

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® Control is an assayed quality control for the verification of the accuracy and precision of the FastPack® IP System when used for the quantitative determination of the analytes listed in the package insert.

SUMMARY AND PRINCIPLE

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

PRODUCT INFORMATION

- Contains the following analytes:

Total PSA (Prostate Specific Antigen) Testosterone	TSH (Thyroid Stimulating Hormone) Free T4 (Free Thyroxine) hCG (Human Chorionic Gonadotropin)
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- Provided ready to use.
- Mix contents by gently inverting before use. Avoid bubble formation.
- Controls: 5.0 mL/vial. Liquid. Contains components of human origin prepared in a Tris buffer solution with protein stabilizers to yield predetermined concentrations for Level 1 and Level 2.
- Preservative: 0.1% sodium azide and 0.1% ProClin® 950.

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 120 days when stored and handled as directed. Do not use controls beyond the expiration date. Control stability is based on both open and closed vial stability studies.
- Avoid microbial contamination of reagent when removing aliquots from the bottles.
- Discard unused or expired control material, in stoppered vial, into a Biohazard container.
- 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 and ProClin® 950 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 and ProClin® 950:

R28	Very toxic if swallowed.
R32	Contact with acids liberates very toxic gas.
R36/3	Irritating to eyes and skin.
R43	May cause sensitization by skin contact.
R50/53	Very toxic to aquatic organisms. May cause long-term adverse effects in the aquatic environment.
S24/25	Avoid contact with skin and eyes.
S28	After contact with skin, wash immediately with plenty of soap-suds.
S36/37	Wear suitable protective clothing and gloves.
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.

- **Human source material. Some antigens used in the preparation are potentially infectious and should be handled according to universal precautions and good clinical laboratory practices. Human source materials were screened for HIV Types 1 and 2, HBV and HCV using FDA approved tests.**

STORAGE INSTRUCTIONS

Store at 2 – 8 °C.



Qualigen, Inc.
Carlsbad, CA 92011 USA
Technical Support
(760) 918-9165
(877) 709-2169

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