Greyfalcon Healthcare Pvt. Ltd.

An ISO 13485:2016 certified company

toxypho™

A Chemiluminometer for EAA™

www.toxypho.com

EAA™ Endotoxin Activity Assay from Spectral Medical Inc. is the only commercially available test to measure endotoxin activity in whole blood that is cleared by the US FDA, licensed by Health Canada in 2003, and CE marked.

SPECTRAL Medical INC

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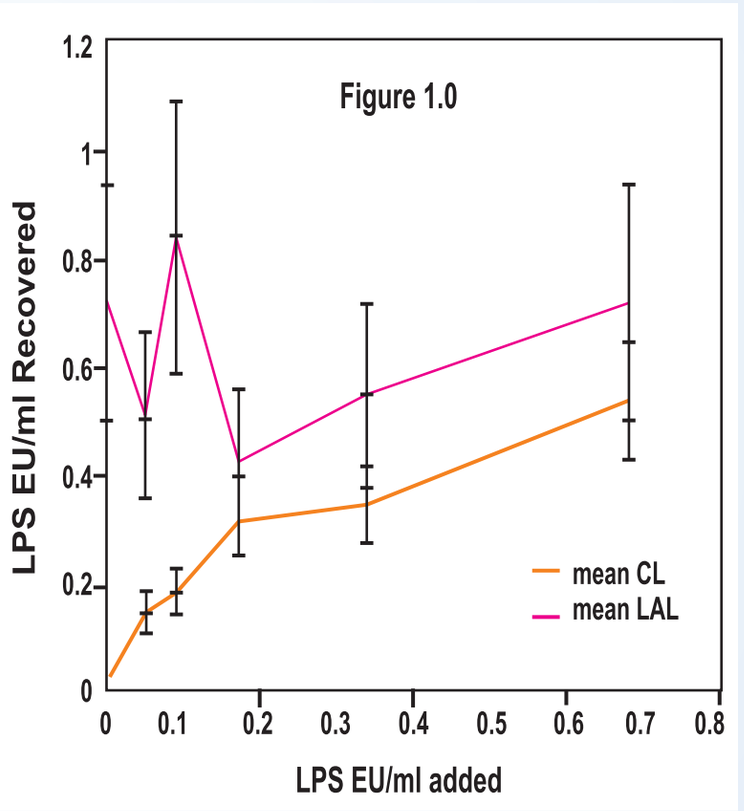
EAA™

Until the EAA™, there has been no reliable method to measure endotoxin accurately in the bloodstream. It is a semi-quantitative test in the measurement of endotoxin activity (EA) and allows for rapid measurements whereby results can be obtained in approximately 30 minutes.

The **Endotoxin Activity Assay** can be used at the bedside as a reliable biomarker of systemic endotoxemia. The use of a whole blood chemiluminescence test that utilizes each patient as their own control is simple,sensitive, and more accurately represents true blood levels of endotoxin.

- The detection of elevated endotoxin activity levels has been repeatedly shown to be associated with increased disease severity in patients with sepsis and septic shock.
- The EAA™ combines the specificity of a murine monoclonal antibody against the Lipid A epitope of endotoxin with the sensitivity of chemiluminescence.
- By providing the caregiver with reliable, time-critical information, the EAA™ allows clinicians to rapidly determine the extent of endotoxemia in their patients and can assist in stratifying patients at high risk for severe sepsis who may benefit from early interventions to prevent the late sequelae of sepsis including multi-organ failure and death.
- Presently there is no known test against which this test can be compared. Further, the endotoxin activity in any given individual's blood is a result of not only the concentration of endotoxin but the individual's cellular and humoral responsiveness to endotoxin-antibody immune complexes.



HOW THE EAA™ IS DIFFERENT

LAL vs. EAA™: The EAA™ uses a highly specific IgM antibody for the most preserved structural component of endotoxin, Lipid-A. This allows the EAA™ to specifically measure endotoxin activity in human whole blood, something the Limulus Amebocyte Lysate (LAL) assay is not capable of doing. The EAA™ is a rapid assay (approximately 30 minutes from sample to result) designed specifically for endotoxin activity measurement in whole blood.

