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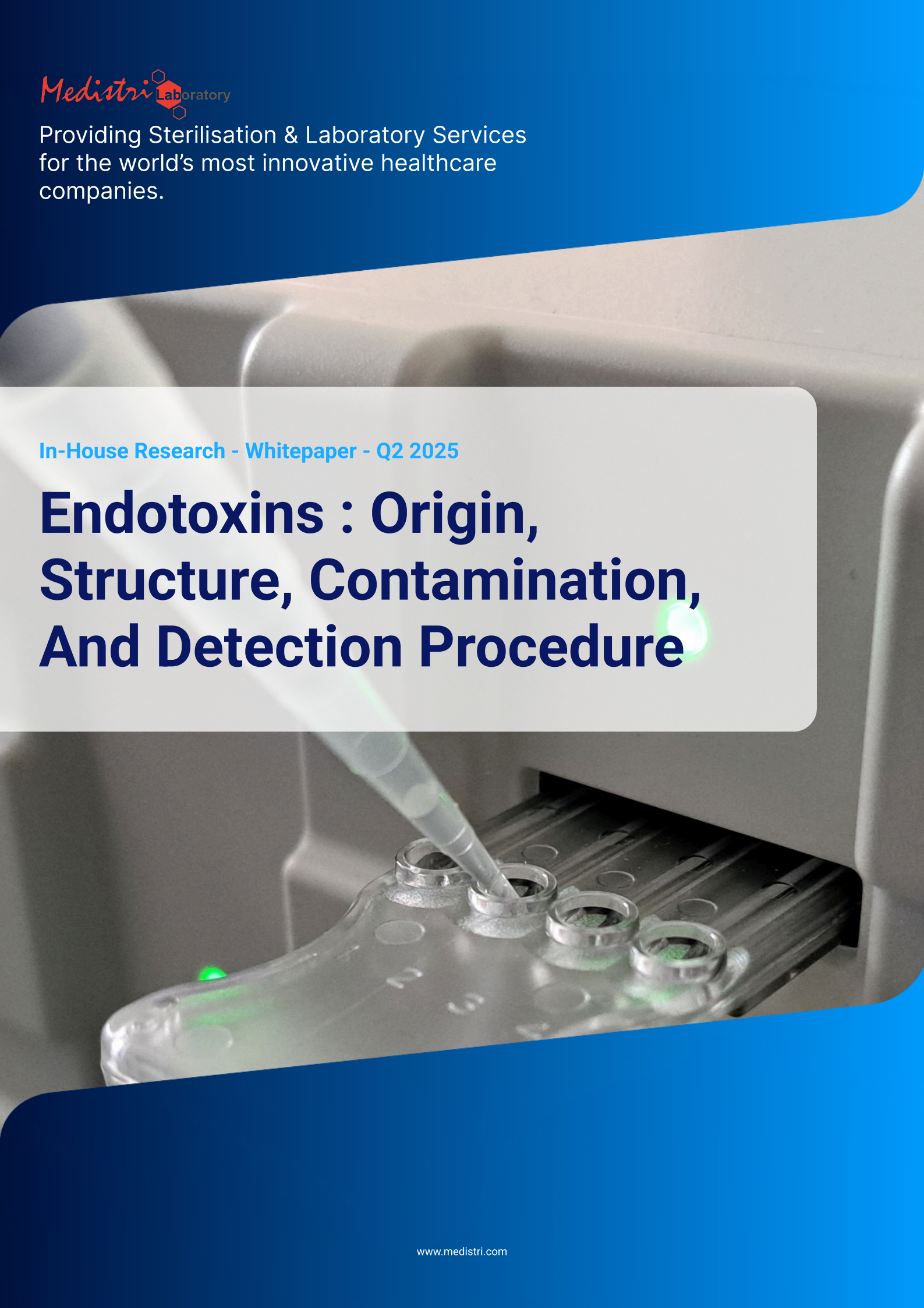

In-House Research - Whitepaper - Q2 2025

Endotoxins : Origin, Structure, Contamination, And Detection Procedure

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About Medistri

Medistri SA, a Swiss company established in 2006, plays a significant role in the medical devices and pharmaceutical industry. With a facility covering 13,193m² and a dedicated team of over 92 employees, Medistri offers specialized services including Sterilisation, Laboratory, Validation, Packaging, and Manufacturing.
With facilities in Domdidier, Fribourg, Switzerland, and Székesfehérvár, Hungary, Medistri operates 24/7 to support a range of clients, from startups to established enterprises.

