

TPHA 200 ref: 72501  
TPHA 500 ref: 72502

Marnes-la-Coquette November 07<sup>th</sup> 2016

**Addendum to the Field Safety Notice**

This information is intended for the end user of this product  
If you are not the end user, please forward this information to the appropriate laboratory personnel

**Subject : Addendum to the Urgent Field Safety Notice - Products TPHA 200 (reference 72501) and TPHA 500 (reference 72502) sent on the 31<sup>th</sup> Oct**

Dear Valued Customer,

On **31<sup>th</sup> Oct**, we sent an Urgent Field Safety Notice published by Trinity Biotech manufacturer about RPR 100 reagents (reference 72501) and TPHA 500 (reference 72502) that were distributed by Bio- rad.

In this notice were listed possible current lots in use.  
However, the notice also concerns expired lots. We just received the Manufacturer's Trinity Biotech list of expired lots.  
Our records indicate that you have received these reagent lots and we want to share the important information below.

| <b>72501 TPHA 200</b> |                 |
|-----------------------|-----------------|
| Lot number            | Expiration Date |
| D035001L              | may-16          |
| D077001L              | august-16       |
| D120001L              | sept-16         |
| D155002L              | oct-16          |

| <b>72502 TPHA 500</b> |                 |
|-----------------------|-----------------|
| Lot number            | Expiration Date |
| C345019L              | april-16        |
| D036021L              | may-16          |
| D056002L              | may-16          |
| D120002L              | sept-16         |
| D155003L              | oct-16          |

Investigations conducted by Trinity Biotech showed that some low positive samples tested with these two reagents may not have been detected.

As a result of this Field Safety Notification, a retest recommendation is mentioned and according to the internal procedures of your laboratory.

We remind you that the reactive TPHA 200 (72501 reference) and TPHA 500 (72502 reference) were replaced to catalog Bio-Rad by the TPHA 200 (72503 reference) and TPHA 500 (72504 reference) manufactured by Bio-Rad and that they are not affected by this Field Safety Notice and will continue to be provided to you by Bio-Rad.

Please fill, sign and return the annex.

We would like to inform you that the Authorities are aware about this notification.

We sincerely apologize for the inconvenience, and remain at your disposal for any further information.

Please forward it to whomever it may concern.

Sincerely

Violaine Mélen (Modify)  
Département des Affaires Réglementaires



**ADDENDUM TO URGENT FIELD SAFETY NOTICE of the 31th Of October 2016**

**Annexe 1**

**Form to fill and return to your customer service**

| <b>72501 TPHA 200</b> |                 |
|-----------------------|-----------------|
| Lot number            | Expiration Date |
| D035001L              | may-16          |
| D077001L              | august-16       |
| D120001L              | sept-16         |
| D155002L              | oct-16          |

| <b>72502 TPHA 500</b> |                 |
|-----------------------|-----------------|
| Lot number            | Expiration Date |
| C345019L              | april-16        |
| D036021L              | may-16          |
| D056002L              | may-16          |
| D120002L              | sept-16         |
| D155003L              | oct-16          |

**PRODUCT / INVOLVED LOTS**

|                           |  |
|---------------------------|--|
| LABORATORY                |  |
| Undersigning Manager :    |  |
| Adresse :                 |  |
| Phone / Fax number:       |  |
| Customer Account Number : |  |

- ☐ I have read information regarding the lots of product TPHA 200 ref. 72505 and TPHA 500 ref. 72506: D035001L, D077001L, D120001L, D155002L, C345019L, D036021L, D056002L, D120002L, D155003L

For Distributors :

- ☐ I have notified my customers of this urgent Field Safety Notice: ☐ YES ☐ No  
Number of notified: \_\_\_\_\_

Date :

Signed and laboratory stamp :

**For any other further information or support contact your local customer service**

## Urgent: Field Safety Notice

### Annex 2

#### **Distributors / Subsidiaries Acknowledgment of Receipt and Certificate of destruction**

Please fill out and sign the information below and return the completed form to Bio-Rad Marnes including **a copy of the translated letter** until the **30<sup>th</sup> of November 2016**.

- by email at [ra-marnes-vigilance@bio-rad.com](mailto:ra-marnes-vigilance@bio-rad.com)

#### PRODUCT:

| 72501 TPHA 200 |                 |
|----------------|-----------------|
| Lot number     | Expiration Date |
| D035001L       | may-16          |
| D077001L       | august-16       |
| D120001L       | sept-16         |
| D155002L       | oct-16          |

| 72502 TPHA 500 |                 |
|----------------|-----------------|
| Lot number     | Expiration Date |
| C345019L       | april-16        |
| D036021L       | may-16          |
| D056002L       | may-16          |
| D120002L       | sept-16         |
| D155003L       | oct-16          |

#### DISTRIBUTORS/SUBSIDIARIES:

|   |  |
|---|--|
| <b>Distributors / Subsidiaries</b>                |  |
| <b>Address<br/>(Street, Postcode, Country)</b>    |  |
| <b>Phone Number</b>                               |  |
| <b>Undersigning manager name</b>                  |  |
| <b>Distributors / Subsidiaries Account Number</b> |  |

#### STATEMENT:

I am aware of information about the issue concerning the above referenced products and have proceeded to the following accordingly to the instructions issued by Bio-Rad:

- If necessary, translation into my national language(s), of the FSN,
- Communication of the FSN to all the concerned customers.

**Number of customers informed:** \_\_\_\_\_

**Date:** .....

**Signature:** .....