The LAL assay is a highly sensitive test for endotoxin measurement in crystalloid solutions and is not accurate when utilized in whole blood or plasma. This is due to the fact that blood contains many components known to inhibit or activate the enzymatic cascade of the LAL, such as serine proteases. In order to attempt to use the LAL for blood-based endotoxin testing, the sample must first be treated with strongly acidic or caustic chemicals, increasing the risk to the user, complexity of the test, and assay time from sample to result.

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- toxypho™ is a CE certified, Ultra low power, Ultra-compact, Android™ application based Chemi-Luminometer manufactured by Greyfalcon Healthcare Pvt. Ltd. It is an innovative product designed to meet the requirements of Endotoxin Activity Assays measurements.

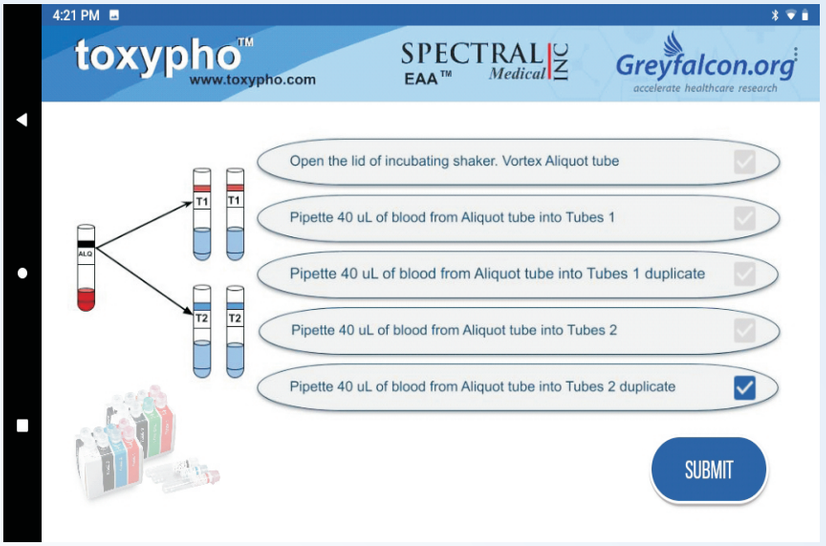
- It is a small, user-friendly instrument that combines a distinctive mechanical design with advanced photon counting electronics and a highly sensitive detector. The machine doesn't require any further on the site calibration.

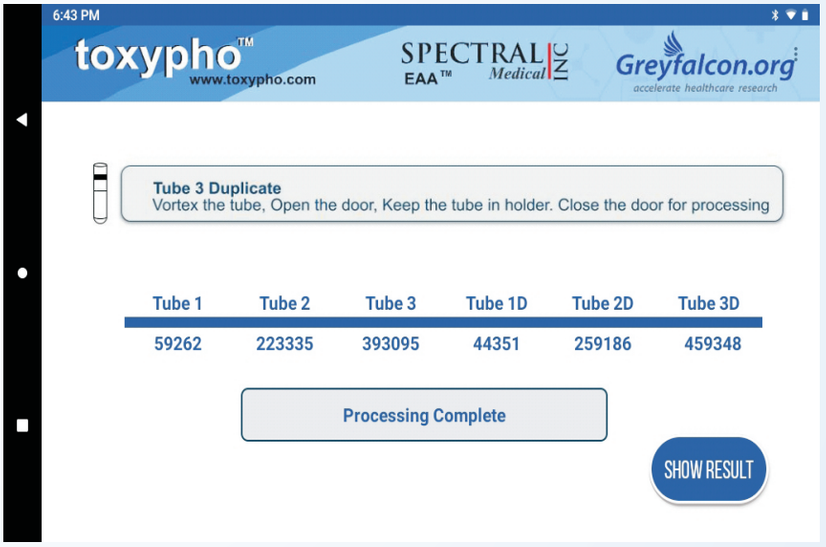
- For the best possible sensitivity, the detector is located under the sample chamber in very close proximity to the sample.

