

QMS™ Tacrolimus APPLICATION

Beckman Coulter DxC 500 AU / 500i



Beckman Coulter Reagent REF A53727

The Application is Intended for the Determination of Tacrolimus in human whole blood.

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
QMS Tacrolimus Assay	R1: 1 x 18 mL R2: 1 x 12 mL	A53727
QMS Tacrolimus Calibrators	Cal A: 1 x 4 mL Cal 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 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.

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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	
QMS Tacrolimus Assay Kit	R1 Compartment	R2 Compartment
Antibody/Substrate Reagent R1	One Bottle (30 mL)	
Microparticles 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 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 and enter the assay name in the *Search* field.

Calibration

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

Reagent Name: QMS Tacrolimus Assay REF A53727 DxC 500 AU / 500i
Settings
Calibrator Name: QMS Tacrolimus Calibrator Kit REF A53728

Reagent ID 559

TEST CONFIGURATION & CHEMISTRY DETAILS

Assay Name	Test	Rev	Discipline	Chemistry		
Test ID	TAC		Calculated Result	<input type="checkbox"/>		
LIS Code	TAC		Result Type	Quantitative ▼		
UNITS AND RANGE SETTINGS						
Use Settings from	None ▼	Units	ng/mL ▼	Decimal Places	x.xx ▼	Other
Test Kind	General ▼	Revision	01	<input checked="" type="checkbox"/> Multi Reagent Switch		
Reagent Name	TAC	Reagent ID	559	<input type="checkbox"/> FSE Test		
ABB Name	TAC1G	Parameter Long Name	Tacrolimus A53727CS TAC1G			
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	10.0 µL	Dilution	0 ▼ µL	REACTION OD LIMIT	Low	-2.0000	High	3.0000
	Predilution Rate	1 ▼			REACTION BLANK OD LIMIT	First: Low	-2.0000	High	3.0000
REAGENT VOLUME	R1-1	125 µL	Dilution	0 µL		Last: Low	-2.0000	High	3.0000
	R2-1	75 µL	Dilution	0 µL	ANALYTICAL MEASURING RANGE	Low	1.00	High	30.00
WAVELENGTH	Primary	700 nm	Secondary	NONE nm	MANUFACTURER FACTOR	A	1	B	0
METHOD	FIXED 1 ▼				REAGENT ONBOARD STABILITY		31 Days		0 Hours
REACTION SLOPE	+				LIH INFLUENCE CHECK	<input type="checkbox"/> Perform LIH check			
MEASURING POINT	Point 1: First	20	Last	27	Lipemia	+	▼		
	Point 2: First		Last		Icterus	+	▼		
					Hemolysis	+	▼		
Linearity Limit		%							
Lag Time Check		<input type="checkbox"/> Perform Lag Time Check							

Reagent Name: QMS Tacrolimus Assay REF A53727 DxC 500 AU / 500i
Settings
Calibrator Name: QMS Tacrolimus Calibrator Kit REF A53728, Continued

Reagent ID 559

CALIBRATION PARAMETERS									
Base Unit	Decimal Place	Unit 1	Factor 1	Unit 2	Factor 2	Unit 3	Factor 3	Unit 4	Factor 4
ng/mL	▼ 2	▼ None ▼	0	None ▼	0	None ▼	0	None ▼	0

CALIBRATOR SPECIFIC

Calibration Type 6AB

Counts 2

Formula Polygonal

MB Factor

Calibrator Name
Add Tacro

Positive Cutoff

☒ SLOPE CHECK Number of Levels 6

Slope Check -

STABILITY AND INTERVAL

Reagent Blank Stability Days Hours
Calibration Stability Days Hours

Interval Bottle
Interval Bottle

CALIBRATION OD AND CONCENTRATION PARAMETERS

☐ Use highest calibrator for Upper AMR

	Calibrator Name	Conc	OD Range Low	OD Range High
Point 1	Tacro CAL-1		-2.00	3.00
Point 2	Tacro CAL-2		-2.00	3.00
Point 3	Tacro CAL-3		-2.00	3.00
Point 4	Tacro CAL-4		-2.00	3.00
Point 5	Tacro CAL-5		-2.00	3.00
Point 6	Tacro CAL-6		-2.00	3.00
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

Limit Points
Limit 1 0
Limit 2 27

☐ Logic Check 3

Check Points
Point 1 0
Interval 1

Limit Points
Limit 1 0
Limit 2 27

Decision Values
Value 1 0
Value 2 0

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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