



CC to the Chairman Medical Board
and relevant Head of Departments

Urgent Field Corrective Action

POC 17-018.A.OUS

August 2017

CLINITEK® Atlas Automated Urine Chemistry Analyzer

AC-03 Errors: Wet Calibration Failures

Our records indicate that your facility may have received the following product:

Table 1. Affected Product(s)

Product	Product Codes	Siemens Material Number (SMN)	Lot Numbers	Expiration Date
CLINITEK® Atlas 10 Reagent Pak	5017	10311120	1A798047	4/30/2018
			1A801057, 1A802057 1A803057, 1A804057 1A805057, 1A806057 1A807057, 1A808057 1A809057	5/31/2018
CLINITEK® Atlas PRO 12 Reagent Pak	5085	10315660	1B800047	4/30/2018
	5084	10334146	A800047	

Reason for the Urgent Safety Notice

Siemens Healthcare has received a number of reports of AC-03 errors (wet calibration failures) regarding the CLINITEK Atlas Reagent Pak lots listed in Table 1. This issue is intermittent, and not all reagent paks are affected.

Risk to Health

There is no impact to patient results or to the safety of operators. The risk to health is negligible.

Actions to be taken by the Customer

- If you experience an AC-03 error using one of the lots in Table 1, contact Siemens Healthcare to request no-charge replacement product.
- Complete and return the Product Replacement Form attached to this letter to request your no-charge replacement product.

Please retain this letter with your laboratory records, and forward it to those who may have received this product.

Unrestricted

Siemens Healthcare Diagnostics Inc. All Rights Reserved.

Page 1 of 3

AC-03 Errors: Wet Calibration Failures

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Customer Care Center or your local Siemens technical support representative.

CLINITEK is a trademark of Siemens Healthcare Diagnostics.

PRODUCT REPLACEMENT FORM

CLINITEK Atlas AC-03 Errors: Wet Calibration Failures

This form is to be used to request no-charge replacement product for the enclosed Siemens Healthcare Diagnostics Urgent Corrective Action Notice POC 17-018.A.OUS, dated August 2017, regarding CLINITEK Atlas AC-03 Errors: Wet Calibration Failures.

Fax this completed form to Siemens Healthcare Diagnostics to the fax number provided at the bottom of this page.

Do you now have any of the noted product(s) on hand? Please check inventories before answering. Yes No

If the answer to the question above is yes, please complete the table below to indicate the quantity of affected product in your laboratory and replacement product required.

Product Description	Lot Numbers	Replacement Quantity Required
CLINITEK Atlas 10 Reagent Pak		
CLINITEK Atlas PRO 12 Reagent Pak		

Name of person completing questionnaire: _____

Title: _____

Institution: _____ Instrument Serial Number: _____

Street: _____

City: _____ State: _____

Phone: _____ Country: _____

Date: _____

Signature: _____

Company stamp: _____

To fax this completed form please send it to the Customer Care Center at (65) 6366-3376. If you have any questions, contact your local Siemens technical support representative.