

# CUSTOMER INFORMATION

## URGENT FIELD SAFETY NOTICE

**New calibrator and control values for TruCal HbA1c liquid and TruLab HbA1c liquid in combination with oneHbA1c FS reagent (Cat. No. 1 3329.... Lot: 24876-24878 and 25044-25046)**

Date March 09, 2018  
Product oneHbA1c FS  
Product Code 1 3329  
Lot 24876-24878 and 25044-25046  
Valid from March 08, 2018

DiaSys would like to inform you that according to reassessment the following calibrator values for TruCal HbA1c liquid (Cat. No. 1 3320...) and control values for TruLab HbA1c liquid (Cat. No. 5 9790.../ 5 9800...) are valid in combination with oneHbA1c FS reagent (Cat. No. 1 3329.... **Lot: 24876-24878 and 25044-25046**).

### Calibrator values for TruCal HbA1c liquid according to reassessment

	Lot No	Expiry date	Assay value [% DCCT]		Assay value [mmol/mol IFCC]	
			3-comp	2-comp	3-comp	2-comp
TruCal HbA1c liquid Level 1	24019	2018-05	5.40	5.53	35.5	36.9
TruCal HbA1c liquid Level 2	24020	2018-05	8.49	8.30	69.3	67.2
TruCal HbA1c liquid Level 3	24021	2018-05	14.0	14.8	129	138
TruCal HbA1c liquid Level 4	24022	2018-05	18.1	18.9	174	183

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	Lot No.	Expiry date	Assay value [% DCCT]		Assay value [mmol/mol IFCC]	
			3-comp	2-comp	3-comp	2-comp
	24269 - 24272					
TruCal HbA1c liquid Level 1	24269	2018-08	5.44	5.25	36.0	33.9
TruCal HbA1c liquid Level 2	24270	2018-08	8.42	8.75	68.5	72.1
TruCal HbA1c liquid Level 3	24271	2018-08	13.5	13.7	124	126
TruCal HbA1c liquid Level 4	24272	2018-08	17.6	16.9	169	161

	Lot No.	Expiry date	Assay value [% DCCT]		Assay value [mmol/mol IFCC]	
			3-comp	2-comp	3-comp	2-comp
	24709 - 24712					
TruCal HbA1c liquid Level 1	24709	2018-12	5.24	5.35	33.8	35.0
TruCal HbA1c liquid Level 2	24710	2018-12	8.25	8.38	66.7	68.1
TruCal HbA1c liquid Level 3	24711	2018-12	13.4	13.6	123	125
TruCal HbA1c liquid Level 4	24712	2018-12	17.7	18.4	170	178

	Lot No.	Expiry date	Assay value [% DCCT]		Assay value [mmol/mol IFCC]	
			3-comp	2-comp	3-comp	2-comp
	25147 - 25150					
TruCal HbA1c liquid Level 1	25147	2019-03	4.84	4.30	29.4	23.5
TruCal HbA1c liquid Level 2	25148	2019-03	7.45	7.32	57.9	56.5
TruCal HbA1c liquid Level 3	25149	2019-03	11.4	11.4	101	101
TruCal HbA1c liquid Level 4	25150	2019-03	15.1	15.6	142	147

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## Control values for TruLab HbA1c liquid according to reassessment

	Lot No.	Expiry date	Assay value [% DCCT]		Assay value [mmol/mol IFCC]	
			3-comp	2-comp	3-comp	2-comp
TruLab HbA1c Level 1	24023	2018-05	6.23 (5.42 – 7.05)	6.19 (5.38 – 6.99)	44.6 (35.7 – 53.5)	44.1 (35.3 – 52.9)
TruLab HbA1c Level 2	24024	2018-05	13.4 (11.2 – 15.7)	13.5 (11.2 – 15.8)	123 (98.4 – 148)	124 (99.2 – 149)

	Lot No.	Expiry date	Assay value [% DCCT]		Assay value [mmol/mol IFCC]	
			3-comp	2-comp	3-comp	2-comp
TruLab HbA1c Level 1	24273	2018-08	6.17 (5.36 – 6.97)	6.14 (5.34 – 6.94)	43.9 (35.1 – 52.7)	43.6 (34.9 – 52.3)
TruLab HbA1c Level 2	24274	2018-08	13.0 (10.9 – 15.2)	13.4 (11.2 – 15.7)	119 (95.2 – 143)	123 (98.4 – 148)

	Lot No.	Expiry date	Assay value [% DCCT]		Assay value [mmol/mol IFCC]	
			3-comp	2-comp	3-comp	2-comp
TruLab HbA1c Level 1	24713	2018-12	5.86 (5.12 – 6.61)	5.98 (5.22 – 6.75)	40.6 (32.5 – 48.7)	41.9 (33.5 – 50.3)
TruLab HbA1c Level 2	24714	2018-12	10.8 (9.05 – 12.5)	10.7 (9.01 – 12.5)	94.3 (75.4 – 113)	93.8 (75.0 – 113)

	Lot No.	Expiry date	Assay value [% DCCT]		Assay value [mmol/mol IFCC]	
			3-comp	2-comp	3-comp	2-comp
TruLab HbA1c Level 1	25151	2019-03	5.27 (4.65 – 5.89)	5.18 (4.57 – 5.78)	34.1 (27.3 – 40.9)	33.1 (26.5 – 39.7)
TruLab HbA1c Level 2	25152	2019-03	9.58 (8.10 – 11.1)	9.54 (8.06 – 11.0)	81.20 (65.0 – 97.4)	80.8 (64.6 – 97.0)

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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.

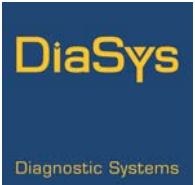
Under current regulations we are obliged to provide a complete chain of evidence of all corrective measures for our products. For this reason, we would like to ask you to fill in and sign the attached confirmation that you have received and communicated this information to all concerned customers. Please send it back by fax or as scan until **23.03.2018**.

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

In case of any further questions please do not hesitate to contact us.

Best regards,

Sabine Befard  
Strategic Product Management



## Confirmation of receipt

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

**Urgent Field Safety Notice - New calibrator and control values for TruCal HbA1c liquid and TruLab HbA1c liquid in combination with oneHbA1c FS reagent (Cat. No. 1 3329.... Lot: 24876-24878 and 25044-25046)**

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 - Neue Kalibrator- und Kontrollwerte für TruCal HbA1c liquid and TruLab HbA1c liquid in Kombination mit dem Reagenz oneHbA1c FS (Bestell-Nr.. 1 3329.... Los-Nr.: 24876-24878 and 25044-25046)**

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-Nummer: +49-6432-9146-167

Vielen Dank für Ihre Bemühungen!

08.03.2018