The Why and How of:
Reagent / QC Lot Roll-over Validation
LabLink Interlab Reports

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Sandy Gardner
Region II Central

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Region III East
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Region I – Carol Shearer

Region II – Sandy Gardner

Region III – Mary Ann Kozy

Alaska

Hawaii
Hemostasis Application Consultant

- **Scope**
  - Field support for Clinical Application Specialist & Field Service Reps
  - Assay application and software
  - Training...customers and Dade Behring personnel
  - Seminar Presentations
  - Instrument Evaluations
  - IDN Instrument Implementation
  - Troubleshooting Escalation

- **Support**
  - 23 Sales Regions
  - 40 CAS’s
  - 146 FSR’s
  - 4200 Hemostasis analyzers

- **Special Projects**
  - Marketing
  - Second Level Support
  - America’s-Product Education Training
  - Sales
  - Global projects
Clinical Application Specialist (CAS)

- Working directly with the lab team on-site, responsibilities include:
  - On-site instrument customization and validation
  - On-site training of primary operator to perform basic operation, calibration, maintenance and troubleshooting
  - Normal Range and Precision studies, Method Correlations, Heparin Therapeutic Range, D-Dimer ROC curves
  - Statistical analyses of data for the lab and summary report
  - On-going training for laboratory as needed
The Why and How of:
Reagent / QC Lot Roll-over Validation

Sandy Gardner B.S., M.T. (ASCP)
Region II
Dade Behring Hemostasis Application Consultant
Lot Roll-over... Regulatory Agency Requirements

**CLIA ’88**
- 493.1255 Calibration
- 493.1269 PT MNPT for INR calculation

**CAP**
- HEM.23360 GeoMean MNPT PT sec
- HEM.23430 Check INR calculation
- HEM.23453 aPTT Therapeutic Range
- HEM.23476 aPTT Therapeutic Range establishment
- HEM.23500 Reference Intervals
- HEM.23575 Recommendation for anticoagulant therapeutic range
- HEM.24575 New reagent lots vs. old reagent lots
- HEM.38006 New lot calibration
- HEM.38008 Quality Control acceptable range
Lot Roll-over...References

- **CLSI**
  - H47-A 1996  One Stage Prothrombin Time (PT)
  - EP18-A 2002  Quality Management for unit-use testing
Calibration

- **Calibrated assays**
  - Fibrinogen
  - Factors
  - D-Dimer
  - ATIII
  - Protein C and Protein S
  - vWF
  - alpha-2 Antiplasmin
  - Plasminogen
  - Heparin Xa

- **Frequency**
  - Reagent lot number change
  - Verification every 6 months
Calibration

- Curve
  - Minimum 3 points
    - Zero
    - Mid point value
    - Maximum value near upper limit of assay
Reference Interval...PT and aPTT

- Reference Interval Verification (Normal Range Study)
  - Minimum 20 samples
  - Represent laboratory’s healthy population guidelines
    - No hospital/clinic patients
    - Questionnaire
      - 10 males / 10 females
      - *a priori* criteria with exclusion before testing
      - *a posteriori* criteria with exclusion after testing
  - Exclude outliers and replace with additional sample
  - Acceptability of 95 % range
    - +/- 10 % within range
    - > 10% outside of range another 20 samples tested
Reference Interval...PT and aPTT

- **Sample Criteria**
  - 3.2% sodium citrate
  - Process per CLSI/CAP Guidelines
    - PT: uncentrifuged/centrifuged unopened 18-24°C 24 hours
    - aPTT: uncentrifuged/centrifuged unopened 2-4°C or 18-24°C 4 hours
    - Platelet poor plasma @ < 10,000/uL
  - Frozen specimens CLSI Guidelines
    - -20°C for 2 weeks
    - -70°C for 6 months
    - Thaw @ 37°C and test immediately or max 2 hours @ 4°C
PT MNPT for INR Calculation

- Geometric Mean of Reference Interval
  - More appropriate estimate of the average value

- Geometric Mean Calculation
  - \( GM = \text{antilog}\left[\frac{\log(X_1) + \log(X_2) + \log(X_3) + \ldots + \log(X_n)}{n}\right] \)
  - Microsoft Excel
  - EP Evaluator version 7

- INR Calculation
  - \( \text{INR} = \left\{ \frac{\text{PT sec Patient}}{\text{GeoMNPT sec}} \right\} \text{ISI} \)
PT MNPT for INR Calculation

- Verification of INR Calculation
  - Yearly
  - Change in lot, reagent, instrument
  - Establishment of new PT reference range
  - Change in INR calculation