Medistri is dedicated to enhancing healthcare product development and scalability. By providing crucial infrastructure and expertise, the company supports both new ventures and established organizations aiming for global expansion. Medistri's laboratory adheres to ISO 17025 standards and holds STS 504 accreditation, conducting a comprehensive range of tests for the Pharmaceutical, MedTech, and BioTech industries. This commitment ensures that products are developed and validated with the highest levels of accuracy and reliability.

To address common challenges in the Pharmaceutical and Medical Device industry, Medistri has prepared a Whitepaper focused on Endotoxins and Pyrogens, a frequent concern associated with Medical Devices. This Whitepaper explores their origin, structure and contamination and offers practical detection strategies. It is intended to support companies in enhancing patient care and optimizing the performance of their Medical Devices.

Medistri invites you to explore this Whitepaper as a resource for understanding and managing endotoxins in Medical Devices. We hope it provides useful insights to assist in your efforts. For further information or to discuss how Medistri can support your projects, please feel free to contact us at contact@medistri.com.

— The Medistri Team

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In-House Research

Endotoxins : Origin, Structure, Contamination, And Detection Procedure

Bacterial endotoxins are a major concern in the pharmaceutical and medical device industries, as they can cause pyrogenic reactions in patients. Various methods are available for measuring bacterial endotoxins, including the rabbit pyrogen test, monocyte activation test, and Limulus amoebocyte lysate (LAL) test. Each method has its own strengths and limitations, and the method's choice depends on the specific needs of the analysis. This whitepaper provides an overview of the different methods for measuring bacterial endotoxins, with a focus on their sensitivity, specificity, and applicability to different types of samples. We also discuss recent developments in animal free endotoxin testing, including the use of recombinant Factor C and monocyte activation test.

Origin Of Pyrogens

Pyrogens are substances of biological (or chemical) origin, causing induction of a febrile response in humans and animals with the potential to be lethal. They are classified in two main groups: 1) endotoxins and 2) non-endotoxin pyrogens (NEPs)[1]. The most common pyrogens are endotoxins, which are lipopolysaccharides (LPS), a major component of the outer layer of the cell wall in Gram-negative bacteria[2]. LPS is extremely resistant to temperature and difficult to remove by conventional methods, therefore, complete inactivation of endotoxin is only possible with dry heat sterilization[3] for at least 30 minutes at a minimal temperature of 250°C. On the other hand, NEPs are derived from Gram-positive bacteria, viruses, yeasts, and fungi.

Structure of LPS

The main function of LPS is to provide structural and functional integrity and to protect the bacterial wall to the entry of potentially deleterious molecules. LPS is a large complex molecule consisting of three main components: 1) a hydrophilic region containing fatty acids linked to a highly hydrophobic region containing the disaccharide phosphate which both form the lipid A, 2) a polysaccharide core composed of the inner core of unusual sugars[4] and the outer core, terminated by 3) a polymer of repeating saccharide subunits called the O-antigen region[5] (see Figure 1). The lipid part of the molecule contains the endotoxic activity and it has a unique structure for a given bacterium.

