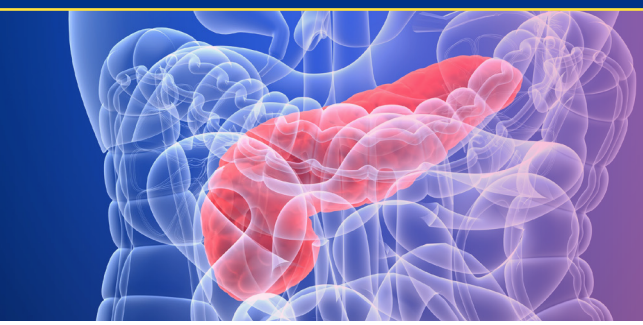
DZ152A

1,5-ANHYDROGLUCITOL (1,5-AG) ASSAY

Diabetic Marker

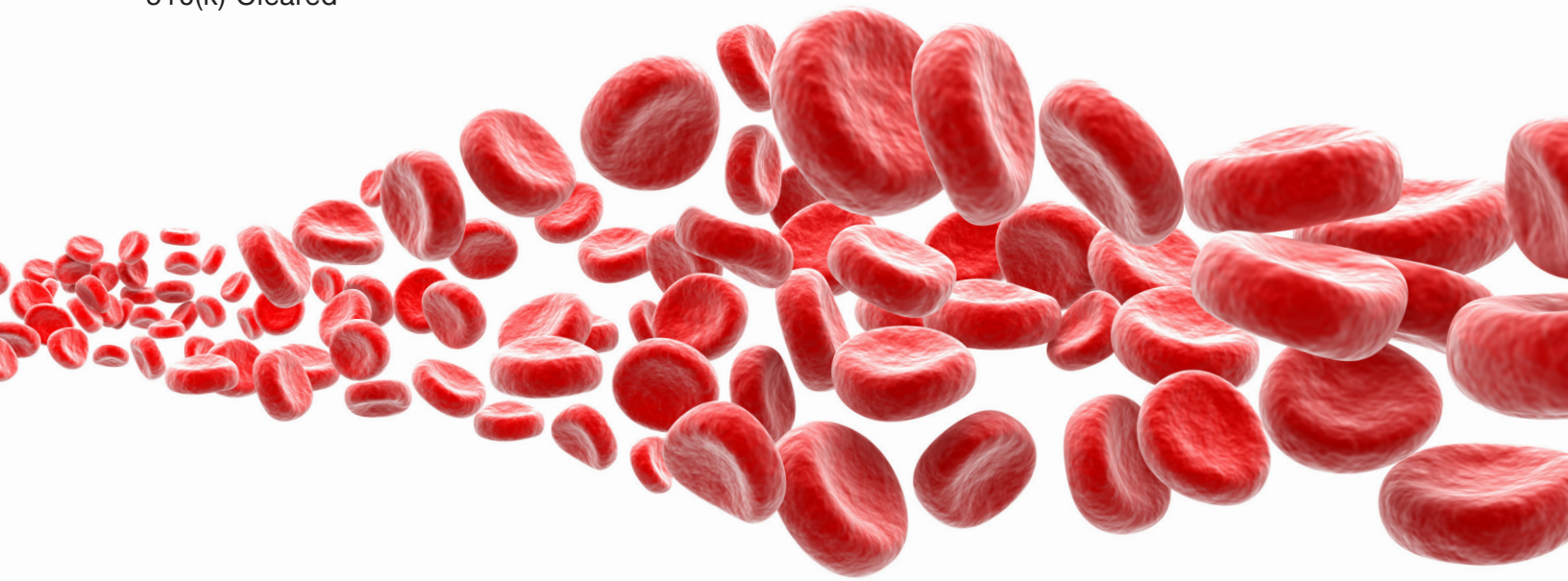


DIAZYME 1,5-AG ASSAY ADVANTAGES

- Diazyme's 1,5-Anhydroglucitol (1,5-AG) Assay is an enzymatic liquid stable assay
- The 1,5-AG Assay is for the intermediate monitoring of glycemic control in people with diabetes
- 1,5-AG values are useful to help fill the "glycemic gap" and offer complimentary information to HbA1c and Glycated Serum Protein (GSP) results
- Diazyme's 1,5-AG has excellent correlation with existing assay in the marketplace
- Assay can utilize both fasting and non-fasting serum and plasma samples
- Good reimbursement in many states
- CPT Code: 84378

REGULATORY STATUS

510(k) Cleared



DIAZYME

Innovations in Clinical Diagnostics

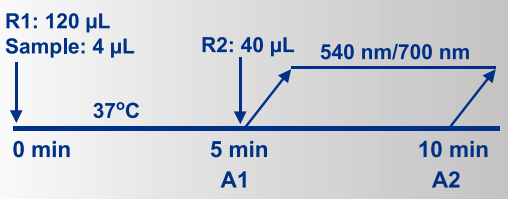
1,5-ANHYDROGLUCITOL (1,5-AG) ASSAY

Dual Vial
Liquid Stable

ASSAY SPECIFICATIONS

Method	Enzymatic Assay
Sample Type & Volume	• Serum • Plasma - EDTA - Heparin Sample Volume 4 µL
Analytical Sensitivity ***Linearity**	0.6 - 110 µg/mL 0 - 110 µg/mL
LOB **LOD** **LOQ**	0.3 µg/mL 0.5 µg/dL 0.6 µg/dL
Interferences	The following substances do not interfere: Hemoglobin - Up to 125 mg/dL Triglycerides - Up to 1000 mg/dL Bilirubin - Up to 5 mg/dL

*1,5 AG Assay Procedure**



***Analyzer Dependent**

For a list of validated parameters please contact Diazyme technical support at 858-455-4768 or email support@diazyme.com

ASSAY PRECISION

The precision of the Diazyme 1,5-AG Assay was evaluated according to CLSI EP5-A2 guideline. In the study, six serum samples, 2 levels of controls, and calibrator were tested in duplicate per run, 2 runs per day for 20 days using three lots of the reagent. The results of the within-run, between-run, between-day, between-lot, and total CV% for three lots of reagent combined are listed in the following table (N=240):

Sample	Mean µg/mL (N=240)	Within-Run SD CV%	Between-Run SD CV%	Between-Day SD CV%	Between-Lot SD CV%	Total SD CV%
Con L	3.62	0.07 2.0%	0.05 1.4%	0.03 0.7%	0.09 2.5%	0.09 2.5%
Con H	12.30	0.09 0.8%	0.10 0.8%	0.03 0.3%	0.14 1.1%	0.14 1.1%
Calibrator	21.15	0.12 0.6%	0.11 0.5%	0.09 0.4%	0.18 0.9%	0.19 0.9%
S1	3.07	0.07 2.3%	0.07 2.3%	0.11 3.5%	0.14 4.7%	0.15 4.8%
S2	5.70	0.07 1.3%	0.08 1.4%	0.07 1.2%	0.13 2.2%	0.13 2.2%
S3	11.56	0.09 0.8%	0.11 1.0%	0.05 0.5%	0.15 1.3%	0.15 1.3%
S4	23.17	0.14 0.6%	0.15 0.6%	0.07 0.3%	0.22 0.9%	0.22 0.9%
S5	61.84	0.32 0.5%	0.36 0.6%	0.42 0.7%	0.63 1.0%	0.64 1.0%
S6	97.26	0.48 0.5%	0.51 0.5%	0.62 0.6%	0.93 1.0%	0.94 1.0%

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