

My5-FU[®]

5-Fluorouracil (My5-FU[™]) Calibrator Kit

Customer Service:













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Key to Symbols Used

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


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Intended Use

The Saladax 5-Fluorouracil (My5-FU) Calibrator Kit is intended for use in calibration of the Saladax My5-FU Assay.

Contents

The My5-FU Calibrator Kit consists of human plasma with the following concentrations of 5-FU:

Vial	Concentration (ng/mL)	Quantity	Volume
CAL A	0	1	3 mL
CAL B	150	1	3 mL
CAL C	300	1	3 mL
CAL D	600	1	3 mL
CAL E	1,200	1	3 mL
CAL F	1,800	1	3 mL

Standardization

There is no internationally recognized standard for 5-FU. The My5-FU Calibrators are prepared gravimetrically by dilution of USP 5-FU into human plasma free of 5-FU at concentrations of 0, 150, 300, 600, 1,200, and 1,800 ng/mL.

Saladax Biomedical, Inc. maintains master calibrators that have been confirmed by a reference method. My5-FU 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.

Materials of human origin were tested for HIV1 and HIV2, Hepatitis B and Hepatitis C by FDA-approved methods and 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.

All My5-FU 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. Do not freeze. Calibrators are stable until the expiration date when stored as directed. Once opened calibrators are stable for 12 months when handled as directed.

Limitations of the Procedure

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

Instructions for Use

- Refer to the Saladax My5-FU Assay package insert 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.

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