

✓	Immediate Action Required
	Action Required
	Information Only

Urgent Field Safety Notice

Product code and description: EXENT® Analyser – IE800
Reference: PDX Identifier - GLB165167/ AE067
Date: 05 April 2024
Issues:

1. Under-quantification of Lambda Mass Shifted Light Chain (MSL) proteins.
2. Missed fitting of a bi-clonal peak when close to an adduct peak.

Summary of Issues:

During an internal investigation, it has come to The Binding Site's (PDX) attention that there are 2 software bugs within the EXENT software, EXENT-iQ®, which relate to the below issues:

1. Under-quantification of Lambda type Mass Shifted Light Chain (MSL) monoclonal proteins.
2. Missed identification and quantification of bi-clonal peaks near a monoclonal adduct peak.

1. Under-quantification of Lambda type Mass Shifted Light Chain (MSL) monoclonal proteins.

During investigations, it was identified that, in approximately 1-2% of all samples run on the EXENT system, the software will fit erroneous peaks for lambda type MSL monoclonal proteins. This could lead to under-quantification of the overall MSL peak, leading to the potentially hazardous situation of falsely decreased concentration of an M-protein result.

The associated potential harms of continued use of EXENT to report MSL patient samples include a remote risk of delayed treatment/diagnosis and inappropriate change in medical treatment. Due to the hazard and potential risk to patients it is recommended that until a software update is available users stop reporting all results where an MSL flag present, regardless of isotype. We are applying this guidance to all MSL isotypes to ensure detectability for the user. For reference, implementing the following guidance is expected to impact ~6%¹ of patients analysed by the assay Immunoglobulin Isotypes (GAM) for the EXENT® Analyser.

2. Missed identification and quantification of bi-clonal peaks near a monoclonal adduct peak

When a monoclonal peak is located within ~10 m/z of the adduct of a different monoclonal protein, the fitting of the second monoclonal peak is suppressed and not fitted. As a result, the second monoclonal peak will not appear in the Test Summary pane for review.

This has the potential to lead to incorrect isotype classification of an M-protein result with potential missed classification. The associated potential harm includes a remote risk of delayed treatment/diagnosis as well as inappropriate change in medical treatment when the results are applied in diagnosis and monitoring.

Details of affected devices:

Product	UDI	Software version/s
EXENT® Analyser – IE800	05051700020879	1.0.13 1.0.14

Actions to be taken by the user:

- ***Under-quantification of Lambda type Mass Shifted Light Chain (MSL) monoclonal proteins.***

Advice for the user:

- Previous, clinically relevant, patient results should be screened for MSL flags and any samples that have an MSL-lambda flag should be assessed for under quantification and repeated using SPE/CZE for quantification where possible/relevant.
- For future patient samples, if any MSL monoclonal protein is reported by the EXENT-iQ software the user should reflex the sample to SPE/CZE for quantification.

- ***Missed identification and quantification of bi-clonal peaks near a monoclonal adduct peak***

Advice for the user:

- Maintain awareness of the potential mismodelling of Bi-clonal samples. Results should be used and reviewed in conjunction with other laboratory and clinical findings.

- **Please return your completed and signed TSWS18 E-back form to tbs.technical.support@thermofisher.com or your local Binding Site Representative within 1 week of receiving this notification.**

Reference:

1. Dispenzieri, A., Larson, D.R., Rajkumar, S.V. *et al.* N-glycosylation of monoclonal light chains on routine MASS-FIX testing is a risk factor for MGUS progression. *Leukemia* **34**, 2749–2753 (2020).

Associated Document(s):

- TSWS18 E-Back Form

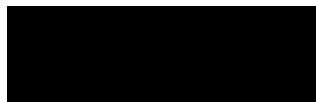
Transmission of this Important information:

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.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

The Binding Site, Part of Thermo Fisher Scientific, thanks you in advance for your cooperation, help and support and sincerely apologise for any inconvenience.

Kind regards,



Ned Merrick, VP QA/RA

Should you require any further information please contact

Your local Binding Site Representative

or

Technical Support Group

UK: +44(0) 1214569696

tbs.technical.support@thermofisher.com

Field Correction E-back Form

Urgent Field Safety Notice

Product code and description: EXENT® Analyser – IE800

UDI: 05051700020879

Reference: GLB165167/AE067

Date: 09/APR/24

Issue:

1. Under-quantification of Lambda Mass Shifted Light Chain (MSL) proteins.
2. Missed fitting of a bi-clonal peak when close to an adduct peak

An *urgent field safety notice* has been issued under Reference **GLB165167/ AE067** which details the required actions for EXENT® Analyser – IE800.

	Information received and understood by:
Print Name:	
Sign:	
Position:	
Organisation:	
Date:	

Please return completed e-back form within 1 week of receipt to your local Binding Site office via the appropriate email address from those listed below.

Local Binding Site office	Return email address
France	tbs.support.client@thermofisher.com
Germany/Switzerland/Austria/Lichtenstein	tbs.techservices.de@thermofisher.com
Spain / Portugal	TBS.servicio.tecnico@thermofisher.com
UK	tbs.technical.support@thermofisher.com
USA	TBS.ustsc@thermofisher.com