Microgenics Corporation
Part of Thermo Fisher Scientific

DRI™ T-UPTAKE APPLICATION
Beckman Coulter DxC 500 AU®

Beckman Coulter Reagent REF 0723

The Application is Intended for the quantitative determination of unsaturated binding sites on the thyroid binding proteins in human serum or plasma.

IVD For In Vitro Diagnostic Use Only
Rx Only

Intended Use

The information provided in this application sheet is intended as a supplement to the package insert. Refer to the package insert for information on intended use, reagent storage, reagent preparation, specimen collection, specimen preparation, specimen storage, quality control, and additional performance data. For package inserts, visit www.thermofisher.com and enter the assay name in the *Search* field.

Ordering Information

Item	Size	Beckman Coulter Reorder Number
DRI T-Uptake Assay	R1: 1 x 100 mL R2: 1 x 34 mL	0723
DRI T-Uptake Calibrators	5 x 2 mL per level	0738
AU Bottle	20 x 30 mL	63094

Technical Support

For Technical Support, please contact your local Beckman Coulter Representative.

Reagent Storage

Refer to the package insert for information on reagent storage. For package inserts, visit www.thermoscientific.com/diagnostics and enter the assay name in the *Search* field.

Continued on next page

Clinical Diagnostics
Microgenics Corporation
46500 Kato Road
Fremont, CA USA
94538
510-979-5000
510-979-5420 fax
www.thermofisher.com
Toll Free: 800-232-3342

Instructions For Use

Procedure for Analyzer

Refer to the operator's manuals for information on analyzer operation. Refer to the package insert for complete reagent preparation.

Prior to pouring into AU bottles, allow the reagent to equilibrate for 15 minutes at refrigerated temperature (2 to 8ºC). Dispense R1 reagent and R2 reagent into appropriate AU bottles as shown in the table below.

	AU Reagent Bottle	
DRI T-Uptake Assay Kit	R1 Compartment	R2 Compartment
Enzyme Conjugate Reagent R1	One Bottle (30 mL)	
Antibody/Substrate Reagent R2		One Bottle (30 mL)

NOTE: *The Enzyme Conjugate (100 mL kit reagent) is placed in the R1 compartment, and the Antibody/Substrate (34 mL kit reagent) is placed in the R2 compartment. This is the reverse of all other DRI applications.*

Warning: These reagents have to be programmed to fixed positions. Do not use the Thermo reagent bottles directly on the AU analyzer.

Results and Data Interpretation

Results for samples will be printed in % T-Uptake.

Specimen Preparation

Refer to the package insert for the complete specimen preparation. The product insert can be found at the Thermo Fisher Scientific website: For package inserts, visit www.thermoscientific.com/diagnostics and enter the assay name in the *Search* field.

Calibration

Use the DRI T-Uptake Calibrator kit. The calibrators are liquid and ready-to-use. Refer to the package insert for the concentration of each calibrator.

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Reagent Name: DRI T-Uptake Assay REF 0723 DxC 500 AU Serum (Plasma) Settings Reagent ID 564
Calibrator Name: DRI T-Uptake Calibrator Kit REF 0738

TEST CONFIGURATION & CHEMISTRY DETAILS

Assay Name	Test	Rev	Discipline	Chemistry

Test ID: cTUP
Calculated Result: ☐
LIS Code: cTUP
Result Type: Quantitative

UNITS AND RANGE SETTINGS

Plasma

Use Settings from: Serum
Units: %
Decimal Places: x.xx
Test Kind: General
Revision: 01
☒ Multi Reagent Switch
Reagent Name: cTUP
Reagent ID: 564
☐ FSE Test

ABB Name: T-U1G
Parameter Long Name: T-Uptake 564 T-U1G Serum

Region: ☒US ☒OUS ☒AP ☐JP ☒EU ☐Other

GENERAL PARAMETERS

SAMPLE VOLUME
Sample Volume: 8.0 µL
Dilution: 0 µL
Predilution Rate: 1

REAGENT VOLUME
R1-1: 180 µL Dilution: 0 µL
R2-1: 60 µL Dilution: 0 µL

WAVELENGTH
Primary: 340 nm
Secondary: 520 nm

METHOD: FIXED 1

REACTION SLOPE: +

MEASURING POINT
Point 1: First: 14 Last: 20
Point 2: First: Last:

Linearity Limit: %

Lag Time Check
☐ Perform Lag Time Check

REACTION OD LIMIT
Low: -2.0000 High: 3.0000

REACTION BLANK OD LIMIT
First: Low: -2.0000 High: 3.0000
Last: Low: -2.0000 High: 3.0000

ANALYTICAL MEASURING RANGE
Low: 15.00 High: 50.00

MANUFACTURER FACTOR
A: 1 B: 0

REAGENT ONBOARD STABILITY
29 Days 0 Hours

LIH INFLUENCE CHECK
☐ Perform LIH check
Lipemia: +
Icterus: +
Hemolysis: +

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Calibrator Name: DRI T-Uptake Calibrator Kit REF 0738, *Continued*

Reagent ID 564

CALIBRATION PARAMETERS									
Base Unit	Decimal Place	Unit 1	Factor 1	Unit 2	Factor 2	Unit 3	Factor 3	Unit 4	Factor 4
%	2	None	0	None	0	None	0	None	0

CALIBRATOR SPECIFIC

Calibration Type: 5AB
Counts: 2
Formula: EIA Type 3
MB Factor:
Calibrator Name
Add: cTUP
Positive Cutoff:
☒ SLOPE CHECK
Number of Levels: 5
Slope Check: +

STABILITY AND INTERVAL

Reagent Blank Stability: Days Hours Interval: Bottle
Calibration Stability: Days Hours Interval: Bottle

CALIBRATION OD AND CONCENTRATION PARAMETERS

☐ Use highest calibrator for Upper AMR

	Calibrator Name	Conc	OD Range Low	OD Range High
Point 1	cTUP CAL-1	15.00	-2.00	3.00
Point 2	cTUP CAL-2	20.00	-2.00	3.00
Point 3	cTUP CAL-3	30.00	-2.00	3.00
Point 4	cTUP CAL-4	40.00	-2.00	3.00
Point 5	cTUP CAL-5	50.00	-2.00	3.00
Point 6				
Point 7				

OD DELTA CHECK

☐ Reagent Blank
☐ Calibration

PROZONE CHECK PARAMETERS

☐ Logic Check 1

Check Points: Point 1: 0; Point 2: 0; Point 3: 0
Decision Values: Value 1: 0; Value 2: 0; Value 3: 0
Limit Points: Limit 1: 0; Limit 2: 27
Check Pattern: Pattern: Pattern 1

☐ Logic Check 2

Check Points: Point 1: 0; Interval: 1
Decision Values: Value 1: 0; Value 2: 0
Limit Points: Limit 1: 0; Limit 2: 27

☐ Logic Check 3

Check Points: Point 1: 0; Interval: 1
Decision Values: Value 1: 0; Value 2: 0
Limit Points: Limit 1: 0; Limit 2: 27

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Additional Information

Important	Since Beckman Coulter does not manufacture the reagent or perform quality control or other tests on individual lots, Beckman Coulter cannot be responsible for the quality of the data obtained which is caused by performance of the reagent, any variation between lots of reagent, or protocol changes by the Manufacturer.
Shipping Damage	Please notify your Beckman Coulter Technical Support Center if this product is received damaged.

End

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