BECKMAN COULTER

ACCESS
Immunoassay Systems

Instructions For Use

ACCESS BD-Tau (RUO)
Brain-derived Tau

REF D24829

FOR PROFESSIONAL USE ONLY

FOR RESEARCH USE ONLY

For use on DxI 9000 Access Immunoassay Analyzers

For use on Access 2 Immunoassay Systems

FOR USE WITH TEST NAME: BDTauRUO

PRINCIPLE

INTENDED USE

For Research Use Only (RUO). 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.

METHODOLOGY

Assay type: two-step, sandwich

The Access BD-Tau (RUO) is a sequential two-step, sandwich immunoenzymatic assay. Paramagnetic particles coated with anti-BD-Tau monoclonal antibody are added to a reaction vessel along with buffer and sample. After a short incubation, materials bound to the solid phase are held in a magnetic field while unbound materials are washed away. In the second step, anti-BD-Tau monoclonal antibody conjugated to alkaline phosphatase is added.

After incubation, materials bound to the solid phase are held in a magnetic field while unbound materials are washed away. Then, the chemiluminescent substrate is added to the vessel and light generated by the reaction is measured with a luminometer. The light production is directly proportional to the concentration of analyte in the sample. Analyte concentration is automatically determined from a stored calibration.

SPECIMEN

SPECIMEN COLLECTION AND PREPARATION

1. The role of preanalytical factors in laboratory testing has been described in a variety of published literature.[1,2] To minimize the effect of preanalytical factors, observe the following recommendations for handling and processing blood samples:[1]
    A. Collect all blood samples observing routine precautions for venipuncture.
        a. Follow blood collection tube manufacturer's recommendations for centrifugation.
        b. Ensure residual fibrin and cellular matter has been removed prior to analysis.

B. Allow serum samples to clot completely before centrifugation in a vertical position, with the collection tube closure directed upwards.

   a. To avoid time related absorption, specimens should not be stored in collection vials with gel separators.[3]

   b. Follow the tube manufacturer's recommendations for the length of serum/cells contact time before centrifuging samples. The clotting may be slower at cooler temperatures.

2. Each laboratory should determine the acceptability of its own blood collection tubes and separation products that are in use. There may be variations in these products between manufacturers and between manufacturing lots.
3. Alternate collection types may be appropriate if the laboratory has established its own performance characteristics, as defined by applicable law.
4. Avoid assaying lipemic/hemolyzed samples.
5. Plasma (K2 EDTA) or serum are the recommended sample type. Other sample types may be evaluated at the user's discretion.

REAGENTS

CONTENTS

Access BD-Tau (RUO) Reagent Pack

Ref. No. D24829: 100 determinations, 2 packs, 50 tests/pack

Well	Contents	Ingredients
R1a:	3.22 mL	Paramagnetic particles coated with sheep monoclonal anti-BD-Tau antibody suspended in HEPES buffered saline with Bovine Serum Albumin (BSA) and surfactant, < 0.1% sodium azide and 0.1% ProClin* 300.
R1b:	11.70 mL	Sheep monoclonal anti-BD-Tau alkaline phosphatase conjugate diluted in TRIS buffered saline with protein (bovine, sheep) and surfactant, < 0.1% sodium azide and 0.1% ProClin 300.
R1c:	3.22 mL	HEPES buffered saline with protein (bovine, sheep, recombinant) and surfactant, < 0.1% sodium azide and 0.1% ProClin 300.
R1d:	3.22 mL	HEPES buffered saline with protein (bovine, sheep, recombinant) and surfactant, < 0.1% sodium azide and 0.1% ProClin 300.

*ProClin is a trademark of LANXESS Corp.

WARNING AND PRECAUTIONS

- **For Research Use Only. Not for use in diagnostic procedures.** No clinical decision or patient notification may be made based on results using this research assay.
- Samples and blood-derived products may be routinely processed with minimum risk using the procedure described. However, handle these products as potentially infectious according to universal precautions and good clinical laboratory practices,[4] regardless of their origin, treatment, or prior certification. Use an appropriate disinfectant for decontamination. Store and dispose of these materials and their containers in accordance with local regulations and guidelines.
- This product contains material(s) of animal origin. Observe general safety guidelines for protection when handling this product.
- For hazards presented by the product refer to the following section: REACTIVE INGREDIENTS and GHS HAZARD CLASSIFICATION.

