



Rev 1: September 2018

FSN Ref: FSN pk TPHA 2000 - 19091202

FSCA Ref: FSCA pk TPHA 2000 - 19091202

Date: 17:JAN:2020

Urgent Field Safety Notice
pk TPHA 2000 Test Kit

For Attention of*:

IffMedic GmbH;

- Dienst voor bloed
Rode Kruis Vlaanderen
DRK Blutspendedienst Baden-Württemberg Hessen GmbH
Blutspendedienst SRK Bern

Contact details of local representative (name, e-mail, telephone, address etc.)*

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Urgent Field Safety Notice (FSN)
pk TPHA 2000 Test Kit
Recall of device. Risk of false negative results

1. Information on Affected Devices*	
1	1. Device Type(s)*
.	IVD, blood screening test
1	2. Commercial name(s)
.	PK TPHA 2000 Test Kit
1	3. Unique Device Identifier(s) (UDI-DI)
.	Not applicable
1	4. Primary clinical purpose of device(s)*
.	Particle agglutination assay for the detection of syphilis antibodies in blood donors
1	5. Device Model/Catalogue/part number(s)*
.	NB004
1	6. Software version
.	Not applicable
1	7. Affected serial or lot number range
.	19091202
1	8. Associated devices
.	Not applicable

2 Reason for Field Safety Corrective Action (FSCA)*	
2	1. Description of the product problem*
.	Data supports low sensitivity of product. Substandard performance is suspected
2	2. Hazard giving rise to the FSCA*
.	Risk of false negative result during blood donation screening. There is no risk to the user of the device. There is a risk to recipient of blood donation. There is a risk to the donor of an undetected Syphilis infection
2	3. Probability of problem arising
.	Manufacturer's batch retain testing has indicated sensitivity of test at the very lower limit of claimed sensitivity
2	4. Predicted risk to patient/users
.	Not applicable
2	5. Further information to help characterise the problem
.	Not applicable
2	6. Background on Issue
.	Reported false negative result from German blood bank. The root cause appears to be the kit being at the lower end of acceptable sensitivity. Only the batch 19091202 is affected, other batches in the field have been tested and accepted. Manufacturer contacted centres that have received this lot number and asked for use of the kit to be ceased. Return of any kits in the field has been arranged via the distributor. Distributor has alternative batch of product available.
2	7. Other information relevant to FSCA
.	Not applicable

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	3. Type of Action to mitigate the risk*	
3.	1. Action To Be Taken by the User* <input type="checkbox"/> Identify Device <input type="checkbox"/> Quarantine Device <input checked="" type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Follow patient management recommendations <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) <input type="checkbox"/> Other <input type="checkbox"/> None Provide further details of the action(s) identified.	
3.	2. By when should the action be completed?	Upon notification, as soon as possible
3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? Yes If the affected lot 19091202 kits have been used, it is recommended if possible a review is conducted of blood donations tested.	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	5. Action Being Taken by the Manufacturer <input checked="" type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Software upgrade <input type="checkbox"/> IFU or labelling change <input type="checkbox"/> Other <input type="checkbox"/> None Specified lot number requested to be removed from the field and returned to manufacturer. Replacement product will be provided	
3	6. By when should the action be completed?	As soon as possible
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	

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4. General Information*		
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	Not applicable
4.	3. For Updated FSN, key new information as follows:	
	Not applicable	
4.	4. Further advice or information already expected in follow-up FSN? *	Not planned yet
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	Not applicable	
4	6. Anticipated timescale for follow-up FSN	Not applicable
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Newmarket Biomedical Ltd
	b. Address	Unit 1, Lanwades Business Park, Kentford, Suffolk, CB8 7PN UK
	c. Website address	www.new-bio.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
	9. Yes	
4.	10. List of attachments/appendices:	If extensive consider providing web-link instead.
4.	11. Name/Signature	
		17 January 2020

Transmission of this Field Safety Notice	
	<p>This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.*</p>

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.