

## QMS<sup>®</sup> TACROLIMUS APPLICATION BECKMAN COULTER AU480<sup>®</sup>/AU680<sup>®</sup>/AU5800<sup>®</sup>

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. The results obtained are used as an aid in the management of kidney, liver, and heart transplant patients receiving tacrolimus therapy. This in vitro diagnostic device is intended for clinical laboratory use only.

For In Vitro Diagnostic Use 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.

### Ordering Information

Item	Size	Beckman Coulter Reorder Number
QMS Tacrolimus Assay	R1 18 mL, R2 12 mL, Extraction Reagent 50 mL	A53727
QMS Tacrolimus Calibrator Set	6 levels, 4 mL – Calibrator A 2 mL – Calibrators B-F	A53728
More Diagnostics Rap/Tac/CsA Control Level Q	4 x 4 mL	B48482
More Diagnostics Rap/Tac/CsA Control Level 1	4 x 4 mL	B51007
More Diagnostics Rap/Tac/CsA Control Level 2	4 x 4 mL	A53712
More Diagnostics Rap/Tac/CsA Control Level 3	4 x 4 mL	A53713
AU Bottle	15 mL	63165
AU Bottle	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.

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## Instructions For Use

### Procedure for Analyzer

Refer to the operator's manuals for information on analyzer operation. Before use, invert several times, avoiding the formation of bubbles. 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
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 reagent bottles directly on the AU analyzer.

Significant interference from QMS Tacrolimus into the Microalbumin (OSR6167) and Urine/CSF Albumin (B38858/B46435) assays has been observed due to reagent carryover in random access analyzers. Setup the recommended contamination parameters below:

AU480 Contamination Parameters									
No.	PRECEDING TEST NAME	Type	FOLLOWING TEST NAME	Type	REAGENT PROBE CLEANER KIND	WASH COUNT	EFFECTIVE OF WATER CLEANING	SAME USE	
								MIXER	CUVETTE
1	TAC	R1	MALB/UALB	R1	CLN 100%*	1	No	Yes	No
2	TAC	R1	MALB/UALB	R2	CLN 100%*	1	No	Yes	No

AU680 Contamination Parameters							
No.	PRECEDING TEST NAME	FOLLOWING TEST NAME	REAGENT PROBE CLEANER KIND	WASH COUNT	EFFECTIVE OF WATER CLEANING	SAME USE	
						MIXER	CUVETTE
1	TAC	MALB/UALB	CLN 100%*	1	No	Yes	No

AU5800 Contamination Parameters							
No.	PRECEDING TEST NAME	FOLLOWING TEST NAME	REAGENT PROBE CLEANER KIND	WASH COUNT	EFFECTIVE OF WATER CLEANING	SAME USE	
						MIXER	CUVETTE
1	TAC	MALB/UALB	CLN 100%*	1	No	Yes	No

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

Note: For the AU5800 it is recommended to separate MALB and UALB from TAC by using designated rings, if possible.

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**Results and  
Data  
Interpretation**

Results for samples will be printed in ng/mL.

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**Specimen  
Preparation**

Refer to the package insert for the complete specimen preparation. Due to sample stability, it is recommended not to exceed a maximum of 24 extracted samples per run. The product insert can be found at the Thermo Fisher website:

[www.thermoscientific.com/Diagnostics](http://www.thermoscientific.com/Diagnostics)

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**Calibration**

Use the QMS Tacrolimus Calibrator Set. The calibrators are prepared like patient samples. The value on the bottle is the value to use in the parameters below. These are lot number specific and should be updated when calibrator lot numbers change.

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## Application Parameters

### Parameters

The following tables outline the QMS Tacrolimus Assay chemistry parameters on the Beckman AU480, AU680, and AU5800 analyzers.

