Lonza

Pharma & Biotech

Recombinant Factor C Assays

Citations List

Literature related to recombinant Factor C assays used to detect bacterial endotoxins, 2010-2020.

This list is provided as a resource to find scientific data related to the recombinant Factor C (rFC)bacterial endotoxins tests. It is a Lonza-curated list of peer-reviewed articles related to recombinant Factor C (rFC) assays for the detection of bacterial endotoxins. Articles are not restricted to Lonza products, and the list may not be exhaustive. It is intended for informational reference purposes.

Title	Abstract/Summary	Citation
Comparison of LAL and rFC assays-participation in a proficiency test program between 2014 and 2019.	rFC test performance in a routine setting within a proficiency test program set-up was investigated. Over a period of six years comparative endotoxin testing was conducted with one kinetic chromogenic LAL assay and two rFC-based assays.Results of this study demonstrate that both rFC-based assays were comparable to LAL. All results met acceptance criteria defined by compendial bacterial endotoxin testing. RFC-based methods generated results with even better endotoxin recovery rates compared to LAL. Therefore, rFC-based tests were found to represent reliable methods, as equivalent or even superior to LAL assays and suitable for routine bacterial endotoxin testing.	Piehler M, Roeder R, Blessing S, Reich J. Comparison of LAL and rFC assays-participation in a proficiency test program between 2014 and 2019. Microorganisms 2020:8.
Application of a Recombinant Three-Factor Chromogenic Reagent, PyroSmart™, for Bacterial Endotoxins Test Filed in the Pharmacopeias	Recently, a new recombinant chromogenic reagent, PyroSmart™, consisting of three recombinant factors was introduced to the market. The authors evaluated the applicability of the reagent to the harmonized bacterial endotoxins test in the United States, European and Japanese pharmacopeias.	Muroi M, Ogura N, Mizumura H, Aketagawa J, Oda T, Tanamoto KI. Application of a Recombinant Three-Factor Chromogenic Reagent, PyroSmart, for Bacterial Endotoxins Test Filed in the Pharmacopeias. Biol Pharm Bull. 2019 Dec 1;42(12):2024-2037. doi: 10.1248/bpb.b19-00517. Epub 2019 Oct 5. PubMed PMID:31588055.
Research Report in FY2015 "Study on the Test Methods in the Japanese Pharmacopoeia" Collaborative Study on the Evaluation of Recombinant Reagents Used in Bacterial Endotoxins Test	In this study, an endotoxin panel consisting of 18 bacterial purified LPS materials and another panel consisting of 11 naturally occurring crude LPS materials (naturally occurring endotoxin, NOE) were measured using recombinant reagents commercially available in Japan and representative lysate reagents, using the Japanese Pharmacopoeia Reference Standard Endotoxin (RSE) as the standard.	Kikuchi, Y. et al., Collaborative Study on the Bacterial Endotoxins Test Using Recombinant Factor C-based Procedure for Detection of Lipopolysaccharides. Pharmaceutical and Medical Device Regulatory Science 48 (4), 252-260 (2017) 2. Kikuchi, Y. et al., Collaborative Study on the Bacterial Endotoxins Test Using Recombinant Factor C-based Procedure for Detection of Lipopolysaccharides, Part 2. Pharmaceutical and Medical Device Regulatory Science 49 (10), 706-718 (2018)
Evaluation of recombinant factor C assay for the detection of divergent lipopolysaccharide structural species and comparison with Limulus amebocyte lysate-based assays and a human monocyte activity assay	Recombinant factor C (rFC)has allowed the development of a new simple, specific and sensitive LPS detection system (PyroGene™). In this work, the potential of the new assay for detecting various LPS structures has been investigated and compared with two LAL-based assays and a human monocyte activity assay.	Abate W, Sattar AA, Liu J, Conway ME, Jackson SK. Evaluation of recombinant factor C assay for the detection of divergent lipopolysaccharide structural species and comparison with Limulus amoebocyte lysate-based assays and a human monocyte activity assay. J.Med. Microbiol., 66, 888–897 (2017).

