

**QMS<sup>®</sup> AMIKACIN ASSAY APPLICATION**



**Beckman Coulter AU400<sup>®</sup>, AU480<sup>®</sup>, AU640<sup>®</sup>, AU680<sup>®</sup>,  
AU2700<sup>®</sup>, AU5400<sup>®</sup>, AU5800<sup>®</sup>**

Catalog No. 0373910 & 10017196

**Intended for the quantitative determination of Amikacin Levels 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.

**Ordering Information**

Materials available from Microgenics, a part of Thermo Fisher Scientific:

Item	Size	Thermo Fisher Scientific Catalog No.
QMS Amikacin Assay	Reagent 1: 2 x 19 mL Reagent 2: 2 x 7 mL	0373910
	Reagent 1: 1 x 19 mL Reagent 2: 1 x 7 mL	10017196
QMS Amikacin Calibrator Set	6 levels, 1 x1.0 mL each	0374157

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



**Microgenics Corporation, part of Thermo Fisher Scientific**  
46500 Kato Rd, Fremont, CA 94538 USA  
U.S. Toll free: (800) 232-3342 / Tel: (510) 979-5000  
U.S. Toll free fax: (888) 527-8001 / Fax: (510) 979-5420

**EC REP** Microgenics GmbH, Spitalhofstrasse 94, 94032 Passau Germany  
Tel: +49 (0)851-88 6890 / Fax: +49(0)851-88 68910

*Continued on next page*  
10012148APPS-2  
01-2016

**Reagent Storage**

Refer to the package insert for information on reagent storage.

**Procedure for Analyzer**

Refer to the operator's manuals 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.	AMIK R1	∞UA1b 224R1	* CLN 100%	2	No	No	Yes
2.*	AMIK R1	∞UA1b 224R2	* CLN 100%	2	No	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.

\* CLN OSR0001/ODR2000, replenish cleaner on a daily basis or as required.

AU640/AU2700/AU5400 Contamination Avoidance Parameters							
No.	PRECEDING TEST NAME	FOLLOWING TEST NAME	REAGENT PROBE CLEANER	WASH COUNT	CANCEL	SAME USE	
						MIXER	CUVETTE
1.	AMIK	∞ UA1b 224	*CLN 100%	2	No	No	Yes

∞ Refers to reagent part numbers B38858/B46435.

\* CLN OSR0001/ODR2000, replenish cleaner on a daily basis or as required.

Note: For, AU2700/AU5400, contamination may also be avoided by placing the assays in separate cuvette rings from each other e.g. Amikacin (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.	AMIK	∞UA1b 224	*CLN 100%	2	No	No	Yes

∞ Refers to reagent part numbers B38858/B46435.

\* CLN OSR0001/ODR2000, replenish cleaner on a daily basis or as required.

Note: For AU5800, contamination may also be avoided by placing the assays in separate cuvette rings from each other e.g. Amikacin (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 Amikacin Assay**  
**Beckman Coulter System Parameters, AU400/AU640/AU2700/AU5400**

Specific Test Parameters	
General	LIH ISE Range
Test Name:	AMIK < > Type: Serum Operation: Yes
Sample:	Volume 2 µL Dilution 0 µL Pre-Dilution Rate: 1
Reagents:	R1 Volume 167 µL Dilution 0 µL Min OD Max OD
	R2 Volume 50 µL Dilution 0 µL Reagent OD limit: L -2.00 H 2.50
Wavelength:	Pri. 700 Sec. First L -2.00 First H 2.50
Method:	FIXED1 Last L -2.00 Last H 2.50
Reaction slope:	+ Dynamic Range: L 1.5 H 50
Measuring Point 1:	First 13 Last 24 Correlation Factor:
Measuring Point 2:	First Last A 1 B 0
Linearity:	% On-board stability period: #
No Lag Time:	No

