

Marburg, 2020-07-29

Field Safety Notice: EIA-6147 Novel Coronavirus COVID-19 IgM ELISA, Lot P810C

Dear Customer,

This notice is to inform you about an issue that you might face with product **Novel Coronavirus COVID-19 IgM ELISA, EIA-6147, Lot # P810C**.

Description of the problem:

The user of this assay may determine lower OD values than usual. This issue is caused by a component of this kit that may have lost activity over time. This was discovered in an incoming complaint and could not be detected during our standardized production and QC process. If a user has recently used the kits of the lot concerned, the user may observe that

- The optical densities (OD) of negative control and samples are lower than expected.
- The positive control is just above or even below the lower limit of 0.5 OD.

Risk assessment:

There is a risk that grey zone and weakly positive patient samples are measured as false negative although the positive control is still within the acceptance range.

Runs with an optical density (OD) below the acceptance criteria of 0.5 OD for the positive control are not considered valid.

Please follow the standard operating procedures of your laboratory to check for any potential discrepancies in results. To further minimize the risk, you are informed with this letter.

Action to be taken by distributors and end-users:

Please check your inventory for the lot in question. If you have kits with the lot number mentioned above, stop using these kits immediately. Please contact us so that we can organize the return of the kits to DRG.

Contact Persons:

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With kind regards,
DRG Instruments GmbH

Dr. Matthias Herkert – Safety Inspector
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