

Produktinformation



Forschungsprodukte & Biochemikalien
Zellkultur & Verbrauchsmaterial
Diagnostik & molekulare Diagnostik
Laborgeräte & Service

Weitere Information auf den folgenden Seiten! See the following pages for more information!



Lieferung & Zahlungsart siehe unsere Liefer- und Versandbedingungen

Zuschläge

- Mindermengenzuschlag
- Trockeneiszuschlag
- Gefahrgutzuschlag
- Expressversand

SZABO-SCANDIC HandelsgmbH

Quellenstraße 110, A-1100 Wien T. +43(0)1 489 3961-0 F. +43(0)1 489 3961-7 <u>mail@szabo-scandic.com</u> www.szabo-scandic.com

PCT Control HumaFIA SR

Package Size	2 x 0.6 mL
REF	16090/26
IVD	

Intended Purpose

PCT Control HumaFIA SR is a control to check the accuracy and reliability of the PCT HumaFIA SR assay.

The control is designed to be used together with the PCT 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 PCT
CTR2	0.6 mL	Control Level 2 (brown), sealed in foil pouch Lyophilized control, spiked with PCT
DIL	1.4 mL	Diluent Buffer

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

Applicable system

REF	
16090	HumaFIA
16090/25	PCT HumaFIA SR

Storage/Stability

Unopened at 28°C	Up to the stated expiration date
Opened pouch at 18-28°C	Reconstitution should be completed
	within 30 mins
Reconstituted at 28°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 PCT HumaFIA SR REF 16090/25.

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.

Beijing HumaDX Tech Co., Ltd.



Address: Room 1309, 3rd Floor, 1st Block, No. 55 Jiachuang 2nd Road, BDA 101111, Beijing, China E-mail: service@humadx.com.cn Tel: +86-10-80828658



HUMAN Gesellschaft für Biochemica und Diagnostica mbH Address: Max-Planck-Ring 21, 65205, Wiesbaden, Germany Tel: +49-6122-99880, E-Mail: human@human.de



Effective Date: Feb 7, 2024 Version: HD/CE 26 202402 V001