REACTIVE INGREDIENTS

> ⚠ **CAUTION**
>
> **Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).**
> **To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.**

GHS HAZARD CLASSIFICATION

Particles (Compartment R1a)	WARNING	
		
	H317	May cause an allergic skin reaction.
	H412	Harmful to aquatic life with long lasting effects.
	P273	Avoid release to the environment.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
	P362+P364	Take off contaminated clothing and wash it before use.
		reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) < 0.05%
Conjugate (Compartment R1b)	WARNING	
		
	H317	May cause an allergic skin reaction.
	H412	Harmful to aquatic life with long lasting effects.
	P273	Avoid release to the environment.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
	P362+P364	Take off contaminated clothing and wash it before use.
		reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) < 0.05%
Ancillary Reagent (Compartment R1c)	WARNING	

	H317	May cause an allergic skin reaction.
	H412	Harmful to aquatic life with long lasting effects.
	P273	Avoid release to the environment.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
	P362+P364	Take off contaminated clothing and wash it before use.
		reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) < 0.05%
Ancillary Reagent (Compartment R1d)	WARNING	

	H317	May cause an allergic skin reaction.
	H412	Harmful to aquatic life with long lasting effects.
	P273	Avoid release to the environment.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
	P362+P364	Take off contaminated clothing and wash it before use.
		reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) < 0.05%

SDS	Safety Data Sheet is available at beckmancoulter.com/techdocs

MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT

1. Access BD-Tau (RUO) Calibrators

   Provided at zero and approximately 1, 5, 20, 80, and 300 pg/mL

   Ref. No. D24830

2. Quality Control (QC) materials:

   - Access BD-Tau (RUO) QC
     Provided at approximately 6, 30, and 150 pg/mL
     Ref. No. D24832

3. Substrate:
    - Access Substrate, Ref. No. 81906
    - Lumi-Phos PRO, Ref. No. B96000
4. Wash Buffer:
    - UniCel DxI Wash Buffer II, Ref. No. A16793
    - Access Wash Buffer II, Ref. No. A16792

REAGENT PREPARATION

Provided ready to use.

REAGENT STORAGE AND STABILITY

Stability	
Unopened at 2 to 10°C	Up to stated expiration date
After opening at 2 to 10°C	31 days

- Store upright.
- Refrigerate at 2 to 10°C for a minimum of two hours before use on the instrument.
- Signs of possible deterioration are a broken elastomeric layer on the pack or quality control values out of range.
- If the reagent pack is damaged (e.g., broken elastomer), discard the pack.
- Discard reagent if any discoloration is observed.
- Do not freeze.

CALIBRATION

CALIBRATION INFORMATION

An active calibration is required for all tests. Calibration is required every 31 days. See calibrator Instructions For Use (IFU) for additional calibration information. Refer to the appropriate system manuals and/or Help system for information on calibration method, configuring calibrators, calibrator test request entry, and reviewing calibration data.

QUALITY CONTROL

Quality control materials are essential for monitoring the system performance. Quality controls with varying concentration ranges should be run individually at least once every 24 hours when the assay is being performed.[5] Quality control ranges should be determined by each laboratory's individual requirements. Follow applicable regulations and guidelines for quality control.

TESTING PROCEDURE(S)

Refer to the appropriate system manuals and/or Help system for a specific description of installation, start-up, principles of operation, system performance characteristics, operating instructions, calibration procedures, operational limitations and precautions, hazards, maintenance, and troubleshooting.

PROCEDURE

1. Refer to the appropriate system manuals and/or Help system for information on managing samples, configuring tests, requesting tests, and reviewing test results.
2. Mix contents of new (unpunctured) reagent packs by gently inverting pack several times before loading on the instrument. Do not invert open (punctured) packs.
3. Use 55 µL of sample for each determination in addition to the sample container and system dead volumes. Refer to the appropriate system manuals and/or Help system for the minimum sample volume required.
4. The system default unit of measure for sample results is pg/mL.

RESULTS INTERPRETATION

Test results are determined automatically by the system software. Test results can be reviewed using the appropriate screen. Refer to the appropriate system manuals and/or Help system for complete instructions on reviewing sample results.

PERFORMANCE CHARACTERISTICS

ASSAY CRITERIA AND REPRESENTATIVE DATA

Representative data is provided for illustration only. Performance obtained in individual laboratories may vary.

MEASURING INTERVAL

Samples can be measured from the Limit of Detection (LoD) to the highest calibrator value.

LINEARITY

A study was performed on the DxI 9000 Access Immunoassay Analyzer and Access 2 Immunoassay System and determined the assay demonstrated linearity across the measuring interval.

