

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

Customer notification

IBL International GmbH

RE54111 CA 72-4 ELISA; lot 95K064

Date: 03.09.2024

Dear Tecan IBL Customer:

We are writing to inform you of a quality issue with the CA 72-4 ELISA, #RE54111, kit lot 95K064.

Reason for Customer Notification and Hazards Associated with the Failure

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.

Investigation Results and Root Cause

The root cause is the filling of a wrong Conjugate Diluent. 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. Tecan IBL takes safety or quality of our products very seriously. Although this specific occurrence has not resulted in any incident, Tecan IBL is alerting the customers of the potential safety issue.

Corrective Action/Required Action

Please check your inventory for lot 95K064 of the CA 72-4 ELISA. 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.

Tecan 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 this has caused. If you have any questions regarding this communication or need assistance, please contact the IBL Product Support Team (ProductSupport.IBL@tecan.com) in writing.

With kind regards


IBL International GmbH

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

Signed by:

Signing Reason: I approve this document
Signing Time: 2024-09-03 | 12:30:39 PM CEST
4906DFDF370844FF9A7956D5F4749EC4

Regulatory Affairs Specialist

Signed by:

Signing Reason: I approve this document
Signing Time: 2024-09-03 | 1:48:25 PM CEST
CC42BEB0D9674A1A907D67196DBE4FAF

Product Manager

Certificate Of Completion

Envelope Id: 910A4E1C9F614F60AD7D21B485E6F894		Status: Completed
Subject: Complete with DocuSign: 3-4-0-9_en_CN_CA 72-4_IBL-2024-004-01_CA 72-4.pdf		
Source Envelope:		
Document Pages: 2	Signatures: 2	Envelope Originator:
Certificate Pages: 2	Initials: 0	
AutoNav: Enabled		
EnvelopeId Stamping: Disabled		
Time Zone: (UTC+01:00) Amsterdam, Berlin, Bern, Rome, Stockholm, Vienna		
		IP Address: 84.46.80.18

Record Tracking

Status: Original	Holder:	Location: DocuSign
2024-09-03 12:16		

Signer Events	Signature	Timestamp
---------------	-----------	-----------

		Sent: 2024-09-03 12:17
		Viewed: 2024-09-03 12:29
		Signed: 2024-09-03 12:30
Regulatory Affairs Specialist		
IBL International GmbH		
Security Level: Email, Account Authentication (Required)	Signature Adoption: Pre-selected Style	
	Signature ID:	
	4906DFDF-3708-44FF-9A79-56D5F4749EC4	
	Using IP Address: 84.46.80.18	
	With Signing Authentication via DocuSign password	
	With Signing Reasons (on each tab):	
	I approve this document	
Electronic Record and Signature Disclosure:		
Not Offered via DocuSign		
		Sent: 2024-09-03 12:30
		Viewed: 2024-09-03 13:48
		Signed: 2024-09-03 13:48
Product Manager		
IBL International GmbH		
Security Level: Email, Account Authentication (Required)	Signature Adoption: Pre-selected Style	
	Signature ID:	
	CC42BEB0-D967-4A1A-907D-67196DBE4FAF	
	Using IP Address: 84.46.80.18	
	With Signing Authentication via DocuSign password	
	With Signing Reasons (on each tab):	
	I approve this document	
Electronic Record and Signature Disclosure:		
Not Offered via DocuSign		

In Person Signer Events	Signature	Timestamp
-------------------------	-----------	-----------

Editor Delivery Events	Status	Timestamp
------------------------	--------	-----------

Agent Delivery Events	Status	Timestamp
-----------------------	--------	-----------

Intermediary Delivery Events	Status	Timestamp
------------------------------	--------	-----------

Certified Delivery Events	Status	Timestamp
---------------------------	--------	-----------

Carbon Copy Events	Status	Timestamp
--------------------	--------	-----------

Witness Events	Signature	Timestamp
----------------	-----------	-----------

Notary Events	Signature	Timestamp
---------------	-----------	-----------

Envelope Summary Events	Status	Timestamps
-------------------------	--------	------------

Envelope Sent	Hashed/Encrypted	2024-09-03 12:17
Certified Delivered	Security Checked	2024-09-03 13:48
Signing Complete	Security Checked	2024-09-03 13:48
Completed	Security Checked	2024-09-03 13:48

Payment Events	Status	Timestamps
----------------	--------	------------

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

RESPONSE FORM – CA 72-4 ELISA, RE54111

To:	IBL International GmbH
Fax:	+49 (0) 40 53 28 91-11
Email:	ProductSupport.IBL@tecan.com
Re:	Customer notification

Customer name:	
Contact person:	
Phone number:	

Please check ALL appropriate box(es)

- ☐ I have read and understood the instructions in the customer notification letter CA 72-4 ELISA, RE54111, lot 95K064 dated 2024-09-03.
- ☐ I have checked my stock and have CA 72-4 ELISA, RE54111, lot 95K064 on hold that need to be replaced. I have scrapped the products on hold.
- ☐ I have used CA 72-4 ELISA, RE54111, lot 95K064 and got invalid run results. Those kits need to be replaced.
- ☐ I don't have CA 72-4 ELISA, RE54111, lot 95K064 in stock and I didn't get any invalid run with that lot. No replacements needed.
- ☐ I have informed my end-users of this customer notification.

Please check ALL boxes to describe your business.

- | | |
|--|---|
| <input type="checkbox"/> Wholesale / 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 quantity of kits remaining at your facility for which you would require replacement:

Product Description, Reference	Lot Number	Quantity of product on stock	Quantity of requested kits for replacement
CA 72-4 ELISA, RE54111	lot 95K064		

PLEASE RESPOND BY 30th Sep 2024.