



Product Correction

Immediate Action Required

Date Issued October 07, 2011

Product ARCHITECT Cyclosporine List Number 1L75 (all in-date lots)

Explanation

- The purpose of this communication is to inform you of a situation with ARCHITECT Cyclosporine and provide instructions on actions your laboratory must take.
- Abbott has confirmed that the ARCHITECT Cyclosporine assay has the potential to generate falsely elevated or depressed results with patient samples due to precision exceeding the Package Insert claim of $\leq 15\%$ total CV. Calibrators and Controls also have the potential to be impacted by the assay imprecision.
- We have determined that the imprecision is due to an interaction between the ARCHITECT Cyclosporine assay and the resin used to produce certain ARCHITECT Reaction Vessel (RV) lots. Assay precision can be impacted if RV lots containing different resin are mixed in the ARCHITECT hopper and used to test ARCHITECT Cyclosporine.
- At this time, there is no data that indicates there is impact to other ARCHITECT assays. We are continuing to investigate this issue.

Patient Impact

Review of worldwide patient results for ARCHITECT Cyclosporine assay was performed. Comparison of patient results obtained prior to July 2011, when this issue began, with patient results after July 2011 determined that approximately 7% of test results demonstrated increased imprecision across the entire dynamic range of the assay.

Necessary Actions

In order to ensure that the ARCHITECT Cyclosporine assay performs within precision stated in the ARCHITECT Cyclosporine package insert ($\leq 15\%$ total CV):

- Only run ARCHITECT Cyclosporine using RV lots manufactured with the same resin as outlined below:
 - RV lots beginning with lot 06083P100 and higher can be used together or,
 - RVs lots lower than 06083P100 can be used together. Any RV lot number that does not begin with a zero (e.g. 90032P100) should also be considered lower than 06083P100

If	Then
You can confirm that your laboratory is only using ARCHITECT RV lot 06083P100 and higher and you will not use RV lots lower than 06083P100 in the future	Recalibrate ARCHITECT Cyclosporine and run Quality Controls per the package insert. Proceed with normal Cyclosporine testing.
You cannot confirm the RV lots loaded on your ARCHITECT	Follow steps 1-3 below to remove the potential for use of mixed RV resin types that may impact ARCHITECT Cyclosporine precision.
You can confirm that your laboratory is only using ARCHITECT RV lots lower than 06083P100 and/or lots that do not begin with zero (e.g. 90032P100).	Proceed with normal Cyclosporine testing until you begin to use RV lot 06083P100 and higher. When you change to lot 06083P100 or higher then follow steps 1-3 below.

**Necessary
Actions
(cont.)**

1. Remove all RVs from the ARCHITECT Hopper before testing ARCHITECT Cyclosporine.
 - Follow instructions in Appendix A of this letter to remove RVs from the hopper of ARCHITECT *i1000SR*.
 - Contact your Abbott Customer Service representative for assistance on removing RVs from the RV hopper of ARCHITECT *i2000/i2000SR*.
 2. Fill hopper only with RV lots that can be used together
 - RV Lots 06083P100 and higher can be used together.
 - RV lots lower than 06083P100 and any RV lot number that does not begin with a zero (e.g. 90032P100) can be used together.
 3. Recalibrate ARCHITECT Cyclosporine and run Quality Controls per the package insert.
 - If you have forwarded any ARCHITECT Cyclosporine kits 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.
 - 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. Fill hopper only with RV lots that can be used together (Lot 06083P100 and higher or lots lower than 06083P100)
7. Perform a second Startup to load RV's correctly and update the inventory.