

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

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

#### INTENDED USE

The FastPack® αGST Sample Diluent is intended for use with the FastPack® IP αGST immunoassay to dilute samples containing αGST in concentrations greater than 200 ng/mL when used for the quantitative determination of Alpha Glutathione S-Transferase (αGST) in human serum or plasma.

#### SUMMARY AND PRINCIPLE

Samples can be accurately measured for αGST if it is within the analytic range of 0.5 – 200 ng/mL without dilution. However, in instances where the analyte level exceeds the assay range of 200 ng/mL, the FastPack® System will not provide a value. The sample must be diluted before running the assay in order to determine the actual αGST concentration.

#### PRODUCT INFORMATION

- Provided in liquid form, ready to use.
- Mix contents by gently inverting before use. Avoid bubble formation.
- Sample Diluent: 4.9 mL/vial. Liquid containing phosphate buffered saline with detergent.
- Preservative: 0.1% 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 diluents from different lots.
- After opening, diluents are stable until the expiration date on the label when stored and handled as directed. Do not use diluents beyond the expiration date. Diluent stability is based on a closed tube stability study.
- Avoid microbial contamination of reagent when removing aliquots from the bottles.
- Refer to the FastPack® IP System Procedure Manual for additional information.
- Discard unused or expired material, in the tube, 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.

#### PROCEDURE

If a sample contains an αGST value greater than 200 ng/mL, the assay must be run again using a diluted sample in order to determine the actual value. To create a diluted sample and determine the actual αGST value, follow the steps listed in the table below. Please read the entire set of instructions before beginning the dilution process.

Step	Instructions
1	Using a <b>new</b> pipette tip, take a <b>fresh</b> 100 µL patient sample and add it to a Sample Diluent tube.
2	Replace the cap on the tube and gently mix by inverting the tube back and forth several times. This will create a 1:50 diluted sample.
3	Now, using a <b>new</b> pipette tip, take a 100 µL sample from the mixture in the Sample Diluent tube.
4	Run this sample together with a <b>fresh</b> FastPack® IP and obtain a result. <b>NOTE: The result displayed on the analyzer IS NOT the αGST value! See step 5.</b>
5	<b>Multiply the result by 50 to obtain the αGST value of the original patient sample. The calculated value should be greater than 200 ng/mL.</b>

If the analyzer reports a value greater than 200 ng/mL for the diluted sample another dilution is necessary using the instructions below.

Step	Instructions
1	Using a <b>new</b> pipette tip, take 100 $\mu$ L of the <b>1:50 diluted sample</b> and add it to a <b>new</b> Sample Diluent tube.
2	Replace the cap on the tube and gently mix by inverting the tube back and forth several times. This will create a 1:2500 diluted sample.
3	Now, using a <b>new</b> pipette tip, take a 100 $\mu$ L sample from the mixture in this Sample Diluent tube.
4	Run this sample together with a <b>fresh</b> FastPack <sup>®</sup> IP and obtain a result. <b>NOTE: The result displayed on the analyzer IS <u>NOT</u> the <math>\alpha</math>GST value! See step 5.</b>
5	<b>Multiply the result by 2500 to obtain the <math>\alpha</math>GST value of the original patient sample. The calculated value should be greater than 200 ng/mL.</b>



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

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