Urgent Field Safety Notice
SBN-CPS-2017-005

CPS / Serum Work Area
Version 2
01-Jun-2017

Fretting corrosion on Sample Probe connector may cause sporadic Liquid Level Detection (LLD) failure

Product Name	PROBE SAMPLE (GMMI 04547241001) PROBE SAMPLE S (GMMI 05899427001) SAMPLE PROBE (GMMI 04945794001)
Product Description	PROBE SAMPLE (GMMI 04547241001) PROBE SAMPLE S (GMMI 05899427001) SAMPLE PROBE (GMMI 04945794001)
GMMI / Part No **Device Identifier**	PROBE SAMPLE (GMMI 04547241001) PROBE SAMPLE S (GMMI 05899427001) SAMPLE PROBE (GMMI 04945794001)
Instrument/System Affected	**cobas c**311 analyzer (cat. no. 04826876001)
SW Version	Not applicable
Type of Action	Field Safety Corrective Action (FSCA)
Reason for version 2	Update of affected lot number for **cobas** c311 (changes marked in yellow)

Dear Valued Customer,

Unfortunately we have to inform you about a change in the attachment "How to identify potentially affected sample probes".
"How to identify potentially affected sample probes version 1":
(Affected Sample Probe for **cobas** c311; P/N 724-0920): Lot number 0490256963 was shown as affected
(Affected Sample Probe for **cobas** c311; P/N 724-0920): Lot number 0490254335 was shown as not affected.

"How to identify potentially affected sample probes version 2":
(Affected Sample Probe for **cobas** c311; P/N 724-0920): Lot number 0490256963 is **not affected**
(Affected Sample Probe for **cobas** c311; P/N 724-0920): Lot number 0490254335 is **affected**.

The following attachments from SBN-CPS-2017-005 V1 are still valid:

- Procedure for cobas 8000 "How to proceed whenever the system alarm "Sample Short" or "Abnormal Aspiration" is issued"
- Procedure for cobas 6000 "How to proceed whenever the system alarm "Sample Short" or "Abnormal Aspiration" is issued"
- Procedure for cobas c311 "How to proceed whenever the system alarm "Sample Short" or "Abnormal Aspiration" is issued"

Fretting corrosion on Sample Probe connector may cause sporadic Liquid Level Detection (LLD) failure

Description of Situation

We regret to inform you that in very rare cases a disturbance of the sample liquid level detection (LLD) may occur due to a fretting corrosion on the sample probe connector due to a production change for the connector.
In those very rare cases where the disturbance of the sample liquid level detection (LLD) occurs, the affected sample probe may dip into the sample material deeper than intended, accordingly the affected sample probe may be not washed adequately (this may lead to carryover, medical risk cannot be excluded).

Since the beginning of 2017, the affected sample probe connector type has been changed in production to a new connector type. With that new connector type the sample liquid level detection (LLD) is ensured to fully function as specified.
The potentially affected sample probes will be exchanged free of charge.

The following analyzers have been delivered with potentially affected sample probes:

cobas ISE module 900 / **cobas** ISE module 1800: serial numbers from 15D5-01 to 17L8-10, 17L9-09 and 17L9-10
cobas c 311 analyzer: serial numbers from 15D0-01 to 16D8-20, from 16D9-02 to 16E0-10, from 16E0-16 to 16F9-08, from 16F9-10 to 16F9-18 and 16F9-20
cobas c 501 module: serial numbers from 15P1-01 to 16Y4-19, from 16Y5-01 to 17Z3-20
cobas c 502 module: serial numbers from 15A6-01 to 16D9-10
cobas c 701 module: serial numbers from 15E6-01 to 17H7-10
cobas c 702 module: serial numbers from 15F6-07 to 17M8-10

Note: If the sample probe in the analyzers with serial numbers listed above have been exchanged for another sample probe, then please refer to the list below with the serial numbers for the potentially affected sample probes.

The sample probes with the following serial numbers (printed on the sample probe) may be affected:

Sample Probes **cobas c** 501 module/ **cobas c** 502 module/ **cobas c** 311 analyzer				
Production site (box print)	**Dot mark (probe print)**	**2015 (probe print)**	**2016 (probe print)**	**2017 (probe print)**
Naka	black	1509-001 to 1521-100	1622-001 to 1687-040	Not affected
Omuta	green	1535-001 to 1537-100	1638-001 to 1684-035	Not affected

Sample Probes **cobas c** 701/ **cobas c** 702/ **cobas** ISE module 900/ **cobas** ISE module 1800	
Production site (box print)	**Dot mark (probe print) ***
Naka	black
Omuta	green

* There is no lot number printed on the sample probes.

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To identify the potentially affected sample probes refer to the attachment “How to identify potentially affected sample probes V2”.

Actions taken by Roche Diagnostics

The manufacturer Hitachi High Technologies Corporation has clearly identified the root cause and since the beginning of 2017, the affected sample probe connector type has been changed in production to a new connector type. With that new connector type the sample liquid level detection (LLD) is ensured to fully function as specified.