### QMS TACROLIMUS, AU480

Specific Test Parameters																					
General		LIH		ISE		Range															
Test Name:		TAC		<		>		Type:		Serum		Operation:		Yes							
Sample Volume		10.0		μL		Dilution		0		μL		OD Limit									
Pre-Dilution Rate		1								Min. OD		-2.00		Max. OD		3.00					
Reagents Volume: R1(R1-1)		125		μL		Dilution		0		μL		Reagent OD limit:									
										First Low		-2.00		High		3.00					
										Last Low		-2.00		High		3.00					
R2 (R2-1)		75		μL		Dilution		0		μL		Dynamic Range Low		1.0		High		30.0			
Wavelength: Pri.		700		nm		Sec.		None		nm		Correlation Factor A		1		B		0			
Method:		FIXED1		▽								Factor for Maker A		1		B		0			
Reaction slope:		+		▽								Onboard Stability		#		Days		#		Hour	
Measuring Point 1: First		20				Last		27				LIH Influence Check		#		▽					
Measuring Point 2: First						Last						Lipemia				▽					
Linearity:				%								Icterus				▽					
No Lag Time:		No		▽								Hemolysis				▽					

Specific Test Parameters															
General		ISE		Range											
Test Name:		TAC		<		>		Type:		Serum					
Value/Flag:		#		▽		Level L:		#		Level H:		#			
Specific Ranges:												Panic Value			
		From		To		Low		High		Low		High			
Sex		Year		Month		Year		Month		#		#			
□ 1.		#		▽		#		#		#		#		#	
□ 2.		#		▽		#		#		#		#		#	
□ 3.		#		▽		#		#		#		#		#	
□ 4.		#		▽		#		#		#		#		#	
□ 5.		#		▽		#		#		#		#		#	
□ 6.		#		▽		#		#		#		#		#	
□ 7.		No demographics				#		#		#		#		#	
□ 8.		Not within expected values				#		#		#		#		#	
Unit		ng/mL				Decimal Places		#							

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## QMS TACROLIMUS, AU480, continued

Calibration Specific												
General		ISE										
Test Name:		TAC		<		>		Type:	Serum	<input type="checkbox"/> Use Serum Cal.		
Calibration Type:		6AB		Formula:		POLYGONAL		Counts:	2			
<Calibrator Parameters>												
	Calibrator †	OD	Conc	Factor Range				Slope Check	-			
				Low	High			Allowable Range Check				
Point 1:	#		*	-2.0	3.0			<input type="checkbox"/> Reagent Blank				
Point 2:	#		*	-2.0	3.0			<input type="checkbox"/> Calibration				
Point 3:	#		*	-2.0	3.0			Advanced Calibration				
Point 4:	#		*	-2.0	3.0			Operation	No			
Point 5:	#		*	-2.0	3.0			Interval (RB/ACAL)				
Point 6:	#		*	-2.0	3.0							
Point 7:												
Point 8:												
Point 9:												
Point 10:												
<Point Cal. For Master Curve>				No. of Correction Points		Use Master Curve		<input type="checkbox"/> Lot Calibration				
	Calibrator	OD	Conc	OD Range				Stability				
				Low	High			Reagent Blanks Calibration	#	Day	#	Hour
Point 1:								Calibration	#	Day	#	Hour
Point 2:												
MB Type Factor:				1-Point Calibration Point		None		<input type="checkbox"/> With CONC-0				

# User defined

\* Lot specific calibrator values

Continued on next page

## QMS TACROLIMUS, AU680

Specific Test Parameters										
General		LIH	ISE	Range						
Test Name:	TAC	<	>	Type:	Serum	Operation:	Yes			
Sample Volume	10.0	μL	Dilution	0	μL	OD Limit				
Pre-Dilution Rate	1					Min. OD	-2.00	Max. OD	3.00	
Reagents Volume:	R1(R1-1)	125	μL	Dilution	0	μL	Reagent OD limit:			
						First Low	-2.00	High	3.00	
						Last Low	-2.00	High	3.00	
R2 Volume	75	μL	Dilution	0	μL	Dynamic Range Low	1.0	High	30.0	
Common Reagent	Type	None	Name			Correlation Factor A	1	B	0	
Wavelength:	Pri.	700	nm	Sec.	None	nm	Factor for Maker A	1	B	0
Method:	FIXED1									
Reaction slope:	+									
Measuring Point 1:	First	20	Last	27	Onboard Stability		#	Days	#	Hour
Measuring Point 2:	First		Last		LIH Influence Check		#			
Linearity:										
No Lag Time:	No									
						Lipemia				
						Icterus				
						Hemolysis				

