

QMS[®] VANCOMYCIN APPLICATION
Beckman Coulter AU400[®], AU480[®], AU640[®], AU680[®],
AU2700[®], AU5400[®] and AU5800[®]



Catalog No. 0373589 & 10017224

Intended for the quantitative determination of Vancomycin in human serum or plasma

For In Vitro Diagnostic 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.

Materials available from Microgenics, a part of Thermo Fisher Scientific

Ordering Information

Item	Size	Thermo Fisher Scientific Catalog No.
QMS Vancomycin Assay	Reagent 1: 22 mL Reagent 2: 22 mL	0373589
	Reagent 1: 19 mL Reagent 2: 19 mL	10017224
QMS Vancomycin Calibrator Set	6 levels, 1 x 1.0 mL each	0373597

To place an order or for technical service contact:

In USA	In Europe
Tel: (800) 232-3342 Fax: 510-979-5420	Tel: +49 (0)851-88 6890 Fax: +49 (0)851-88 68910



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U.S. Toll free: (800) 232-3342 / Tel: (510) 979-5000
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Reagent Storage

Refer to the package insert for information on reagent storage.

Analyzer Procedure

Refer to the operator's manual for information on analyzer operation.

AU400/AU480 Contamination Avoidance Parameters							
No.	PRECEDING TEST NAME	FOLLOWING TEST NAME	REAGENT PROBE CLEANER	WASH COUNT	CANCEL	SAME USE	
						MIXER	CUVETTE
1.	VANCO R1	∞UAlb 224R1	Water	5	Yes	No	Yes
2.*	VANCO R1	∞UAlb 224R2	Water	5	Yes	No	Yes

∞ Refers to reagent part numbers B38858/B46435.

Note: When selecting a preceding R1 and a following R1, R2 to R2 is also automatically selected. There is no facility for selecting a preceding R2 and a following R2 on the AU400/AU480 instrument.

AU640/AU2700/AU5400 Contamination Avoidance Parameters							
No.	PRECEDING TEST NAME	FOLLOWING TEST NAME	REAGENT PROBE CLEANER	WASH COUNT	CANCEL	SAME USE	
						MIXER	CUVETTE
1.	VANCO	∞ UAlb 224	Water	5	Yes	No	Yes

∞ Refers to reagent part numbers B38858/B46435.

Note: For the AU2700/AU5400, contamination may also be avoided by placing the assays in separate cuvette rings from each other e.g. Vancomycin (inner ring) and Urine Albumin (outer ring).

AU680/AU5800 Contamination Avoidance Parameters							
No.	PRECEDING TEST NAME	FOLLOWING TEST NAME	REAGENT PROBE CLEANER	WASH COUNT	EFFECTIVE OF WATER CLEANING	SAME USE	
						MIXER	CUVETTE
1.	VANCO	∞UAlb 224	Water	5	Yes	No	Yes

∞ Refers to reagent part numbers B38858/B46435.

Note: For the AU5800, contamination may also be avoided by placing the assays in separate cuvette rings from each other e.g. Vancomycin (inner ring) and Urine Albumin (outer ring).

**Results and
Data
Interpretation**

Results for samples will be printed in µg/mL.

Refer to the package insert for information on results and data interpretation.

Additional, user-definable parameters present results that are interpretable in different ways. For further information, contact Microgenics Technical Support or your local Microgenics representative.

QMS Vancomycin Assay Beckman Coulter System Parameters, AU400/AU640/AU2700/AU5400

Specific Test Parameters										
General		LIH	ISE	Range						
Test Name:	VANCO		<	>	Type:	Serum		Operation:	Yes	
Sample:	Volume	2.0	μL	Dilution	0	μL	Pre-Dilution Rate:	1		
Reagents:	R1 Volume	125	μL	Dilution	0	μL	Min OD	Max OD		
	R2 Volume	125	μL	Dilution	0	μL	L	-2.00	H	2.50
Wavelength:	Pri.	700	▼	Sec.	None		Reagent OD limit:			
Method:	FIXED1				▼		First L	-2.00	First H	2.50
							Last L	-2.00	Last H	2.50
Reaction slope:	+		▼	Dynamic Range:						
Measuring Point 1:	First	13		Last	24		L	2.5	H	100
Measuring Point 2:	First			Last			Correlation Factor:			
Linearity:			%			A		1.000000	B	0.000000
No Lag Time:			▼	On-board stability period:						#

