

My5-FU

5-Fluorouracil (My5-FU™) Control Kit

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Key to Symbols Used

IVD	<i>in vitro</i> Diagnostic Device		Consult Instructions for Use
REF	Catalog Number		Use By
LOT	Batch Code		Temperature Limitation
	Manufacturer		Biological Risks
	Caution: Consult accompanying documents	CON L	Low Control
		CON M	Medium Control
		CON H	High Control
CH REP	Authorized Representative in Switzerland		
EC REP	Authorized Representative in the European Community		


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Intended Use

The Saladax 5-Fluorouracil (My5-FU) Control Kit is intended for use in quality control of the Saladax My5-FU Assay.

Contents

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

Vial		Concentration (ng/mL)	Concentration Range (ng/mL)	Quantity	Volume
CON	L	225	191 -259	2	3 mL
CON	M	450	382-518	2	3 mL
CON	H	900	765-1035	2	3 mL

The control is evaluated by the Saladax My5-FU Assay to be within 15% of the target value. Each laboratory should establish its own range and reassess control targets and ranges following a change of reagent (kit) or control lot.

Precautions and Warnings

For In Vitro Diagnostic Use.

The controls in this set are designed for use as a unit. Do not substitute or mix controls 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 Controls 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 controls are ingested or come into contact with eyes.

Storage and Stability`

Store controls refrigerated at 2 - 8°C. Do not freeze. Controls are stable until the expiration date when stored as directed. Once opened controls 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 controls immediately upon removal from 2 - 8°C storage.
- Mix each control by gentle inversion several times before dispensing.
- After each use, tightly close the caps and return control to 2 - 8°C.



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

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