

CUSTOMER INFORMATION

URGENT FIELD SAFETY NOTICE

TruCal CRP Cat. No. 1 7000 99 10 039

False lots, expiry date and calibrator values in the German part of the package insert

Date	November 12, 2019
Product	TruCal CRP Cat. No.: 1 7000 99 10 039
Lot:	Level 1: 26869, expiry date 2020-09 Level 2: 26870, expiry date 2020-09 Level 3: 26871, expiry date 2020-09 Level 4: 26872, expiry date 2020-09 Level 5: 26873, expiry date 2020-09
Kit Lot:	60134183
Explanation	In the German part of the bilingual package insert (English, German) false lots, expiry date and calibrator values were mentioned. Instead of information on lots 26869 – 26873 information on lots 26606 – 26610 was given.
Impact on patient results	No impact on patient results, since a maximum deviation of about 4% for patient results is expected which is regarded as uncritical.
Measures	The incorrect package insert was corrected. The correct package insert is provided on the DiaSys website (www.diasys-diagnostics.com).

The incorrect package insert of the above mentioned kit lot must not be used anymore and must be exchanged with the corrected package insert. It must be checked whether false calibrator values have been used although the false lot was mentioned.

Please discuss with the head of laboratory if patient values determined with above mentioned lot should be repeated.

Please inform all users of the affected products immediately.

CUSTOMER INFORMATION

DiaSys has announced the urgent 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 to us by fax or as scan until **November 22, 2019**.

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

Kind regards,

Christiane Wernz
Technical Product Management