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# Meeting with Management

## Microbial Solutions

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# Focus Areas of Today's Discussion on Microbial Solutions



## **Innovation**

Robust new product offerings, strong internal R&D capabilities, and strategic partnerships position us well for continued strong growth

## **Sustainability**

Committed to offering sustainable product alternatives as demonstrated by our recent animal-free Endosafe® Trillium® launch and our proprietary cartridge technology

## **Digitally enabled growth**

Digital solutions for our clients will drive efficiencies and improved connectivity across our portfolio and improve the overall client experience

# Microbial Solutions

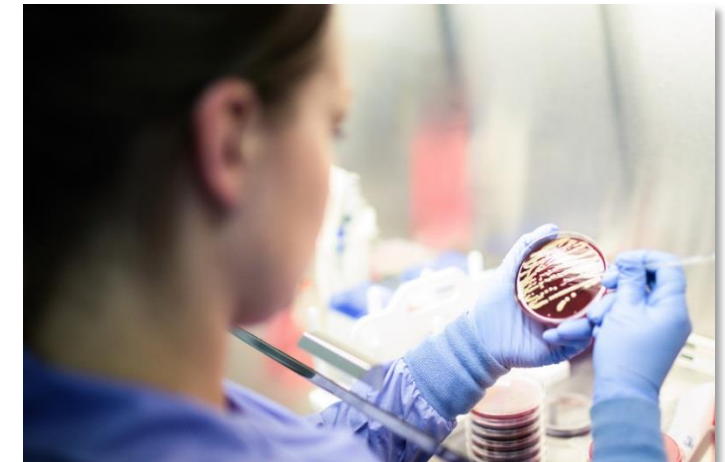
Advancing the safety of patients and consumers by empowering our clients with sustainable and data-driven solutions that meet the highest quality standards in microbial contamination control



**Endosafe® Endotoxin Testing  
for Sterile Applications**  
Traditional & Cartridge Technology



**Celsis® Rapid Microbial  
Detection for Sterile & Non-  
Sterile Applications**



**Accugenix® Microbial  
Identification & Strain Typing**

# Premier Global Provider of Manufacturing Quality Control (QC) Testing Products and Services for Sterile and Non-Sterile Applications

## Endosafe® Bacterial Endotoxin Testing

>2,500,000

FDA-licensed cartridges sold in 2022 for the use of our highly flexible Endosafe® rapid testing platforms

## Celsis® Rapid Microbial Detection

>470

Successful installations for Celsis® rapid microbial detection systems for bioburden testing

