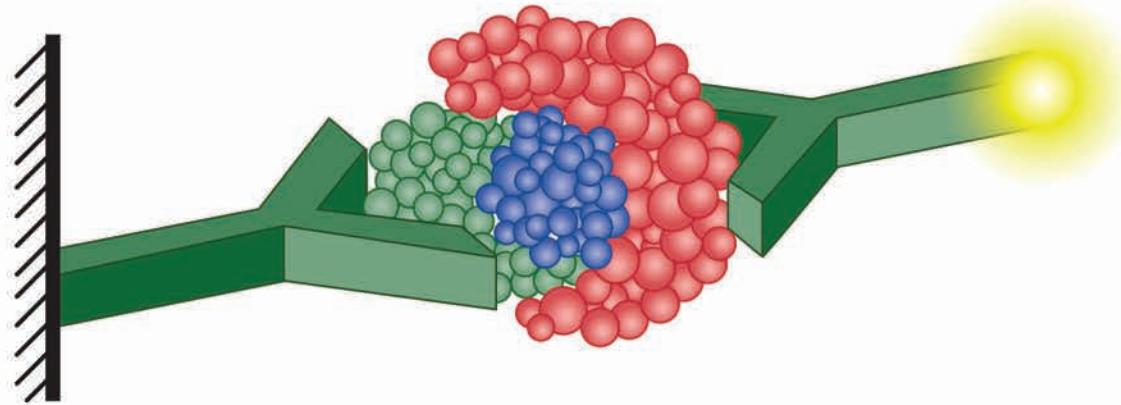


# **SCANTIBODIES** Laboratory, Inc.



**Harnessing God's Elegant  
Antibody Creation**

**CONTRACT MANUFACTURING  
SERVICES**

# Scantibodies Laboratory

An international leader in the world of medical diagnostics manufacturing for more than 44 years.

We are a laboratory and OEM manufacturer that is set up to work with you to fulfill your manufacturing needs. Our offerings include Antibodies, Custom Controls, Diagnostic Kits, Lyophilization, Packaging, Serum and Contract Manufacturing for Raw Materials, In-Process and Finished Goods.

Our expertise in immunodiagnostics and manufacturing of medical products allows us to meet your quality standards and with a quality department team of more than 50 well trained individuals you can be sure that we will exceed your expectations. This is why our products and services continue to be used by top biotech companies worldwide.

