

**QMS™ TACROLIMUS APPLICATION**  
**Beckman Coulter DxC 700 AU®**



Beckman Coulter Reagent REF A53727

The QMS Tacrolimus Immunoassay is intended for the quantitative determination of tacrolimus in human whole blood on automated clinical chemistry analyzers.



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](http://www.thermoscientific.com/diagnostics) and enter the assay name in the *Search* field.

**Ordering Information**

Item	Size	Beckman Coulter Reorder Number
QMS Tacrolimus Assay	R1: 1 x 18 mL R2: 1 x 12 mL Extraction Reagent: 1 x 50mL	A53727
QMS Tacrolimus Calibrator Set	Cal A: 1 x 4mL Cals B-F: 1 x 2 mL	A53728
More Diagnostics Control Level 1	4 x 4 mL	B51007
More Diagnostics Control Level 2	4 x 4 mL	A53712
More Diagnostics Control Level 3	4 x 4 mL	A53713
AU Bottle	20 x 15 mL	63165
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](http://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:

QMS Tacrolimus Assay Kit	AU Reagent Bottle	
	R1 Compartment	R2 Compartment
Anti-Tacrolimus Monoclonal Antibody [R1]	One Bottle (30 mL)	
Tacrolimus-Coated Microparticles [R2]		One Bottle (15 mL)

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

Significant interference from QMS Tacrolimus into Urine/CSF Albumin (B38858/B46435) assays has been observed due to reagent carryover in random access analyzers. Setup the recommended contamination parameters below:

DxC 700 AU Contamination Parameters							
No.	Providing Test Name	Receiving Test Name	Reagent Probe	Wash Count	Effective of Water	Prevent Use	
						Mixer	Cuvette
1	TAC (A53727)	UALB (B38858/B46435)	CLN 100%*	1	No	Yes	No

\*CLN OSR0001/ODR2000, replenish cleaner on a daily basis or as required.

### Results and Data Interpretation

Results for samples will be printed in ng/mL.

### 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](http://www.thermoscientific.com/diagnostics) and enter the assay name in the *Search* field.

### Calibration

Use the QMS Tacrolimus Calibrator set. The calibrators are prepared like patient samples. Refer to the value assignment card for calibrator values to program in the parameters below. These are lot number-specific and should be updated when calibrator lot numbers change.

## QMS Tacrolimus Assay Beckman Coulter System Parameters, DxC 700 AU

General		LIH		ISE		Calculated Test		Range	
<b>Test Name:</b>		#		<b>Type:</b>		Serum		<b>Operation</b>	
		▼				▼		Yes ▼	
Sample Volume		<input type="text" value="10"/>	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="125"/>	μL	Dilution	<input type="text" value="0"/>	μL	Reagent OD Limit		
	R1-2	<input type="text"/>	μL	Dilution	<input type="text"/>	μL	1 <sup>st</sup>	Low <input type="text" value="-2.0000"/>	High <input type="text" value="3.0000"/>
	R2 (R2-1)	<input type="text" value="75"/>	μL	Dilution	<input type="text" value="0"/>	μL	Last	Low <input type="text" value="-2.0000"/>	High <input type="text" value="3.0000"/>
Common Reagent	Type	<input type="text" value="None"/>		Name	<input type="text" value="None"/>		Analytical Measuring Range	Low <input type="text" value="1.00"/>	High <input type="text" value="30.00"/>
Wavelength	Pri	<input type="text" value="700"/>	▼ nm	Sec	<input type="text" value="None"/>		Correlation Factor	A <input type="text" value="1"/>	B <input type="text" value="0"/>
Method		<input type="text" value="FIXED1"/>					Manufacturer Factor	A <input type="text" value="1"/>	B <input type="text" value="0"/>
Reaction Slope		<input type="text" value="+"/>					Onboard Stability Period	<input type="text" value="30"/>	Day <input type="text" value="0"/>
Measuring Point-1	1st	<input type="text" value="20"/>		Last	<input type="text" value="27"/>		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		
<b>Test Name:</b>		#		<b>Type:</b>		Serum		▼		
		▼				▼				
Value/Flag		<input type="text" value="#"/>		Level	Low	<input type="text" value="#"/>	High	<input type="text" value="#"/>		
<b>Specific Ranges</b>										
		From			To		Other Type	Low	High	
<input type="checkbox"/>	1:	Sex <input type="text" value="#"/>	Year <input type="text" value="#"/>	Month <input type="text" value="#"/>	Year <input type="text" value="#"/>	Month <input type="text" value="#"/>	<input type="text" value="None"/>	<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="text" value="#"/>	<input type="text" value="None"/>	<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="text" value="#"/>	<input type="text" value="None"/>	<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="text" value="#"/>	<input type="text" value="None"/>	<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="text" value="#"/>	<input type="text" value="None"/>	<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="#"/>	<input type="text" value="#"/>	<input type="text" value="None"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	
	7:	Standard demographics							<input type="text" value="#"/>	<input type="text" value="#"/>
	8:	Not within expected values							<input type="text" value="#"/>	<input type="text" value="#"/>
Critical Limits		Low	<input type="text" value="#"/>		High	<input type="text" value="#"/>		Unit	<input type="text" value="ng/mL"/>	
								Select	Decimal Places <input type="text" value="2"/>	

