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**Urgent Field Safety Notice**

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**Commercial name/Ref:** *Total Prostate Specific Antigen (CLIA)/TPSA111***FSCA-identifier:** *CP2002-CR01201***Type of action:** *Reagent Kits Exchange*

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3<sup>rd</sup> Mar. 2020**Attention:** [[Hospital/Distributor Name](#)]

Dear Sir or Madam,

Through the continuous monitoring of the products distributed by Mindray, we have become aware of a potential issue associated with the Total Prostate Specific Antigen (CLIA) kits. This letter is intended to provide you with information as following:

**Details on affected products:**

The affected products are listed in **Table 1** and the method of identifying the affected kits is explained in **Appendix 1**.

**Table 1**

Assay	P/N	REF	LOT#	Barcode #
TPSA (2x50 Test Kit)	105-004219-00	TPSA111	2019030100	ADP2019030100 <b>5003</b> ~ ADP2019030100 <b>5336</b>

**Description of the problem:**

Mindray has identified that TPSA kits of a different lot were mistakenly packaged into a limited number of TPSA 2x50T kits of LOT 2019030100. Both lots are of good quality. However, due to lot-to-lot variation, mixing two lots of reagent kits may cause out-of-acceptable-range control results or abnormal results (increased or decreased) of patient samples if the user is unaware of the issue.

To date, there are no reports of serious incident associated with this potential issue.

**Advise on actions to be taken by the Hospital/Laboratory administrator:**

1. Please pass this Notice to all those who need to be aware of the issue within your organization or to any organization where the potentially affected reagent kits have been transferred.
2. Please discontinue to use and discard the affected kits listed in Table 1. Your local Mindray Service Representative will contact you as soon as possible to replace the affected reagent kits.

**Advise on actions to be taken by the distributor:**

1. Please pass this Notice to all those who need to be aware of the issue within your organization or to any organization where the potentially affected reagent kits have been delivered.
2. Please do not sell these affected reagent kits to customers. Mindray Regional Product Specialist will contact you to replace the affected reagent kits.

**Transmission of this Field Safety Notice:**

This Notice needs to be passed to all those who need to be aware of the issue within your organization or to any organization where the potentially affected reagent kits have been transferred.

Please maintain awareness of this notice and the resulting action for an appropriate period to ensure the effectiveness of the corrective actions.

We would be grateful if you could confirm receipt of this letter. Please fill in the Acknowledgement Form below and return via E-mail or Fax.

**Contact reference person:**

We apologize for the inconvenience caused by this situation. If you have any questions, please contact with your local Mindray Service Representative or designated Product Specialist – Wang Yu

Organization: Shenzhen Mindray Bio-Medical Electronics Co., LTD  
Tel: 0086-755-81887112  
Fax: 0086-755-26582680  
Email: will.wang@mindray.com

This Notice has been notified to the appropriate Regulatory Agency.

**Signature:**

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Phoebe Zhang  
Representative of Post-market surveillance      Quality Center

SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD  
Mindray building, Keji 12th Road South, High-tech Industrial Park, Nanshan,  
Shenzhen 518057, P.R.China  
Tel: 0086-755-81885479  
Fax : 0086-755-26582680  
Email : mr@mindray.com

Acknowledgement Form

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**Confirmation of Receipt of Field Safety Notice**

**Affected Products :** *Total Prostate Specific Antigen (CLIA)*  
**FSCA :** *CP2002-CR01201*  
**Type of FSCA :** *Reagent Kits Exchange*

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**Please fill in this form and return this confirmation by E-mail or Fax immediately.**

**Fax:** 0086-755-26582680  
**Email:** will.wang@mindray.com

Name: \_\_\_\_\_

Tel. No.: \_\_\_\_\_

E-mail address: \_\_\_\_\_

Date and Signature: \_\_\_\_\_

Address of the Organization:

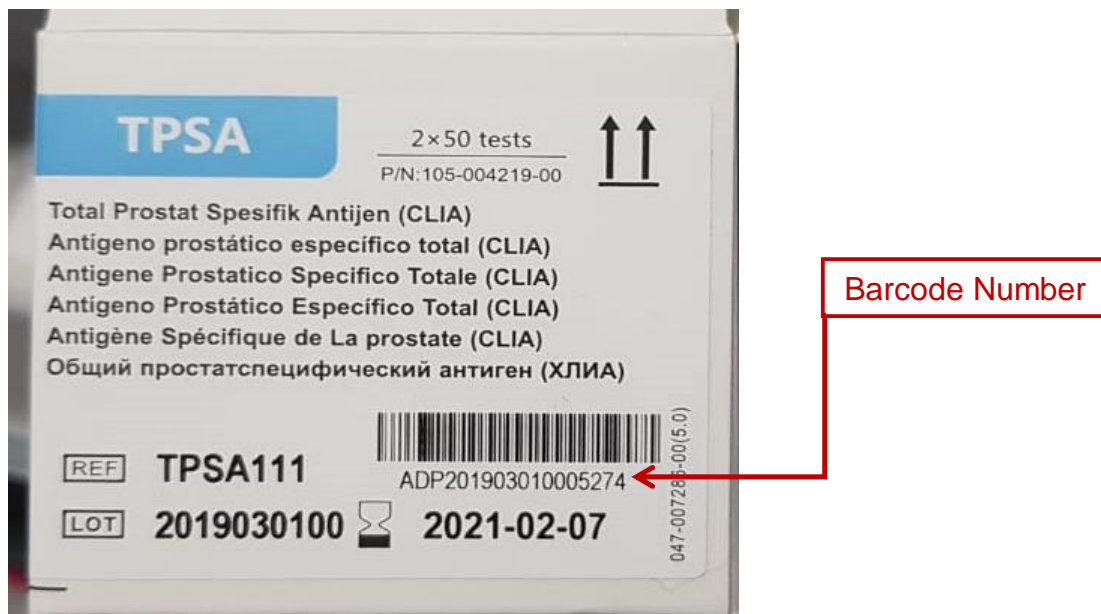
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**Appendix 1**

The label on the reagent kit contains P/N, REF number, lot number, and barcode number. Please refer to the picture below.

**Figure 1 The information on the label**



The range of barcode number of the affected TPSA 2x50T kits of LOT 2019030100 is between ADP20190301005003 (included) to ADP20190301005336 (included).