Specific Test Parameters									
General		ISE	Range						
Test Name:	#	<	>	Type:	Serum				
Value/Flag:	TAC	Level L:	#	Level H:	#				
Specific Ranges:									
	Sex	Year	Month	Year	Month	Low	High	Panic Value	
<input type="checkbox"/>	#	#	#	#	#	#	#	Low	High
<input type="checkbox"/>	#	#	#	#	#	#	#	#	#
<input type="checkbox"/>	#	#	#	#	#	#	#	#	#
<input type="checkbox"/>	#	#	#	#	#	#	#	#	#
<input type="checkbox"/>	#	#	#	#	#	#	#	#	#
<input type="checkbox"/>	#	#	#	#	#	#	#	#	#
<input type="checkbox"/>	7. No demographics					#	#		
<input type="checkbox"/>	8. Not within expected values					#	#		
Unit	ng/mL		Decimal Places	#					

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## QMS TACROLIMUS, AU680, continued

Calibration Specific												
General		ISE										
Test Name:		TAC		<		>		Type:	Serum	<input type="checkbox"/> Use Serum Cal.		
Calibration Type:		6AB		Formula:		POLYGONAL		Counts:	2			
<Calibrator Parameters>												
	Calibrator †	OD	Conc	Factor Range				Slope Check	-			
				Low	High			Allowable Range Check				
Point 1:	#		*	-2.0	3.0			<input type="checkbox"/> Reagent Blank				
Point 2:	#		*	-2.0	3.0			<input type="checkbox"/> Calibration				
Point 3:	#		*	-2.0	3.0			Advanced Calibration				
Point 4:	#		*	-2.0	3.0			Operation	No			
Point 5:	#		*	-2.0	3.0			Interval (RB/ACAL)				
Point 6:	#		*	-2.0	3.0							
Point 7:												
Point 8:												
Point 9:												
Point 10:												
<Point Cal. For Master Curve>		No. of Correction Points				Use Master Curve				<input type="checkbox"/> Lot Calibration		
	Calibrator	OD	Conc	OD Range				Stability				
				Low	High			Reagent Blanks	#	Day	#	Hour
Point 1:								Calibration	#	Day	#	Hour
Point 2:												
MB Type Factor:				1-Point Calibration Point		None		<input type="checkbox"/> With CONC-0				

# User defined

\* Lot specific calibrator values

Continued on next page

## QMS TACROLIMUS, AU5800

Parameters		Specific Test Parameters									
General	LIH	ISE	HbA1c		Calculated Test	Range					
Test Name:		TAC	<	>	Type:	Serum	Operation	Yes			
Sample Volume	10.0	μL	Dilution	0	μL	OD Limit					
Pre-Dilution Rate	1	▽	Diluent Bottle	#	▽	Min.OD	-2.00	Max.OD	3.00		
Rgt. Volume	R1(R1-1)	125	μL	Dilution	0	μL	Reagent OD Limit				
	R1-2		μL	Dilution		μL	First	Low	-2.00	High	3.00
							Last	Low	-2.00	High	3.00
	R2(R2-1)	75	μL	Dilution	0	μL					
Common Rgt. Type	None		Name			Dynamic Range Low	1.0	High	30.0		
Wavelength	Pri	700	▽nm	Sec.	None	▽nm	Correlation Factor A	1	B	0	
Method	FIXED1					Factor for Maker A	1	B	0		
Reaction Slope	+					Onboard Stability Period	#	Day	#	Hour	
Measuring Point1 1 <sup>st</sup>	20		Last	27		LIH Influence Check	#	▽			
Measuring Point2 1 <sup>st</sup>			Last			Lipemia		▽			
Linearity Limit						Icterus		▽			
Lag Time Check	No					Hemolysis		▽			

Parameters		Specific Test Parameters						
General	LIH	ISE	HbA1c		Calculated Test	Range		
Test Name:		TAC	<	>	Type:	Serum		
Value/Flag:	#							
Specific Ranges:	From		Level To		Low	#	High	#
	Sex	Year	Month	Year	Month	Low	High	
<input type="checkbox"/> 1.	#	▽	#	#	#	#	#	
<input type="checkbox"/> 2.	#	▽	#	#	#	#	#	
<input type="checkbox"/> 3.	#	▽	#	#	#	#	#	
<input type="checkbox"/> 4.	#	▽	#	#	#	#	#	
<input type="checkbox"/> 5.	#	▽	#	#	#	#	#	
<input type="checkbox"/> 6.	#	▽	#	#	#	#	#	
7.	Standard demographics				#	#	#	
8.	Not within expected values				#	#	#	
Panic Value	Low	#	High	#	Unit	ng/mL	Decimal Places	#

