

**Sender****2023-04-13**

LDN Labor Diagnostika Nord GmbH & Co. KG · Am Eichenhain 1 · 48531 Nordhorn

Field Safety Notice

regarding

AA E-1900 DHT ELISA Lot 221081A**Recipient****Identification of the concerned product**

AA E-1900 DHT ELISA Lot 221081A

Description of the issue including cause analysis

The product AA E-1900 DHT ELISA lot 221081A shows a descend in the OD-values below 0.5 OD. Samples cannot be analyzed any more, the provided controls clearly indicate the defect of the product. The descend of the OD values is due to an unexpected decay of a component. This component is not used in subsequent lots. Thus, only the lot 221081A is showing this issue. The lot 221081A is not providing results. There are neither false-positive, nor false-negative patient results. The defect of the ELISA may lead to a delayed analysis or an additional sample collection.

The analyte Dihydrotestosterone (DHT) is the most active natural androgen in humans and plays a principal role in the development of the primary and secondary sexual characteristics. Thus, a short delay in the analysis does not add a significant risk to the patient.

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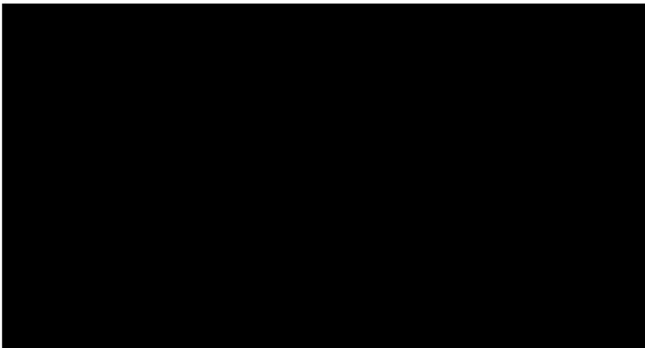
Actions to be taken

The product BA E-1900 lot 221081A must not be sold or used any more. Please inform your customers accordingly. Please report your current stock of the lot and dispose the lot, according to your local disposal regulation. Please send back the attached form. We will replace the discarded kits.

Contact

Please direct your questions to:

Georg Manz
gmanz@ldn.de
+49 5921 8197 200



Response Form

Send to
LDN Labor Diagnostika Nord GmbH & Co. KG
Am Eichenhain 1
48531 Nordhorn
E-Mail: info@ldn.de
Fax: +49 5921 8197 222

Product: DHT ELISA
REF: AA E-1900
Lot: 221081A

Problem description:
Decreased OD-values. Product cannot be used anymore.

Please check the following points and confirm:

- I have received and understood the customer notification from 13.04.2023.
- I confirm that I have forwarded this information to the end-users.

Product	Lot	Number of kits received	Number of kits used up	Number of kits returned / discarded
DHT ELISA AA E-1900	221081A			

Company Name:

Company Address:

Date:

Contact Person:

Signature:

E-Mail address:

Please complete and return this Response Form until 2023-04-27!