

Change Notification

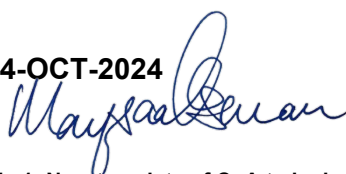
Date: 14-OCT -2024

Change Control Number: CC0085

Change Notification Number: CN0081

| | |
|---------------------------------|---|
| Description of change: | In order to align our Certificates of Analysis (CoAs), changes are introduced to the CoA's of Buffer and Stabilizer products. Neither the products nor the QC methods are affected by this change. |
| The following will be changed: | As a result of this change the corresponding CoA's will be updated: <ul style="list-style-type: none"> • CoA 4530 HRP-StabilPLUS • CoA 4540 AP-StabilPLUS • CoA 4660 Antibody Enhancer • CoA 5230 UNI-StabilPLUS • CoA 5350 Sample X-tra |
| Implementation date/lot number: | The implementation date for this change is: 18.OCT.2024 |
| Additional Information: | Attached are samples/templates of the current CoA and the upcoming CoA. |

Date/Sign: 14-OCT-2024



- **Appendix 1: New template of CoA to be implemented – 4530 HRP-StabilPLUS ver. 4**
- Appendix 2: Current template of CoA (ver. 3) to be discontinued and replaced by new version (appendix 1)
- **Appendix 3: New template of CoA to be implemented – 4540 AP-StabilPLUS ver. 4**
- Appendix 4: Current template of CoA (ver. 3) to be discontinued and replaced by new version (appendix 3)
- **Appendix 5: New template of CoA to be implemented – 4660 Antibody Enhancer ver. 4**
- Appendix 6: Current template of CoA (ver. 3) to be discontinued and replaced by new version (appendix 5)
- **Appendix 7: New template of CoA to be implemented – 5230 UNI-StabilPLUS ver. 4**
- Appendix 8: Current template of CoA (ver. 3) to be discontinued and replaced by new version (appendix 7)
- **Appendix 9: New template of CoA to be implemented – 5350 Sample X-tra ver. 4**
- Appendix 10: Current template of CoA (ver. 3) to be discontinued and replaced by new version (appendix 9)

CERTIFICATE OF ANALYSIS

kementec

HRP-StabilPLUS

BUFFERS & STABILIZERS

HRP Conjugate Stabilizer

Cat. No. 4530

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

Analysis: The product is tested by measuring the pH and by visual inspection of the appearance.

Specifications: Appearance: Clear solution with no distinct color.
pH: 6.80 – 7.20

Results: Appearance: Passed
pH: x.xx

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

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-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: 04-5-05-401 Ver. 4

CERTIFICATE OF ANALYSIS

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HRP-StabilPLUS

BUFFERS & STABILIZERS

HRP Conjugate Stabilizer

Cat. No. 4530

Lot No.: xxxxxxXxxDate of manufacture: xx-xxxxExpiry date: xx-xxxx (When stored at 2-8 °C in an unopened bottle)

Analysis: The product is tested by measuring the pH in the final solution and by visual inspection of the color.

Specifications: pH: 6.80 - 7.20
Color: Clear solution with no distinct color.

Results: pH: x.xx
Color: xxxxxx.....

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

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: xx-XXX-xxxx Signature: XX

Approved by: Date: xx-XXX-xxxx Signature: XX



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CERTIFICATE OF ANALYSIS

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AP-StabilPLUS

BUFFERS & STABILIZERS

AP Conjugate Stabilizer

Cat. No. 4540

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

Analysis: The product is tested by measuring the pH and by visual inspection of the appearance.

Specifications: Appearance: Clear solution with no distinct color.
pH: 6.60 – 7.00

Results: Appearance: Passed
pH: x.xx

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

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

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DOC ID: 04-5-05-402 Ver. 4

AP-StabilPLUS

BUFFERS & STABILIZERS

AP Conjugate Stabilizer

Cat. No. 4540

Lot No.: xxxxxxXxxDate of manufacture: xx-xxxxExpiry date: xx-xxxx (When stored at 2-8 °C in an unopened bottle)

Analysis: The product is tested by measuring the pH in the final solution and by visual inspection of the color.

