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| **Document Contact:** | *Tamara Sabih: Medical Technologist Lead* |
| **Area:** | *Laboratory-Hematology* |
| **Key Words:** | |
| **Applicability:** | *Royal Oak* |

# Coagulation Correlations-RO

Document Type: Procedure

# I. PURPOSE AND OBJECTIVE:

This document outlines how to perform correlation between each coagulation analyzer.

# II. PRINCIPLES:



The CLIA ’88 regulations state that “if a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple sites, the lab must have a system that twice a year evaluates and defines the relationship (comparable results) between test results” (FR 493.1709). Beaumont Hospital Coagulation Laboratory will perform correlations of 5 patient samples between the IL ACL TOPs analyzers twice a year for each of the following assays: Prothrombin Time (PT), Activated Partial Thromboplastin Time (aPTT), Fibrinogen (FIB), Thrombin Time (TT) and D-dimer (DD). Target limits have been defined from precision/comparison studies that are considered analytically and clinically acceptable differences between such instruments/methods.

# III. ACRONYMS:

A. Abnormal (ABN)

B. Activated Partial Thromboplastin Time (aPTT)

C. Clinical Laboratory Improvement Amendments (CLIA)

D. D-Dimer HS 500 (DD)

E. Fibrinogen Equivalent Units (FEU)

F. International Normalized Ratio (INR)

G. Instrumentation Laboratory (IL)

H. Laboratory Information System (LIS)

I. Normal (N)

J. Prothrombin Time (PT)

K. Standard Deviation (SD)

L. Thrombin Time (TT)

# IV. PROCEDURE:

A. Select 5 patient samples that are within the following ranges for the respective assays:

1. **PT / INR:**
   a. Select 2 patient specimens that are within the current normal range with an INR of 0.9-1.1.
   b. Select 3 patient specimens with INR's > 2.0; one of these specimens must be "very high".
2. **aPTT:**
   a. Select 2 patient specimens that are within the current normal range.
   b. Select 3 patient specimens that are greater than the current normal range; one of these specimens must be "very high".
3. **FIBRINOGEN:**
   a. Select 2 patient specimens that are within the current normal range.
   b. Select 3 patient specimens that are outside the current normal range.
4. **TT:**
   a. Select 2 patient specimens that are within the current normal range.
   b. Select 3 patient specimens that are greater than the current normal range.
5. **D-Dimer**
   a. Select 2 patient specimens that are within the current normal range.
   Select 3 patient specimens that are greater than the current normal range.



B. **The IL ACL TOPs will be correlated as follows:**

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|---|---|
| IL ACL TOP 2 | IL ACL TOP 1 |
| IL ACL TOP 3 | IL ACL TOP 1 |
| IL ACL TOP 4 | IL ACL TOP 1 |

1. Review a recent worklist in the LIS to determine which specimens are suitable for correlations.
2. Run the specimen on all four analyzers in the "Manual Mode" so that the desired analyzer is used.
3. NOTE: The specimen must also be run on the original analyzer since values may change depending on the time it has been stored at room temperature.
4. Record all data on the "Coagulation Correlations" logsheet and leave for Coagulation management/ Medical Director Review in the Correlation Binder.

C. **Limits of Acceptability (Target Limits)**

1. Record the specified differences between the indicated coagulation analyzers in the spaces provided on the "Twice a Year Coagulation Correlations" logsheet. **See attachment A**
2. Verify that the difference results are within the following target limits of acceptability for each of the assays. The following are the acceptable target limits for instrument comparison:

| ASSAYS | Tolerance Limits |
|---|---|
| PT (N) | ± 0.5 sec |
| PT (ABN) | ± 2.7 sec |

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|---|---|
| INR (N) | ± 0.2 |
| INR (ABN) | ± 0.4 |
| aPTT (N) | ± 3.5 sec |
| aPTT (ABN) | ± 6.5 sec |
| Fibrinogen (<400) | ± 30 mg/dL |
| Fibrinogen (300-400) | ± 45 mg/dL |
| Fibrinogen (>400) | ± 60 mg/dL |
| D-Dimer HS 500 (<500) | ±100 ng/mL FEU |
| D-Dimer HS 500(500-1000) | ±150 ng/mL FEU |
| D-Dimer HS 500 (>1000) | ±250 ng/mL FEU |
| TT (N) | ± 3.5 sec |
| TT(ABN) | ± 15 sec |

3. Coagulation management and the Medical Director will review the correlation data twice a year.
4. The 2004 CG2-B, CGL-B 2008 and CGL-A 2009 surveys SD ranges were used as a starting point for determination of allowable limits.

D. **Corrective Action;**

1. If the difference comparisons are within acceptable limits, no further testing is necessary.
2. If any one parameter is outside the limits of acceptability two or more times, find alternate specimen(s) to run and compare. If problem persists, notify the IL service rep of the specific problem. Fill out a corrective action form explaining corrective measures taken and repeat the parameter with new specimens.



## Attachments

Attachment A-Twice Per Year Correlations.pdf

## Approval Signatures

| Step Description | Approver | Date |
|---|---|---|
| CP Chief Medical Director | Peter Millward: Chief, Pathology Service Line | 5/13/2021 |
| Coagulation Medical Director Designee | Marc Smith: System Med Dir, Coagulation | 5/13/2021 |
| Policy and Forms Steering Committee Approval (if needed) | Tamara Sabih: Medical Technologist Lead | 5/10/2021 |
| Policy and Forms Steering Committee Approval (if needed) | Gail Juleff: Project Mgr Policy | 5/10/2021 |
| System Manager | Rebecca Bacarella: Mgr Laboratory | 5/10/2021 |
| | Tamara Sabih: Medical Technologist Lead | 4/28/2021 |

## Applicability

Royal Oak