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Instructions for use

SERA PURE

Electronic instructions for use see www.bag-healthcare.com

For General Laboratory Use

REF 728197: SERA PURE (20 tests)

Version: 01 / 2018

Issue: 2018-04

1. INTENDED USE

SERA PURE is a diluent buffer intended to reduce low-affinity and nonspecific interactions of substances in human sera with the HLA proteins on the surface of the test wells in the HISTO SPOT[®] HLA AB Screen/ID kits. The HISTO SPOT[®] HLA AB Screen/ID kits are miniaturized and multiplexed solid phase enzyme linked immunosorbent assay for a high resolution anti-HLA antibody (Ab) identification.

2. TEST PRINCIPLE

Some sera can generate high background or a polyreactivity against more than 80% of the HLA antigens on the chip. In such cases, the SERA PURE diluent buffer reduces the low-affinity and nonspecific interactions causing a high background or a polyreactivity.

3. MATERIAL

3.1 Reagents provided

SERA PURE **Sample diluent buffer**, 20 tests, ready to use;
Contains 0.05% Proclin[®] 300.

3.2 Equipment required but not provided

- Variable pipettes (range 1 – 100 µl) and disposable tips

4. STORAGE AND STABILITY

SERA PURE has to be stored at 2...8°C. The expiry date is indicated on the label and is valid for the originally sealed reagents. Assay performance is dependent on reagents stability, they must not be used after their expiration date.

5. TEST PROCEDURE

For a detailed description of the test procedure please refer to the instructions for use for the HISTO SPOT[®] HLA AB Screen/ID kits. SERA PURE should be used in a second test if the original protocol leads to unspecific reactions or a very high background in the test well.

SERA PURE is used for sample dilution instead of the sample buffer provided in the HISTO SPOT[®] AB Reagent kit.

- ◆ Homogenize the SERA PURE by gentle vortex mixing.
- ◆ In the sample plate, dilute only sera that cause high background or nonspecific binding.

- **HLA AB ID Class I: 1:20** → Add **5 µl of the serum** and **95 µl of SERA PURE** in the sample plate. Mix at least 5 times with the pipette.
- **HLA AB ID Class II: 1:50** → Add **2 µl of the serum** and **98 µl of SERA PURE** in the sample plate. Mix at least 5 times with the pipette.

Then follow the protocol for the HISTO SPOT[®] HLA AB Screen/ID kits.

6. WARNINGS AND PRECAUTIONS

SERA PURE is a diluent buffer that should be used by properly trained, qualified staff. All work should be performed using Good Laboratory Practices.

SERA PURE contains ProClin[®]300 in a very low concentration of 0.05% as preservative, nevertheless avoid contact with the skin and mucous membranes.

A **Material Safety Data Sheets (MSDS)** for SERA PURE is available to download at www.bag-healthcare.com.

7. SPECIFIC PERFORMANCE CHARACTERISTICS

In an internal study, SERA PURE have been shown an efficiency to reduce the unspecific interactions from 50% of sera with a high background or a polyreactivity.







8. LIMITATIONS OF THE METHOD

This sample diluent buffer may be ineffective with some sera, depending on the source of the unspecific interactions. If a higher serum dilution is tested together with SERA PURE, there is a risk to mask some specific interactions between antibodies and HLA-Antigen.

9. TRADEMARKS USED IN THIS DOCUMENT/PRODUCT

Proclin[®] is a trademark of Rohm and Haas company.

10. EXPLANATION OF SYMBOLS USED ON LABELING

	Storage temperature / Temperature limitation
	Use by
	Consult instructions for use
	Manufacturer
	Batch code
	Catalogue number

Instructions for use in other languages see <http://www.bag-healthcare.com>
<http://service.bag-healthcare.com> or phone +49 (0)6404-925-125