

# CUSTOMER INFORMATION

## AVVISO DI SICUREZZA URGENTE

**Nuovo valori per calibratore e controllo per il TruCal HbA1c liquido e il TruLab HbA1c liquido in combinazione con il reagente oneHbA1c FS (Cat. No. 1 3329... Lotto: 24876-24878 e 25044-25046)**

Data: 09-03-2018  
 Prodotto: oneHbA1c FS  
 Cod. Prodotto: 1 3329  
 Lotto: 24876 – 24878 e 25044 – 25046

DiaSys ci informa che, sono stati rivalutati i valori target del calibratore TruCal HbA1c liquido (Cat. N° 1 3320 ...) ed i valori di controllo per TruLab HbA1c liquido (Cat. N° 5 9790 ... / 5 9800 ...), tali nuovi valori si applicano esclusivamente in combinazione con i lotti del reagente oneHbA1c FS indicati (Cat. N° 1 3329 ... Lotto reagente: 24876-24878 e 25044-25046).

### valori target del calibratore

	Lotto	scadenza	Valori target [%DCCT]		Valori target [mmol/mol IFCC]	
			3-comp	2 comp	3 comp	2 comp
	24019-24022					
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

	Lotto	scadenza	Valori target [%DCCT]		Valori target [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

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	Lotto	scadenza	Valori target [%DCCT]		Valori target [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

	Lotto	scadenza	Valori target [%DCCT]		Valori target [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

## valori target del controllo

	Lotto	scadenza	Valori target [%DCCT]		Valori target [mmol/mol IFCC]	
			3-comp	2 comp	3 comp	2 comp
TruLab HbA1c liquid 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 liquid 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)

	Lotto	scadenza	Valori target [%DCCT]		Valori target [mmol/mol IFCC]	
			3-comp	2 comp	3 comp	2 comp
TruLab HbA1c liquid 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 liquid 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)

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	Lotto	scadenza	Valori target [%DCCT]		Valori target [mmol/mol IFCC]	
			3-comp	2 comp	3 comp	2 comp
TruLab HbA1c liquid 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 liquid 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)

	Lotto	scadenza	Valori target [%DCCT]		Valori target [mmol/mol IFCC]	
			3-comp	2 comp	3 comp	2 comp
TruLab HbA1c liquid 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 liquid Level 2	25152	2019-03	9.58 (8.10-11.1)	9.54 (8.06-11.0)	81.2 (65.0-97.4)	80.8 (64.6-97.0)

Vi preghiamo di accettare le nostre più sincere scuse per l'inconveniente causato. Nel caso in cui abbiate domande, non esitate a contattarci.

Cordiali saluti,

Sabine Befard  
Product Management Reagents