

Change Notification

Date: 18-MAR-2025

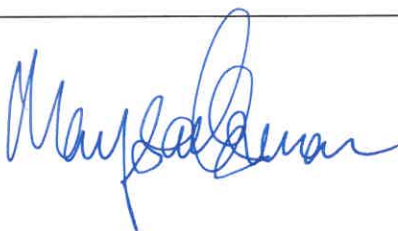
Deviation Number: DEV0236

Change Notification Number: CN0086

Description of change:	<p>Due to a non-conformity in the CoAs for some of the Buffers & Stabilizers and Labels & Conjugates introduced in NOV 2024 these CoAs will be updated to reflect the correct details on the CoAs for impacted products listed below.</p> <p>In this regard you are kindly asked to disregard Change Notification #82 and related CoAs.</p> <p>All customers that have received lot numbers affected by this deviation have been contacted directly.</p> <p>Changes made: In order to align our Certificates of Analysis (CoAs), changes are introduced to the CoA's of Buffer & Stabilizer and Labels & Conjugates products. Neither the products nor the QC methods are affected by this change except for Streptavidin (Cat. No. 4610). For this product the QC method for the activity test has been changed and the specifications accordingly. This change has no impact on the product's functionality.</p>
The following will be changed:	<p>As a result of this change the following CoAs will be updated:</p> <p>Buffers & Stabilizers:</p> <ul style="list-style-type: none"> • Protein-StabilPLUS (Cat. No. 4720) • HRP-StabilPLUS2 (Cat. No. 4730) • Effect Diluent Low, Animal-free (Cat. No. 7070) • Effect Diluent Medium, Animal-free (Cat. No. 7080) • Effect Diluent High, Animal-free (Cat. No. 7090) <p>Labels & Conjugates:</p> <ul style="list-style-type: none"> • HRP (Cat. No. 4120) • Streptavidin (Cat. No. 4610)
Implementation date/lot number:	<p>The implementation date for this change was:</p> <p>13-MAR-2025</p>

Additional Information:	Attached are samples/templates of the corrected CoAs.
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Date/Sign: 18-MAR-2025



List of appendices:

New templates of CoAs to be implemented:

- Appendix 1: New template of CoA to be implemented - 4720 Protein-StabilPLUS - Ver. 4
- Appendix 2: New template of CoA to be implemented - 4730 HRP-StabilPLUS2 - Ver. 4
- Appendix 3: New template of CoA to be implemented - 7070 Effect Diluent Low, Animal-free – Ver. 3
- Appendix 4: New template of CoA to be implemented - 7080 Effect Diluent Medium, Animal-free – Ver. 3
- Appendix 5: New template of CoA to be implemented - 7090 Effect Diluent High, Animal-free – Ver. 3
- Appendix 6: New template of CoA to be implemented - 4120 HRP – Ver. 5
- Appendix 7: New template of CoA to be implemented - 4610 Streptavidin – Ver. 5

Former templates of CoAs to be replaced:

- Appendix 8: Former template of CoA to be replaced - 4720 Protein-StabilPLUS - Ver. 3
- Appendix 9: Former template of CoA to be replaced - 4730 HRP-StabilPLUS2 - Ver. 3
- Appendix 10: Former template of CoA to be replaced - 7070 Effect Diluent Low, Animal-free – Ver. 1
- Appendix 11: Former template of CoA to be replaced - 7080 Effect Diluent Medium, Animal-free – Ver. 1
- Appendix 12: Former template of CoA to be replaced - 7090 Effect Diluent High, Animal-free – Ver. 1
- Appendix 13: Former template of CoA to be replaced - 4120 HRP – Ver. 3
- Appendix 14: Former template of CoA to be replaced - 4610 Streptavidin – Ver. 3

CERTIFICATE OF ANALYSIS

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Protein-StabilPLUS

BUFFERS & STABILIZERS

Antibody/Antigen Stabilizer

Cat. No. 4720

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

Analysis: The protein stabilizer is inspected visually for appearance and the pH is measured.

Specifications: Appearance: Yellow-brown, slightly cloudy solution
pH: 6.80 – 7.20

Results: Appearance: Passed
pH: x.xx

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

Performed by: Date: dd-MMM-yyyySignature: XXApproved by: Date: dd-MMM-yyyySignature: 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!



DOC ID: 04-5-05-405 Ver. 4

CERTIFICATE OF ANALYSIS

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HRP-StabilPLUS2

BUFFERS & STABILIZERS

HRP Conjugate Stabilizer

Cat. No. 4730

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

Analysis: The stabilizer is inspected visually for appearance and the pH is measured.

