





Bridging the gap in diabetes testing

The Glycated Serum Protein (GSP) LiquiColor® test serves as a 2-3 week indicator of average blood glucose closing the information gap between daily blood glucose testing and the 2-3 month HbA1c reading.

GSP serves as an accurate intermediate marker of glycemia in instances where HbA1c may be of limited value such as pregnancy, reduced RBC lifespan and hemodialysis.

The Glycation Gap

Studies suggest that combining GSP results with HbA1c measurements provides a better assessment of long term risk of diabetic complications.

The difference between actual measured HbA1c and predicted HbA1c from glycated serum protein is called the glycation gap.

Measuring HbA1c and GSP together offers improved diagnostic accuracy by more reliably predicting complications of diabetes including nephropathy and retinopathy.

Glycated serum protein vs conventional fructosamine assays

Stanbio's GSP test utilizes the specificity of fructosyl-amino oxidase to eliminate significant interferences

Enzymatic specificity and accuracy

Stanbio's enzymatic method is more reliable and specific than the older non-enzymatic fructosamine NBT method.

Stanbio's method eliminates the inaccuracies caused by non-glycated protein reducing substances which interfere with the NBT fructosamine method.





Specifications

Method	Enzymatic
Correlation to Predicate Method	• N = 65 • R2 = 0.9966 • Slope = 0.9542 • y Intercept = 14.567 • Range of values = 60 - 1249 µmol/L GSP
Linearity	21.0 - 1354.0 µmol/L
On-Board Stability*	Four weeks
Calibration	Two point Sold separately
Sample Type	Serum
Sample Size*	10 µL



Assay procedure**

*Analyzer dependent **For Hitachi® 917

Bridge the gap in diabetes monitoring

- Provides superior specificity and accuracy compared to fructosamine assays (NBT method) for monitoring and assessment of short-term to medium-term (past 2-3 week period) average blood glucose levels.
- Complementary to HbA1c in diagnosis and screening of diabetes.

Precision per CLSI EP5-A

Within-Run Precision

	Control Level 1	Control Level 2	Serum Level 1	Serum Level 2
Ν	80	80	80	80
Mean (µmol/L)	204	751	251	373
SD (µmol/L)	2.2	4.9	1.9	2.4
CV (%)	1.1%	0.7%	0.8%	0.6%

Total Precision

	Control Level 1	Control Level 2	Serum Level 1	Serum Level 2
N	80	80	80	80
Mean (µmol/L)	204	751	251	373
SD (µmol/L)	2.4	5.6	3.2	3.7
CV (%)	1.2%	0.7%	1.3%	1.0%

Ordering information

STANBIOChemistry

from EKF Diagnostics

Description	Reference Number	Contents
GSP LiquiColor® Reagent	2350-062	R1: 1x50 mL R2: 1x12.5 mL
Calibrator Set	2360-401	(4 x 1 mL) Calibrator 1 - 2 vials Calibrator 2 - 2 vials
Controls Set	2370-401	(4 x 1 mL) Level 1 control - 2 vials Level 2 control - 2 vials

EU: CE IVD



SSP REAGENT (K) ^KNeito Cont. 50 mL (€ IVD []] 2°C |^{8°C} [®] 2351-050 LOT 33641 ∑ 2016²⁰



Manufacturer

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RSS0085.01 DAR# 16.1419 Eff. Date: 23 Nov 2016 ©2016 Stanbio