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CEDIA® TOBRAMYCIN II APPLICATION

CE

Beckman Coulter AU400®, AU480®, AU640®, AU680®, AU2700®, AU5400®, AU5800®

Catalog No. 100018

Homogeneous Enzyme Immunoassay for the Quantitative Determination of Tobramycin Levels in Serum and 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
CEDIA Tobramycin II Assay Reagents	13 mL 11 mL	100018
CEDIA TDM Antibiotic Multi-Cal	2x5 mL 2x7.5 mL	100017
MAS PAR TDM Level 1	6x5 mL	PTD1-1001
MAS PAR TDM Level 2	6x5 mL	PTD2-2002
MAS PAR TDM Level 3	6x5 mL	PTD3-3003

[1]

To place an order or for technical service contact:

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Continued on next page

Reagent Storage	Refer to the package insert for information on reagent storage.
Analyzer Procedure	Refer to the operator's manuals for information on analyzer operation. Dispense adequate amounts of EA Reagent (first reagent) and ED Reagent (second reagent) into appropriate containers place reagents onboard the analyzer prior starting analysis. **Ensure that the reagents have equilibrated to the temperature of the analyzer reagent compartment before starting analysis** **Note**: Under Specific Test Parameters/General Tab, Linearity % should be left blank, as reflected in the following pages. **Do Not Enter 0.**
Calibration	Refer to the package insert for information on calibration.
Results and Data Interpretation	For further information, contact Microgenics Technical Support or your local Microgenics representative.

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CEDIA TOBRAMYCIN Application
Beckman Coulter System Parameters, AU400/AU640/AU2700/AU5400

Specific Test Parameters

General | LIH | ISE | Range

Test Name: TOBRA ∇ < > Type: Serum ∇ Operation: Yes ∇

Sample Volume		6.5 µL	Dilution	0 µL	OD Limit			
Pre-Dilution Rate		1				Min. OD	-2.00	Max. OD 2.50
Reagents Volume:	R1(R1-1)	82 µL	Dilution	0 µL	Reagent OD limit:			
						First Low	-2.00	High 2.50
						Last Low	-2.00	High 2.50
	R2 (R2-1)	62 µL	Dilution	0 µL				
						Dynamic Range Low	*	High *
						Correlation Factor A	1	B 0
Wavelength:	Pri.	570 nm	Sec.	660 nm		Factor for Maker A		B
Method:		RATE1 ∇						
Reaction slope:		+ ∇				Onboard Stability	#	Days 0 Hour
Measuring Point 1:	First	24	Last	27		LIH Influence Check	# ∇	
Measuring Point 2:	First		Last			Lipemia	∇	
Linearity:		%				Icterus	∇	
No Lag Time:		No ∇				Hemolysis	∇	

Specific Test Parameters

General | | ISE | Range

Test Name: TOBRA ∇ < > Type: ∇

Value/Flag: # ∇ Level L: # Level H: #

Specific Ranges:

			From		To			
	Sex	Year	Month	Year	Month	Low	High
☐ 1.	# ∇	#	#	#	#	#	#
☐ 2.	# ∇	#	#	#	#	#	#
☐ 3.	# ∇	#	#	#	#	#	#
☐ 4.	# ∇	#	#	#	#	#	#
☐ 5.	# ∇	#	#	#	#	#	#
☐ 6.	# ∇	#	#	#	#	#	#
7. No demographics						#	#
8. Not within expected values						#	#

Panic Value

Low	High
#	#

Unit * Decimal Places #

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CEDIA TOBRAMYCIN Assay
Beckman Coulter System Parameters, AU400/AU640/AU2700/AU5400, Continued

Calibration Specific

General | ISE

Test Name: TOBRA ∇ < > Type ∇ ☐ Use Serum Cal.

Calibration Type: 2AB ∇ Formula: POLYGONAL ∇ Counts: 2

<Calibrator Parameters> Slope Check + ∇

	Calibrator †	OD	Conc	Factor Range Low	Factor Range High
Point 1:	# ∇		**	-2.00	3.00
Point 2:	∇		**	-2.00	3.00
Point 3:	∇				
Point 4:	∇				
Point 5:	∇				
Point 6:	∇				
Point 7:	∇				
Point 8:	∇				
Point 9:	∇				
Point10:	∇				

Allowable Range Check
☐ Reagent Blank
☐ Calibration

Advanced Calibration
Operation ∇
Interval (RB/ACAL) ∇

<Point Cal. For Master Curve> No. of Correction Points ∇ Use Master Curve ∇ ☐ Lot Calibration

	Calibrator	OD	Conc	OD Range Low	OD Range High
Point 1:					
Point 2:					

Stability
Reagent Blanks ____ Day ____ Hour
Calibration ____ Day ____ Hour

MB Type Factor: 1-Point Calibration Point ∇ ☐ With CONC-0

\# User Defined
****** Lot specific calibrator value.