ISO 13485 Certified  
ISO 9001:2015 Certified

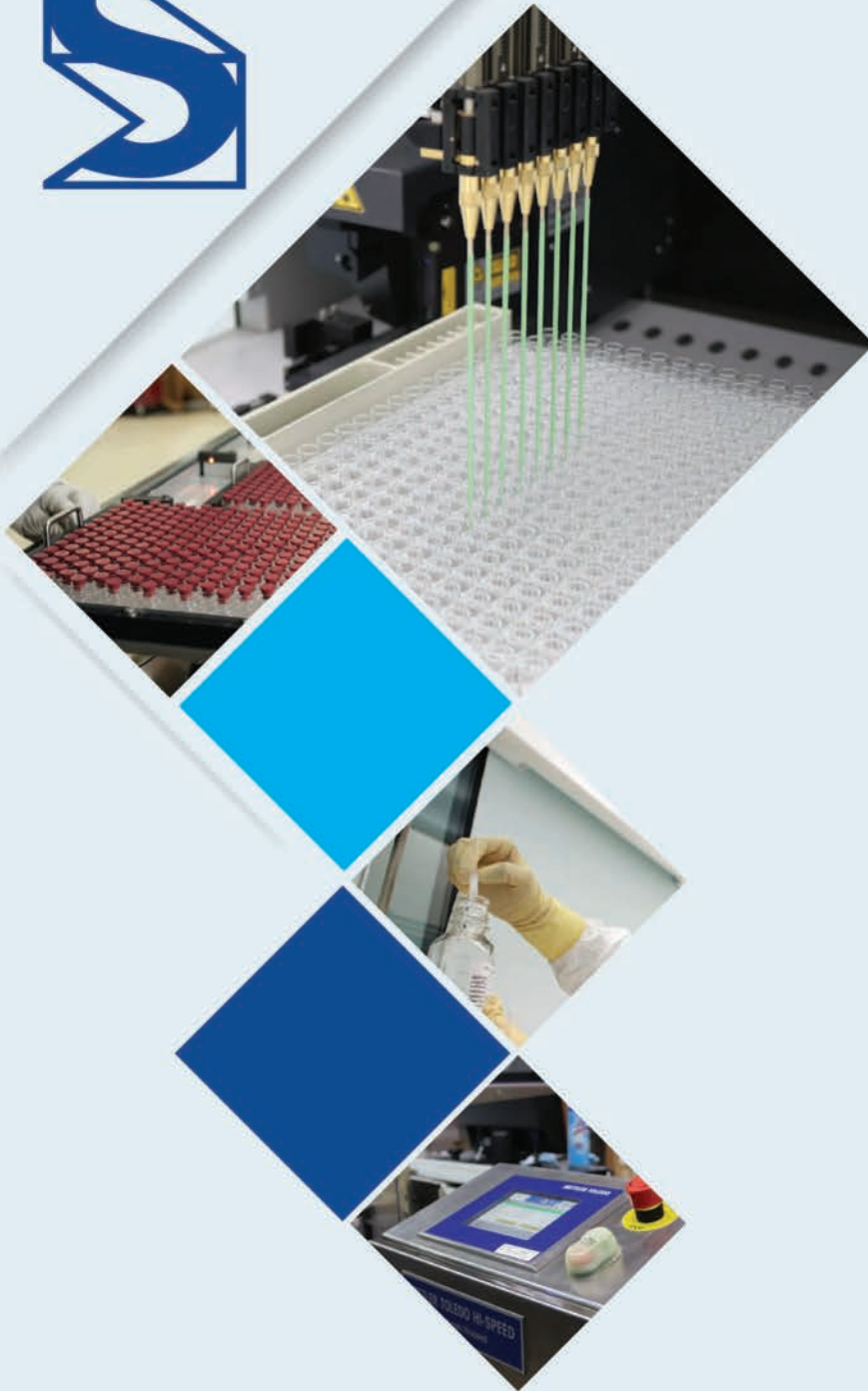






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Your Product, Your Specifications,  
Our Expertise!

