BECKMAN COULTER

CE 2797

ACCESS
Immunoassay Systems

Instructions For Use

ACCESS PROGESTERONE CALIBRATOR S0

REF 33556

FOR PROFESSIONAL USE ONLY

Rx Only

FOR USE WITH TEST NAME: P4DE / PROGESTERONE

PRINCIPLE

INTENDED USE

The Access Progesterone Calibrator S0 is intended for use with the Access Progesterone assay to dilute patient samples containing analyte concentrations greater than the analyte specific S5 calibrator.

SUMMARY AND EXPLANATION

The analyte level in patient samples may exceed the level of the specific S5 calibrator. If a quantitative value is required, it will be necessary to dilute the samples in order to determine the analyte concentration.

REAGENTS

PRODUCT INFORMATION

Access Progesterone Calibrator S0

Cat. No. 33556: 4 mL/vial

- Provided ready to use.
- Store at -20°C.
- Mix contents by gently inverting before use. Avoid bubble formation.
- Stable until the expiration date stated on the label when stored at -20°C.
- After thawing, stable for three months when stored at 2 to 10°C.

S0:	Human serum, < 0.1% sodium azide, and 0.025% Cosmocil* CQ. Contains 0.0 ng/mL (nmol/L) progesterone.

*Cosmocil is a registered trademark of Arch Chemicals, Inc.

WARNING AND PRECAUTIONS

- For *in vitro* diagnostic use.
- Human source material used in the preparation of the reagent has been tested and found negative or non-reactive for Hepatitis B, Hepatitis C (HCV), and Human Immunodeficiency Virus (HIV-1 and HIV-2). Because no known test method can offer complete assurance that infectious agents are absent, handle reagents and patient samples as if capable of transmitting infectious disease.[1]

- Each serum/plasma pool used in the preparation of this product has been tested and found negative for the presence of fibrinogen.
- For hazards presented by the product refer to the following sections: REACTIVE INGREDIENTS and GHS HAZARD CLASSIFICATION.

REACTIVE INGREDIENTS

> ⚠ **CAUTION**
>
> **Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).**
> **To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.**

GHS HAZARD CLASSIFICATION

Not classified as hazardous

SDS	Safety Data Sheet is available at beckmancoulter.com/techdocs

TESTING PROCEDURE(S)

PROCEDURE

If a sample contains more analyte than the highest calibrator, dilute the sample following dilution instructions in the assay Instructions for Use. Refer to the appropriate system manuals and/or Help system for instructions on how to enter a sample dilution in a test request.

PROCEDURAL NOTES

LIMITATIONS

If there is evidence of microbial contamination or excessive turbidity in the reagent, discard the vial.

ADDITIONAL INFORMATION

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/746/EU on In vitro Diagnostic Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and to your national authority.

REVISION HISTORY

Revision J

IFU updated to add Dutch, Finnish, Macedonian, Traditional Chinese, and Estonian

Revision K

New release of IVDR compliant IFU.

Revision L

Added Translations.

Revision M

Added Translations.

Revision N

Added Translations.

SYMBOLS KEY

Glossary of Symbols is available at beckmancoulter.com/techdocs (document number C02724).

REFERENCES

1. HHS Publication, 5th ed., December 2009. Biosafety in Microbiological and Biomedical Laboratories.

EC REP Beckman Coulter Ireland Inc., Lismeehan, O'Callaghan's Mills, Co. Clare, Ireland +(353) (0) 65 683 1100

Beckman Coulter, Inc., 250 S. Kraemer Blvd., Brea, CA 92821 U.S.A.
+(1) 800-854-3633
www.beckmancoulter.com