LOT CONVERSION PROTOCOL

Purpose

To define the policy for new lot conversion in coagulation studies for KP Moreno Valley Medical Center

To provide continuous quality data management after the full instrument validation has been completed.

Policy

The following must be performed on a new lot number of coagulation reagents prior to patient testing:

- Current lot and New lot Correlation
- Establishing Geometric Mean (PT)
- Total Precision (QC range)
- Determining normal reference range

Specimen collection

Collect patient samples in 3.2% sodium citrate according to the CLSI collection guidelines (CLSI H21-A4).

Centrifuge the blood for platelet poor plasma.

Perform double spinning samples before freezing specimens for coagulation testing.

Current Reagent Lot vs. New Reagent Lot Correlation

Prothrombin time:

Collect **40 patient** samples across the reportable range.
Recommended samples:

- 20 normal samples
- 15 therapeutic (1.5 – 4.0 INR)
- 3 samples (4.0-8.0 INR)
- 2 samples (8.0 - >10 INR)

- If there are no high samples, create by diluting with OK buffer.
- Enter the correct ISI for the new lot of reagent. Alternately, program New PT in raw mode and calculate INR in an Excel template.

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Current Reagent Lot vs. New Reagent Lot Correlation

APTT

Collect **40 patient** samples across reportable. Recommended samples:

- 20 normal samples
- 15 therapeutic (45-115 secs)
- 3 samples (120-200 secs)
- 2 sample (200-250 secs)

- If there are no high samples, create by diluting with OK buffer.

Fibrinogen

Because Fibrinogen is a calibrated test, it is not necessary to perform a lot conversion. Recommended samples:

Collect 10 patient samples across reportable range.

- Run 3 normal samples (200-450 mg/dl)
- Run 7 abnormal samples (60-190 mg/dl)

D-Dimer

Because D-Dimer is a calibrated test, it is not necessary to perform a lot conversion. Recommended samples:

Collect 10 patient samples across reportable range.

- Run 3 normal samples (0.00-0.50 ug/ml)
- Run 7 abnormal samples (0.50-20.00 ug/ml)

Unfractionated Heparin

Collect 20 patient samples across reportable range. Recommended samples:

- Run 10 samples (0.0-0.3 IU/mL)
- Run 8 samples (0.3-0.70 IU/mL)
- Run 2 samples (0.70-1.10 IU/mL)

Note

Submit data to Stago TSS for review

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Establishing Geometric Mean

A new Geometric mean must be verified for each new lot of PT (Neoplastine)

Run a minimum **of 20 screened normal samples** with the new PT on both analyzers.

- Run on each analyzer
- Geometric Means from all instruments must agree within 5%

INR Computation Validation

Manual INR verification must be performed:

- When the Geometric Mean has been changed
- Bi-annual

Retention of Current reference range and therapeutic range

Perform combined data analysis for normal and therapeutic ranges statistics

If all data meets acceptable criteria, the current ranges may be retained and no further action is necessary

If the data does not meet criteria, consult with the CLIA Director and Regional QA.

Total Precision (New QC range)

- Use control material that will be used for the assay
- Run each level several times a day or about six (6) times per day over five (5) days
- Run over the life of both the reagent and control
- Data will be used to create ‘site specific’ quality control range

Total: 30 points per analyte is recommended for routine assays. This is to verify that the new lot of reagent is working within the manufacturer’s specifications. It is acceptable to use the assigned control range for a short period of time (30 days) while control data is being

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Determination of QC Ranges

Standard deviation (SD) from the mean is computed and applied to the mean value to determine the actual reference range.

The control range is the mean of the results plus or minus 2 SD.

Normal Reference Range

Reference range data must be collected if current vs. new lots do not meet criteria.

The reference interval verification study may be performed using a minimum of **20 screened normal samples**:

- Centrifuge the blood for platelet poor plasma
- Perform routine tests within 4 hours of collection
- The collection should encompass several days to cover reagent life.