275,000 ft<sup>2</sup> available for you

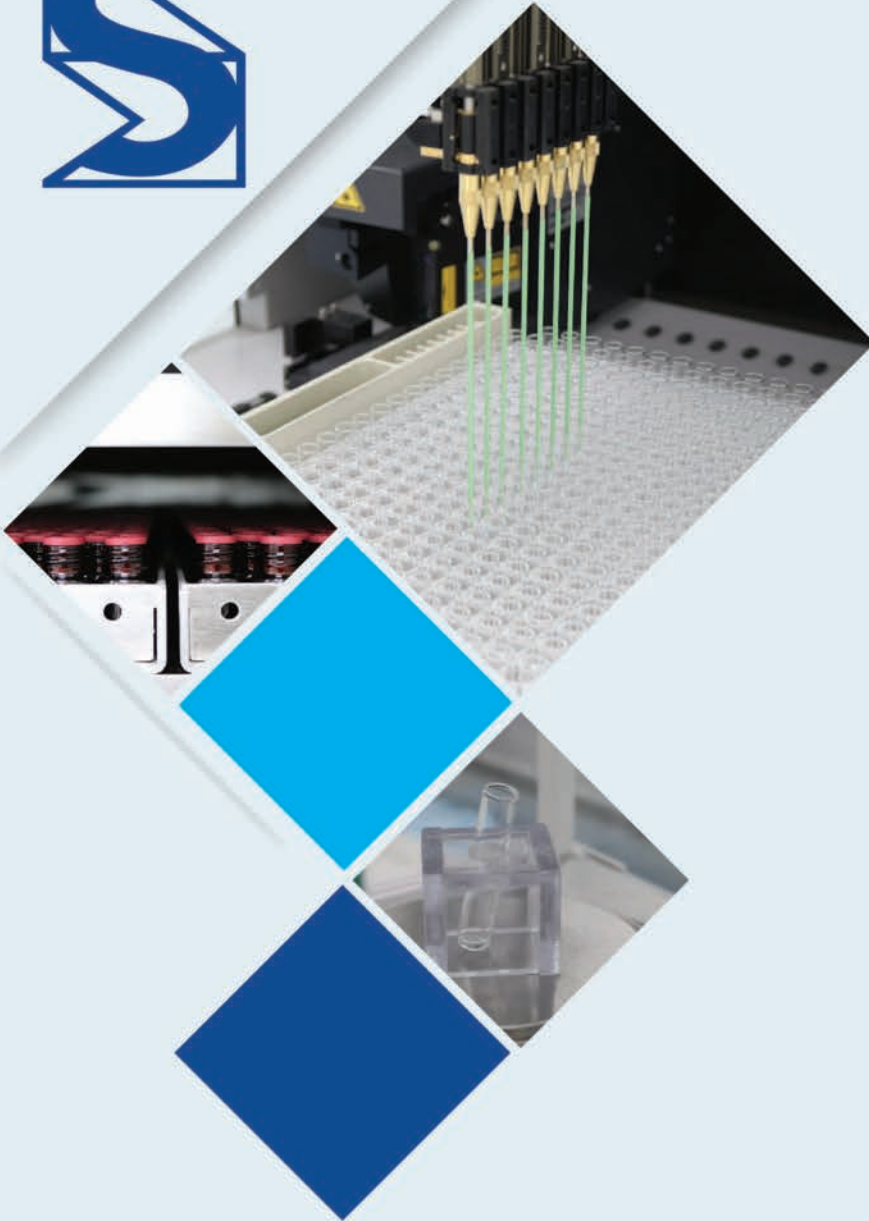






# Manufacturing Capabilities:

- Up to 1,400 ft<sup>2</sup> of lyophilization shelf capacity in Tecate facilities, with additional capacity in Santee facilities.
- Formulation and cycle development.
- Filling of vial/bottle sizes 0.5 ml to 125 ml.
- Complete capping, labeling and packaging services.
- Inventory storage.
- Analytical and biochemical testing.
- HPLC: Analysis for purity.
- Karl Fischer: Moisture analysis.
- UV/VIS: Concentration determination.
- ELISA customer specific assays.
- Microbial testing.
- Customer specific performance, in-process and stability testing protocols.
- Validated water system.
- Clean rooms.
- Flash Freeze.



# Lyophilization 733



733 ft<sup>2</sup> capacity





# Freeze Dryer Hull 733

- Lyophilization shelf capacity: 733 ft<sup>2</sup>
- Double latching of shelves to accommodate taller vials
- Hydraulic stoppering with stainless steel bellows
- Condenser capacity: 800 L
- Product temperature probe per shelf
- Product chamber and condenser chamber steam sterilizable

