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Marburg, 2024-08-22

## **Field safety notice (FSN): TM-CA 72-4 ELISA (EIA-5071), kit lot 95K064**

Dear Customer,

This notice is to inform you about an issue with DRG's product  
**TM-CA 72-4 ELISA (EIA-5071), kit lot 95K064.**

### **Description of the problem:**

Due to an investigation of an incoming complaint, it was found that the optical densities (OD) of Standards, Controls, and patient sample were measured above the acceptance ranges. Due to the overall high ODs a valid standard curve cannot be deduced and a calculation of sample concentrations is not possible.

The root cause is the filling of a wrong Conjugate Diluent.

### **Risk assessment:**

Due to the wrong Conjugate Diluent, exclusively contained in kit lot 95K064, CA 72-4 values cannot be calculated. Therefore reporting of results can be delayed. However, there is at no time a critical health risk for the patient, because the error is always recognized.

### **Action to be taken by distributors and end-users:**

Please check your inventory for lot 95K064 of the DRG TM-CA 72-4 ELISA and transfer the kits into quarantine. Please contact DRG or your local distributor for replacement.

If you have any questions concerning this issue, please do not hesitate to contact us.

### **Contact Persons:**

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With kind regards,  
DRG Instruments GmbH

Dr. Hero Brahms – PRRC  
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