

# EMBARK ON THE REMARKABLE

CELL AND GENE  
THERAPY LABORATORY  
EQUIPMENT



# CTS Series lab equipment

Thermo Scientific™ Cell Therapy Systems (CTS™) Series laboratory equipment supports your GMP and cleanroom needs for cell and gene therapy manufacturing. CTS series cell and gene therapy bundles consist of equipment, documentation, and certifications, as well as compliance services.

Our fit-for-purpose solutions help you get up and running faster, stay compliant, navigate regulatory audits, and stay on schedule as you translate your cell therapy from discovery to clinical research and commercial manufacturing.



**Product**



**Documentation  
package**



**Compliance  
services**

# Heracell Vios CR CO<sub>2</sub> Incubator—CTS Series

## Next-generation cleanroom confidence



### Product

The Thermo Scientific™ Heracell™ Vios™ CR CO<sub>2</sub> Incubator—CTS™ Series is a third party–certified, cleanroom-compatible CO<sub>2</sub> incubator, suitable for use in ISO Class 5 and GMP Grade A/B environments.

### Features:

- Active particle control system
- Thermo Scientific™ THRIVE™ active airflow technology for homogeneous growth conditions
- 180°C high-temperature decontamination cycle
- Enhanced cleanability and compatibility with common cGMP facility protocols and cleanroom procedures, including STERIS™ vaporized hydrogen peroxide (VHP) biodecontamination technology
- IR sensor
- 4–20 mA data output
- Optional variable oxygen control
- 165 L (160i model) or 255 L (250i model) capacity
- Inner chamber options: stainless steel, copper, or a Thermo Scientific™ Cell Locker™ System (160i model only)



### Documentation package

The documentation package consists of regulatory certificates, recommended protocols, and product-specific factory documentation and specifications (see page 8 for details).



### Compliance services

Gain confidence with our requalification services that can help reduce your risk of non-compliant instruments. Service options include installation qualification (IQ), operation qualification (OQ), and temperature mapping (see page 10 for details).





# Herasafe 2030i BSC—CTS Series

## Smarter protection that never takes a day off



### Product

Our most technologically advanced Class II cabinets available, Thermo Scientific™ Herasafe™ 2030i Biological Safety Cabinets (BSCs)—CTS™ Series optimize contamination prevention, convenience, and information management. Designed for performance and precision, they are equipped with smart, self-monitoring safety features; intuitive, graphic touchscreen interfaces; and built-in connectivity. They are ideal for demanding cell culture applications in the biopharmacy and other industries that require safe handling of products and protection of personnel and the environment.

#### Features:

- Precise autonomous protection—Thermo Scientific™ SmartFlow™ Plus and DAVE™ Plus technology, and a self-adjusting UV germicidal light help maintain and monitor critical conditions
- Simplified operation and ergonomics—intuitive user interface and fully opening, electronic front sash enable user safety and easy cleaning
- Enhanced information management—can be connected to remotely monitor and preserve important performance data



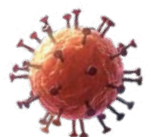
### Documentation package

This product is manufactured within an ISO 13485 environment and is provided with comprehensive FAT documentation to facilitate timely validation including regulatory certificates, recommended protocols, and product-specific factory documentation and specifications (**see page 8 for details**).



### Compliance services

Gain confidence with our requalification services that can help reduce your risk of non-compliant instruments. Service options include IQ and OQ and chamber mapping (**see page 10 for details**).



# General Purpose Pro Centrifuges—CTS Series

## Optimal g-force and speed for cellular separation



### Product

Cellular separation is a critical and essential step in your process and it is important to consider and select the correct specification that can assure your success. The proper speed and g-force, the adaptability to your sample containers, the biocontainment certification, the usability and reliability, and the mobility in the cleanroom are all important features that Thermo Scientific™ General Purpose Pro Centrifuges—CTS™ Series can provide for your demanding environment. A solid portfolio of validation and support services comes with each CTS Series centrifuge to help ensure uptime and compliance.

Refrigerated 4 L (4 x 1,000 mL) floor and bench models provide:

- Simple touchscreen programming
- Thermo Scientific™ Auto-Lock™ Rotor Exchange helps save time for faster results
- Thermo Scientific™ Fiberlite™ rotor and lid combinations offer superior ergonomics with enhanced performance
- Thermo Scientific™ ClickSeal™ Biocontainment Lids provide one-handed sample protection



### Documentation package

The documentation package consists of regulatory certificates, recommended protocols, and product-specific factory documentation and specifications (see page 8 for details).



