



Dialine Diagnostic Systems Pte Ltd

627A Aljunied Road #08-12 Biztech Centre Singapore 389842

Tel : (65) 6747 2009 Fax : (65) 6247 7516

Email : dialinesys@yahoo.com

Business Registraton No : 200007902E

URGENT FIELD SAFETY NOTICE RECALL

Precipitations in Reagent CRP

Date: 06 March 2019

Product: CRP Cat No. 1450021
Brand Name BioRex
Lot: 3239/ 80245001
Expiry Date 2019-06

Explanation: Base on the analysis of a customer complaint to our supplier (Diasys Diagnostic Systems GmbH) the a.m. lot CRP has been reviewed by them. Their internal inspection confirmed that R2 show precipitates of previously unknown cause.

Impact on Patient Resilts

When using CRP reagent Lot 3239/ 80245001, problem occur in the measurement process. Measurements of patient samples give invorrect results.

Measures: As a safety measure, the above mentioned lot of CRP reagent is withdrawn from the market.

Please ensure the replacement of the reagent and stop immediately further measurements with CRP reagent Lot 3239/ 80245001. Existing stock must be disposed of. Our supplier and Dialine offers a replacement for the affected CRP kits.

Results measured with a.m. reagent lot must be verified by using a different lot.

Please inform all users of the affected products immediately.



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Dialine has announced the field safety notice to the relevant authorities of Singapore.

Please handle necessary announcements to authorities in your country if necessary.

We have attached the "Confirmation of Receipt" to ensure that you have received the above mentioned information and communicated to all concerned customers.

Please sign with your company stamp and send it back to us by 20 March 2019.

Thank you,

With best regards,

Chiyo Yorizane

Product Manager

Dialine Diagnostic Systems Pte Ltd