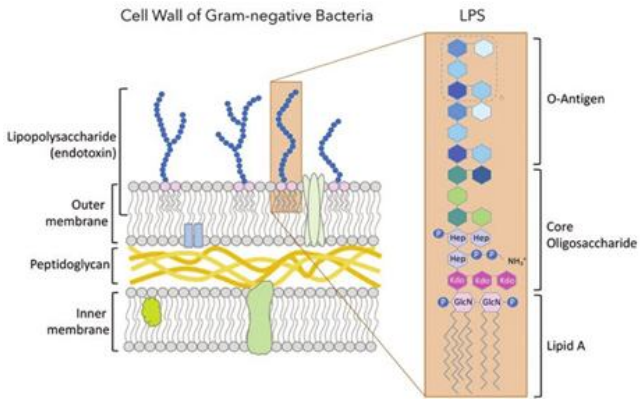

***Figure 1**: Schematic representation of the LPS.*
Source: Montero and al., Journal of Animal Science, 2020.

Mechanisms In Endotoxin-Induced Toxicity

The human immune system has two main parts: innate and adaptive immunity. The innate immune response acts quickly and is the first line of defense against infections, toxins, and cancer. It responds in the same way to any threat. The adaptive immune response is slower, taking 1–2 weeks to specifically target and remember new infections.

After infection, the bacterial toxin LPS (lipopolysaccharide) can enter the bloodstream and bind with various proteins. Its persistence in the bloodstream is influenced by its structural type and the immunological status of the host, including the presence or absence of pre-existing antibodies specific to the LPS[6]. In animals, HDL (good cholesterol) mainly carries LPS[7], while in humans, LDL (bad cholesterol) is

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also involved. The body also produces a protein called LBP (LPS-binding protein) that helps carry LPS in the blood. LBP helps LPS attach to CD14 on immune cells called macrophages[8], which then triggers an inflammatory response by releasing cytokines like TNF-α and IL-1[9].

TLR4 is a key receptor on immune cells that recognizes LPS[10], but it needs another molecule called MD2 to do so. When LPS, MD2, and TLR4 come together, they activate the immune response.

Other important receptors involved in detecting infections include[11]:

- NOD-like receptors (NLRs) – detect internal threats and help activate inflammation by forming structures called inflammasomes. LPS can activate these, triggering a type of cell death called pyroptosis.
- RIG-I-like receptors (RLRs) – detect viral RNA and help cells respond to infection.
- C-type lectin receptors (CLRs) – recognize sugars on microbes. When activated by LPS, they attract more immune cells and help present antigens to the immune system.

These receptors work together to detect different parts of pathogens and activate immune responses. For example, DC-SIGN, a CLR, can cooperate with TLR4 to switch the immune response type[12].

LPS can also cause macrophages to undergo apoptosis (programmed cell death) in two ways: 1) through TNF-α (a signaling molecule made by the cell itself), and 2) through nitric oxide (NO), which is produced by the enzyme iNOS[13].

In severe conditions such as septic shock, excessive production of nitric oxide (NO) contributes to hypotension, impaired tissue oxygenation, and subsequent organ dysfunction. Therapeutic intervention is challenging, as both the TNF-α and NO pathways are implicated, and targeting a single pathway may be insufficient to reduce the overall inflammatory damage.

In summary, the immune system employs a diverse array of receptors to detect LPS and other danger-associated molecular patterns (DAMPs). While this response is essential for host defense against infection, excessive activation can lead to detrimental outcomes, including systemic inflammation, tissue injury, and potentially fatal complications.

Contamination by endotoxins

LPS has several functions: it acts as a permeability barrier for the bacterial cell, plays an important role in the development of biofilms to protect bacteria from hostile environmental conditions and helps trap macromolecules from the surrounding environment.

Gram-negative bacteria constantly synthesize LPS to renew cell surfaces losses and, upon bacterial death, cell wall LPS is released into the environment. Free LPS molecules will be present in an environment containing Gram-negative species. It is therefore important to control the growth of Gram-negative species in the medical manufacturing environment to prevent the production of pyrogens and their introduction into the bloodstream, through contaminated intravenous devices or medications. Such contamination is estimated to be responsible each year for 44,000 deaths in the United Kingdom[14] and approximately 200,000 deaths in the US[15]. LPS can persist for very long periods of time in liquids and on dry surfaces in the absence of viable bacteria. Tests specifically addressed to detect endotoxin/LPS are essential for demonstrating the safety of pharmaceutical products and medical devices.

