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QMS® EVEROLIMUS APPLICATION BECKMAN COULTER AU480®/AU680®/AU5800®

Beckman Coulter Reagent REF A53716 (International)

The QMS Everolimus assay is intended for the quantitative determination of everolimus in human whole blood on automated clinical chemistry analyzers. The results obtained are used as an aid in the management of organ transplant patients receiving everolimus therapy.

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® Everolimus Assay	R1 22 mL, R2 8 mL, Precipitation Reagent 8 mL	A53716
QMS Everolimus Calibrator Set	6 levels, 3mL 1 bottle ea	A53724
QMS Everolimus Control Set	3 levels, 3mL 1 bottle ea	A53717
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 Everolimus Assay Kit	R1 Compartment	R2 Compartment
Anti-Everolimus Polyclonal Antibody R1	One Bottle (30 mL)	
Everolimus-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 Everolimus 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	EVR	R1	MALB/UALB	R1	Water	3	Yes	Yes	No
2	EVR	R1	MALB/UALB	R2	Water	3	Yes	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	EVR	MALB/UALB	Water	3	Yes	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	EVR	MALB/UALB	Water	3	Yes	Yes	No

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

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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. 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
Calibration	Use the QMS Everolimus Calibrator Set. The calibrators are prepared like patient samples. The value on the bottle is the value to use in the parameters below. Lot-to-lot values do not change.

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Application Parameters

Parameters

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

QMS EVEROLIMUS, AU480

Specific Test Parameters

General | LIH | ISE | Range

Test Name: EVER ∇ < > 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)	175	µL	Dilution	0	µL	Reagent OD limit:			
						First Low	-2.00	High	3.00
						Last Low	-2.00	High	3.00
R2 (R2-1)	45	µL	Dilution	0	µL				
						Dynamic Range Low	1.5	High	20.0
						Correlation Factor A	1	B	0
Wavelength: Pri.	700	nm	Sec.	None	nm	Factor for Maker A	1	B	0
Method:	FIXED1 ∇								
Reaction slope:	+ ∇					Onboard Stability	#	Days #	Hour
Measuring Point 1: First	24		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: EVER ∇ < > Type: Serum ∇

Value/Flag: # ∇ Level L: # Level H: #

Specific Ranges:

	Sex	From Year	From Month	To Year	To Month	Low	High
☐ 1.	# ∇	#	#	#	#	#	#
☐ 2.	# ∇	#	#	#	#	#	#
☐ 3.	# ∇	#	#	#	#	#	#
☐ 4.	# ∇	#	#	#	#	#	#
☐ 5.	# ∇	#	#	#	#	#	#
☐ 6.	# ∇	#	#	#	#	#	#
7. No demographics						#	#
8. Not within expected values						#	#

Panic Value

Low	High
#	#

Unit ng/mL Decimal Places #

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QMS EVEROLIMUS, AU480, continued

Calibration Specific

General | ISE

Test Name: EVER ∇ | < | > | Type Serum ∇ | ☐ Use Serum Cal.

Calibration Type: 6AB ∇ | Formula: EIA Type 1 ∇ | Counts: 2

<Calibrator Parameters> | Slope Check - ∇

	Calibrator †	OD	Conc	Factor Range Low	Factor Range High
Point 1:	# ∇		0.00	-2.0	3.0
Point 2:	# ∇		1.50	-2.0	3.0
Point 3:	# ∇		3.00	-2.0	3.0
Point 4:	# ∇		6.00	-2.0	3.0
Point 5:	# ∇		12.00	-2.0	3.0
Point 6:	# ∇		20.00	-2.0	3.0
Point 7:	∇				
Point 8:	∇				
Point 9:	∇				
Point10:	∇				

Allowable Range Check
☐ Reagent Blank
☐ Calibration

Advanced Calibration
Operation ∇
Interval (RB/ACAL) ∇

<Point Cal. For Master Curve> | No. of Correction Points ∇ | Use Master Curve ∇ | ☐ Lot Calibration

