

QMS™ TACROLIMUS APPLICATION CE
**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. 10015556

This Application is Intended for the Quantitative Determination of Tacrolimus in Human Whole Blood



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.



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U.S. Toll free fax: (888) 527-8001 / Fax: (510) 979-5420



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 42 days.

Reagents are supplied liquid ready to use. Each kit contains 1 bottle of each reagent. One bottle of R1 Antibody Reagent (18 mL) transferred into one UDxx/A bottle; one bottle R2 Micro-particle Reagent (12 mL) can be transferred into one UDxx/B bottle. This will produce ~110 tests per pack.

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 lot change, after calibrator lot change, after performance of monthly instrument maintenance and as required following quality control procedures.

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

Configure Assay

Full Assay Name: _QMS Tacrolimus_ Version Date: 5/20/2013
 Short Assay Name: QTAC Fluid Type: Wh Blood
 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: 42 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: 5.0 to 20.0
 Significant Digits: 4 Precision Digits: 2 Supplementary: 0.0 to 90000000
 User Adjusted Parameters Reportable Range: 1.5 to 30.0
 Slope: 1.0 Intercept: 0.0 **(More Assay ParmS) – Edit 2 Pt Rate Additional Parameters**
 CuveTip Exp Time: 10 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	125 uL	UDxx /A		
2. Incubation			0.0	
3. Sample	10 uL			
4. Incubation			304.0	
5. Reagent	75 uL	UDxx /B		
6. Incubation			190	
7. Read				700 nm
8. Incubation			114	
9. Read				700 nm

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

Edit Calibration Parameters

Bottle #	Dil Factor	Cal Rep Resp Range	Calibrator Lot: <u>Cal Kit lot</u>
1	<u>1.0</u>	<u>0.20</u>	Cal value: <u>per cal lot</u>
2	<u>1.0</u>	<u>0.20</u>	Cal Value: <u>per cal lot</u>
3	<u>1.0</u>	<u>0.20</u>	Cal Value: <u>per cal lot</u>
4	<u>1.0</u>	<u>0.20</u>	Cal Value: <u>per cal lot</u>
5	<u>1.0</u>	<u>0.20</u>	Cal Value: <u>per cal lot</u>
6	<u>1.0</u>	<u>0.20</u>	Cal Value: <u>per cal lot</u>

(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.:	<u>1.5</u>	<u>5.0</u> %
Critical Conc.:	<u>15.0</u>	<u>10.0</u> %
Reportable Max.:	<u>30.0</u>	<u>10.0</u> %

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