Detection methods

Rabbit pyrogen test (RPT)

The first pyrogenic test was developed in adult rabbits in 1912 and is still used to this day. After being administrated a potential pyrogenic substance, the rabbit's body temperature is monitored over a 3 hours' period and any increase in bodily temperature of + 0.5 °C means that the administrated substance was, in fact, pyrogenic. This method has several disadvantages that can lead to erroneous results[16] such as, the restraining of the animals, the fact that the procedure is invasive, the animal intrinsic sensibility, and the fact that some substances cannot be administrated by injection. This method is also raising some concerns regarding animal welfare and is now used mainly for non-endotoxin pyrogenicity.

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Limulus Amebocyte Lysate (LAL) Test

In 1956, Bang[17] showed that a bacterial infection caused coagulation of the hemolymph of Limulus polyphemus (Fig. 2) and confirmed, with his colleague Levin[18] in 1964, that this coagulation was in fact due to a reaction of the amebocytes against the bacterial endotoxins. The horseshoe crab (common name of Limulus) has no immune system, but it does have a type of cell, the amebocyte, which defends it against infection. Since the 1970s, horseshoe crab hemolymph has been used to produce a reagent called Limulus amebocyte lysate (LAL) for diagnosing endotoxins and the method has been approved by the FDA in 1977[19].

The Limulus Amebocyte Lysate (LAL) assay is currently the reference method for endotoxin detection. Although not entirely free of animal-derived components, it is significantly less invasive than the Rabbit Pyrogen Test (RPT) and has substantially reduced the number of animals required for pyrogen testing.

Figure 2 *- Limulus polyphemus.*
Source : aquariumbcn.com

LAL Principle

Three main approved tests[20] methodologies use LAL and TAL (Tachypleus Amebocyte Lysate) reagents for endotoxin testing: gel-clot (limit and semi-quantitative tests), kinetic and chromogenic turbidimetry (endpoint and chromogenic kinetic methods). LAL/TAL tests operate in a similar way: the presence of bacterial endotoxins in a sample triggers a cascade of reactions and the appearance of turbidity or color (Fig. 3). Amoebocyte lysate contains several proteins involved in endotoxin detection. Factor C recognizes bacterial endotoxins and activates another protein called factor B. Factor B then converts a proenzyme into a coagulation enzyme. This enzyme then catalyzes a reaction that produces a gel, turbidity or the appearance of a color. Once detected, this reaction can be used to determine the concentration of endotoxins in the sample. Factor C is sensitive to picogram quantities of lipid A[21].

Gel-clot method

The gel-clot endotoxin assay is a convenient endotoxin qualitative test based on gelation principle and occurs when proteins are coagulated due to the presence of endotoxins. The detection limit is normally between 0.01 and 0.03 units of endotoxin per milliliter of the test solution.

Turbidimetric method

The turbidimetric method measures either the time taken for the reaction mixture to reach a predetermined absorbance level or the rate at which turbidity develops. The turbidimetric assay can either be performed as a single endpoint or as a kinetic measurement. The modified LAL reagent contains a lower amount of coagulogen, resulting in a turbid mixture unable to form a solid clot when exposed to endotoxin, an effect that can be measured photometrically[22]. The time taken for the mixture to reach optical density is inversely proportional to the amount of endotoxin present, measured using a standard curve. The advantage of the turbidimetric method is that it gives a quantitative result, indicating the level of endotoxin in the sample solution with sensitivity limits of 0.005EU/ml.

Chromogenic method

This method uses a synthetic chromogenic substrate containing a specific amino acid sequence that mimics the coagulogen cleavage site and contains the chromophore pNA (p-nitroanilide)[23] and can (as the

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turbidimetric method) be performed as a single endpoint or as a kinetic measurement.