### Compliance services

Gain confidence with our requalification services that can help reduce your risk of non-compliant instruments. Service options include IQ, OQ, and cycle testing (see page 10 for details).

# Forma Steri-Cult CO<sub>2</sub> Incubator—CTS Series

High-volume culturing and contamination control



## Product

Thermo Scientific™ Forma™ Steri-Cult™ CO<sub>2</sub> Incubator—CTS™ Series is designed for contamination control, providing compatibility with common cGMP facility protocols and clean room procedures, and cleanability in high-volume culturing conditions.

This stackable incubator combines the most advanced components available into a single incubator:

- CO<sub>2</sub> sensor
- Precise microprocessor controls
- Active humidity control
- HEPA air filtration
- High-temperature decontamination capability



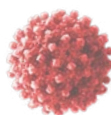
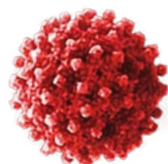
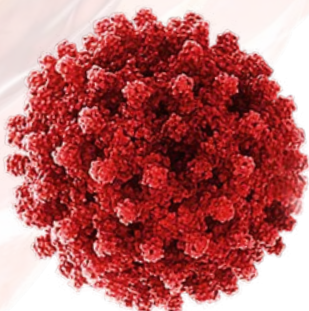
## Documentation package

The package consists of regulatory certificates, recommended protocols, and product-specific factory documentation and specifications (see page 8 for details).



## Compliance services

Gain confidence with our requalification services that can help reduce your risk of non-compliant instruments. Service options include IQ and OQ (see page 10 for details).





# CryoMed Controlled-Rate Freezer—CTS Series

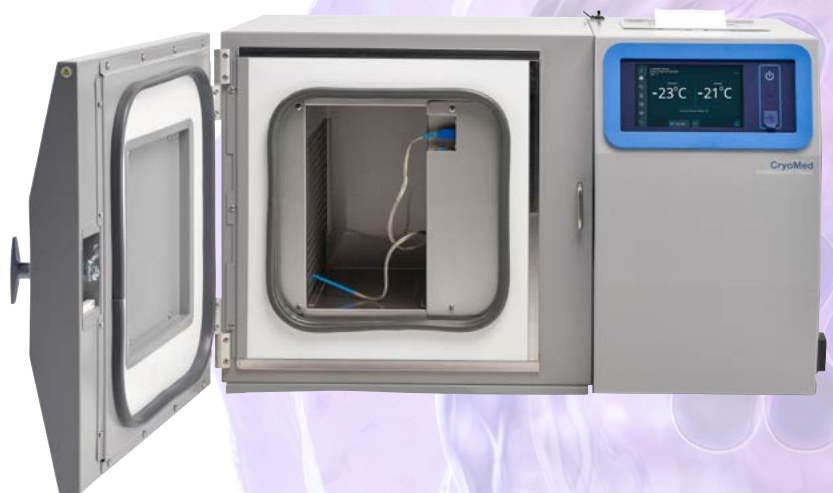
## User-friendly operation with enhanced data traceability



### Product

Thermo Scientific™ CryoMed™ Controlled-Rate Freezers (CRFs)—CTS™ Series provide precise, repeatable freezing results that protect precious samples from intracellular freezing. They are equipped with enhanced data traceability features to support audit requirements and they offer customizable freezing profiles while supporting 21 CFR part 11 compliance and GMP needs. Once frozen, samples can be placed into long-term cryo storage or shipped near and far with cryo transport solutions.

- Intuitive touchscreen display allows for easy setup, operation, and review of a freezing run
- UI logs usage and events to comply with 21 CFR part 11 requirements
- User security: 3 levels of user accessibility
- USB data export of PDF file run logs support 21 CFR part 11 compliance
- FDA-listed Class II medical device, 510K exempt (North American version only)
- Real-time run monitoring for sample protection
- Reliable temperature performance for high-throughput usage



### Documentation package

The package consists of regulatory certificates, recommended protocols, and product-specific factory documentation and specifications (**see page 8 for details**).