Specific Test Parameters									
General		LIH	ISE	Range					
Test Name:	VANCO		<	>	Type:	Serum			
Value/Flag:	#		▼	Level L:	#		Level H:	#	
Normal Ranges:									
		Age L		Age H		L		H	
	Sex	Year	Month	Year	Month				
o 1.	#	#	#	#	#	#	#	#	#
o 2.	#	#	#	#	#	#	#	#	#
o 3.	#	#	#	#	#	#	#	#	#
o 4.	#	#	#	#	#	#	#	#	#
o 5.	#	#	#	#	#	#	#	#	#
o 6.	#	#	#	#	#	#	#	#	#
7. None Selected						#	#	#	#
8. Out of Range		L		H		#	#	#	#
Panic Value:	#			#		Unit:	μg/mL	Decimal places:	#

#: User defined

QMS Vancomycin Assay
Beckman Coulter System Parameters, AU400/AU640/AU2700/AU5400, continued

Calibration Specific					
General		ISE			
Test Name:	VANCO ▾	<	>	Type	Serum ▾
Calibration Type:	6AB ▾	Formula:	POLYGONAL ▾	Counts:	2
				Process:	# ▾
Point 1:	Cal. No. #	OD	CONC 0.0	Factor/OD-L -2.0000	Factor/OD-H 2.5000
Point 2:	#		5.0	-2.0000	2.5000
Point 3:	#		10.0	-2.0000	2.5000
Point 4:	#		25.0	-2.0000	2.5000
Point 5:	#		50.0	-2.0000	2.5000
Point 6:	#		100.0	-2.0000	2.5000
Point 7:					
1-Point Cal. Point:	<input type="checkbox"/>	With CONC-0	Slope Check	- ▾	Advanced Calibration: <input type="checkbox"/>
MB Type Factor:	<input type="text"/>			Calibration Stability Period:	#

#: User define

QMS Vancomycin Assay Beckman Coulter System Parameters, AU480/AU680

Specific Test Parameters										
General		LIH	ISE	Range						
Test Name:	VANCO	<	>	Type:	Serum	Operation:	Yes			
Sample Volume	2.0	μL	Dilution	0	μL	OD Limit				
Pre-Dilution Rate	1		Min. OD	-2.00	Max.	3.00				
Reagents	R1(R1-	125	μL	Dilution	0	μL	Reagent OD			
							First Low	-2.00	High	3.00
							Last Low	-2.00	High	3.00
	R2 (R2-1)	125	μL	Dilution	0	μL	Dynamic Range	2.5	High	100
							Correlation Factor A	1	B	0
Wavelength:	Pri.	700	nm	Sec.		nm	Factor for Maker A	1	B	0
Method:	FIXED1									
Reaction slope:	+									
Measuring Point 1:	First	13	Last	24	Onboard Stability	32	Days	0	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:	VANCO	<	>	Type:	Serum										
Value/Flag	#	Level L:	#	Level H:	#										
Specific Ranges:															
	Sex	Year	Mont	Year	Mont	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. No demographics					#	#								
	8. Not within expected					#	#								
	Unit	μg/mL													
	Decimal Places	#													
<table border="1" style="margin-left: auto; margin-right: auto;"> <tr><td colspan="2">Panic</td></tr> <tr><td>Low</td><td>High</td></tr> <tr><td>#</td><td>#</td></tr> </table>										Panic		Low	High	#	#
Panic															
Low	High														
#	#														

: User defined

QMS Vancomycin Assay
Beckman Coulter System Parameters, AU480/AU680, continued

Calibration Specific																
General		ISE														
Test Name:		VANCO ▾			< ▾		> ▾		Type		Serum ▾		<input type="checkbox"/> Use Serum Cal.			
Calibration Type:		6AB ▾			Formula		POLYGONAL ▾		Counts:		2		Slope Check		- ▾	
<Calibrator																
	Calibrator	OD	Conc	Factor Range				Allowable Range Check								
				Low	High											
Point 1:	# ▾		0	-2.00	3.00			<input type="checkbox"/> Reagent Blank								
Point 2:	# ▾		5	-2.00	3.00			<input type="checkbox"/> Calibration								
Point 3:	# ▾		10	-2.00	3.00			Advanced Calibration								
Point 4:	# ▾		25	-2.00	3.00			Operation								
Point 5:	# ▾		50	-2.00	3.00			Interval (RB/ACAL) ▾								
Point 6:	# ▾		100	-2.00	3.00											
Point 7:	▾															
Point 8:	▾															
Point 9:	▾															
Point10:	▾															
<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											
Point 1:						Reagent Blanks		#	Day	#	Hour					
Point 2:						Calibration		18	Day	0	Hour					
MB Type Factor:		▾		1-Point Calibration Point		▾		<input type="checkbox"/> With CONC-0								