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

Calibration Specific	
General	ISE
Test Name:	AMIK < > Type: Serum
Calibration Type:	6AB Formula: POLYGONAL* Counts: 2 Process: CONC
Point 1:	Cal. No. OD CONC Factor/OD-L Factor/OD-H
Point 2:	# # 0 -2.00 2.500
Point 3:	# # 3 -2.00 2.500
Point 4:	# # 10 -2.00 2.500
Point 5:	# # 20 -2.00 2.500
Point 6:	# # 35 -2.00 2.500
Point 7:	# # -2.00 2.500
1-Point Cal. Point:	With CONC-0 Slope Check - Advanced Calibration: #
MB Type Factor:	Calibration Stability Period: #

\*: AU640: Use EIA Type 1 for formula.  
 #: User defined

**QMS Amikacin Assay**  
**Beckman Coulter System Parameters, AU480 & AU680**

Specific Test Parameters										
General		LIH	ISE	Range						
Test Name:	AMIK	<	>	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-	167	μL	Dilution	0	μL	Reagent OD			
							First Low	-2.00	High	3.00
							Last Low	-2.00	High	3.00
	R2 (R2-1)	50	μL	Dilution	0	μL	Dynamic Range	1.5	High	50
							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	LIH Influence Check					
Measuring Point 2:	First		Last		Lipemia					
Linearity:										
No Lag Time:	No									
							Icterus			
							Hemolysis			

Specific Test Parameters															
General		LIH	ISE	Range											
Test Name:	AMIK	<	>	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="float: right; margin-left: 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 Amikacin Assay**  
**Beckman Coulter System Parameters, AU480 & AU680 (continued)**

Calibration Specific										
General										
Test Name:		AMIK		< >		Type		Serum		<input type="checkbox"/> Use Serum
Calibration Type:		6AB		Formula:		POLYGONAL		Counts:		2
<Calibrator										
	Calibrator	OD	Conc	Factor Range		Slope Check				
	#			Low	High	-				
Point 1:	#		0.0	-2.0000	3.0000					<input type="checkbox"/> Allowable Range Check
Point 2:	#		3.0	-2.0000	3.0000					<input type="checkbox"/> Reagent Blank
Point 3:	#		10.0	-2.0000	3.0000					<input type="checkbox"/> Calibration
Point 4:	#		20.0	-2.0000	3.0000					Advanced Calibration
Point 5:	#		35.0	-2.0000	3.0000					Operation
Point 6:	#		50.0	-2.0000	3.0000					Interval (RB/ACAL)
Point 7:										
Point 8:										
Point 9:										
Point 10:										
<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	Reagent Blanks		#	Day	#
Point 1:						Calibration		16	Day	0
Point 2:										
MB Type Factor:		1-Point Calibration Point							<input type="checkbox"/> With CONC-0	

