

MEDICAL DEVICE RECALL **Eurotrol Hemoglobin Controls**

22nd of October 2018

Attention to Customer

Customer Name
Device Name
Street Address
City, State, Postal Code

Dear Device Customer/Distributor,

Purpose of this letter

The purpose of this letter is to advise you that Eurotrol is voluntarily recalling the following batches of Eurotrol Hemoglobin Controls.

Product name	Catalogue number	Batch number
HemoTrol Normal (Level 2)	022.002.002	81102
HemoTrol High (Level 3)	022.003.002	82403
HemoTrol Normal (Level 2)	202.002.002	81102
HemoTrol High (Level 3)	202.003.002	82403
CueSee® tHb Level 2	253.002.002	25302811
CueSee® tHb Level 3	253.003.002	25303824

Reason for the Voluntary Recall

This recall has been initiated due to incorrect measurement results caused by microbial contamination of the product. The failure results in values lower than assigned values.

We are aware of 23 complaints associated with the problem.

Approximately 20% of devices with batch number 81102 and 25302811 is affected by this problem.

Devices with batch numbers 82403 and 25303824 are recalled as a precaution. No complaints have been received regarding these batches nor did testing show deviating measurements.



Risk to Health

There are 2 scenarios possible that could lead to a hazardous situation:

- 1. The product is malfunctioning and thereby causes a fail on a proper functioning analyzer.
- 2. The product is malfunctioning and wrongfully passes a malfunctioning analyzer.

The user of the control material is not at risk due to deviating measurement results caused by microbial contamination when the product is handled according to the IFU. There is however an indirect health hazard to the patient.

Conclusion from following subsections: The product is not likely to cause any adverse health consequences.

Fail to Qualify a Proper Functioning Analyzer

If an IVD analyzer has wrongfully failed Quality Control (QC) test due to a quality control material which is malfunctioning, this could result in delayed examination results. Local regulation may require regular QC measurement of IVD analyzers in order to release these for use. If the IVD analyzer is wrongfully rejected it cannot be used for measurements on patient samples. In such cases an alternative quality control material is required to release the equipment. If not available a hazardous situation may occur when a physician solely relies on the result of the analyzer and not take into account other patient symptoms and test results.

Wrongfully Pass a Malfunctioning Analyzer

Only if multiple failures occur sequentially this could result in harm to the patient. When the IVD analyzer has a malfunction which compensates (same magnitude, opposite direction) the malfunction of the quality control material, the analyzer reports measurements results within the assigned range. Malfunction of the QC could, in this unlikely case, lead to a wrongful pass of a malfunctioning IVD analyzer. This, in turn, could result in an incorrect examination result when measuring a patient sample and as a possible consequence lead to incorrect medical treatment of this patient. Resulting incorrect treatment could cause harm to a patient. This hazardous situation is considered to be highly unlikely because a physician does not solely rely on the hemoglobin result of the IVD analyzer but takes into account other patient symptoms and test results.

How to recognize that the device may fail

Too low readings on the analyzer could be an indication of a malfunctioning quality control material. Increase in viscosity of the liquid and/or presence of particles indicates a malfunction.

Actions to be taken by the Customer/User

Immediately discontinue use of the listed batches and discard the product according local regulation on medical waste. In addition, if you may have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter.

Contact you distributor for alternative batches of the product in order to replenish your stock.

Please complete and return the enclosed response form as soon as possible. The acknowledgement can be given through email or telephone.



Your Global Reference Point for Quality Control

Product and Distribution Information

Product Names	Catalog Number	UDI	Lot Number	Manufacturing Date	Expiration Date
HemoTrol Normal (Level 2)	022.002.002	-	81102	March 2018	October 2019
HemoTrol High (Level 3)	022.003.002	-	82403	June 2018	January 2020
HemoTrol Normal (Level 2)	202.002.002	-	81102	March 2018	October 2019
HemoTrol High (Level 3)	202.003.002	-	82403	June 2018	January 2020
CueSee® tHb Level 2	253.002.002	-	25302811	March 2018	October 2019
CueSee® tHb Level 3	253.003.002	-	25303824	June 2018	January 2020

Type of Action by the Company

The products will be removed from the market to resolve the potential health hazard. Alternative batches are available to ensure uninterrupted use of the products.

Other Information

Your assistance is appreciated and necessary to prevent failure to pass properly functioning Hb201 analyzers. Please complete and return the enclosed response form as soon as possible.

If you have any questions, please contact:

Name: Eurotrol B.V.
Address: Keplerlaan 20
Zip code & city: 6716 BS Ede
Country: The Netherlands
Phone: +31 318 695777
E-mail: office@eurotrol.com

Authorized by:		
Name: (Print)	 ·	
Signature:		
Title:		



MEDICAL DEVICE RECALL RETURN RESPONSE Acknowledgement and Receipt Form

Response is Required

Customer Informati	on:				
Customer Name					
Street Address					
Town, State, Postal Code	9				
	EuroTrol I	Jamaglahir	Contro	lo.	
	Eurorron	Hemoglobir	Contro	15	
Lot numbers:					
81102, 82403, 25302811	, 25303824				
Please check ALL appro	opriate boxes and s	ign the form:			
☐ I have read and under☐ I have checked my sto		•			
Any adverse events assorting yes, please explain:	ciated with recalled p	roduct? Yes	□ No		
Please check the approp	riate box(es) to descr	ibe your business			
☐ wholesaler/distributor	☐ hospital/me	-	□ me	dical laboratory	
Affected product informat	tion: Include informati	on that is applicable	e for affected p	oroduct.	
Product Names	Catalog Number	UDI	Lot Number	Quantity in inventory	Quantity discarded
HemoTrol Normal	022.002.002	-	81102		
(Level 2)					
HemoTrol High	022.003.002	-	82403		
(Level 3)					
HemoTrol Normal	202.002.002	-	81102		
(Level 2)					
HemoTrol High (Level 3)	202.003.002	-	82403		

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CueSee® tHb Level 2

CueSee® tHb Level 3

253.002.002

253.003.002

<u>253</u>02811

25303824



Return Response Bo	DX:
	additional information, if applicable.
(specify date and me	d notified my customers that were shipped or may have been shipped this product by ethod of notification in return response box); or
	customers who received/may have received this product. Please notify my customers.
Signature:	T
Name/Title	
Telephone	
Email address	
Signature:	Date:

PLEASE MAIL COMPLETED RESPONSE FORM TO: recall@eurotrol.com