

INFORMATION BULLETIN

Using the new Access p-Tau217 (RUO) assay in your laboratory

Access p-Tau217 (RUO) assay (REF D14230) for use with the Dxl 9000 Immunoassay Analyzer

Beckman Coulter is pleased to announce that the Access p-Tau217 (RUO) assay (REF D14230) is now available for use with the 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 p-Tau217 (RUO) Instructions for Use (IFU)^{1,2,3} before using this assay in your laboratory. Follow the IFU and adhere to all warnings and precautions contained therein.

Tau proteins play a crucial role in stabilizing microtubules, supporting the neuronal cytoskeleton, and are primarily found in neurons of the central nervous system (CNS). In normal physiological conditions, tau proteins bind to microtubules, promoting their assembly and stability. Phosphorylation of tau at specific sites, such as threonine 217, is part of the normal regulatory process that modulates tau's binding affinity to microtubules. However, abnormal hyper-phosphorylation can disrupt tau's function, leading to its detachment from microtubules and impaired neuronal transport. Accumulation of detached insoluble hyper-phosphorylated tau contributes to the disintegration of neuronal function.

Ordering Information

Access p-Tau217 (RUO) Ordering Information	REF
Access p-Tau217 (RUO) Reagent Kit (100 determinations, 50/pack, 2 packs/kit)	D14230
Access p-Tau217 (RUO) Calibrator (S0-S5: 1 vial/level, 2.5 mL/vial)	D14244
Access p-Tau217 (RUO) QC (QC1-QC3: 2 vials/level, 2.5 mL/vial)	D14232



Laboratory Operating Essentials

Access p-Tau217 (RUO) Software Codes for the Dxl 9000 Immunoassay Analyzer	
Test name / Test ID	pTau217RUO / 202
Calibrator ID	pTau217RUOCal / 202

Assay Characteristics

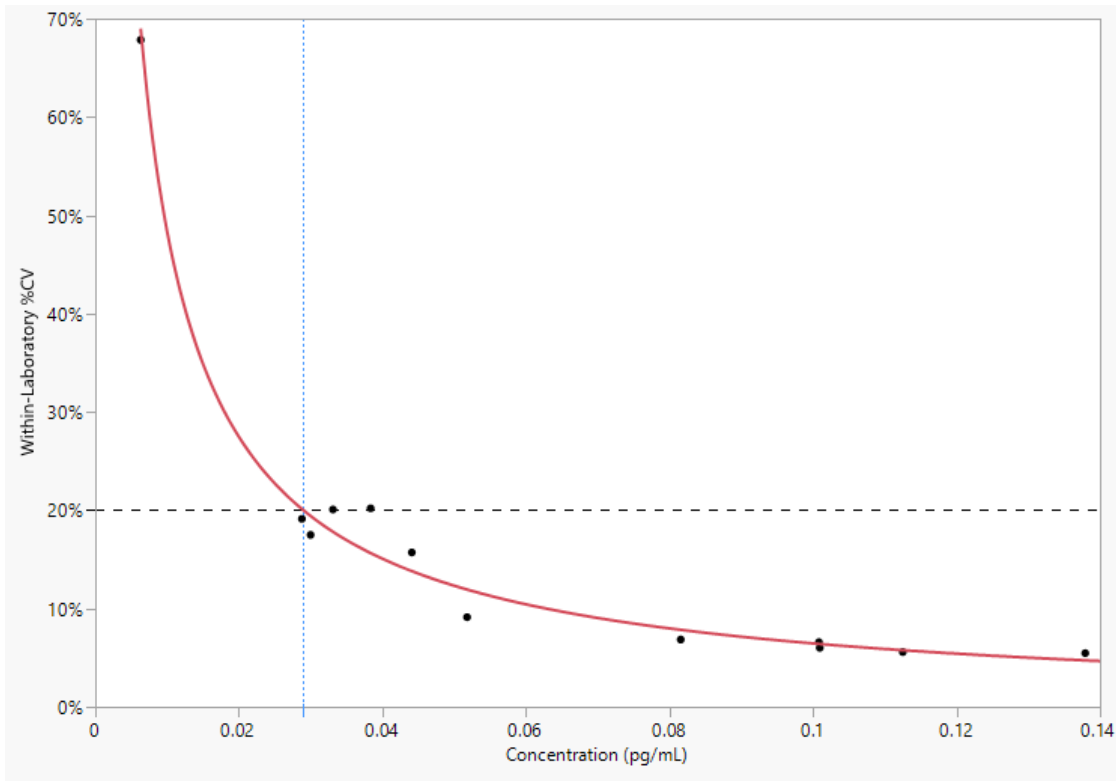
The following results are derived from internal studies and are intended solely for informational purposes. These findings are not intended to serve as official specifications or guarantees of performance.