:User defined

QMS Vancomycin Assay Beckman Coulter System Parameters, AU5800

Parameters		Specific Test Parameters									
General	LIH	ISE	HbA1c		Calculated Test	Range					
Test Name:		VANCO ▾		<	>	Type:	Serum ▾	Operation	Yes ▾		
Sample Volume	2.0	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	1 st .	Low	-2.00	High	3.00
							Last	Low	-2.00	High	3.00
	R2(R2-1)	125	μL	Dilution	0	μL					
Common Rgt. Type	None		Name			Dynamic Range Low	2.5	High	100		
Wavelength	Pri	700	▾nm	Sec.	None	▾nm	Correlation Factor A	1	B	0	
							Factor for Maker	1	B	0	
Method	FIXED1										
Reaction Slope	+						Onboard Stability Period	32	Day	0	Hour
Measuring Point1 1 st	13				Last	24	LIH Influence Check				
Measuring Point2 1 st					Last		Lipemia				
Linearity Limit							Icterus				
Lag Time Check	No						Hemolysis				

Parameters		Specific Test Parameters						
General	LIH	ISE	HbA1c		Calculated Tests	Range		
Test Name:		VANCO ▾		<	>	Type:	Serum ▾	
Value/Flag:	#							
Level			Low	#	High	#		
Specific Ranges:								
	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	μg/mL	Decimal Places	#

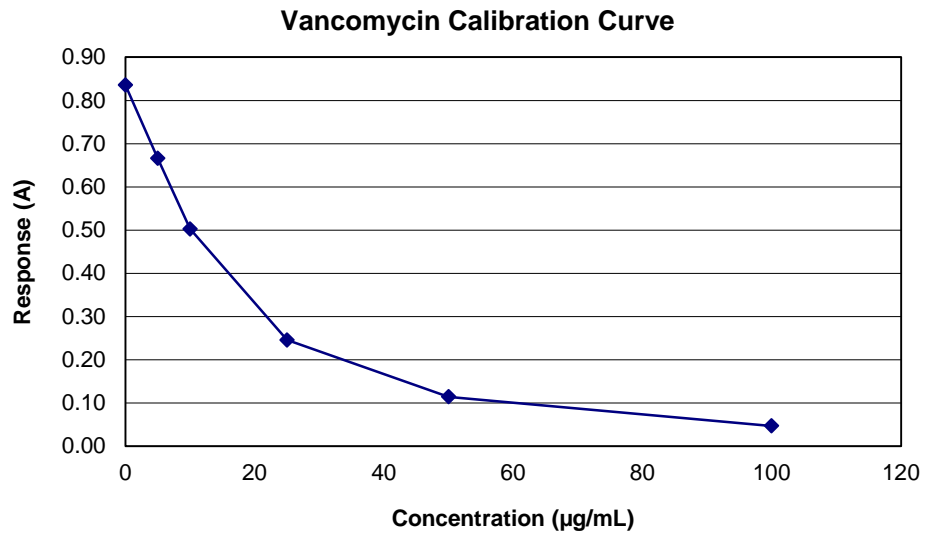
#: User defined

QMS Vancomycin Assay
Beckman Coulter System Parameters, AU5800, *continued*

Parameters		Calibration Parameters			
Calibrators		Calibration Specific			
General		ISE			
Test Name: VANCO ▾		< >		Type: Serum ▾	Cuvette: ▾
<input type="checkbox"/> Use Serum Cal.					
Calibration Type: 6AB ▾		Formula: POLYGONAL ▾		Counts: 2 ▾	
<Calibrator Parameters>					
	Calibrator	OD	Conc	Range	
				Low	High
Point 1:	# ▾		0	-2.00	3.00
Point 2:	# ▾		5	-2.00	3.00
Point 3:	# ▾		10	-2.00	3.00
Point 4:	# ▾		25	-2.00	3.00
Point 5:	# ▾		50	-2.00	3.00
Point 6:	# ▾		100	-2.00	3.00
Point 7:	▾				
Point 8:	▾				
Point 9:	▾				
Point 10:	▾				
				Slope Check: - ▾	
Allowance Range Check					
				<input type="checkbox"/> Reagent Blank	
				<input type="checkbox"/> Calibration	
Advanced Calibration Operation: ▾					
Interval (RB/ACAL): ▾					
<Point Cal. For Master Curve>		No. of Correction Points: ▾		Use Master Curve: ▾	
<input type="checkbox"/> Lot Calibration					
	Calibrator	OD	Conc	OD Range	
				Low	High
Point-1	▾				
Point-2	▾				
Stability				Reagent Blank	# Day # Hour
				Calibration	7 Day 0 Hour
MB Type Factor: ▾		1-Point Calibration Point: ▾		<input type="checkbox"/> with Conc-0	

