July 07, 2021

URGENT FIELD SAFETY NOTICE UPDATE

Access SARS-CoV-2 IgG II Reagent and Calibrator

REF	LOT	
ACCESS SARS-CoV-2 IgG II Reagent: C69057 ACCESS SARS-CoV-2 IgG II CALIBRATOR: C69058	Multiple (All)	Multiple (All)

Attention Beckman Coulter Customer,

On May 7, 2021 Beckman Coulter initiated an Urgent Field Safety Notice, FA-21032, for the Access SARS-CoV-2 IgG II reagent and calibrator. A copy of this notification is attached for your reference. The communication notified customers that numerical results for the Access SARS-CoV-2 IgG II assay may be multiplied by a factor of 1000 on systems running with the assay protocol file (APF) and access assay file (AAF) versions listed in the following table.

System	APF/AAF Version
Access 2	2.9.178.2
DxI Includes: DxI 600, DxI 800, DxC 660i, DxC 680i, DxC 860i, and DxC 880i	2.10.225-A.2 (APF) / 6.89.00 (AAF)

The May communication also informed customers that Beckman Coulter would release a new APF/AAF name and number for the Access SARS-CoV-2 IgG II assay to correct this issue, and that an additional communication would be sent once the new APF/AAF name and number is available.

This current Urgent Field Safety Notice update is a notification that the new APF/AAF name and number for the Access SARS-CoV-2 IgG II assay is now available.

ISSUE

- Access SARS-CoV-2 IgG II reagent and calibrator products with expiration dates after October 31st, 2021 will use the new APF/AAF name and number indicated in the table below beginning with lots 124629 (reagent) and 124676 (calibrator).

	Current Access SARS-CoV-2 IgG II	New Access SARS-CoV-2 IgG II
Reagent and Calibrator Lots with Expiration Date	31-Oct-2021 or Before	After 31-Oct-2021
Test ID	224/11224	177/11177
Test Name	COVII/dCOV	COVG/dCOVG

<table>
<tr><td></td><td>

In order to run the new Access SARS-CoV-2 IgG II test name and number, the following APF/AAF versions (or higher) are required:

<table>
<tr><th>System</th><th>APF/AAF Version Required</th></tr>
<tr><td>Access 2</td><td>2.9.179.2</td></tr>
<tr><td>DxI
Includes: DxI 600, DxI 800, DxC 660i, DxC 680i, DxC 860i, DxC 880i</td><td>2.10.227-A.2 (APF) / 6.91.00 (AAF)</td></tr>
<tr><td>DxC 600i</td><td>D2.9.179.2 (APF) / 5.56.00 (AAF)</td></tr>
</table>
</td></tr>
<tr><td>IMPACT</td><td>

An additional Access SARS-CoV-2 IgG II instructions for use (IFU) with the new APF/AAF test name is available (Ref C69158B or higher revisions).
A stuffer will be included in Access SARS-CoV-2 IgG II reagent and calibrator kits with expiration dates after October 31st, 2021. The stuffer will outline kits requiring the current and new APF/AAF test names and numbers.
The current and new APF/AAF test names and numbers are not interchangeable.
No change is being made to the Access SARS-CoV-2 IgG II assay formulation, claims, performance, or part numbers.

</td></tr>
<tr><td>ACTION</td><td>

Prior to installation of the new APF/AAF test name and number, ensure all instructions from letter FA-21032 (attached) have been followed.
Ensure your system is using the appropriate APF/AAF version listed in the following table:

<table>
<tr><th>System</th><th>APF/AAF Version Required</th></tr>
<tr><td>Access 2</td><td>2.9.179.2</td></tr>
<tr><td>DxI (US and Puerto Rico)
Includes: DxI 600, DxI 800, DxC 660i, DxC 680i, DxC 860i, and DxC 880i</td><td>2.10.227-A.2 (APF) / 6.91.00 (AAF)</td></tr>
<tr><td>DxC 600i</td><td>D2.9.179.2 (APF) / 5.56.00 (AAF)</td></tr>
</table>

