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Microgenics Corporation
Part of Thermo Fisher Scientific

QMS™ EVEROLIMUS APPLICATION
Beckman Coulter DxC 700 AU®

CE

Beckman Coulter Reagent REF A53729 (US), A53716 (OUS)

The QMS Everolimus Assay is to be used for the quantitative determination of everolimus in human whole blood on automated clinical chemistry analyzers.

IVD 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
QMS Everolimus Assay	R1: 1 x 22 mL R2: 1 x 8 mL Precipitation Reagent: 1 x 8 mL	A53729 (US) A53716 (OUS)
QMS Everolimus Calibrator Set	6 levels 1 x 3 mL per level	A53721 (US) A53724 (OUS)
QMS Everolimus Control Set	3 levels 1 x 3 mL per level	A53717
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 and enter the assay name in the *Search* field.

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Clinical Diagnostics
Microgenics Corporation
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510-979-5420 fax
www.thermofisher.com
Toll Free: 800-232-3342

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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 8ºC). 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 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	EVR (A53729 US) (A53716 OUS)	UALB (B38858/B46435)	Water	3	Yes	Yes	Yes

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 Everolimus Calibrator set. The calibrators are prepared like patient samples.

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QMS Everolimus Assay
Beckman Coulter System Parameters, DxC 700 AU

General | LIH | ISE | Calculated Test | Range

Test Name: # ▼ **Type:** Serum ▼ **Operation** Yes ▼

Sample Volume		10 µL	Dilution	0 ▼ µL	OD Limit					
Pre-Dilution Rate		1 ▼					Min. OD	-2.0000	Max OD	3.0000
					Reagent OD Limit					
Reagent Volume	R1 (R1-1)	175 µL	Dilution	0 µL	1st		Low	-2.0000	High	3.0000
	R1-2	µL	Dilution	µL	Last		Low	-2.0000	High	3.0000
	R2 (R2-1)	45 µL	Dilution	0 µL	Analytical Measuring Range		Low	1.500	High	20.00
Common Reagent	Type	None	Name	None	Correlation Factor		A	1	B	0
Wavelength	Pri	700 ▼ nm	Sec	None ▼ nm	Manufacturer Factor		A	1	B	0
Method		FIXED1 ▼								
Reaction Slope		+ ▼			Onboard Stability Period		29 Day		0 Hour	
Measuring Point-1	1st	24	Last	27	LIH Influence Check		No ▼			
Measuring Point-2	1st		Last		Lipemia		+ ▼			
Linearity Limit		%			Icterus		+ ▼			
Lag Time Check		No ▼			Hemolysis		+ ▼			

General | LIH | ISE | Calculated Test | **Range**

Test Name: # ▼ **Type:** Serum ▼

Value/Flag # Level Low # High #

Specific Ranges

	Sex	From Year	From Month	To Year	To Month	Other Type	Low	High
☐ 1:	# ▼	#	#	#	#	None	#	#
☐ 2:	# ▼	#	#	#	#	None	#	#
☐ 3:	# ▼	#	#	#	#	None	#	#
☐ 4	# ▼	#	#	#	#	None	#	#
☐ 5:	# ▼	#	#	#	#	None	#	#
☐ 6:	# ▼	#	#	#	#	None	#	#
7:	Standard demographics						#	#
8:	Not within expected values						#	#

Critical Limits Low # High # Unit ng/mL Select Decimal Places 2

User-defined

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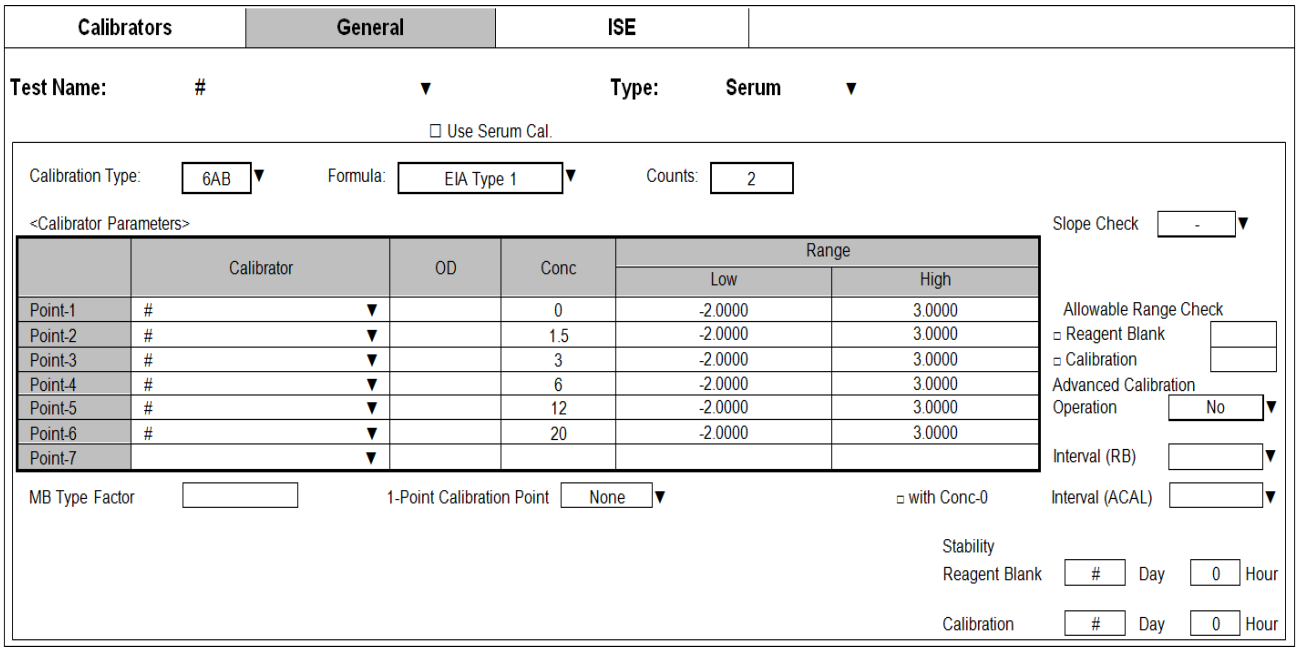
QMS Everolimus Assay
Beckman Coulter System Parameters, DxC 700 AU, *continued*



Calibrators | General | ISE

Test Name: # ▼ Type: Serum ▼

☐ Use Serum Cal.

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

<Calibrator Parameters>

	Calibrator	OD	Conc	Range Low	Range High
Point-1	# ▼		0	-2.0000	3.0000
Point-2	# ▼		1.5	-2.0000	3.0000
Point-3	# ▼		3	-2.0000	3.0000
Point-4	# ▼		6	-2.0000	3.0000
Point-5	# ▼		12	-2.0000	3.0000
Point-6	# ▼		20	-2.0000	3.0000
Point-7	▼				

Slope Check - ▼

Allowable Range Check
□ Reagent Blank
□ Calibration
Advanced Calibration Operation No ▼

Interval (RB) ▼

MB Type Factor 1-Point Calibration Point None ▼ □ with Conc-0 Interval (ACAL) ▼

Stability
Reagent Blank # Day 0 Hour
Calibration # Day 0 Hour

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.

CE

EC REP B·R·A·H·M·S GmbH, Neuendorfstrasse 25, 16761, Hennigsdorf, Germany

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