Health Technology Review	
Technology Ref.:	HTA-23045
Technology Name:	Endosafe®-PTS™ system & Endosafe®-PTS™ cartridges
Approvals by International Bodies:	US FDA Approval for (Cartridge) , EU, Malaysia, Indonesia, Thailand
Company name:	Charles River
Agent in UAE:	Al Nawras Medi-Lab Supplies -Business Tower, 38th Floor, Al Majaz 2, Sharjah, United Arab Emirates
Email:	Dawood@alnawras.ae

Short Description of the Technology:	The Endosafe® nexgen-PTS™ is a rapid, point-of-use handheld spectrophotometer that uses USP/BET-compliant disposable cartridges for accurate, convenient, and real-time endotoxin testing, glucan concentration determination, and Gram identification. With its small benchtop footprint, the Endosafe® nexgen-PTS™ is ideal for small to mid-size pharmaceutical companies, Dialysate Water System and compounding pharmacies .

Health Technology Assessment Team Recommendation:	**Approve**

Summary of Review:

The technology is a versatile test that can be used to test a variety of biological samples (Pharmaceutical , Dialysis Clinics , laboratory and environmental), and it can provide a consistency, accuracy, time saving , less Probability of human error, traceability and quantification.
This technology as it uses artificial intelligence inadvance by using wifi capabilities, password protected login, optional barcode scanning for data entry, minimum of 8GB internal storage and also designed for wireless data export , remote system control and cable free printing.

Advantages	Disadvantages
Technology utilizes FDA-licensed (limulus amebocyte lysate) LAL cartridges.	Both the Endosafe nexgen-MCS and the Endosafe nexgen-PTS utilize the FDA-licensed Endosafe cartridge technology for LAL testing, however an Endosafe nexgen-MCS is better for a higher volume of 5 samples at once verses with Endosafe nexgen-PTS can process only one sample at a time.
No significant history of device recall, or failure was detected.	Only Charles River Endosafe® instruments use cartridge technology. No other brand of endotoxin testing instruments is equipped to use cartridge technology.
It is a sensitive and specific test that can detect endotoxin at very low levels.	
It is a rapid test that can provide results in a short period of time.	

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We recommend an **approval of using this technology** with the following conditions:

The approval on using Endosafe®-PTS™ system & Endosafe®-PTS™ cartridges:

1. To be performed by medical lab technology and clinical pharmacist .
2. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
3. Provision of regular updates and reports about the product to DOH upon request.

Moreover, DOH has the right to stop the product at any stage if deemed necessary, initial conditions and any subsequent conditions must be satisfied before obtaining final approval. Failure to do so will reflect in provoking the approval.

Technology Image

Population, setting and intended user for Technology "Endosafe®-PTS™ system & Endosafe®-PTS™ cartridges"."

- **Population/ Intended User**;
  - NA
- **To be performed by**:
  - By medical lab technology and clinical pharmacist
- **Clinical Setting:**
  - Hospitals, enviromenal lab , pharmacy, in-centre and community dialysis units (CDUs) that provide hemodialysis (HD) and/or hemodialfiltration(HDF).
- **Condition of use:**
  - All injectable pharmaceuticals.
  - Implantable medical devices.
  - Water dialysis unit
  - Surgical Instruments, Cleanroom and Gloves.
  - Cell therapy.
- **Exclusion criteria:**
  - This test is not meant to identify endotoxins for patient liquid samples or to make a medical diagnosis.