



Calibrators and Controls for Biotech

Confidence in your osmolality testing

Calibrators and Controls for osmometers

Advanced Instruments Calibrators and Controls are used on osmometers across the bioprocessing and cell and gene therapy workflows. These products are designed to ensure osmometers' optimal performance and accuracy of test results across instrument reportable range.

Osmolality, the measurement of total solute concentration, is a reliable control specification and in-process parameter that can deliver information across the process development and manufacturing workflows. Osmolality is considered a critical quality attribute and critical process parameter in bioprocessing. Using the calibrators and controls ensure the results are accurate and precise—protecting the quality of your batch samples. These products work hand in hand with our Advanced Instruments osmometers to comply with the pharmacopeia guidelines listed below to perform osmolality testing, calibration and verification.

- United States Pharmacopeia
- Japanese Pharmacopeia
- European Pharmacopeia
- Chinese Pharmacopeia

Calibration for peace of mind

Calibration is the process of configuring an instrument to provide a result for a sample within an acceptable range. Calibration precisely adjusts the osmolality of the instrument using the Advanced Instruments calibration standards.

Advanced Instruments osmometers are factory calibrated. You only need to use the Clinitrol 290 and require minimum testing prior to use.

During the preventative maintenance, we recommend the use of the linearity set to verify the calibration check which ensures the accuracy of the result and monitors a full range of instrument performance.

Our instruments are calibrated with a minimum of two points and comply with the pharmacopeia guidelines. Please see the table below for the different calibration points used for Advanced Instruments osmometers.

The zero point calibration standard is used to determine the lowest osmolality value of the instrument to be compliant with the European Pharmacopeia.

Calibration Standards required for Advanced Instruments Osmometers for Biotech

	OsmoTECH® XT	OsmoTECH	OsmoTECH PRO	A ₂ O®
Low Range (mOsm/kg)	0, 500, 1500	0*, 50, 850, 2000*	0*, 50, 850, 2000*	100, 900, 2000
High Range (mOsm/kg) **	1500, 3000, 4000	NA	NA	100, 900, 2000, 3000

* As optional

** Full Range for A₂O



Trusted results with streamlined daily checks

According to the Pharmacopeia guidelines for osmolality testing, it is important to perform a daily calibration check or verification prior to testing your samples, therefore ensuring instrument calibration and performance. Advanced Instruments Calibrators and Controls are manufactured to a tight tolerance so you can quickly spot shifts in performance.



Clinitrol™ 290 for Calibration Check

Clinitrol is the instrument reference solution and it is used for calibration check. It is a daily system check to strengthen your laboratory's quality control program.



Controls for Sample Osmolality Check

In addition to instrument verification, it is important to test an osmolality standard that is closer to your sample osmolality to ensure sample testing accuracy. We offer a wide range of osmolality standards from 0-4000 mOsm/kg H₂O. Refer to the "Interpreting Results" page in the instrument user's guide for each osmolality standard's expected specification.



Protinol™ Control for Protein Based Samples

When testing protein-based samples, Protinol is recommended to use as an additional precise reference solution. It is ready to use and available in three relevant levels: 240, 280, and 320 mOsm/kg H₂O.

Dedicated to quality

With more than 60 years of experience in osmolality testing, Advanced Instruments Quality Management System is certified according to ISO 9001 and ISO 13485.

Each lot of our osmolality standards is tested and analyzed by the Advanced Instruments laboratory using an osmometer that is calibrated against NIST Traceable Reference Solutions to ensure accurate and precise testing.

Certificates of Analysis (COA) are available for each specific lot, providing all required information about the standards. For your convenience, these COAs are available electronically on our website.



Easy & Ready-to-use



Tap

The Advanced Instruments Calibrators and Controls are pre-mixed with the right concentration of Sodium Chloride in individual ampules available in either 2 mL or 5 mL. The ampules are designed to be easily opened and ready-to-use.



Snap

Open a new ampule before each test. These can be used straight out of the box and are specifically made to work with our Advanced Instruments osmometers.

Parts and supplies

Part number	Calibration Standard	Volume/Size
3MA000	0 mOsm/kg H ₂ O	10 x mL ampules
3MA005	50 mOsm/kg H ₂ O	10 x 2mL ampules
3LA011	100 mOsm/kg H ₂ O	10 x 5mL ampules
3MA020	200 mOsm/kg H ₂ O	10 x 2mL ampules
3MA003	300 mOsm/kg H ₂ O	10 x 2mL ampules
3MA040	400 mOsm/kg H ₂ O	10 x 2mL ampules
3LA051	500 mOsm/kg H ₂ O	10 x 5mL ampules
3MA085	850 mOsm/kg H ₂ O	10 x 2mL ampules
3LA091	900 mOsm/kg H ₂ O	10 x 5mL ampules
3MA100	1000 mOsm/kg H ₂ O	10 x 2mL ampules
3LA151	1500 mOsm/kg H ₂ O	10 x 5mL ampules
3MA200	2000 mOsm/kg H ₂ O	10 x 2mL ampules
3LA201	2000 mOsm/kg H ₂ O	10 x 5mL ampules
3LA301	3000 mOsm/kg H ₂ O	10 x 5mL ampules
3MA400	4000 mOsm/kg H ₂ O	10 x 2mL ampules
Part number	Osmolality Linearity set	
3LA028	100-2000 mOsm/kg H ₂ O	5 x 2 x 5mL ampules
Part number	Reference solution	
3LA029	Clinitrol™ 290	10 x 5mL ampules
3MA029	Clinitrol™ 290	10 x 2mL ampules
Part number	Control solutions	
3MA028	Protinol protein-based controls 240, 280, 320 mOsm/kg	3 x 3 x 3mL vials



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