

# INFORMATION BULLETIN

## Using the new Access APOE ε4 (RUO) assay in your laboratory

### Access APOE ε4 (RUO) assay (REF D16691) for use with the Access 2 Immunoassay System and the Dxl 9000 Immunoassay Analyzer

Beckman Coulter is pleased to announce that the Access APOE ε4 (RUO) assay (REF D16691) is now available for use with the Access 2 Immunoassay System and Dxl 9000 Immunoassay Analyzer. This assay is For Research Use Only (RUO) and is not for use in diagnostic procedures. No clinical decision or patient notification may be made based on results using this research assay. Intended use has not been established.

**NOTE: Beckman Coulter recommends that you refer to the Access APOE ε4 (RUO) Instructions for Use (IFU)<sup>1,2</sup> before using this assay in your laboratory. Follow the IFU and adhere to all warnings and precautions contained therein.**

The Apolipoprotein E (APOE) gene provides instructions for ApoE, which forms lipoproteins to transport cholesterol and lipids in the bloodstream. ApoE regulates lipid homeostasis by mediating lipid transport and is primarily produced by astrocytes and microglia in the CNS, transporting cholesterol to neurons via LDLR family receptors. It is encoded by the APOE gene with three alleles, resulting in three isoforms (APOE ε2, APOE ε3, APOE ε4) and six phenotypes.

### Ordering Information

Access APOE ε4 (RUO) Ordering Information	REF
Access APOE ε4 (RUO) Reagent Kit (100 ratio determinations, 50 tests/ pack, 2 packs/kit)	D16691
Access APOE ε4 (RUO) QC (QC1-QC3: 2 vials/level, 2.5 mL/vial)	D16692

### Laboratory Operating Essentials

Access APOE ε4 (RUO) Software Codes for the Access 2 Immunoassay System and Dxl 9000 Immunoassay Analyzer	
Test name / Test ID	PanRUO / 216 e4RUO / 217



## Assay Characteristics

The following results are derived from internal studies and are intended solely for informational purposes. These findings are not intended to serve as official specifications or guarantees of performance.

Assay Characteristic	Access APOE ε4 (RUO)	
Assay format	Two-step sandwich	
Recommended sample type(s)	Plasma (K <sub>2</sub> -EDTA)	
Unit of measure	Relative Light Units (RLU)	
Open reagent pack stability	2 to 10°C for 14 days	
Open QC vial stability	2 to 10°C for 14 days	
Sample volume (uptake)	Access 2: 30 µL/ratio determination	DxI 9000: 20 µL/ratio determination
Time to first result (approximate)	Access 2: ~22 minutes	DxI 9000: ~15 minutes
Imprecision (%CV RLU Ratio)*	Access 2: ~7.9 - 13.4%	DxI 9000: ~6.4 - 10.4%

\* Imprecision values are based on samples that contain APOE ε4 allele.

## Ratio Determination Instructions

The following instructions are system dependent. Choose the system or systems used by your laboratory, and then follow the corresponding instructions to generate the ratio determination for the Access APOE ε4 (RUO) assay (REF D16691).

**Access 2 Immunoassay System:** APOE ε4 (RUO) Calculated Result Ratio using Derived Result

**Note:** For additional information see the Access 2 Immunoassay IFU, section 4.6: Derived Result Setup.

**Step 1. Verify that the correct assay protocol file (APF) version is loaded on your Access 2 system**

APF version (or higher)	To verify the APF version:
<b>APF Versions:</b> 2.9.190.2 or 2.9.190.3	<b>From the Main Menu:</b> <ul style="list-style-type: none"> <li>&gt; <b>Configure F8</b> → <b>System Setup F1</b> → <b>System Revisions F1</b></li> <li>&gt; Verify APF version</li> </ul>

**Note:** If the required APF version is not installed, contact your local Beckman Coulter Customer Technical Support representative.

