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technology

microINR[®] EasyControl

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Intended use

The microINR EasyControl is intended for quality control performed on the microINR Meter when used with the microINR disposable analytic strips (Chips).

The microINR EasyControl is intended for professional use only.

Summary and principles

The microINR system has a number of integrated and independent quality controls (On-board controls) intended to assure a reliable result and performance of the system. These are based on a multilevel strategy to detect defective microINR Chips or misuse of them.

For further information refer to the microINR system instructions.

Additionally to the microINR On-board controls, the microINR EasyControl has been developed as a liquid quality control solution. In some cases, the performance of liquid controls is required by local regulations. The microINR EasyControl must be used only by healthcare professionals in order to verify the functionality of the microINR system.

The microINR EasyControl contains lyophilized human citrated plasma from healthy donors (not heparinized plasma or plasma samples under oral anticoagulant therapy) modified by means of a dedicated process to simulate an abnormal coagulation sample and a calcium chloride solution. The lyophilized plasma is reconstituted with calcium chloride solution.

Composition

Each microINR EasyControl contains:

- 5 vials of 2mL lyophilized human abnormal plasma with buffers, stabilizers and preservatives.
- 5 unit-dose containers of Calcium Solution 2 mL with calcium chloride dissolved in distilled water.
- 5 capillary droppers.

Materials required (but not provided)

- microINR Meter.
- microINR Chips.

Precautions and warnings

For *in vitro* diagnostic use.

The plasma control contains human source material that was tested and found nonreactive for HIV antibody, Hepatitis B Surface Antigen and Anti-HCV at the donor stage. This product, as with all human based specimens, should be handled with proper laboratory safety procedures to minimize the **risk of transmission of infectious disease**.

Calcium chloride **causes serious eye irritation**. Wear gloves when handling all kit components. Avoid contact with eyes and skin. Do not empty into drains.

All components of this kit can be discarded as **Biohazard waste** according to the local guidelines.

Refer to the product safety data sheet for risk and safety phrases and disposal information.

The product safety data sheet is available for professional users upon request.

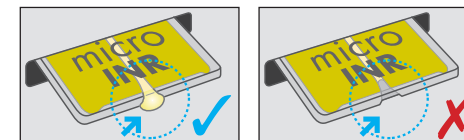
Storage and Stability

Store at 2-8° C. The lyophilized plasma and the Calcium Chloride solution are stable until the expiration date shown in the packaging.

At 15-25° C the quality control solution is stable for 14 minutes after reconstitution.

Preparation

1. Take one microINR Control vial and one Calcium Solution unit-dose container from the kit stored in the refrigerator and wait 2 or 3 minutes before using it.
2. Open the Calcium Solution unit-dose container and transfer the whole volume (2mL) inside the lyophilized plasma vial. It is important to dispense all of the Calcium Solution into the plasma.
3. Close the vial and tilt it gently 4-5 times. DO NOT shake.
4. Wait about 4 minutes until the solution is ready.
5. Insert a Chip in the microINR Meter and wait until the countdown has started.
6. Use the capillary dropper to dispense the solution into the microINR Chip. Take enough plasma volume (at least 3 µL) with the dropper. Form a drop and put it in contact with the Chip entry channel horizontally. The device beeps when it detects that the plasma is in contact with the reagent inside the Chip. Hold the drop for two seconds and remove the capillary dropper gently upwards. Make sure that a remaining volume stays at the Chip entry channel.
7. Read the result on the screen.
8. Repeat the steps 5 to 7, in order to get another result and work out an average INR.
9. If you get an inaccurate result due to incorrect sample application or an error message, check there is not an air bubble into the entry port channel as it is shown at the incorrect picture below. Repeat the steps from 5 to 7, making sure that a remaining volume stays at the Chip entry channel as it is represented at the correct picture below, until 2 results with the right procedure are obtained.
10. The average INR result should lie within the acceptance range shown at the label attached on these instructions.



Note: Refer to the "Troubleshooting" sections should any error message or values outside the acceptable control range come out during this procedure.

PERFORMANCE CHARACTERISTICS

Expected values

Acceptable ranges are published on this instruction. These values have been established at the manufacturer's facility. The system is working properly and all handling has been done correctly when the obtained test results lie within the permitted control range. Products only deliver reliable results if used as intended.

Troubleshooting

If the value obtained with microINR EasyControl solution is outside the acceptable control range:

- Check whether the plasma reconstitution was prepared with the whole calcium chloride solution volume.
- Make sure the testing procedure has been followed in accordance with these guidelines.
- When applying the plasma solution, make sure that a remaining volume stays at the Chip entry channel and there is not an air bubble into the entry port channel. See the correct and the incorrect pictures above.
- Repeat the quality control test according to the instructions and make sure the correct sample application is followed.
- Verify the microINR EasyControl has been properly stored and has been used within 14 minutes once reconstituted.
- If you have any questions related to the microINR system use, read the Meter and Chip instructions.













Limitations

This product is designed as a liquid control for quality control performed exclusively by the microINR system. The control is subjected to the limitations of the assay system. Deviations may indicate potential problems with one or more components in the test system. As it has been described, the system already has On-board controls to detect errors and prevent false INR results when analysis is performed. So deviations on the microINR EasyControl would not invalidate previous results obtained on the microINR.



This product is guaranteed to perform as described on the label and in the instruction sheet. The manufacturer declines all responsibility arising out of the use or sale of this product in any way or for any purpose other than this described therein.

SYMBOLS

	"Catalogue number"
	"Manufacturer"
	"Batch code/ Lot number"
	"Consult instructions for use"
	" <i>in vitro</i> diagnostic medical devices"
	"Control material"
	"Biological Risk"
	"Temperature limitation (store at)"
	"Use by"
	"Contains sufficient for "n" tests"
	"GHS07 Symbol H319 Causes severe eye irritation"
	"This product fulfills the requirements of the European Directive 98/79/EC for <i>in vitro</i> medical devices"



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