Criteria for Reference Range Normal Donors

- Age: Include ages that span the population reflecting your patient diversity.
- Sex: Equal numbers of males and females
- Drug History: Patients excluded if taking the following drugs:
  - Birth control or estrogen containing products
  - Coumadin
  - Heparin (UFH, LMWH or heparinoid)
  - Direct Thrombin Inhibitors
  - Antibiotics
- Conditions: Patients excluded if they are pregnant or have any known immunologic diseases.

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Correlation studies: Current Reagent Lot vs New Reagent Lot Summary

	Number of Samples	Normal	Stago Instrument	Abnormal/ Therapeutic	Form
PT/INR	40	20	A & B (geometric mean study)	20	CO-0231 A CO-0231 B
APTT	40	20	A	20	CO-0231 A
Fibrinogen	10	3	A	7	CO-0232
D-Dimer	10	3	A	7	CO-0232
Unfractionated Heparin	20	10	A	10	CO-0233

Instrument: Use Stago A as the 1st choice, if not available use Stago B.
For Geometric Mean study, run normal samples on both Stago A and Stago B

Total Precision Studies: New QC Lot Summary

	Number of Samples	Stago Instrument	Normal	Abnormal/ Therapeutic	Form
New QC Lot	30	A & B	30	30	CO-0234

Acceptance Criteria

Precision limits

Analyte	Intra-Run Precision				Total Precision (QC)			
	CV		SD		CV		SD	
	NL	ABN	NL	ABN	NL	ABN	NL	ABN
Prothrombin Time	≤ 2.5	≤ 2.5			≤5.0	≤5.0		
aPTT	≤ 2.5	≤ 2.5			≤5.0	≤10.0		
Fibrinogen	≤5.0	≤8.0			≤10.0	≤10.0		
D-Dimer			≤ 0.1	≤ 0.2			≤ 0.2	≤ 0.4
Heparin Assay			≤ 0.1	≤ 0.1			≤ 0.1	≤ 0.1

NOTE: Empty Cells = CV or SD Limit not applicable

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System Correlations: Comparison Between Identical Instrument and Reagent Systems

Analyte	System Correlations		
	R value	Slope	Mean Bias (%) from Average*
Prothrombin Time	≥ 0.95	0.9 – 1.1	+/- 5
INR	≥ 0.95	0.9 – 1.1	+/- 10
aPTT	≥ 0.95	0.9 – 1.1	+/- 8
Fibrinogen	≥ 0.95	0.9 – 1.1	+/- 10
D-Dimer	≥ 0.95	0.9 – 1.1	+/- 20
Heparin Assay	≥ 0.95	0.8 – 1.2	+/- 15

Lot Conversion

Analyte	Correlations			
	R value	Slope	Mean Bias (%) from Reference Value*	Mean Bias (Raw) from Reference Value^
Prothrombin Time	≥ 0.95	0.9 – 1.1	+/- 5	
INR	≥ 0.95	0.9 – 1.1	+/- 10	
aPTT Normal	≥ 0.95	0.9 – 1.1	+/- 5	
aPTT Overall	≥ 0.95	0.9 – 1.1	+/- 8	
Fibrinogen	≥ 0.95	0.9 – 1.1	+/- 10	
D-Dimer < 1.0	≥ 0.95	0.9 – 1.1	+/- 20	+/- 0.15 ug/mL FEU
D-Dimer ≥1.0 – 4.0	≥ 0.95	0.9 – 1.1	+/- 20	+/- 0.5 ug/mL FEU
Heparin Assay	≥ 0.95	0.8 – 1.2	+/- 15	+/- 0.2 IU

* The Mean Bias (Mean Difference) % is calculated using the following formula:
Mean of Raw Differences/Mean of Reference Values) x 100

^ The Mean Bias (Raw Difference) is the average of the individual differences between the "new" and the reference values in the reported unit of the assay.

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Reference Retrieved from Stago Lot Conversion Protocol (August 18, 2017). Document no. 17-UCSD-011.

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Reviewed and approved by:

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HISTORY PAGE

Effective Date**:** _____

Change type: New, major, minor	Changes made to SOP - describe	Signature responsible person/date	Medical Director review/date	Laboratory Director review/date	Date change implemented