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## QMS TACROLIMUS, AU5800

Parameters		Calibration Parameters			
Calibrators		Calibration Specific			
General		ISE			
Test Name: TAC		< >		Type: Serum	Cuvette:
<input type="checkbox"/> Use Serum Cal.					
Calibration Type: 6AB		Formula: POLYGONAL		Counts: 2	
<b>&lt;Calibrator Parameters&gt;</b>					
	Calibrator	OD	Conc	Range	
				Low	High
Point 1:	#		*	-2.0	3.0
Point 2:	#		*	-2.0	3.0
Point 3:	#		*	-2.0	3.0
Point 4:	#		*	-2.0	3.0
Point 5:	#		*	-2.0	3.0
Point 6:	#		*	-2.0	3.0
Point 7:					
Point 8:					
Point 9:					
Point 10:					
<b>&lt;Point Cal. For Master Curve&gt;</b>		No. of Correction Points	<input type="checkbox"/>	Use Master Curve	<input type="checkbox"/>
				<input type="checkbox"/>	Lot Calibration
	Calibrator	OD	Conc	OD Range	
				Low	High
Point-1					
Point-2					
MB Type Factor:		<input type="checkbox"/> 1-Point Calibration Point	<input type="checkbox"/> None	<input type="checkbox"/> with Conc-0	
				Stability	
				Reagent Blank	# Day # Hour
				Calibration	# Day # Hour
				Slope Check	-
				Allowance Range Check	
				<input type="checkbox"/> Reagent Blank	
				<input type="checkbox"/> Calibration	
				Advanced Calibration Operation	No
				Interval (RB/ACAL)	

# User defined

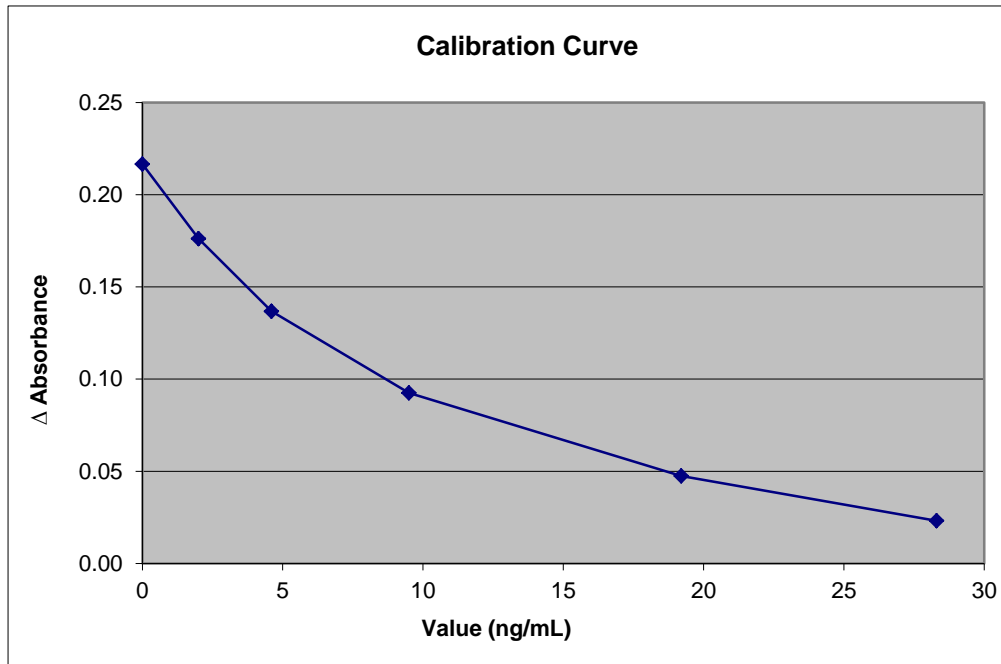
\* Lot specific calibrator values

## Results and Data Interpretation

**Performance Data**

Refer to the QMS Tacrolimus assay kit package insert for additional information on results and data interpretation.

