DaraEx-PC

Version 2_EN_RUO, 2020-08

RUO	For research use only
Σ	11 - 18 tests
2°C 8°C	2...8°C
	See package printings

1. Introduction

1.1. Overview

This manual describes the protocol for the imusyn

DaraEx process control (DaraEx-PC)

for the control reaction of DaraEx-treated cells. DaraEx inhibits the agglutination effect of the anti-CD38 antibody Daratumumab in indirect antiglobulin tests (IAT).

1.2. Test Principle

DaraEx-PC contains an anti-CD38 antibody that induces agglutination of red blood cells. DaraEx inhibits this agglutination. DaraEx-PC can therefore be used to confirm the successful treatment of red blood cells with DaraEx.

1.3. Statement of Intended Use

For research use only.

2. Materials and Equipment

2.1. Definition of Symbols

DaraEx-PC DaraEx-PC

2.2. Components

DaraEx-PC DaraEx-PC 450 µl (0.1 mg/ml anti-CD38 antibody)

⚠ WARNING! May cause an allergic skin reaction (H317). Please wear safety gloves (P280). DaraEx-PC must be disposed in compliance with local regulations.

2.3. Storage and Expiry Date

Store at 2…8°C. Expiry Date is given on the immediate container.

⚠ WARNING! Do not freeze DaraEx-PC! The reactivity of frozen or frozen and thawed DaraEx-PC cannot be guaranteed. The according vial has to be disposed of immediately!

2.4. Materials and Equipment Supplied by the User

2.4.1. Materials

Material	Supplier
LISS/Coombs ID-Cards Test cell reagents for the ID-System	Bio-Rad
Alternatively Cellbind Screen Test cell reagents for the Cellbind Screen system	Sanquin Reagents B.V. other
Alternatively ORTHO MTS Test cell reagents for the ORTHO MTS system	Ortho Clinical Diagnostics
Pipette tips	Multiple suppliers

3. Preparation and Usage

Contaminations have to be avoided during all steps.

3.1. Cell Concentration

Use cells at a concentration of 0.5 or 0.8%, depending on the gel card system at hand.

3.2. Test Procedure

Use DaraEx-PC with DaraEx-treated cells in the IAT system. DaraEx-PC should be used like other samples according to the gel card manufacturer's protocol. For the Cellbind Screen system, use 40 – 50 µl DaraEx-PC.

4. Analysis

The DaraEx-treated cells incubated with DaraEx-PC should not agglutinate. If they do, the test result is invalid and cannot be used.

5. Limitations

DaraEx-PC has been tested with the standard volumes used in the given gel card systems. Usage of other volumes than described in the manual of the respective gel card system, especially usage of lower volumes can lead to insufficient agglutination. The usage of other gel card systems or IAT procedures than listed in 2.4.1 has to be validated by the user.

Very high concentrations of Daratumumab in a sample may lead to agglutination even though the red blood cells have been successfully treated with DaraEx. Please also refer to the DaraEx user manual.

Contamination of reagents, usage of reagents over their life-time, and usage of reagents not included or recommended may lead to false results.

Changes to the previous version are highlighted.

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