

QMS™ Everolimus APPLICATION Beckman Coulter DxC 500 AU / 500i

Beckman Coulter Reagent REF A53729

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



For In Vitro Diagnostic Use Only
For US and Canada Use 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 Everolimus (Ever) Assay	R1: 1 x 22 mL R2: 1 x 8 mL	A53729
QMS Everolimus (Ever) Calibrators	3 mL per level	A53721
QMS Everolimus (Ever) Controls	3 mL per level	A53717
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 Everolimus 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 Everolimus Calibrator kit. The calibrators are liquid and ready-to-use. Refer to the package insert for the concentration of each calibrator.

Reagent Name: QMS Everolimus Assay REF A53729 DxC 500 AU / 500i Settings
Calibrator Name: QMS Everolimus Calibrator Kit REF A53721

Reagent ID 560

TEST CONFIGURATION & CHEMISTRY DETAILS

Assay Name	Test	Rev	Discipline	Chemistry		
Test ID	EVER		Calculated Result	<input type="checkbox"/>		
LIS Code	EVER		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	EVER	Reagent ID	560	<input type="checkbox"/> FSE Test		
ABB Name	EVL1U	Parameter Long Name	Everolimus A53729 EVL1U Other			
Region	<input checked="" type="checkbox"/> US	<input type="checkbox"/> OUS	<input type="checkbox"/> AP	<input type="checkbox"/> JP	<input 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	175	μL	Dilution	0	μL		Last: Low	-2.0000	High	3.0000	
	R2-1	45	μL	Dilution	0	μL	ANALYTICAL MEASURING RANGE	Low	1.50	High	20.00	
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	24		Last	27		Lipemia	+ ▼				
	Point 2: First			Last			Icterus	+ ▼				
							Hemolysis	+ ▼				
Linearity Limit												
Lag Time Check	<input type="checkbox"/> Perform Lag Time Check											

Reagent Name: QMS EverolimusAssay REF A53729 DxC 500 AU / 500i Settings
Calibrator Name: QMS Everolimus Calibrator Kit REF A53721, *Continued*

Reagent ID 560

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

Counts

Formula

MB Factor

Calibrator Name

Positive Cutoff

☒ SLOPE CHECK

Number of Levels

Slope Check

STABILITY AND INTERVAL

Reagent Blank Stability Days Hours

Interval

Calibration Stability Days Hours

Interval

CALIBRATION OD AND CONCENTRATION PARAMETERS

☐ Use highest calibrator for Upper AMR

	Calibrator Name	Conc	OD Range Low	OD Range High
Point 1	Ever CAL-1	0.00	-2.00	3.00
Point 2	Ever CAL-2	1.50	-2.00	3.00
Point 3	Ever CAL-3	3.00	-2.00	3.00
Point 4	Ever CAL-4	6.00	-2.00	3.00
Point 5	Ever CAL-5	12.00	-2.00	3.00
Point 6	Ever CAL-6	20.00	-2.00	3.00
Point 7				

OD DELTA CHECK

☐ Reagent Blank

☐ Calibration

PROZONE CHECK PARAMETERS

☐ Logic Check 1

Check Points

Point 1
Point 2
Point 3

Decision Values

Value 1
Value 2
Value 3

Limit Points

Limit 1
Limit 2

Check Pattern

Pattern

☐ Logic Check 2

Check Points

Point 1
Interval

Limit Points

Limit 1
Limit 2

☐ Logic Check 3

Check Points

Point 1
Interval

Limit Points

Limit 1
Limit 2

Decision Values

Value 1
Value 2

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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