**Example Calibration Curve, Tacrolimus (AU480):**



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## Precision

These degrees of precision and equivalency were obtained in typical testing procedures on an AU system and are not intended to represent the performance specifications for this reagent.

Four levels of control samples were tested in replicates of 2, twice per day for 20 days, total N = 80 on the AU480/AU5800. The results are presented in the following table:

Controls	Control 1	Control 2	Control 3	Control 4
<b>AU480</b>				
Mean (ng/mL)	3.6	10.5	17.6	25.9
Within-Run SD (ng/mL)	0.12	0.29	0.24	0.45
Within-Run CV (%)	3.4	2.7	1.3	1.7
Total SD (ng/mL)	0.26	0.70	0.63	0.95
Total CV (%)	7.2	6.6	3.6	3.7
<b>AU5800</b>				
Mean (ng/mL)	3.7	10.8	17.9	25.8
Within-Run SD (ng/mL)	0.16	0.23	0.97	1.09
Within-Run CV (%)	4.3	2.2	5.4	4.2
Total SD (ng/mL)	0.22	0.60	1.07	1.23
Total CV (%)	6.0	5.6	6.0	4.8

Three whole blood pools comprised of samples obtained from patients taking Tacrolimus and three negative whole blood pools spiked with Tacrolimus were tested in replicates of 2, twice per day for 20 days, total N = 80 on the AU680. The results are presented in the following table:

Controls	Spiked A	Spiked B	Spiked C	Patient Pool A	Patient Pool B	Patient Pool C
<b>AU680</b>						
Mean (ng/mL)	3.0	10.0	20.9	3.2	10.4	24.2
Within-Run SD (ng/mL)	0.15	0.19	0.39	0.13	0.23	0.52
Within-Run CV (%)	4.9	1.9	1.9	4.1	2.2	2.1
Total SD (ng/mL)	0.21	0.36	1.05	0.20	0.37	1.11
Total CV (%)	7.1	3.6	5.0	6.2	3.6	4.6

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**Linearity**

Eleven levels of calibrator and calibrator blends were run against a single calibration curve and the linearity calculated on the AU480 and AU5800.

Ten levels of diluted calibrators were run against a single calibration curve and the linearity calculated on the AU680.

The analytical range for this assay is 1.0 to 30.0 ng/mL. Error flags will appear for samples recovering above or below the assay range.

The Tacrolimus assay recovered between 97 – 110% of expected values on the AU480.

The Tacrolimus assay recovered between 96 – 103% of expected values on the AU680.

The Tacrolimus assay recovered between 100 – 109% of expected values on the AU5800.

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**Limit of Quantitation**

Six levels of low end known samples were run across 5 days, 5 replicates per level and their limit of quantitation calculated.

The observed LoQ for Tacrolimus on the AU480 was 1.0 ng/mL.

The observed LoQ for Tacrolimus on the AU680 was 0.9 ng/mL.

The observed LoQ for Tacrolimus on the AU5800 was 0.8 ng/mL.

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**Accuracy and Correlation**

One hundred and seven blood samples were assayed with the QMS Tacrolimus Assay on the Beckman Coulter AU480 and tested with reference method AU680.

One hundred and eight blood samples were assayed with the QMS Tacrolimus Assay on the Beckman Coulter AU5800 and tested with reference method AU680.

A Deming's Analysis yielded the following:

$AU480 = 1.00*(AU680) - 0.08$  with a correlation coefficient of 0.999.

$AU5800 = 1.02*(AU680) + 0.23$  with a correlation coefficient of 0.998.

Two hundred and sixty-six samples were assayed on the AU680 and compared to the LC-MS/MS method.

A Deming's Analysis yielded the following:

$AU680 = 1.13*(LC-MS/MS) + 0.54$  with a correlation coefficient of 0.965.

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## Additional Information

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**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.

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**Shipping  
Damage**

Please notify your Beckman Coulter Clinical Support Center if this product is received damaged.

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*End*