

SERVICE ALERT

Date: October 29, 2019

Subject: Manufacturer Recommendation for QC

Instruments Affected: Osmometers

Overview:

We are issuing this service alert to ensure customer awareness of manufacturer recommendations for serum and urine QC.

Impact:

Internal <u>quality testing</u> has shown third-party controls may fail to detect when an osmometer is out of calibration. Controls with broad osmolality specifications may fail to detect shifts in instrument performance adversely affecting the accuracy of test results. Use of serum and urine controls from other manufacturers may adversely affect system calibration, performance, and operation.

Parts that contact controls from other manufacturers are not covered under warranty.

Recommended Action:

Use our manufacturer recommended **Protinol[™] Protein-Based Controls** and **Renol[™] Urine Osmolality Controls** to ensure optimal performance when testing serum, plasma, and urine osmolality.

Clinical laboratories testing **Protinol** and **Renol** can access the **AdvancedQC™** peer group. Users can quickly spot shifts in performance and compare QC data to other laboratories in real-time and on a monthly basis. Clinical laboratories currently testing **Protinol** and **Renol** can <u>register for AdvancedQC</u> on our website.

Product Information:

Protinol is intended for use by laboratories testing serum and plasma osmolality. It comes premixed in 3-mL vials and is formulated at three clinically relevant 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 is intended for use by laboratories testing urine osmolality. It comes premixed in 3-mL vials and is formulated at two clinically relevant levels: 300 and 800 mOsm/kg H2O. For more information on Renol, Part # 3LA085, please visit the <u>Renol Product Page</u> on our website.

Protinol and **Renol** are manufactured to tight tolerances so you can quickly spot shifts in instrument performance. They are formulated at clinically relevant levels to meet CAP and CLIA guidelines. They are liquid and ready-to-use, to avoid spending valuable time thawing or reconstituting.

For assistance transitioning your lab to Protinol and Renol please contact us by email at <u>quality@aicompanies.com</u> or phone at 781-471-2164. To request a quote for Protinol and Renol, please visit <u>aicompanies.com/protinol-renol-quote</u>.

Sincerely,

Mark Boyle

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