

**Sender****2023-11-03**

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

Field Safety Notice

regarding

AA E-1500 Androstanediol-Glucuronide ELISA Lot 230083C**Recipient**

Users and distributors

Identification of the medical device concerned.

AA E-1500 Androstanediol-Glucuronide ELISA Lot 230083C

Description of the problem including the identified cause

For the product AA E-1500 Androstanediol Glucuronides ELISA Lot 230083C it has been detected that the standards D (AA E-1504 Lot S2875) and E (AA E-1505 Lot S2875) are interchanged for some products.

The swapping results in an incorrectly graded standard curve (does not correspond to the typical standard curve in the IFU). In addition, the measured values of kit control 1 are outside the target range.

Consequently, the approach does not provide valid results. This means that no incorrect patient results can be passed on if the test is classified as invalid. Delayed analysis of samples or additional sampling may occur.

Effects of the problem

The swapped standards result in an incorrectly graded standard curve. It is likely that kit control 1, which are used to verify the approach, are not in the corresponding target ranges due to the changed standard curve. As a result, the run must be classified as invalid, and the results obtained cannot be used.

A further effect could be that users swap the values of standards D and E independently during the evaluation, as a swap is recognized. This would result in a correct standard curve, which would pass verification of the kit controls and the gradation of the standard curve with quality control certificate (QC report).

Due to these two effects, it can be concluded that either no results or correct results of patient samples are determined. The severity of this mix-up is therefore classified as low, as the maximum that can occur is a new sample being taken from the patient.

Consequence of no result: delay in the delivery of the patient result. The progress of the treatment of idiopathic hirsutism can only be detected after a delay. This leads to at most a brief reversible impairment of well-being. The measurement of 3 α -Diol-G is not a critical parameter required to make an urgent medical decision.

What measures should be taken by the addressee?

Re-evaluate invalid tests by swapping the determined OD values of standards D and E. The results obtained are valid if they fulfill the following criteria:

- The determined results of both included kit controls of the test performance must be within the acceptance ranges specified on the quality control certificate (QC report).
- The standard curve must have the following gradation:
O.D. Standard 1 > O.D. Standard 2 > O.D. Standard 3 > O.D. Standard 4 > O.D. Standard 5 > O.D. Standard 6

The results obtained with this kit should never be used as the sole basis for clinical diagnosis. Unused products AA E-1500 Androstenediol-Glucuronide ELISA with lot 230083C may no longer be sold or used. Please forward this information to your customers. Please inform us about your current stock and dispose of the product according to your disposal regulations. Confirm the disposal on the enclosed form. We will replace the discarded kits.

To prove that you have read this safety information, please complete the form on page 4 and return it to the e-mail address or fax number given on the reply form by 2023-11-17.

Passing on the information described here:

This notification must be forwarded to all users and distributors of the above-mentioned product.

Thank you for your cooperation! We apologize for any inconvenience this may cause you.

Contact

Please direct your questions to:

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

General Manager

LDN
GmbH
Königsplatz 1
13086 Berlin Nord
Germany

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: Androstenediol-Glucuronide ELISA

REF: AA E-1500

Lot: 230083C

Problem description:

Possible interchange of standard D and standard E. Invalid standard curve possible and therefore no test results.

Please check the following points and confirm by ticking and completing where applicable:

| | |
|--------------------------|---|
| <input type="checkbox"/> | I have received the customer notification dated 2023-11-03. I have taken note of and implemented the information and required actions and their safety-relevant benefits. |
| <input type="checkbox"/> | I confirm that I have forwarded this information to the end users. |

| Product | Lot | Number of kits received *1 | Number of kits already used *1 | Number of kits to be destroyed *1 |
|--|---------|----------------------------|--------------------------------|-----------------------------------|
| AA E-1500 Androstenediol- Glucuronide ELISA | 230083C | | | |

*1 Number of kits used + number of kits destroyed = number of kits received

Company Name: _____

Company Address: _____

Date: _____

Contact Person: _____

Signature: _____

E-Mail address: _____

Please complete and return this Response Form until 2023-11-17!