

FIELD SAFETY NOTICE

Kiel, 2026-07-13

This letter contains important information that requires your immediate and urgent attention. Demeditec Diagnostics GmbH is conducting a Field Safety Corrective Action for the product identified below.

Identification of the affected medical device:

Product Name: Anti-Spermatozoa Antibody (ASA) serum ELISA
Product Code: DE1020
Lot number: 320K115
Problem: Defective 8-well-strips in Microtiter plate leading to high ODs or failure in standard curve

Description of the problem:

A defect has been identified in certain plates of the affected lot (320K115). In affected plates, the majority of the twelve 8-well-strips exhibit unexpectedly high optical density (OD) values, while only a limited number of strips perform as intended. This issue may result in falsely elevated assay results and potential false-positive patient results.

Risk assessment:

If affected wells are used for the calibration curve and controls, the assay may fail to generate a valid standard curve and the internal control will not pass, resulting in no reportable patient results. If functional wells are used for calibration and controls, a valid run may be obtained, however patient samples processed in affected wells may yield false-positive results.

False-positive results may lead to unnecessary follow-up investigations or treatment, but no serious impact on patient health is expected. Moreover, the uniformly elevated OD-levels are likely to be identified. Overall, the risk to patient health is considered low.

Action to be taken by distributors and end-users:

Please check your stocks for the batches in question (320K115), stop using these kits immediately and quarantine these products without delay. Please destroy the kits and send us the confirmation with the completed response form. If you have transferred any of the affected products to another laboratory, please provide them with a copy of this letter.

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected products have been transferred. Please transfer this notice to other organizations on which this action has an impact. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. In case of further questions contact your local distributor.

Contact person for further information:

ppa. Dr. Manfred Czapp
Authorized Signatory / Responsible Person
Demeditec Diagnostics GmbH
Lise-Meitner-Str. 2, 24145 Kiel
Tel: +49-(0)431-71922-32
Fax: +49-(0)431-71922-55
E-mail: czapp@demeditec.de
Web: www.demeditec.com

Signature:

Field Safety Notice – Customer Response Form

Return acknowledgement to sender
Demeditec Diagnostics GmbH
Lise-Meitner-Str. 2, 24145 Kiel, Germany
Email: czapp@demeditec.de (preferred)
FAX: +49 (0)431-71922-55

Product name: Anti-Spermatozoa Antibody (ASA) serum ELISA
Product code: DE1020
Product lot: 320K115
FSN Date: 2026-07-13

Customer name:	
Contact person:	
Phone number:	
Email:	
Signature	

Please check ALL appropriate box(es)

- ☐ I have read and understood the instructions in the letter dated 2026-07-13
- ☐ I have checked my stock and have ____ product(s) on hold, of which ____ kits that need to be replaced.
- ☐ I have informed my end-users of this Field Corrective Action

Please check ALL boxes to describe your business

- ☐ Wholesale / Distributor ☐ Re-packer
☐ Hospital / Medical Facility ☐ Medical Laboratory

Please confirm the quantity of kits remaining at your facility for which you would require replacement:

Product, Description, Reference	Lot Number	Quantity of Products on stock or identified as affected	Quantity of requested kits

Please return this form by 2026-07-22 at latest.

**It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.
Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.**