# Lyophilization 220



220 ft<sup>2</sup> capacity



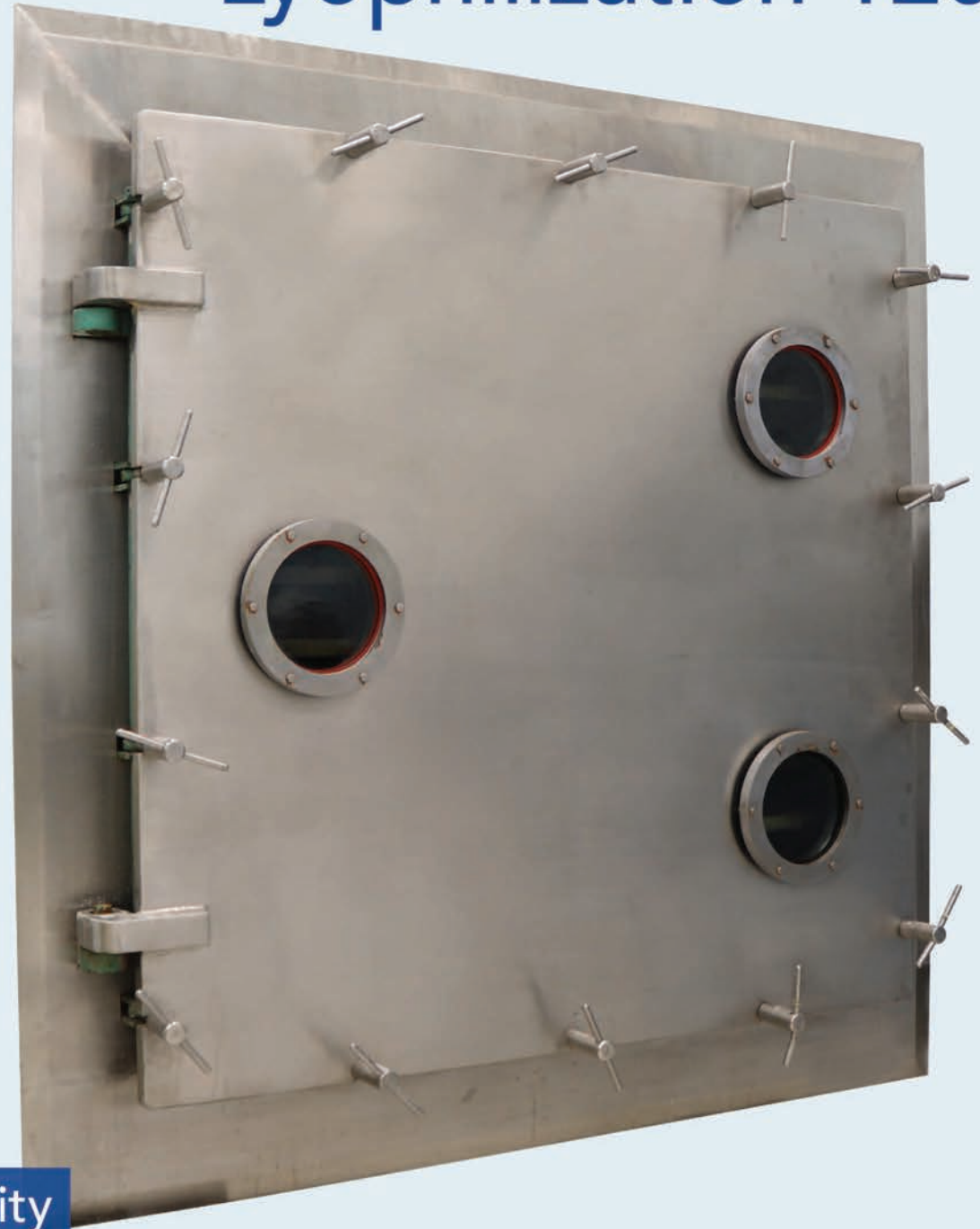


# Freeze Dryer Hull 220



- Lyophilization shelf capacity: 220 ft<sup>2</sup>
- Hydraulic stoppering
- Condenser capacity: 350 L
- Product temperature probe per shelf

