Date Issued: 28th Nov 2018

Complaint Reference: 363 Action Type: Device Modification

Detail on Affected Devices:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Device Name  | Catalogue Number | GTIN | Batch / Lot number  | Expiry Date  | Manufacturing Date |
| Human Assayed Elevated Serum, level 3 | HE1532 | 05055273203608 | 1005UE | 28th March 2022 | 13th November 2018 |

Reason for Notification:

The IFU packed into CAT No. HE1532, lot 1005UE states Direct and Total Bilirubin reconstituted stability as 4 days. The correct Direct and Total Bilirubin reconstituted stability is 2 days at +2°C to +8°C.

Action to be taken:

Rework the packed kits with the updated IFU and Important Notice, you will find these in the e-mail attachments.

Complete and return the response form (12187-QA) to technical.services@randox.com within five working days.

Please accept our apologies for any inconvenience caused. Thank you for your patience and understanding. If you have any questions or concerns please contact Randox Technical Services.