Microgenics Corporation
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CE

QMS™ AMIKACIN APPLICATION
ORTHO CLINICAL DIAGNOSTICS VITROS® XT 7600 INTEGRATED SYSTEM, VITROS® 5600 INTEGRATED SYSTEM, VITROS® 4600 CHEMISTRY SYSTEM, AND VITROS® 5,1 FS CHEMISTRY SYSTEM

Reference No. 10017196, 0373910

This Application is Intended for the Quantitative Determination of Amikacin in Human Serum or Plasma

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.orthoclinicaldiagnostics.com > Ortho Care > Technical Documents > MicroTip Partnership Assays (MPA).

Ordering Information

Please place your order with Ortho Clinical Diagnostics. Ordering information available on www.orthoclinicaldiagnostics.com.

Technical Support Information

Contact Ortho Clinical Diagnostics for technical support. Contact information available on www.orthoclinicaldiagnostics.com.

Microgenics Corporation, part of Thermo Fisher Scientific
46500 Kato Road, 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 B·R·A·H·M·S GmbH, Neuendorfstrasse 25, 16761 Hennigsdorf, Germany

Reagent Pack Storage

Unopened reagents are stable until the expiration date when stored at 2 to 8°C.

Reagents stored in UDxx reagent packs onboard the analyzer are stable for 28 days.

Reagents are supplied liquid ready-to-use. Each kit contains 2 bottles of each reagent. One bottle of the R1 Antibody Reagent (19 mL) can be transferred to the UDxx/A bottle; one bottle of the R2 Microparticle Reagent (7 mL) can be transferred to the UDxx/B bottle. This will produce 86 tests per pack (172 tests total/kit).

***NOTE**: Once the individual UDxx pack number is selected for use during the protocol programming, it is the only UDxx pack number to use for this protocol.*

Special Reagent Packs for User Defined Assays
(Please order from Ortho Clinical Diagnostics; not available from Microgenics)

Part Number	Description	Quantity
680 2246	UD01 Packs (Empty)	1 BOX/6PKS
680 2247	UD02 Packs (Empty)	1 BOX/6PKS
680 2248	UD03 Packs (Empty)	1 BOX/6PKS
680 2249	UD04 Packs (Empty)	1 BOX/6PKS
680 2250	UD05 Packs (Empty)	1 BOX/6PKS
680 2251	UD06 Packs (Empty)	1 BOX/6PKS
680 2252	UD07 Packs (Empty)	1 BOX/6PKS
680 2253	UD08 Packs (Empty)	1 BOX/6PKS
680 2254	UD09 Packs (Empty)	1 BOX/6PKS
680 2255	UD10 Packs (Empty)	1 BOX/6PKS
684 4449	UD11 Packs (Empty)	1 BOX/6PKS
684 4448	UD12 Packs (Empty)	1 BOX/6PKS
684 4445	UD13 Packs (Empty)	1 BOX/6PKS
684 4442	UD14 Packs (Empty)	1 BOX/6PKS
684 4447	UD15 Packs (Empty)	1 BOX/6PKS
684 4444	UD16 Packs (Empty)	1 BOX/6PKS
684 4441	UD17 Packs (Empty)	1 BOX/6PKS
684 4446	UD18 Packs (Empty)	1 BOX/6PKS
684 4443	UD19 Packs (Empty)	1 BOX/6PKS
684 4440	UD20 Packs (Empty)	1 BOX/6PKS
680 2256	UDDL1 Packs (Empty)	1 BOX/6PKS
680 2257	UDDL2 Packs (Empty)	1 BOX/6PKS

Calibration Frequency

It is recommended that recalibration occur after reagent pack change, after calibrator lot change, after performance of monthly instrument maintenance and as required following quality control procedure.

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QMS Amikacin Assay
Ortho Clinical Diagnostics VITROS® XT 7600 System, VITROS® 5600 System, VITROS® 4600 System, and VITROS® 5,1 FS System Parameters

Configure Assay

Full Assay Name: Amikacin Version Date: 28 March 2017

Short Assay Name: AMIK Fluid Type: serum

Assay Model Type: 2 Point Rate Template: *2Pt R1-S-R2

Cal Model Type: Logit/Log4 Calibrator Bottles: 6 Reagent Reps per Cal : 2

Reagent Lot Information

On-Board Stability: 28 Days

Reagent Lot Num: *Kit Lot*

Shelf Exp. Date: *Kit Exp Date*

Edit Dilution Parameters

Diluent: None Standard Dilution Factor: 1.0

Reflex Dilution: OFF Dilution Factor: 1.0

Reduction Factor: 1.0

Edit Result Parameters

Units: µg/mL Reference Interval: 0.0 to 90000000

Significant Digits: 4 Precision Digits: 2 Supplementary: 0.0 to 90000000

User Adjusted Parameters Reportable Range: 1.67 to 55

Slope: 0.9 Intercept: 0.0 **(More Assay Parms) – Edit 2 Pt Rate Additional Parameters**

CuveTip Exp Time: 35 Temp Sens : No Initial Abs. Limits: -0.20 to 2.70

Second Abs. Limits: -0.20 to 2.70

Antigen Excess Factor: 9.0

Edit Protocol Parameters

	Step	Volume	Pack ID	Seconds	Wavelength
1.	Reagent	190 µL	UDxx /A		
2.	Incubation			0.0	
3.	Sample	2.7 µL			
4.	Incubation			304.0	
5.	Reagent	57.0 µL	UDxx /B		
6.	Incubation			38.0	
7.	Read				700 nm
8.	Incubation			190	
9.	Read				700 nm

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QMS Amikacin Assay
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Edit Calibration Parameters

Bottle #	Dil Factor	Cal Rep Resp Range	Calibrator Lot: *Cal Kit lot*
1	1.0	0.20	Cal value: *0.0*
2	1.0	0.20	Cal Value: *3.0*
3	1.0	0.20	Cal Value: *10.0*
4	1.0	0.20	Cal Value: *20.0*
5	1.0	0.20	Cal Value: *35.0*
6	1.0	0.20	Cal Value: *50.0*

(More Cal Parms) – Edit Linear or Logit/Log Additional Parameters

Monotonicity: Decrease

Max Resp High: 3.00 Min. Resp. High: 3.00 Cal Fit Goodness Limit: 0.990

Max Resp. Low: -3.00 Min Resp. Low: -3.00

Edit Triple Read Parameters

	Reportable Conc.	Triple Read Limit
Reportable Min.:	1.67	5
Critical Conc.:	25	8.0 %
Reportable Max.:	55	8.0 %

Note: As per the package insert, the reportable range for the QMS Amikacin assay is 1.5 to 50 µg/mL. The application sheet lists the range as 1.67 to 55 µg/mL with a slope of 0.9. These values are entered prior to the PPA correction, therefore, the true reportable range is the application range multiplied by the slope, which will yield a range consistent with the package insert range.

End

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