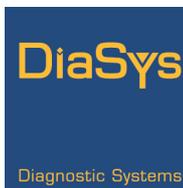


FIELD SAFETY CORRECTIVE ACTION



oneHbA1c FS

Falsely low patient values - Restandardization

Date November 27, 2014

Product	TruCal HbA1c liquid Cat. No. 1 3320... Lot 19433-19436, 19949-19952
	TruLab HbA1c liquid Level 1 Cat. No. 5 9790... Lot 19437, 19953
	TruLab HbA1c liquid Level 2 Cat. No. 5 9800... Lot 19438, 19954

Explanation Internal measurements showed that values detected with oneHbA1c FS Cat. No. 1 3329 (2/3-component system) are detected lower compared to measurements with the established comparison system HPLC.

It is assumed that the reagent reacts in a different way with fresh sample material in contrary to the frozen IFCC material which is used for standardization of the assay.

Impact on patient results: So far, values around the decision points (48 mmol/mol as cut off value for diagnosis, 53 mmol/mol as target of therapy) are determined 6 – 10% too low.

Because HbA1c is mainly used as a long term parameter for monitoring no critical impact on results is expected. Anyway, the influence on the therapy must be checked and the therapy adapted if required.

Measures DiaSys has restandardized the assay to fresh sample material which was standardized to the HPLC method calibrated by IFCC material. Please, from now on, use the enclosed calibrator and control values for a.m. lots only. InnovaStar calibrator and control values are not affected.

Please discuss with the head of laboratory if patient values determined with a.m. lots should be repeated.

Please inform all users of a.m. products accordingly.

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.

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 4, 2014**.

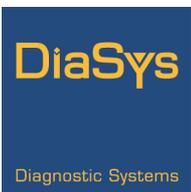
Please accept our sincere apologies for the inconveniencies caused. In case you have any questions please do not hesitate to contact us.

Best regards,

DiaSys Diagnostic Systems GmbH
Christiane Wernz

Technical Product Management

FIELD SAFETY CORRECTIVE ACTION



Valid target values for calibrator TruCal HbA1c liquid and control TruLab HbA1c liquid Level 1 and Level 2 after restandardization of oneHbA1c FS:

TruCal HbA1c liquid - Calibrator Values in mmol/mol (IFCC)

Calibrator Level	Lot No.	Expiry date	3-component system	2-component system
Level 1	19433-19436	2015-03	34.2	32.6
Level 2			67.1	68.4
Level 3			127	130
Level 4			192	199
Level 1	19949-19952	2015-07	33.0	33.6
Level 2			67.2	69.3
Level 3			122	125
Level 4			178	182

TruCal HbA1c liquid - Calibrator Values in % (DCCT)

Calibrator Level	Lot No.	Expiry date	3-component system	2-component system
Level 1	19433-19436	2015-03	5.28	5.13
Level 2			8.29	8.41
Level 3			13.8	14.0
Level 4			19.7	20.4
Level 1	19949-19952	2015-07	5.17	5.22
Level 2			8.30	8.49
Level 3			13.3	13.6
Level 4			18.4	18.8

FIELD SAFETY CORRECTIVE ACTION

TruLab HbA1c liquid Level 1/ Level 2 - Control Values in mmol/mol (IFCC)

Control Level	Lot No.	Expiry date		Target value	Range
Level 1	19437	2015-03	3-component system	42.5	34.0 – 51.0
			2-component system	43.6	34.9 – 52.3
Level 1	19953	2015-07	3-component system	43.1	34.5 – 51.7
			2-component system	45.6	36.5 – 54.7
Level 2	19438	2015-03	3-component system	118	94.4 – 142
			2-component system	122	97.6 – 146
Level 2	19954	2015-07	3-component system	121	96.8 – 145
			2-component system	126	101 – 151

TruLab HbA1c liquid Level 1/ Level 2 - Control Values in % (DCCT)

Control Level	Lot No.	Expiry date		Target value	Range
Level 1	19437	2015-03	3-component system	6.04	5.26 – 6.82
			2-component system	6.14	5.34 – 6.94
Level 1	19953	2015-07	3-component system	6.09	5.31 – 6.88
			2-component system	6.32	5.49 – 7.16
Level 2	19438	2015-03	3-component system	12.9	10.8 – 15.1
			2-component system	13.3	11.1 – 15.5
Level 2	19954	2015-07	3-component system	13.2	11.0 – 15.4
			2-component system	13.7	11.4 – 16.0