

DRI™ THYROXINE (T4) APPLICATION

Beckman Coulter DxC 500 AU / 500i



Beckman Coulter Reagent REF 0454

The Application is Intended for the Determination of Total Thyroxine 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 Thyroxine (T4) Assay	R1: 1 x 100 mL R2: 1 x 34 mL	0454
DRI Thyroxine (T4) Calibrators	6 x 2 mL per level	0476
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

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 8°C). Dispense R1 reagent and R2 reagent into appropriate AU bottles as shown in the table below:

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

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 µg/dL.

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

Reagent Name: DRI Thyroxine (T4) Assay REF 0454 DxC 500 AU / 500i Serum (Plasma)
Settings
Calibrator Name: DRI Thyroxine Calibrator Kit REF 0476

Reagent ID 563

TEST CONFIGURATION & CHEMISTRY DETAILS

Assay Name	Test	Rev	Discipline	Chemistry
Test ID	<input type="text" value="cT4"/>		Calculated Result	<input type="checkbox"/>
LIS Code	<input type="text" value="cT4"/>		Result Type	<input type="text" value="Quantitative"/>
UNITS AND RANGE SETTINGS				
Use Settings from	<input type="text" value="Serum"/>	Units	<input type="text" value="µg/dL"/>	Decimal Places
				<input type="text" value="x.xx"/>
Test Kind	<input type="text" value="General"/>	Revision	<input type="text" value="01"/>	<input checked="" type="checkbox"/> Multi Reagent Switch
Reagent Name	<input type="text" value="cT4"/>	Reagent ID	<input type="text" value="563"/>	<input type="checkbox"/> FSE Test
ABB Name	<input type="text" value="THY1G"/>	Parameter Long Name	<input type="text" value="Thyroxine 454 THY1G Serum"/>	
Region	<input checked="" type="checkbox"/> US	<input checked="" type="checkbox"/> OUS	<input checked="" type="checkbox"/> AP	<input type="checkbox"/> JP
			<input checked="" type="checkbox"/> EU	<input type="checkbox"/> Other

GENERAL PARAMETERS

SAMPLE VOLUME	Sample Volume	<input type="text" value="4.0"/>	µL	Dilution	<input type="text" value="0"/>	µL	REACTION OD LIMIT	Low	<input type="text" value="-2.0000"/>	High	<input type="text" value="3.0000"/>
	Predilution Rate	<input type="text" value="1"/>					REACTION BLANK OD LIMIT	First: Low	<input type="text" value="-2.0000"/>	High	<input type="text" value="3.0000"/>
REAGENT VOLUME	R1-1	<input type="text" value="180"/>	µL	Dilution	<input type="text" value="0"/>	µL		Last: Low	<input type="text" value="-2.0000"/>	High	<input type="text" value="3.0000"/>
	R2-1	<input type="text" value="60"/>	µL	Dilution	<input type="text" value="0"/>	µL	ANALYTICAL MEASURING RANGE	Low	<input type="text" value="0.70"/>	High	<input type="text" value="20.00"/>
WAVELENGTH	Primary	<input type="text" value="340"/>	nm	Secondary	<input type="text" value="520"/>	nm	MANUFACTURER FACTOR	A	<input type="text" value="1"/>	B	<input type="text" value="0"/>
METHOD	<input type="text" value="FIXED 1"/>						REAGENT ONBOARD STABILITY	<input type="text" value="33"/> Days <input type="text" value="0"/> Hours			
REACTION SLOPE	<input type="text" value="+"/>						LIH INFLUENCE CHECK	<input type="checkbox"/> Perform LIH check			
MEASURING POINT	Point 1: First	<input type="text" value="14"/>		Last	<input type="text" value="20"/>		Lipemia	<input type="text" value="+"/>	<input type="text" value="▼"/>		
	Point 2: First	<input type="text" value=""/>		Last	<input type="text" value=""/>		Icterus	<input type="text" value="+"/>	<input type="text" value="▼"/>		
							Hemolysis	<input type="text" value="+"/>	<input type="text" value="▼"/>		
Linearity Limit	<input type="text" value=""/>						%				
Lag Time Check	<input type="checkbox"/> Perform Lag Time Check										

Reagent Name: DRI Thyroxine (T4) Assay REF 0454 DxC 500 AU / 500i Serum (Plasma)
Settings

Reagent ID 563

Calibrator Name: DRI Thyroxine Calibrator Kit REF 0476, *Continued*

CALIBRATION PARAMETERS

Base Unit	Decimal Place	Unit 1	Factor 1	Unit 2	Factor 2	Unit 3	Factor 3	Unit 4	Factor 4
µg/dL	2	None	0	None	0	None	0	None	0

CALIBRATOR SPECIFIC

Calibration Type

Counts

Formula

MB Factor

Calibrator Name

Positive Cutoff

☒ SLOPE CHECK

Number of Levels

Slope Check

STABILITY AND INTERVAL

Reagent Blank Stability Days

Hours

Interval

Calibration Stability Days

Hours

Interval

CALIBRATION OD AND CONCENTRATION PARAMETERS

☐ Use highest calibrator for Upper AMR

	Calibrator Name	Conc	OD Range Low	OD Range High
Point 1	cT4 CAL-1	0.00	-2.00	3.00
Point 2	cT4 CAL-2	2.00	-2.00	3.00
Point 3	cT4 CAL-3	4.00	-2.00	3.00
Point 4	cT4 CAL-4	8.00	-2.00	3.00
Point 5	cT4 CAL-5	12.00	-2.00	3.00
Point 6	cT4 CAL-6	20.00	-2.00	3.00
Point 7				

OD DELTA CHECK

☐ Reagent Blank

☐ Calibration

PROZONE CHECK PARAMETERS

☐ Logic Check 1

Check Points

Point 1
Point 2
Point 3

Limit Points

Limit 1
Limit 2

Check Pattern

Pattern

☐ Logic Check 2

Check Points

Point 1
Interval

Limit Points

Limit 1
Limit 2

☐ Logic Check 3

Check Points

Point 1
Interval

Limit Points

Limit 1
Limit 2

Decision Values

Value 1
Value 2

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.

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