

FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES (U.S. ONLY).

For use in conjunction with the FastPack® IP α GST Immunoassay and the FastPack® IP System

INTENDED USE

The FastPack® α GST Calibrator is intended to calibrate the FastPack® IP System when used for the quantitative determination of Alpha Glutathione S-Transferase (α GST) 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® IP reagents. Since FastPack® IP System analyzers vary in response levels, the initial starting point per lot needs to be determined on each analyzer and normalized to fit the manufacturer's generated calibration curve. The FastPack® α GST Calibrator Kit is used for this purpose. For the calibration procedure, please see the FastPack® IP System Procedure Manual (or wherever this information is located).

PRODUCT INFORMATION

- Provided in liquid form, ready to use.
- Mix contents by gently inverting before use. Avoid bubble formation.
- Calibrator: 3.0 mL/vial. Contains components of recombinant α GST prepared in a PIPES buffer solution with protein stabilizers.
- Calibration Card: 1
- Preservative: 0.25% ProClin® 300.

WARNINGS AND PRECAUTIONS

- **For *in vitro* 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 FastPack® IP Procedure Manual for calibration procedures.
- Discard unused or expired calibrator material, in stoppered vial, into a Biohazard container.
- The components containing ProClin® are classified per applicable European Economic Community (EEC) Directives as: Irritant (Xi). The following are appropriate Risk (R) and Safety (S) phrases for ProClin®:

R36/38 Irritating to eyes and skin

R43 May cause sensitization by skin contact

S24/25 Avoid contact with skin and eyes

S36/37 Wear suitable protective clothing and gloves

S60 This material and/or its container must be disposed of as hazardous waste

STORAGE INSTRUCTIONS

Store at 2 – 8 °C. Stable until expiration date on the label when stored and handled as directed.



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