Specifications: pH: 6.60 - 7.00
Color: Clear solution with no distinct color.

Results: pH: x.xx
Color: xxxxxx.....

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

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: xx-XXX-xxxx Signature: XX

Approved by: Date: xx-XXX-xxxx Signature: XX



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CERTIFICATE OF ANALYSIS

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Antibody Enhancer

BUFFERS & STABILIZERS

AP/HRP Conjugate Stabilizer/Amplifier

Cat. No. 4660

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

Analysis: The product is tested by measuring the pH and by visual inspection of the appearance.

Specifications: Appearance: Clear solution with no distinct color.
pH: 5.50 – 5.90

Results: Appearance: Passed
pH: x.xx

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

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

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DOC ID: 04-5-05-404 Ver. 4

Antibody Enhancer

BUFFERS & STABILIZERS

AP/HRP Conjugate Stabilizer/Amplifier

Cat. No. 4660

Lot No.: xxxxxxXxxDate of manufacture: xx-xxxxExpiry date: xx-xxxx (When stored at 2-8 °C in an unopened bottle)

Analysis: The product is tested by measuring the pH in the final solution and by visual inspection of the color.

Specifications: pH: 5.50 – 5.90
Color: Clear solution with no distinct color.

Results: pH: x.xx
Color: xxxxxx.....

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

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: xx-XXX-xxxx Signature: XX

Approved by: Date: xx-XXX-xxxx Signature: XX



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UNI-StabilPLUS

BUFFERS & STABILIZERS

AP/HRP Conjugate Stabilizer

Cat. No. 5230

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

Analysis: The product is tested by measuring the pH and by visual inspection of the appearance.

Specifications: Appearance: Clear solution with no distinct color.
pH: 6.60 – 7.00

Results: Appearance: Passed
pH: x.xx

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

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

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DOC ID: 04-5-05-415 Ver. 4

UNI-StabilPLUS

BUFFERS & STABILIZERS

AP/HRP Conjugate Stabilizer

Cat. No. 5230

Lot No.: xxxxxxXxxDate of manufacture: xx-xxxxExpiry date: xx-xxxx (When stored at 2-8 °C in an unopened bottle)

Analysis: The product is tested by measuring the pH in the final solution and by visual inspection of the color.

Specifications: pH: 6.60 – 7.00
Color: Clear solution with no distinct color.

Results: pH: x.xx
Color: xxxxxx.....

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

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: xx-XXX-xxxx Signature: XX

Approved by: Date: xx-XXX-xxxx Signature: XX



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Sample X-tra

BUFFERS & STABILIZERS

Sample Dilution Buffer

Cat. No. 5350

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

Analysis: The product is tested by measuring the pH and by visual inspection of the appearance.

Specifications: Appearance: Clear solution with no distinct color.
pH: 6.70 – 7.10

Results: Appearance: Passed
pH: x.xx

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

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

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CERTIFICATE OF ANALYSIS

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Sample X-tra

BUFFERS & STABILIZERS

Sample Dilution Buffer

Cat. No. 5350

Lot No.: xxxxxxXxxDate of manufacture: xx-xxxxExpiry date: xx-xxxx (When stored at 2-8 °C in an unopened bottle)

Analysis: The product is tested by measuring the pH in the final solution and by visual inspection of the color.

Specifications: pH: 6.70 – 7.10
Color: Clear solution with a slightly yellow to no distinct color

Results: pH: x.xx
Color: xxxxxx.....

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

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: xx-XXX-xxxx Signature: XX

Approved by: Date: xx-XXX-xxxx Signature: XX



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DOC ID: 04-5-05-415 Ver. 03