## Accugenix® Microbial Identification & Strain Typing

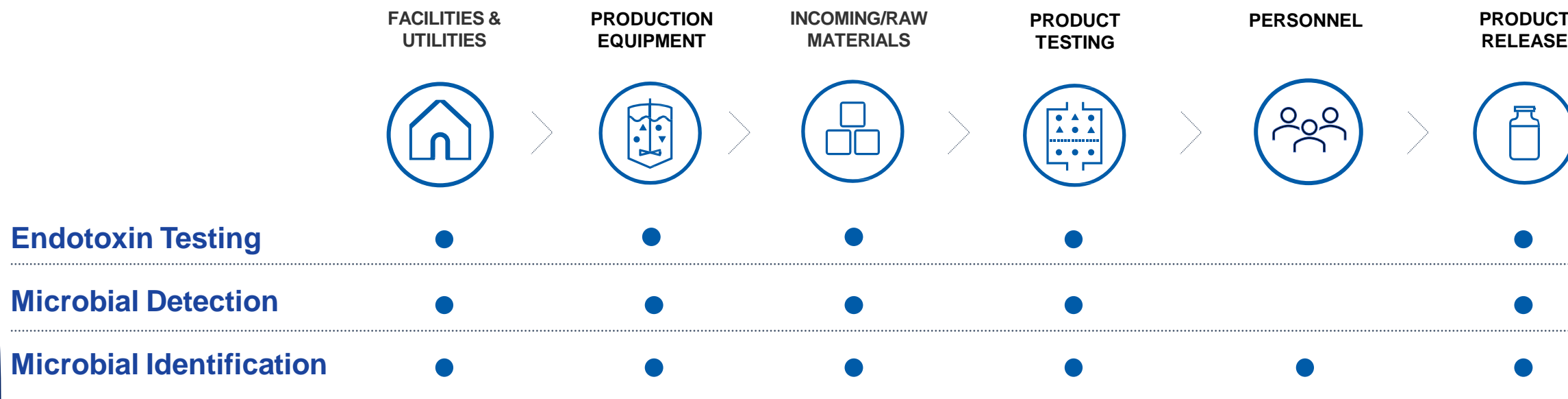
>600,000

Samples and microbial identification reports were processed by Accugenix® in 2022



# QC Microbial Testing for Contamination Control

Our portfolio supports clients through the biopharma manufacturing process



Precise Endotoxin Detection  
with Endosafe® Bacterial Testing

Rapid Contamination Detection  
with Celsis® Microbial Testing

Environmental Monitoring  
Support with Accugenix®  
Identification & Strain Typing

# Endosafe® Endotoxin Testing

The most comprehensive FDA-mandated lot release testing platform for endotoxin detection



## Traditional LAL Reagents

- Robust formulation that increases sensitivity, linearity, and superior interference resistance to deliver accurate and reliable results

>50% share by  
endotoxin test volume



## LAL Cartridge Technology

- Rapid, efficient, and flexible: Our FDA-licensed LAL cartridge technology enhances efficiency, minimizes variability, and enables data integrity compliance

>10% of endotoxin  
tests converted to  
rapid methods



## Recombinant Cascade Reagent

- Trillium®: An enriched animal-free assay for bacterial endotoxin testing that includes an optimized 3-factor enzymatic cascade formulation

Trillium® cartridges  
available in 4Q23

# Celsis® Rapid Microbial Detection

- A complete solution for rapid microbial detection with focus on sterility and bioburden testing
- Conventional methods represent 95% of current microbial detection tests performed
  - Large runway for future growth for rapid microbial methods
- Benefits of the Celsis® rapid platform:
  - Integration into clients' current testing protocols
  - Eliminate days of incubation
    - Sterility results in 6 days
    - Bioburden results in 24 hours
  - Objective results that replace manual eye counts or visual turbidity checks with automated, instrument-based analysis



# Accugenix<sup>®</sup> Microbial Identification

Maximize environmental control with unparalleled accuracy in strain typing and next-generation sequencing



**>600,000**

Samples processed  
in 2022



**90%**

Species identification  
rate



**>14,000**

Unique bacterial and  
fungal species entries in  
our proprietary libraries

*Global footprint*



**>91,000**

Samples processed  
with same-day  
turnaround time



**2,600**

Samples a day  
tested in our labs



**>70**

Axcess<sup>®</sup> systems  
installed

# Microbial Solutions Growth Targets

Microbial Solutions expected to continue to grow faster than market sector for manufacturing QC testing

- Continued portfolio expansion, product innovation, and geographic expansion
- Accelerated conversion of clients to Endosafe® cartridges
  - Enables share gains since we have the only comprehensive rapid testing platform
  - Endosafe® cartridge tests are priced at a premium compared to traditional LAL tests because rapid results and ease of use drive greater efficiency and cost savings for our clients
- Increased penetration of high-volume clients through enhanced system automation (i.e., Endosafe® Nexus 200™)
- Expanded offering for a growing number of clients looking for recombinant or sustainable alternatives (i.e., Trillium®)
- Momentum with global pharma clients adopting Celsis® for rapid sterility, enabling faster release of products and greater operational efficiencies
- Maintain robust growth for Accugenix® microbial identification solutions
  - Continued market adoption of outsourcing trend, favorable regulatory environment, and additional Europe/Asia-Pac expansion

~\$3B

Microbial Solutions addressable market sector opportunity

**High-single digit**

CRL Microbial Solutions revenue growth target for 2023-26E (CAGR)

~70%

Microbial Solutions revenue from reagents/consumables, creating a recurring revenue stream

