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IBL International GmbH, Flughafenstraße 52a, 22335 Hamburg

Hamburg, 2018-10-15

Field Corrective Action / Customer Notification Yersinia enterocolitica IgA ELISA, RE56971

Dear Customer,

This notice is to inform you about a possible deviation in the results obtained with the product Yersinia enterocolitica IgA ELISA, RE56971, lot YA-180, expiring 2019-08-17.

Description of the Problem and Hazards Associated with Failure

IBL detected a degradation of the conjugate used in the Yersinia enterocolitica IgA ELISA, RE56971, lot YA-180. This leads to overall lower OD values; and the standard values are below the acceptable ranges stated on the Quality Control Certificate.

Investigation Results and Root Cause

A CAPA Investigation has been opened. The CAPA ensures corrective and preventive actions are implemented to prevent recurrence of the instability of the conjugate.

Risk to Health

The risk to health is considered to be negligible, as the results obtained with the kit cannot be released. The quality criteria for the runs are not met, the OD for the calibrators are below the acceptable range. The laboratory can immediately identify that the run is not valid.

Please follow your laboratory standard operational procedures to review any potential aberrant results that may have occurred.

Required Action to be taken by end-users

Please immediately examine your stock for the affected lot. If you have any kits with the above lot number, promptly stop using and quarantine these kits. Please enter the quantity quarantined on the attached response form. IBL is arranging for replacement product upon request.

Please contact IBL International by returning the enclosed response form by either fax or email as soon as possible, so that we can organize the replacement of Yersinia enterocolitica IgA ELISA.

We apologize for this issue and if you have any questions, please contact IBL.

With kind regards

IBL International GmbH



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Product Manager



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