ORBITO ASIA
diagnostics

Name	: XXXXXXXXXX	Id	: XXXXXXXXXX
Age/Gender	: YY/F	Ordered On	: XXXXXXXXXX
Referred By	: XXXXXXXXXX	Collected On	: XXXXXXXXXX
		Reported On	: XXXXXXXXXX

TEST	RESULT	UNITS	NORMAL VALUES

DEPARTMENT OF MICROBIOLOGY

BACTERIAL ENDOTOXIN TEST			
(Method: Tube Gel Clot Assay)			
Sample Type	WATER		
Place of Collection	Pushpagiri Dialysis Unit R O Water		
Date of Sample Collection	28/11/2023		
Date of Testing	1/12/2023		
REAGENT DETAILS			
Lysate LOT No	0001080927		
CSE LOT No	0001039594		
LRW LOT No	0001197024		
Lysate Sensitivity	0.125 EU/ml		
CSE Potency	19 EU/ml		
INCUBATION DETAILS			
Incubation Temperature	37 °C		
Incubation Start Time	3.25 PM		
Incubation End Time	4.25 PM		
Incubation Total Time	1 hour ± 2 minutes		
RESULT DETAIL			
Result Observed	>0.125	EU/ml	
Negative Control	Negative		
Negative Control (Replicate)	Negative		
Sample	***Positive***		
Sample (Replicate)	***Positive***		
PPC	Positive		
PPC (Replicate)	Positive		

REMARKS

Comments:

Endotoxins are toxic complexes which is invariably associated with the cell-wall of the Gram-negative bacteria irrespective of bacterial pathogenicity. Endotoxins are rarely fatal, but they cause fever and hence Endotoxin carrying bacteria are known as 'Pyrogen'. Endotoxin is toxic substances which is bound with the bacterial cell wall and are released when the bacterium disintegrates. Endotoxin composed of lipopolysaccharide and lipoprotein complexes. The components that are protein determine its antigenic property; and the polysaccharide component determines the antibody type that can react with the Endotoxin molecule. Endotoxin is rarely fatal, although they often cause fever. Thus, Bacterial Endotoxin test is the confirmatory test that assures the presence or absence of the Endotoxin in the medicine sample. Mostly bacterial Endotoxin test are performed for the inject-able pharmaceutical products, e.g. SWFI (Sterile Water for Injection), Normal Saline (Sodium Chloride Sterile) and other injections.

Endotoxin test is an in vitro assay for detection and quantitation of endotoxins secreted by Gram negative bacteria in Dialysis water & Dialysate used in hemodialysis patient management. The quality of dialysis solutions have been implicated in adverse patient outcomes hence asserting that dialysate quality is critical and an important factor in protecting the health of hemodialysis patients. At high endotoxin concentrations, it causes pyrogenic reactions while at lower concentrations they are associated with chronic lower - level activation of the immune response, dyslipidemia, oxidative stress, impaired nutrition, loss of residual kidney function, and erythropoietin resistance. Clinically this may lead to fever (≥38.3°C/101°C), septic shock, chills (visible rigors), malaise, abdominal pain, nausea, vomiting, diarrhea, anxiety, confusion, and shortness of breath in patient undergoing dialysis treatment. In case the test results exceed the acceptable limit, the actionable committee of the hospital must be notified immediately to undertake the disinfection of the Dialysis/RO water system with and repeat sample must be submitted for Endotoxin levels after disinfection.

The LAL test is only valid for detecting endotoxins and not any other type of pyrogen (a name that is given to any compound that could cause fever). In many occasions, this test is used with the goal of detecting other pyrogens, which is wrong. The Gel-Clot method is based on the presence or absence of a gel clot in your sample tube. The test is performed along with negative control (NC) and positive product control (PPC). The gelation occurs when proteins are coagulated due to the presence of endotoxins. The detection limit of the tests depends on the manufacturer of the kit that contains the LAL reagent. A criterion used in the method of gelation is to turn the test tube 180° and ascertain that the gel remains intact. The Gel-Clot method can be used in a qualitative manner, yielding positive results or negative ones if the gel is not formed. The method can also be used in a semi-quantitative fashion.

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TEST	RESULT	UNITS	NORMAL VALUES

The procedure is simple, but it should be conducted with a lot of precaution in order to avoid the contamination of the samples. After incubating the tubes where the test is conducted at 37°C for one hour, the tubes are turned face down to check if the gel is formed or not. This is a qualitative test.

INTERPRETATION

Results in EU/ml	*Remarks*	*Comments*
<0.125	*Negative*	*Indicates absence of microbial contamination specially by Gram negative bacteria*
>0.125	*Positive*	*Indicates presence of microbial contamination specially by Gram negative bacteria*

Note:

1. A positive test indicates presence of Endotoxin in the submitted sample and is a marker for exposure to Gram negative bacteria.
2. A negative test indicates absence of Endotoxin specially secreted by Gram negative bacteria in the submitted sample.
3. False positive results can be seen in case of contamination from exogenous sources by Gram negative bacteria and presence of Beta-glucans like cellulosic material in sample.
4. This LAL Gel clot assay cannot distinguish between Gram negative bacterial species.

--- End of the Report ---

No : 54,Paul Wells Road,St Thomas Mount,Guindy,Chennai - 600032 |Email: info@orbitoasia.com | Web: www.orbitoasia.com
Tamilnadu I Kerala I Bangalore I Pondicherry I Mumbai