### Compliance services

Gain confidence with our requalification services that can help reduce your risk of non-compliant instruments. Service options include IQ and OQ and chamber mapping during freeze cycle (**see page 10 for details**).



# Documentation package

## Factory Acceptance Test (FAT) documentation

Binder element	CO <sub>2</sub>	BSC	CENT	CRF*	Description
<b>Product support</b>					
Design qualification (Technical Data Sheet, drawings)**					Basic spec descriptions of the product and may include some summary drawings
Recommended customer maintenance schedule					Vendor-supplied customer-based maintenance and schedule
Consumables and customer-replaceable parts					Replaceable parts based upon usage or wear
Recommended cleaning procedures					Effective and typical procedures to keep product clean
<b>Regulatory and compliance</b>					
Declaration of Conformity with EU Laws (CE)					CE certificate proof
CSA Certificate					CSA certificate proof
UL Certificate					UL certificate proof
Certificate of Environmental Status					Regulatory certificates for various sustainability items
Quality Management System (QMS) Certificate					Factory/site-based quality system description
REACH Statement					Regulatory certificates for various sustainability items
DIN EN12469 TUV Certification					Regulatory compliance certificate
DIN ISO 14644-1 Cleanroom Compatibility Certificate					Regulatory compliance certificate

\* Documentation package is stored on a USB device, not a physical binder.

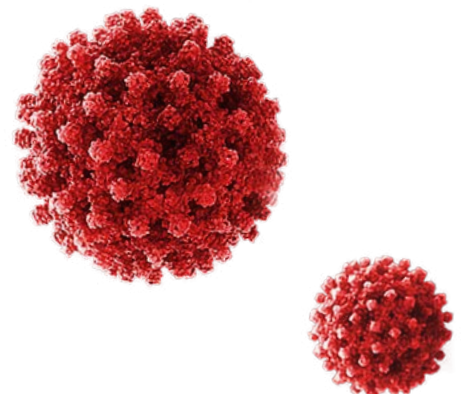
\*\*These documents are available from the factory prior to purchase upon request (in addition to CAD format drawings).

CO<sub>2</sub> = Forma Steri-Cult CO<sub>2</sub> Incubator—CTS Series or Heracell Vios CR CO<sub>2</sub> Incubator—CTS Series

BSC = Herasafe 2030i Biological Safety Cabinet—CTS Series

CENT = General Purpose Pro Centrifuges—CTS Series

CRF = CryoMed Controlled-Rate Freezer—CTS Series



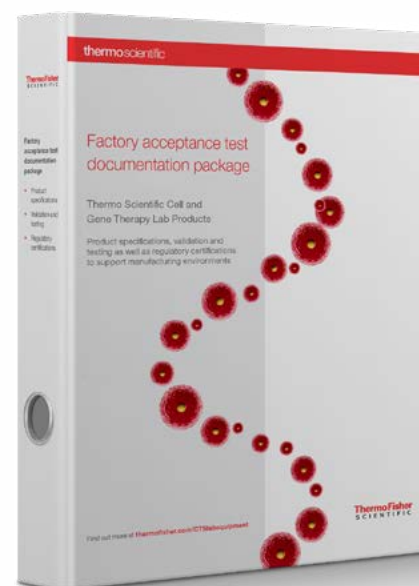




Binder element	CO <sub>2</sub>	BSC	CENT	CRF	Description
<b>Traceability/validation</b>					
Certificate of Conformance					Production certificate
FAT Report*					End-of-line test summary with checklist of performance
Key Material of Construction Specifications					Technical specifications
Steris VHP compatibility certificate					Test certificate for vaporized hydrogen peroxide cleaning
Particle Emission Certificate	**				Test certificate defining particle emissions of product
Porton Down Certificate					Test certificate for centrifuge rotor biocontainment
HEPA Filter Certificate*					Certificate of filter performance
Temperature Sensor Calibration Document*					Certificate from supplier on calibration
RH Sensor Calibration Document*					Certificate from supplier on calibration
CO <sub>2</sub> Sensor Calibration Document*					Certificate from supplier on calibration
CO <sub>2</sub> Calve Certificate of Compliance*					Certificate from supplier on compliance
Certificate of Electropolishing*					Material certificate of surface finish

\* These are serialized documents.