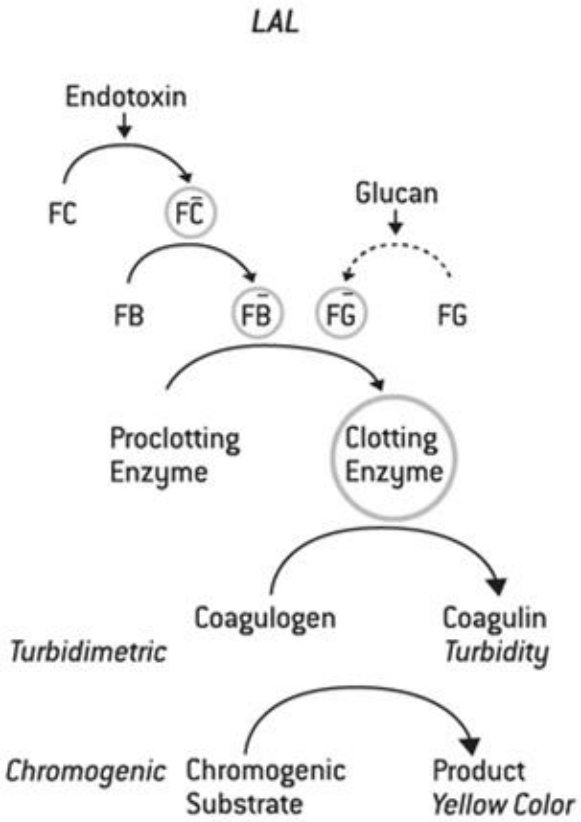

Figure 3 *- Schematic representation of the LAL principle for each type of Endotoxin detection method.*
Source: Lonza Pyrogene rFC testing

The LAL lysate is activated in the presence of endotoxin and cleaves this specific site, resulting in the release of pNA. Colored molecules absorb light at a wavelength of 405nm, so the measurement of light absorbance is directly proportional to the amount of endotoxin contained in the sample. The chromogenic end-point method reads the endotoxin value in each sample only after a predetermined incubation period has elapsed, while the kinetic method reads the endotoxin value as the rate of color development or the time needed to reach a predetermined absorbance. The method uses a standard curve which requires a minimum of three known endotoxin concentrations, with sensitivity limits of 0.005 EU/ml. The magnitude of the coefficient of variation (CV) measures the analytical repeatability of the tests, which are only valid when the CV values are ≤25%, depending on the manufacturer recommendations. The higher the CV% value, the lower the level of analytical repeatability.

To avoid under- or over-estimating the obtained results, which can occur if interfering factors are present in the test sample at a significant level, a validation of the method is performed. Interferences are commonly caused by suboptimal pH, endotoxin aggregation or adsorption, container effects, unbalanced cation concentration, enzyme or protein modification, and non-specific LAL activation[24]. During the validation, a Maximum Valid Dilution (MVD) is calculated. The MVD is specific for each medical device tested and depends on the extraction volume used, the detection limit set by the method and the acceptance criteria (set by the customer). The MVD allows for the extract to be diluted up to the MVD set value, in case interference factors are detected during the analysis. If the MVD is not enough to counter those interferences, the extract can be treated using a "glucan blocker" or other specific treatments, depending on the type of interferences present in the extract.

Alternative in vitro methods

rFC (recombinant Factor C) assay

Recombinant horseshoe crab factor C (rFC) methods[2] represent one of the latest state-of-the-art solution for efficient testing of bacterial endotoxins. Factor C is an endotoxin-sensitive protein that serves as a primer in the coagulation cascade reaction of LAL assays. The production of factor C by genetic engineering makes it possible to obtain a protein that reacts strongly with bacterial endotoxins and cleaves a synthetic substrate that results in the release of a fluorogenic compound (see Figure 4). It replicates only the Factor C recognition and activation instead of the complete clotting pathway. The fluorescence is measured twice, first at time zero and then after the endotoxin has been introduced. The difference in fluorescence is proportional to an endotoxin concentration in the sample and is used to calculate a final endotoxin result.

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The test result is not influenced by β-1,3-D-glucans, thus eliminating the occurrence of false positive reactions to glucans and represents a highly selective test for bacterial endotoxins. In 2018, the U.S. Food and Drug Administration (FDA) has approved the first drug (a monoclonal antibody) which has been tested by the recombinant factor C methods instead of the traditional LAL assay. The European Pharmacopeia (since July 1, 2020)[25], Japanese, and Chinese Pharmacopeia (2021) and US Pharmacopeia (since May 2025)[26] organizations all recognize rFC as an equivalent to LAL assay.

