyte to a subsequent one with a low level is a potential problem with automated analyzers. A minute degree of carry-over could have significant clinical implications.

Scope

This procedure provides instructions for the CLS in evaluating whether carryover effects are present in the Stago analytical instrument.

Policy

- Carryover study shall be performed as part of the initial evaluation of an instrument.
- Carryover study performance shall take place after fluidics part replacements on the pipetting assembly of the Stago analyzer/s that are neither routine nor would fall under a general preventive maintenance. It is not necessary to perform carryover study on other major maintenance or repair.
- Representative examples of the wide range of analyte concentration, a low and a high level, are selected for each instrument in the laboratory.
- Carryover effect on the instrument is determined based on established criteria.

Principle

- Carryover testing is performed to help prove or disprove carryover from the integrated sampling syringe pipette system of the Stago analyzer.
- Carryover may be determined by using two samples, one with a high concentration of analyte and one without detectable or low concentration of the analyte.

Equipment

- Stago StaR Max
- Stago Compact Max

Continued on next page

Performing Pipette Carryover Study on Stago Analyzers,
Continued

Reagents

The following contains the list of materials and supplies required.

- Normal Pooled Plasma
- STA-Quality HNF/UFH Level 2
- STA PTT Automate

Materials and Supplies

The following contains the list of materials and supplies required.

- Tubes
- Micro cups
- Pipettes

Safety

Refer to the safety manual for general safety requirements.

Before you begin

- Ensure that the instrument analyzer is done with testing of all patient specimens on board.
- Ensure that latest instance of Quality Control performance is acceptable.

Preparation of Carryover Materials

Prepare the materials needed to perform carryover studies on the Stago analyzer.

A. Normal Pooled Plasma aliquots

1) From the same pool, make two equal aliquots to be named N1 and N2.
2) Dispense N2 into five (5) aliquots.
3) Label each N2 aliquots as N2-1, N2-2, N2-3, N2-4, and N2-5.

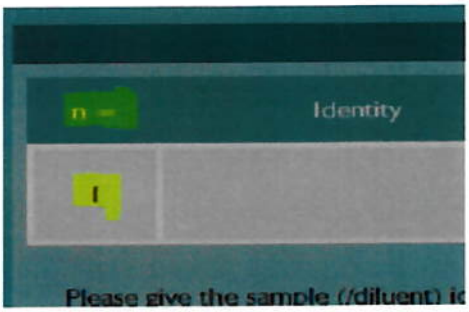
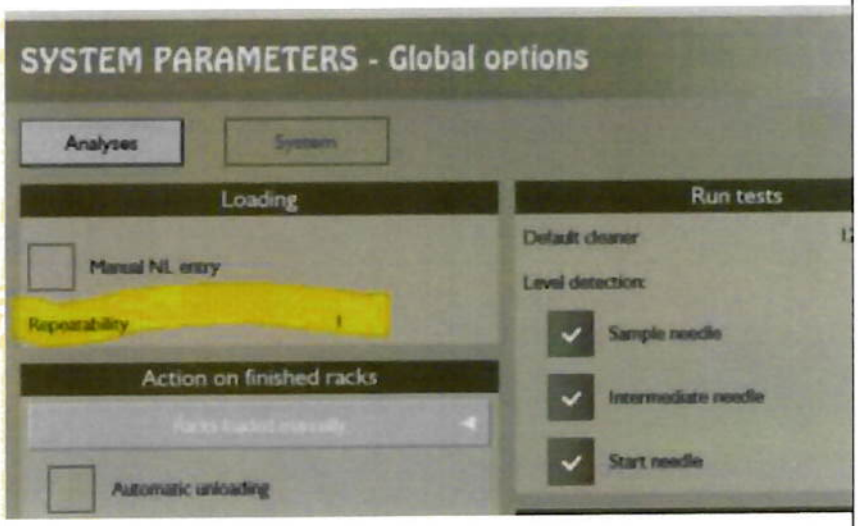
B. STA-Quality HNF/UFH Level 2 named H

1) Dispense H into five (5) aliquots.
2) Label each as H-1, H-2, H-3, H-4, H-5.

Continued on next page

Performing Pipette Carryover Study on Stago Analyzers,
Continued

Procedure Follow the steps below to perform carryover studies on the Stago analyzer.

Step	Action
1	Program and run a repeatability test on N1 of five (5) replicates of APTT. a. On Compact Max, there is an n=1 field to the left of the ID field on the sample loading screen. For this test, program it to be five (5).  b. On StarMax, the repeatability can be set under System Parameters, Global Options tab. 

Continued on next page

Performing Pipette Carryover Study on Stago Analyzers,
Continued

Procedure, continuation Continuation

Step	Action
2	Run APTT for each sample listed below in the order indicated. These can be loaded in micro cups. i. Tube 1 Plasma H ii. Tube 1 Plasma N2 iii. Tube 2 Plasma H iv. Tube 2 Plasma N2 v. Tube 3 Plasma H vi. Tube 3 Plasma N2 vii. Tube 4 Plasma H viii. Tube 4 Plasma N2 ix. Tube 5 Plasma H x. Tube 5 Plasma N2
3	Calculate the deviation of N1 mean to N2 mean using the following equation: $\frac{(\text{mean of N1} - \text{mean of N2}) \times 100}{\text{Mean of N1}}$
4	Evaluate the deviation as measure of carryover.

IF	Then
Deviation is less than 5%	Carryover test passed. No further action is necessary, proceed to patient specimen testing.
Deviation is greater than 5%	Carryover test failed. Do not proceed to patient specimen testing. Seek further action from instrumentation service representative (internal and external if applicable). Repeat carryover study if indicated.

Continued on next page

Performing Pipette Carryover Study on Stago Analyzers,
Continued

Evaluation

The deviation of N2 mean from N1 mean should be less than 5%.
The value of 5% is the Stago manufacturer's recommended between run (total precision) limit on the APTT normal quality control. The same limit is applicable for the carryover study since it is looking at variance in normal APTT.

Controlled Documents

The following controlled document support this policy.

- Stago Carryover Evaluation Form

Non-Controlled Documents

The following non-controlled documents support this policy.

- College of American Pathologist All Common Checklist
- 24-CRD-030 Recommended Carryover Study, Diagnostica Stago, New Jersey, USA.

Author(s)

- SCPMG Coagulation Working Group
- Eleanor E. Callasan
- Marlon Esguerra
- Robyn Kanemoto

Regional Parent Document Reference Number: SCPMG-PPP-0582 Rev: 01

Signature Manifest

Document Number: RIV-PPP-1166 **Revision:** 01
Title: Performing Pipette Carryover Study on Stago Analyzers
Effective Date: 02 May 2024

All dates and times are in Pacific Standard Time.

Coagulation Regional Docs

Operations Director Approval

Name/Signature	Title	Date	Meaning/Reason
Annaleah Raymond (Q741709)	Laboratory Operations Director	25 Apr 2024, 04:25:04 PM	Approved

Medical Director Approval

Name/Signature	Title	Date	Meaning/Reason
Mark Taira (P161328)	CLIA Director	01 May 2024, 05:27:28 PM	Approved