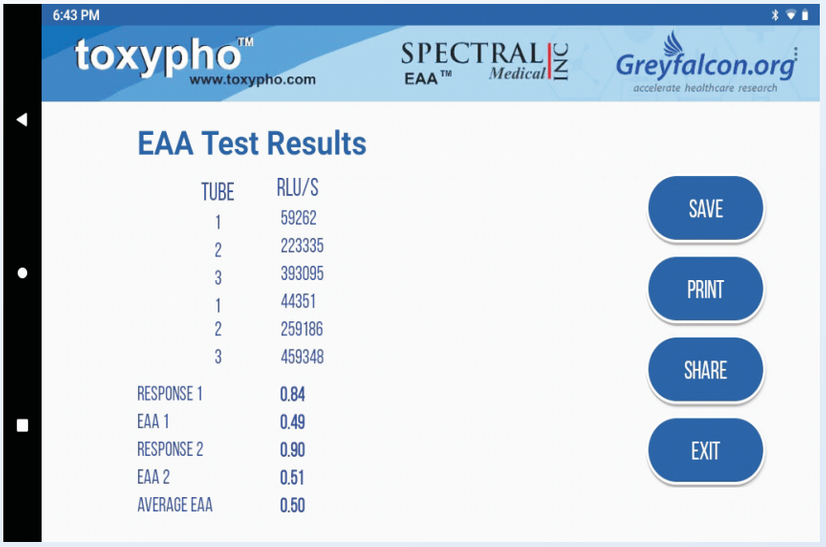
- Operating device with Rich UI, Android™ powered Tablet for user input gives high definition user experience.

- EAA Test Results of each Sample can be printed instantly on the inbuilt thermal printer, shared instantly over email or saved in a report in .xls format for later reference. The report file can be emailed or shared over WiFi

- Progress of the activity and error alerts are shown on the display unit.







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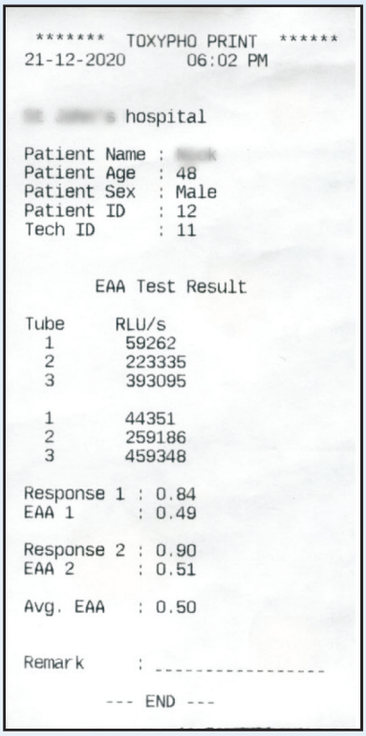
TECHNICAL SPECIFICATION

Dimension and body	13" x 9" x 11" (inches) Fibre-Reinforced Polymer (FRP) body to avoid electrical hazards.
Weight	7 Kgs
User Interface	7″ Android-powered Tablet for User Interface
Printer	Panel mount Thermal printer with 32 characters per line.
Sample Format	Tube 12 mm in diameter (75 or 55mm length).
Electrical Data	Power Supply 110/230VAC, 50/60Hz Current consumption - 0.4A In-built Tablet USB charger included



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******* TOXYPHO PRINT ******
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[illegible] hospital

Patient Name : [illegible]
Patient Age  : 48
Patient Sex  : Male
Patient ID   : 12
Tech ID      : 11

        EAA Test Result

Tube      RLU/s
  1       59262
  2       223335
  3       393095

  1       44351
  2       259186
  3       459348

Response 1 : 0.84
EAA 1      : 0.49

Response 2 : 0.90
EAA 2      : 0.51

Avg. EAA   : 0.50

Remark     : ----------

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CE

Manufactured by :

Greyfalcon Healthcare Pvt. Ltd.

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