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Coagulation Autoverification Policy

Document Type; Policy

Status (Active) PolicyStat ID (15584565)

I. PURPOSE AND OBJECTIVE:

It is the department policy that all normal results and selected abnormal results from the coagulation analyzers will be auto-verified in the laboratory's LIS.

II. POLICY STATEMENT:

The coagulation laboratory initiated auto-verification on 10/6/01. It is the policy of Corewell Health to provide autoverification guidelines for INR, aPTT, Fibrinogen, D Dimer, and Thrombin Time.

III. 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)
- H. Laboratory Information System (LIS)

IV. AUTO VERIFICATION CRITERIA:

- A. Values outside of the limits below will require technologist intervention. (Check previous values; look at trend).
- B. When all of the following criteria evaluate as "True", then the LIS system will auto-verify INR, aPTT, FIB, TT, or D-dimer.

C.	Criteria Name	Range
	INR	0.9 – 3.0
	INR (AMS)	0.9 – 3.0
	aPTT	25 - 110 sec
	FIB	101 - 450 mg/dL
	TT	16 - 25 sec
	D-dimer	250 – 10,000 ng/mL FEU

D. Any sample with instrument flags will stop autoverification so that the tech can review the instrument results and sample to properly identify the best course of action for resulting the patient.

V. DELTA CHECK RULES:

- A. In addition, an assay will not be autoverified in the middleware if the following delta checks are triggered:
- B.
 Criteria Name
 Range

 All INR's
 Difference Between Previous INR and Current INR ≥ 2.0

VI. QUALITY CONTROL:

- A. Validation of autoverification will be performed initially and whenever there is a change to the system that could affect the autoverification logic. This is done by using selected patient samples including samples that have been previously tested and are expected to either pass or fail the criteria stated above.
- B. If multiple sites use the same LIS and server, only one site needs to perform the autoverification validation. If there are any site specific rules, those rules must be validated per site. All labs must retain a copy of the autoverification validation.
- C. Evaluation will be performed on routine patient samples to document auto verification of samples that passed criteria and lack of autoverification for samples, which failed the criteria.
- D. This is a zero tolerance system for errors in the software application. Any detected failure of the software system to detect appropriate samples for autoverification will be immediately reported to Werfen or Corewell Health Laboratory Information Technology group as applicable for correction/ modification of the software.

Attachments

Attachment A-Coagulation Autoverification Validation Worksheet.pdf

Approval Signatures

Step Description	Approver	Date
	Hassan Kanaan: OUWB Clinical Faculty	10/29/2024
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Coagulation Medical Director Designee	Marc Smith: System Med Dir, Coagulation	10/25/2024
Policy and Forms Steering Committee Approval (if needed)	Megan Masakowski: Mgr, Division Laboratory	10/25/2024
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Applicability

Dearborn, Farmington Hills, Grosse Pointe, Royal Oak, Taylor, Trenton, Troy, Wayne

