



Endosafe®-PTS™ Glucan Assay

We understand that you need to ensure that your products are as free of contaminants as possible. Recent inspections have indicated a need to verify the absence of glucans. Charles River is proud to offer the Endosafe®-PTS™ Glucan Assay, a rapid test designed for investigational purposes to validate that your products are free of (1,3)- β -D glucans.

(1,3)- β -D Glucans

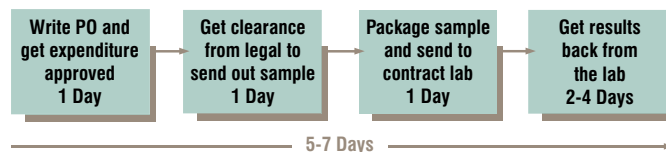
The (1,3)- β -D glucan molecules can be found in the cell walls of most yeasts and molds. These glucans contaminate cell culture fluid, yeast protein production, air quality samples, and cellulose filter preparations. Glucans are known to cause false-positive results in LAL assays, triggering investigations.

Charles River's new PTS™ Glucan Assay allows you to quickly and easily quantify these glucans, leading to better process monitoring and faster out-of-specification (OOS) resolutions. The Charles River glucan cartridges have a sensitivity range of 10-1,000 pg/ml, yield results in less than 30 minutes, and can be run on the same Charles River instrument that is used for PTS™ endotoxin detection or PTS™ Gram ID. The appropriate glucan-detection software comes standard with current PTS™ models.

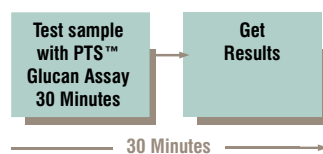
Utilizing PTS™ Glucan Assay for OOS Investigations

A Biopharmaceutical QC lab routinely performs LAL testing on water, in process and product release samples. When a high spike recovery occurs, the invalid test triggers an investigation. The first step of the investigation is to rule out a false positive due to glucan contamination which involves sending samples out to a contract testing lab.

Typical OOS Investigation



OOS Investigation with Endosafe®-PTS™ Glucan Assay



As these timelines show, testing immediately with the PTS™ Glucan Assay to confirm or rule out glucan contamination is a fast, convenient, and efficient method for handling an OOS investigation. The immediacy of the test results allows manufacturing to move forward quickly with the appropriate course of action, eliminating delays and hold steps in the process.

Applications

- LAL endotoxin OOS results
- Yeast protein production
- Cell culture fluid
- Air quality
- Cellulose filter preparation

Advantages of Endosafe®-PTS™ Glucan Assay

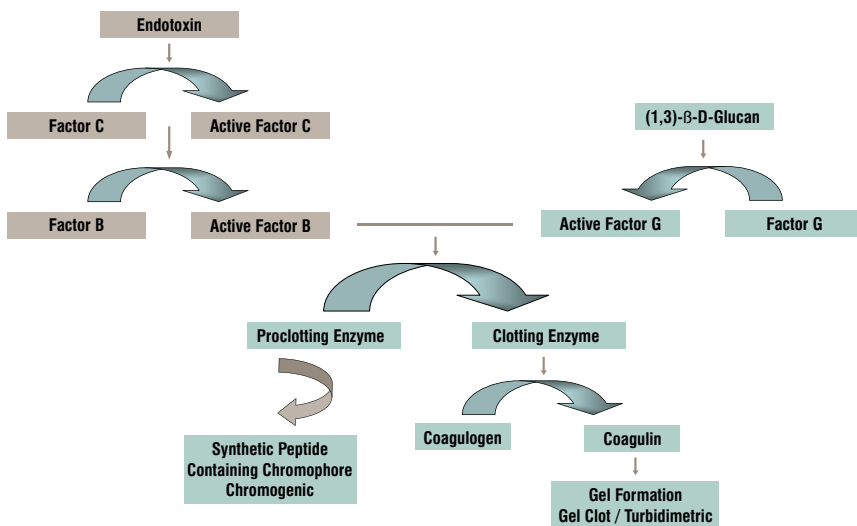
- Results in about 30 minutes
- Self-contained, disposable cartridges
- Same PTS™ reader for LAL and Gram ID
- No need to prepare a standard curve
- Portable, handheld test system
- Single-step, quantitative test



Test Principle

The Endosafe®-PTS™ glucan assay employs the *Limulus* enzyme cascade to detect (1,3)- β -D glucan in a sample. The Endosafe®-PTS™ cartridge and its interface with the reader have been designed to mimic kinetic chromogenic methods by measuring color intensity directly related to the (1,3)- β -D glucan concentration in a sample. Each cartridge contains precise amounts of glucan-specific LAL formulation, chromogenic substrate, and glucan standard.

Limulus Enzyme Cascade



Test Procedure

To perform the test, simply pipette 25 μ l of a sample into each of the four sample reservoirs of the cartridge. Insert the cartridge into the Endosafe®-PTS™ and press Enter. The reader draws and mixes the sample with the LAL reagent in two channels (the sample channels) and the LAL reagent and positive product control in the other two channels (the spike channels). The sample is incubated and then combined with the chromogenic substrate. After mixing, the optical density of the wells is measured and analyzed against an internally archived standard curve. The results are then displayed onscreen in less than 30 minutes.

Data Analysis

With the PTS™, data reporting is simple. At the conclusion of the test, the glucan measurement and the assay acceptance criteria are displayed on the screen. The PTS™ reader measures the reaction time in each cartridge channel and compares the results to an archived standard curve specific for that lot of cartridges. The sample and spike values are calculated by extrapolation from the standard curve using reaction times. The PTS™ reader can store up to 100 assays in memory, and glucan test results may be sent directly to a printer or downloaded to a computer.