IMPRECISION

A study was performed on the DxI 9000 Access Immunoassay Analyzer and Access 2 Immunoassay System which tested multiple samples in replicates of 5 with 2 runs per day for a minimum of 5 days on a single instrument per platform.

Table 1.0 Imprecision Study Results

			Repeatability (Within-Run)		Between-Run		Within-Laboratory	
Sample	**N**	**Mean (pg/mL)**	**SD (pg/mL)**	**%CV**	**SD (pg/mL)**	**%CV**	**SD (pg/mL)**	**%CV**
Access 2 Immunoassay System								
1	50	3.28	0.096	2.9	0.060	1.8	0.113	3.5
2	50	15.59	0.500	3.2	0.323	2.1	0.596	3.8
3	50	61.69	1.154	1.9	0.848	1.4	1.432	2.3
4	50	224.15	3.990	1.8	5.139	2.3	6.506	2.9
DxI 9000 Access Immunoassay Analyzer								
1	50	2.69	0.039	1.5	0.034	1.3	0.052	1.9

Table 1.0 Imprecision Study Results, Continued

			Repeatability (Within-Run)		Between-Run		Within-Laboratory	
Sample	N	Mean (pg/mL)	SD (pg/mL)	%CV	SD (pg/mL)	%CV	SD (pg/mL)	%CV
2	50	12.47	0.207	1.7	0.184	1.5	0.277	2.2
3	50	49.28	0.705	1.4	1.160	2.4	1.358	2.8
4	50	185.24	2.954	1.6	2.942	1.6	4.169	2.3

INTERFERING SUBSTANCES

The Access BD-Tau assay was evaluated for interferences. A single K2 EDTA plasma sample containing approximately 3 pg/mL of BD-Tau, was spiked with the substances below and run on a single DxI 9000 Access Immunoassay Analyzer. The testing was performed by evaluating controls (no interfering substance added) and matched test samples (with interfering substance added) at the concentrations indicated. Of the compounds tested, none were found to cause significant interference using the highest test concentrations indicated in the following table.

Table 2.0 Interfering Substances Tested

Substance	Highest Concentration Added	Substance	Highest Concentration Added
Donepezil	300 ng/mL	Hemoglobin	5 mg/mL
Memantine	450 ng/mL	Ibuprofen	0.219 mg/mL
Galantamine	500 ng/mL	Acetaminophen	0.156 mg/mL
Aripiprazole	1,800 ng/mL	Heparin	3.3 U/mL
Conjugated Bilirubin	0.4 mg/mL	Triolein	15 mg/mL
Unconjugated Bilirubin	0.4 mg/mL	Rivastigmine	1,200 ng/mL
HSA	60 mg/mL		

DETECTION CAPABILITY

Limit of Blank (LoB), Limit of Detection (LoD), and Limit of Quantitation (LoQ) studies were estimated on the DxI 9000 Access Immunoassay Analyzer and Access 2 Immunoassay System using a protocol based on CLSI guideline EP17-A2.[6] The LoB study was conducted on 1 reagent lot and 1 instrument per platform over a minimum of 3 days. The LoD and LoQ studies were conducted on 1 reagent lot and 1 instrument per platform over a minimum of 5 days.

Table 3.0 Detection Capability Results

	Observed Results	
	pg/mL	
	Access 2 Immunoassay System	DxI 9000 Immunoassay Analyzer
Limit of Blank (LoB)	0.083	0.034
Limit of Detection (LoD)	0.181	0.057
Limit of Quantitation (LoQ) ≤ 20% within-lab CV	0.337	0.131

ADDITIONAL INFORMATION

REVISION HISTORY

Revision A

Initial Release.

SYMBOLS KEY

Glossary of Symbols is available at beckmancoulter.com/techdocs (document number C02724).

REFERENCES

1. Approved Guideline - Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests, GP44-A4. May 2010. Clinical and Laboratory Standards Institute.

2. Approved Guideline - Collection of Diagnostic Venous Blood Specimens, GP41, 7th Edition, April 2017. Clinical and Laboratory Standards Institute.

3. Wild D. The Immunoassay Handbook 1994; 249-250.

4. Biosafety in Microbiological and Biomedical Laboratories. HHS Publication, 6th ed., June 2020.

5. Cembrowski GS, Carey RN. Laboratory quality management: QC ⇌ QA. ASCP Press, Chicago, IL, 1989.

6. Approved Guideline - Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures, EP17-A2. June 2012. Clinical and Laboratory Standards Institute.

Beckman Coulter, Inc., 250 S. Kraemer Blvd., Brea, CA 92821 U.S.A.
+(1) 800-854-3633
www.beckmancoulter.com