Urgent Field Safety Notice

New Calibrator values of AUTOCAL LOT 0019 for CHOLESTEROL liquicolor and revised Kit Standard values for CHOLESTEROL liquicolor
Recall

October 16th, 2025

Attention:
Distributors of HUMAN and end users of:

Details on affected devices:

Product Name	**REF**	**LOTs** including all sublots
AUTOCAL	13160	0019

when used to calibrate the following CHOLESTEROL reagent kits.

Product Name	**REF**	**Size**
CHOLESTEROL liquicolor	10028300	2 x 100 tests
	10028600	3 x 150 tests
	10028	4 x 100 mL
	10017	4 x 30 mL
	10019	3 x 250 mL

And the kit standards included in the following reagent kits:

Product Name	**REF**	**Size**
CHOLESTEROL liquicolor	10028	4 x 100 mL
	10017	4 x 30 mL
	10019	3 x 250 mL

Description of the problem:

In the course of internal quality assurance activities, we noted that the concentration for CHOLESTEROL liquicolor in AUTOCAL REF 13160 LOT 0019 has increased over time. Based on this observation the usage of AUTOCAL LOT 0019 in combination with the CHOLESTEROL liquicolor reagent leads to falsely low Cholesterol values in patient samples up to 12% These discrepancies occur when the above-mentioned Cholesterol reagents are calibrated either with AUTOCAL LOT 0019 or with the kit standard included in the CHOLESTEROL liquicolor kits.

As a measure the Cholesterol value in AUTOCAL LOT 0019 was revised as indicated below:

Product	**REF**	**LOT**	**Old concentration**	**New concentration**	**Deviation**
AUTOCAL	13160	0019	311 mg/dl	348 mg/dl	12 %

As a consequence, the Cholesterol values for corresponding kit standards were revised as well, as indicated below:

Kit standard LOT	Kit REF	Kit LOT	Old concentration in mg/dL	New concentration in mg/dL	Deviation in %
0120	10017	24006 24007	195	214	10
	10028	24010 24011			
0121	10017	24008 24009	195	214	10
	10019	24002			
	10028	24012 24013			
0122	10017	24010 24011	196	213	9
	10028	24014 24015 24016			
0123	10017	24012	195	216	11
	10019	24003			
	10028	24017 24018			
0124	10017	25001	194	214	10
	10019	25001			
	10028	24019 25001 25002			
0125	10017	25002 25003	193	215	11
	10028	25003			
0126	10017	25004 25005	193	216	11
	10019	25002			
	10028	25004 25005 25006			
0127	10017	25006	193	212	10
	10028	25007 25008 25009			
0128	10017	25007	192	215	12
	10019	25003			
	10028	25010 25011			

Additionally, the target values and ranges for the HUMAN Quality Controls Serodos, Serodos plus, HumaTrol N and HumaTrol P were revised and are accessible on https://www.human.de/

Advice on action to be taken by:
Distributor:
Please inform your customers about the issue of the affected Lots and the revised cholesterol values. Please fill in the attached Reply Form confirming receipt of this Urgent Field Safety Notice and send it to support@human.de

User:
Please use the revised cholesterol values from now on and ensure that the instructions resulting from this Urgent Field Safety Notice are implemented in the laboratory accordingly.
End users should confirm receipt of this Urgent Field Safety Notice to the local distributor

Transmission of this Urgent Field Safety Notice:
This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.
Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of this corrective action.

The Federal Institute for Drugs and Medical Devices (BfArM) and 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):

Petzold, Tony
e-mail: support@human.de
Telephone: +49-6122-9988-383

We regret the inconvenience.

With kind regards,

Attachment
Reply Form

Reply Form

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Please return by e-mail this filled in and signed Reply Form latest until October, 26, 2025 to:

support@human.de

I confirm receipt of this Urgent Field Safety Notice and have informed all end users, who have obtained the affected products, 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.)

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.

Date: _____

Company: _____

Name: _____ Signature: _____