

A sure BET for workflow automation

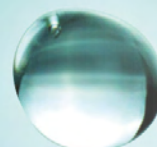


Bacterial endotoxin testing (BET) is an important quality control check for the pharmaceutical and biomedical industries, ensuring that injectable or intravenous drugs and implantable medical devices are safe to use. Lonza offers a wide range of reliable BET solutions for QC labs, including high throughput, automated systems for microplate-based endotoxin detection.

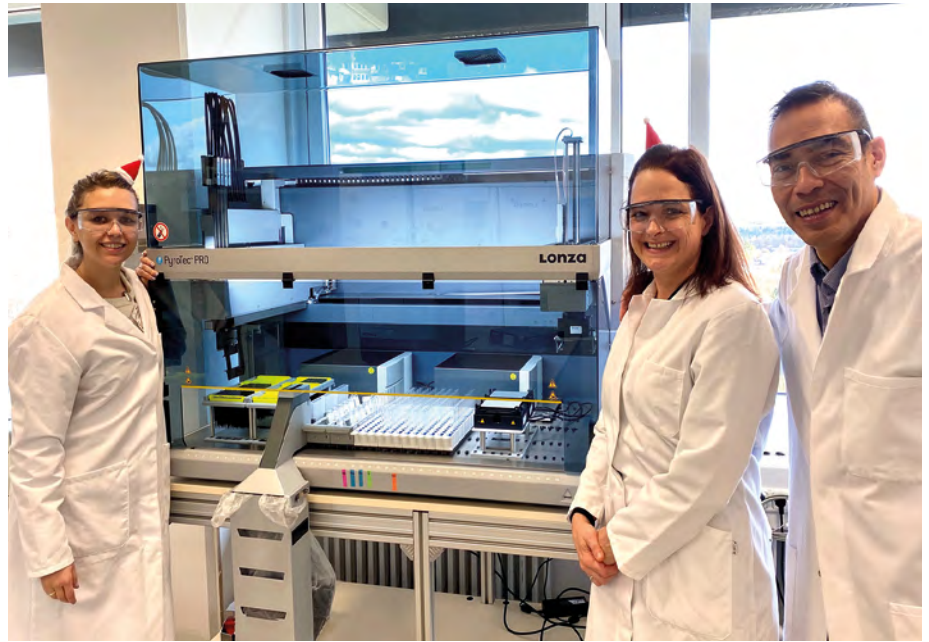
Lonza

Endotoxins are large molecules found in the outer membrane of Gram-negative bacteria, helping the bacteria to survive in harsh environments. This role in nature makes the presence of endotoxins difficult to control in a laboratory environment, as they are resistant to extreme conditions, including high heat and chemical treatments. Unfortunately, when present in ng/kg concentrations *in vivo*, endotoxins can cause symptoms such as fever and pyrogenic shock, making it essential that parenteral medicines – drugs using non-oral means of administration – vaccines and implantable medical devices are routinely tested for the presence of endotoxins during production. Ruth Noé, a Senior Product Manager at Lonza, has been working in this area for 20 years, and explained the process: “Our partners test production waters, raw materials, in-process samples and manufactured products to both meet the regulators’ requirements and to mitigate contamination risk in their processes. For pharmaceutical companies, around 60-70 percent of all BET is on production waters and, if any contamination is detected, it can impact the final product integrity, so testing needs to be both fast and highly reliable for corrective and preventative action to be taken in a timely manner.”

Automation is the obvious solution to this challenge, and Lonza wanted to build on the success of its early PyroTec® Platform – a Freedom EVO®-based system mainly used in the dialysis market – by creating a fully automated, integrated BET system specifically for QC activities in the pharmaceutical and biomedical sectors. Ruth continued: “The PyroTec® PRO Automated Solution offers users the ability to move away from manual benchtop endotoxin detection protocols to a fully automated workflow. It has been developed from the outset for mid-sized pharma and biotech companies around the world performing QC testing in GMP environments, where reliable technology and strong support are critical. Many of these customers are already using manual, plate-based testing solutions, and might have automated other processes in areas like chemistry, so it’s a natural progression.”



“We are very happy with our ongoing relationship with Tecan. Moving forward, we have a clear product development roadmap for our BET portfolio.”



The PyroTec® PRO System offers a fully automated endotoxin detection workflow (NOTE: Photo taken prior to social distancing)

Lonza's goal for the PyroTec® PRO System was to provide a user-friendly, fully integrated automated system to help increase the productivity of BET for its customers. Ruth commented: “From our previous experience working with the Tecan Synergence™ team on the original PyroTec® System, it was an obvious choice to use this partnership when discussing the development of the PyroTec® PRO System, as it was evolution rather than revolution. Tecan has extensive experience with liquid handling and automation, and we have the expertise in endotoxin testing, so putting the two together is great. We also take pride in the fact that both companies have experience in the GMP-QC environment, where many other suppliers may not.”

“The PyroTec® PRO System is based on a proven and reliable technology – Tecan's Freedom EVO 150 workstation – with both a Liquid Handling Arm™ and a Robotic Manipulator Arm™ to completely automate the liquid handling processes. Crucially, the system also features an integrated Sunrise™ absorbance microplate reader to allow walkaway measurement and data acquisition. Endotoxin detection assays must be performed within a specific temperature range to comply with pharmacopeial regulations, so temperature management is critical for the acceptance of the results. We

worked with Tecan to develop a special firmware that takes the temperature readings at a slightly different time point than usual, to confirm testing is performed within the specified temperature range. The system also features an additional insulation plate to help minimize temperature fluctuations.”

A lot of focus when developing the PyroTec® PRO System was on the software. Ruth explained: “Scripting the workstation's movements in Freedom EVOware® was really just the first step, as our vision for this system was that customers could simply set up their samples using a template within our WinKQCL® Endotoxin Detection & Analysis Software, populate the deck, click go, walk away and come back to results later. However, about 30-40 percent of all tests are on sample matrices that require dilution or additional diluents or additives – such as magnesium chloride – to overcome assay interference before running. Scripting for each individual sample in Freedom EVOware simply wasn't feasible so, with Tecan's support, our software developers created a Lonza patented dynamic scripting interface that seamlessly integrated our market-leading WinKQCL® Endotoxin Detection & Analysis Software with the system. Whether the data is from a manual or automated process, the

WinKQCL® Software allows users to save and manage the data on a central database, accessible to any authorized individuals within the company – at any site – streamlining data management and giving our customers greater flexibility.”

“We are very happy with our ongoing relationship with Tecan and are constantly working with the Tecan team to keep our customers happy, from the initial installation to making sure that processes and documentation are updated and adhered to. Moving forward, we have a clear product development roadmap for our BET portfolio with Tecan, including the possibility of future system iterations based on new decks, platforms and readers,” concluded Ruth.

To find out more about Tecan Synergence, go to
www.tecan.com/synergence

To learn more about product disclaimers and Lonza's automated endotoxin testing, visit
www.lonza.com/endotoxin-automation