INFORMATION BULLETIN

Using the new Access GFAP (RUO) assay in your laboratory

Access GFAP (RUO) assay (REF D11672) for use with the Access 2 Immunoassay System & DxI 9000 Access Immunoassay Analyzer.

Beckman Coulter is pleased to announce that the Access GFAP (RUO) assay (REF D11672) is now available for use with the Access 2 Immunoassay System & DxI 9000 Access 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 GFAP (RUO) *Instructions for Use* (IFU)[1, 2, 3] before using this assay in your laboratory. Follow the IFU instructions and adhere to all warnings and precautions contained therein.

Glial Fibrillary Acidic Protein (GFAP) is a class-III intermediate filament protein predominantly expressed in astrocytic glial cells within the central nervous system. Astrocytes are essential for neuronal architecture and activity, as well as maintaining homeostasis and responding to injury. GFAP plays a crucial role in various central nervous system processes, including cell communication, the functioning of the blood-brain barrier, and the structural integrity of astrocytes. Additionally, GFAP is critical for the astrocytic response to stress and injury, often observed through astrocytic activation or reactive gliosis.

Ordering Information

Access GFAP (RUO) Ordering Information	REF

Access GFAP (RUO) Reagent Kit (100 determinations, 50/pack, 2 packs/kit)	D11672
Access GFAP (RUO) Calibrator (S0-S5: 1 vial/level, 2.5 mL/vial)	D11673
Access GFAP (RUO) QC (QC1-QC3: 2 vial/level, 2.5 mL/vial)	D11674

Laboratory Operating Essentials

Access GFAP (RUO) Software Codes	Access 2	DxI 9000
Test name/Test ID	GFAPRUO / 204	GFAPRUO / 204
Calibrator ID	GFPRUOCL / 204	GFAPRUOCal / 204

Assay Characteristics

The results below 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 GFAP (RUO)	
Assay format	One-step, sandwich	
Recommended sample type(s)	Plasma (K2 EDTA), Serum, or CSF	
Unit of measure	pg/mL.	
Analytical Measuring Range (approximate)	0.2 - 700 pg/mL	
Linearity	+/- 10% across measuring interval	
Imprecision	<10% Within-lab CV	
Open reagent pack stability	2 to 10°C for 14 days	
Open calibrator vial stability	2 to 10°C for 14 days	
Open QC vial stability	2 to 10°C for 14 days	
	Access 2	*DxI 9000*
Time to first result (approximate)	33 minutes	26 minutes
Sample volume (uptake)	110 µL	105 µL
Analytical sensitivity (Surrogate)	LOB: 0.16 pg/mL	LOB: 0.070 pg/mL
	LOD: 0.34 pg/mL	LOD: 0.15 pg/mL
	LOQ: 0.59 pg/mL	LOQ: 0.26 pg/mL

Contact Information

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

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

References

1. Access GFAP (RUO) IFU D18925
2. Access GFAP (RUO) Calibrator IFU D18926
3. Access GFAP (RUO) QC IFU D18927

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.”

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