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:	320K046
Problem:	Low results

Description of the problem:

Due to an investigation of an complaint, it was found that internal quality controls and patients results are found lower than before. During root-cause analysis, a lower activity of the 96-well plate was identified.

Risk assessment:

1. Negative samples: Results may be lower than expected but will remain below the cut-off value (60 U/mL). Interpretation will not change, and patients will still be reported as negative.
2. Positive samples: Results may be lower but will generally remain above the cut-off value of 60 U/mL. Interpretation will not change, and patients will still be reported as positive.
3. Borderline/weakly positive samples: Results may be lower than expected, causing samples with values close to the cut-off to fall below this threshold. As a result, weakly positive patients may be classified as borderline, and borderline patients may be classified as negative. Consequently, follow-up treatment may be omitted.

Conclusion: Although false-negative results may occur in borderline cases and could lead to omitted treatment, no serious adverse health effects are expected. In addition, other routinely applied diagnostic measures such as sperm agglutination tests would identify a false low result. Therefore, the overall patient risk associated with the affected device is considered low.

Action to be taken by distributors and end-users:

Please check your stocks for the lot in question (320K046), 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.
If in previous runs with lot 320K046 you have measured samples with a result between 36 U/mL and 60 U/mL, re-valuate the samples.

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:

[redacted]

Signature:

Field Safety Notice –
Customer Response Form

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

Product name: Anti-Spermatozoa Antibody (ASA) serum ELISA
Product code: DE1020
Product lot: 320K046
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
☐ Hospital / Medical Facility
☐ Re-packer
☐ 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, even if you do not have any of the affected products.

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.