

INTENDED USE

The FastPack® hCG Calibrator is intended to calibrate the FastPack® System when used for the quantitative determination of Human Chorionic Gonadotropin (hCG) in human serum or plasma.

SUMMARY AND PRINCIPLE

Quantitative assay calibration is the process by which a set of samples with known analyte concentrations (i.e. assay standards) is tested to measure the response. The mathematical relationship between the measured responses and the known analyte concentrations establishes the calibration curve. A master calibration curve is generated for each lot of FastPack® reagents. Since FastPack® System analyzers vary in response levels, the initial starting point needs to be determined on each analyzer and normalized to fit the manufacturer's generated calibration curve. The FastPack® hCG Calibrator Kit is used for this purpose.

PRODUCT INFORMATION

- Provided ready to use.
- Mix contents by gently inverting before use. Avoid bubble formation.
- Calibrator: 2.0 mL/vial. Liquid containing a protein matrix with stabilizers.
- Calibration Card: 1
- Preservative: <0.1% sodium azide and 0.25% 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.
- After opening, calibrators are stable until the expiration date on the label when stored and handled as directed. Do not use calibrators beyond the expiration date. Calibrator stability is based on a closed vial stability study.
- Avoid microbial contamination of reagent when removing aliquots from the bottles.
- Refer to the QA Manual for additional information.
- Discard unused or expired calibrator material, in stoppered vial, into a Biohazard container.
- ProClin® 300 is an irritant. The following are appropriate Risk (R) and Safety (S) phrases for ProClin® 300:
 - R43 May cause sensitization by skin contact.
 - S28-37 After contact with skin, wash immediately with plenty of soap and water. Wear suitable gloves.
- 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.
- **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.**

STORAGE INSTRUCTIONS

Store at 2 – 8 °C. Opened vials are stable for up to 140 days when stored at 2 – 8 °C.

Manufactured by:

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

© 2000 Qualigen, Inc. All rights reserved. Qualigen and FastPack are trademarks or registered trademarks of Qualigen, Inc. All other trademarks are the property of their respective owners.