werfen MC102331

GEM Hemochron 100 ACT Performance Verification Plan

Site Name: Corewell Health - Farmington

Current/New Method Matrix

Clinical Setting OR-vascular	Physician Contact Name	Reference Instrument	Reference Assay & Activator	Prewarmed (circle one)	Current Target	GEM Hemochron 100 Cuvette
~~Cath lab~~	GtHAMoeri	HSE	~~ACT~~ LR	(Y) N NA	302s	Act LR
				Y N NA		
				Y N NA		
				Y N NA		
				Y N NA		
				Y N NA		
				Y N NA		
				Y N NA		
				Y N NA		

Instrument Performance Verification

This part of the verification is used to verify Werfen specifications for acceptable analyzer performance

- Verify acceptable electronic quality control
- Run Level 1 and Level 2 ACT-LR and /or ACT+ QC with results in package insert range

Test System Performance Verification

These studies are intended to test system performance. The AC will assist the laboratory as needed during the installation. It is possible some studies may not be completed while the AC is on site. Additional data may be collected and sent to the AC for data analysis. Reagents are not provided for this part of the verification unless otherwise specified.

Performance Verification

Study	within 10 rep Laboratory Requirement
Precision (each instrument/s)	☐ Run ~~20~~ replicates of Level 1 (Normal) and Level 2 (Abnormal) QC (minimum 10 each) Between run 30
Accuracy	Use the results from the precision study
Method Comparison (Primary GEM Hemochron 100 to Reference Method)	Whole blood from desired patient population(s) to be tested or spiked samples ☐ Run 20 samples spanning range (minimum 20 samples) for each assay being verified Determine acceptance criteria while considering differences in ACT methodologies
Clinical Decision Targets	Calculate new targets as compared to the reference method. Minimum of 40 samples required.

It is the responsibility of the Medical Director to confirm both the suitability of the cuvette type and the medical decision target for each clinical setting.

This verification plan supersedes any and all previous Werfen performance verification procedures.

Verification Plan Acceptance:

Medical Director or Designee — Date: 9.13.23

IL Representative — Date: 9-13-23

ORDERING INFORMATION			
CATALOG NUMBERS	**DESCRIPTION**	**QUANTITY**	**Quantity to Order**
000GACT-LR	ACT- LR Test Cuvettes (Celite)	45/box	
000DCGLR-1	ACT-LR Level 1 Control Normal	15/box	
000DCGLR-2	ACT-LR Level 2 Control Abnormal	15/box	
000GACT+	ACT + Test Cuvettes (Kaolin)	45/box	
000DCGACT-1	ACT + Level 1 Control Normal	15/box	
000DCGACT-2	ACT + Level 2 Control Abnormal	15/box	