	Calibrator	OD	Conc	OD Range Low	OD Range High
Point 1:					
Point 2:					

Stability
Reagent Blanks # Day # Hour
Calibration # Day # Hour

MB Type Factor: | 1-Point Calibration Point ∇ | ☐ With CONC-0

User defined

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QMS EVEROLIMUS, AU680

Specific Test Parameters

General | LIH | ISE | Range

Test Name: EVER ▽ < > 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)	175 µL	Dilution	0 µL	Reagent OD limit:			
						First Low	-2.00	High 3.00
						Last Low	-2.00	High 3.00
	R2 Volume	45 µL	Dilution	0 µL				
						Dynamic Range Low	1.5	High 20.0
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:		+ ▽				Onboard Stability	# Days	# Hour
Measuring Point 1:	First	24	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: EVER ▽ < > Type: Serum ▽

Value/Flag: # ▽ Level L: # Level H: #

Specific Ranges:

		From		To				Panic Value	
	Sex	Year	Month	Year	Month	Low	High	Low	High
☐ 1.	# ▽	#	#	#	#	#	#	#	#
☐ 2.	# ▽	#	#	#	#	#	#		
☐ 3.	# ▽	#	#	#	#	#	#		
☐ 4.	# ▽	#	#	#	#	#	#		
☐ 5.	# ▽	#	#	#	#	#	#		
☐ 6.	# ▽	#	#	#	#	#	#		
7. No demographics						#	#		
8. Not within expected values						#	#		

Unit ng/mL Decimal Places #

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QMS EVEROLIMUS, AU680, continued

Calibration Specific

General | ISE

Test Name: EVER ∇ | < | > | Type Serum ∇ | ☐ Use Serum Cal.

Calibration Type: 6AB ∇ | Formula: EIA Type 1 ∇ | Counts: #

<Calibrator Parameters> | Slope Check: - ∇

	Calibrator †	OD	Conc	Factor Range Low	Factor Range High
Point 1:	# ∇		0.00	-2.0	3.0
Point 2:	# ∇		1.50	-2.0	3.0
Point 3:	# ∇		3.00	-2.0	3.0
Point 4:	# ∇		6.00	-2.0	3.0
Point 5:	# ∇		12.00	-2.0	3.0
Point 6:	# ∇		20.00	-2.0	3.0
Point 7:	∇				
Point 8:	∇				
Point 9:	∇				
Point10:	∇				

Allowable Range Check
☐ Reagent Blank
☐ Calibration

Advanced Calibration
Operation ∇
Interval (RB/ACAL) ∇

<Point Cal. For Master Curve> | No. of Correction Points ∇ | Use Master Curve ∇ | ☐ Lot Calibration

	Calibrator	OD	Conc	OD Range Low	OD Range High
Point 1:					
Point 2:					

Stability
Reagent Blanks ____ Day ____ Hour
Calibration ____ Day ____ Hour

MB Type Factor: | 1-Point Calibration Point ∇ | ☐ With CONC-0

User defined

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QMS EVEROLIMUS, AU5800

Parameters			Specific Test Parameters		
General	LIH	ISE	HbA1c	Calculated Test	Range

Test Name: EVER ∇ | < | > | Type: Serum ∇ | Operation Yes ∇

Sample Volume		8.9 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)	156 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)	40 µL	Dilution	0 µL						
					Dynamic Range	Low	1.5	High	20.0	
Common Rgt. 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		+ ∇			Onboard Stability Period		# Day	# Hour		
Measuring Point1 1st		24	Last	27	LIH Influence Check		# ∇			
Measuring Point2 1st			Last		Lipemia		∇			
Linearity Limit		%			Icterus		∇			
Lag Time Check		No ∇			Hemolysis		∇			

Parameters			Specific Test Parameters		
General	LIH	ISE	HbA1c	Calculated Test	Range

Test Name: EVER ∇ | < | > | Type: Serum ∇

Value/Flag: # ∇

Level Low # High #

Specific Ranges:

