Beaumont

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Document Contact:	*Tamara Sabih: Medical Technologist Lead*
Area:	*Laboratory-Hematology*
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Coagulation Autoverification-RO

Document Type; Policy

I. PURPOSE AND OBJECTIVE:

The purpose of this policy is to identify how to detect any failure of the software system to release or not release sample results for auto-verification based on special criteria and reported to Information Technology (IT) for correction / modification of the software. This is a zero-tolerance system for errors in the Laboratory Information System (LIS) software application.

II. POLICY STATEMENT:

The Coagulation laboratory initiated auto-verification on 10/6/01. It is the department policy that all normal results and selected abnormal results from the IL ACL-Top coagulation analyzers will be auto-verified in the laboratory's LIS.

III. ANNUAL REVIEW:

Validation of auto-verification will be performed annually and whenever there is a change to the system that could affect the autoverification logic.

IV. ACRONYMS:

A. Activated Partial Thromboplastin Time (aPTT)

B. Anticoagulant Management Services (AMS)

C. Fibrinogen Equivalent Units (FEU)

D. Fibrinogen (FIB)

E. International Normalized Ratio (INR)

F. Seconds (sec)

G. Thrombin Time (TT)

V. PROCEDURE:

A. The following criteria will be used for autoverification:

Autoverification Criteria

IL ACL TOP Coagulation Analyzers

B. When all of the following criteria evaluate as "True", then the LIS system will auto-verify INR, aPTT,FIB, TT, or D-dimer.

Criteria Name	Range
INR	0.9 – 3.0
INR (AMS)	0.9 – 3.0
aPTT	25 - 95 sec
FIB	101 - 449 mg/dL
TT	16 - 25 sec
D-dimer	250 – 10,000 ng/mL FEU

Delta Check Rules

C. In addition, an assay not passing the following delta check rules assigned into the LIS will not be auto-verified:

Criteria Name:	Range:
All INR's	Difference Between Previous INR and Current INR ≥ 2.0

D. Validation of auto-verification done by using previously tested patient samples, which are selected in order to challenge each of the previously stated criteria as listed below.

Assay	Criteria
INR/INR AMS	0.9-3.0 sec, passed delta check, autoverified
INR/INR AMS	0.9-3.0 sec failed delta check, did not autoverify
INR/INR AMS	> 3.0 sec, did not autoverify
aPTT	< 25 sec, did not autoverify
aPTT	25-95 sec, autoverified
aPTT	> 95 sec, did not autoverify
FIB	0-100 mg/dL, did not autoverify
FIB	101-449 mg/dL, autoverified
FIB	450-1000 mg/dL, did not autoverify
TT	<16 sec, did not autoverify
TT	16-25 sec, autoverified
TT	> 25 sec, did not autoverify
D-Dimer	<250 ng/mL FEU, did not autoverify
D-Dimer	250 – 10,000 ng/mL FEU, autoverified
D-Dimer	>10,000 ng/mL FEU, did not autoverify

Attachments

Attachment A-Coagulation Autoverification Validation Worksheet.pdf

Approval Signatures

Step Description	Approver	Date
CP Chief Medical Director	Peter Millward: Chief, Pathology Service Line	5/1/2021
Coagulation Medical Director Designee	Marc Smith: System Med Dir, Coagulation	4/30/2021
Policy and Forms Steering Committee Approval (if needed)	Tamara Sabih: Medical Technologist Lead	4/22/2021
Policy and Forms Steering Committee Approval (if needed)	Gail Juleff: Project Mgr Policy	4/22/2021
System Manager	Rebecca Bacarella: Mgr Laboratory	4/22/2021
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Applicability

Royal Oak