

DRI™ THYROXINE (T4) APPLICATION

Beckman Coulter DxC 700 AU®



Beckman Coulter Reagent REF 0454

The homogeneous thyroxine enzyme immunoassay is to be used for the quantitative determination of total thyroxine in human serum or plasma.



For In Vitro Diagnostic Use Only
Rx Only

Purpose



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.thermoscientific.com/diagnostics 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:

DRI Thyroxine Assay Kit	AU Reagent Bottle	
	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.

DRI Thyroxine (T4) Assay Beckman Coulter System Parameters, DxC 700 AU

General	LIH	ISE	Calculated Test	Range
Test Name: # ▼ Type: Serum ▼ Operation: Yes ▼				
Sample Volume	<input type="text" value="4.0"/> µL	Dilution <input type="text" value="0"/> ▼ µL	OD Limit	
Pre-Dilution Rate	<input type="text" value="1"/> ▼		Min. OD <input type="text" value="-2.0000"/> Max OD <input type="text" value="3.0000"/>	
Reagent Volume	R1 (R1-1) <input type="text" value="180"/> µL	Dilution <input type="text" value="0"/> µL	Reagent OD Limit 1 st	Low <input type="text" value="-2.0000"/> High <input type="text" value="3.0000"/>
	R1-2 <input type="text"/> µL	Dilution <input type="text"/> µL	Last	Low <input type="text" value="-2.0000"/> High <input type="text" value="3.0000"/>
	R2 (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"/>
Common Reagent	Type <input type="text" value="None"/>	Name <input type="text" value="None"/>	Correlation Factor	A <input type="text" value="1"/> B <input type="text" value="0"/>
Wavelength	Pri <input type="text" value="340"/> ▼ nm	Sec <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="FIXED1"/> ▼			
Reaction Slope	<input type="text" value="+"/> ▼		Onboard Stability Period	<input type="text" value="30"/> Day <input type="text" value="0"/> Hour
Measuring Point-1	1st <input type="text" value="14"/>	Last <input type="text" value="20"/>	LIH Influence Check	<input type="text" value="No"/> ▼
Measuring Point-2	1st <input type="text"/>	Last <input type="text"/>	Lipemia	<input type="text" value="+"/> ▼
Linearity Limit	<input type="text"/> %		Icterus	<input type="text" value="+"/> ▼
Lag Time Check	<input type="text" value="No"/> ▼		Hemolysis	<input type="text" value="+"/> ▼

General	LIH	ISE	Calculated Test	Range
Test Name: # ▼ Type: Serum ▼				
Value/Flag	<input type="text" value="#"/>	Level	Low <input type="text" value="#"/> High <input type="text" value="#"/>	
Specific Ranges				
	Sex	From Year	Month	To Year
				Month
				Other Type
<input type="checkbox"/> 1:	<input type="text" value="#"/> ▼	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>
<input type="checkbox"/> 2:	<input type="text" value="#"/> ▼	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>
<input type="checkbox"/> 3:	<input type="text" value="#"/> ▼	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>
<input type="checkbox"/> 4:	<input type="text" value="#"/> ▼	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>
<input type="checkbox"/> 5:	<input type="text" value="#"/> ▼	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>
<input type="checkbox"/> 6:	<input type="text" value="#"/> ▼	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>
7:	Standard demographics			<input type="text" value="#"/>
8:	Not within expected values			<input type="text" value="#"/>
Critical Limits	Low <input type="text" value="#"/>	High <input type="text" value="#"/>	Unit <input type="text" value="µg/dL"/>	Select <input type="text" value="2"/> Decimal Places

User-defined

DRI Thyroxine (T4) Assay Beckman Coulter System Parameters, DxC 700 AU, *continued*

Calibrators	General	ISE																																																		
Test Name: # Type: Serum																																																				
<input type="checkbox"/> Use Serum Cal.																																																				
Calibration Type: <input type="text" value="6AB"/> Formula: <input type="text" value="POLYGONAL"/> Counts: <input type="text" value="2"/>																																																				
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User-defined

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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