

## Change Notification

Date: 27-FEB-2025

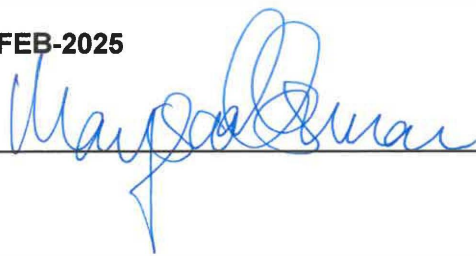
Change Control Number: CC0096

Change Notification Number: CN0085

Description of change:	One of the components used in the manufacture of WellChampion (Cat. No. 4900) has been discontinued by the supplier. Thus, this component is exchanged by another component. The exchange is a like-to-like, thus not affecting the product's function. In order to align our Certificates of Analysis (CoAs), changes are introduced to the CoA of WellChampion. The QC method is not affected by this change.
The following will be changed:	As a result of this change the corresponding CoAs will be updated: <ul style="list-style-type: none"> <li>CoA 4900 WellChampion</li> </ul>
Implementation date/lot number:	The implementation date for this change is:  14.MAR.2025
Additional Information:	Attached are samples/templates of the current CoA and the upcoming CoA.

Date/Sign: 27-FEB-2025

QA/RA Manager:



- **Appendix 1: New template of CoA to be implemented – 4900 WellChampion ver. 4**
- **Appendix 2: Current template of CoA (ver. 3) to be discontinued and replaced by new version (Appendix 1)**

## CERTIFICATE OF ANALYSIS

kementec

## WellChampion®

## BUFFERS &amp; STABILIZERS

## Microwell Plate Blocker/Stabilizer

Cat. No. 4900

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

**Analysis:** The product is analyzed for stabilizing effect, Non-Specific Binding (NSB), appearance, and pH. Only the procedure for stabilizing effect and NSB is described in the CoA.

**Stabilizing effect and NSB:** The stabilizing effect and NSB are determined in a 2-layer ELISA. First layer is a Goat anti-rabbit IgG dilution protected by WellChampion overnight at 37 °C. Second layer is Rabbit anti-human IgG-HRP. NSB is tested without adding the first layer. 100 µL TMB ONE substrate is added to each well and incubated for 13 minutes. The reaction is stopped by addition of 100 µL 0.2 M sulfuric acid. The absorbance is read at 450/620 nm.

Internal references are used for calculation of the stabilizing effect.

**Specifications:**

Stabilizing effect:	90-110%
NSB:	< 0.075 Abs.
pH:	5.60 - 6.00
Appearance:	Clear solution with light yellow to yellow color

**Results:**

Stabilizing effect:	<u>xxx%</u>
NSB:	<u>x.xxx</u> Abs.
pH:	<u>x.xx</u>
Appearance:	<u>Passed</u>

**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-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!**



DOC ID: 04-5-05-410 Ver. 4

## CERTIFICATE OF ANALYSIS

kementec

## WellChampion®

BUFFERS &amp; STABILIZERS

## Microwell Plate Blocker/Stabilizer

Cat. No. 4900

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

## Analysis:

The product is analyzed for stabilizing effect, Non Specific Binding (NSB) and pH.

**Stabilizing effect and NSB:** The stabilizing effect and NSB are determined in a 2-layer ELISA. First layer is a Goat anti-rabbit IgG protected by WellChampion for 18 hours. Second layer is rabbit anti-human IgG-HRP. NSB is tested without the first layer. 100 µL TMB ONE substrate is added to each well and incubated for 13 minutes. The reaction is stopped by addition of 100 µL 0.2M sulfuric acid. The absorbance is read at 450/620 nm. An internal reference is used for calculation of the stabilizing effect.

## Specifications:

Stabilizing effect: 90 – 110%

NSB: &lt; 0.075

pH: 5.60 – 6.00

Color: Yellow

## Results:

Stabilizing effect: \_\_\_\_\_

NSB: \_\_\_\_\_

pH: \_\_\_\_\_

Color: \_\_\_\_\_

## Storage:

Short-term storage: Ambient.

Long-term storage: 2-8 °C.

## Performed by:

Date: xx-xxx-2021Signature: xx

## Approved by:

Date: xx-xxx-2021Signature: 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: 04-5-05-410 Ver. 03