

Testing Oil Solutions with the PYROGENT™-5000 and Kinetic-QCL™ Assays Technical Tips

By Scientific Support, U.S.

Oil-based parenterals have always been a challenge in endotoxin detection assays. Below, a liquid-liquid extraction procedure is described that can be used to remove the endotoxin from the oil into an aqueous phase, which can then be tested in a conventional manner. Water alone is usually not sufficient for this extraction. Endotoxins, due to their lipid character, tend to remain associated with oils and do not readily enter the aqueous phase of water-oil mixtures. The use of PYROSPERSE™, a dispersing agent, allows for dissociation of the endotoxin from the oils and for subsequent detection of endotoxin in the aqueous phase by Limulus Amebocyte Lysate (LAL).

The procedure has to be validated and, if necessary, adapted for different oily samples.

Materials

- PYROGENT™-5000 Kinetic Turbidimetric LAL Assay
or
- Kinetic-QCL™ Kinetic Chromogenic LAL Assay
- PYROSPERSE™ Dispersing Agent
- LAL Reagent Water (LRW) – LAL Reagent Water is equivalent to Water for Bacterial Endotoxins Test (BET)



Test Procedure

1. Place 5 ml of oil sample into a 16x 150 mm screw cap depyrogenated culture tube or similar glass container that can be sealed.
2. To the oil, add 5 ml of LRW and 0.025 ml of PYROSPERSE™ Dispersing Agent.
3. Shake the tube vigorously in a back and forth motion until the solutions form a homogenous mixture (approximately 30 minutes). Then, before the phases have had a chance to start separating, vortex the tube for 30 seconds to allow the solutions to extract thoroughly.
4. The two layers can now be allowed to separate on their own or they can be centrifuged. After the layers have separated, remove a sample of the aqueous phase and perform the PYROGENT™-5000 or Kinetic-QCL™ Assay as described in the package insert.
 - a. Note that some sample types will test better using the PYROGENT™-5000 Assay and others will test better using the Kinetic-QCL™ Assay. This can only be known by running interference studies on both assay types.

Contact Information

North America

Customer Service: 800 638 8174 (toll free)
order.us@lonza.com
Scientific Support: 800 521 0390 (toll free)
scientific.support@lonza.com

Europe

Customer Service: +32 87 321 611
order.europe@lonza.com
Scientific Support: +32 87 321 611
scientific.support.eu@lonza.com

International

Contact your local Lonza distributor
Customer Service: +1 301 898 7025
Fax: +1 301 845 8291
scientific.support@lonza.com

Lonza Walkersville, Inc. – Walkersville, MD 21793

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