



KAISER PERMANENTE®

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VALIDATION OF NEW LOT NUMBERS

Purpose	This document describes the procedure for validating new lot numbers for reagents in Coagulation department.
Scope	The intended users of this document include Clinical Laboratory Scientists (CLS) working in Coagulation department.
Policy	Before a new lot number of reagent is used, it must demonstrate that it can obtain performance specification comparable to those established by the manufacturer.
Specimen sources	<ul style="list-style-type: none">• Plasma from citrated whole blood (blue top) drawn by venipuncture
Specimen collection	<ul style="list-style-type: none">• Citrated whole blood (blue top) should be collected, handled, transported and processed accordingly.
Materials and supplies	<ul style="list-style-type: none">• Current reagent lot materials• New reagent lot materials• Pipette tips (as needed)• Micro vials (as needed)• Micro vial adapters (as needed)
Equipment	Diagnostic Stago Coagulation Analyzer

VALIDATION OF NEW LOT NUMBERS, Continued

**Safety or
Special Safety
Precautions**

All laboratory personnel are expected to maintain a safe working environment and an injury-free workplace. Laboratory employees are responsible for their own safety and the safety of others and adhering to all department and medical center safety policies and procedures.

- For standard precautions and safety practices in the laboratory; see LAMC-PPP-0123, specifically, but not limited to, equipment safety, proper body mechanics, sharp exposure and proper use of personal protective equipment (PPE).
 - For Universal Body Substance precautions, see LAMC-PPP-0128, specifically, but not limited to, exposure to body fluids.
 - For proper hand washing, see LAMC-PPP-0132, specifically, not limited to, proper hand washing.
 - For proper infection control, see LAMC-PPP-0127, specifically, but not limited to, proper use of gloves.
 - For proper handling of regular and infectious waste, see LAMC-PPP-0129, specifically, but not limited to, proper disposal of regular and biohazardous waste.
 - For proper cleaning of work area, see LAMC-PPP-0130 – Cleaning Work Areas.
 - For proper handling of chemicals and reagents, see Chemical Hygiene Plan.
 - For proper storage and disposal of chemical hazardous waste, see LAMC-PPP-0134
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Quality Control Refer to STA-R Quality Control and Start-up Procedures for specific guidelines.

VALIDATION OF NEW LOT NUMBERS, Continued

Procedure: Follow the steps below to

Step	Action
1	Accuracy Study- Parallel test at least 20 patient samples, using the OLD and NEW lot numbers of reagents. Patient samples should represent values across the reportable range.
2	Reference Range and Normal Population Mean Verification for PT, INR and PTT. To verify the current reference ranges for PT, INR and PTT assays; and to verify the normal patient mean for the new lot numbers of PT and PTT: Run at least 20 normal samples using the new lot numbers. Do not use Acute Care patient samples for this study.

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VALIDATION OF NEW LOT NUMBERS, Continued

**Acceptance
Criteria**

For each assay, the following acceptable criteria must be observed:

Accuracy Study-

Inaccuracy or the bias must fall within the total allowable errors as defined by CLIA:

- PT - $\pm 15\%$
- INR - $\pm 15\%$
- D Dimer - $\pm 20\%$
- Fibrinogen - $\pm 20\%$
- Anti-Xa - $\pm 30\%$
- Correlation Coefficient must be at least 0.90 or higher

Reference Range and Normal Population Mean Verification – for PT, INR and PTT:

The current reference ranges will be verified based on 2 SD and deemed acceptable by statistical analysis using EP Evaluator for reference range verification.

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VALIDATION OF NEW LOT NUMBERS, Continued

Non-Controlled Documents The following non-controlled documents support this procedure.

- STA-R Max Reference Manual
- STAGO Compact Reference Manual
- STAGO Compact Max Reference Manual

Controlled Documents The following controlled documents support this procedure.

Document No.	Procedure
LAMC-PPP-0026	Quality Manual, Quality Control Policy
LAMC-PPP-0123	Safety Practices
LAMC-PPP-0127	Infection Control
LAMC-PPP-0128	Universal Body Substance Precautions
LAMC-PPP-0129	Handling of Regular and Infectious Waste
LAMC-PPP-0130	Cleaning Work Areas
LAMC-PPP-0132	Hand Washing Policy
LAMC-PPP-0134	Storage and Disposal of Chemical Hazardous Waste

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Signature Manifest

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Validation of New Lot Numbers

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