# Lyophilization 120



120 ft<sup>2</sup> capacity





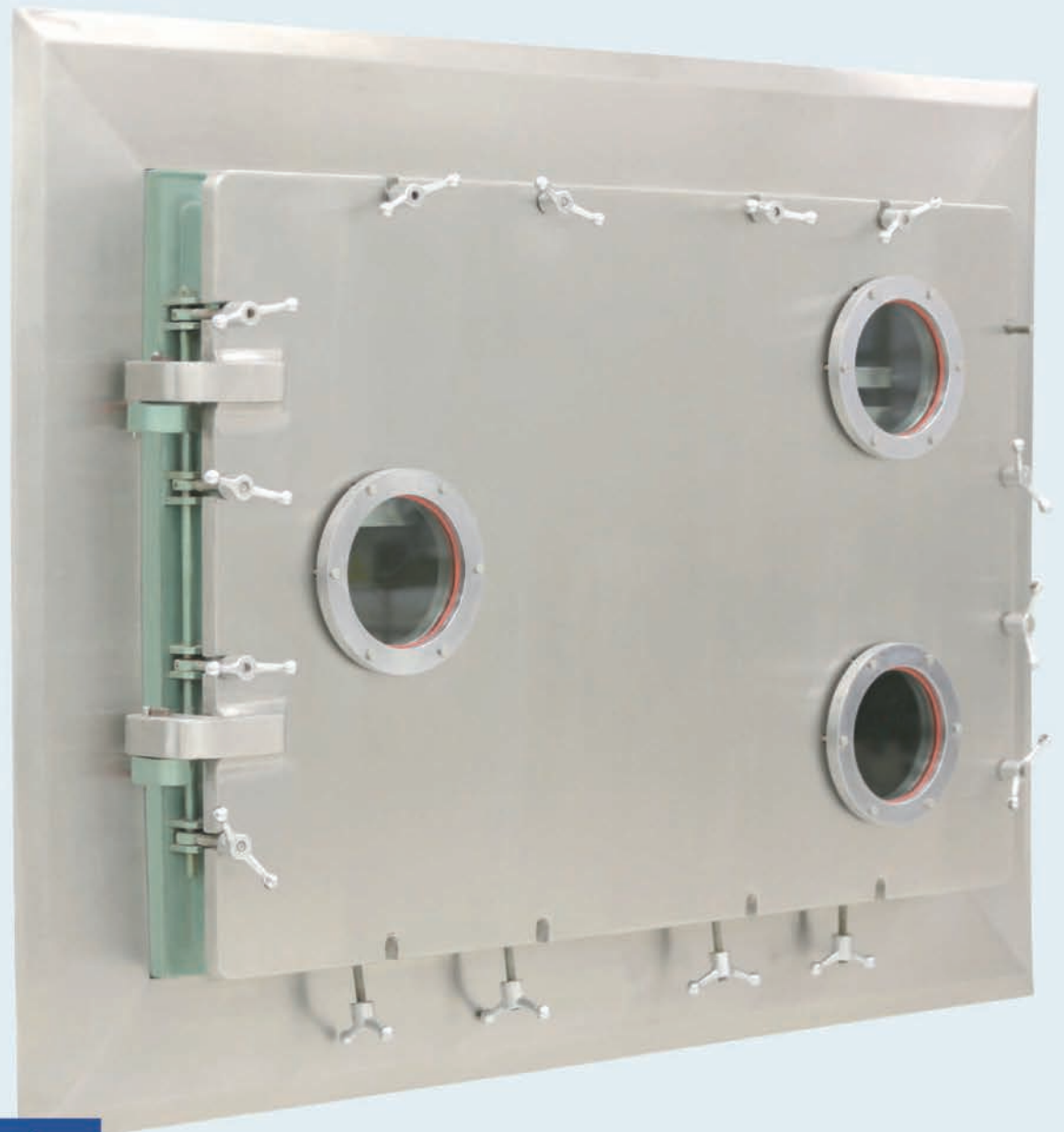
# Freeze Dryer

## Pennwalt Stokes 120

- Lyophilization shelf capacity: 120 ft<sup>2</sup>
- Hydraulic stoppering
- Condenser capacity: 350 L
- Product temperature probe per shelf