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CEDIA TOBRAMYCIN Assay
Beckman Coulter System Parameters, AU480 & AU680

Specific Test Parameters

General | LIH | ISE | Range

Test Name: TOBRA ∇ < > Type: Serum ∇ Operation: Yes ∇

Sample Volume		6.5 µL	Dilution	0 µL	OD Limit			
Pre-Dilution Rate		1				Min. OD	-2.00	Max. OD 3.00
Reagents Volume:	R1(R1-1)	82 µL	Dilution	0 µL	Reagent OD limit:			
						First Low	-2.00	High 3.00
						Last Low	-2.00	High 3.00
	R2 (R2-1)	62 µL	Dilution	0 µL				
						Dynamic Range Low	0.07	High 11.8
						Correlation Factor A	1	B 0
Wavelength:	Pri.	570 nm	Sec.	660 nm		Factor for Maker A		B
Method:		FIXED1* ∇						
Reaction slope:		+ ∇				Onboard Stability	30 Days	0 Hour
Measuring Point 1:	First	24	Last	27		LIH Influence Check	# ∇	
Measuring Point 2:	First		Last			Lipemia	∇	
Linearity:		%				Icterus	∇	
No Lag Time:		No ∇				Hemolysis	∇	

Specific Test Parameters

General | | ISE | Range

Test Name: TOBRA ∇ < > Type: ∇

Value/Flag: # ∇ Level L: # Level H: #

Specific Ranges:

	Sex	From Year	From Month	To Year	To Month	Low	High
☐ 1.	# ∇	#	#	#	#	#	#
☐ 2.	# ∇	#	#	#	#	#	#
☐ 3.	# ∇	#	#	#	#	#	#
☐ 4.	# ∇	#	#	#	#	#	#
☐ 5.	# ∇	#	#	#	#	#	#
☐ 6.	# ∇	#	#	#	#	#	#
7. No demographics						#	#
8. Not within expected values						#	#

Panic Value

Low	High
#	#

Unit * Decimal Places #

* Can also be run as RATE1

User Defined Values

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CEDIA TOBRAMYCIN
Beckman Coulter System Parameters, AU480 & AU680, Continued

Calibration Specific

General | ISE

Test Name: TOBRA ∇ < > Type ∇ ☐ Use Serum Cal.

Calibration Type: 2AB ∇ Formula: POLYGONAL ∇ Counts: #

<Calibrator Parameters> Slope Check + ∇

	Calibrator †	OD	Conc	Factor Range Low	Factor Range High
Point 1:	# ∇		**	-2.00	3.00
Point 2:	# ∇		**	-2.00	3.00
Point 3:	∇				
Point 4:	∇				
Point 5:	∇				
Point 6:	∇				
Point 7:	∇				
Point 8:	∇				
Point 9:	∇				
Point10:	∇				

Allowable Range Check
☐ Reagent Blank
☐ Calibration

Advanced Calibration
Operation ∇
Interval (RB/ACAL) ∇

<Point Cal. For Master Curve> No. of Correction Points ∇ Use Master Curve ∇ ☐ Lot Calibration

	Calibrator	OD	Conc	OD Range Low	OD Range High
Point 1:					
Point 2:					

Stability
Reagent Blanks Day Hour
Calibration 3 Day 0 Hour

MB Type Factor: 1-Point Calibration Point ∇ ☐ With CONC-0

\# User Defined
****** Lot specific calibrator value.

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CEDIA TOBRAMYCIN Assay

Beckman Coulter System Parameters, AU5800

Parameters | Specific Test Parameters

General | LIH | ISE | HbA1c | Calculated Test | Range

Test Name: TOBRA ∇ < > Type: Urine ∇ Operation Yes ∇

Sample Volume		6.5 µL	Dilution	0 µL	OD Limit				
Pre-Dilution Rate		1 ∇	Diluent Bottle	# ∇	Min.OD	-2.000	Max.OD	3.000	
Rgt. Volume	R1(R1-1)	82 µL	Dilution	0 µL	Reagent OD Limit				
	R1-2	µL	Dilution	µL	1st.	Low	-2.000	High	3.000
					Last	Low	-2.000	High	3.000
	R2(R2-1)	62 µL	Dilution	0 µL					
					Dynamic Range	Low	0.07	High	11.8
Common Rgt. Type		None	Name	None	Correlation Factor	A	1	B	0
Wavelength	Pri	570 ∇nm	Sec.	660 ∇nm	Factor for Maker	A	1	B	0
Method		FIXED1* ∇							
Reaction Slope		+ ∇			Onboard Stability Period		30 Day	0 Hour	
Measuring Point1 1st		24	Last	27	LIH Influence Check		# ∇		
Measuring Point2 1st			Last		Lipemia		∇		
Linearity Limit		%			Icterus		∇		
Lag Time Check		∇			Hemolysis		∇		

Parameters | Specific Test Parameters

General | LIH | ISE | HbA1c | Calculated Test | Range

Test Name: TOBRA ∇ < > Type: Urine ∇

Value/Flag: # ∇

Level Low # High #

Specific Ranges:

