

**QMS™ EVEROLIMUS APPLICATION**  
**QuidelOrtho Vitros® XT 7600 INTEGRATED SYSTEM, Vitros® CE**  
**5600 INTEGRATED SYSTEM, Vitros® 4600 CHEMISTRY**  
**SYSTEM, AND Vitros® 5,1 FS CHEMISTRY SYSTEM**

Reference No. 0380000 and 0373852

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



For In Vitro Diagnostic Use Only  
Rx Only

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**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.quidelortho.com](http://www.quidelortho.com) > Resources > MicroTip Partnership Assays (MPA).

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**Ordering Information**

Please place your order with QuidelOrtho. Ordering information available on [www.quidelortho.com](http://www.quidelortho.com).

**Technical Support Information**

Contact QuidelOrtho for technical support. Contact information available on [www.quidelortho.com](http://www.quidelortho.com).



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## 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 1 bottle of each reagent. One bottle of R1 Antibody Reagent (22 mL) can be split into two UDxx/A bottles (11 mL each); one bottle R2 Micro-particle Reagent (8mL) can be split into two UDxx/B bottles (4 mL each). This will produce ~ 46 tests per pack (92 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 QuidelOrtho; 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 |

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## 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 Everolimus Assay QuidelOrtho Vitros® XT 7600 System, Vitros® 5600 System, Vitros® 4600 System, and Vitros® 5,1 FS System Parameters

## Configure Assay

Full Assay Name: Everolimus Version Date: proposed new protocol  
 Short Assay Name: EVER 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: 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: 2 Supplementary: 0.0 to 90000000  
 User Adjusted Parameters Reportable Range: 2 to 20  
 Slope: 1.0 Intercept: 0.0 **(More Assay Parm) – 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    | 175 µL  | UDxx /A |         |            |
| 2. Incubation |         |         | 0.0     |            |
| 3. Sample     | 10 µL   |         |         |            |
| 4. Incubation |         |         | 304.0   |            |
| 5. Reagent    | 45.0 µL | UDxx /B |         |            |
| 6. Incubation |         |         | 76      |            |
| 7. Read       |         |         |         | 700 nm     |
| 8. Incubation |         |         | 228     |            |
| 9. Read       |         |         |         | 700 nm     |

**QMS Everolimus Assay**  
**QuidelOrtho 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: <u>Cal Kit lot</u> |
|----------|------------|--------------------|------------------------------------|
| 1        | <u>1.0</u> | <u>0.20</u>        | Cal value: <u>0.0</u>              |
| 2        | <u>1.0</u> | <u>0.20</u>        | Cal Value: <u>1.5</u>              |
| 3        | <u>1.0</u> | <u>0.20</u>        | Cal Value: <u>3.0</u>              |
| 4        | <u>1.0</u> | <u>0.20</u>        | Cal Value: <u>6.0</u>              |
| 5        | <u>1.0</u> | <u>0.20</u>        | Cal Value: <u>12.0</u>             |
| 6        | <u>1.0</u> | <u>0.20</u>        | Cal Value: <u>20.0</u>             |

**(More Cal Parm) – 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>2</u>         | <u>5</u>          |
| Critical Conc.:  | <u>10</u>        | <u>8.0</u> %      |
| Reportable Max.: | <u>20</u>        | <u>8.0</u> %      |

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