

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 Controls are assayed quality control materials for the verification of the accuracy and precision of the FastPack® IP System when used for the quantitative determination of α GST in human serum or plasma.

SUMMARY AND PRINCIPLE

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

PRODUCT INFORMATION

- Provided in liquid form, ready to use.
- Mix contents by gently inverting before use. Avoid bubble formation.
- Controls: 3.0 mL/vial. Liquid. Contains components of recombinant α GST prepared in a PIPES buffer solution with protein stabilizers to yield predetermined concentrations.
 - Control 1
 - Control 2
- Preservative: 0.25% ProClin® 300
- Established ranges are provided in each kit.

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 controls from different lots.
- 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. After opening, controls are stable for 60 days.
- Avoid microbial contamination of reagent when removing aliquots from the bottles.
- Refer to the FastPack® IP System Procedure Manual for control procedures.
- Discard unused or expired control 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.



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