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Change Notification

Date: 12-APR-2024

Change Control Number: CC0079

Change Notification Number: CN0075

Description of change:	Due to discontinuation from supplier of one of the basic components in the QC assay for pNPP and pNPP ONE products, the QC setup for these products is being updated.
The following will be changed:	As a result of this change the following CoAs will be updated: • pNPP (Cat. No. 4400) • pNPP ONE (Cat. No. 4401)
Implementation date/lot number:	The implementation date for this change is: 12.APR.2024
Additional Information:	Attached are samples/templates of the current CoAs and the upcoming CoAs.

Date/Sign: 12-APR-2024

- **Appendix 1: New template of CoA to be implemented - 4400 pNPP**
- Appendix 2: Current template of CoA to be discontinued and replaced by new version (appendix 1) – 4400 pNPP
- **Appendix 3: New template of CoA to be implemented – 4401 pNPP ONE**
- Appendix 4: Current template of CoA to be discontinued and replaced by new version (appendix 3) – 4401 pNPP ONE

Appendix 1: New template of CoA to be implemented

CERTIFICATE OF ANALYSIS

kementec

pNPP

CHROMOGENIC SUBSTRATES

ELISA AP Substrate
Cat. No. 4400

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, background, appearance, and pH. Only the procedure for activity and background is described in the CoA.

Background: 100 µL substrate is pipetted into four wells of a standard microtiter plate, prefilled with 100 µL 1 M sodium hydroxide. The background absorbance is read at 405/620 nm.

Activity: The activity is determined in a 2-layer ELISA. First layer is a human IgG antibody dilution. Second layer is a Rabbit-anti-Human-IgG-AP dilution. 100 µL substrate is added to each well and incubated for 30 minutes. The reaction is stopped by addition of 100 µL 1 M sodium hydroxide. The absorbance is read at 405/620 nm and converted to activity using a standard curve.

Specifications:

Activity:	90 – 110%
Background:	< 0.080 Abs.
Appearance:	Clear solution with slightly yellow color
pH:	9.35 – 9.75

Results:

Activity:	xxx%
Background:	x.xxx Abs.
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

DOC ID: 04-5-05-004 Ver. 3

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Appendix 2: Current template of CoA to be discontinued and replaced by new version

CERTIFICATE OF ANALYSIS

kementec

pNPP

CHROMOGENIC SUBSTRATES

ELISA AP Substrate
Cat. No. 4400

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

Analysis:

The substrate is analyzed for consistent activity, background, color and pH (only the procedure for activity and background is described in the COA).
Background: 100 µL substrate is pipetted into four wells of a standard microtiter plate, followed by addition of 100 µL 1M sodium hydroxide. The background absorbance is read at 405/620 nm.
Activity: The activity is determined in a 2-layer ELISA. First layer is a standard Human serum dilution. Second layer is Rabbit anti Human IgG-AP. 100 µL substrate is added to each well and incubated for 30 minutes. The reaction is stopped by addition of 100 µL 1 M sodium hydroxide. The absorbance is read at 405/620 nm.
The activity is compared to a standard p-NPP solution with known activity.

Specifications:

Activity: 90 - 110%
Background: Abs. < 0.080
pH: 9.35 - 9.75
Color: Clear to slightly yellow

Results:

Activity test: _____
Background: _____
Color: _____
pH: _____

Storage:

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

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

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DOC ID: 04-5-05-004 Ver. 02

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Appendix 3: New template of CoA to be implemented

CERTIFICATE OF ANALYSIS

kementec

pNPP ONE

CHROMOGENIC SUBSTRATES

ELISA AP Substrate
Cat. No. 4401

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, background, appearance, and pH. Only the procedure for activity and background is described in the CoA.

Background: 100 µL substrate is pipetted into four wells of a standard microtiter plate, prefilled with 100 µL 1 M sodium hydroxide. The background absorbance is read at 405/620 nm.

Activity: The activity is determined in a 2-layer ELISA. First layer is a human IgG antibody dilution. Second layer is a Rabbit-anti-Human-IgG-AP dilution. 100 µL substrate is added to each well and incubated for 30 minutes. The reaction is stopped by addition of 100 µL 1 M sodium hydroxide. The absorbance is read at 405/620 nm and converted to activity using a standard curve.

Specifications:

Activity:	90 – 110%
Background:	< 0.080 Abs.
Appearance:	Clear solution with slightly yellow color
pH:	9.35 – 9.75

Results:

Activity:	xxx%
Background:	x.xxx Abs.
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

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CERTIFICATE OF ANALYSIS

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pNPP ONE

CHROMOGENIC SUBSTRATES

ELISA AP Substrate
Cat. No. 4401

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

Analysis:
The substrate is analyzed for consistent activity, background, color and pH (only the procedure for activity and background is described in the COA).
Background: 100 µL substrate is pipetted into four wells of a standard microtiter plate, followed by addition of 100 µL 1 M sodium hydroxide. The background absorbance is read at 405/620 nm.
Activity: The activity is determined in a 2-layer ELISA. First layer is a standard Human serum dilution. Second layer is Rabbit anti Human IgG-AP. 100 µL substrate is added to each well and incubated for 30 minutes. The reaction is stopped by addition of 100 µL 1 M sodium hydroxide. The absorbance is read at 405/620 nm.
The activity is compared to a standard p-NPP solution with known activity.

Specifications:
Activity: 90 - 110%
Background: Abs. < 0.080
pH: 9.35 - 9.75
Color: Clear to slightly yellow

Results:
Activity test: ____
Background: ____
Color: ____
pH: ____

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

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

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