



IBL International GmbH
Flughafenstraße 52 a
22335 Hamburg
Germany

Tel. +49 (0) 40 53 28 91-0
Fax +49 (0) 40 53 28 91-11
IBL@tecan.com
www.tecan.com/ibl

Urgent Customer Notification ANA Profile 8 ELISA, RE75401 Lot: 0210V

Date: 29.03.2023

Dear Tecan IBL Customer:

As part of the post market activities IBL has identified that ANA Profile 8 ELISA (catalog number RE75401) lot 0210V (exp.: 2023-08-31) measurement signal of the positive control for the parameter SS-B / La is not found within the acceptance range stated in the quality control certificate. The problem is limited to the combination of solid phase and positive control used in this lot, whereby the measurement signals for SS-B / La are below the permissible ones even before the shelf life has expired.

Reason for Field [Safety] Corrective Action and Hazards Associated with the Failure

IBL International received no complaints regarding positive control out of range for the affected lot 0210V, which met all manufacturing and QC criteria when originally released.

There are no risks for users and patients, as the internal control reports results as not valid. Delayed results are not critical, since a diagnosis and therapy recommendation are not directly derived from the result, but only an initial screening of the patient is carried out. There are no further risks from the product.

Investigation Results and Root Cause

A Corrective and preventive action (SCAR) investigation was opened, which ensures preventive corrective actions are implemented to avoid reoccurrence.

Health hazard

Health Hazard Analysis indicates no health hazard risk. A positive result should be considered as an indication for the associated disease. As follow-up diagnosis, the causative autoantibody should be determined by means of a monospecific, quantitative ELISA. As with any serological test, the results should be interpreted in the light of the patient's symptoms and other diagnostic criteria.



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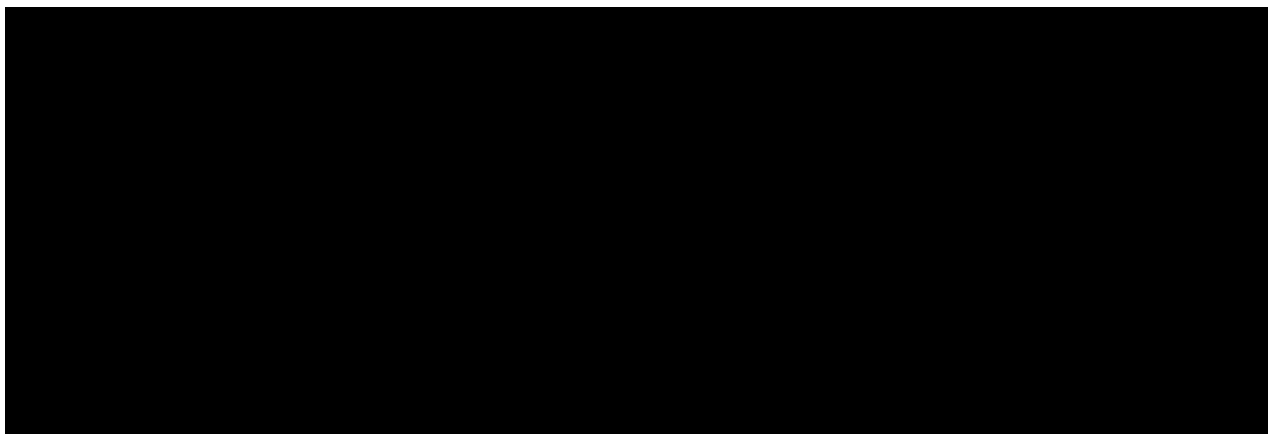
Corrective Action/Required Action

Please check your measurement data concerning the explained issue. Please discuss with the head of the laboratory whether patient values should be repeated. Decide whether re-testing of samples is to be carried out according to your internal work instructions/specifications. Furthermore, check your inventory for the affected lot immediately. If you have kits with the above lot number, please discontinue use of these kits and scrap them. Please enter the quantity of kits scrapped in the attached Response Form to get the correct amount of replacement and return the form to Tecan/IBL immediately.

IBL strives to provide you with products of the highest quality. We value your business and thank you for your continued support. We apologize for the inconvenience. If you have any questions regarding this communication or need assistance, please contact IBL in writing at dajana.domik@tecan.com.

Yours sincerely

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Response form – ANA Profile 8 ELISA, RE75401

To:	IBL International GmbH
Fax:	+49 (0) 40 53 28 91- 11
Email:	Dajana.Domik@tecan.com
Subject	Urgent Customer Information ANA Profile 8 ELISA, RE75401

Customer:	
Contact person:	
Phone number:	
Email:	

Please check ALL boxes that apply

- I have read and understood the information of the customer information dated 2023-03-29.
- I have checked the stock, I have scrapped the affected product kits according to local law.
- I have informed my end customers about this occurrence.

Please check ALL boxes that apply to your facility

- | | |
|--|---|
| <input type="checkbox"/> Distributor | <input type="checkbox"/> Re-packer |
| <input type="checkbox"/> Hospital / Medical facility | <input type="checkbox"/> Medical laboratory |
| <input type="checkbox"/> University Laboratory | <input type="checkbox"/> Research Institute |

Please confirm the number of kits scrapped:

Product name, catalogue number	Lot number	Amount of products scrapped, asking for replacement:
ANA Profile 8 ELISA, RE75401	0210V	

PLEASE RESPOND UNTIL 2023-04-10.