# INFORMATION BULLETIN

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

### Access BD-Tau (RUO) assay (REF D24829) for use with the Access 2 Immunoassay System and the DxI 9000 Immunoassay Analyzer

Beckman Coulter is pleased to announce the release of our new Access BD-Tau (RUO) assay (REF D24829) for use with the Access 2 Immunoassay System and DxI 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 BD-Tau (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 cautions contained therein.**

Emerging research highlights BD-Tau, an isoform of brain-derived tau, as a highly promising blood-based investigational biomarker for neurodegenerative research applications. Studies across various cohorts consistently demonstrate a robust correlation between plasma BD-Tau levels and cerebrospinal fluid (CSF) total tau (t-tau), with this association proving particularly strong in cases exhibiting both amyloid-beta (Aβ) and tau tangle pathologies. A key advantage of BD-Tau lies in its enhanced specificity compared to other tau markers such as t-tau and phosphorylated tau (p-tau). By enabling the direct detection of a specific short form of brain-derived tau in blood, BD-Tau is posited to more accurately reflect central nervous system pathology, thus minimizing confounding contributions from peripheral tau sources. This enhanced precision and accessibility positions BD-Tau as a valuable tool for researchers investigating neurodegeneration and for stratifying cohorts in clinical research studies.

## Ordering Information

| Access BD-Tau (RUO) | REF |
|---|---|
| Access BD-Tau (RUO) Reagent Kit<br>(100 determinations, 50 determinations/pack, 2 packs/kit) | D24829 |
| Access BD-Tau (RUO) Calibrators<br>(S0 – S5; 1 vial(s)/level, 2.5mL/vial) | D24830 |
| Access BD-Tau (RUO) QC<br>(3 levels; 2 vial(s)/level, 2.5mL/vial) | D24832 |

## Laboratory Operating Essentials

| Access BD-Tau (RUO) Software Codes for the Access 2 Immunoassay and DxI 9000 Immunoassay Analyzer Systems | |
|---|---|
| **Test name / Test ID number** | 236 / BDTauRUO |
| **Calibrator name** | 236 / BDRUOCal |

## 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.

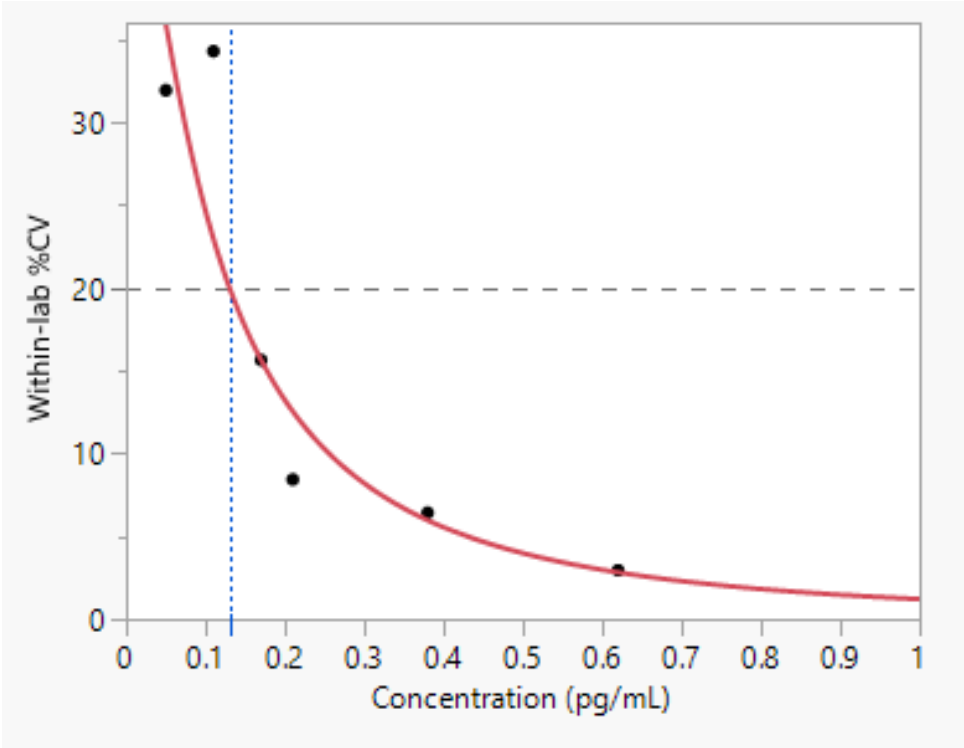
| Assay Characteristic | Access BD-Tau (RUO) | |
|---|---|---|
| **Assay Format** | Two-step sandwich | |
| **Recommended Sample Type** | Plasma (K2-EDTA), Serum, or CSF | |
| **Sample volume (uptake)** | 55 µL | |
| **Unit of measure** | pg/mL | |
| **Analytical measuring range (approximate)** | 0.057 – 300 pg/mL | |
| **Linearity** | -3.0% – 2.4% across measuring interval | |
| **Imprecision** | < 4.0% 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)** | Access 2: 38 minutes | DxI 9000: 32 minutes |
| **Analytical sensitivity (approximate)** | Access 2:<br>LoB: 0.083 pg/mL<br>LoD: 0.181 pg/mL<br>LoQ: 0.337 pg/mL | DxI 9000:<br>LoB: 0.034 pg/mL<br>LoD: 0.057 pg/mL<br>LoQ: 0.131 pg/mL |

The characteristics listed in this table vary from assay-to-assay.