The potentially affected sample probes will be exchanged free of charge.

Actions to be taken by the customer/user

Please check the sample probe in use in your analyzer (based on the serial number information on the previous page) referring to the attachment “How to identify potentially affected sample probes.”

Only if the sample probe(s) in use is from the potentially affected serial numbers, then please:

- Inform your local Roche affiliate about the total quantity of the affected sample probes used in your analyzer(s). With that information, we will plan for the exchange of the affected sample probe(s).
- Enable the “Clot Detection” and “Clot Detection for Calib./Control” settings in “Utility-System-Alarm Settings” (refer to step 1 in the attachment(s) “How to proceed whenever the system alarm “Sample Short” or “Abnormal Aspiration” is issued” relevant to the analyzer/module type used in your laboratory).
- Until the sample probe exchange takes place, whenever the analyzer issues the system alarm “Sample Short” or “Abnormal Aspiration” for a sample with sufficient sample volume, please follow the instructions in the attachment(s) “How to proceed whenever the system alarm “Sample Short” or “Abnormal Aspiration” is issued” relevant to the analyzer/module type used in your laboratory.
- If carryover cannot be excluded, affected samples should be handled according to the local regulations including the decision whether previously generated results should be reviewed.

Communication of this Field Safety Notice (if appropriate)

This notice must be passed on to all those who need to be aware within your organization or to any organization/individual where the potentially affected devices have been distributed/supplied.

Please transfer this notice to other organizations/individuals on which this action has an impact.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure

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the effectiveness of the corrective action.

The following statement is mandatory in FSNs for EEA countries but is not required for the rest of the World:

Include if applicable: The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

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

Best regards,

Contact Details

To be completed locally:
Name
Title
Company Name
Address
Tel. +xx-xxx-xxxx xxxx
Email name@roche.com

The following statement is mandatory in FSNs for EEA countries but is not required for the rest of the World:

Include if applicable: The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

Target

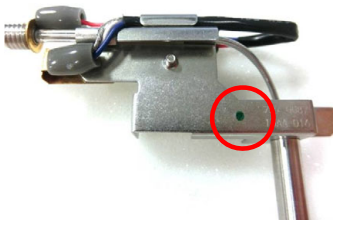
With this procedure potentially affected Sample Probes can be identified both already installed Sample Probes and still boxed Sample Probes.

Identification of potentially affected sample probes for cobas c501/ cobas c502 and cobas c311

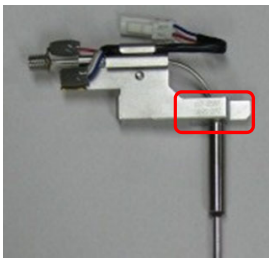
There are two HHT production plants NAKA & OMUTA producing Sample Probes. Potentially affected Sample Probes can be easily encountered by the following procedure. If a yellow dot is applied to the Sample Probe connector the Sample Probe is already equipped with a modified connector.

<table>
<tr><td colspan="2">04547241001 PROBE SAMPLE (cobas c501/ cobas c502)</td></tr>
<tr><td colspan="2">05899427001 PROBE SAMPLE S (cobas c311)</td></tr>
<tr><td>Affected serial number which printed on the probe</td><td>NAKA; 1509-001 onward, and no marked yellow dot on the connector.
OMUTA; 1535-001 onward, and no marked yellow dot on the connector.

Refer to Place of yellow dot on the connector in this table for detail.</td></tr>
<tr><td>Identification of production site in HHT</td><td> 



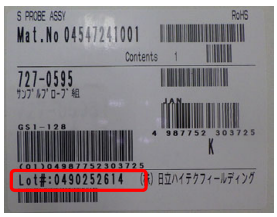
Either NAKA or OMUTA is indicated on the original package.
Either Black or Green dot is marked on the sample probe.

Black dot: Produced by NAKA
Green dot: Produced by OMUTA</td></tr>
<tr><td>Printed place on sample probe</td><td> 


Refer to Rule of printed serial number for detail.</td></tr>
</table>

<table>
<tr><td>Rule of printed serial number</td><td>
727-0587 ← Part number
YY AA – BBB ← Serial number
Sequential number (From 001 to 999)
Production number (From 01 to 99)
Production year
Serial number printed on the probes for cobas c501/c502 and cobas c311 are making a common numbering by HHT’s two production lines.
</td></tr>
<tr><td>Place of yellow dot on the connector</td><td>

<u>No yellow dot mark</u> on the connector is affected.
If the yellow mark on the connector is existed, the probe was modified done by HHT despite if the Serial number which printed on the probe was met.
</td></tr>
<tr><td>SAP lot number which printed on the original package</td><td>