Enable both the current test name and number COVII/dCOV (224/11224) and the new test name and number COVG/dCOVG (177/11177) on the system.
You may continue to use Access SARS-CoV-2 IgG II reagent and calibrator inventory with expiration dates of October 31st, 2021 or earlier.
Ensure the appropriate Access SARS-CoV-2 IgG II IFU is being used:

</td></tr>
</table>

	○ For reagent and calibrator inventory with expiration dates of October 31st, 2021 or earlier, IFU C69158A should be used. ○ For reagent and calibrator inventory with expiration dates after October 31st, 2021 IFU C69158B or higher revisions should be used.
RESOLUTION	• The new APF/AAF corrects an error in the original Access SARS-CoV-2 IgG II APF/AAF file in order to ensure that the issue outlined in FA-21032 does not occur again.

The national competent authority has been informed of this field safety corrective action.

Please share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation. If you have forwarded any of the affected product(s) listed above to another laboratory, please provide them a copy of this letter.

If you have not previously responded to the prior notification for this field action (FA-21032), please complete and return the enclosed Response Form within 10 days so we are assured you have received this important communication.

If you have any questions regarding this notice, please contact our Customer Support Center:

- From our website: http://www.beckmancoulter.com
- Outside of the United States, contact your local Beckman Coulter representative.

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

[redacted]

Director, Quality and Regulatory Affairs

Enclosure: Response Form. Urgent Field Safety Notice Letter FA-21032

Previous Customer Notification

May 07, 2021

URGENT FIELD SAFETY NOTICE

Access SARS-CoV-2 IgG II Reagent and Calibrator

REF	LOT	⌛
C69057 C69058	Multiple (All)	Multiple (All)

Attention Beckman Coulter Customer,

Beckman Coulter is initiating a field action for the products listed above. This letter contains important information that needs your immediate attention.

ISSUE:

- The Access SARS-CoV-2 IgG II numerical results for calibrator, quality control (QC), and patient sample values may be multiplied by a factor of 1000 on systems running with the assay protocol file (APF) and access assay file (AAF) versions listed in the following table:

System	APF/AAF Version
Access 2	2.9.178.2
DxI Includes: DxI 600, DxI 800, DxC 660i, DxC 680i, DxC 860i, and DxC 880i	2.10.225-A.2 (APF) / 6.89.00 (AAF)

IMPACT:

- Sample results may be multiplied by 1000 causing falsely elevated numerical values to be reported.
- If the falsely elevated numerical result is used to determine the qualitative interpretation based on the cutoff in the instructions for use (IFU), non-reactive samples may be incorrectly interpreted as reactive.

ACTION:

- Do not install any of the APF/AAF versions listed in the table.
- Determine your current APF/AAF version.
  - From the Main Menu: select **Configure F8** → **System Setup F1** → **System Revisions F1**.
  - Verify the APF/AAF version displayed on the screen.
- If the APF/AAF version is listed in the table:

	• Stop using the Access SARS-CoV-2 IgG II assay. Contact your local Beckman Coulter representative for further instruction. • Review all Access SARS-CoV-2 IgG II patient test results from April 13, 2021 onward. • Do not install any additional APF/AAF versions prior to contacting Beckman Coulter. • If the APF/AAF version is lower than those listed in the table, you are not impacted. You may continue to operate your system normally.
RESOLUTION:	• The APF/AAF versions listed in the table are no longer available on the Beckman Coulter website. • Beckman Coulter will release a new APF/AAF name and number for the Access SARS-CoV-2 IgG II assay. • Additional communication will be sent once the APF/AAF is made available.

The national competent authority has been informed of this field safety corrective action.

Please share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation. If you have forwarded any of the affected product(s) listed above to another laboratory, please provide them a copy of this letter.

Please complete and return the enclosed Response Form within 10 days so we are assured you have received this important communication.

If you have any questions regarding this notice, please contact our Customer Support Center:

- From our website: http://www.beckmancoulter.com
- Outside of the United States, contact your local Beckman Coulter representative.

We apologize for the inconvenience that this caused your laboratory.

Sincerely,

[redacted]

Director, Quality and Regulatory Affairs

Enclosure: Response Form