- Check INR calculated by analyzer or LIS
  - Check @ 2.0 and 3.0 INR
  - Manual calculation
  - Microsoft Excel calculation
aPTT Unfractionated Heparin Therapeutic Range

- **aPTT vs. Heparin Xa assay**
  - 30 – 40 patients receiving only UFH
  - Samples should cover the assay range
  - INR <1.3 to assure no concomitant Coumadin therapy
  - 5 – 10 normal samples
  - aPTT processed and assayed per CLSI Guidelines
  - Heparin Xa assayed fresh or frozen
    - Double centrifuge sample
    - Platelet poor plasma <10,000/uL
    - CLSI storage guidelines

- **Calculation of Therapeutic Range**
  - Plot Heparin Xa IU/mL (X) vs. aPTT seconds (Y)
  - Heparin Xa Therapeutic Range = 0.3 – 0.7 IU/mL
  - Calculate aPTT Range from Regression Line
    - Lower aPTT value = Slope (0.3) + Intercept
    - Upper aPTT value = Slope (0.7) + Intercept
aPTT Unfractionated Heparin Therapeutic Range

Therapeutic Range

<table>
<thead>
<tr>
<th>Hep Xa</th>
<th>aPTT</th>
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</thead>
<tbody>
<tr>
<td>0.3</td>
<td>65</td>
</tr>
<tr>
<td>0.7</td>
<td>95</td>
</tr>
</tbody>
</table>

N = 77
Corr Coef (R) = 0.67
Slope = 75.7
Intercept = 41.9
Things to Consider

- INR > 1.3 should not be used
- Evaluate “unusual” results
  - Elevated aPTT with 0.0 Heparin Xa
  - Low aPTT with elevated Heparin Xa
  - Must justify deletion of data point
- Consider
  - Sample processing
  - Direct Thrombin Inhibitors
  - Other drugs
- Avoid
  - Insufficient samples
  - aPTT values above reportable range
  - Heparin Xa values above calibration curve
  - More than 2 samples per patient unless dose change
aPTT Therapeutic Range Validation

- Establish initial reagent lot using Heparin Xa vs. aPTT
- Subsequent reagent lot validation based on Method Correlation
- 20 - 30 samples (statistically significant) covering range of assay
- Plot current lot on X axis & new lot on Y axis
- Evaluate regression data
- Record difference between the means of old & new
- Year 3, 4, etc. determine cumulative mean difference
- Acceptable difference of mean or cum mean = < 7 seconds
# Validation of Heparin Sensitivity

## with Existing, Validated aPTT Reagent

<table>
<thead>
<tr>
<th>Year</th>
<th>Mean Current</th>
<th>Mean New</th>
<th>New – Current</th>
<th>Cum Sum</th>
<th>Accept</th>
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<tbody>
<tr>
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<tr>
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<tr>
<td>2004a</td>
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<td>71.2</td>
<td>+9.2</td>
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<td>2004b</td>
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</table>

A difference of $\geq 7$ sec between Means or change in Cum Sum requires evaluation and action. 0 – 5 sec preferred.

**ACTION for $> 7$ second difference:**

1. Evaluate second lot
2. Reestablish Therapeutic Range
Method Verification (Correlation)

- Patient sample comparisons recommended as good laboratory science

- Normal samples "rarely" change lot to lot

- Abnormal samples detect differences in reagent sensitivity

- Allows comparison of assay data range to detect differences in patient result recovery
Method Verification Study

- 40 patient samples
- 20 normal + 20 abnormal
- Values cover range of assay normal to abnormal
- Assay on current and new lots within 1 hour optimally
- Calculate data with regression analysis

Lot to Lot Consistency
- Corr Coef (R) 0.90 – 0.95 acceptable
  0.96 – 0.98 good
  0.99 – 1.00 excellent
- Slope 1.00 +/- 0.05
- Intercept 0.00 +/- 95%

\[\text{Dade Behring}\]
\[\text{Every minute of every day}\]
Quality Control Ranges

- Establish QC ranges for new lot numbers
  - New lot reagent + new lot QC material
  - Current lot reagents + new lot QC material
  - Unassayed controls
  - Assayed controls...recommend establish lab range

- Establish Range
  - Minimum 20 measurements
    - 20 working days
    - 10 working days / 2 runs per day
    - Outliers...discard and replace
  - Multiple vials, multiple techs, multiple days builds system variability into data

- QC Data Significant Figure
  - One more significant digit than reportable value
  - Provides better mean and SD for data calculation
Quality Control

- **Data Calculation**
  - Mean......average of data
  - SD........accounts for random error in system
  - % CV......variation around the mean

