

# 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.

### Applications

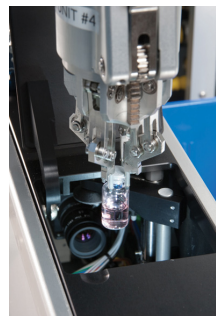
- Rapidly characterize a wide range of biologics formulations with limited material
- Perform developability and preformulation screens
- Evaluate formulation robustness
- Easily implement DOE to find your optimal formulation
- Prepare and analyze formulations for pH, viscosity, turbidity and visible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

### 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



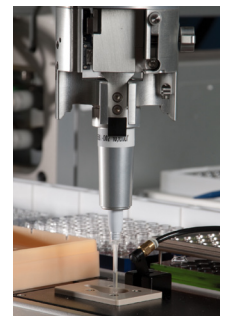
Big Kahuna configured for biologics formulation



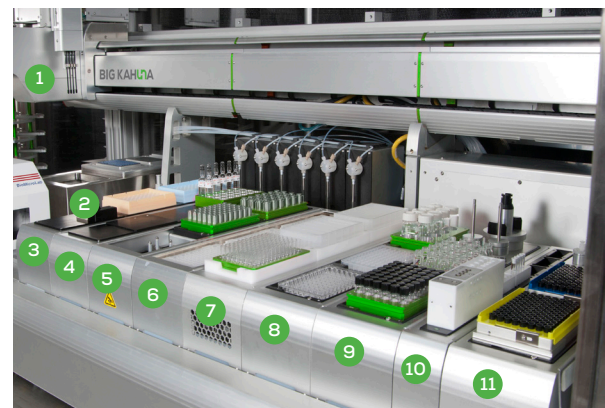
Visual inspection station



Multi-channel pH probes



Viscosity station



Example Big Kahuna for biologics formulation deck layout

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

## Available options

### pH measurement

**Configuration:** 4-channel glass probe  
**Measurement time per 96-well plate:** <45 minutes  
**Range:** 0–14 pH  
**Resolution:** 0.01 pH units  
**Accuracy:** ±0.03 pH units  
**Precision:** ±0.05 pH units

### Multi-channel liquid dispenser

**Liquid dispense:** 6-channel variable volume 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  
**Maximum payload:** 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:**
- 0–100 NTU: ≤±5 NTU
  - >100–1,000 NTU: ≤5%
- Repeatability:** ≤1 NTU for 10 consecutive samples

### Color measurement

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

### Buffer exchange

**Pressure range:** Up to 60 psi  
**Vortexing:** Up to 1000 rpm; speed and duration fully programmable

### Unchained Labs Unfilter

**Format:** 96- and 24- well Unfilters  
**Volume:** 450 µL (Unfilter 96); 8 mL (Unfilter 24)  
**Filter membrane material:** Regenerated cellulose (RC)  
**MCWO Options:**

- **24-well:** 10, 30, 100 kDa
- **96-well:** 3, 10, 30, 100 kDa

### On-deck third-party instrument physical integration

- DLS
  - UV-Vis plate reader
  - Centrifuge
  - Plate sealer
  - Shaking incubator
  - Incubators
  - Freeze/thaw blocks
  - Labelers
- 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

**CDA or Nitrogen:**

- **Pressure:** 0.55–0.9 Mpa (80–130 psi)
- **Flow rate:** 40 L/s (85 cfm) minimum



### Unchained Labs

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