

URGENT SAFETY INFORMATION

RECALL

Calcium CPC FS Cat. No. 1 1121

Precipitations may influence quality of results

Date November 24, 2011

Product **Calcium CPC FS Cat. No. 1 1121**

Lot **13401**

Kit lots	40138917	60070131	60071335
	60069262	60070179	60071583
	60069622	60070250	60070410
	60069724	60070519	60071195
	60069973	60070847	60070714
	60070081	60071194	
	60070105	60071255	

Explanation Precipitations were observed in reagent 2 of samples of above mentioned kit lots. Function tests showed that falsely low values may be found for patient samples, eventually also falsely high values.

Impact on patient results Patient samples may be found wrong. It is possible that results of quality control material do not show aberrant results.

Measures Determinations which were performed using a.m. kit lots should be repeated.

The a.m. kit lots must not be used any more. Existing stocks must be disposed of or returned.

DiaSys replaces the products by another lot of the same reagent or, if desired, by Calcium P FS (Cat. No. 1 1181). Other reagent lots of Calcium CPC FS are not affected.

Please inform all users of the affected kit lots immediately.

DiaSys has announced the recall to the relevant authorities of the European Union.

We would like to ask you to fill in and sign 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 **December 9, 2011**.

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

Best regards,

DiaSys Diagnostic Systems GmbH



Product/Project Management