

URGENT FIELD SAFETY NOTICE

RECALL Albumin in Urine/CSF FS (Microalbumin), Product code: 1 0242

Precipitations in reagent R2

Date	2022-03-14
Product / Lot	Albumin in Urine/CSF FS (Microalbumin) Product code: 1 0242 Lot: 31646 and 32011
Explanation	During internal process control a precipitation in reagent 2 of the a.m. lots of Albumin in Urine/CSF FS (Microalbumin) has been observed. The precipitation results in turbidity of component R2 that leads to deviating results. The cause of the precipitation is under investigation and corrective actions will be taken.
Impact on patient results	Using the a.m. lots measurements of controls and patient samples lead to deviating results.
Measures	<p>The a.m. lots of Albumin in Urine/CSF FS (Microalbumin) are withdrawn from the market.</p> <p>Please immediately inform all involved users about this recall. Immediately stop further measurements and replace the reagents at the customer's site. Existing stock must be disposed of. DiaSys offers replacement for the affected kits.</p> <p>Determinations performed using a.m. lots shall be assessed with care. Please discuss with the head of laboratory if patient values determined with a.m. lots should be repeated.</p>

DiaSys has announced this field safety notice to the relevant authorities of the European Union. Customers outside the EU are asked to handle necessary announcements to authorities in their countries.

Under current regulations, we are obliged to provide a complete chain of evidence of all corrective measures for our products. For this reason, we ask you to fill in and sign the attached confirmation of receipt as proof that you have received and communicated this information to all concerned customers. Please return it by fax or as scan until March 30, 2022.



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Please accept our sincere apologies for the inconvenience caused. In case you have any questions, please do not hesitate to contact us.

Best regards,

Malte Hilsch

Strategic Product Management Reagents