FastPack® IP SHBG Calibrator

For use in conjunction with the FastPack® IP SHBG Immunoassay and FastPack® IP System analyzer

CAUTION: United States Federal law restricts this device to sale and distribution by or on the order of a physician, or to a clinical laboratory; and use is restricted to, by or on the order of a physician.

In Canada, use of this product is restricted to laboratories only.

INTENDED USE

The FastPack® IP SHBG Calibrator is intended to calibrate the FastPack® IP System when used for the quantitative determination of SHBG in human serum and plasma.

SUMMARY AND PRINCIPLE

Quantitative assay calibration is the process by which a set of samples with known analyte concentrations (i.e. assay calibrators) is tested to measure the response. The mathematical relationship between the measured responses and the known analyte concentrations establishes the calibration curve. The FastPack® IP System analyzer must be calibrated by the user to ensure that it is properly adjusted for the particular lot of FastPacks that are being used. The FastPack® IP SHBG Calibrator is used for this purpose.

PRODUCT INFORMATION

- The FastPack® IP SHBG Calibrator is included in the FastPack® IP SHBG Immunoassay Kit Complete – Cat. No. 25000080.
- Provided ready to use.
- Mix contents by gently inverting before use. Avoid bubble formation.
- Calibrator: 2.0 mL/vial. Liquid. Contains a buffer solution with protein stabilizers to yield a predetermined concentrations.
  Calibrator B
- Calibration Card: 1
- Preservatives: 0.1% Sodium azide and 0.1% ProClin® 300

WARNINGS AND PRECAUTIONS

- **For *In Vitro* diagnostic use only.**
- Do not pipette by mouth.
- Do not eat, drink or smoke in designated work areas.
- Do not mix calibrators from different lots.
- Method Verifiers are stable until the expiration date on the label when stored and handled as directed. Do not use Method Verifiers beyond the expiration date.
- After opening, calibrators are stable for 225 days when stored and handled as directed. Do not use calibrators beyond the expiration date.
- Avoid microbial contamination of reagents when removing aliquots from the bottles.
- Refer to the FastPack® IP System Procedure Manual for calibration procedures.
- Discard unused or expired calibrator material, in stoppered vial, into a Biohazard container.
- The components containing ProClin® 300 are classified per applicable European Economic Community (EEC) Directives as: Irritant (Xi). The following are appropriate Risk (R) and Safety (S) phrases for ProClin® 300:
- Reagents in this kit contain sodium azide as a preservative, which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volume of water to prevent azide build-up.
- The components containing sodium azide are classified per applicable European Economic Community (EEC) Directives as: Very toxic (T+) and Harmful to the environment (N). The following are the appropriate Risk (R) and Safety (S) phrases:

R28	Very toxic if swallowed.
R32	Contact with acids liberates very toxic gas.
R50/53	Very toxic to aquatic organisms may cause long-term adverse effects in the aquatic environment.
S28	After contact with skin, wash immediately with plenty of soap and water.
S45	In case of accident or if you feel unwell, see medical advice immediately (show the label where possible).
S60	This material and its container must be disposed of as hazardous waste.
S61	Avoid release to the environment. Refer to special instructions/safety data sheets.
R36/38	Irritant to eyes and skin.
R43	May cause sensitization by skin contact.
S37	Wear suitable gloves.

- **Human source material. The antigens used in the preparation are potentially infectious and should be handled according to universal precautions and good clinical laboratory practices. Where appropriate, the donors were screened for HIV, HBV and HCV using FDA approved tests and found to be negative.**

STORAGE INSTRUCTIONS

Store at 2 – 8 °C.

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