投稿 ▶原著

Collaborative Study of Bacterial Endotoxins Test Using Recombinant Factor C–Based Procedure for Detection of Lipopolysaccharides (Part 3)

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（Received: January 30, 2023; Accepted: May 18, 2023）

Summary

Two new recombinant cascade reagents (rCRs), PyroSmart NextGen® and PYROSTAR™ Neo, have recently become available for endotoxin testing of parenteral drugs in the Japanese market. This study investigated whether these two rCRs, as well as the current commercially available recombinant factor C reagents (rFCs) PyroGene™ and EndoZyme® II, can be used as alternative reagents to the amoebocyte lysate reagents currently used in the compendial Bacterial Endotoxins Test. The two rFCs were investigated in the previous two-year study.

An *Escherichia coli* O113: H10: K negative culture supernatant and seven water samples (six different tap waters and one deionized water) were tested for autochthonous endotoxin, and the endotoxin levels detected with four amoebocyte lysates and four recombinant protein reagents were compared. The results indicate that the four recombinant protein reagents can detect autochthonous endotoxin in culture supernatant samples at levels comparable (within the 50%–200% range as defined in the Pharmacopeias) to those measured with limulus amoebocyte lysate reagents. One of the four recombinant reagents detected autochthonous endotoxin in water at comparable levels to those obtained with lysate reagents in all samples, whereas the other three reagents detected comparable or lower levels among different samples. These findings suggest that there are differences in the detectability of autochthonous endotoxin in water among the recombinant protein reagents.

Key words

Bacterial endotoxin test, Amoebocyte lysate reagent, Recombinant factor C reagent, Recombinant cascade reagent