Recombinant Factor C Assays

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Application of Recombinant Factor C Reagent for the Detection of Bacterial Endotoxins in Pharmaceutical Products	The successful validation of several pharmaceutical products by an end-point fluorescence-based endotoxin method using the rFC reagent is reported. The method is equivalent or superior to the compendia bacterial endotoxins test method.	Bolden JS, Smith KR. Application of recombinant Factor C reagent for the detection of bacterial endotoxins in pharmaceutical products. PDA J. Pharm. Sci. Technol., 71, 405–412 (2017):
Genetic Engineering Approach to Develop Next Generation Reagents for Endotoxin Quantification	Recombinant cascade reagents (RCRs) were prepared to reconstruct the reaction cascade in the amebocyte lysate reagent. The protease activity of the RCR containing recombinant factor C was much greater than that of recombinant factor C alone, indicating the efficiency of signal amplification in the cascade. The standard curve of the RCR containing mammalian cell-derived recombinant factor C had a steeper slope than the curves for those containing natural lysate reagents, suggesting a greater sensitivity to endotoxin.	Mizumura H, Ogura N, Aketagawa J, Aizawa M, Kobayashi Y, Kawabata S, Oda T. Genetic engineering approach to develop next- generation reagents for endotoxin quantification. Innate Immunity, 23, 136–146 (2017).
Factor B Is the Second Lipopolysaccharide-binding Protease Zymogen in the Horseshoe Crab Coagulation Cascade	Here we found that wild-type factor B expressed in HEK293S cells is activated by α-factor C, but not by β-factor C, in an LPS-dependent manner and that β-factor C loses the LPS binding activity of factor C through additional cleavage by chymotrypsin within the N-terminal LPS-binding region. We conclude that the clip domain of factor B has an important role in localizing factor B to the surface of Gram-negative bacteria or LPS released from bacteria to initiate effective proteolytic activation by α-factor C.	Kobayashi Y, Takahashi T, Shibata T, Ikeda S, Koshiba T, Mizu- mura H, Oda T, Kawabata S. Factor B is the second lipopolysaccharide-binding protease zymogen in the horseshoe crab coagulation cascade. J. Biol. Chem., 290, 19379–19386 (2015).
Evaluation of lot-to-lot Repeatability and Effect of Assay Media Choice in the Recombinant Factor C Assay	The lot-to-lot repeatability of commercially available recombinant Factor C (rFC) kits as an alternative to LAL was investigated. Specifically, endotoxin estimates obtained from rFC assay of twenty indoor dust samples, using four different extraction and assay media, were compared to endotoxin estimates previously obtained by Limulus amebocyte lysate (LAL) assay and amounts of 3-hydroxy fatty acids (3-OHFA) in lipopolysaccharide (LPS) using gas-chromatography mass spectroscopy (GC-MS).	McKenzie JH, Alwis KU, Sordillo JE, Kalluri KS, Milton DK. Evaluation of lot-to-lot repeatability and effect of assay media choice in the recombinant Factor C assay. J. Environ. Monit., 13, 1739–1745 (2011).
A Recombinant Factor C Procedure for the Detection of Gram-Negative Bacterial Endotoxin	The purpose of this study is to demonstrate that the rFC photometric procedure is comparable to LAL photometric procedures as described in US Pharmacopeia Bacterial Endotoxin Test <85> in its ability to measure endotoxin with respect to other validation characteristics. A comparison of kinetic chromogenic LAL and the proposed recombinant quantitative photometric procedure is the subject of this article.	Loverock B, Simon B, Burgenson A, Baines A. A recombinant factor C procedure for the detection of Gram-negative bacterial endotoxin. Pharmacop. Forum, 36, 321–329 (2010).

Literature related to Recombinant Factor C (rFC) assays used to detect endotoxins, 2010-2020.

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