INFORMATION BULLETIN

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

Access NfL (RUO) assay (REF D15673) for use with the Access 2 Immunoassay System & DxI 9000 Access Immunoassay Analyzer.

Beckman Coulter is pleased to announce that the Access NfL (RUO) assay (REF D15673) is now available for use with the 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 NfL (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.

Neurofilament light chain (NfL) is a 68 kDa cytoskeletal intermediate filament protein uniquely characteristic of neurons. It combines with the 125 kDa Neurofilament medium (NfM) and the 200 kDa Neurofilament heavy (NfH) to form neurofilaments, which are essential components of the neuronal cytoskeleton. These neurofilaments, found in both central nervous system (CNS) and peripheral nervous system (PNS) neurons, primarily provide structural support to axons and regulate their diameter. When neurons experience injury or disease, neurofilaments are released in substantial amounts. Once released into the cerebrospinal fluid (CSF), they eventually migrate to the peripheral bloodstream, making them detectable in both plasma and serum.

Ordering Information

Access NfL (RUO) Ordering Information	REF
Access NfL (RUO) Reagent Kit (100 determinations, 50/pack, 2 packs/kit)	D15673
Access NfL (RUO) Calibrator (S0-S5: 1 vial/level, 2.5 mL/vial)	D15674
Access NfL (RUO) QC (QC1-QC3: 2 vial/level, 2.5 mL/vial)	D15675

Laboratory Operating Essentials

Access NfL (RUO) Software Codes	Access 2	DxI 9000
Test name/Test ID	NfLRUO / 241	NfLRUO / 241
Calibrator ID	NfLRUOCl / 241	NfLRUOCAL / 241

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 NfL (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)	3.1 – 10,000 pg/mL	
Linearity	+/- 15% across measuring interval	
Imprecision	<8% 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)	31 minutes	25 minutes
Sample volume (uptake)	110 µL	105 µL
Analytical sensitivity (Surrogate)	LOB: 1.46 pg/mL	LOB: 0.88 pg/mL
	LOD: 2.95 pg/mL	LOD: 2.19 pg/mL
	LOQ: 4.20 pg/mL	LOQ: 3.10 pg/mL

Contact Information

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

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

References

1. Access NfL (RUO) IFU D18928

2. Access NfL (RUO) Calibrator IFU D18929
3. Access NfL (RUO) QC IFU D18930

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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