Beaumont Laboratory
Royal Oak

Effective Date: 11/18/2019
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Related Documents:
CAP Survey 2009 CGL-A2009
CAP Survey 2008 CGL-B2008
CAP Survey 2004 CG2-B2004

COAGULATION CORRELATIONS PROCEDURE

RC.HM.CG.PR.007.r10

Introduction

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.

Specimen Requirements

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

A. PT / INR:
- Select 2 patient specimens that are within the current normal range with an INR of 0.9-1.1.
- Select 3 patient specimens with INR's > 2.0; one of these specimens must be "very high".

B. aPTT:
- Select 2 patient specimens that are within the current normal range.
- Select 3 patient specimens that are greater than the current normal range; one of these specimens must be "very high".

C. FIBRINOGEN:
- Select 2 patient specimens that are within the current normal range.
- Select 3 patient specimens that are outside the current normal range.

D. TT:
- Select 2 patient specimens that are within the current normal range.
- Select 3 patient specimens that are greater than the current normal range.

E. DD:
- Select 2 patient specimens that are within the current normal range.
- Select 3 patient specimens that are greater than the current normal range.

Instruments Correlated

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The IL ACL TOPs will be correlated as follows:

IL ACL TOP 2	IL ACL TOP 1
IL ACL TOP 3	IL ACL TOP 1
IL ACL TOP 4	IL ACL TOP 1

Procedure

- Review a recent worklist in the LIS to determine which specimens are suitable for correlations.
- Run the specimen on all four analyzers in the “Manual Mode” so that the desired analyzer is used.
  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.
- Record all data on the “Coagulation Correlations” logsheet and leave for Coagulation management/Medical Director Review in the Correlation Binder.

Limits of Acceptability (Target Limits)

- Record the specified differences between the indicated coagulation analyzers in the spaces provided on the "Twice a Year Coagulation Correlations” logsheet.
- 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:

	IL ACL TOP
PT (N)	± 0.5 sec
PT (ABN)	± 2.7 sec
INR (N)	± 0.2
INR (ABN)	± 0.4
aPTT (N)	± 3.5 sec
aPTT (ABN)	± 6.5 sec
FIB (< 300)	± 30 mg%
FIB (300-400)	± 45 mg %
FIB (>400)	± 60 mg%
TT (N)	± 8.5 sec
TT (ABN)	± 15 sec
DD (<500)	± 50 ng/mL FEU
DD (500-1000)	± 150 ng/mL FEU
DD (>1000)	± 250 ng/mL FEU

- Coagulation management and the Medical Director will review the correlation data twice a year.
- 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.

Corrective Action

- If the difference comparisons are within acceptable limits, no further testing is necessary.
- 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 Siemens service rep of the specific problem. Fill out a corrective action form explaining corrective measures taken and repeat the parameter with new specimens.

Authorized Reviewers

Medical Director, Coagulation

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Document Control

Location of Master: Coagulation Procedure Manual
Master electronic file stored on the Beaumont Laboratory server:
S:\HEMACOAG\Document Control\Coagulation\Procedure\Master Documents\Coagulation Correlations Procedure.doc
Number of Controlled Copies posted for educational purposes: 0
Number of circulating Controlled Copies: 0
Location of circulating Controlled Copies: NA

Document History

Signature	Date	Revision #		Related Documents Reviewed/ Updated
Prepared by: Jon B. Goller	10/2001			
Approved by: Joan C. Mattson, MD	12/05/2001			
Reviewed by: (Signature)	**Date**	**Revision #**	**Modification**	**Related Documents Reviewed/ Updated**
Joan C Mattson, MD	12/05/2001		New protocol	
Joan C Mattson, MD	08/01/2002		Change from monthly to quarterly.	
Noelle Procopio, MT (ASCP) SH	12/29/2003		No change	
Joan C Mattson, MD	01/02/2004		No change	
Joan C Mattson, MD	10/03/2004		Adjusted target limits for the CA 1500 and the BCS.	
Joan C Mattson, MD	12/23/2004		Pg 1 changed name “Twice a year Correlation procedure”; Pg 2 Note: Fibrogen and TT run on CA 1500 only. Changed “LASC” to PCDPS.” Under procedure deleted assigned to Coag tech last Tuesday of the month; pg 3 changed CA 1500 INR to + 0.18.	
Joan C Mattson, MD	12/30/2005	00	Standardized procedure format; updated acceptable limits and corrective action, pg 2.	
Joan C Mattson, MD	12/12/2006	01	Updated procedure to include STAT lab analyzer, pg 1 and 2; added STAT lab controlled copy, pg 2	
Marc Smith, MD	05/09/2007		No change	
Marc Smith, MD	11/14/2007	02	Pg 3 changed INR (N) and (AB). Added FIB >400.	
Marc Smith, MD	09/08/2008	03	Updated analyzers; deleted references to PCDPS; updated Dade to Siemens.	
Marc Smith, MD	04/30/2009	04	Updated CAP surveys and changed PT(ABN) and INR(ABN) tolerance limits.	
Marc Smith, MD	04/04/2010	05	Added header CA 7000 and BCS tolerance limits. Change BCS INR (ABN) from ± 0.4 to ± 0.5.	
Marc Smith, MD	05/23/2011		RC.HM added to SOP#; new format	
Marc Smith, MD	03/14/2012	06	Added D-dimer tolerance limits.	

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Document History - continued

Marc Smith, MD	12/30/2014	07	Pg 1 added specimen requirements and target limits for the following assays:LMWH,UNFH,F8,vWFag, F9.	OK
Marc Smith, MD	06/22/2016	08	Pg 2 added RCF	OK
Marc Smith, MD	10/02/2017	09	Pg 1 deleted BCS/BCSXP correlations of special coag tests; removed BCS and associated tests from correlation testing; updated logo.	OK
Elizabeth Sykes, MD	02/22/2018			
Peter Millward, MD	3/13/2019			
Marc Smith, MD	11/18/2019	**10**	Changed CA7000 to IL ACL TOPs	OK

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