

QMS™ EverolimusAPPLICATION Beckman Coulter DxC 500 AU / 500i



Beckman Coulter Reagent REF A53716

The Application is Intended for the Determination of Everolimus 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 Everolimus (Ever) Assay	R1: 1 x 22 mL R2: 1 x 8 mL	A53716
QMS Everolimus (Ever) Calibrators	3 mL per level	A53724
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 EverolimusAssay REF A53716 DxC 500 AU / 500i Settings
Calibrator Name: QMS Everolimus Calibrator Kit REF A53724

Reagent ID 560

TEST CONFIGURATION & CHEMISTRY DETAILS

Assay Name	Test	Rev	Discipline	Chemistry
Test ID	EVER+		Calculated Result	☐
LIS Code	EVER+		Result Type	Quantitative ▼
UNITS AND RANGE SETTINGS				
Use Settings from	None ▼	Units	ng/mL ▼	Decimal Places
				x.xx ▼
Test Kind	General ▼	Revision	01	☒ Multi Reagent Switch
Reagent Name	EVER	Reagent ID	560	☐ FSE Test
ABB Name	EVL1N	Parameter Long Name	Everolimus A53716 EVL1N Other	
Region	☐ US	☒ OUS	☒ AP	☐ JP
		☒ EU	☐ 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	☐ Perform LIH check			
MEASURING POINT	Point 1: First	24		Last	27		Lipemia	+ ▼			
	Point 2: First			Last			Icterus	+ ▼			
							Hemolysis	+ ▼			
Linearity Limit											
Lag Time Check	☐ Perform Lag Time Check										

Reagent Name: QMS Everolimus Assay REF A53716 DxC 500 AU / 500i Settings
Calibrator Name: QMS Everolimus Calibrator Kit REF A53724, 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 6AB

Counts 2

Formula EIA Type 1

MB Factor

Calibrator Name

Positive Cutoff

☒ SLOPE CHECK

Number of Levels 6

Slope Check -

STABILITY AND INTERVAL

Reagent Blank Stability Days

Interval Bottle

Calibration Stability Days

Interval Bottle

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 0
Point 2 0
Point 3 0

Decision Values

Value 1 0
Value 2 0
Value 3 0

☐ Logic Check 2

Check Points

Point 1 0
Interval 1

Decision Values

Value 1 0
Value 2 0

☐ Logic Check 3

Check Points

Point 1 0
Interval 1

Decision Values

Value 1 0
Value 2 0

Limit Points

Limit 1 0
Limit 2 27

Limit Points

Limit 1 0
Limit 2 27

Limit Points

Limit 1 0
Limit 2 27

Check Pattern

Pattern Pattern 1

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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