



Urgent Field Safety Notice Product Recall

Immediate Action Required

Date Issued

September 20, 2012

Product

ARCHITECT HAVAb-IgG
List Numbers: 6C29-20 and 6C29-25
Lot Numbers: Refer to Attachment 1

Explanation

The ARCHITECT HAVAb-IgG assay shows a shift in the serum and plasma results to higher S/CO values over time, potentially leading to reduced specificity and increased false reactive results.

Patient Impact

- The reactive rates are elevated leading to reduced specificity.
- There is the potential for false reactive patient results.
- Assay sensitivity is not impacted.

Necessary Actions

1. Revise Reagent Kit Expiration Dating

- Refer to Attachment 1. Determine if you have any of the reagent lots listed in your inventory.
- Revise the expiration date for all reagent lots identified in your inventory per instructions of Attachment 1.
- After applying new expiration dates to reagent kits as listed in Attachment 1, discontinue use of those kits which are now outdated, and discard the material according to your laboratory procedures.
- Contact Abbott to order replacement material.

2. Apply the following interpretation of results after revision of reagent kit expiration dating

- No action is required for serum samples processed utilizing lots within revised expiration dating.
- When results are generated with plasma samples in the range of 1.00 - 3.55 S/CO, additional testing, e.g. with a secondary method, is recommended to confirm the result. Internal studies have demonstrated that potential false reactive results occur in this range.

NOTE: The above actions are taken as a precaution until permanent preventive measures are implemented.

**Necessary
Actions**

- **Results obtained previously:**
Results released with ARCHITECT HAVAb-IgG Reagent lots outlined in Attachment 1 are **not** impacted if the following conditions apply:
 - a) The result was < 1.00 S/CO or > 3.55 S/CO.
 - b) Results generated with serum samples within the new expiration date (refer to Attachment 1).

Internal studies have confirmed that there is potential for false reactive results when S/CO results are in the range of 1.00 – 3.55 S/CO.

Results not meeting conditions a) or b) above may be impacted. Abbott recommends that you follow your laboratory procedure in discussing these results with your physicians.

Retain this letter for your laboratory records. If you have forwarded any kits of the lots listed in Attachment 1 to other laboratories, please inform them of this Product Recall and provide a copy of this letter to them.

**Additional
Information**

We sincerely regret any inconvenience this issue may cause. If you or any of the health care providers you serve have any questions regarding this information, or if you have questions concerning credit, please contact your local area Customer Support. Please refer to the control number: FA20SEP2012

Attachment 1

Table 1 contains a listing of ARCHITECT HAVAb-IgG Reagents that are **NOW** expired as a result of the shortened expiration dating. Please note that any patient results generated with these reagent lots should be evaluated as outlined in section **Necessary Actions**.

Table 1

| List Number | Lot Number | Original Expiration Date | New Expiration Date |
|-------------|------------|--------------------------|---------------------|
| 6C29-20 | 07658LI00 | 26-SEP-2012 | 26-MAR-2012 |
| 6C29-25 | 07659LI00 | 26-SEP-2012 | 26-MAR-2012 |
| 6C29-20 | 09297LI00 | 22-OCT-2012 | 22-APR-2012 |
| 6C29-25 | 09298LI00 | 22-OCT-2012 | 22-APR-2012 |
| 6C29-20 | 09299LI00 | 30-NOV-2012 | 30-MAY-2012 |
| 6C29-25 | 09300LI00 | 30-NOV-2012 | 30-MAY-2012 |
| 6C29-20 | 10326LI00 | 13-DEC-2012 | 13-JUN-2012 |
| 6C29-25 | 10327LI00 | 13-DEC-2012 | 13-JUN-2012 |
| 6C29-20 | 10340LI00 | 30-JAN-2013 | 30-JUL-2012 |
| 6C29-25 | 10341LI00 | 30-JAN-2013 | 30-JUL-2012 |
| 6C29-20 | 13364LI00 | 16-FEB-2013 | 16-AUG-2012 |
| 6C29-25 | 13365LI00 | 16-FEB-2013 | 16-AUG-2012 |

Table 2 contains a listing of ARCHITECT HAVAb-IgG Reagents that require the assigned expiration date to be revised.

Table 2

| List Number | Reagent Lot | Original Expiration Date | New Expiration Date |
|-------------|-------------|--------------------------|---------------------|
| 6C29-20 | 14105LI00 | 22-MAR-2013 | 22-SEP-2012 |
| 6C29-25 | 14106LI00 | 22-MAR-2013 | 22-SEP-2012 |
| 6C29-20 | 15229LI00 | 18-APR-2013 | 18-OCT-2012 |
| 6C29-25 | 15230LI00 | 18-APR-2013 | 18-OCT-2012 |
| 6C29-20 | 16298LI00 | 15-MAY-2013 | 15-NOV-2012 |
| 6C29-25 | 16299LI00 | 15-MAY-2013 | 15-NOV-2012 |
| 6C29-20 | 16300LI00 | 25-JUN-2013 | 25-DEC-2012 |
| 6C29-25 | 16301LI00 | 25-JUN-2013 | 25-DEC-2012 |

All new reagent lots of ARCHITECT HAVAb-IgG will be shipped with dating already reduced.