Making the Medicines of Tomorrow

redberry
A **Lonza** Company

Red One™ System

Rapid microbial detection

Why speed matters

In pharmaceutical and bioprocessing QC, time is the enemy. Traditional microbiology requires days to weeks of incubation, delaying batch release and slowing manufacturing. For biologics, cell therapies, and short shelf-life products, this delay is **unsustainable**. Your products cannot wait for legacy methods to catch up.

The Red One™ System speed advantage

Red One™ System directly addresses this challenge by delivering true rapid microbial detection that reduces or eliminates dependence on microbial growth.

Instead of waiting days for colonies to form, Red One™ System detects metabolically active viable cells directly, providing 10-minute microbial screening, 4-hour bioburden results, and 4-day sterility outcomes.

Application	Traditional	Red One™ System
Direct Viable Count (screening)	3 – 5 days	**10 minutes**
Bioburden Testing	5 – 7 days	**4 hours**
Sterility Testing	14 days	**4 days**

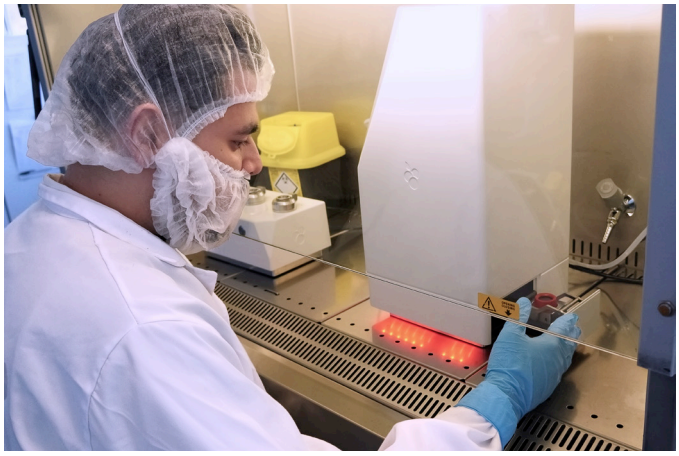
Red One™ System enables QC labs to keep up with modern manufacturing and clinical realities. Speed can mean:

- Faster batch release
- Reduced inventory burden
- Better support for therapies with short shelf lives
- Early detection of contamination
- More reliable and consistent results

And ultimately: **Patients get safe therapies sooner.**

How Red One™ System delivers this speed

Red One™ System uses solid-phase cytometry (SPC) to detect single viable cells—not colonies. Traditional methods rely on visible colonies or turbidity to confirm contamination—requiring the presence of millions of cells. The Red One™ System detects down to a single cell, exceeding the sensitivity of conventional rapid methods such as flow cytometry or ATP assays (typical LOD ~1,000 cells/mL). No manual microscopy. No operator-dependent interpretation.



GMP-compliant and fully validated

- Validated to Ph. Eur. 5.1.6 / USP <1223> – Primary Validation Package available.
- 21 CFR Part 11 compliant software – Audit trails, user management, data integrity.
- Broad matrix compatibility – Cell-based products, radiopharmaceuticals, mRNA vaccines, filterable liquids.
- Validation support included – Redberry team guides you through product-specific (PQ) validation for seamless adoption.

Ready to accelerate your release testing?
Learn more: **redberry.net**

Contact us

North America
Customer Service: +1 800 638 8174 (toll free)
order.us@lonza.com
Scientific Support: +1 800 521 0390 (toll free)
scientific.support@lonza.com

Europe
Customer Service: +32 87 321 611
order.europe@lonza.com
Scientific Support: +49 221 99199 400
scientific.support.eu@lonza.com

International
Contact your local Lonza distributor
Customer Service: +1 301 898 7025
scientific.support@lonza.com

Lonza Walkersville, Inc. – Walkersville, MD 21793

Learn more.

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