FastPack® Testo Method Verification Kit

For use in conjunction with the FastPack® IP Testo 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.

INTENDED USE

The FastPack® Testo Method Verification Kit consists of assayed quality control materials for verification of the calibration and reportable range of the FastPack® Testo Immunoassay 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 3 or more levels of calibration materials that include a low, mid, and high value at least every 6 months.

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

PRODUCT INFORMATION

- Provided ready to use.
- Mix contents by gently inverting before use. Avoid bubble formation.
- Method Verifiers: 1.0 mL/vial. Liquid. Contain components of human origin prepared in a TRIS Buffer with protein stabilizers to yield predetermined concentrations.
  See Verifier Range Card for values.
- Preservatives: 0.04% ProClin® 150

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.
- Avoid microbial contamination of reagents when removing aliquots from the bottles.
- Refer to the FastPack® QA Manual for method verification procedures.
- 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 Proclin® 150 are classified per applicable European Economic Community (EEC) Directives as: Corrosive (C). The following are appropriate Risk (R) and Safety (S) phrases for Proclin® 150:

R34	Causes burns.
R43	May cause sensitization by skin contact.
S26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S36/37/39	Wear suitable protective clothing, gloves and eye/face protection.
S45	In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

- **Human source material. Treat as potentially infectious.**

STORAGE INSTRUCTIONS

Store at 2 - 8 ˚C.

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