#: User defined

# QMS Amikacin Assay

## Beckman Coulter System Parameters, AU5800

Parameters		Specific Test Parameters			
General	LIH	ISE	HbA1c	Calculated Test	Range
Test Name: <input type="text" value="AMIK"/> < > Type: <input type="text" value="Serum"/> Operation <input type="text" value="Yes"/>					
Sample Volume	<input type="text" value="2.0"/> $\mu\text{L}$	Dilution	<input type="text" value="0"/> $\mu\text{L}$	OD Limit	
Pre-Dilution Rate	<input type="text" value="1"/>	Diluent Bottle	<input type="text" value="#"/>	Min. OD	<input type="text" value="-2.00"/> Max. OD <input type="text" value="3.00"/>
Rgt. Volume R1(R1-1)	<input type="text" value="167"/> $\mu\text{L}$	Dilution	<input type="text" value="0"/> $\mu\text{L}$	Reagent OD Limit	
R1-2	<input type="text"/>	Dilution	<input type="text"/>	1 <sup>st</sup> Low	<input type="text" value="-2.00"/> High <input type="text" value="3.00"/>
R2(R2-1)	<input type="text" value="50"/> $\mu\text{L}$	Dilution	<input type="text" value="0"/> $\mu\text{L}$	Last Low	<input type="text" value="-2.00"/> High <input type="text" value="3.00"/>
Common Rgt. Type	<input type="text" value="None"/>	Name	<input type="text"/>	Dynamic Range Low	<input type="text" value="1.5"/> High <input type="text" value="50"/>
Wavelength Pri	<input type="text" value="700"/> $\text{nm}$	Sec.	<input type="text" value="None"/>	Correlation Factor A	<input type="text" value="1"/> B <input type="text" value="0"/>
Method	<input type="text" value="FIXED1"/>	Factor for Maker A	<input type="text" value="1"/>	B	<input type="text" value="0"/>
Reaction Slope	<input type="text" value="+"/>	Onboard Stability Period	<input type="text" value="32"/> Day <input type="text" value="0"/> Hour		
Measuring Point1 1 <sup>st</sup>	<input type="text" value="13"/>	Last	<input type="text" value="24"/>	LIH Influence Check	<input type="text"/>
Measuring Point2 1 <sup>st</sup>	<input type="text"/>	Last	<input type="text"/>	Lipemia	<input type="text"/>
Linearity Limit	<input type="text"/>			Icterus	<input type="text"/>
Lag Time Check	<input type="text" value="No"/>			Hemolysis	<input type="text"/>

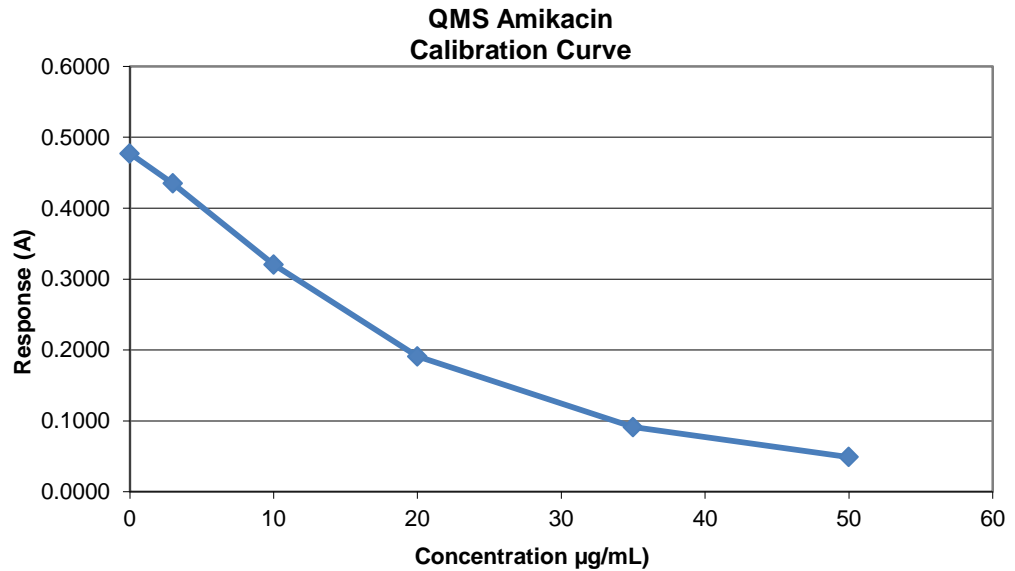
Parameters		Specific Test Parameters			
General	LIH	ISE	HbA1c	Calculated Test	Range
Test Name: <input type="text" value="AMIK"/> < > Type: <input type="text" value="Serum"/>					
Value/Flag: <input type="text" value="#"/>					
Level Low <input type="text" value="#"/> High <input type="text" value="#"/>					
Specific Ranges: From To Low High					
<input type="checkbox"/> 1.	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>
<input type="checkbox"/> 2.	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>
<input type="checkbox"/> 3.	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>
<input type="checkbox"/> 4.	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>
<input type="checkbox"/> 5.	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>
<input type="checkbox"/> 6.	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>
7. Standard demographics					
8. Not within expected values					
Panic Value	Low	<input type="text" value="#"/>	High	<input type="text" value="#"/>	Unit <input type="text" value="ug/mL"/> Decimal Places <input type="text" value="#"/>

