ZYTOMED SYSTEMS GmbH • Anhaltinerstraße 16 • 14163 Berlin

{*Adresse*}

Berlin, December 5, 2019

Important Notification for all Users!

It has come to our attention that some units of one particular lot of the antibody Rabbit anti-CDX2 (EPR2764Y) might give weak 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.
The reason for poor staining results is probably due to inhomogeneous mixing of the different components during the manufacturing process.

Details on affected device:

Name of product:	Rabbit anti-CDX2 (EPR2764Y)	Catalog number (REF): BRB028
Affected lot number (LOT):	X474	Expiration date: 31.05.2021

Advise on action to be taken by the user:

1. Immediately inspect all BRB028 (Rabbit anti-CDX2) in your possession, including partially used product, and identify those with the above listed lot number.
2. Please immediately discontinued use and distribution of the identified affected lot number.
3. If you may have further distributed this product, please identify those customers and notify them at once by sending them a copy of this notification letter.
4. Please complete the enclosed response form and send the completed form to us by December 31, 2019 by email to info@zytomed-systems.de or by fax to 0049 (0)30 804 984 999 (att. Sicherheitsbeauftragter MPG).
5. 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.

Actions taken by Zytomed Systems:
Zytomed Systems has tested the affected lot number X474 in several staining runs in comparison to other lots which have been produced both earlier and later and found that only lot X474 gave weak staining results. All remaining material oft he affected lot has been discarded. Appropriate training with all personell in manufacturing has been carried out.

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 all BRB028 (Rabbit anti-CDX2) in our possession and identified the following quantities of the affected lot:

____ BRB028 lot X474

☐ 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.

_____

Place, date, signature

_____

Print name

_____

_____

_____

_____

Facility name and address

Please fax or email the completed response form by December 31, 2019 to Zytomed Systems GmbH.

Fax: 0049 (0)30 804 984 999

Email: info@zytomed-systems.de