

Field Safety Notice

SBN-CPS-2017-011

CPS / Serum Work Area
Version 1
30-Jun-2017

cobas e 411 analyzer: Software malfunction

Product Name / Device Identifier	cobas e 411 analyzer (disk system) (GMMI 04775279001) cobas e 411 analyzer (rack system) (GMMI 04775201001)
Product Description	cobas e 411 analyzer for Immuno Chemistry
Production Identifier (Lot No./Serial No.)	Not applicable
SW Version	All SW versions
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

We would like to inform that due to a software (SW) malfunction in the Sample&Control data files, a potential data mismatch can occur. This SW malfunction only occurs when:

- The instrument has been used for a long time and “Sample Data Clear” is not done. The Sample Database is thus filled with not documented samples.
- Sample&Control data files of the **cobas e 411** analyzer is filled with ≥ 2000 records.

All tests that are run on **cobas e 411** are potentially affected so the impact of the data mismatch cannot be predicted. Roche has received a total of four complaints on this issue.

The alarm triggered by the SW and colour change seen in “Sample Data Clear” tab of “System Overview screen”,

- **yellow** alarm when 1900 records are stored in the Sample&Control datafile
- **red** alarm when 2000 records are stored in the Sample&Control datafile

does not prevent the operator from ordering new samples.

cobas e 411 analyzer: Software malfunction

Risk Assessment

Frequency of Occurrence

To date, we have received four confirmed cases.

Detectability

Not certain

Severity

The issue described above can lead to result mismatch (wrong test order and wrong result reporting). All tests that are run on the affected analyzers are potentially affected whereas the extent of the bias cannot be predicted. Both erroneous increased/positive and decreased/negative results are possible. From the medical point of view, the most relevant immediate impact is related to results which are triggering directly medical therapy such as cardiac markers. Also, in case of false negative results for infectious diseases a spread of infection cannot be excluded. Considering the poor detectability of the issue and unknown extent of erroneous results, relevant medical risk cannot be entirely excluded.

Actions taken by Roche Diagnostics

Our hardware manufacturer, Hitachi High Technologies Corporation (HHT), has confirmed this malfunction of the system. A new software version is in the works and this new software will prevent samples from being ordered and run on the **cobas e 411** analyzer when the Sample&Control datafile is full.

Distribution of the next software version is planned for Q4/2017 and it will be installed as a mandatory update to the system. This new SW will prevent samples from being ordered and run on the **cobas e 411** analyzer when the Sample&Control datafile is full. You will be informed accordingly.

Actions to be taken by the customer/user

Till the new SW is installed, the lab is advised to perform the following actions:

- Perform a "Sample Data Clear" daily.
"Sample Data Clear" is step no. 2 in the Work Flow Guide in the System Overview window

Please note:

Sample Data Clear deletes all sample records and moves QC data to the QC view. It is recommended to perform the backup procedure on a regular basis, depending on data volume and the laboratory practice. If your system is connected to a host, make sure that all data has been uploaded before performing a sample data clear.

cobas e 411 analyzer: Software malfunction

System Overview window

System Overview

Work Flow Guide: Maintenance → Sample Data Clear → Reagent Load List → Calib/OC Load List → Parameter Download → Sample Tracking

No.	Test	Status	Determinations
1	TSH 0	Current	60
2	T3 0	Standby	109
3	A-HBC 0	Current	98
4	P.A.HBC	Current	98
5	B12 0	Current	97
6	P-B12	Current	97
7	A-HBCIGM 0	Current	1
8	A-HBCIGM 0	Standby	100
9			
10	TSH 0	Standby	200
11	T3 0	Current	74
12	FT3 1	Current	161
13	CA15-3.2	Current	91
14			
15			
16			
17	Dil MA		8
18	Dil Uni		70

Control buttons: Stop, Logout, S.Stop, Stat Mode, Alarm, Print, Start, Help, Print Screen

Work Flow Guide: Maintenance → Sample Data Clear → **Reagent Load List** → **Calib/OC Load List** → Parameter Download → Sample Tracking

Choose Sample Data Clear to open the Sample Data Clear window.

Sample Data Clear

Buttons: Clear, Export and Clear, Cancel, OK

Select **Export and Clear** option and choose OK to export the data stored in memory before it is cleared.

This action deletes all records of the samples and moves QC data to the QC view. If your system is connected to a host, make sure that all data have been uploaded before performing the Sample Data Clear.



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Communication of this Field Safety Notice

This notice must be passed on to all those who need to be aware within your organization or to any other organization/individual where the potentially affected devices have been distributed/supplied. Please pass on this notice to the Chairman Medical Board and Head of Department as well, as required by HSA. Please maintain awareness of this notice and resulting action for an appropriate period to ensure the effectiveness of the corrective action

We apologize for any inconvenience this may cause and thank you for your understanding and support.

Sincerely,

Roche Diagnostics Asia Pacific Pte Ltd

Email: sg.regulatory@roche