



Urgent Field Safety Notice Product Correction

Immediate Action Required

Date Issued December 12, 2012

Product ARCHITECT 25-OH Vitamin D List Number 3L52 (all lots)

Explanation

- The purpose of this communication is to inform you of a situation with the ARCHITECT 25-OH Vitamin D assay and provide instructions on actions your laboratory must take.
- Abbott has confirmed that the ARCHITECT 25-OH Vitamin D assay has the potential to generate falsely elevated or falsely depressed results when the assay is used with the following ARCHITECT Reaction Vessel (RV) (LN 7C15-01) lots:

| Lot # on Box (lot # on bag) | Lot # on Box (lot # on bag) | Lot # on Box (lot # on bag) |
|-----------------------------|-----------------------------|-----------------------------|
| 19320P100 (6F9891501) | 19344P100 (4N5891091) | 19404P100 (1J1948151) |
| 19322P100 (LM3891731) | 19373P100 (6F9891521) | 19407P100 (4N5948361) |
| 19324P100 (NK8891921) | 19374P100 (JG7891631) | 19408P100 (5P4948471) |
| 19340P100 (1J1890911) | 19375P100 (LM3891741) | 19497P100 (2L2948281) |
| 19341P100 (2L2891001) | 19379P100 (NK8891931) | 20026P100 (LM3947841) |

- We have determined that this issue is due to an interaction between the ARCHITECT 25-OH Vitamin D assay and the resin lots used to produce the impacted RV lots listed above. Patient results can be affected if the impacted RV lots are mixed with non-impacted RV lots in the ARCHITECT hopper and used to test ARCHITECT 25-OH Vitamin D.
- There is no product performance issue with the ARCHITECT 25-OH Vitamin D assay when using non-impacted RV lots.
- The investigation has shown a component unique to the ARCHITECT 25-OH Vitamin D conjugate is interacting with the impacted RV lots. At this time, there is no data that indicates there is impact to other ARCHITECT assays when using the impacted RV lots listed above.

Patient Impact

Through our investigation, we assessed the potential magnitude of falsely depressed or falsely elevated patient results and the frequency of the shift in patient results. For example:

- It is possible a patient sample in a range of 20 ng/mL – 27.76 ng/mL could exhibit a negative bias up to -27.97%, resulting in reported values < 20 ng/mL (as low as 14.4 ng/mL). The frequency of this shift was estimated to be 0.24%.
- It is possible that patient samples in a range of 13.05 ng/mL to 20 ng/mL could exhibit a positive bias up to 53.25%, resulting in reported values > 20 ng/mL (as high as 30.65 ng/mL). The frequency of this shift was estimated to be 0.10%.

**Necessary
Actions**

In order to ensure that the ARCHITECT 25-OH Vitamin D assay performs accurately, please follow these necessary steps:

- Discontinue use and destroy any remaining inventory of the ARCHITECT RV lots listed above according to your laboratory procedures.
 - If the ARCHITECT RV lots above are the only lots available in your laboratory, immediately order a new lot as replacement RV lots are available.
 - Discontinue testing ARCHITECT 25-OH Vitamin D until a new RV lot arrives.
 - Prior to continued use of the ARCHITECT 25-OH Vitamin D assay, clear the ARCHITECT RV hopper of impacted RV lots following the instructions in Appendix A.
 - If you have forwarded any ARCHITECT 25-OH Vitamin D kits or impacted RV lots listed above to other laboratories, please inform them of this Product Correction and provide a copy of this letter to them.
 - Please return the Customer Reply form.
 - Follow your laboratory procedure in discussing previously reported results with your physicians.
 - Retain this letter for your laboratory records.
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**Contact
Information**

We sincerely apologize for any inconvenience this may cause. Abbott is committed to providing you with the highest quality diagnostic products and support services to meet the needs of your laboratory and the providers and patients you serve.

If you or any of the health care providers you serve have any questions regarding this information, U.S. customers should call Customer Service at 1-877-4ABBOTT. Customers outside the U.S., please contact your local Customer Service representative.

Appendix A:

Instruction for removing RVs from an ARCHITECT i1000SR:

1. The Processing Module must be in STOPPED or OFFLINE status.
2. Log on as General User or Admin
3. Manually remove all RV's from the upper hopper.
4. Manually remove all RV's from the lower hopper by following the instructions below:
 - Using the green thumb screws, carefully remove the hopper cover and place it to the side of the hopper, keeping the sensor wire attached (DO NOT remove this wire).
 - Manually remove all RV's from the lower hopper
 - Do not disturb any RV that may be on the picker arm at the top of the hopper (it will be removed later).
 - Replace the hopper cover, and tighten the green thumb screws.
5. Perform a Startup to clear RV's from the picker arm and process path. This will also reset the inventory to zero.
6. Instrument will generate Error Code 5212: Empty RV hopper detected during initialization. Add RVs, update supplies and press run. Note: Fill hopper with only RV lots that are NOT listed in the Explanation section of this letter.
7. Perform a second Startup to clear remaining RV's from Process Path. Startup will load RV's correctly and update the inventory.

Instruction for removing RVs from an ARCHITECT i2000/i2000SR:

Contact your Abbott Customer Service representative for assistance on removing RVs from the RV hopper of ARCHITECT i2000/i2000SR.