

Lonza

Endotoxin Detection

內毒素檢測試劑領導品牌



動力呈色法



名稱: Kinetic-QCL™ Kinetic Chromogenic LAL Assay

靈敏度: 0.005-50 EU/mL

Cat. No. 50-650U, 50-650H

Kinetic-QCL™

Kinetic Chromogenic LAL Assay

動力呈色法

- > 藥典標準方法
- > 設備判讀, 減少人為干擾
- > 靈敏度佳, 尤適生物製劑
- > 數據可追溯、保持數據完整性
- > 搭配專屬WinKQCL™ 軟體(21 CFR part 11)

動力濁度法



名稱: Pyrogen™-5000 Kinetic Turbidimetric LAL Assay

靈敏度: 0.01-100 EU/mL

Cat. No. N383, N588

Pyrogen™-5000

Kinetic Turbidimetric LAL Assay

動力濁度法

- > 藥典標準方法
- > 成本合宜, 操作簡單
- > 設備判讀, 減少人為干擾
- > 大量樣本、水樣、大體積樣品適用
- > 數據可追溯、保持數據完整性
- > 搭配專屬WinKQCL™ 軟體(21 CFR part 11)



- > 非動物來源、人道對待
- > 批次間變異更小
- > 減少β-Glucan干擾
- > EP 5.1.10列為替代方法
- > EP 2018/5表示未來將列為標準方法
- > 已經有藥品使用此方法檢測內毒素並獲得美國FDA許可

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Lonza

News Release

FDA Approves First Drug Using the Recombinant Factor C Assay for Endotoxin Testing

Walkersville, MD (USA) / Basel (CH), 8 November 2018 – Lonza announced today that the recombinant Factor C (rFC) Assay has been used for endotoxin testing of Eli Lilly's Emgality™ (galcanezumab), the first drug approved by the U.S. Food and Drug Administration (FDA) to have been released using this method instead of traditional Limulus

Tachypleus Amebocyte Lysate (TAL) will look to the North American species, *Limulus polyphemus*, to fulfill their ever increasing needs in order to release non-pyrogenic pharmaceutical products to the market. Use of recombinant products, such as recombinant Factor C for endotoxin detection will greatly reduce the pressure on these species."

rFC 螢光法



名稱: PyroGene™
Recombinant Factor C
Assay

靈敏度: 0.005-5 EU/mL

Cat. 50-658U
No. 50-658NV

螢光法可搭配使用之軟體及儀器

PyroWave™ XM
螢光偵測儀



- > 四區恆溫控制
- > 高性能光學
- > 效能提升
- > 針對PyroGene試劑優化

WinKQCL™
Software



- > 符合21 CFR Part 11電子紀錄與簽章規範
- > 使用身分權限控制
- > 直覺式操作分析介面
- > 數據管理及簡便的MVD計算功能