# Lyophilization 72



72 ft<sup>2</sup> capacity





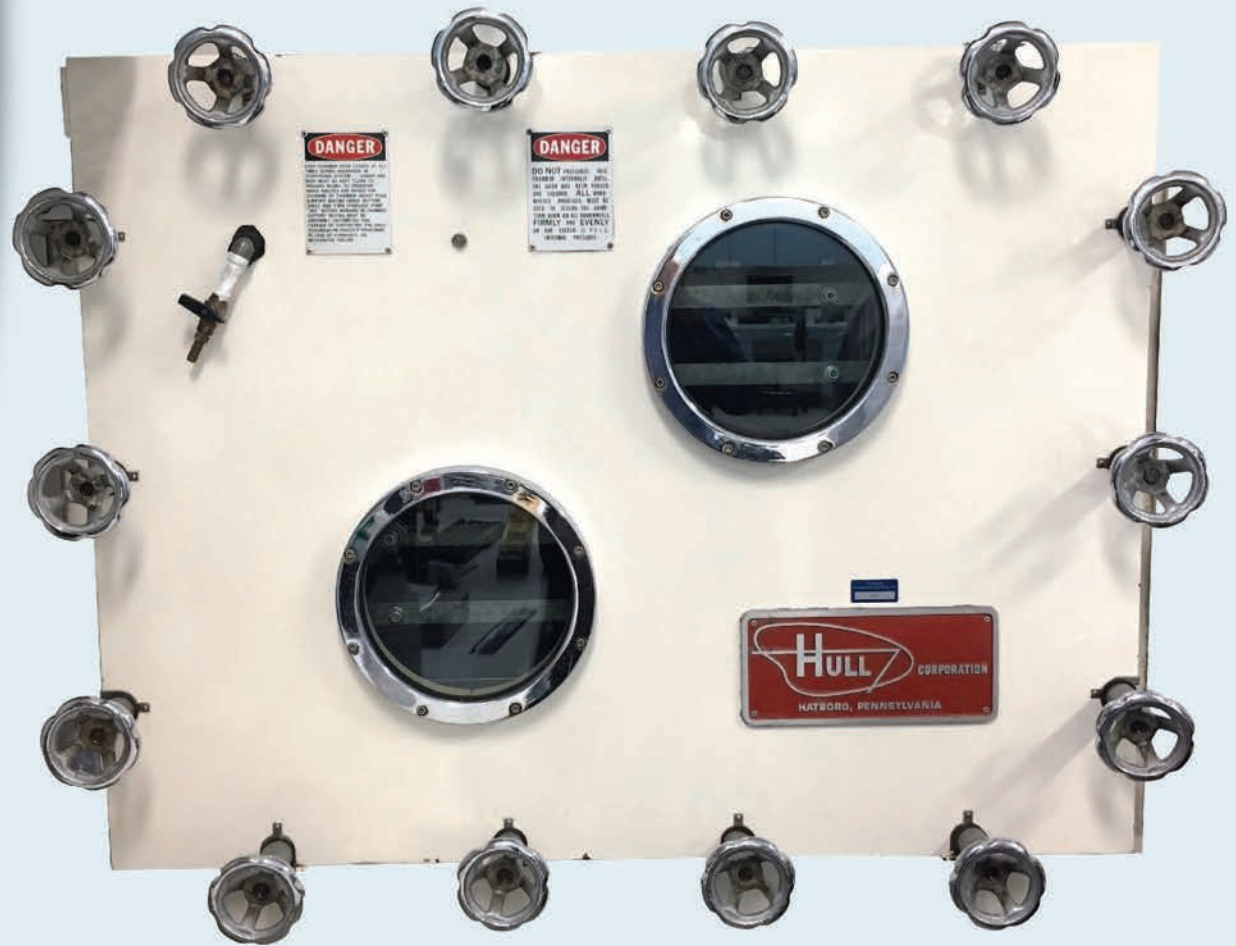
# Freeze Dryer

## Pennwalt Stokes 72



- Lyophilization shelf capacity: 72 ft<sup>2</sup>
- 2 product temperature probes per shelf
- Condenser capacity: 75 L

# Lyophilization 36



36 ft<sup>2</sup> capacity





# Freeze Dryer Hull 36



- Lyophilization shelf capacity: 36 ft<sup>2</sup>
- Stoppering: Mechanical or pneumatic hydraulic
- Condenser capacity: 65 L