	From Sex	From Year	From Month	To Year	To Month	Low	High
☐ 1.	# ∇	#	#	#	#	#	#
☐ 2.	# ∇	#	#	#	#	#	#
☐ 3.	# ∇	#	#	#	#	#	#
☐ 4.	# ∇	#	#	#	#	#	#
☐ 5.	# ∇	#	#	#	#	#	#
☐ 6.	# ∇	#	#	#	#	#	#
7. Standard demographics						#	#
8. Not within expected values						#	#

Panic Value Low # High # Unit ng/mL Decimal Places #

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QMS EVEROLIMUS, AU5800, continued

Parameters | Calibration Parameters
Calibrators | Calibration Specific
General | ISE

Test Name: EVER ▽ < > Type Serum ▽ Cuvette . ▽
□ Use Serum Cal.

Calibration Type: 6AB ▽ Formula: EIA Type 1 ▽ Counts: 2 ▽

<Calibrator Parameters>

	Calibrator	OD	Conc	Range Low	Range High
Point 1:	# ▽		0.00	-2.0	3.0
Point 2:	# ▽		1.50	-2.0	3.0
Point 3:	# ▽		3.00	-2.0	3.0
Point 4:	# ▽		6.00	-2.0	3.0
Point 5:	# ▽		12.00	-2.0	3.0
Point 6:	# ▽		20.00	-2.0	3.0
Point 7:	▽				
Point 8:	▽				
Point 9:	▽				
Point 10:	▽				

Slope Check - ▽

Allowance Range Check
□ Reagent Blank
□ Calibration

Advanced Calibration Operation No ▽

Interval (RB/ACAL) ▽

<Point Cal. For Master Curve> No. of Correction Points ▽ Use Master Curve ▽ □ Lot Calibration

	Calibrator	OD	Conc	OD Range Low	OD Range High
Point-1	▽				
Point-2	▽				

Stability
Reagent Blank # Day # Hour
Calibration # Day # Hour

MB Type Factor: 1-Point Calibration Point None ▽ □ with Conc-0

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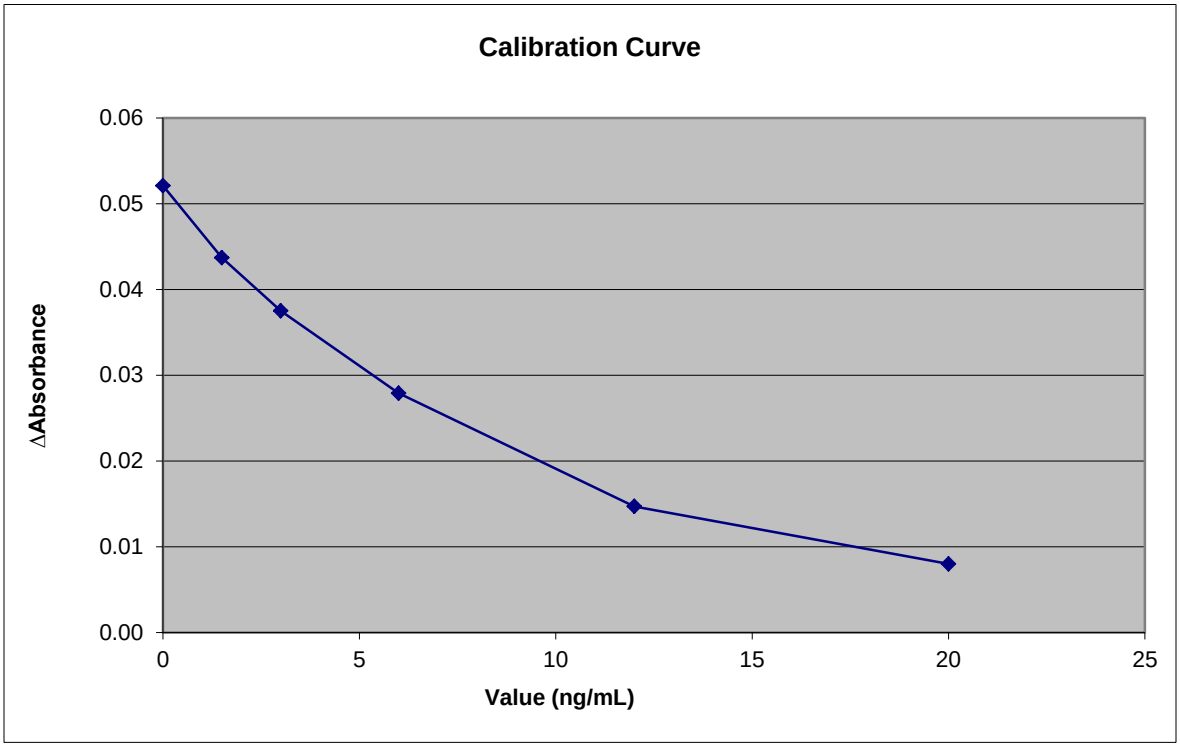
Results and Data Interpretation

