



PRODUCT ANNOUNCEMENT

All AU Clinical Chemistry Systems Apolipoprotein A1 OSR6142

March 2017

Dear Valued Customer,

Beckman Coulter Inc. wishes to inform you that from Apo A1 (OSR6142) Lot 1202 onward, you may observe variations in quality control and *External Quality Control* material. A worldwide shortage of the antiserum used to manufacture the Apo A1 (OSR6142) reagent has led to this variability in results.

As a consequence, you may need to re-establish your Quality Control targets and ranges when switching between OSR6142 Apo A1 reagent lots.

Due to matrix differences between patients' samples and control material Beckman Coulter do not anticipate that patient samples will be significantly affected. Additionally, we assign reagent lot specific calibrator values for Apo A1 (OSR6142) to minimize lot to lot bias in patients' results.

The *Quality Control Section* of the Apo A1 *Instructions for Use (IFU) BAOSR6142 (US Market) and BLOSR6142 (Outside US Market)* will be updated with the following statement:

"Due to variations in antisera material, quality control targets and ranges should be reassessed when switching between reagent lots"

We apologize for any inconvenience this may cause your laboratory.

Please share this information with your laboratory staff and retain this notification as part of your laboratory documentation.

If you have any questions regarding this letter, please contact the Beckman Coulter Customer Support at 1-800-854-3633 in the US and Canada, +353-65-6831170 in Europe, or your local Beckman Coulter Representative. For your convenience, the electronic format of this Product Announcement Letter is available through techdocs.beckmancoulter.com.

Thank you for your continued support of Beckman Coulter products and services.

Sincerely,

A handwritten signature in black ink, appearing to read "K. Breasley", with a long horizontal stroke extending to the right.

Kerri Breasley
Product Manager
Chemistry Systems Beckman Coulter, Inc.

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