Parameters		Calibration Parameters			
Calibrators	Calibration Specific				
General	ISE				
Test Name: <input type="text" value="AMIK"/> < > Type: <input type="text" value="Serum"/> Cuvette: <input type="text"/>					
<input type="checkbox"/> Use Serum Cal.					
Calibration Type: <input type="text" value="6AB"/> Formula: <input type="text" value="POLYGONAL"/> Counts: <input type="text" value="2"/>					
<Calibrator Parameters>					
Calibrator	OD	Conc	Low	High	Slope Check <input type="text" value="-"/>
Point 1:	<input type="text" value="#"/>	<input type="text" value="0"/>	<input type="text" value="-2.00"/>	<input type="text" value="3.00"/>	Allowance Range Check <input type="checkbox"/> Reagent Blank <input type="text"/> <input type="checkbox"/> Calibration <input type="text"/>
Point 2:	<input type="text" value="#"/>	<input type="text" value="3"/>	<input type="text" value="-2.00"/>	<input type="text" value="3.00"/>	
Point 3:	<input type="text" value="#"/>	<input type="text" value="10"/>	<input type="text" value="-2.00"/>	<input type="text" value="3.00"/>	
Point 4:	<input type="text" value="#"/>	<input type="text" value="20"/>	<input type="text" value="-2.00"/>	<input type="text" value="3.00"/>	
Point 5:	<input type="text" value="#"/>	<input type="text" value="35"/>	<input type="text" value="-2.00"/>	<input type="text" value="3.00"/>	
Point 6:	<input type="text" value="#"/>	<input type="text" value="50"/>	<input type="text" value="-2.00"/>	<input type="text" value="3.00"/>	
Point 7:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Advanced Calibration Operation <input type="text"/>
Point 8:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
Point 9:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
Point 10:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
<Point Cal. For Master Curve>					
Calibrator	OD	Conc	Low	High	Interval (RB/ACAL) <input type="text"/>
Point-1	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Stability Reagent Blank <input type="text" value="#"/> Day <input type="text" value="#"/> Hour Calibration <input type="text" value="16"/> Day <input type="text" value="0"/> Hour
Point-2	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
MB Type Factor: <input type="text"/> 1-Point Calibration Point <input type="text"/> <input type="checkbox"/> with Conc-0					

#: User defined

---

**Example  
Calibration  
Curve**



**Limit of  
Detection  
(LDD)**

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

The observed LDDs for QMS Amikacin Assay on the AU480, AU680 and AU5800 were 0.25, 0.32, and 0.60 µg/mL, respectively.

---

**Linearity**

Eleven levels of diluted calibrators were run against a single calibration curve and the linearity calculated.

The QMS Amikacin assay recovered between 93.8%-105.3% of expected values on the AU480.

The QMS Amikacin assay recovered between 92.5%-106.6% of expected values on the AU680.

The QMS Amikacin assay recovered between 100.1%-107.5% of expected values on the AU5800.

---



## Precision

Tests for within-run and total precision, evaluated with packaged reagents, controls and calibrators, yielded the following results (N=80/level):

