kementec PROVIDING IMMUNOASSAY SOLUTIONS

Change Notification

Date: 03-MAY-2024

Deviation Number: DEV0208

Change Notification Number: CN0077

Description of change:	Due to a non-conformity the CoA for Synthetic Blocking Buffer, Blotting will be updated to reflect the correct details of the QC-test method of the product (Cat. No. 4650).
The following will be changed:	As a result of this change the following CoAs will be updated: • Synthetic Blocking Buffer, Blotting (Cat. No. 4650)
Implementation date/lot number:	The implementation date for this change is: 03.MAY.2024
Additional Information:	Attached are samples/templates of the current CoAs and the upcoming CoAs.

Date/Sign: 03-MAY-2024

- **Appendix 1: New template of CoA to be implemented - 4650 Synthetic Blocking Buffer, Blotting**
- Appendix 2: Current template of CoA to be discontinued and replaced by new version (appendix 1) – 4650 Synthetic Blocking Buffer, Blotting

Appendix 1: New template of CoA to be implemtned

CERTIFICATE OF ANALYSIS

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Synthetic Blocking Buffer, Blotting

BUFFERS & STABILIZERS

Membrane Blocker, Protein Free
Cat. No. 4650

Lot No.: xxxxxx

Date of manufacture: xx-xxxx

Expiry date: xx-xxxx (When stored at 2-8 °C in an unopened bottle)

Analysis: The blocking buffer is analyzed for blocking effectiveness in a semi-quantitative dot blot test and a pH measurement is performed. Only the procedure for the dot blot is described in the CoA.

Dot blot: A nitrocellulose strip dotted with a dilution with Human IgG is blocked with Synthetic Blocking Buffer, Blotting for 10 min. A Tris-Tween buffer is used as reference. Following the strip is incubated in a Rabbit anti-human IgG-HRP dilution. After washing, the dot is developed in a 3,3'-diaminobenzidine tetrahydrochloride solution and visually inspected. If the background on the strip is colorless, the analysis is passed.

Specifications:
Dot Blot: Colorless background
pH: 8.5 – 8.7
Color: Clear with no distinct color

Results:
Dot Blot: _____
pH: _____
Color: _____

Storage:
Short-term storage: Ambient.
Long-term storage: 2-8 °C.

Performed by: Date: DD.MMM.YYYY Signature: xx

Approved by: Date: DD.MMM.YYYY Signature: xx

ENVIRONMENTAL ECO-TEK® CONSIDERATION

Our Immunoassay Solutions are eco-friendly, creating a healthy work environment and preserving natural resources, while helping our customers fulfill significant regulatory requirements. **We call it ECO-TEK.**

DOC ID: 04-5-05-403 Ver. 3

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Appendix 2: Current template of CoA to be replaced by CoA itemplate in appendix 1

CERTIFICATE OF ANALYSIS

kementec

Synthetic Blocking Buffer, Blotting

BUFFERS & STABILIZERS

Membrane Blocker, Protein Free
Cat. No. 4650

Lot No.: xxxxxx

Date of manufacture: xx-xxxx

Expiry date: xx-xxxx (When stored at 2-8 °C in an unopened bottle)

Analysis: pH measurement.
Dot Blot: The blocking buffer is tested by a semi-quantitative test using a dilution of Rabbit anti-Horse radish peroxidase in dot-blot. A nitrocellulose strip dotted with a dilution of Rabbit anti-HRP is blocked by the blocking buffer and incubated in a HRP solution. A Tris-Tween buffer is used as reference. After washing, the dot are developed in a 3,3-diaminobenzidine tetrahydrochloride solution and visual inspected.
If the background on the strip is colorless, the analysis is passed.

Specifications: Dot Blot: Colorless background
pH: 8.5 – 8.7
Color: Clear with no distinct color

Results: Dot Blot: _____
pH: _____
Color: _____

Storage: Short-term storage: Ambient.
Long-term storage: 2-8 °C.

Performed by: Date: xx-xxx-2021 Signature: xx

Approved by: Date: xx-xxx-2021 Signature: xx

ENVIRONMENTAL ECO-TEK® CONSIDERATION

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