

Marburg, 2022-01-05

Field safety notice (FSN): C-Peptide ELISA (REF: EIA-1293) lot 20K061, 20K071 & 20K081

Dear Customer,

This notice is to inform you about a quality issue with DRG product **C-Peptide ELISA (EIA-1293) lot 20K061, 20K071 and 20K081**. This is a follow-up to the FSN concerning lot 20K081, that was issued on 2021-12-21.

Description of the problem:

The user of this assay may determine Optical Densities of Standard 0 below the acceptance criterium of 1.2 OD, specified in the COA.

This issue is caused by a component of this kit that might have lost activity over time. This was found out with an incoming complaint and could not be detected during our standardized production and QC process.

In case an operator has used the kits of the affected lot recently, they may observe that

- optical densities (OD) of standards are lower than expected (< OD 1.2)
- controls are in acceptance range and
- patients results are not affected.

Risk assessment:

The loss of kit activity may lead to reduced OD, however, has no impact on the patient results. Controls are within acceptance ranges.

A health risk is improbable, because the error is detected due to too low OD-values (OD S0 <1.2) and the run characterized as invalid. To further minimize the risk this FSN is initiated.

Action to be taken by distributors and end-users:

Please check your inventory for the respective lot, stop using these kits immediately and promptly quarantine these products.

If you have forwarded any of the affected product(s) to another customer or laboratory, please provide them a copy of this letter.

If you faced above mentioned issue, please ask for replacement of the kits that were affected. All unused kits of the affected lot will be replaced as well.

Please complete and return the enclosed Response Form within 10 days so we are assured you have received this important communication.

Contact Persons:

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