Specifications: Appearance: Yellow-brown, slightly cloudy solution
pH: 6.80 – 7.20

Results: Appearance: Passed
pH: x.xx

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

Performed by: Date: dd-MMM-yyyySignature: XXApproved by: Date: dd-MMM-yyyySignature: XX

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DOC ID: 04-5-05-406 Ver. 4

CERTIFICATE OF ANALYSIS

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Effect Diluent Low, Animal-free

BUFFERS & STABILIZERS

Sample Diluent & RF/HAMA Blocker

Cat. No. 7070

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

Analysis: The diluent is inspected visually for appearance and the pH is measured.

Specifications: Appearance: Solution with slightly yellow to no distinct color
pH: 7.00 – 7.40

Results: Appearance: Passed
pH: Passed

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

Performed by: Date: dd-MMM-yyyySignature: XXApproved by: Date: dd-MMM-yyyySignature: XX

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DOC ID: 04-5-05-420 Ver. 3

CERTIFICATE OF ANALYSIS

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Effect Diluent Medium, Animal-free

BUFFERS & STABILIZERS

Sample Diluent & RF/HAMA Blocker

Cat. No. 7080

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

Analysis: The diluent is inspected visually for appearance and the pH is measured.

Specifications: Appearance: Solution with slightly yellow to no distinct color
pH: 7.00 – 7.40

Results: Appearance: Passed
pH: Passed

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

Performed by: Date: dd-MMM-yyyy Signature: XXApproved by: Date: dd-MMM-yyyy Signature: XX

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DOC ID: 04-5-05-421 Ver. 3

CERTIFICATE OF ANALYSIS

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Effect Diluent High, Animal-free

BUFFERS & STABILIZERS

Sample Diluent & RF/HAMA Blocker

Cat. No. 7090

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

Analysis: The diluent is inspected visually for appearance and the pH is measured.

Specifications: Appearance: Solution with slightly yellow to no distinct color
pH: 7.00 – 7.40

Results: Appearance: Passed
pH: Passed

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

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DOC ID: 04-5-05-422 Ver. 3

CERTIFICATE OF ANALYSIS

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Horseradish Peroxidase (HRP)

LABELS & CONJUGATES

Enzyme, lyophilized, extracted from horseradish roots

Cat. No. 4120

Lot No.: xxxxxxXxx

Date of manufacture: mm-yyyy

Expiry date: mm-yyyy

Analysis: The purity is measured as the absorbance ratio A_{403}/A_{275} (RZ) which is a measure of the hemin content of the peroxidase. The peroxidase activity is expressed by measuring the oxidation of pyrogallol, while the solubility is tested as the solubility in deionized water.

Specifications:

Purity:	≥ 3 Rz (A_{403}/A_{275})
Activity:	≥ 250 U/mg material, Pyrogallol
Solubility:	5 mg/mL

Results:

Purity:	<u>x</u>
Activity:	<u>xxx</u>
Solubility:	<u>Passed</u>

Storage: Dry at -20 °C. Equilibrate the product to room temperature before opening.

Remarks: For research use only. Not for human or drug use.

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

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

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DOC ID: 04-5-05-600 Ver. 5

CERTIFICATE OF ANALYSIS

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Streptavidin

LABELS & CONJUGATES

Lyophilized, from *Streptomyces avidinii*

Cat. No. 4610

Lot No.: xxxxxxXxxDate of manufacture: mm-yyyyExpiry date: mm-yyyy

Analysis: The biotin-binding activity in U/mg protein is determined using a modification of the HABA dye-binding assay where 1 U corresponds to binding 1 µg biotin at pH 7.0. The homogeneity is analyzed by SDS-PAGE.

Specifications: Activity: ≥ 14.0 U/mg protein
Homogeneity: The protein shows predominantly a single band by SDS-PAGE

Results: Activity: xx.x U/mg protein
Homogeneity: Passed

Storage: Dry at -20 °C. Equilibrate the product to room temperature before opening.

Remarks: For in vitro use only.