**Step 2. Enable and configure the Access APOE ε4 (RUO) assay on your Access 2 system**

To enable and configure the Access APOE ε4 (RUO) assay:
<b>From the Access 2 Main Menu:</b> <b>Enable the test</b> <ul style="list-style-type: none"> <li>&gt; Select <b>Configure F8</b> to display the Configure menu, then select <b>Derived Results F4</b></li> <li>&gt; Select <b>Add Derived Result F4</b> to display the Add Derived Result window</li> <li>&gt; In the <b>Derived Result Name</b> field, enter <b>APOERES</b></li> <li>&gt; In the <b>Formula</b> field, enter <b>1/(e4RUO/PanRUO)</b></li> <li>&gt; Select <b>OK F1</b> to save and apply the changes and exit the window</li> </ul>

### Step 3. Configure the derived result calibration setup on your Access 2 system

To configure the Access APOE ε4 (RUO) derived result calibration setup:	
To facilitate Calculating a Derived Result a mock calibration is required for all tests. For the Access APOE ε4 (RUO) assay, a mock calibration is required once per reagent pack lot.	
<b>From the Access 2 Main Menu:</b>	
<ul style="list-style-type: none"> <li>&gt; <b>Calibration F5 → Calibrator Setup F5 → Add Calibrator F1</b></li> <li>&gt; Scan the provided calibrator barcodes → <b>OK F1</b> to save               <ul style="list-style-type: none"> <li>• To manually enter calibrator information, enter <b>216</b> followed by the 6-digit reagent pack lot number and the current date (<b>DDMMYY</b>), e.g. 21643975526SEP24 → <b>Enter</b></li> <li>• In the <b>Bar Code</b> field, enter <b>216C01</b> → <b>OK F1</b></li> </ul> </li> <li>&gt; To request a calibration, select <b>Sample Manager F1 → Test Request F3 → Request Calibration F6</b> → select <b>PanRUO</b> (test ID <b>216</b>) → <b>OK F1</b></li> <li>&gt; Run wash buffer to calibrate the <b>PanRUO</b> assay</li> </ul>	
Refer to the appropriate system manuals and/or Help system for more information about calibration theory, configuring calibrators, calibrator test request entry, and reviewing calibration data.	

**Note:** This setup produces one mean calculated test result ratio per sample, regardless of the total number of replicates. If a ratio of a single replicate of **e4RUO** and **PanRUO** is desired, it is necessary to prepare multiple runs of the same sample, each with only one replicate of each test.

**DxI 9000 Analyzer:** APOE ε4 (RUO) Calculated Result Ratio using Calculated Result when LIS is available

**Note:** For additional information see the DxI 9000 IVD IFU, section 13: Configuring Calculated Results.

### Step 1. Verify that the correct assay protocol file (APF) version is loaded on your DxI 9000 analyzer

APF version (or higher)	To verify the APF version:
<b>APF Versions:</b>	<b>From the DxI 9000 Main Menu:</b> <ul style="list-style-type: none"> <li>&gt; Select <b>Menu</b> → <b>Tools</b> → <b>Diagnostics</b></li> <li>&gt; Select <b>Intrusive Diagnostics</b></li> <li>&gt; Select <b>APF Package Management</b></li> <li>&gt; Verify the APF version listed under <b>APF Base Package</b></li> </ul>

**Note:** If the required APF version is not installed, contact your local Beckman Coulter Customer Technical Support representative.

### Step 2a. LIS AVAILABLE. Enable and configure the Access APOE ε4 (RUO) assay on your DxI 9000 analyzer

To enable and configure the Access APOE ε4 (RUO) assay:
<b>From the DxI 9000 Main Menu:</b> <b>Enable the e4RUO and PanRUO tests</b> <ul style="list-style-type: none"> <li>&gt; Select <b>Menu</b> → <b>System Configuration</b></li> <li>&gt; Select <b>Test Menu</b> from the System Configuration menu</li> <li>&gt; Enable the <b>e4RUO</b> and <b>PanRUO</b> tests</li> </ul>