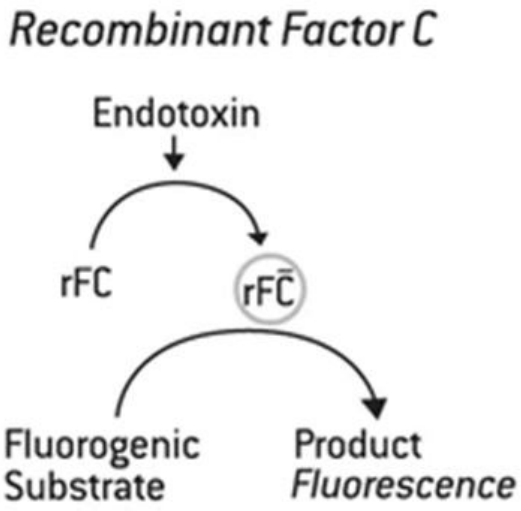

Figure 4 *- Schematic representation of the Recombinant Factor C assay (rFC). Source: Lonza Pyrogene rFC testing*

Another recombinant assay, the rCR (recombinant Cascade Reaction) can also be used. Unlike rFC where only Factor C is recombined, the rCR recombine the entire reaction cascade leading to the detection of endotoxins. For the European Pharmacopeia, rCR is still considered an alternative method, but is fully recognized as a substitution method by the US Pharmacopeia since May 2025[26].

Monocyte activation test (MAT)

The MAT was originally developed in the 1990s as an in vitro pyrogen test[27], in which endogenous pro-inflammatory cytokines such as tumor necrosis factor, interleukins 1 and 6 or prostaglandin E2 are quantified by ELISA technology from whole blood. The use of whole blood, with all its serum components and its complete set of immune cells, makes this test system in a better position to reproduce the in vivo response to pyrogenic substances. The assay is based on the human immune response by measuring cytokine production of human monocytic cells. In addition, it has the ability to detect the full range of pyrogenic contaminants in a sample, including uncharacterized pyrogens and non-endotoxin pyrogens (NEP)[1´28]. In brief, the parenteral product or medical device is incubated with peripheral blood mononuclear cells (PBMC), allowing pyrogen activation of Toll-like receptors on monocytes, which generate the immune response by releasing pro-inflammatory cytokines.

Endotoxins can be calculated by measuring the different cytokines using ELISA technology and comparing them with the standard LPS curve. However, there are different supplements to the culture medium which can lead to different results and there is variation between donors within immune cells, leading to technical limitations. The MAT developed on whole blood is also carried out on the basis of a monocytic cell line.

The Monocyte Activation Test (MAT), utilizing either peripheral blood mononuclear cells (PBMCs) or monocytic cell lines, is now recognized as the gold standard alternative to the Rabbit Pyrogen Test (RPT). As a fully animal-free method, the MAT offers several advantages, including significantly lower cost (less than 10% of that of the RPT), faster turnaround times, higher sensitivity, and the ability to directly expose medical devices to human immune cells. These attributes make the MAT a highly suitable and ethically favorable replacement for traditional rabbit-based pyrogen testing. Reflecting this shift, the European Pharmacopoeia has announced the removal of the Rabbit Pyrogen Test from Chapter 5.1.13, effective July 1, 2025. An update from the United States Pharmacopeia (USP) is still pending, as further validation studies are required. These updates to the pharmacopoeias reflect the concerted efforts of the scientific community to advance and implement reliable non-animal testing alternatives.

