MAYO CLINIC
Mayo Medical Laboratories

1-800-533-1710

TEST UPDATE/FILE DEFINITION CHANGE REFERRAL

NOTIFICATION DATE: February 17, 2014
EFFECTIVE DATE: Immediately

LIMULUS AMEBOCYTE LYSATE (LAL) ASSAY, QUANTITATIVE
Test ID: FLALA

EXPLANATION OF CHANGE: Per notification received from Focus Diagnostics, Inc., the following changes will go in to effect immediately.

CURRENT METHODOLOGY: Chromogenic Assay

NEW METHODOLOGY: Kinetic

CURRENT REPORTING NAME: Limulus Amebocyte Lysate Assay, QN

NEW REPORTING NAME: Limulus Amebocyte Lysate, Endotoxin

CURRENT STABILITY:

Specimen Type	Temperature	Time
Varies	Frozen	

NEW STABILITY:

Specimen Type	Temperature	Time
Varies	Frozen	30 days

CURRENT REFERENCE VALUES:

LEVEL DETECTED	INTERPRETATION
<0.05 EU/mL	None Detected (Negative)
0.25 EU/mL	USP acceptable limits for injectable or irrigation water.
0.50 EU/mL	USP acceptable limits for inhalatory water.
2.00 EU/mL	Acceptable upper limit for Hemodialysis reuse water.

The LAL is used as a quantitative test to detect gram-negative endotoxin in aqueous solutions used in patient management. The LAL assay is not recommended for serum or plasma samples due to the presence of inhibitory factors. It is essential to maintain specimen sterility and prevent false positive results from exogenous gram negative bacteria.

NEW REFERENCE VALUES:

LEVEL DETECTED	INTERPRETATION
<0.05 EU/mL	None Detected
0.125 EU/mL	Action level for dialysis water
<0.25 EU/mL	Maximum allowable level for dialysis water and USP acceptable limits for injectable or irrigation water
0.25 EU/mL	Action level for dialysis fluid
<0.50 EU/mL	Maximum allowable level for dialysis fluid and USP acceptable limits for inhalatory water.
2.00 EU/mL	Acceptable upper limit for Hemodialysis reuse water.

The LAL is used as a quantitative test to detect gram-negative endotoxin in aqueous solutions used in patient management. The LAL assay is not recommended for serum or plasma samples due to the presence of inhibitory factors. It is essential to maintain specimen sterility and prevent false positive results from exogenous gram negative bacteria.

QUESTIONS: Contact Mary Erath, MML Referrals Supervisor
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