

Bioendo™ Rapid Gel Clot Endotoxin Assay Kit

CATALOG NUMBER

RG05003, RG05006, RG050125, RG05025, RG05050

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INTENDED USE: Rapid Gel Clot Endotoxin Assay Kit is a rapid endotoxin test specially designed for water, dialysate or other testing in applications that do not require FDA-licensed Amebocyte Lysate. Lyophilized Amebocyte Lysate (AL, TAL or LAL) is an aqueous extract of circulating amebocytes of Chinese horseshoe crab (*Tachypleus tridentatus*).

WARNING

For *In Vitro* use only. Do not use it for the detection of endotoxemia in human.

KIT CONTENTS:

	Kit contents	Specification	Usage
1	AL reagent for Sample (SPL) reaction tube	1 vial / 10 vials	Sample (SPL) reaction tube
2	Positive Product Control (PPC) tube	1 vial / 10 vials	Positive Product Control (PPC)
3	Endotoxin-free Sample Bottle	10 ml × 1 vial / 10 ml × 10 vial	Sample Container
4	Depyrogenated Pipette tips	4 pcs/pack	Sample and reagent Pipetting
5	Instruction for use	1	
6	Certificate of Analysis	1	Indicates kit sensitivity and reaction time

MATERIALS REQUIRED BUT NOT SUPPLIED:

1. Test tube rack
2. Water bath or dry heat incubator at $37 \pm 1^{\circ}\text{C}$.

TEST PROCEDURE:

1. Preheat incubator to $37 \pm 1^{\circ}\text{C}$.
2. Collect test sample in supplied endotoxin-free sample bottle. Be careful not to contaminate sample.
3. Open SPL and PPC tubes.
4. Use depyrogenated pipette tip to transfer 0.5 ml test sample into SPL tube. Gently mix the contents of the tube by lightly tapping the bottom several times with your

finger to dissolve the AL reagent.

5. Use depyrogenated pipette tip to transfer 0.25 ml AL reagent **from step 4** into PPC tube. Gently mix the contents of the tube by lightly tapping the bottom several times with your finger.
6. Immediately place the SPL tube and PPC tube in $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$ incubator or water bath. Incubate for the amount of time indicated on the Certificate of Analysis.
7. When time is up, immediately and carefully remove the tubes one by one from the incubator. Gently invert the tubes 180 degree. Do not shake the tubes when reading the test.
8. If a solid clot has formed, the result is positive (+) ; if no clot or the clot breaks, the result is negative (-).
9. Positive Product Control (PPC) tube should be positive (+) . If it does not, you have an invalid test. A negative of the PPC tube indicates either sample inhibition or improper performance of the assay. You may repeat the test. If Sample (SPL) tube is negative, the sample's endotoxin concentration is less than the sensitivity of AL reagent. If Sample (SPL) tube is positive, the sample's endotoxin concentration is equal to or greater than the sensitivity of the AL reagent.

STORAGE: Store the unopened kit at $2-20^{\circ}\text{C}$, best at $2-8^{\circ}\text{C}$, avoid light.

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