

Pyrochrome® Kinetic Chromogenic Endotoxin Testing



General Product Description

Pyrochrome is a versatile quantitative reagent that is used to perform kinetic or endpoint assays. It is a sensitive and flexible reagent that can be used for testing in compliance with the USP, EP and JP bacterial endotoxins test chapter. Pyrochrome is offered with either Pyrochrome Buffer or for endotoxin-specific testing, with Glucashield® Buffer. Pyrochrome can be used with the new Pyros Kinetix® Flex tube reader at a 1:1 and economical 4:1 sample to LAL ratio.

Pyrochrome can be used for a wide variety of endotoxin tests, ranging from standard water testing to samples requiring high sensitivity, such as intrathecal products and those requiring high dilutions to overcome interference.

It is also offered in a diazo kit for endpoint tests. (The diazo reagents shift the absorption wavelength making it especially useful for testing samples with color interference.)

Sensitivity

The sensitivity for chromogenic assays is determined by the lowest standard concentration on the standard curve used for the assay. The maximum sensitivity of Pyrochrome is 0.001 EU/mL when run in Pyros Kinetix Flex tube reader or incubating microplate reader with Glucashield Buffer.

Sample to LAL Ratio

In the Pyros Kinetix Flex tube reader, Pyrochrome can be used at an economical ratio of 4:1 using 50 µL of reagent per well or at 1:1 using 100 µL/well. In a microplate reader, the reagent is used at a ratio of 1:1 and a volume of 50 µL/well (60 tests/vial) or 100 µL/well (30 tests/vial).

Performing the Test

The Pyrochrome – sample mixture is incubated in an optical reader at 37±1°C and read at wavelengths depending on the instrumentation and user choice. For diazo method, this mixture is read in a microplate reader at 540–550 nm. The time of incubation is dependent on the lowest standard concentration in the standard curve. Software is used to construct the standard curve and calculate the endotoxin concentrations.

Reconstitution

Pyrochrome lysate is reconstituted with an optimized Pyrochrome reconstitution buffer (C1500-5). Pyrochrome can also be reconstituted with Glucashield buffer, a (1→3)-β-D-Glucan inhibiting buffer, to render the assay endotoxin specific (CG1500-5).

Stability

Once reconstituted, Pyrochrome is stable for 8 hrs. when stored at 2–8°C.

Packaging

Pyrochrome is offered with a choice of reconstitution buffer and is recommended for use with the 10 ng/vial Control Standard Endotoxin (CSE, EC010). Certificates of Analysis, specific to the Pyrochrome and CSE lot, can be obtained from ACC or online at www.acciusa.com.

Accessory Products

1. LAL Reagent Water, available in multiple package sizes, see page 14
2. Control Standard Endotoxin 10 ng/vial, *E. coli* O113:H10 (EC010-5)
3. Glucashield Buffer, (1→3)-β-D-Glucan Inhibiting Buffer (GB051-5)
4. Pyrotubes® - 13 x 100 mm borosilicate glass dilution tubes (TB013-5)
5. Pyroplate® - 96-well microplate (CA961)
6. 250 µL Pipette tips (PPT25)
7. 1000 µL Pipette tips (PPT10)
8. Pyros Kinetix® Flex tube reader and EQS Software, see pages 12 and 13
9. Pyrotubes®, for use with Pyros Kinetix® Flex (TK100-10)

Pyrochrome®

#C1500-5 ----- 5 pack (300 Test)

#C1500-25 ----- 25 pack (1500 Test)

#CD060 ----- 60 Test
(with Diazo-reagents)

#CG1500-5 ----- 5 pack (300 Test)

#CG1500-25 ----- 25 pack (1500 Test)
(with Glucashield Buffer)