

Customer Notification

CN-2015-010

June 2015

Important Information on Siemens Berichrom[®] Protein C reagent
(Reference S-Corp FCA 1514)

Dear Valued Sysmex Customer,

This is to inform you on the issue found on Siemens Berichrom[®] Protein C reagent. The affected product are listed as follows:-

Product code	Product name
OUVV	Berichrom [®] Protein C

Description of the Problem

Below are the description of the problem detected:-

A number of lots can lead to failure of the calibration curve on Sysmex CA-1500, CA-7000/8000, CS-1600, CS-2000i, CS-2100i, CS-2400, CS-2500 and CS-5100 instruments when your laboratory uses the 0% calibration point for this assay. Same problem will also occurred to CA-8000, CS-1600, CS-2400 and CS-2500.

The applicable reagent lots showing this failure are Lot Number **44841** and thereafter.

Action To Be Taken

If the Berichrom[®] Protein C calibration curve on your system is indicated as being invalid due to the 0% calibration point having reported a Reaction Curve ERROR, the mentioned calibration point has to be entered manually as follows. For the detailed instructions to enter the dOD manually, please refer to page 3.

System	Error Code	Error Message	Required Manual Entry
CA-1500 CA-7000/8000	408	Reaction Curve ERROR	0.001 dOD
CS-Series	4008	Reaction Curve ERROR	0 dOD

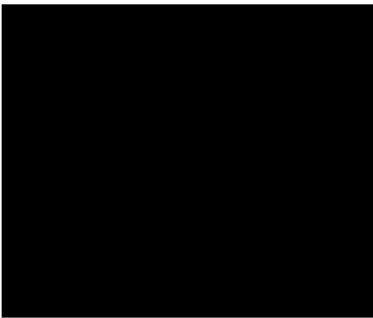
Contact Reference

Please contact your local Sysmex representative or distributors if you have any future questions regarding this matter.

We deeply apologize for any inconvenience caused, and we thank you for your kind patience and continued support.

Kindly sign on the acknowledgement form to acknowledge that you have received the information on this FCA and email me back.

Yours sincerely,



How to enter dOD at the 0% calibration point on CA-1500 and CA-7000/8000

1. If “Reaction Curve Error” occurs and dOD shows “*.****” when the calibration curve is made using affected lots the calibration curve shows “Not Validated” Error.
2. Edit the calibration curve by pressing **Manual Entry** and enter “0.001” into dOD for the 0% point and press **ENTER**. After pressing **ENTER**, press **QUIT** on the Manual Entry screen of the Standard data window.
3. Check the calibration curve including all other points and press **Update** if there is no issue.

How to enter dOD at the 0% calibration point on CS-series

1. If “Reaction Curve Error” occurs and dOD shows “*.****” when the calibration curve is made using affected lots the calibration curve shows “Not Validated” Error.
2. Edit the calibration curve by pressing **Edit** and enter “0” into dOD for the 0% point and push **OK**.
3. Check the calibration curve including all other points and press **Validate** if there is no issue.