

CUSTOMER INFORMATION

URGENT FIELD SAFETY NOTICE

PRETERM RECALIBRATION OF CRP IS AND TARGET VALUE UPDATE FOR TRULAB CRP LEVEL 1 FOR INNOVASTAR®

Falsely results in patient samples for CRP determinations on InnovaStar®

Date	May 02, 2018
Product and Lots	CRP IS, cat. no. 2 7069..., lots 13 and 14 Kit lots 40215316, 40215317, 60119851, 60120789, 60121317, 60121461, 60121878, 60121879, 60122171, 60122462, 60122769, 60123712, 60123992 TruLab CRP Level 1, cat. no. 5 9600..., lot 25057 Kit lots 60122511, 60123350, 60123894
Explanation	The calibration stored on the ParamCard for CRP IS reagent with above mentioned kit lot numbers shows falsely high results for patient samples as well as for control TruLab CRP Level 1 lot 25057. Therefore, a preterm recalibration of CRP IS reagent and a reassignment of the target value in TruLab CRP lot 25057 are mandatory for the affected kit lots.
Impact on patient results	Falsely high results (up to +30%) for patient samples and the above mentioned control were observed.
Measures	Please inform immediately all affected users about the preterm recalibration of CRP IS reagent and about the reassigned target value for TruLab CRP lot 25057 for all above mentioned kit lots. For peculiar samples, DiaSys recommends reviewing previously obtained results with these lots together with the laboratory management. Please immediately recalibrate your InnovaStar® by typing in the recalibration codes (see next page). Do not use the previously stored calibration anymore. Instructions for entering the recalibration codes can be found in the manual. Please immediately use the updated target value (see next page) for TruLab CRP lot 25057 for CRP measurements on InnovaStar®.

CUSTOMER INFORMATION

DiaSys has announced this field safety notice to the relevant authorities of the European Union. Customers outside the EU are asked to handle necessary announcements to authorities in their countries.

Under current regulations we are obliged to provide a complete chain of evidence of all corrective measures for our products. For this reason, we would like to ask you to fill in and sign the attached confirmation that you have received and communicated this information to all concerned customers. Please send it back by fax or as scan until **15.05.2018**.

Recalibration codes CRP IS lot 13 and 14

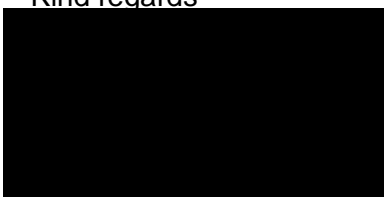
Parameter	Lot	Expiry Reagent	Recalibration-codes	Security-code	Expiry recalibration
CRP	13	2018-11	610606622	176	2018-11
			745786226		
			811396489		
			931706882		
			030006117		
	14	2019-07	611001000	125	2019-02
			729611139		
			813771414		
			985201844		
			030001111		

Reassigned target value for control TruLab CRP lot 25057

Control	Lot	Parameter	New target value	New range
TruLab CRP Level 1	25057	CRP	21,6 mg/L 2,16 mg/dL	15,8 – 27,4 mg/L 1,58 – 2,74 mg/dL

Please accept our sincere apologies for the inconvenience caused. In case you have any questions, please do not hesitate to contact us.

Kind regards



Confirmation of receipt

Please confirm that the customer information below is received by your facility:

URGENT FIELD SAFETY NOTICE

PRETERM RECALIBRATION OF CRP IS AND TARGET VALUE UPDATE FOR TRULAB CRP LEVEL 1 FOR INNOVASTAR

Herewith I confirm that above named customer information reached me and is forwarded to the users of these DiaSys products.

Customer name: _____

Contact person: _____
(same as signature)

Date / Signature: _____

Please send this fax to DiaSys Diagnostic Systems GmbH (Holzheim / Germany)

Fax-Number: +49-6432-9146-167

Thank you for your efforts!

Empfangsbestätigung

Bitte bestätigen Sie, dass Sie die folgende Kundeninformation erhalten haben.

DRINGENDE SICHERHEITSINFORMATION

VORZEITIGE REKALIBRATION DES CRP IS TESTES UND ANPASSUNG DES SOLLWERTES FÜR TRULAB CRP LEVEL 1

Hiermit bestätigen wir, dass wir die oben genannte Kundeninformation erhalten und an unsere Kunden weitergeleitet haben.

Name des Distributors: _____

Kontaktperson: _____
(Name des Unterzeichners)

Datum / Unterschrift: _____

Bitte senden Sie das ausgefüllte und unterzeichnete Dokument per Fax an: DiaSys Diagnostic Systems GmbH (Holzheim / Deutschland)

Fax-Number: +49-6432-9146-167

Vielen Dank für Ihre Bemühungen!