For the attention of the Head of Laboratory

Reference: Event-2244-FSN

11th January 2021

URGENT FIELD SAFETY NOTICE

Emicizumab medicine and Factor VIII assays on Tcoag instruments

Dear Customer,

According to our lot traceability records, you are using TriniCLOT Factor VIII Deficient Plasma (ref. T1508). This Field Safety Notice (FSN) is about a potential risk of contamination by Emicizumab - of Factor VIII assays on the Tcoag DT 100® and Destiny Max® instruments.

Description:

The Emicizumab medicine (trade name Hemlibra®), used for hemophilia A treatment, has recently entered the market. According to the manufacturer, "laboratory tests based on the extrinsic coagulation pathway should not be performed on patient samples that contain Emicizumab, either for the substitution factor assay, anticoagulant factor assay or to titrate for anti-factor VIII inhibitors".

Tcoag has detected there is a risk of sample to sample carry-over of this molecule on Tcoag instruments and, has assessed this contamination impact on coagulation tests.
A risk has been identified in the case of the Factor VIII assay on hemophilia A patients. If factor VIII assays are performed following a sample that contains Emicizumab, the factor VIII results may be affected. In this case, the clotting times will be shortened, and the factor VIII levels will falsely increase. For other coagulation tests, impact is negligible (others factors, lupus, APC-R ..).

Actions:

To remove this contamination risk, Tcoag recommend to carry out any haemostasis assays required on samples containing Emicizumab separately followed by a needle decontamination. And that all Factor VIII samples should be tested in batch with a needle decontamination prior to testing.

Please use the normal decontamination procedure as described in Section 10.3.2 in both the Destiny Max and DT 100 Reference Manuals.

According to our risk analysis regarding Emicizumab contamination, the most critical clinical case would be a Factor VIII assay on a hemophilia A patient preceded by testing on a patient sample treated by this new medicine. The probability of this combination of tests is estimated to be very low. As a consequence of patient results being interpreted in a global clinical and biological context, along with the low probability of this sequence of testing it is unlikely this defect could have resulted in an adverse patient event. Therefore, it is not necessary for previous patient results reported to be reassessed.

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Please return to us, by fax or by e-mail, the completed enclosed form confirming that you have read this letter and will apply the instructions.

The Competent Administrative Authority of the country of origin (Ireland) has been informed. Please accept our apologies for this inconvenience. We thank you in advance for your support. For additional information, please contact us.

Yours sincerely,

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