<b>Controls</b>	<b>Control 1</b>	<b>Control 2</b>	<b>Control 3</b>
<b>AU480</b>			
Mean (µg/mL)	5.1	15.3	31.5
Within-Run SD (µg/mL)	0.09	0.13	0.17
Within-Run CV (%)	1.8	0.8	0.5
Total SD (µg/mL)	0.26	0.21	0.49
Total CV (%)	5.1	1.4	1.6
<b>AU680</b>			
Mean (µg/mL)	5.0	15.2	31.5
Within-Run SD (µg/mL)	0.14	0.10	0.20
Within-Run CV (%)	2.7	0.7	0.6
Total SD (µg/mL)	0.30	0.28	0.32
Total CV (%)	5.9	1.8	1.0
<b>AU5800</b>			
Mean (µg/mL)	4.7	15.2	31.4
Within-Run SD (µg/mL)	0.28	0.18	0.2
Within-Run CV (%)	5.9	1.2	0.6
Total SD (µg/mL)	0.41	0.36	0.42
Total CV (%)	8.8	2.3	1.3

---

## Accuracy and Correlation

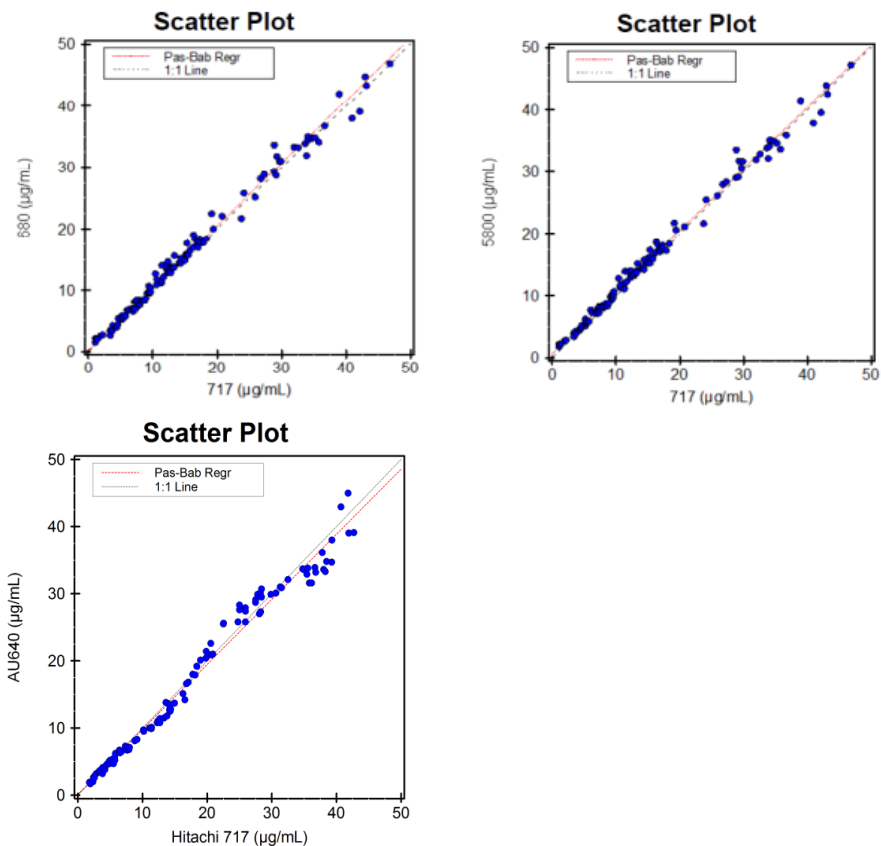
Serum samples were assayed with the QMS Amikacin Assay on the Beckman Coulter AU640, AU480 and AU5800 and tested with reference method Hitachi 717.

A Passing-Bablok's Analysis yielded the following:

AU480 = 1.024 (Hitachi 717) - 0.632,  $r = 0.992$ ,  $n = 108$  samples

AU680 = 1.018 (Hitachi 717) + 0.138,  $r = 0.995$ ,  $n = 110$  samples

AU5800 = 0.996 (Hitachi 717) + 0.565,  $r = 0.996$ ,  $n = 110$  samples



© 2015 Thermo Fisher Scientific, Inc. All rights reserved.  
AU Series Systems are the registered trademarks of Beckman Coulter.  
All other trademarks are the property of Thermo Fisher Scientific or its subsidiaries.

End