

**K-ASSAY®**

# Fructosamine Control

**Lot: 507501, Exp. 2018-02-28****Cat. No. K52C-6M****INTENDED USE**

These Fructosamine Controls are intended for use in fructosamine test systems to validate performance of the assay. The controls may also be useful in assessing test precision or analytical errors.<sup>1</sup> *FOR IN VITRO DIAGNOSTIC USE ONLY.*

**INTRODUCTION AND SUMMARY**

Glycated proteins are formed by a non-enzymatic reaction between glucose and protein in which unstable Schiff bases are formed, followed by an Amadori conversion to form stable ketoamines.<sup>2</sup> These glycated proteins include glycohemoglobin, glycoalbumin and glycated total protein. Fructosamine is a term that has come into acceptance and refers to both glycoalbumin and glycated total protein.<sup>3</sup> As the average life span of these proteins is about 2-3 weeks, the level of fructosamine provides a reflection of the average glucose concentration over that time.<sup>4</sup>

Fructosamine and glycohemoglobin are both used to monitor diabetic control. However, each assay provides information for a specific time frame that is related to the analyte being measured. Since the life span of hemoglobin is closer to 6-8 weeks, glycohemoglobin measurements reflect the average glucose concentration over this longer period of time.<sup>4</sup> Therefore, in comparison to glycohemoglobin determinations, fructosamine provides an index of intermediate-term diabetic control as opposed to the longer term for glycohemoglobin. Also, because of the shorter life span of the glycated albumin and total proteins, fructosamine measurements are more sensitive to changes in diabetic control. This provides a means to alert the physician to improvement, or deterioration in control much earlier than glycohemoglobin determinations.<sup>5</sup>

There have been several methods developed for the determination of fructosamine. These methods include phenylhydrazine, furosine, affinity chromatography and several colorimetric procedures.<sup>6</sup> A procedure using furosine and HPLC is accepted as the reference method however, a colorimetric procedure using nitroblue tetrazolium (NBT) has gained popularity due to its speed, reproducibility and ease of automation.<sup>7</sup> The controls presented here have been designed to be used in the verification of the manufacturer's NBT method for determination of fructosamine.

**SET COMPOSITION**

**Fructosamine Control** **6 x 2 mL**  
 3 x 2 mL Fructosamine Control – Level 1  
 3 x 2 mL Fructosamine Control – Level 2

Human serum containing buffers, stabilizers and fillers

**WARNINGS AND PRECAUTIONS**

*FOR IN VITRO DIAGNOSTIC USE.* Rx only.

Human serum was used to manufacture this product. Each donor unit was tested and found negative for HBsAg and HCV and non-reactive for HIV-1/2 antibody. Since no test method can assure that products derived from human blood do not contain HIV-1/2 and Hepatitis B and Hepatitis C viruses, these controls should be handled as though capable of transmitting infectious diseases.

Good laboratory safety practices should be followed when handling any laboratory reagent. Refer to a recognized laboratory safety program for additional information. (See NCCLS document GP17-T, Clinical Laboratory Safety; Tentative Guideline, 1994)

**CONTROL PREPARATION**

1. Controls are liquid stable, ready to use.
2. For assay use, remove a suitable aliquot of control for instrumentation used; cap and refrigerate the vial.

DO NOT dilute these controls. Results from diluted controls will not correspond to the original value in a linear manner.

**STABILITY AND STORAGE**

Unopened, the Fructosamine Controls are stable until the expiration date listed on the vial if stored at 2-8°C. After opening the controls are stable for 30 days at 2-8°C.

**LIMITATIONS OF PROCEDURE**

Refer to the "LIMITATIONS" section of the package insert for the Fructosamine Reagent. Improper handling and/or storage of the control can have an effect on the recovered results. Inaccurate reconstitution of the control and errors in assay technique can cause erroneous results.

DO NOT use the product if there is visible evidence of microbial growth in the vial.

## REFERENCE RESULTS

For reference value ranges, please see the chart below. The values listed were obtained using in-date reagents at the time of testing. Any modification in more recent reagent lots may give values different from the printed expected values. The assay values and ranges provided are derived using the manufacturer's Fructosamine Reagent. The mean of several assay values may not duplicate the assay value indicated, but should be within the range given. An individual assay value may be outside the range given.

It is recommended that each laboratory establish its own mean and precision parameters for these controls.

## REFERENCES











1. *Textbook of Clinical Chemistry*, Tietz, N.W., Ed., W.B. Saunders Company, Philadelphia, 1986, p 424-458.
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4. Day, J.F., et al, *Diabetes* 29:524 (1980).
5. Burtis, C.A., Ashwood, E.R., *Tietz Fundamentals of Clinical Chemistry*, Philadelphia (PA), W.B. Saunders, p. 370 (1996).
6. Burtis, C.A., Ashwood, E.R., *Tietz Textbook of Clinical Chemistry*, Philadelphia (PA), W.B. Saunders, p. 796 (1999).
7. Scleicher, E.D., Vogt, B.W., *Clin. Chem.* 36:136 (1990).

## ASSAY DATA

Lot: 507501, Exp. 2018-02-28

ASSAY	MANUFACTURER	UNITS	L1	VALUES	L2	VALUES
			MEAN	EXPECTED RANGE	MEAN	EXPECTED RANGE
Fructosamine	KAMIYA BIOMEDICAL COMPANY	mmol/L	1.9	1.5 – 2.3	5.1	4.1 – 6.1

## LABELING SYMBOLS

	Lot Number
	Control
	Expiration or "Use By" Date
	Catalog Number
	For <i>In Vitro</i> Diagnostic Use
	2-8°C Temperature Limitation. Store between 2 and 8 degrees C
	Potential Human Biohazard
	Manufacturer
	Consult Package Insert for Instructions for Use
	Authorized Representative in the European Community

## EU AUTHORIZED REPRESENTATIVE



 **EC|REP**

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