#: User defined

**Example
Calibration
Curve**



**Limit of
Detection
(LDD)**

A negative sample was run against the same calibration curve for 21 replicates. The LDD is calculated as $2 \times SD$.

The observed LDDs for the QMS Vancomycin Assay on the AU480, AU680 and AU5800 were 0.54, 0.27 and 0.40 µg/mL, respectively.

Linearity

Six levels of calibrators and five calibrator blends were run against a single calibration curve and the linearity calculated.

The QMS Vancomycin assay recovered between 91.6% and 109.5% of expected values on the AU480.

The QMS Vancomycin assay recovered between 96.6% and 106.8% of expected values on the AU680.

The QMS Vancomycin assay recovered between 92.9% and 107.4% of expected values on the AU5800.

Precision

Control samples were tested in replicates of 2, twice per day for 20 days, total N = 80 on the Beckman Coulter AU480, AU680, AU5800 analyzer. Results are presented in the following tables:

AU480			
	Control 1	Control 2	Control 3
Mean (µg/mL)	7.5	22.0	39.5
Within-run SD (µg/mL)	0.11	0.14	0.30
Within-run CV (%)	1.4	0.6	0.8
Total SD (µg/mL)	0.34	0.41	0.90
Total CV (%)	4.5	1.8	2.3
AU680			
	Control 1	Control 2	Control 3
Mean (µg/mL)	7.8	22.6	40.8
Within-run SD (µg/mL)	0.19	0.17	0.25
Within-run CV (%)	2.4	0.8	0.6
Total SD (µg/mL)	0.32	0.41	1.00
Total CV (%)	4.1	1.8	2.4
AU5800			
	Control 1	Control 2	Control 3
Mean (µg/mL)	7.5	22.3	39.9
Within-run SD (µg/mL)	0.16	0.18	0.33
Within-run CV (%)	2.1	0.8	0.8
Total SD (µg/mL)	0.25	0.42	0.86
Total CV (%)	3.4	1.9	2.1

Accuracy and Correlation

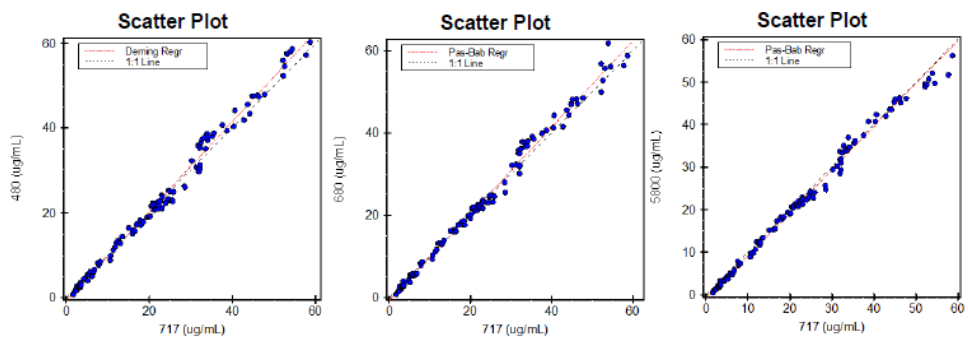
Serum samples were assayed using the QMS Vancomycin Assay on the Beckman Coulter AU480, AU680 and AU5800 and tested against the reference method Hitachi 717.

A Passing-Bablok Analysis yielded the following:

$$\text{AU480} = 1.06 * (\text{Hitachi 717}) - 0.823, r = 0.996, n = 110 \text{ samples}$$

$$\text{AU680} = 1.05 * (\text{Hitachi 717}) - 0.754, r = 0.995, n = 110 \text{ samples}$$

$$\text{AU5800} = 1.01 * (\text{Hitachi 717}) - 0.937, r = 0.996, n = 110 \text{ samples}$$



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