12 January 2023

protetanus
from Prospect Diagnostics

Anti-tetanus antibody assay

Field Safety Notice (FSN – Safety Information)
Commercial name – Protetanus : Reference TE 40B : Batch SGZ20B-142

Principle of the assay: -
An immunochromatographic test for the detection of tetanus antitoxin antibodies in whole blood plasma and serum. For in vitro diagnostic use only.

The quality management team at Eurobio Scientific SA the manufacturers of the Protetanus immunochromatographic assays have received a unique non-compliance report.
It was observed that ONE ProTetanus platform from the above batch was positioned upside down during the assembly of the platform. As a result, a pink band corresponding to the particle filter, usually hidden within the platform, became visible and could be interpreted as the (C) – Control band.
The 'Point of Care' practitioner could then have reported a negative but valid result since there is apparently a pink band in the control area (C) potentially a FALSE -ve.

This nonconformity remains easily identifiable by the 'Point of Care' practitioner when opening the platform 'pouch'

Figure 1 : Compliant platform when opened

Figure 2 : Non-compliant platform when opened

Accordingly, the notifiable bodies in each country have been informed and this Field Safety Notice (FSN) provides all the supportive details.

Patient Risk: -
There is no serious risk to the patient. A false negative result would give rise to a complementary vaccination for a potentially fully immunised patient. There is no possibility of a false positive result in this instance as no band can appear in the test zone (T) when interpreting the test.

- The instructions for use (IFU) for Protetanus have been changed to clarify and re-emphasise the correct presentation of the immunochromatographic platform on opening the platform 'pouch'.

Actions to be taken by the 'Point of Care' Co-ordinator

- **Reject any Protetanus platform if not compliant and return to Prospect Diagnostics Ltd for immediate replacement.**
- **Make note of the changed / enhanced Instructions for Use (IFU) .**

Actions taken by Eurobio Scientific SA

- **Investigation / Re structuring of the relevant Manufacturing QC procedures to eliminate the possibility of a recurrence.**
- **Modifications to Instructions for Use (IFU)**

PLEASE COMPLETE AND RETURN THE BELOW FORM OF ACKNOWLEDGEMENT on or before 31st January 2023

I, the undersigned, confirm that I have sent the information mentioned in the above Field Safety Notice (FSN) to all the identified 'Point of Care' Practitioners in my department involved in the management of Tetanus Prone wounds.

Institution / Department: -…….

Contact: -…….

Signature and Date: -…….

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Email: Customercare@prospectdiagnostics.co.uk