FDA CLEARED for clinical use

Lucica® Glycated Albumin-L

Manufactured by
Asahi Kasei Pharma Corporation

STANBIO® Chemistry

EKF Diagnostics for life

Lucica® Glycated Albumin-L

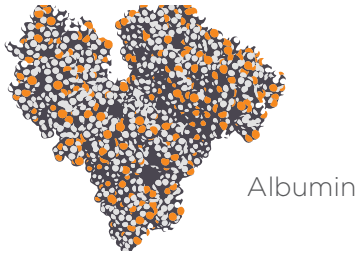
The Lucica® method for Glycated Albumin, manufactured by Asahi Kasei Pharma Corporation, is a specific test for glycated albumin that is now FDA cleared for sale in the U.S. The Lucica® Glycated Albumin-L test is distributed exclusively by Stanbio Labs (an EKF company). The Lucica® Glycated Albumin-L test is one of the most widely used and published Glycated Albumin methods worldwide.

What are the advantages?

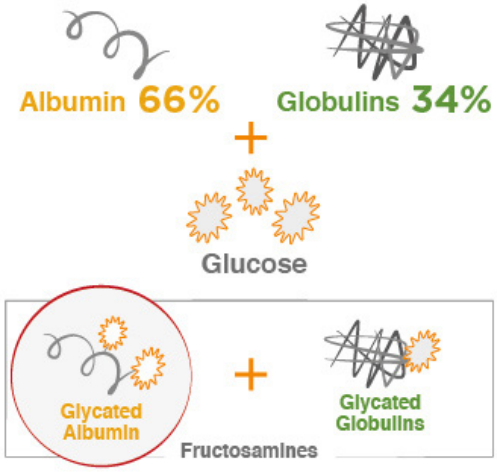
- Lucica® Glycated Albumin-L is **specific** for glycated albumin. It does not measure other glycated proteins such as glycated immunoglobulins.
- Lucica® Glycated Albumin-L measures **both** glycated albumin and total albumin in separate reactions.
- Lucica® Glycated Albumin-L results are expressed as a **ratio**, thus minimizing differences in protein concentrations between patients.
- Lucica® Glycated Albumin-L is standardized to an established reference (JCCRM611) via JSCC (Japan Society of Clinical Chemistry).
- Over the last decade, numerous studies have been published utilizing the Lucica® methodology. See Bibliography List.

Glycated Albumin

Albumin is the most abundant extracellular protein in the circulatory system. Albumin is involved primarily with regulation of osmotic pressure and as a carrier protein for hydrophobic molecules in the bloodstream including drugs, bile acids and free fatty acids. Albumin has a half-life (turnover) of approximately 21 days and is very sensitive to 'glycation' by glucose and other sugars in the blood.



Albumin



Glycated albumin differs from traditional fructosamine tests as it measures glycated albumin only. In a fructosamine measurement the majority of the signal is due to glycated albumin (~66% of serum proteins is albumin). The remaining signal is comprised of other glycated globulins (~34%). There are numerous fructosamine methods available but these methods lack standardization and don't report results as a ratio.

Glycation of Albumin

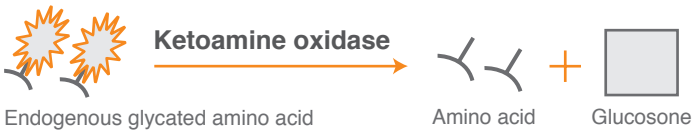
Similar to other glycated proteins, albumin undergoes a non-enzymatic conversion (Maillard reaction) where glucose and other sugars react with amino terminal residues on the protein to form an unstable Schiff base. This molecule in the acyclic form can either reverse back to glucose and protein or undergo an Amidori arrangement to a stable molecule known as a glycated albumin.

Principle of the test

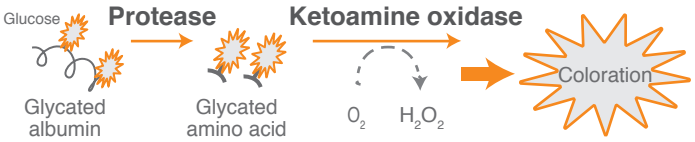
The Lucica® Glycated Albumin-L test is performed on serum and consists of two steps: (1) an enzymatic assay for glycated albumin and (2) a test for total albumin via a Bromcresol Purple analysis or BCP. The GA value is calculated by dividing the GA concentration by the albumin concentration.

In the primary, enzymatic reaction, endogenous glycated amino acids are eliminated and the resulting glycated albumin is reacted with specific enzymes to produce a colorimetric signal at 546/700 nm.

1. Elimination of glycated amino acid



2. Determination of glycated albumin



In the total albumin reaction the sample reacts with the pretreatment solution to convert reduced albumin to oxidized albumin. The treated solution reacts with bromocresol purple (BCP) forming a blue conjugate of albumin and BCP. The absorbance of this blue conjugate is measured to quantify albumin concentration at 600/660 nm.

Determination of albumin

Calculation of glycated albumin (GA) value

The obtained GA concentration is divided by the albumin concentration thereby yielding the glycated albumin value (mmol/mol or %) of the sample.

The Lucica® Glycated Albumin-L test is performed as a user-defined assay on liquid based, chemistry analyzers that have 'open-channel' capability.

Intended use

Lucica® Glycated Albumin-L is intended to be used for the quantitative measurement of glycated albumin in human serum on compatible clinical chemistry analyzers. The measurement of glycated albumin is useful for the intermediate term (preceding 2-3 weeks) monitoring of glycemic control in patients with diabetes. For in vitro diagnostic use only.

Outcomes

There is peer-reviewed literature supporting the use of glycated albumin (GA) as a good marker of glycemic control based on clinical outcomes for microvascular and macrovascular complications, diabetes risk, prognosis in hemodialysis patients and predicting pregnancy outcomes. GA has been shown to be useful for the intermediate term monitoring of glycemic control in patients with diabetes.

For microvascular complications, studies involving collectively over 11,000 subjects in the U.S. and in China followed for 5 to 20 years revealed that GA is associated with the onset and progression of diabetic microvascular complications.

For macrovascular complications, studies in the U.S., Japan, Korea and China involving collectively over 11,000 subjects revealed that GA is associated with vascular outcomes, atherosclerosis, poor prognosis and mortality

Item description	Ref. no.
Lucica® Glycated Albumin-L test kit Includes: GA R1 2 x 40 mL GA R2 2 x 10 mL ALB R1 2 x 40 mL ALB R2 2 x 20 mL	L210GA
Calibrator for Lucica® Glycated Albumin-L Low: 1 x 1 mL; High: 1 x 1 mL	G252GA
Control for Lucica® Glycated Albumin-L Low 1 x 3 mL; High 1 x 3 mL	G282GA

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Association with Long Term Complications (EDIC/ARIC) and Diabetes Risk

a) Microvascular Complications (e.g. retinopathy)

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b) Macrovascular Complications (e.g. arteriosclerosis)

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Diabetes in Specific Ethnic Populations

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