# QC Analytical Equipment

Pharmacia, Phast System,  
SDS PAGE



Beckman-Coulter  
Spectrophotometer DU640,  
OD Determination





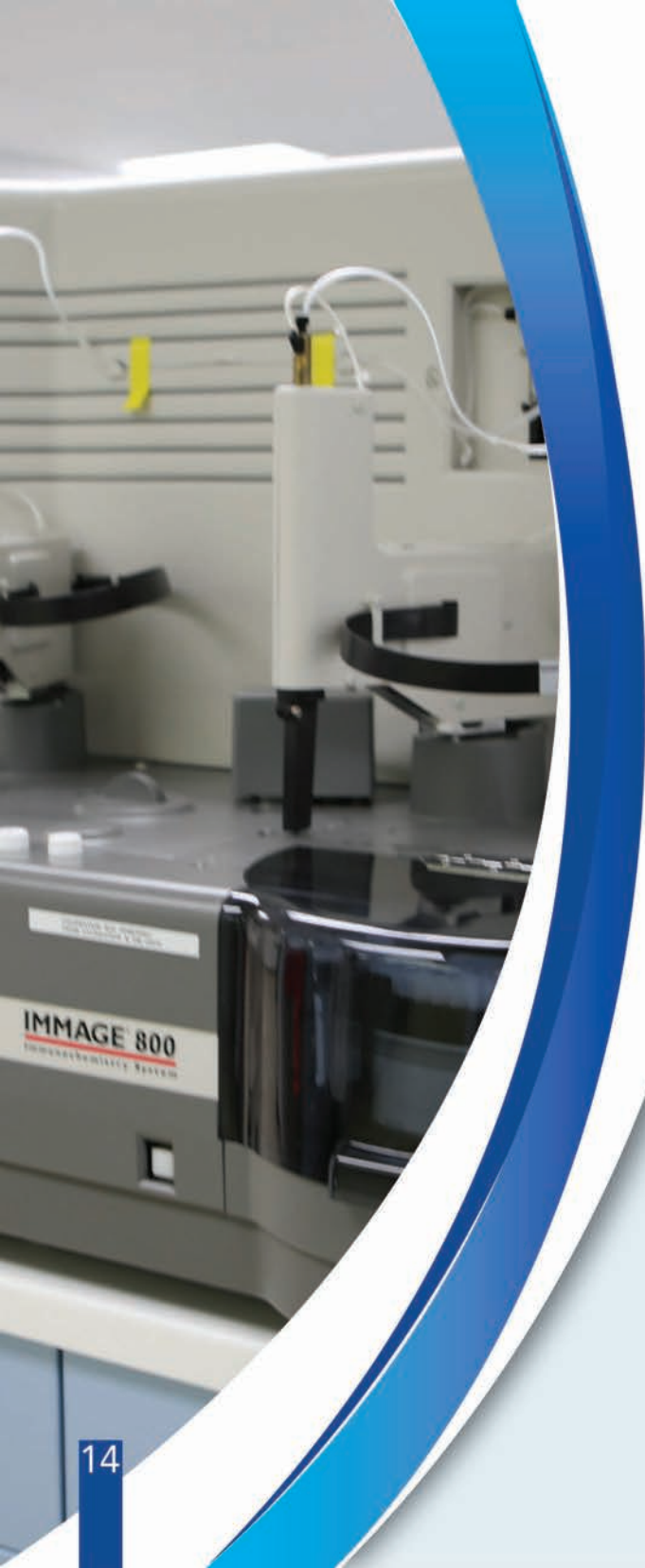
## Metrohm 915 KF Moisture Analyzer



## UFLC Shimadzu, HPLC Purity Modules:

- DGU-20A5
- CBM-20A
- SPD-20A
- SLI-20A HT





Roche Cobas 411e  
Analyzer



Roche Cobas Integra  
400 Plus Analyzer



Beckman Coulter  
Immunochemistry  
System





pH Meter



SEBIA Hydrasis



## Biacore X100



## Bioburden Testing





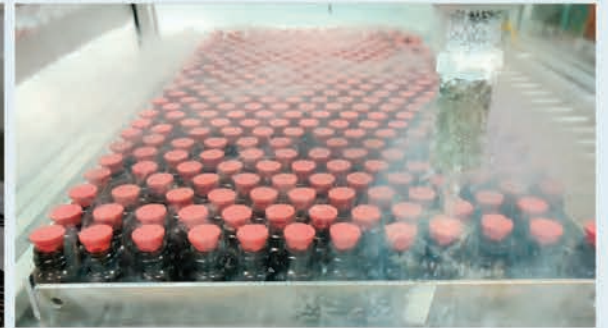
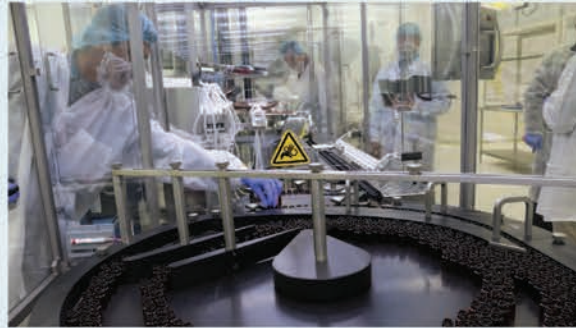
## Ortho Clinical Diagnostic Vitros Eci Immunodiagnostic System



## Abbott Architect Plus



# Automated Filling, Capping, Weight Check and Flash Freeze







# Automated Filling, Capping, Weight Check and Flash Freeze



- Accomodates vial sizes from 2 mL to 7 mL
- Autoadjustable filling pumps
- 85 to 100 caps per minute (18mm octagonal and round)
- Capable of checking 100% dispensed solution by weight
- Capacity up to 300 cpm\* (0% cw\*\*)
- Capacity up to 125 cpm\* (100% cw\*\*)
- Programmable random cw\*\*
- Filling under HEPA filters
- In line stoppering
- Vials placed in trays automatically
- Automated equipment to Flash Freeze solution in vials using Liquid Nitrogen (LN)

\*cpm = containers per minute

\*\*cw = check weight



# Water Treatment System







# Water Treatment System

Daily reading of pressure gauges, flow meter, resistivity, chlorine levels and redox potential.

## Features

- Validated system
- Reverse osmosis water system: 4.0 gpm
- Deionized (DI) water system: 2.0 gpm
- UV lamp for soft water
- UV lamp for DI water

## Specifications

- Boiler feed pressure (40 - 60 PSI)
- Production circulation pressure (40 - 60 PSI)