Performance Data

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

Example Calibration Curve, Everolimus (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.

Control samples were tested in replicates of 2, twice per day for 20 days, total N = 80. The results are presented in the following table:

Controls	Control 1	Control 2	Control 3
AU480			
Mean (ng/mL)	3.9	7.5	14.1
Within-Run SD (ng/mL)	0.28	0.46	0.81
Within-Run CV (%)	7.1	6.1	5.7
Total SD (ng/mL)	0.41	0.52	1.02
Total CV (%)	10.5	6.9	7.2
AU680			
Mean (ng/mL)	4.2	8.0	15.6
Within-Run SD (ng/mL)	0.17	0.35	0.81
Within-Run CV (%)	4.1	4.4	5.2
Total SD (ng/mL)	0.20	0.43	0.91
Total CV (%)	4.9	5.3	5.8
AU5800			
Mean (ng/mL)	3.9	7.4	14.1
Within-Run SD (ng/mL)	0.27	0.41	0.90
Within-Run CV (%)	6.8	5.5	6.4
Total SD (ng/mL)	0.40	0.64	1.14
Total CV (%)	10.1	8.7	8.1

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Linearity

Eleven levels of calibrators and calibrator blends were run against a single calibration curve and the linearity calculated. The analytical range for this assay is 1.5 to 20.0 ng/mL. Error flags will appear for samples recovering above or below the assay range.

The Everolimus assay recovered between 93 – 103% of expected values on the AU480.

The Everolimus assay recovered between 97 – 106% of expected values on the AU680.

The Everolimus assay recovered between 93 – 103% of expected values on the AU5800.

LDD

The negative calibrator was run against the same calibration curve for 21 replicates. The LDD is calculated as 2*SD.

The observed LDD for the Everolimus Assay on the AU480 was 0.3 ng/mL.

The observed LDD for the Everolimus Assay on the AU680 was 0.2 ng/mL.

The observed LDD for the Everolimus Assay on the AU5800 was 0.2 ng/mL.

Accuracy and Correlation

One hundred and twenty-one blood samples were assayed with the QMS Everolimus Assay on the Beckman Coulter AU480 and tested with reference method Hitachi 917.

One hundred and fifty blood samples were assayed with the QMS Everolimus Assay on the Beckman Coulter AU680 and tested with reference method Hitachi 917.

One hundred and six blood samples were assayed with the QMS Everolimus Assay on the Beckman Coulter AU5800 and tested with reference method Hitachi 917.

A Deming's Regression Analysis for Everolimus yielded the following:

Beckman Coulter AU480 = 0.95*(Hitachi 917) -0.10 with a correlation coefficient of 0.992

Beckman Coulter AU680 = 0.99*(Hitachi 917) - 0.13 with a correlation coefficient of 0.923

Beckman Coulter AU5800 = 0.99*(Hitachi 917) + 0.13 with a correlation coefficient of 0.982

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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 Clinical Support Center if this product is received damaged.

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