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Change Notification

Date: 24-OCT-2025

Change Control Number: CC0103

Change Notification Number: CN0089

Description of change:	In order to address raw material supply challenges, smaller modifications to the manufacturing of the product TMB-D Blotting (cat. no. 4600) have been implemented. As part of the change the QC method for the product has also been updated. The functionality of the product is unchanged.
The following will be changed:	As a result of this change the corresponding CoA will be updated: • CoA 4600 TMB-D Blotting
Implementation date/lot number:	The implementation date for this change is: 14-NOV-2025
Additional Information :	Attached are samples/templates of the current CoA (Appendix 1) and the upcoming CoA (Appendix 2).

Date/Sign:

24-OCT-2025

QA/RA Manager: Maysaa Shamma

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Appendix 1: Current template of CoA

CERTIFICATE OF ANALYSIS

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TMB-D Blotting

CHROMOGENIC SUBSTRATES

Precipitating HRP Substrate
Cat. No. 4600

Lot No.:	xxxxxxXxx	
Date of manufacture:	mm-yyyy	
Expiry date:	mm-yyyy	(When stored at 2-8 °C in an unopened bottle)

Analysis:

The substrate is analyzed for consistent sensitivity, background of the strips, appearance, and pH. Only the procedure for sensitivity and background is described in the CoA.

Dot blot: The sensitivity is determined as a dot blot analysis based on dilutions of HRP in various concentrations on nitrocellulose membranes. The membrane is blocked in Synthetic Blocking Buffer for Blotting, before it is incubated in the substrate for 10 minutes. Following the reaction is stopped by rinsing the strips with ELIX water. The sensitivity and background are compared to a reference substrate lot with known sensitivity and background.

Specifications:

Sensitivity:	Detects < 0.025 ng HRP
Background:	The background of the strips must be light blue to colorless
Appearance:	Clear solution with no distinct color
pH:	4.72 – 5.12

Results:

Sensitivity:	Passed
Background:	Passed
Appearance:	Passed
pH:	x.xx

Storage:

Short-term storage: Ambient; protected from light.
Long-term storage: 2-8 °C; protected from light.

It is hereby confirmed that the product was manufactured according to our standard operating procedures and that the product complies with all specifications.

Performed by:	**Date:** dd-MMM-yyyy	**Signature:** XX
Approved by:	**Date:** dd-MMM-yyyy	**Signature:** XX

Our Immunoassay Solutions are developed in order to create a healthy and safe work environment and preserving natural resources, while helping our customers fulfill significant regulatory requirements.
We call it ECO-TEK!

ENVIRONMENTAL ECO-TEK® CONSIDERATION

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Appendix 2: Upcoming template of CoA

CERTIFICATE OF ANALYSIS

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TMB-D Blotting

CHROMOGENIC SUBSTRATES

Precipitating HRP Substrate
Cat. No. 4600

Lot No.:	xxxxxxXxx	
Date of manufacture:	mm-yyyy	
Expiry date:	mm-yyyy	(When stored at 2-8 °C in an unopened bottle)

Analysis:

The substrate is analyzed for consistent activity and background of the strips.

Dot blot: The activity is determined as a dot blot analysis based on dilutions of HRP conjugated antibody in various concentrations on nitrocellulose membranes. After drying, the membrane is incubated in the substrate for 10 minutes. Following the reaction is stopped by washing with a wash buffer for 3 minutes. The activity and background are compared to a reference substrate lot with known activity and background.

Specifications:

Activity:	There must be no significant difference in the dots intensities between the tested lot and the reference substrate.
Background:	There must be no significant difference in the background intensities between the tested lot and the reference substrate.

Results:

Sensitivity:	Passed
Background:	Passed

Storage:

Short-term storage: Ambient; protected from light.
Long-term storage: 2-8 °C; protected from light.

Performed by:	**Date:** dd-MMM-yyyy	**Signature:** XX
Approved by:	**Date:** dd-MMM-yyyy	**Signature:** XX

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