Urgent Field Safety Notice

APTT Si L Minus REF: 5558SLQ, 5559SLQ, 5560SLQ, 5562SLQ, OQLS493502, OQLS955502
Type of action: Field Safety Corrective Action (FSCA)

Date: 23-June-2017

Dear Customer,

Description of the problem:
As a result of recent routine in-house testing of normal plasma and investigations into the performance of the APTT assay, it has been identified that certain lots listed below are exhibiting inappropriate extended APTT clot times. Clot time above normal reference range is sample dependent with a significant number of normal samples remaining within expected range. Moderately elevated clot times are also observed with abnormal samples when compared to other unaffected lots.

Details of affected Lots:

REF: 5558SLQ	
LOT	Expiry
21412399	28/02/2018
21418125	28/02/2018
21430096	30/04/2018
21434024	30/06/2018
21434139	30/04/2018
21451571	31/10/2018
21452022	30/06/2018

REF: 5559SLQ	
LOT	Expiry
21349237	31/03/2017
21411115	28/02/2018
21430101	30/04/2018
21434016	30/06/2018
21434147	30/04/2018
21456555	30/09/2018

REF: 5560SLQ	
LOT	Expiry
21430119	30/04/2018
21434008	31/05/2018
21443895	30/04/2018

REF: 5562SLQ	
LOT	Expiry
21430177	30/04/2018
21433997	31/05/2018
21440091	30/04/2018
21443900	30/04/2018
21452268	31/05/2018

REF: OQLS493502	
LOT	Expiry
11422360	30/06/2018
11453882	31/10/2018

REF: OQLS955502	
LOT	Expiry
11422378	30/04/2018
11437933	30/06/2018

Risk to health:
The clinical implications have been reviewed extensively and the root cause identified as batch specific and not product degradation. As such lot specific patient management over time should not be affected. Extended clot times of normal samples would be evaluated in the context of the patient's clinical history and merit further diagnostic tests by qualified personnel prior to clinical intervention.

Actions required:

Immediate

1. Inform distributors to quarantine any stock they hold and request that this notice be forwarded to customers that received any of the specific batches.
2. Do not use, or continue to use, the reagent lots listed above.
3. Review your inventory and identify and quarantine affected lots for replacement.
4. Complete the attached acknowledgement to confirm that this action has been undertaken.
5. Consult with relevant personnel to determine whether a review of past results obtained from the affected lots is clinically warranted.

Permanent

The Root cause has been identified and replacement lots have been manufactured for immediate circulation. Corrective action is in place to prevent reoccurrence.

We apologise for any inconvenience that this has caused.

Contact reference person:

Carol Sandercock
QA and Regulatory Affairs

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The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

Signature and confirmation of receipt:

Institution/Distributor: _____

Name: _____

Address: _____

_____

_____

Signed: _____

Date: _____