

{Adresse}

Berlin, 28.05.2021

### **Important Notification for all Users!**

It has come to our attention that lot 055-HRP of product „ZytoChem-Plus HRP Kit, Broad Spectrum“ gives negative staining results when used in immunohistochemistry on formalin-fixed paraffin sections. This may lead to problems in the analysis of the stained tissue specimens in case that no validated positive test controls were included in the same staining run.

#### **Details on affected device:**

Name of product: ZytoChem-Plus HRP Kit, Broad Spectrum	Catalog number (REF): HRP060
Affected lot (LOT): 055-HRP	Expiration Date: 31.10.2021

#### **Advise on action to be taken by the user:**

1. Immediately inspect all “ZytoChem-Plus HRP Kit, Broad Spectrum“ in your possession, including partially used product, and identify those with the above listed lot number.
2. Please immediately discontinue the use of the identified affected lot number. Please note references below for reshipment of affected product.
3. Please complete the enclosed response form and send the completed form to us by 30.06.2021 by email to [info@zytomed-systems.de](mailto:info@zytomed-systems.de) or by fax to 0049 (0)30 804 984 999 (att. Sicherheitsbeauftragter MPG).
4. As an invalid test would be observable via the use of validated test controls, no clinical diagnosis would be confirmed. Upon receipt of a new lot, a retest shall be performed following the protocol addressed in the instruction for use.

#### **Advice on product reshipment:**

Please send the product to:     Zytomed Systems GmbH  
   Anhaltinerstr. 16  
   14163 Berlin

Please use one of the following courier services for collection:

GO! – Customer ID:	32387
Trans-o-flex-Customer ID:	138354000
UPS-Customer ID:	009V3E

#### **Actions taken by Zytomed Systems:**

Zytomed Systems has tested lot 055-HRP and found the outcome of users/customers confirmed. In stock inventory of this specific lot has been disposed. Corrective action and adequate training of personnel in production have been executed.

#### **Remarks:**

Zytomed Systems is liable to inform the Competent Authority about this corrective action. We ask you to send the response form to us by the date indicated above.

This notification is being made with the knowledge of the regulatory authorities.

We apologize for any inconvenience this action may cause. Thank you for your attention and support in this matter. In case of any questions or concerns, please don't hesitate to contact our customer service at 0049 (0)30 804 984 990 (Monday through Friday 07.00 am – 4.30 pm).

Sincerely,  
Zytomed Systems GmbH

## Response Form

☐ I have inspected our inventory and identified the following quantities of the affected lot:  
\_\_\_\_\_ {Stückzahl} von Charge {Charge}

☐ I have quarantined inventory consisting of affected lot.

☐ No material of the affected lot was identified.

☐ I have notified my customer(s) that were shipped the affected product lot.

☐ The affected products will completely be send back to Zytomed Systems.

\_\_\_\_\_  
Place, date, signature

\_\_\_\_\_  
Print name

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_  
Facility name and address

Please fax or email the completed response form by {Datum} to Zytomed Systems GmbH.

Fax: 0049 (0)30 804 984 999  
Email: [info@zytomed-systems.de](mailto:info@zytomed-systems.de)