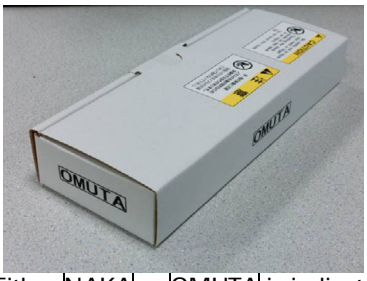
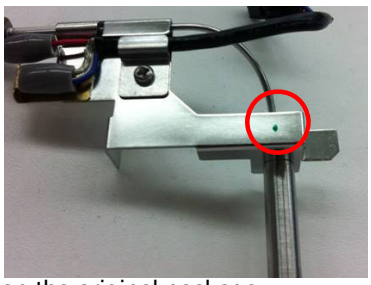



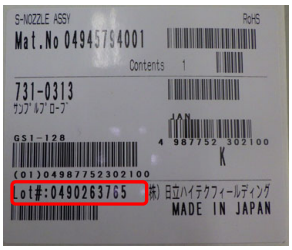
</td></tr>
<tr><td>Affected Sample Probe for cobas c311 (P/N 724-0920)</td><td>
Lot number which indicated on the logistics label
0490232027, 0490233855, 0490236427, 0490238543, 0490241937, 0490248322, 0490250880, 0490235713, 0490252029,
0490256963 (not affected),
0490254335 (new)
</td></tr>
</table>

Affected Sample Probe for **cobas** c 501 and c502 (P/N 727-0595)	0490233762, 0490233764, 0490233766, 0490233767, 0490233777, 0490235904, 0490235905, 0490235906, 0490235907, 0490235949, 0490235950, 0490237594, 0490237595, 0490237353, 0490237354, 0490237597, 0490237598, 0490237600, 0490237602, 0490237604, 0490237606, 0490238955, 0490238957, 0490238893, 0490238895, 0490238896, 0490238898, 0490238899, 0490242149, 0490242151, 0490242153, 0490242155, 0490242327, 0490242328, 0490242329, 0490242330, 0490242331, 0490250491, 0490250492, 0490250493, 0490250494, 0490250495, 0490250496, 0490251032, 0490251033, 0490251034, 0490251036, 0490252524, 0490252527, 0490252529, 0490252532, 0490252247, 0490252249, 0490252251, 0490252252, 0490252272, 0490252398, 0490254550, 0490254551, 0490254552, 0490254553, 0490254554, 0490254555, 0490254804, 0490254805, 0490254806, 0490254807, 0490256999, 0490257000, 0490256993, 0490256994, 0490256995, 0490256996, 0490256997, 0490256998, 0490254808, 0490257001, 0490257847, 0490257848, 0490257849, 0490257850, 0490257851, 0490258652

Identification of potentially affected sample probes for cobas c701/ cobas c702

HHT production plants NAKA & OMUTA producing Sample Probes as well for **cobas** c701/ **cobas** c702 and ISE. Potentially affected Sample Probes can be encountered by the following procedure.

04945794001 SAMPLE PROBE (**cobas** c701/ **cobas** c702)	
Affected serial number which printed on the probe	ISE and Sample Probe for **cobas** c701/ **cobas** c702 do not have serial number printed on the probe itself.
Identification of production site in HHT	  Either NAKA or OMUTA is indicated on the original package. Either Black or Green dot is marked on the sample probe. Black dot : Produced by NAKA Green dot : Produced by OMUTA
Place of yellow dot on the connector	  No yellow dot mark on the connector is affected. If the yellow mark on the connector is existed, the Sample Probe was already modified by HHT.

SAP lot number which printed on the original package	  Refer to the separate attachment for detail of SAP lot numbers which printed on the original package.
Affected Sample Probe for **cobas** c701/ **cobas** c702 (P/N 731-0313)	0490238960, 0490238961, 0490238961, 0490238961, 0490238963, 0490242332, 0490251040, 0490251041, 0490252546, 0490252547, 0490252547, 0490254810, 0490254811, 0490221658, 0490223228, 0490223229, 0490225255, 0490226172, 0490226173, 0490226174, 0490227626, 0490227627, 0490227628, 0490230276, 0490230277, 0490230279, 0490232203, 0490232204, 0490232205, 0490232206, 0490233778, 0490233779, 0490233780, 0490233781, 0490233783, 0490235909, 0490235910, 0490235911, 0490235912, 0490235913, 0490237365, 0490237366, 0490237367, 0490237368, 0490237369, 0490237370, 0490238901, 0490238902, 0490238903, 0490238904, 0490242160, 0490242161, 0490242163, 0490242165, 0490242166, 0490250498, 0490250499, 0490250500, 0490250501, 0490250502, 0490252308, 0490252312, 0490252318, 0490252320, 0490252322, 0490254558, 0490254559, 0490254560, 0490254561, 0490254562, 0490257035, 0490257036, 0490257037, 0490257038, 0490257039, 0490257854, 0490257855, 0490257856, 0490257857, 0490257858

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