Assay Characteristic	Access p-Tau217 (RUO)
Assay format	Two-step sandwich
Recommended sample type(s)	Plasma (K ₂ -EDTA)
Unit of measure	pg/mL
Analytical measuring range (approximate)	0.021 - 8.0 pg/mL
Linearity	-5.4 - 6.0% across measuring interval
Imprecision	3.0 - 9% 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
Time to first result (approximate)	38 minutes
Sample volume (uptake)	105 µL
Analytical sensitivity (approximate)	Limit of Blank (LoB): 0.011 pg/mL Limit of Detection (LoD): 0.021 pg/mL Limit of Quantitation (LoQ): 0.029 pg/mL

Assay Sensitivity

Limit of Blank (LoB), Limit of Detection (LoD), and Limit of Quantitation (LoQ) were estimated on the Dxl 9000 Immunoassay Analyzer for the Access p-Tau217 (RUO) assay, based on CLSI EP17-A2 guidelines, using 3 reagent lots on 3 instruments.

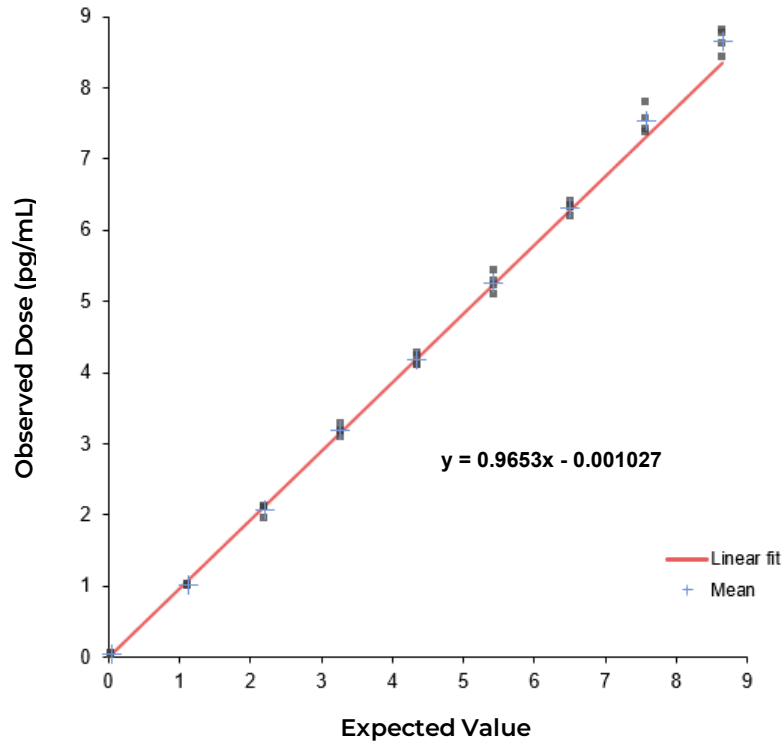
Representative Data of LoQ Precision Profile



The LoQ at 20% CV is 0.029 pg/mL.

Linearity

Assay linearity was evaluated following CLSI EP06 guidelines, with a high and low sample being mixed at various proportions to span the analytical measuring range.



Access p-Tau217 (RUO)			
Expected Concentration (pg/mL)	Observed Concentration (pg/mL)	Linear Fit	Nonlinearity
0.047	0.047	0.044	6.0%
1.122	1.024	1.082	-5.4%
2.198	2.070	2.121	-2.4%
3.274	3.181	3.159	0.7%
4.350	4.180	4.198	-0.4%
5.426	5.263	5.236	0.5%
6.501	6.317	6.275	0.7%
7.577	7.543	7.313	3.1%
8.653	8.653	8.352	3.6%

Contact Information

For more information about the Access p-Tau217 (RUO) assay or for reagent ordering information, please contact your local Beckman Coulter representative.

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

References

1. Access p-Tau217 (RUO) IFU D18922.
2. Access p-Tau217(RUO) Calibrators IFU D18923
3. Access p-Tau217 (RUO) QC IFU D18924.

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."

