Erba Lachema s.r.o.

ADVISORY NOTICE

MISTAKE IN PACK INSERT

Cat. No.	Pack Name	Lot
XSYS0057	HbA1c CAL SET	2010113

Dear customer,

We apologize for a mistake in the pack inserts of above stated product. In the table of attested values were stated a wrong Lot numbers.

ASSIGNED VALUES
Target values according to IFCC (mmol/mol):

HbA1c Level	Lot No.	Expiry Date	Calibrator Value	
			3-component system (mmol/mol)	2-component system (mmol/mol)
1	29651	11/2021	29.0	30.0
2	29652	11/2021	71.3	71.9
3	29653	11/2021	119	116
4	29654	11/2021	145	145

Calibrator values according to DCCT/NGSP (%):

HbA1c Level	Lot No.	Expiry Date	Calibrator Value	
			3-component system	2-component system
1	29651	11/2021	4.80 %	4.90 %
2	29652	11/2021	8.67 %	8.73 %
3	29653	11/2021	13.04 %	12.76 %
4	29654	11/2021	15.42 %	15.42 %

The correct Lot numbers are mentioned in the headline of the pack inserts and on the labels.

HbA1c CALIBRATOR SET

Lot: 2010113

Cat. No.	Pack Name	Packaging (Content)
XSYS0057	HBA1C CAL SET	4 x 0.25 ml

Since the next batch we decided to remove the information about Lot and expiry from the table of attested values and mention this information in the headline only.

Best regards,

Erba Lachema s.r.o.
Karásek 2219/1d, 621 00 Brno
DIČ: CZ26918846 -22-

Erba Lachema s.r.o.
Technical Product Management

Brno, 16. 2. 2021