

Glycated Serum Protein (GSP) Control Procedure No. 2370

Intended Use

Stanbio Glycated Serum Protein (GSP) Control Kit is intended to be used for quality control procedures in examining the accuracy and precision of Stanbio Glycated Serum Protein LiquiColor® Assay (REF 2350-062). For *in-vitro* diagnostic use only.

Summary

The Stanbio GSP Control Kit (REF 2370-401) is a set of two level 1 and two level 2 controls. These two levels are to be used as reference samples for checking the functionality of the Stanbio Glycated Serum Protein (GSP) assay (REF 2350-062).

Reagents – Working Solutions

Reactive Components

Buffer base and additives

Non-reactive components

Sodium azide (NaN₃) <0.1%

Stanbio GSP Control Kit includes two levels of controls that is supplied in lyophilized form.

Control Values

The exact Control values are stated on each vial label.

Precautions and Warnings

1. Exercise the normal precautions for handling all laboratory reagents. Each donor unit of serum used in the preparation of this Calibrator Set was tested by FDA-approved methods and found negative for the Human Immunodeficiency Virus Antibody (HIV I/II Ab), Hepatitis B Surface Antigen (HBsAg), and Hepatitis C Virus Antibody (HCV). Because no method can offer complete assurance as to the absence of infectious agents, however, this material and all patient samples should be handled as though capable of transmitting infectious disease and disposed of accordingly.
2. Additional safety information concerning storage and handling of this product is provided within the Material Safety Data Sheet for this product.
3. Avoid contact with skin and eyes.
4. Contains sodium azide, which may react with lead or copper plumbing to form explosive compounds. Flush drains with copious amounts of water when disposing of this reagent.

Handling

Reconstitute lyophilized contents of each vial with 1 mL of distilled water. To ensure complete reconstitution, equilibrate vial at room temperature for 30 minutes with gentle swirling a few times before first use, make sure all the contents are dissolved.

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Storage and Stability

Store at 2 to 8°C. **DO NOT FREEZE.**

Note: Store Controls tightly capped when not in use.

Stability

Unreconstituted material: stability is up to the expiration date on label when stored at 2 to 8°C

Reconstituted material: stability is up to 14 days when stored at 2 to 8°C

Materials Provided

The Stanbio GSP Control Kit consists of four vials.

Materials required (but not provided)

Stanbio GSP Assay reagents (REF 2350-062)

Distilled water

General laboratory equipment

Assay

Prepare Control 1 and 2 as stated in the Handling section. Take care to avoid the formation of bubbles. Use in the same way as a sample. Follow the applicable government regulations and local guidelines for quality control.

Note: The Stanbio Glycated Serum Protein Control kit is recommended to be used as daily quality control.

References

1. Armbuster DA, Fructosamine: Structure, Analysis and Clinical Usefulness. *Clin. Chem.* 1987; 33 (12): 2153-2163.
2. Kouzuma, T. *et al.* An Enzymatic Method for the Measurement of Glycated Albumin in Biological Samples. *Clin. Chim. Acta* 2002; 324: 61-71

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