

SERVICE ALERT

Date:	June 2018
Subject:	Bio-Rad Product Quality Notice - Impact on Advanced Instruments Products
Instrument Affected:	Osmometers

Overview:

We are issuing this alert to follow-up on the Product Quality Notice issued by Bio-Rad Laboratories on May 11, 2018. See <u>http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2018/66906r-eng.php</u> for more information.

Impact:

Use of Bio-Rad controls may cause potential damage to your osmometer. We have received customer complaints indicating that Liquicheck Urine Chemistry Control Level 2 Lot 68512 is causing frequent sample pre-freeze errors on Advanced Instruments osmometers. Normal cleaning may not remedy the errors and, in some cases, the sample probe has required replacement. The use of controls from other suppliers could impact your warranty.

Recommended Action:

Use of consumables from manufacturers other than Advanced Instruments is not recommended and may adversely affect system calibration, performance, operation, and accuracy of test results. We recommend that you use Advanced Instruments brand consumables with Advanced Instruments osmometers.

Advanced Instruments' line of control products is designed specifically for your osmometers:

Renol is a line of urine-based osmolality controls. It is intended for use by laboratories to evaluate osmometer performance when testing urine. **Renol** comes pre-mixed and ready-to-use in 3-mL vials. **Renol** is specifically formulated at 300 and 800 mOsm/kg H₂O. For more information about **Renol**, Part # 3LA085, please visit the <u>Renol Product Page</u> on our website.

Protinol is a line of serum-based osmolality controls. It is intended for use by laboratories to evaluate osmometer performance when testing serum. **Protinol** comes premixed and ready-to-use in 3-mL vials. **Protinol** is specifically formulated at three clinically relevant decision levels, 240, 280, and 320 mOsm/kg H₂O. For more information about **Protinol**, Part # 3MA028, please visit the <u>Protinol Product Page</u> on our website.

Renol and Protinol are formulated at clinically relevant levels to meet CAP and CLIA guidelines. They are manufactured to tight tolerances so you can quickly spot shifts in instrument performance. They are liquid and ready-to-use, so you are not spending valuable time thawing or reconstituting.

Please contact us at <u>quality@aicompanies.com</u> if you have any questions regarding this service alert. To request a quote for Protinol and Renol, please visit <u>aicompanies.com/protinol-renol-quote</u>.

Sincerely,

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Mark Boyle Advanced Instruments, LLC Director, Quality Assurance & Regulatory Affairs