



Date: 21.OCT.2020

**Urgent Field Safety Notice**  
**APTT Si L Minus / APTT (SILICA) Ref: SLQ / OQLS**

For Attention of\*:Distributors in Northern Ireland, Romania, Czech Republic, Germany, Bulgaria, Lithuania, Switzerland, Mauritius, Russia, Kazakhstan, Indonesia, Botswana, Nepal, Oman, Bolivia, Mali, Armenia, Pakistan, Ukraine, Moldova. Customers in England, Spain, Italy, Turkey

Contact details of local representative (name, e-mail, telephone, address etc.)*
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This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages
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**Urgent Field Safety Notice (FSN)**  
**Device Commercial Name**  
**Risk addressed by FSN**

1. Information on Affected Devices*	
1	1. Device Type(s)*
.	Activated Partial Thromboplastin Time Coagulation Reagent
1	2. Commercial name(s)
.	APTT Si L Minus, APTT (SILICA)
1	3. Primary clinical purpose of device(s)*
.	The APTT Si L Minus kit is intended for carrying out clot based haemostasis assays. For use in the determination of activated partial thromboplastin times (aPPT) and related coagulation procedures using phospholipid extract and a near-colloidal particle activator.
1	4. Device Model/Catalogue/part number(s)*
.	See appendix
1	5. Affected serial or lot number range
.	See appendix
1	6. Associated devices
.	Any IVD Coagulometer used alongside reagent.

2 Reason for Field Safety Corrective Action (FSCA)*	
2	1. Description of the product problem*
.	White flocculates visible within some vials.
2	2. Hazard giving rise to the FSCA*
.	Potential blockage of automated instrument needles may occur. Slight extension of clot times has been observed at a customer site but is not reproducible using in-house materials. The greatest hazard to the patient/end user is a delay in testing. Where clot time extension is noted at customer site, controls will fall out of range and prevent patient reporting.
2	3. Probability of problem arising
.	Intermittent problem that has been noticed to varying degrees.
2	4. Predicted risk to patient/users
.	There is no direct risk to patients or end users. The indirect predicted risk to the patient/end user is a delay in testing. Where clot time extension is noted at customer site, controls will fall out of range and prevent patient reporting.
2	5. Background on Issue
.	Customers reported white flocculate material within some vials which may lead to needle blockage when used with automated instruments.

	<b>3. Type of Action to mitigate the risk*</b>	
3.	<b>1. Action To Be Taken by the User*</b>  <input checked="" type="checkbox"/> Identify Device <input checked="" type="checkbox"/> Quarantine Device <input checked="" type="checkbox"/> Destroy Device  Provide further details of the action(s) identified.	
3.	2. By when should the action be completed?	Immediately
3.	3. Particular considerations for: IVD  Is follow-up of patients or review of patients' previous results recommended? No  Reagent performance or inappropriate performance will be detected by the use of controls and patient results would not be provided.	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	<b>5. Action Being Taken by the Manufacturer</b>  <input checked="" type="checkbox"/> Product Removal  Product replacement	
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

4. General Information*		
4.	1. FSN Type*	New
4.	2. Further advice or information already expected in follow-up FSN? *	No
4.	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Helena Biosciences Europe
	b. Address	Queensway South, Team Valley Trading Estate, Gateshead, Tyne and Wear, NE11 0SD, United Kingdom
	c. Website address	www.helena-biosciences.com
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	5. List of attachments/appendices:	FSN Ref. NC299 Appendix
4.	6. Name/Signature	Carol Sandercock QA & Regulatory Affairs Officer
		

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.

## FSN Ref.NC299 Appendix

List of lot numbers and part numbers of APTT Si L Minus / APTT (SILICA) impacted

Product Code / part numbers	Product Name	Lot Number	Expiry
5558SLQ	APTT Si L Minus	21635688	2021-06
5559SLQ	APTT Si L Minus	21607936	2021-06
5559SLQ	APTT Si L Minus	21627180	2021-03
5559SLQ	APTT Si L Minus	21671561	2021/09
5559SLQ	APTT Si L Minus	21676951	2022-01
5559SLQ	APTT Si L Minus	21695492	2022-04
5560SLQ	APTT Si L Minus	21590969	2020-11
5560SLQ	APTT Si L Minus	21597602	2020-12
5560SLQ	APTT Si L Minus	21660405	2021/12
5560SLQ	APTT Si L Minus	21669077	2022-03
5562SLQ	APTT Si L Minus	21660413	2021/09
5562SLQ	APTT Si L Minus	21641029	2021/09
5562SLQ	APTT Si L Minus	21644564	2021/06
OQLS065502	APTT (SILICA)	11628720	2021/09
OQLS265502	APTT (SILICA)	11630620	2021/06
OQLS265502	APTT (SILICA)	11631406	2021/06
OQLS365502	APTT (SILICA)	11648958	2021/12
OQLS493502	APTT (SILICA)	11628542	2021/06

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 United Kingdom

OQLS493502	APTT (SILICA)	11634496	2021/09
OQLS493502	APTT (SILICA)	11668885	2022-03
OQLS955502	APTT (SILICA)	11608403	2021-06
OQLS955502	APTT (SILICA)	11628534	2021/06
OQLS955502	APTT (SILICA)	11639179	2021/06
OQLS955502	APTT (SILICA)	11655696	2021/09
OQLS955502	APTT (SILICA)	11668877	2022-03