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Lieferung & Zahlungsart

siehe unsere [Liefer- und Versandbedingungen](#)

Zuschläge

- Mindermengenzuschlag
- Trockeneiszuschlag
- Gefahrgutzuschlag
- Expressversand

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D-Dimer Control

HumaFIA SR

Package Size 2 x 0.6 mL

REF 16090/51

IVD

Intended Purpose

D-Dimer Control HumaFIA SR is a control to check the accuracy and reliability of the D-Dimer HumaFIA SR assay.

The control is designed to be used together with the D-Dimer HumaFIA SR reagent on semi-automated HumaFIA analyzer.

For professional in vitro diagnostic use only.

Reagents and Contents

CTR1	0.6 mL	Control Level 1 (green), sealed in foil pouch Lyophilized control, spiked with D-Dimer
CTR2	0.6 mL	Control Level 2 (brown), sealed in foil pouch Lyophilized control, spiked with D-Dimer
DIL	1.4 mL	Diluent Buffer

The CTR concentrations levels are lot specific, see target value sheet.

Applicable system

REF	
16090	HumaFIA
16090/50	D-Dimer HumaFIA SR

Storage/Stability

Unopened at 2...8°C	Up to the stated expiration date
Opened pouch at 18-28°C	Reconstitution should be completed within 30 mins
Reconstituted at 2...8°C	5 days open vial

Store upright and protected from light.

Procedure

Follow the procedure exactly as described.

Procedural Notes

1. Do not use CTR after the expiration date.
2. Bring CTR to room temperature (18-28°C) before use.
3. Gently invert the reconstituted CTR at least 10 times avoiding the formation of foam.
4. Treat the control in the same manner as patient specimen in the assay procedure. Test should be completed at 22-24°C.
5. Read the control results, refer to the target value sheet.
6. Do not return remaining CTR to the original vial once used.

Reconstitution

1. Before reconstitution, gently tap the vial to ensure the lyophilized material is at the bottom of the vial.
2. Before reconstitution, first remove carefully the cap to prevent the contents from ejection.
3. Reconstitute CTR by adding exactly 0.6 mL DIL.
4. Gently invert the reconstituted CTR at least 10 times, avoiding the formation of foam. Check all CTR has dissolved.
5. Close the cap and keep CTR at room temperature for 15 minutes. After 15 minutes, coat all surfaces of the bottle by rotating and inverting the bottle. Continue mixing until the solution is homogeneous and all lyophilized material is reconstituted.
6. Use the necessary volume of CTR.
7. Close the cap and store the remaining volume at 2-8°C.

Notes

1. This product is not intended to be used as standard material.

Assay Procedure

Refer to the instruction for the use of D-Dimer HumaFIA SR

REF 16090/50.

Safety Notes

All patient specimens, calibrators and controls should be handled as potentially infectious. All materials of animal origin avoid many risks associated with the use of human serum (e.g. Hepatitis B and C, HIV). Nevertheless, all material of human or animal origin should still be treated as potentially infectious material.

For users in the European Union only: Please report any serious incident that has occurred in relation to the device to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

P234 Keep only in original container.

P260 Do not breathe dust/fume/gas/mist/vapors/spray.

P262 Do not get in eyes, on skin, or on clothing.

P281 Use personal protective equipment as required.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337+P313 If eye irritation persists: Get medical advice/attention.

P401 Store in accordance with local/regional/national/international regulations.

P501 Dispose of contents/container in accordance with local/regional/ national/international regulations.



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