

Bioprocess External Quality Control
110

For research use only. Not for use in
diagnostic procedures. Chemically-
defined, animal component free.

Lot Number: 241203
Product Reference: 5173110
Expiration Date: 2025-12-03
Storage Temp: 15°C - 30°C
Storage Instructions: Protect from light
Ampoule Volume: 2.0 mL

TEST	IDENTIFICATION	SPECIFICATION	RESULT	UNITS
pH	ABG001	6.720 - 6.920	6.784	
pCO ₂	ABG001	72.0 - 108.0	91.06	mmHg
pO ₂	ABG002	132.0 - 198.0	165.1	mmHg
Osmolality	OSM003	176 - 184	180	mOsmol/Kg
Glucose	CHE003	0.40 - 0.60	0.50	g/L
Lactate	CHE003	1.36 - 2.04	1.73	g/L
Glutamate	CHE003	0.47 - 0.67	0.57	mmol/L
Ammonium	CHE002	0.75 - 1.25	0.83	mmol/L
Calcium	CHE002	7.36 - 11.04	9.25	mmol/L
Sodium	CHE002	56.00 - 84.00	71.28	mmol/L
Potassium	CHE002	1.60 - 2.40	2.07	mmol/L
Endotoxin Testing	CON001	Test and record	<0.05	EU/mL
Sterility Testing	CON002	Negative	Negative	



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Date: 04-Dec-24

References

ABG001	Potentiometric	PCS Biotech Specification
ABG002	Amperometric	PCS Biotech Specification
OSM003	Freezing-Point Depression	PCS Biotech Specification
CHE003	Amperometric	PCS Biotech Specification
CHE002	Potentiometric	PCS Biotech Specification
CHE001	Potentiometric	PCS Biotech Specification
CON001	Limulus Amebocyte Lysate (LAL) test for Gram-negative bacterial endotoxin	United States Pharmacopeia (USP) European Pharmacopoeia (Ph. Eur) Japanese Pharmacopoeia (JP)
CON002	USP 71	United States Pharmacopeia (USP)

Intended Use

AccuCell® Bioprocess External Quality Control (EQC) standards are designed to verify the performance of upstream bioprocess analysers. When used in addition to equipment Quality Control (QC), AccuCell® EQCs can verify calibration, sensor linearity, analytical error, imprecision and instrument variation for In-Process Control (IPC) laboratories. AccuCell® EQCs provide third-party QC verification beyond manufacturer-provided materials. Ampoules may be measured on any analyser intended for cell culture analysis.

AccuCell® EQCs are not intended to replace manufacturer equipment-specific QCs.

Product Description

The pack contains 30 glass-filled ampoules of 2 mL aqueous solution. The AccuCell® sample matrix is designed to replicate eukaryotic culture media as closely as possible, to ensure analytical results are representative of process sample measurements.

Composition

The AccuCell® range standards consist of a buffered bicarbonate solution, containing amino acids, vitamins, inorganic salts and trace metals. All solutions are chemically-defined, animal component free, and do not contain constituents of human origin. Components may vary in pH and concentration to achieve the desired analytical range for each level.

Storage and Shelf Life

Protect from light. Store at 15.0°C - 30.0°C. 12 month shelf life.

Directions for Use

Equilibrate to 25.0°C ±3.0°C for one hour prior to analysis. Mix ampoule thoroughly prior to use. Exercise caution when opening. Use safety cap if available to protect fingers. Once opened, analyse immediately using normal analytical sample-mode. Do not select QC or proficiency mode. Use ampoule once and discard in accordance with local non-hazardous regulations.

Warnings

Do not freeze. Analyse immediately once open to ensure accurate pH, pCO₂ and pO₂ measurements.

Limitations

For internal research or professional laboratory applications only. Not for use in clinical diagnostic procedures.

Specifications

See "Specification" ranges on Certificate of Analysis.

Regulatory and Compliance

Complies with ICH Q2 (R2) Validation of Analytical Procedures. Products must be used in accordance with instructions. Ensure the product complies with applicable laws, regulations and governmental policies.

Technical Support and Resources:

Contact support@pcsbiotech.com for support.

Product Code: 5173110