Microgenics Corporation
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CEDIA® CYCLOSPORINE PLUS HIGH RANGE 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. 100147

This Application is Intended for the Quantitative Determination of Cyclosporine 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.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
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EC REP B·R·A·H·M·S GmbH, Neuendorfstrasse 25, 16761 Hennigsdorf, Germany

Reagent Pack Storage

Reconstituted reagents are stable for 60 days at 2-8°C when stored in their original container or in UDxx reagent packs.

Reconstituted reagents stored in UDxx reagent packs onboard the analyzer are stable for 28 days. Reagent life can be extended by storing the reagent packs in a refrigerator at 2-8°C between use.

To split the reconstituted reagent among reagent packs of the same UDxx ID, follow the chart below:

Number of packs	EA (mL) in UDxx/A	ED (mL) in UDxx/B	Tests/pack
3	13.7	6.3	74

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. The same pack can be used for both the Low Range and High Range Cyclosporine PLUS assays at the same time (each is calibrated separately).*

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.

Sample Preparation

Follow the CEDIA Cyclosporine PLUS Assay Sample Preparation as described in the package insert.

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CEDIA Cyclosporine PLUS High Range 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: Cyclosporine HR Version Date: 9/15/2010

Short Assay Name: CsAHR Fluid Type: Wh Blood

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

Cal Model Type: Linear Calibrator Bottles: 2 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: ng/mL Reference Interval: 0.0 to 90000000

Significant Digits: 4 Precision Digits: 3 Supplementary: 0.0 to 90000000

User Adjusted Parameters Reportable Range: 450 to 2000

Slope: 1.0 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 3.50 (2.7 for 5,1 FS*)

Second Abs. Limits: -0.20 to 3.50 (2.7 for 5,1 FS*)

Antigen Excess Factor: 9.0

Edit Protocol Parameters

	Step	Volume	Pack ID	Seconds	Wavelength
1.	Reagent	150 uL	UDxx /A		
2.	Incubation			0.0	
3.	Sample	2.6 uL			
4.	Incubation			304.0	
5.	Reagent	66.4 uL	UDxx /B		
6.	Incubation			228.0	
7.	Read				575 nm
8.	Incubation			76.0	
9.	Read				575 nm

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CEDIA Cyclosporine PLUS High Range Assay
Ortho Clinical Diagnostics VITROS® XT 7600 System, VITROS® 5600 System, VITROS® 4600 System, and VITROS® 5,1 FS System Parameters, *continued*

Edit Calibration Parameters

Bottle #	Dil Factor	Cal Rep Resp Range	Calibrator Lot: *Cal Kit lot*
1	1.0	0.20	Cal value: *per cal lot*
2	1.0	0.20	Cal Value: *per cal lot*

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

Monotonicity: Increase

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.:	450	10
Critical Conc.:	1000	8.0 %
Reportable Max.:	2000	8.0 %

Comments: Please see important assay and analyzer notes on page 2.

*** For the 5,1 FS the upper limit for initial and secondary abs limits is 2.70. Samples with high hematocrit levels may return a cuvette blank error. In these cases, please dilute the sample as per the package insert instructions and re-run.**

End

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