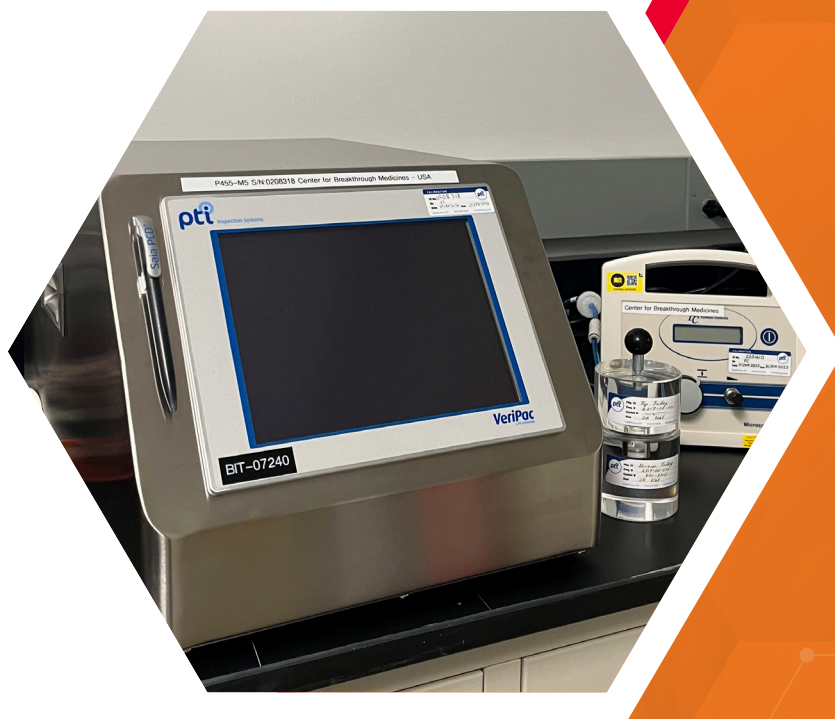


DATA SHEET

# Microbiology Analytical Services



AVAILABLE AT:



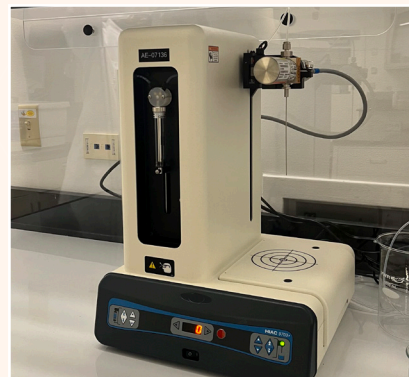
[www.breakthroughmedicines.com](http://www.breakthroughmedicines.com)  
[www.skpharmteco.com](http://www.skpharmteco.com)

## CURRENT OFFERINGS

- Method Development & Verification
- Release Testing
- Reference Standard Qualification
- Compendial Testing (USP / EP / BP / JP)
- Sterility USP <71> EP 2.6.1
- BacT alert – Rapid Sterility
- pH USP <791> EP 2.2.3
- Endotoxin USP <85> EP 2.6.14
- Osmolality USP <785> EP 2.2.35
- USP <61> EP 2.6.12 Bioburden testing
- USP <841> Specific Gravity
- USP <841> Density
- Milliflex Oasis
- Environmental monitoring
- Gram staining
- Growth Promotion of media

## FUTURE DEVELOPMENT

- Container closure integrity testing – Vacuum Decay, Co2 Headspace analyzer
- Particulate Matter USP <788>, <787>
- Vitek MS – Microbial Identification
- Total Organic Carbon USP <643>
- Milliflex Quantum
- Mycoplasma USP <63>



## STATE-OF-THE-ART EQUIPMENT

Type	Manufacturer	Model
BioSafety Cabinets	Baker	SterilGARD e3
Microbial Detection system	Biomerieux	BACT/ALERT 3D
Isolator	Getinge	Isoflex-R ETF 4G+BDC
Isolator	Ecolab	QUBE
Maldi-TOF	Biomerieux	Vitek MS prime
Container Closure	PTI	Veripac 455
Container Closure	Lighthouse instruments	Co2 Headspace analyzer
Endotoxin	Charles River	Endosafe MCS/PTS
Osmometer	Advanced Instruments	OsmoTECH XT
TOC Analyzer	Sievers	Sievers Mg TOC analyzer
Pycnomter	Kimax	Pycnometer
Ligth box	VWR	Light boxes
HIAC	Thermofisher	HIAC 9703+
Incubators	ThermoScientific	FORMA 3900
pH Meters / Conductivity	Mettler/Orion	Various
Microbial Detection system	Millipore	Milliflex Oasis/Quantus
Microscope	Leica	Microscope
Air sampling	Lighthouse Worldwide Solutions	Activecount 100
Particle counters	Lighthouse Worldwide Solutions	ApexZ