FastPack® IP SHBG Control

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 Controls are assayed quality control materials for the verification of the accuracy and precision of the FastPack® IP System when used for the quantitative determination of SHBG in human serum and plasma.

SUMMARY AND PRINCIPLE

The use of control material is indicated as an objective assessment of the precision of methods and techniques in use. Two levels of control are available to allow performance monitoring within the clinical range.

PRODUCT INFORMATION

- The FastPack® IP SHBG Control 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.
- Controls: 2.0 mL/vial. Liquid. Contains components of human origin prepared in a buffer solution with SHBG to yield predetermined concentrations of SHBG.
  - Control 1
  - Control 2

For the current Expected Range values, refer to the Control Range Card found in the FastPack® IP SHBG Immunoassay Kit Complete.

- Preservative: 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 controls from different lots.
- After opening, controls are stable for 75 days when stored and handled as directed. Do not use controls beyond the expiration date.
- Avoid microbial contamination of reagent when removing aliquots from the bottles.
- Refer to the FastPack® IP System Procedure Manual for control procedures.
- Discard unused or expired control 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 volumes of water to prevent azide build up.
- The components containing sodium azide are classified per applicable European Economic Community (EEC) Directives as: Very toxic and dangerous to the environment (T+ N). The following are appropriate Risk (R) and Safety (S) phrases for sodium azide:

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-suds.
S45	In case of accident or if you feel unwell, seek 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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