\*\* Particle Emission Certificate is only available for the Heracell Vios CR CO<sub>2</sub> Incubator.





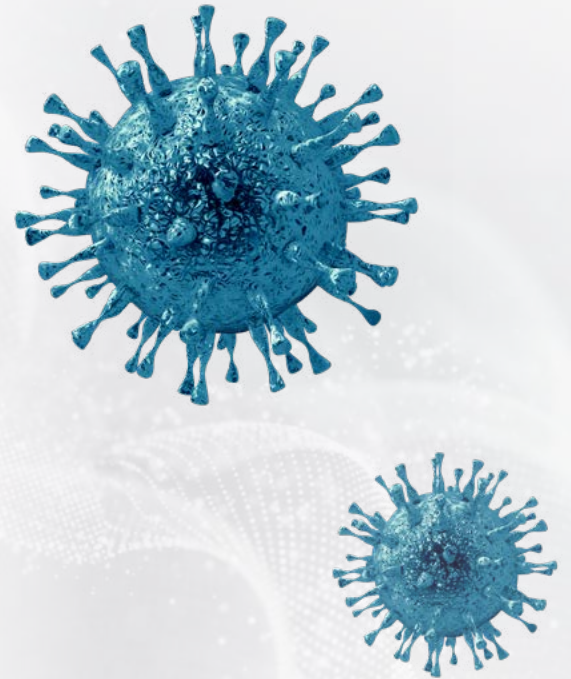
# Compliance services\*

Unity™ Lab Services, as part of Thermo Fisher Scientific, offers on-site qualification services that help ensure your laboratory equipment meets global standards and mitigates the risk of regulatory non-compliance. With our services, you'll receive a full range of qualification capabilities that provide

improved productivity, single-vendor convenience, a no-charge requalification\*\*, and comprehensive documentation reports. You'll have peace of mind knowing we're supporting your quality management systems, traceability, and audit readiness.

## Validation services

Installation Qualification (IQ)†	CO <sub>2</sub>	BSC	CENT	CRF
Component verification				
Assembly verification				
Installation verification				
Site verification				
Operational Qualification (OQ)				
System configuration				
Set points				
Alarms and safety				
System functionality				
All functional attributes				
System performance per factory specification				
System alarms				
Power failure				
Reference measurements for				
CO <sub>2</sub>				
Temperature				
Humidity				
O <sub>2</sub>				
Speed				
Time				
Performance tests				
HEPA filter leakage				
Air velocity				
Airflow				
KI-DISCUS™ system				



\* Our standardized Field Validation Packages for Laboratory Equipment—CTS Series include installation qualifications, operation qualifications, mapping, and cycle testing that vary by product. Additional mapping, calibration services, and semi-customized protocols are available. Contact your sales or service team for further information.

\*\* Our no-charge requalification applies only to instruments under the original factory warranty or a qualifying Unity Lab Services instrument service plan and covers requalification on the corrective maintenance repair at no additional charge. Terms and conditions apply.

† Installation of equipment is not included within our IQ services. Additional fees apply for inside delivery shipping method or for full installation and setup of equipment.



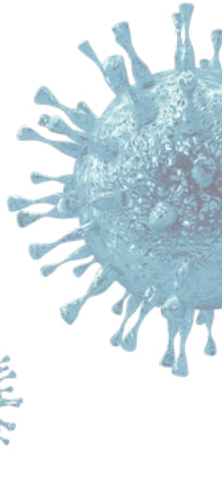
**Mapping and cycle testing services‡**

	CO <sub>2</sub>	BSC	CENT	CRF	Description
Temperature mapping	One				Single multipoint temperature mapping for a 24-hour period with one-minute data intervals typically between 9 and 15 points, depending on the model. Probes are spaced out to cover all the usable space in the chamber. For the controlled-rate freezer test coverage phase change portion of curve.
RH mapping	Available				Not included as standard. Contact your sales or service organization for quote.
Cycle testing					A point-in-time test exercise of predefined duration surpasses singular calibration and routine speed, time, and temperature monitoring activities for helping to ensure that the equipment is performing in accordance with the intended use of the system.
Door open recovery	One				Temperature map during door open recovery.
Power failure recovery	One				Temperature map during power failure.

