

# MyImatinib™

## MyImatinib™ Calibrator Kit






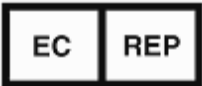




This package insert must be read carefully prior to product use. Package insert instructions must be followed accordingly. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

### Customer Service:

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### Key to Symbols Used

	<i>in vitro</i> Diagnostic Device		Temperature Limitation
	Batch Code (Lot)		Use By
	Catalog Number		Authorized Representative in the European Community
	Caution: Consult accompanying documents		Manufacturer
	Consult Instructions for Use		Calibrator A through Calibrator F



Saladax Biomedical, Inc.  
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Bethlehem, PA 18015  
USA



## Intended Use

The Saladax MyImatinib Calibrator Kit is intended for use in calibration of the Saladax MyImatinib Assay.

## Contents

The MyImatinib Calibrator Kit consists of a buffer matrix with the following concentrations of imatinib:

CAL Vial	Concentration (ng/mL)	Quantity	Volume
A	0	1	3 mL
B	300	1	3 mL
C	600	1	3 mL
D	1,000	1	3 mL
E	2,000	1	3 mL
F	3,000	1	3 mL

## Standardization

There is no internationally recognized standard for imatinib. The MyImatinib Calibrators are prepared gravimetrically by dilution of imatinib into a buffer matrix at concentrations of 0, 300, 600, 1,000, 2,000, and 3,000 ng/mL.

Saladax Biomedical, Inc. maintains master calibrators that have been confirmed by a reference method. MyImatinib Calibrators are traceable to this master set of calibrators.

## Precautions and Warnings

For In Vitro Diagnostic Use.

The calibrators in this set are designed for use as a unit. Do not substitute or mix calibrators with those from other lots.



Exercise the normal precautions required for handling all laboratory reagents.

All MyImatinib Calibrators contain less than 0.1% sodium azide. Avoid contact with skin and mucous membranes. Flush affected areas with copious amounts of water. Seek immediate medical attention if calibrators are ingested or come into contact with eyes.

## **Storage and Stability**

Store calibrators refrigerated at 2-8°C (35-46°F). Do not freeze. Calibrators are stable until the expiration date when stored as directed. Once opened calibrators are stable for 8 weeks (2 months) when handled as directed.

## **Limitations of the Procedure**

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

## **Instructions for Use**

- Refer to the Saladax MyImatinib Assay package insert, included in the reagent kit, for a complete summary and explanation of the test.
- Use calibrators immediately upon removal from 2-8°C storage.
- Mix each calibrator by gentle inversion several times before dispensing.
- After each use, tightly close the caps and return calibrators to 2-8°C.



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