- **Coagulation Quality Control**
  - Every 8 hours of testing
  - 2 levels minimum
    - Normal level
    - Abnormal level
Tips & Tricks for Lot Roll-over

- Communicate with QAP Coordinators
  - Establish volumes
  - Establish ship dates
  - Monitor usage

- Automated analyzers
  - Simultaneous assay of current and new lot numbers
  - PT vs. New PT
  - aPTT vs. New aPTT
  - Current QC with current reagent lots
  - New QC with new reagent lots or current lots

- Dade Behring analyzers...refer to Lot Roll-over procedures
  - Contact local CAS or TAC
The Why and How of:
LabLink Interlab Reports

Carol Shearer B.S., CLS (NCA), M.T.(ASCP)
Region I
Dade Behring Hemostasis Application Consultant
Interlab Program...What Is It?

- Comparison of lab data to group data
- Gives reference point to assure system is in control
- Additional Tool
  - Assess stability of test system
  - Aid in setting QC limits and rules
  - Aid in troubleshooting
Interlaboratory Survey Group

- QC lot number specific
- Analyte specific
- Reagent type not lot specific
- Same instrument + all instruments
- Data submitted monthly
LabLink® On-line Set-up

- www.dadebehring.com
- Register
- Configure
- Tools
  - LabLink® On-line Quick Instructions
  - QAP Coordinator 1-800-242-DADE opt 4 opt 2
**Interlaboratory Report Data Entry**

- Submit monthly
  - N (number of data points)
  - Mean
  - SD

<table>
<thead>
<tr>
<th>Instrument: SYSMEX CA 1500</th>
<th>Lot#: 548111/538277/548311/LFC/HPL/HPH</th>
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<tbody>
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<td>Month: JUN 2007</td>
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<table>
<thead>
<tr>
<th>Prothrombin Time (seconds)</th>
<th>DADE INNOVIN, LIGHT SCATTER</th>
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<tbody>
<tr>
<td>Form Type: NONE</td>
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</table>

| Ci-Trol 1 - Lot# 548111    |                                        |
| Shift Day Points Mean SD   |                                        |
| 1  55  10.713  0.261       |                                        |

| Ci-Trol 2 - Lot# 538277    |                                        |
| Shift Day Points Mean SD   |                                        |

| Ci-Trol 3 - Lot# 548311    |                                        |
| Shift Day Points Mean SD   |                                        |
| 1  50  47.43  1.77         |                                        |
## Lab Statistics Report

### Product: Ci-Trol Lot#: 548111/538277/548311/LFC/HPL/HPH

### Shift:  Month: JUN  Year: 2007  Test: Prothrombin Time

### Level 1: 548111

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<tr>
<th>Prothrombin Time (seconds)</th>
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<tr>
<td></td>
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<td>&quot;DADE INNOVIN&quot;</td>
<td>10.7</td>
<td>0.26</td>
</tr>
<tr>
<td>&quot;Test System Peer&quot;</td>
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<tr>
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### Level 3: 548311

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## Prothrombin Time (seconds)

### Ci-Trol 1 - Lot# 548111

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<tr>
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<tr>
<td>Jun</td>
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<tr>
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### Ci-Trol 3 - Lot# 548311

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<td>Period</td>
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</tr>
<tr>
<td>LTD</td>
<td>46.6</td>
</tr>
</tbody>
</table>

### Total Error Graph (Peer vs Test System Peer)

- **LTD**
  - CLIA: 12.117
  - CLIA: 8.008

- **Jun**
  - CLIA: 12.112
  - CLIA: 8.852

### Total Error Graph (Peer vs Test System Peer)

- **LTD**
  - CLIA: 53.802
  - CLIA: 39.878

- **Jun**
  - CLIA: 53.712
  - CLIA: 39.705
# Individual Lab Report Data

## Prothrombin Time (seconds)

<table>
<thead>
<tr>
<th>Period</th>
<th>Mean</th>
<th>SD</th>
<th>CV</th>
<th># Points</th>
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## Test System Peer

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<tr>
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<th>SD</th>
<th>Avg. CV</th>
<th>Peers</th>
<th># Points</th>
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<th>CVI</th>
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## Method Principle Peer

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<th>Period</th>
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</thead>
<tbody>
<tr>
<td>Jun</td>
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<td>0.32</td>
<td>1.6</td>
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<tr>
<td>LTD</td>
<td>10.5</td>
<td>0.32</td>
<td>2.0</td>
</tr>
</tbody>
</table>

## Total Error Graph (Peer=Test System Peer)

- LTD: CLIA 12.187, Peer Mean 12.112
- Jun: CLIA 9.006, Peer Mean 8.052
# Individual Lab Report Data