# Microbial Solutions Growth Drivers

Accelerating market penetration through expanding innovation



## Portfolio Expansion Fueled by Market Drivers

- Next-generation sequencing bolsters our microbial identification portfolio
- Endosafe® Nexus 200™ for endotoxin testing addresses automation needs for lab efficiency
- Celsis Adapt™ provides microbial detection for cell-based products within C&GT



## Investment in Research and Development

- Developing and/or acquiring new skillsets in automation, AI, software development, and optics to maintain leading portfolio development
- Exploratory technology development to successfully design solutions to close critical gaps in the QC testing process



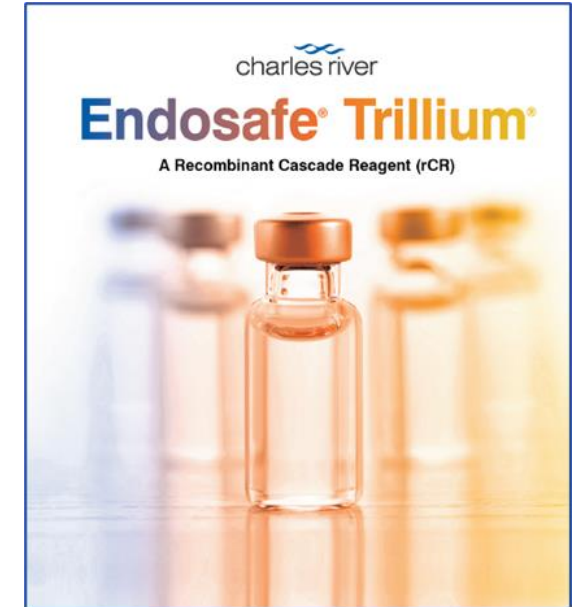
## Maximize Global Footprint

- Introducing lab support for feasibility and validation in Ireland and Singapore
- Expanding core capabilities in South Carolina, Korea, Australia, and Ireland with facility expansions
- >60% of revenue outside the US

# Introduction of Animal-Free Endosafe® Trillium®

Dedicated to identifying sustainable technologies that reduce animal use while ensuring patient safety

- Robust, animal-free recombinant cascade reagent (rCR) represents a next-generation solution to our industry-leading Endosafe® bacterial endotoxin detection portfolio
  - Enriched proprietary assay for bacterial endotoxin testing provides confidence and safety in product manufacturing
- Trillium® utilizes 3 biological proteins, which we believe provides superior accuracy and testing outcomes to competitors' single-protein alternatives, as well as equivalence to LAL-based testing methods
- Believe client adoption will be gradual over next several years, but an important development for those clients focused on adopting more sustainable practices



Evolution in  
**Responsible** and  
Sustainable  
Endotoxin  
Testing

Gel-Clot  
LAL



**0%**  
Reduction

**Kinetic  
Turbidimetric LAL**

Zero reduction in horseshoe  
crab blood from Gel-Clot

**54%**  
Reduction

**Kinetic  
Chromogenic LAL**

54% reduction in horseshoe  
crab blood from Gel-Clot

**95%**  
Reduction

**LAL Cartridge  
Technology**

95% reduction in horseshoe  
crab blood from Gel-Clot



**100%**  
Replacement

**Recombinant Cascade  
Reagent (rCR)**

100% horseshoe crab blood free



# Microbial Solutions Strategic Imperatives



## Enhance Portfolio

**Continue to build leadership position with dynamic portfolio focused on rapid microbial detection and identification**

- Leverage strength in sterile and non-sterile QC markets to drive client adoption of comprehensive testing portfolio



## Innovative Growth

**Continue to innovate product/service offerings through internal development, acquisitions, and/or licensing**

- Position portfolio to capitalize on innovation and key market drivers



## Sustainable Science

**Drive sustainability initiatives through adoption and positioning of diverse endotoxin products**

- Recent launch of animal-free Trillium® endotoxin test demonstrates our commitment to sustainable alternatives



## Digitally Enabled

**Address industry need for lab efficiency through automation and improved data integrity**

- Provide data analytics solutions to improve client lab efficiency and decision making



## Advance Culture

**Delivering meaningful contributions through an exceptional work environment**

- Focused on opportunities for growth, well-being, employee development, and recognition



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