Rev 1: September 2018

FSN Ref: NC 647 FSCA Ref: NC 647

Date: 10-FEB-2023

Urgent Field Safety Notice
PT/Thromboplastin L

For Attention of*: Identify either by name or role who needs to be aware of the hazard and/or take action. If this is multiple recipients then include full list.

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

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Company Name/Logo

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Urgent Field Safety Notice (FSN)
Thromboplastin L
Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Thromboplastin L is a liquid reagent that is used in conjunction with calibrators and QC materials as a quantitative assay that measures the prothrombin time (PT) in citrated plasma samples. The results are used to aid in monitoring of the function of the common and extrinsic coagulation pathways in the general adult population and in patients receiving warfarin therapy. The assay may be performed manually, semi-automated or automated by a trained laboratory professional in a clinical laboratory.
1.	2. Commercial name(s)
	Thromboplastin L; PT
1.	3. Unique Device Identifier(s) (UDI-DI)
	Complete when this becomes available.
1.	4. Primary clinical purpose of device(s)*
	Thromboplastin L is a quantitative assay that measures the prothrombin time (PT) in citrated plasma samples. The results are used to aid in monitoring of the function of the common and extrinsic coagulation pathways in the general adult population and in patients receiving warfarin therapy. The assay may be performed manually, semi-automated or automated by a trained laboratory professional in a clinical laboratory.
1.	5. Device Model/Catalogue/part number(s)*
	5262L, 5265L, 5267L, OL262501, OL762501, OL962501
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	11744500, 11767087, 11764623, 11761984, 11764055, 11762508, 11761992, 11767079, 11762516
1.	8. Associated devices
	For use with Semi-Automated or Automated Coagulation Analysers as a screening test or alternatively in conjunction with Factor Deficient Plasma in Factor Activity Assays.

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	This lot of Thromboplastin L has extended clot times for Prothrombin Time (PT) tests affecting controls and sample material. The control results will not meet the defined reference range criteria and therefore, testing should be ceased and an alternative lot should be used.
2.	2. Hazard giving rise to the FSCA*
	The risk to patient is a delay on patient result reporting as the controls will not meet the reference range criteria and therefore, an alternative lot should be used to mitigate the issue. Please ensure that adequate controls are in place to identify aberrant results, comprehensive analysis using Levy Jennings rules should be performed to identify any developing trends or bias. This will identify any potential issue.
2.	3. Probability of problem arising
	Current investigations are such that the issue limited to this lot however, please enact the above advice to ensure the quality of result on any lot as standard practice.
	4. Predicted risk to patient/users

2.	This issue is easily identifiable using control measures therefore, there should be no risk to the patient. Please ensure that adequate control measures are implemented.
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	A customer complaint highlighted that this lot of Thromboplastin L has prolonged clot times, which do not meet the reference range criteria of the normal and abnormal controls. Investigations confirmed that clot times are extended.
2.	7. Other information relevant to FSCA
	N/A

	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User***	
	☒ Identify Device ☒ Quarantine Device ☒ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None Provide further details of the action(s) identified.	
3.	2. By when should the action be completed?	Identification and Quarantine of Device must be completed immediately. Return of the Device as soon as possible through MRA process.
3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? No. Any QC bias or trends should have alerted concern even prior to controls being out of range. When controls out of range, patient results should not be reported. Provide further details of patient-level follow-up if required or a justification why none is required	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**5. Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None Provide further details of the action(s) identified.	
3	6. By when should the action be completed?	2 months post release of FSN to allow for material returns and reconciliation.
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?	
	Choose an item.	Choose an item.

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	**3.** For Updated FSN, key new information as follows:	
	N/A	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	Eg patient management, device modifications etc	
4	6. Anticipated timescale for follow-up FSN	For provision of updated advice.
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Only necessary if not evident on letter-head.
	b. Address	Only necessary if not evident on letter-head.
	c. Website address	Only necessary if not evident on letter-head.
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	If extensive consider providing web-link instead.
4.	10. Name/Signature	Insert Name and Title here and signature below

	Transmission of this Field Safety Notice
	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) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. 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..*

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