## Step 2a. Continued

### To enable and configure the Access APOE ε4 (RUO) assay:

#### Enable the APOERUO test

- > Select **Menu** → **System Configuration**
- > Select **Test Menu** from the System Configuration menu
- > Create the calculated result test
  - Select **New** in the lower left corner of the **Tests** list
  - In the **Name** field enter **APOERUO**
  - Select **Immunoassay** from the **Discipline** list
  - Select **OK**
  - Select the field for **Test ID** or **LIS Code**
  - In the **Test ID** field enter **APOERUO**
  - In the **LIS Code** field enter the code that the LIS or middleware will use for receiving results
  - Select **Done**
  - Select the **Calculated Result** checkbox
  - In **Result Type** select **Quantitative**
- > Configure the units and ranges
  - Select **Serum** from the **Add Sample Type** menu
  - From the **Units** list select **None**
  - In **Decimal Places** select **X.XXX** (three decimal places) to report
  - Configure the ranges
    - For sex select **Any**
    - For age range select **Unknown** (the analyzer will not flag any age)
    - For reference insert from **0** to **99999**
    - For critical limits insert below **-99999** above **99999**
- > Select **System Configuration**
- > Add a new rule
  - Select **Rules**
  - Select **New**
  - In the **Name** field enter **APOERES**
  - Select **OK**
- > Configure the general settings for the rule
  - In the general settings select the **Description** field, and in the **Text Input** dialog enter **RLU ratio of e4RUO assay result divided by PanRUO result**
  - Select **Done** and select **Next**
  - Do not select any conditions because conditions are not supported for calculated results
  - Select **Next**

## Step 2a. Continued

### To enable and configure the Access APOE ε4 (RUO) assay:

- > Configure the action for a calculated result rule
  - Select **Add Calculated Result: [Expression]** (do not select any other actions)
  - Select the **Expression** link
  - In **Name of the Calculated Result** select **APOERUO**
  - In **Sample Type** select **Serum**
  - Define the calculated result.
    - Select **e4RUO** from the test buttons
    - Add the / mathematical operator,
    - Select **PanRUO** from the test buttons
  - Select **OK** to close the **Set Value** dialog
  - The calculated result should read: **APOERUO=[e4RUO]/[PanRUO]**
  - Select **Next**
  - Do not select any exclusions because exclusions are not supported for calculated results
- > When ordering samples ensure that both **e4RUO** and **PanRUO** are selected to run for each sample
- > The calculated result appears on the analyzer and is sent to the LIS

## Step 2b. LIS UNAVAILABLE. Enable and configure the Access APOE ε4 (RUO) assay on your Dxl 9000 analyzer

### To manually extract the data needed to calculate the ratio of the Access APOE ε4 (RUO) assay:

#### From the Dxl 9000 Main Menu:

#### Enable the test

- > Select **Menu** → **Advanced** → **Results to Disk**
- > Select start date time and end date time surrounding desired test results
- > Enter a file name for the file to be exported (if desired)
- > Select **Generate Results**
- > The generated file is sent to a designated folder on the hard drive (typically, C:\ProgramData\Beckman Coulter\Falcon\Results)
  - See the status bar below the **Generate Results** button to find the exact location
- > The **RLU** column displays the raw RLU result for the given sample/replicate
  - **SampleID** or **PatientID** may be used to sort sample data
  - **TestName** may be used to sort between **PanRUO** and **e4RUO** test results

## Manual Calculation of APOE ε4 (RUO) Calculated Result Ratio

**Note:** These instructions are applicable for both Access 2 and Dxl 9000 raw RLU results.

The APOE ε4 (RUO) Calculated Result Ratio can be obtained from exported results using the following formula:

$$\text{APOE } \epsilon 4 \text{ (RUO) Calculated Result Ratio} = \frac{\text{e4RUO Assay RLU Result}}{\text{PanRUO Assay RLU Result}}$$

## Contact Information

For more information about the Access APOE ε4 (RUO) assay or for reagent ordering information, please contact your local Beckman Coulter representative.

Learn more at: <https://www.beckmancoulter.com>.

## References

1. Access APOE ε4 (RUO) IFU D22221.
2. Access APOE ε4 (RUO) QC IFU D22222.

**Not all products are available in all countries.**

**Product availability and regulatory status depends on country registration per applicable regulations.**

**RUO: Research Use Only Product. These products are labeled "For Research Use."**