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

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

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DOC ID: 04-5-05-601 Ver. 5

CERTIFICATE OF ANALYSIS

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Protein-StabilPLUS

BUFFERS & STABILIZERS

Antibody/Antigen Stabilizer

Cat. No. 4720

Lot No.: XXXXXXDate of manufacture: XX-XXXXExpiry date: XX-XXXX (When stored at 2-8 °C in an unopened bottle)

Analysis: pH measurement

Specifications: pH: 6.80-7.20
Color: Yellow-brown solution, slightly cloudy

Results: pH: _____
Color: _____

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

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

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DOC ID: 04-5-05-405-Ver. 02

CERTIFICATE OF ANALYSIS

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HRP-StabilPLUS2

BUFFERS & STABILIZERS

HRP Conjugate Stabilizer

Cat. No. 4730

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

Specifications: pH: 6.80-7.20
Color: Yellow-brown solution, slightly cloudy

Results: 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



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DOC ID: 04-505-406 Ver. 02

CERTIFICATE OF ANALYSIS

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Effect Diluent Low, Animal-free

BUFFERS & STABILIZERS

Sample Diluent & RF/HAMA Blocker

Cat. No. 7070

Lot No.: XXXXXXDate of manufacture: XX-XXXXExpiry date: XX-XXXX (When stored at 2-8 °C in an unopened bottle)

Analysis: pH measurement.

Specifications: pH: 7.00 – 7.40
Color: Slightly yellow to no distinct color

Results: pH: ____
Color: ____

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

Performed by: Date: xx-xxx-2022 Signature: xxApproved by: Date: xx-xxx-2022 Signature: xx

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: 04-5-05-420 Ver. 01

Effect Diluent Medium, Animal-free

BUFFERS & STABILIZERS

Sample Diluent & RF/HAMA Blocker

Cat. No. 7080

Lot No.: XXXXXXDate of manufacture: XX-XXXXExpiry date: XX-XXXX (When stored at 2-8 °C in an unopened bottle)**Analysis:** pH measurement.**Specifications:** pH: 7.00 – 7.40
Color: Slightly yellow to no distinct color**Results:** pH: ____
Color: ____**Storage:** Short-term storage: Ambient.
Long-term storage: 2-8 °C.**Performed by:** Date: xx-xxx-2022 Signature: xx**Approved by:** Date: xx-xxx-2022 Signature: xx

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CERTIFICATE OF ANALYSIS

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Effect Diluent High, Animal-free

BUFFERS & STABILIZERS

Sample Diluent & RF/HAMA Blocker

Cat. No. 7090

Lot No.: XXXXXXDate of manufacture: XX-XXXXExpiry date: XX-XXXX (When stored at 2-8 °C in an unopened bottle)**Analysis:** pH measurement.**Specifications:** pH: 7.00 – 7.40
Color: Slightly yellow to no distinct color**Results:** pH: ____
Color: ____**Storage:** Short-term storage: Ambient.
Long-term storage: 2-8 °C.**Performed by:** Date: xx-xxx-2022 Signature: xx**Approved by:** Date: xx-xxx-2022 Signature: xx

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: 04-5-05-422 Ver. 01

CERTIFICATE OF ANALYSIS

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Horseradish Peroxidase (HRP)

LABELS & CONJUGATES

Enzyme, lyophilized from roots of horseradish

Cat. No. 4120

Lot No.: XXXXXXDate of manufacture: XX-XXXXExpiry date: XX-XXXX**Analysis:** Purity number, activity, and solubility.**Specifications:** Purity number, Rz (A_{403}/A_{275}): ≥ 3
Activity: ≥ 250 U/mg material, Pyrogallol
Solubility: 5 mg/ml in deionised water**Results:** Rz: _____
Activity: _____
Solubility: _____**Storage:** Dry at -20 °C. Equilibrate the product to room temperature before opening.**Remarks:** For research use only. Not for human or drug use.**Performed by:** Date: xx-xxx-2022 Signature: xx**Approved by:** Date: xx-xxx-2022 Signature: xx

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.**

CERTIFICATE OF ANALYSIS

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Streptavidin

LABELS & CONJUGATES

Lyophilized, From *Streptomyces avidinii*

Cat. No. 4610

Lot No.: XXXXXXDate of manufacture: XX-XXXXExpiry date: XX-XXXX**Analysis:** Activity, protein and homogeneity.**Specifications:** Activity: > 13 U/mg protein, 1 U corresponds to binding of 1 µg biotin
Homogeneity: The protein gives predominantly a single band by SDS-PAGE**Results:** Activity: _____ U/mg protein
Homogeneity: _____**Remarks:** For in vitro use only**Storage:** Dry at -20 °C. Equilibrate the product to room temperature before opening.**Performed by:** Date: xx-xxx-2021 Signature: xx**Approved by:** Date: xx-xxx-2021 Signature: xx

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-S-05-601 Ver. 03