## Assay Sensitivity

Limit of Blank (LoB), Limit of Detection (LoD), and Limit of Quantitation (LoQ) were estimated on the Access 2 and DxI 9000 Immunoassay Analyzers for the Access BD-Tau (RUO) assay, based on CLSI EP17-A2 guidelines, using 1 reagent lot on 1 instrument.

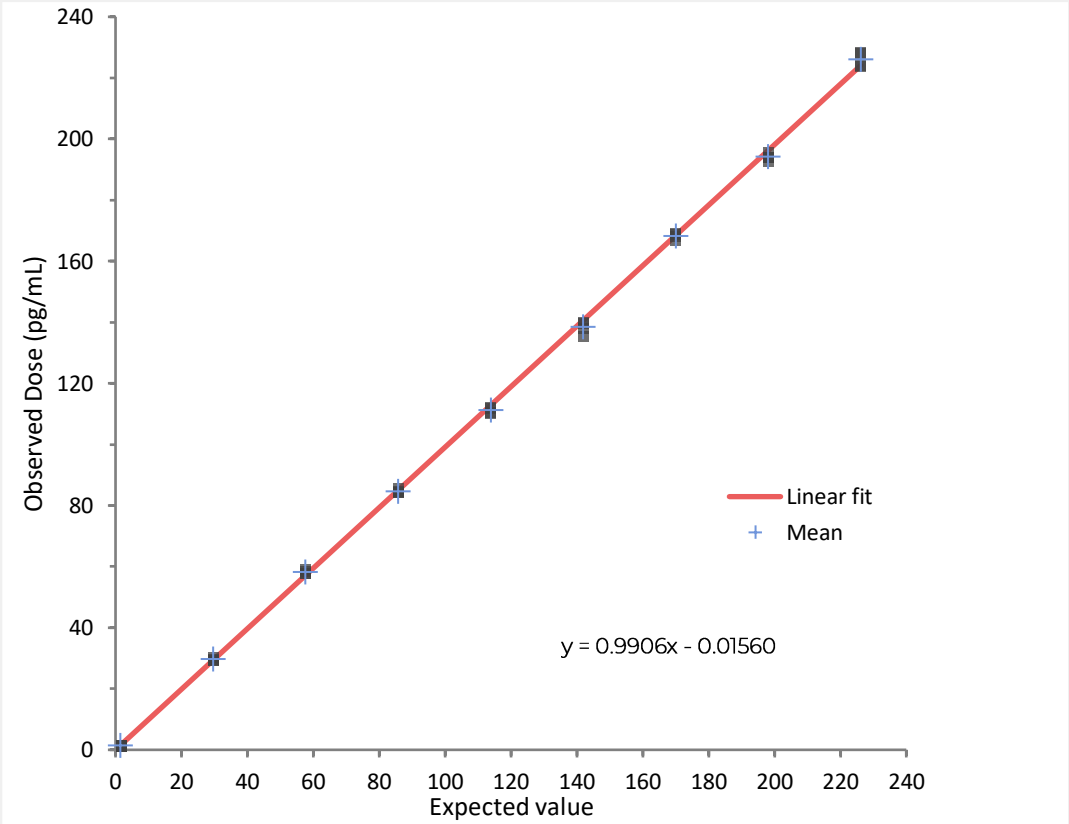
Representative Data of LoQ Precision Profile on DxI 9000




The LoQ at 20% CV is 0.131 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 BD-Tau (RUO) | | | |
|---|---|---|---|
| Expected Concentration (pg/mL) | Observed Concentration (pg/mL) | Linear Fit | Nonlinearity |

| | | | |
|---|---|---|---|
| 1.523 | 1.523 | 1.524 | -0.1% |
| 29.606 | 29.760 | 29.343 | 1.4% |
| 57.689 | 58.402 | 57.161 | 2.2% |
| 85.772 | 84.776 | 84.979 | -0.2% |
| 113.856 | 111.233 | 112.798 | -1.4% |
| 141.939 | 138.477 | 140.616 | -1.5% |
| 170.022 | 168.367 | 168.435 | 0.0% |
| 198.105 | 194.284 | 196.253 | -1.0% |
| 226.189 | 226.189 | 224.072 | 0.9% |

## Contact Information

For more information about the Access BD-Tau (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-Tau (RUO) IFU D29898.
2. Access BD-Tau RUO) Calibrators IFU D29899.
3. Access BD-Tau (RUO) QC IFU D29900.


**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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