

Change Notification

Date: 13-DEC -2024

Change Control Number: CC0085

Change Notification Number: CN0083

Description of change:	In order to align our Certificates of Analysis (CoAs), changes are introduced to the CoA's of Conjugates 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 4740 Enhanced Strep-HRP
Implementation date/lot number:	The implementation date for this change is: 27.DEC.2024
Additional Information:	Attached are samples/templates of the current CoA and the upcoming CoA.

Date/Sign: 13-DEC-2024

QA Manager: 

List of appendices:

Appendix #	Text	Cat. No.	Product name	CoA Ver.#
1	New template of CoA to be implemented 27-DEC-2024	4740	Enhanced Strep-HRP	3.1
2	Current template of CoA to be discontinued and replaced by new version (Appendix 1) 27-DEC-2024	4740	Enhanced Strep-HRP	3

Enhanced Streptavidin-HRP

LABELS & CONJUGATES

Streptavidin, poly-HRP linker

Cat. No. 4740 (1 mg HRP/ml)

Lot No.: xxxxxxXxx**Date of manufacture:** mm-yyyy**Expiry date:** mm-yyyy (When stored at 2-8°C in an unopened bottle)**Description:** Horseradish Peroxidase (HRP) and Streptavidin conjugated to a polymer backbone.**Concentration:** 1 mg HRP/ml**Buffer:** Stabilized in 50% TRIS Buffer and 50% HRP Conjugate Stabilizer.**Analysis:** The conjugate is analyzed for consistent activity and Non Specific Binding (NSB).

Activity: The activity is determined in a 3-layer ELISA. The first layer is a standard Goat anti-rabbit IgG dilution. The second layer is Biotinylated rabbit IgG and the third layer is Enhanced Streptavidin-HRP, tested in dilution range from 15.000 to 30.000.

NSB: The Non Specific Binding is tested in the same assay, without addition of the second layer. 100 µL TMB ONE substrate is added to each well and incubated for 20 minutes. The reaction is stopped by addition of 100 µL 0.2 M sulphuric acid. The absorbance is read at 450/620 nm. The activity is compared to a standard conjugate solution with known activity.

Specifications:

Activity:	90 – 110%
NSB:	< 0.150 Abs.

Results:

Activity:	<u>xxx%</u>
NSB:	<u>x.xxx Abs.</u>

Storage: Store at 2-8 °C. Do not freeze.

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



CERTIFICATE OF ANALYSIS

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Enhanced Streptavidin-HRP

LABELS & CONJUGATES

Streptavidin, poly-HRP linker

Cat. No. 4740 (1 mg HRP/ml)

Lot No.: XXXXXXDate of manufacture: XX-XXXXExpiry date: XX-XXXX (When stored at 2-8 °C in an unopened bottle)**Description:** Horseradish Peroxidase (HRP) and Streptavidin conjugated to a polymer backbone.**Concentration:** 1 mg HRP/ml**Buffer:** Stabilized in 50% TRIS Buffer and 50% HRP Conjugate Stabilizer.

Analysis: The conjugate is analyzed for consistent activity and Non Specific Binding (NSB).
Activity: The activity is determined in a 3-layer ELISA. The first layer is a standard Goat anti-rabbit IgG dilution. The second layer is Biotinylated rabbit IgG and the third layer is Enhanced Streptavidin-HRP, tested in dilution range from 15.000 to 30.000.
NSB: The Non Specific Binding is tested in the same assay, without addition of the second layer. 100 µL TMB ONE substrate is added to each well and incubated for 20 minutes. The reaction is stopped by addition of 100 µL 0.2 M sulphuric acid. The absorbance is read at 450/620 nm. The activity is compared to a standard conjugate solution with known activity.

Specifications: Activity: 90 – 110 %
 NSB: Abs. < 0.150

Results: Activity test: _____
 NSB: _____

Storage: Store at 2-8 °C. Do not freeze.**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.**

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