FastPack® IP SHBG Method Verification Kit

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

INTENDED USE

The FastPack® IP SHBG Method Verification Kit consists of assayed quality control materials for use in the quantitative verification of calibration and assay range of the quantitative FastPack® IP SHBG Immunoassay on the FastPack® Analyzer to meet CLIA requirements.

SUMMARY AND PRINCIPLE

The verification of method performance should provide evidence that the accuracy, precision, and reportable range of the procedure are adequate to meet the customer's needs. Accuracy is verified by determining that a method produces correct results. Precision is verified by assessing day-to-day, run-to-run, and within-run variation, as well as operator variance. Verification of the reportable range is accomplished by assaying low and high materials.

Calibration verification occurs through the testing of 2 or more levels of calibration materials that include a low, mid, and high value at least every 6 months.

The FastPack® IP SHBG Method Verification Kit includes materials to meet the requirements for calibration verification and verification of the reportable range.

PRODUCT INFORMATION

- Mix contents by gently inverting before use. Avoid bubble formation.
- Method Verifiers: 0.5 mL/vial. Liquid. Contain components of human origin prepared in a Buffer with protein stabilizers to yield predetermined concentrations:
  See Verifier Range Card for values.
- Preservatives: 0.1% Sodium azide and 0.1% Proclin® 300

WARNING 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 verification materials 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.
- Method Verifiers are intended for single use only; once opened, do not store for use at a later date.
- Avoid microbial contamination of reagents when removing aliquots from the bottles.
- Refer to the FastPack® QA Manual for method verification procedures.
- 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-suds.
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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