# User defined

## QMS Tacrolimus Assay Beckman Coulter System Parameters, DxC 700 AU, *continued*

Calibrators	General	ISE																																																		
<b>Test Name:</b> # <b>Type:</b> Serum																																																				
<input type="checkbox"/> Use Serum Cal.																																																				
Calibration Type: 6AB      Formula: Polygonal      Counts: 2																																																				
<Calibrator Parameters>																																																				
<table border="1"> <thead> <tr> <th rowspan="2"></th> <th rowspan="2">Calibrator</th> <th rowspan="2">OD</th> <th rowspan="2">Conc</th> <th colspan="2">Range</th> </tr> <tr> <th>Low</th> <th>High</th> </tr> </thead> <tbody> <tr> <td>Point-1</td> <td>#</td> <td></td> <td>*</td> <td>-2.0000</td> <td>3.0000</td> </tr> <tr> <td>Point-2</td> <td>#</td> <td></td> <td>*</td> <td>-2.0000</td> <td>3.0000</td> </tr> <tr> <td>Point-3</td> <td>#</td> <td></td> <td>*</td> <td>-2.0000</td> <td>3.0000</td> </tr> <tr> <td>Point-4</td> <td>#</td> <td></td> <td>*</td> <td>-2.0000</td> <td>3.0000</td> </tr> <tr> <td>Point-5</td> <td>#</td> <td></td> <td>*</td> <td>-2.0000</td> <td>3.0000</td> </tr> <tr> <td>Point-6</td> <td>#</td> <td></td> <td>*</td> <td>-2.0000</td> <td>3.0000</td> </tr> <tr> <td>Point-7</td> <td>#</td> <td></td> <td>*</td> <td>-2.0000</td> <td>3.0000</td> </tr> </tbody> </table>				Calibrator	OD	Conc	Range		Low	High	Point-1	#		*	-2.0000	3.0000	Point-2	#		*	-2.0000	3.0000	Point-3	#		*	-2.0000	3.0000	Point-4	#		*	-2.0000	3.0000	Point-5	#		*	-2.0000	3.0000	Point-6	#		*	-2.0000	3.0000	Point-7	#		*	-2.0000	3.0000
	Calibrator	OD					Conc	Range																																												
			Low	High																																																
Point-1	#		*	-2.0000	3.0000																																															
Point-2	#		*	-2.0000	3.0000																																															
Point-3	#		*	-2.0000	3.0000																																															
Point-4	#		*	-2.0000	3.0000																																															
Point-5	#		*	-2.0000	3.0000																																															
Point-6	#		*	-2.0000	3.0000																																															
Point-7	#		*	-2.0000	3.0000																																															
MB Type Factor:      1-Point Calibration Point: None																																																				
<input type="checkbox"/> with Conc-0																																																				
Slope Check: -																																																				
Allowable Range Check: <input type="checkbox"/> Reagent Blank <input type="checkbox"/> Calibration Advanced Calibration Operation: No																																																				
Interval (RB): Interval (ACAL):																																																				
Stability: Reagent Blank: # Day 0 Hour Calibration: # Day 0 Hour																																																				

# User defined  
\* Lot specific calibrator values

## 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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