

Urgent Field Safety Notice

HUMAN HumaMeter A1c Reagent Kit Recall/Replacement

19.03.2024

Attention:

Distributors of HUMAN and end users of:

Details on affected devices

REF 16085/50, Lot Numbers:

Lot	Expiry date on the box	New expiry date	Lot	Expiry date on the box	New expiry date
026274	2024-04-27	2023-10-28	026336	2024-09-28	2024-03-30
026275	2024-04-27	2023-10-28	026338	2024-10-05	2024-04-06
026292	2024-06-22	2023-12-23	026339	2024-10-05	2024-04-06
026293	2024-06-29	2023-12-30	026351	2024-11-09	2024-05-11
026294	2024-06-29	2023-12-30	026352	2024-11-09	2024-05-11
026305	2024-08-03	2024-02-03	026353	2024-11-09	2024-05-11
026306	2024-08-03	2024-02-03	026362	2024-11-23	2024-05-25
026307	2024-08-03	2024-02-03	026363	2024-11-30	2024-06-01
026321	2024-08-31	2024-03-02	026374	2024-12-28	2024-06-29
026322	2024-09-07	2024-03-09	026375	2024-12-28	2024-06-29
026323	2024-09-07	2024-03-09	026376	2024-12-28	2024-06-29
026325	2024-09-07	2024-03-09	026391	2025-01-25	2024-07-27
			026392	2025-02-01	2024-08-03

Description of the problem:

During routine internal testing of retained samples of REF16085/50, HUMAN identified failures to meet the product's stability specification of 12 months. Reagent kit stored longer than 6 months from date of manufacture could result in false low measurements. This can potentially be harmful for patients, as false-low results just below the recommended 7% (53 mmol/mol) HbA1c might prevent physicians from changing therapy. Thus, for the LOTs indicated above the shelf-life had to be reduced to 6 months.

Due to the reduced stability and shelf-life in the above-mentioned LOTs, HUMAN requests to discontinue immediately the use of any LOT beyond a 6-month shelf-life from date of manufacture (marked **RED** in the table above). All other LOTs shown above are stable until the newly indicated expiry date and may still be used until then.

All LOTs mentioned in the table above are affected by this customer information. HUMAN will replace affected kits if required. Replacing and future LOTs will have a shelf life of 6 months from date of manufacture.

Advice on action to be taken by:**Distributor:**

- Please inform the end user of the above product lots about the problem described here, based on this customer information.
- Identify any remaining kits on stock with **LOTs 026274 to 026325** and stop shipping them to your customers. Kits of LOTs 026336 to 026392 must be shipped together with this FSN.
- Please fill in the attached reply form confirming receipt and request the number of kits to be replaced. Send the reply form to support@human.de
- Distributors located in Europe are required to translate this customer information into their local language which is used to inform their local end customers. The translated document should be sent to support@human.de along with the reply form.

User:

End users should confirm receipt of the customer information and

- Check patient results from testing performed with a product that was beyond the above new expiry date at the time of measurement.
- Identify and no longer use any product from the above lots that has been stored beyond six months (i.e. is now beyond its new expiry date).
- Make sure that other unused stock with LOT numbers 0263336 to 026392 is not used beyond the newly assigned expiry date (i.e. beyond six months after manufacture).

Transmission of this Field Safety Notice

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

The National Competent Authorities of European countries, which are affected by the recall, have received a copy of this urgent field safety notice.

Contact reference person:

(for distributors only. Distributors should provide their own detailed contact information to their end users):

Dörschmann, Hendrik
Customer Support & Applications
e-mail: support@human.de
Telephone: +49-6122-9988-310

We apologize for the inconvenience.

With kind regards,

Hendrik Dörschmann
Customer Support & Applications

Carola Henche
Product Manager

Attachment

Reply Form

Reply Form

Urgent Field Safety Notice

for HUMAN HumaMeter A1c Reagent Kit REF 16085/50, multiple lots

Please return by e-mail this filled in and signed Reply Form latest until April 2nd, 2024 to:
support@human.de

I confirm receipt of this Urgent Field Safety Notice and have informed all end users, who have obtained the affected Lot(s), in writing about the problem and the HUMAN recommendations.

If requested by national regulations, I have informed the respective authorities about the problem. (Note: to comply with European regulatory requirements HUMAN will inform European competent authorities directly.)

I confirm that the affected kits in my stock and those kits, which will be returned from my customers, will be destroyed according to local regulations.

For distributors in the European Economic Area (EEA) and Turkey:

Please also provide the Urgent Field Safety Notice in your national language, which you have sent out to your end customers, as HUMAN will be approached by your national competent authority to provide this.

Kits to be replaced: Lot: _____ Number: _____

Kits to be replaced: Lot: _____ Number: _____

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Kits to be replaced: Lot: _____ Number: _____

Company: _____ Name: _____

Date: _____ Signature: _____