**Test System Peer**

<table>
<thead>
<tr>
<th>Period</th>
<th>Avg. Mean</th>
<th>SD</th>
<th>Avg. CV</th>
<th>Peers</th>
<th># Points</th>
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**Method Principle Peer**

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</table>

**SDI** = Lab mean - Group Mean

**Group SD**

**CVI** = Lab CV / Group CV

---

**Prothrombin Time (seconds)**

**Ci-Trol 1 - Lot# 548111**

**Total Error Graph (Peer=Test System Peer)**

- LTD
  - CLIA: 12.187
  - Peer Mean: x 10.700
- Jun
  - CLIA: 12.112
  - Peer Mean: x 10.713
Total Error = % bias + (2 x CV)

% bias = (Lab mean – Group mean)x100 / Group mean
Total Error

- Lab’s Imprecision
- Lab’s Bias
- Lab’s Total Error
# Monthly Summary Report

## DADE LAB LINK

### Notes

## Monthly Summary Report

Ci-Trol Jun, 2007

## Prothrombin Time (seconds)

<table>
<thead>
<tr>
<th>Test</th>
<th>LTD</th>
<th>Jun</th>
<th>May</th>
<th>Apr</th>
<th>Mar</th>
<th>Feb</th>
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<th>Dec</th>
<th>Nov</th>
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<tr>
<td><strong>CI-Trol 1 - Lot# 548111</strong></td>
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<td></td>
<td></td>
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<td></td>
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</tr>
<tr>
<td><strong>Your Lab</strong></td>
<td>SYSMEX CA 1500/7000, LIGHT SCATTER, DADE INNOVIN</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Mean</td>
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<td>10.6</td>
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<tr>
<td>SD</td>
<td>0.17</td>
<td>0.26</td>
<td>0.17</td>
<td>0.17</td>
<td>0.17</td>
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<td>1.6</td>
<td>1.6</td>
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<td>1.4</td>
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<td><strong>Test System Peer</strong></td>
<td>SYSMEX CA 1500/7000, LIGHT SCATTER, DADE INNOVIN</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Avg Mean</td>
<td>10.6</td>
<td>10.6</td>
<td>10.6</td>
<td>10.6</td>
<td>10.6</td>
<td>10.6</td>
<td>10.6</td>
<td>10.6</td>
<td>10.6</td>
<td>10.6</td>
</tr>
<tr>
<td>Peers</td>
<td>56</td>
<td>43</td>
<td>50</td>
<td>51</td>
<td>49</td>
<td>51</td>
<td>49</td>
<td>47</td>
<td>47</td>
<td>46</td>
</tr>
<tr>
<td>SDI</td>
<td>0.6</td>
<td>0.6</td>
<td>0.9</td>
<td>1.0</td>
<td>0.7</td>
<td>0.5</td>
<td>0.5</td>
<td>0.7</td>
<td>0.8</td>
<td>0.2</td>
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<tr>
<td>CVI</td>
<td>0.9</td>
<td>1.8</td>
<td>1.0</td>
<td>1.0</td>
<td>0.9</td>
<td>0.8</td>
<td>0.7</td>
<td>0.7</td>
<td>0.9</td>
<td>1.0</td>
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</tbody>
</table>

| **CI-Trol 2 - Lot# 548311** |
| **Your Lab** | SYSMEX CA 1500/7000, LIGHT SCATTER, DADE INNOVIN |
| Mean | 47.3 | 47.4 | 47.5 | 47.2 | 47.3 | 47.2 | 47.3 | 47.4 | 47.4 | 46.7 |
| SD | 1.40 | 1.77 | 1.43 | 1.22 | 1.28 | 1.22 | 1.36 | 1.10 | 1.37 | 1.65 |
| CV | 3.0 | 3.7 | 3.0 | 2.6 | 2.7 | 2.6 | 2.9 | 2.3 | 2.9 | 3.5 |
| # Points | 513 | 50 | 60 | 61 | 61 | 61 | 60 | 58 | 53 | 40 |
| **Test System Peer** | SYSMEX CA 1500/7000, LIGHT SCATTER, DADE INNOVIN |
| Avg Mean | 40.8 | 46.7 | 40.8 | 46.8 | 46.9 | 46.9 | 46.9 | 47.0 | 47.1 | 46.9 |
| Peers | 55 | 41 | 48 | 50 | 48 | 51 | 51 | 48 | 45 | 40 |
| SDI | 0.8 | 1.0 | 1.0 | 0.5 | 0.6 | 0.3 | 0.5 | 0.5 | 0.4 | -0.3 |
| CVI | 1.1 | 1.5 | 1.2 | 1.0 | 1.0 | 0.9 | 1.0 | 0.9 | 1.2 | 1.5 |
Exception Notes Report

The flags below are based on the statistical analysis of your data compared to your test system peer and do not necessarily indicate a quality control problem. See Individual Lab Report for additional detail.