	Sex	From Year	From Month	To Year	To Month	Low	High
o 1.	# ∇	#	#	#	#	#	#
o 2.	# ∇	#	#	#	#	#	#
o 3.	# ∇	#	#	#	#	#	#
o 4.	# ∇	#	#	#	#	#	#
o 5.	# ∇	#	#	#	#	#	#
o 6.	# ∇	#	#	#	#	#	#
7. Standard demographics						#	#
8. Not within expected values						#	#

Panic Value Low # High # Unit * Decimal Places #

Parameters | Calibration Parameters

Calibrators | Calibration Specific

General | ISE

Test Name: TOBRA ∇ < > Type Urine ∇ Cuvette . ∇

□ Use Serum Cal.

Calibration Type: 2AB ∇ Formula: Polygonal ∇ Counts: # ∇

<Calibrator Parameters>

	Calibrator	OD	Conc	Range Low	Range High
Point 1:	# ∇		**	-2.000	3.000
Point 2:	# ∇		**	-2.000	3.000
Point 3:	∇				
Point 4:	∇				
Point 5:	∇				
Point 6:	∇				
Point 7:	∇				
Point 8:	∇				
Point 9:	∇				
Point 10:	∇				

Slope Check + ∇

Allowance Range Check

□ Reagent Blank

□ Calibration

Advanced Calibration Operation ∇

Interval (RB/ACAL) ∇

<Point Cal. For Master Curve> No. of Correction Points ∇ Use Master Curve ∇ □ Lot Calibration

	Calibrator	OD	Conc	OD Range Low	OD Range High
Point-1	∇				
Point-2	∇				

Stability

Reagent Blank		Day		Hour
Calibration	3	Day	0	Hour

MB Type Factor: 1-Point Calibration Point None ∇ □ with Conc-0

\# User defined.

* Can also be run as RATE1.

****** Lot specific calibrator value.

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Precision

Three control levels were tested in replicates of 2, twice per day for 20 days, total N = 80. The results are presented in the following tables:

*N=60

	C1	C2	C3
Quantitative AU400*			
Mean (ng/mL)	1.8	4.7	7.8
Within-Run SD (ng/mL)	0.11	0.16	0.23
Within-Run CV (%)	6.3	3.5	3.0
Total SD (ng/mL)	0.16	0.19	0.26
Total CV (%)	9.1	4.0	3.4
Quantitative AU480			
Mean (ng/mL)	2.0	4.6	7.9
Within-Run SD (ng/mL)	0.04	0.06	0.19
Within-Run CV (%)	2.1	1.3	2.4
Total SD (ng/mL)	0.07	0.09	0.34
Total CV (%)	3.3	2.0	4.2
Quantitative AU640*			
Mean (ng/mL)	1.7	4.7	7.8
Within-Run SD (ng/mL)	0.08	0.13	0.17
Within-Run CV (%)	4.8	2.9	2.2
Total SD (ng/mL)	0.10	0.18	0.21
Total CV (%)	5.7	4.0	2.7
Quantitative AU680			
Mean (ng/mL)	2.0	4.6	8.0
Within-Run SD (ng/mL)	0.07	0.10	0.13
Within-Run CV (%)	3.6	2.1	1.6
Total SD (ng/mL)	0.08	0.13	0.18
Total CV (%)	3.9	2.8	2.2
Quantitative AU5800			
Mean (ng/mL)	2.0	4.6	8.0
Within-Run SD (ng/mL)	0.09	0.08	0.16
Within-Run CV (%)	4.2	1.8	2.0
Total SD (ng/mL)	0.12	0.16	0.24
Total CV (%)	5.9	3.5	3.0

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Assay Accuracy and Correlation Beckman AU400	One hundred twenty-four (124) samples were assayed with the Tobramycin II Assay on both the Beckman AU400 and Hitachi 911 analyzers with the following results: y = 0.98x + 0.06; r = 0.999
Assay Accuracy and Correlation Beckman AU480	One hundred and eleven (111) samples were assayed with the Tobramycin II Assay on both the Beckman AU480 and Hitachi 911 analyzers with the following results: y = 1.02x + 0.22; r = 0.998
Assay Accuracy and Correlation Beckman AU640	One hundred twenty-four (124) samples were assayed with the Tobramycin II Assay on both the Beckman AU640 and Hitachi 911 analyzers with the following results: y = 0.98x + 0.14; r = 0.997
Assay Accuracy and Correlation Beckman AU680	One hundred and eleven (111) samples were assayed with the Tobramycin II Assay on both the Beckman AU680 and Hitachi 911 analyzers with the following results: y = 1.00x + 0.24; r = 0.998
Assay Accuracy and Correlation Beckman AU5800	One hundred and fifteen (115) samples were assayed with the Tobramycin II Assay on both the Beckman AU5800 and Hitachi 911 analyzers with the following results: y = 1.05x + 0.22; r = 0.998

End

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