Beaumont Laboratory
Royal Oak

Effective Date: 12/10/2019
Supersedes: 10/02/2018
Related Documents: NA

AUTOVERIFICATION POLICY

RC.HM.CG.PY.001.r09

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. The following criteria will be used for autoverification:

Autoverification Criteria
IL ACL-Top Coagulation Analyzers

When all of the following criteria evaluate as "True", then the LIS system will auto-verify INR, Activated Partial Thromboplastin Time (aPTT), Fibrinogen (FIB), Thrombin Time (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

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

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Validation of auto-verification will be performed annually and whenever there is a change to the system that could affect the autoverification logic. This is done by using previously tested patient samples, which are selected in order to challenge each of the previously stated criteria as listed below.

Validation Samples

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	0-150 mg/dL, did not autoverify
FIB	151-449 mg/dL, autoverified
FIB	449-1000 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

This is a zero-tolerance system for errors in the LIS software application. Any detected failure of the software system to release or not release sample results for auto-verification based on these criteria will be reported to IT for correction / modification of the software.

Authorized Reviewers

Medical Director, Coagulation

AUTOVERIFICATION POLICY

Document Control

Location of Master: Coagulation Procedure Manual
Master electronic file stored on the Clinical Pathology server:
S:\HEMACOAG\Document Control\Coagulation\Policy\Master Document\Autoverification policy.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		
Prepared by: Karri Henderson MT (ASCP)	03/28/2007		
Approved by: Marc Smith MD	03/28/2007		
Reviewed by: (Signature)	**Date**	**Revision #**	**Modification**
Marc Smith, MD	12/05/2007	00	New procedure format
Marc Smith, MD	02/13/2008	01	Changed PT, PT-NH, PT-AMS and TT autoverification ranges on pg 1. Changed PT, PT-NH, PT-AMS and TT autoverification criteria on pg 2. Deleted signature lines on pg 2.
Marc Smith, MD	02/11/2009	02	Changed PT, PT-NH, PT-AMS, aPTT, Heparin aPTT and TT autoverification ranges and criteria.
Marc Smith, MD	08/18/2009	03	Corrected PT-AMS delta check, did not autoverify range.
Marc Smith, MD	02/23/2010	04	Change autoverification ranges for PT, PT-NH and PT-AMS.
Marc Smith, MD	07/13/2011	05	Changed PT autoverification ranges to INR autoverification ranges. Changed Mysis to LIS or IT. Added selected abnormal results.
Mark Kolins, MD	10/20/2011		No change
Marc Smith, MD	10/25/2013		No change
Marc Smith, MD	07/24/2015	06	Deleted autoverification for PT-NH
Marc Smith, MD	04/04/2017	07	Changed TT autoverification to 16-20 second
Elizabeth Sykes, MD	02/22/2018		
	10/02/2018	08	Changed instrumentation from Sysmex to IL ACL-Top. Changed autoverification range for INR and INR/AMS to 3.0, aPTT to 25-95, FIB to 151-449, TT to 16-25, and D-dimer to 250-10,000.
Peter Millward, MD	03/13/2019		

Marc Smith, MD	12/10/2019	**09**	Autoverification range for FIB updated to 101-449 mg/dL