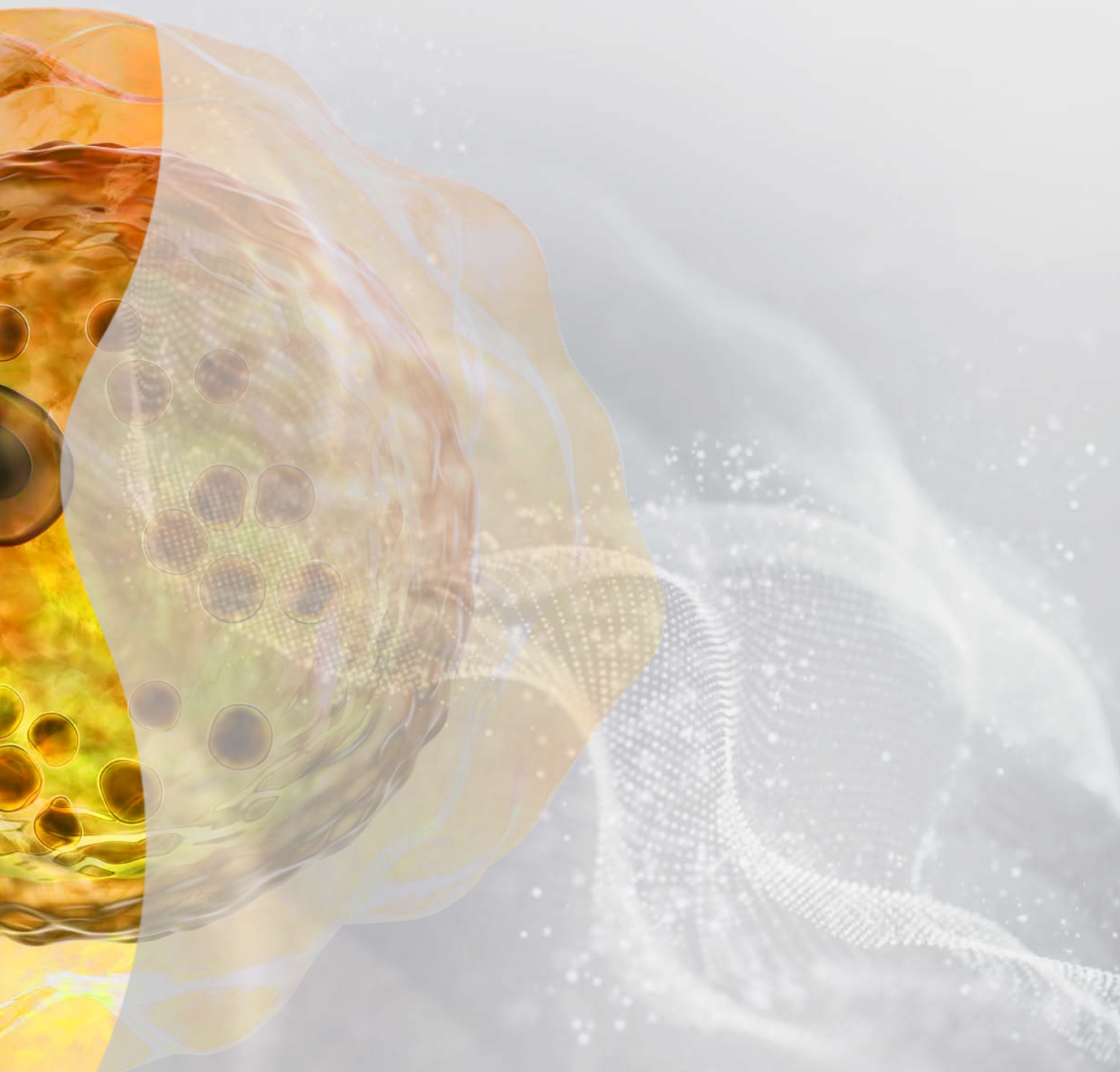
‡ Key test offerings may vary by region.

Selecting the right compliance services solution is a significant part of your quality system. The CTS series lab equipment bundles include these proven on-site services. Our local teams that are specially trained will support your project from the time

of order until regulatory sign off to help you pass qualifications the first time with our one-and-done best practices, which ultimately save resources and maintain operational uptime.







Learn more at [thermofisher.com/ctslabequipment](https://thermofisher.com/ctslabequipment)

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