Decisions regarding these flags should be based both on analytical significance and also medical significance of your quality control data compared to test system peer data.

Q.C. Monitor Flags
This section flags SDI, CVI, and Total Error data from the current month based on comparison with the Test System Peer.

<table>
<thead>
<tr>
<th>Abnormal Fibrinogen (mg/dL) SYSMEX CA 1500 - 1 DADE THROMBIN</th>
<th>LIGHT SCATTER</th>
</tr>
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<tbody>
<tr>
<td>Control</td>
<td>Flag</td>
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<tr>
<td>Abnormal Flag Control Lot # LFC</td>
<td>Total Error</td>
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</tbody>
</table>

Reviewed By: __________________________ Date: __/__/____
Action taken: __________________________

Data Exclusion Flags
These data have not been included in the peer statistics based on Dade LabLink database checks. The data are also provided on your Data Verification Report (an optional report).

No flagged data for this month
### Condensed Interlab Report

**Product:** Ci-Trol  
**Instrument Group:** SYSMEX CA 1500/7000  
**Lot #:** 548111/538277/548311/LFC/HPL/HPH

#### Test: Prothrombin Time  
**Month:** JUN  
**Year:** 2007

#### Prothrombin Time (seconds)

<table>
<thead>
<tr>
<th>LIGHT SCATTER</th>
<th>JUN-2007</th>
<th>LTD</th>
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<tbody>
<tr>
<td></td>
<td>Level</td>
<td>Mean</td>
</tr>
<tr>
<td><strong>SYSMEX CA 1500/7000</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DADE INNOVIN</td>
<td>L1</td>
<td>10.59</td>
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<tr>
<td></td>
<td>L2</td>
<td>27.01</td>
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<tr>
<td></td>
<td>L3</td>
<td>46.71</td>
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<tr>
<td><strong>Method Principle Peer</strong></td>
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<tr>
<td>L1</td>
<td>10.55</td>
<td>3.13</td>
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<tr>
<td>L2</td>
<td>26.81</td>
<td>4.24</td>
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<tr>
<td>L3</td>
<td>46.65</td>
<td>2.85</td>
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<tr>
<td><strong>All Test Systems Peer</strong></td>
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<tr>
<td>L1</td>
<td>10.66</td>
<td>4.70</td>
</tr>
<tr>
<td>L3</td>
<td>45.19</td>
<td>10.85</td>
</tr>
</tbody>
</table>

[Back](#)
Value of Interlaboratory Program

- Allows comparison to many other labs
- Aids in setting QC limits
- Aids in assessing accuracy and precision
- Aids in troubleshooting
- Assists in evaluating lot to lot variation
Web Sites

- www.dadebehring.com
- www.cap.org
- http://wwwn.cdc.gov/clia/regs/subpart_k
- www.dgrhoads.com
- www.westgard.com
- www.clsi.org
Questions & Answers

-To ask a question in the webcast window:
  - Type your question in the Question Box below the presentation.
  - Click Submit.

-To ask a question via the telephone:
  - Dial (800) 661-2563.
  - Press *1 on your touch-tone keypad.
Thank You!

For assistance with Dade Behring Hemostasis products contact the local Dade Behring Sales Representative, CAS or TAC.

For LabLink® assistance contact the Dade Behring QAP Coordinator

1-800-242-DADE
References

- College of American Pathology Hematology-Coagulation Checklist, revised 10-31-06
- CLIA '88, Subpart K, Quality Systems for Nonwaived Testing
- CLSI, H47-A, One-Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (APTT) Test, June 1996
- CLSI, EP5-A, Evaluation of Precision Performance of Quantitative Measurement Methods, August 2004
- CLSI, EP15-A2, User Verification of Performance for Precision and Trueness, April 2006
- CLSI, C28-A2, How to Define and Determine Reference Intervals in the Clinical Laboratory, June 2000
- Establishing APTT Values Corresponding to the Heparin Therapeutic Range, Dade Behring, Hemostasis Technical Bulletin 01-2004, January 2004
- CAP Today, How to Validate Heparin Sensitivity of aPTT, Dr. John Olson, October 2004
- EP Evaluator version 7, David Rhoads, Interpretation Guidelines, 2005
- Dade Behring Control Plasma N and Control Plasma P package insert, January 2005
- Dade Behring LabLink® Quality Assurance Program