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Conclusion

Bacterial endotoxins, particularly lipopolysaccharides (LPS) from Gram-negative bacteria, are significant contaminants in pharmaceutical and medical device manufacturing due to their strong pyrogenic potential. Traditional detection methods, such as the Rabbit Pyrogen Test (RPT), have increasingly been replaced by in vitro alternatives owing to ethical concerns and limitations in reproducibility. The Limulus Amebocyte Lysate (LAL) assay—based on the coagulation cascade initiated by Factor C in horseshoe crab amebocytes—remains the regulatory standard for detecting endotoxins of Gram-negative bacterial origin, with gel-clot, turbidimetric, and chromogenic formats enabling both qualitative and quantitative analysis. However, approximately 30'000 rabbits[29] are still used annually in Europe for pyrogen testing, as LAL-based methods do not detect non-endotoxin pyrogens. Horseshoe crabs also face significant conservation pressure, with an estimated 500'000 individuals[30] harvested annually to meet the global demand for their blood used in LAL testing.

Due to overconsumption, due to fishing and its use in medicine, the species has been listed as "Vulnerable" by the IUCN since 2016[31]. To align with evolving ethical standards in biomedical research, validated animal-free methods such as the Monocyte Activation Test (MAT)—which uses human monocytic cells to detect a broad range of pyrogens via cytokine release—and the Recombinant Factor C (rFC) assay—which replicates endotoxin recognition without animal-derived materials—are gaining prominence as viable and more comprehensive alternatives to RPT and LAL.

At Medistri, we are committed to applying the 3Rs principles (Replace, Reduce, Refine) and limiting in vivo and animal by-product analyses as much as possible, in order to respect animal welfare. In the near future, we plan to implement both alternative in vitro methods at our facility as part of our ongoing effort to expand laboratory capacity and enhance our testing offering.

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About the Author

With over eight years of experience in Biology, Dr. Jordan joined Medistri in 2023 as a Biology Technical Expert Assistant. In her role, she supports the development of laboratory protocols and reports, oversees the implementation of new analytical methods, and plays a key role in ensuring the scientific accuracy and regulatory compliance of testing procedures.

At Medistri, she regularly works with the different endpoints of ISO 10993-1, providing guidance to pharmaceutical and medical industries. Driven by a passion for scientific integrity and patient safety, Dr. Jordan brings a pragmatic and research-based approach to Medistri's laboratory operations.

The Medistri Lab team's expertise spans across biocompatibility testing, microbiology, chemical characterization, and method validation, ensuring compliance with international standards such as ISO 10993 and ISO 17025. Medistri Lab and its team of experts support manufacturers and regulatory professionals in navigating the evolving landscape of biocompatibility assessments with confidence, clarity and regulatory compliance.

The team's commitment to precision, reliability, and continuous improvement reflects Medistri's broader mission to deliver integrated solutions that meet the highest standards of safety and quality in pharmaceutical and medical device testing.

Dr. Aurore Jordan
Biology Technical Expert Assistant, Medistri

Dr. Jordan holds a PhD in Biology from the University of Fribourg (CH), where her research focused on the Neurogenetic and Behavioral aspects of pain perception. Before joining Medistri, she worked in Academia, contributing to research in both behavioral and cellular responses. Her background combines a deep understanding of biological systems with practical experience in laboratory environments, making her a valuable contributor to the advancement of Medistri's testing capabilities.

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About Medistri

Founded in 2006, Medistri has been focused on building infrastructure for the healthcare industry. Companies of every size, from startups & university projects to Fortune 500 companies use our services to save time, scale and focus on what they do best. Medistri combines all its technical infrastructure together and places quality at the heart of our day-to-day operations. Allowing you to simplify your supply chain management and focus on growth.

At Medistri, we've built the infrastructure that tomorrow's healthcare companies need today. By combining sterilisation, laboratory, validation, and manufacturing services under one roof, we help you move faster, simplify complexity, and bring your products to life — all while maintaining the highest standards of precision and quality.

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Medistri is continually innovating its **in-house** range of services. We're expanding our infrastructure to offer a completely integrated stack of services for healthcare companies. Organisations of every size — from startups to large enterprises use our suit of services to start, grow & optimise their business.

Within our site located at the heart of Switzerland, Medistri **combines all its technical infrastructure together** and places quality at the heart of its day-to-day operations. Allowing you to simplify your supply chain management, focus on growth & maintain excellence.

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