- QC-DI (Deionized water) Circulation pressure (40 - 60 PSI)
- DI resistivity ( $> 15.00 \text{ M}\Omega\cdot\text{cm}$ )
- DI flow rate ( $\geq 2.0 \text{ gpm}$ )
- Production chlorine level (0.5 - 5.0 ppm)
- RO rejecting water flow (2.0 - 3.0 gpm)
- RO product water flow (3.0 - 4.0 gpm)
- RO membrane pressure (150 PSI - 180 PSI)



# Clean Rooms







# Clean Rooms Capabilities

## ISO 5, ISO 6, ISO 7 & ISO 8 Classification

Currently used for proteins and drug product development, including therapeutic proteins, antibodies, human derived proteins and recombinant proteins.

- Positive pressure room that meets class ISO 14644-1 standards for ISO class 6, 7 & 8.
- Includes aseptic ISO class 5 areas.
- Peripheral and support areas for drug manufacturing.
- Environment monitored 24/7 for relative humidity and temperature; supported by an Multi Channel Process System recording and trending program.
- Tested for particle count and bioburden in accordance with ISO 14644.
- Total combined area for two independent clean room modules: 1,711 ft<sup>2</sup>
- Total area for ISO Class 6 and ISO Class 7 module: 855 ft<sup>2</sup>





# Packaging Lines







# Packaging Lines Capabilities:

- Current installed annual capacity:  
Approximately 2.5 million kits
- Historic annual capacity:  
34 million pregnancy and ovulation kits
- Ability to scale up capacity upon request
- Automated weight check and reject system
- Expiration date and lot number laser engraving
- UDI inkjet printing





Available in USA and MEXICO

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U.S.A. Headquarters  
9336 Abraham Way  
Santee, CA 92071 USA

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