

QMS[®] Tacrolimus Calibrators

IVD For In Vitro Diagnostic Use

Rx Only

REF 10015573

INTENDED USE

The QMS[®] Tacrolimus Calibrator set is intended for use in calibration of the QMS Tacrolimus Immunoassay **REF** 10015556.

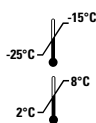
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The calibrator set is sold separately and can be used with any reagent lot. The calibrators contain human blood matrix and tacrolimus.

Each calibrator kit contains six (6) calibrators with the following target concentrations of tacrolimus.

Level	Concentration (ng/mL)	Quantity	Fill Volume
A	0.0	1	4.0 mL
B	2.0	1	2.0 mL
C	5.0	1	2.0 mL
D	10.0	1	2.0 mL
E	20.0	1	2.0 mL
F	30.0	1	2.0 mL

STORAGE AND STABILITY



- Store calibrators at $-20^{\circ}\text{C} \pm 5^{\circ}\text{C}$ until first use.
- Calibrators are stable until the expiration date printed on the label. Once thawed, the QMS Tacrolimus Calibrators will be stable for 30 days when stored tightly capped at $2\text{--}8^{\circ}\text{C}$.
- Do not allow the calibrators to remain at room temperature longer than is required to perform the assay.
- Calibrators will clot when exposed to high temperatures.

STANDARDIZATION

The QMS Tacrolimus Calibrators were prepared by gravimetric addition of tacrolimus to human whole blood. The purity and accuracy of each calibrator concentration was verified by an LC-MS/MS method.

INSTRUCTION FOR USE

- Refer to the QMS Tacrolimus Immunoassay package insert, included in the reagent kit, for a complete summary and explanation of the test.
- QMS Tacrolimus Calibrators should be treated the same as patient specimens, and assayed in accordance with the package insert and the instrument application instructions.
- The QMS Tacrolimus Calibrators are intended for use **only** with the QMS Tacrolimus Immunoassay.

CALIBRATOR PREPARATION

1. Calibrators are stored frozen. Thaw completely before use, and allow calibrators to come to room temperature.
2. Mix calibrators thoroughly by rocking for 15-20 minutes. Avoid the formation of bubbles.
3. Pipette exactly 200 μL of calibrator material into a round bottom microcentrifuge tube.
4. Pipette exactly 200 μL of extraction solution to the microcentrifuge tube.
5. Cap and vortex the microcentrifuge tube at maximum speed immediately for 15-30 seconds.
6. Let the mixture in the microcentrifuge tube sit at room temperature for 5-7 minutes.
7. Place the microcentrifuge tube into a centrifuge and centrifuge for 5 minutes at 13,000 rpm.
8. Decant the supernatant into a sample cup (avoid the formation of bubbles*) and immediately run the measurement.

CAUTION: Bubbles may interfere with proper detection of calibrator level in the sample cup, causing insufficient calibrator aspiration that could impact results.

LIMITATIONS

QMS Tacrolimus Calibrators should not be used past the expiration date. If there is evidence of microbial contamination, discard the vial.

Accurate and reproducible results are dependent upon properly functioning instruments, reagents, calibrators, storage of product as directed, and good laboratory technique.

WARNINGS AND PRECAUTIONS

Precautions for Users

- **For In Vitro Diagnostic Use Only**
- Contains Human Source Material
- Exercise the normal precautions required for handling all laboratory reagents.



CAUTION/WARNING: Materials of human origin were tested for HIV1 and 2, Hepatitis B and Hepatitis C by an FDA-approved method. The findings were negative. However, as no test method can rule out the potential risk of infection with absolute certainty, the material must be handled just as carefully as a patient sample. In the event of exposure, the directives of the responsible health authorities should be followed.

TRADEMARKS

QMS is a registered trademark of Thermo Fisher Scientific Inc. and its subsidiaries.

Glossary:

<http://www.thermofisher.com/symbols-glossary>



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