

INFORMATION BULLETIN

Using the new Access BD-pTau217 (RUO) assay in your laboratory

Access BD-pTau217 (RUO) assay (REF D33684) for use with the Dxl 9000 Immunoassay Analyzer

Beckman Coulter is pleased to announce that the Access BD-pTau217 (RUO) assay (REF D33684) is now available for use with the Dxl 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 BD-pTau217 (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.

BD-pTau217 is a cutting-edge, brain-derived phosphorylated tau assay designed to deliver a clearer, more biologically specific signal of Alzheimer's disease pathology. By targeting CNS-derived tau (Tau-J), the assay minimizes interference from peripheral tau sources, enabling more accurate detection of amyloid-related neurodegenerative processes.

Ordering Information

Access BD-pTau217 (RUO)	REF
Access BD-pTau217 Reagent Kit (100 determinations, 50/pack, 2 packs/kit)	D33684
Access BD-pTau217 Calibrators (S0-S5: 1 vial/level, 2.5mL/vial)	D33686
Access BD-pTau217 QC (QC1-QC3: 2 vial/level, 2.5mL/vial)	D33688



Laboratory Operating Essentials

Access BD-pTau217 (RUO) Software Codes for the Dxl 9000 Access Immunoassay Analyzer	
Test name/ Test ID	269 / BDpT217RUO
Calibrator ID	269 / BDpT217RUOCal

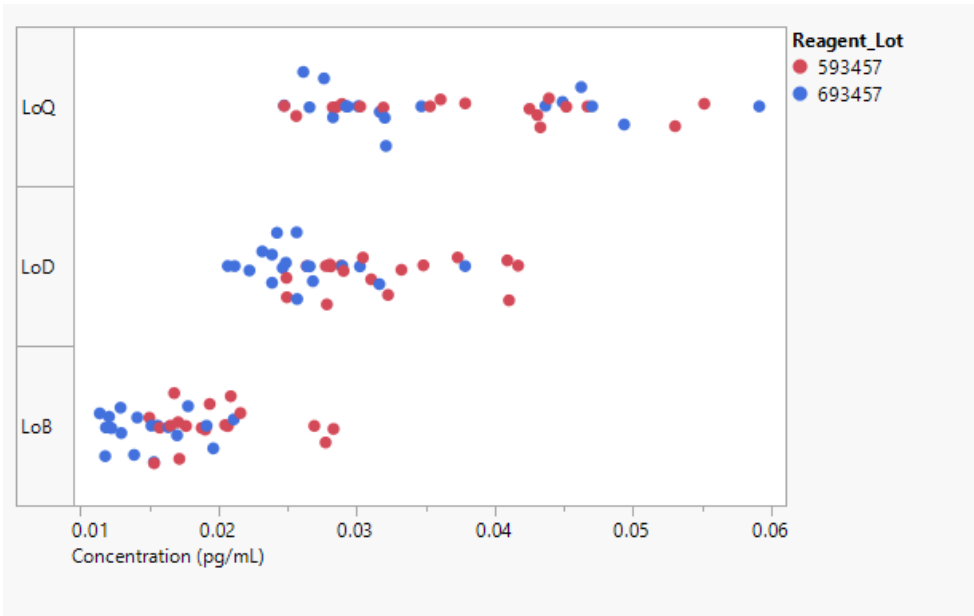
Assay Characteristics

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 BD-pTau217 (RUO)
Assay format	Two-step, sandwich
Recommended sample type	Plasma (K2 EDTA)
Unit of measure	pg/mL
Analytical Measuring Range (approximate)	0.03– 10 pg/mL
Linearity	≥-5.8 – 8.3% across measuring interval
Imprecision	≤10% Within-lab CV
Open reagent pack stability	2° to 10°C for 31 days
Open calibrator vial stability	2° to 10°C for 31 days
Open QC vial stability	2° to 10°C for 31 days
Time to first result (approximate)	38 minutes
Sample volume (uptake)	210 µL plasma
Analytical sensitivity	LoB: 0.02 pg/mL
	LoD: 0.03 pg/mL
	LoQ: 0.05 pg/mL

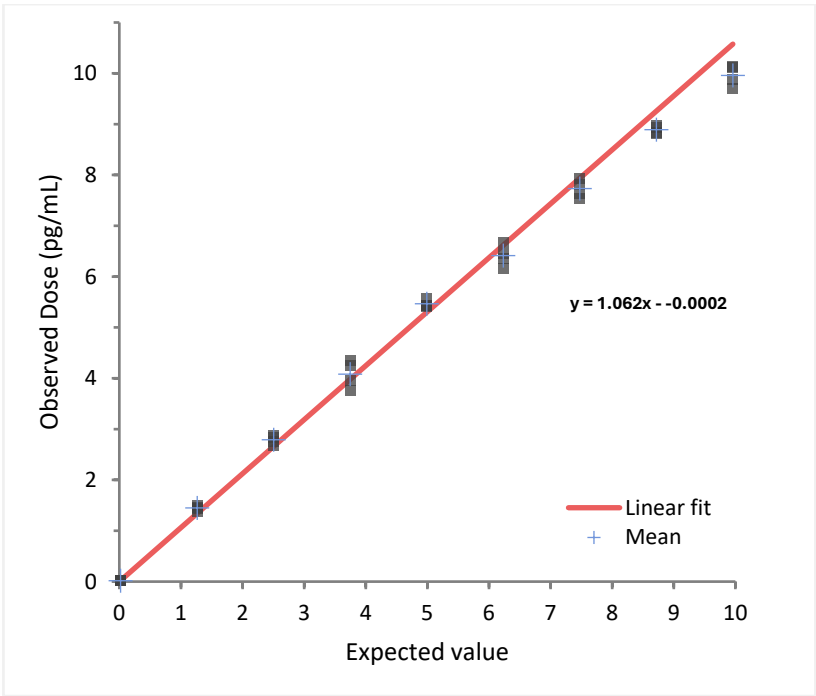
Assay Sensitivity

Limit of Blank (LoB), Limit of Detection (LoD), and Limit of Quantitation (LoQ) were estimated on the Dxl 9000 Access Immunoassay Analyzer using two reagent lots on 3 instruments over a minimum of 3 days. Maximum mean estimates for LoB, LoD, and LoQ on were 0.02, 0.03, and 0.05 pg/mL, respectively.



Linearity

Assay linearity was evaluated following CLSI EP06. A high sample supplemented with recombinant full-length pTau217 antigen was mixed at various ratios with a low sample. Mixtures were tested in replicates of 4-8 and estimates of non-linearity were calculated.



Access BD-pTau217 (RUO)			
Expected Value	Mean	Linear Fit	Nonlinearity
0.020	0.020	0.021	-4.9%
1.262	1.451	1.340	8.3%
2.505	2.790	2.659	4.9%
3.747	4.081	3.979	2.6%
4.989	5.468	5.298	3.2%
6.232	6.414	6.617	-3.1%
7.474	7.735	7.936	-2.5%
8.716	8.894	9.256	-3.9%
9.959	9.959	10.575	-5.8%

Contact Information

For more information about the Access BD-pTau217 (RUO) assay or for reagent ordering information, please contact your local Beckman Coulter representative.

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

References

1. Access BD-pTau217 (RUO) IFU D42287
2. Access BD-pTau217 (RUO) Calibrator IFU D42285
3. Access BD-pTau217 (RUO) QC IFU D42286

Not all products are available in all countries.

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

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

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