



# FastPack<sup>®</sup> hCG Sample Diluent

For use in conjunction with the FastPack<sup>®</sup> hCG Immunoassay and FastPack<sup>®</sup> System Analyzer

## INTENDED USE

The FastPack<sup>®</sup> hCG Sample Diluent is intended for use with FastPack<sup>®</sup> hCG assay to dilute samples containing hCG concentration greater than 1000 mIU/mL for the quantitative determination of Human Chorionic Gonadotropin (hCG) in human serum or plasma.

## SUMMARY AND PRINCIPLE

The analyte levels in patient samples may exceed the assay range of 1000 mIU/mL. If quantitative value is required, it will be necessary to dilute the samples in order to determine hCG concentrations.

## PRODUCT INFORMATION

- Provided ready to use.
- Mix contents by gently inverting before use. Avoid bubble formation.
- Sample Diluent: 2.5 mL/vial. Liquid containing a protein matrix with stabilizers.
- Preservative: <0.1% sodium azide and 0.25% ProClin<sup>®</sup> 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 until the expiration date on the label when stored and handled as directed. Do not use controls beyond the expiration date. Control 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 control material, in stoppered vial, into a Biohazard container.
- ProClin<sup>®</sup> 300 is an irritant. The following are appropriate Risk (R) and Safety (S) phrases for Proclin<sup>®</sup> 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.

## PROCEDURE

Samples can be accurately measured for hCG if it is within the analytic range of 1.8 - 1000 mIU/mL. If the sample contains an hCG value greater than 1000 mIU/mL, the assay must be run again using a diluted sample that will produce results within the above analytic range.

To create a diluted sample, pipette a fresh 25 µL sample using a new pipette tip and add this to a Sample Diluent tube. Replace the screw cap on the tube and mix by gently inverting the tube back and forth several times. This will create a 1:100 dilution. Using a new pipette tip, take a 25 µL sample from the diluted sample in the Sample Diluent tube. Run this sample together with a fresh FastPack<sup>®</sup> and the FastPack<sup>®</sup> System as per the instructions stated in the Procedure Manual. Multiply the result by 100 to obtain the hCG value of the original sample.

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