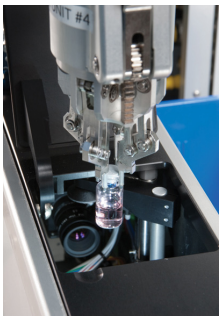
Big Kahuna
Biologics formulation

Big Kahuna takes on your entire biologics formulation development process and automates it end-to-end. It'll tackle buffer prep, buffer exchange, pH checks, sample prep and analysis. Get your accelerated stability studies done with integrated sample incubation and automated freeze/thaw systems. Do it all using a single, totally configurable platform and crank through more candidates and formulations than ever.

Big Kahuna configured for biologics formulation

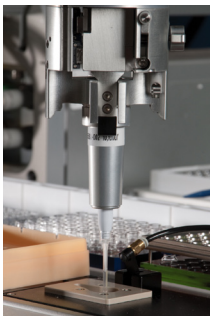
Applications

- Rapidly characterize a wide range of protein formulations with limited material
- Perform developability and preformulation screens
- Evaluate formulation robustness
- Easily implement DOE to find your optimal formulation
- Prepare and analyze formulations for pH, viscosity, turbidity and visible particles
- Perform automated agitation and temperature stress studies
- Manage and track formulations and analytical results to facilitate rapid scientific decisions



Visual inspection station

Multi-channel pH probes



Viscosity station

Key features

- Versatile liquid handling for viscous and non-viscous solutions
- Compatible with a wide range of plates and vials
- Automated plate-based buffer exchange
- Automated protein stressing – heat, cool, stir and shake formulations
- On-deck visible particle, turbidity and color analysis
- High-throughput pH and viscosity measurements
- Low-bioburden enclosures with HEPA filters

Example Big Kahuna for biologics formulation deck layout

1 4-tip pH probe
2 Volume check
3 Buffer exchange module
4 Viscosity station
5 Visual inspection station
6 Vial capping and decapping station
7 Vortexing station
8 Cooled storage bay
9 Heating/stirring station
10 Tip/rack holder
11 Wash station
12 Tip/rack holder

Available options

pH measurement
Configuration: Single or 4-channel probe
Measurement time per 96-well plate: <90 minutes
Range: 1–13 pH units
Resolution: 0.05 pH units
Repeatability: ±0.1 pH units

Multi-channel liquid dispenser
6-channel variable volume liquid dispense
Disposable tips: For no washing, no sample carry-over
Automated variable pitch: For reformatting between plates and vials

Viscous liquid dispense
Technology: Positive Displacement Tip (PDT)
Disposable tips: 10 µL to 10,000 µL from Eppendorf and Rainin
Viscosity: 1 cP to 1,000 cP

Vial/plate gripper
Plate size: Standard microtiter
Vial size: 1–125 mL
Total mass: Up to 3 kg

Vortexing station
Orbital: 60–3570 rpm
Maximum vortexing mass: 2268 g (5 lb/plate)

Heating/cooling/stirring station
Temperature range: -20–180 °C
Mixing: Up to 750 rpm
Mixing type: Magnetic tumble stirring

Rack/plate carousel
- Additional storage for samples, solutions, buffers and tips
- Plate transfer between robotic systems enabling full integration

Viscosity station
Measurement range: 1–100 cP
Accuracy: ±0.5 cP + 10% of the actual viscosity
Repeatability: StDev <0.5 cP + 5% of mean
Sample volume: 100 µL
Minimum volume in well: 200 µL
Temperature range: 4–40 °C
Temperature accuracy: ±1 °C
Measurement time: 6 min/sample
Throughput: 10 samples/h

Vial capping/de-capping station
Vial range: 2 mL to 125 mL

Visual inspection station (VIS) analyses
Includes:
- Visual particle analysis
- Turbidity
- Color measurement

Vial size: 2–20 mL
Recommended sample volume: 1 mL in 2 mL serum vial
Measurement time: 2–3 min per vial

Suspended visible particle detection
Minimum particle size detected: 80 µm
Maximum solution viscosity: Dependent on vial configuration
- **2 mL vial:** 30 cP
- **20 mL vial:** 35 cP

Particle count accuracy:
- **No particles:** 0 particles detected
- **1–3 particles:** Detect at least 1 particle
- **4–9 particles:** Actual particle count ±2 particles
- **10–25 particles:** Actual particle count ±5 particles

Turbidity
Measurement range: 10–1,000 NTU
Measurement accuracy: ±5 NTU (for non-absorbing samples)
Repeatability: ≤3 NTU for 10 consecutive samples

Color measurement
Color: Correct match of Euro Pharmacopeia BY1–BY7 standards

Buffer exchange
Pressure range: 0–60 psig
Vortexing: Up to 1000 rpm; speed and duration fully programmable

Unchained Labs Unfilter
Format: 96-well microtiter plate
Volume: 450 µL
Filter membrane: 10 kDa MWCO regenerated nitrocellulose

On-deck third-party instrument physical integration
- DLS
- Centrifuge
- Shaking incubator
- Freeze/thaw blocks
- UV-Vis plate reader
- Plate sealer
- Incubators

Other systems are available for on-deck integrations.
Please contact Unchained Labs for a full list of systems.

Off-deck third-party instrument virtual integration
- HPLC
- cIEF

Other systems available for virtual integration.
Please contact Unchained Labs for a full list of systems.

Facilities requirements

Physical: 243.3 cm W x 152.4 cm D x 257.1 cm H, 647 kg
Electrical:
Big Kahuna:
208–230 V ±10 %, 50–60 Hz, 16–20 A
Computer:
US: 115 V ±10 %, 60 Hz, 10 A
EU: 220–230 V ±10 %, 50 Hz, 16 A
Compressed dry air: 0.5–0.9 MPa (70–130 PSI), 4L/min

Unchained Labs
6870 Koll Center Parkway
Pleasanton, CA 94566
Phone: 1.925.587.9800
Toll-free: 1.800.815.6384
Email: info@unchainedlabs.com

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