| | |
|---|---|
| Ö | **Immediate Action Required** |
| | **Action Required** |
| | **Information Only** |

# URGENT FIELD SAFETY NOTICE

## IMMEDIATE ACTION REQUIRED

**Field Safety Notice Ref No: BFSN_02_14 White Deposits PB 2014_008**
**Update 1**
**Document Date: 16/12/2014**
**Type of Action: < Field Corrective Action >**

| | |
|---|---|
| **System Affected:** | **cobas b 221 system <5> Roche OMNI S5 instruments**<br>**cobas b 221 system <6> Roche OMNI S6 instruments** |
| **Summary of Issue:** | **'White Deposits' in the fluidic system of the cobas b 221 <5>/<6> Roche OMNI S5/S6 may cause a reduced lifetime of the metabolite sensor cartridges.** |

| | |
|---|---|
| **Material No:** | 03337154001<br>03337146001 |

| | |
|---|---|
| **Reason for Notice:** | As communicated in July 2014, we would like to give you an update of the situation and want to inform you that regular visits by Field Service Representatives (FSRs) will be required for **cobas b** 221 <5>/<6> Roche OMNI S5/S6 systems.<br><br>Roche has received complaints for **cobas b** 221 <5>/<6>/OMNI S 5/6 systems related to issues with the calibration and QC stability of the MSS parameters. Other **cobas b** 221/OMNI S systems are not affected since they do not contain a MSS measurement chamber and do not use the S3 Fluid Pack. Until recently, contamination was only known to affect the Standby solution fluidic pathway. The latest investigations have revealed that the pathways of calibration solutions Cal 1 to Cal 4 (from the S3 Fluid Pack) can be affected as well. This has the potential to affect patient results.<br>It should be noted that a retrospective case review confirmed that there were no customer complaints, in which an erroneous patient result was generated due to the influence of bacterial contamination of the MSS calibration solutions. We observed this in our internal proactive study only involving high throughput use of severely contaminated |

Roche Diagnostics
Charles Avenue
Burgess Hill
West Sussex
RH15 9RY

Registered No 571546

| | |
|---|---|
| Ö | **Immediate Action Required** |
| | **Action Required** |
| | **Information Only** |

instruments.

Initially, the underlying failure was identified within the Standby solution of the S3 Fluid Pack. Since the problem is not lot number specific, all currently available S3 Fluid Packs can potentially contribute to the problem. In spite of this, not all instruments are affected by this issue as the environment an instrument is placed into plays an important role.

It has been found that the root cause is the preservative component Kathon® 893. Analysis confirmed decay products of the preservative compound Kathon® 893 in the 'white deposits' found in the tubes of the affected instruments. Additionally, bacteriological examination of several affected tube samples from various customers showed that the 'white deposits' also contain Gram-negative bacteria. Analysis revealed that the current Kathon® 893 concentration is not sufficient to fully suppress the externally introduced Gram-negative bacterial contamination which exist in the environments the instruments are used in. **We stress that these bacteria are not introduced to the system via the Fluid Packs.**

For instruments affected by 'white deposits', issues with the calibration and stability of QC measurements of the glucose and lactate parameters have been observed. As previously communicated, the lifetime of the metabolite sensor cassettes may also be reduced in the presence of the 'white deposits'.

We performed studies regarding the system reliability, in the presence of the 'white deposits'. Data from this initial study and comparison with the reference system (Hitachi c501) confirmed that affected instruments were fully within specification for the measurement results of all sample types.

Recently, we received complaint data and material from the field indicating that this bacterial contamination can also affect the MSS calibration solutions fluid paths (Cal1, Cal 2, Cal 3 and Cal 4) from the S3 Fluid Pack, even if there are no 'white deposits' visible.

Roche Diagnostics
Charles Avenue
Burgess Hill
West Sussex
RH15 9RY

Registered No 571546

| | |
|---|---|
| Ö | **Immediate Action Required** |
| | **Action Required** |
| | **Information Only** |

A performance study using instruments received back from customers, revealed that the effect on the calibration of the glucose and lactate parameters may lead to patient results being affected as well. This is because calibration drifts are not certainly detected by the existing calibration and QC procedure currently in place.

However, as the detection of the calibration drifts by the software cannot be guaranteed, we regret to inform you that it will be necessary to actively monitor all in use instruments with activated glucose and/or lactate parameters by scheduling customer visits on a regular basis. During these visits, the instruments need to be checked for indicators of early contamination and need to be cleaned should bacterial contamination be identified.

As a consequence, for each **cobas b** 221 <5> and <6> Roche OMNI S5/S6 system, with activated parameters for glucose and/or lactate, an initial and then follow-up customer visit on a four weekly basis is mandatory to exclude an effect on patient results.

We clearly want to state that this above described activity is an interim corrective action. In order to make these regular customer visits obsolete in the near future, a software based solution to automatically detect contamination and act accordingly is currently in development. We expect this to be available at the end of Q2/2015 for first country monitoring.

As previously communicated, the final solution to this issue is the implementation of changes to the reagents. In October, we received the results of the feasibility study aimed at increasing the concentrations of Kathon® 893 in the Standby solution. The outcome of this study indicated that increasing the Kathon® 893 concentration was effective against some but not all bacteria found in the affected instruments from the field and thus would not significantly improve the situation. Therefore, a reformulation of Standby and calibration solutions of the S3 Fluid Pack is required to eliminate the root cause. Currently we expect this to be available at the end of 2016.

Roche Diagnostics
Charles Avenue
Burgess Hill
West Sussex
RH15 9RY

Registered No 571546

| | |
|---|---|
| Ö | **Immediate Action Required** |
| | **Action Required** |
| | **Information Only** |

**Action Required:**

1. Run and maintain the **cobas b** 221system/OMNI S as per manufacturers instructions for use.

2. An initial and then follow-up customer visit on a four weekly basis will be carried out by the Field Service Representatives in order to carry out the maintenance procedure. You will be contacted by a member of the Technical Services Team to organise this and subsequent visits.

3. Please complete the fax back and return by no later than 22nd December 2014.

This issue is taken very seriously and our organisation is making every effort to provide you with a resolution as soon as possible.

We apologise for any inconvenience caused by this issue.

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

**Attachments:** BFSN_02_14 White Deposits PB 2014_008 Update fax back.

**This action is being conducted with the knowledge of the Medicines and Healthcare products Regulatory Agency (MHRA), the Health Products Regulatory Authority, and other International Regulatory Agencies.**

** Please bring this notice to the attention of all personnel in your hospital/ Health Care facility who need to be aware of this safety issue. If you have forwarded the affected product(s) listed above to another laboratory, please provide a copy of this letter to them. **

**If you require any further information please contact our Professional Services Department / Technical Support Hotline on:**
**UK: 0808 100 19 20**
**Ireland：1800 40 9 564**

**A copy of this notice can also be found on www.cobas-roche.co.uk**

**To enable Roche Diagnostics to fulfil its vigilance duties in entirety with respect to the IVD Directive 98/79 EC, please complete and return the fax-back form which accompanies this Field Safety Notice.**

Roche Diagnostics
Charles Avenue
Burgess Hill
West Sussex
RH15 9RY

Registered No 571546