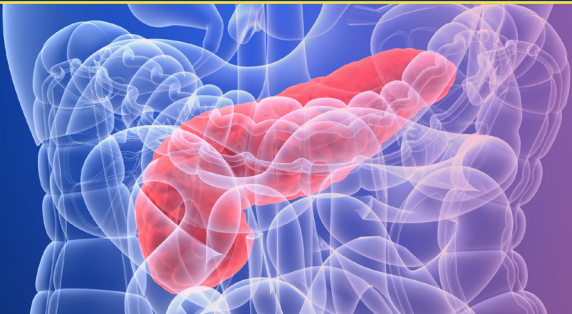


# 1,5-ANHYDROGLUCITOL (1,5-AG) ASSAY



Diabetic  
Marker

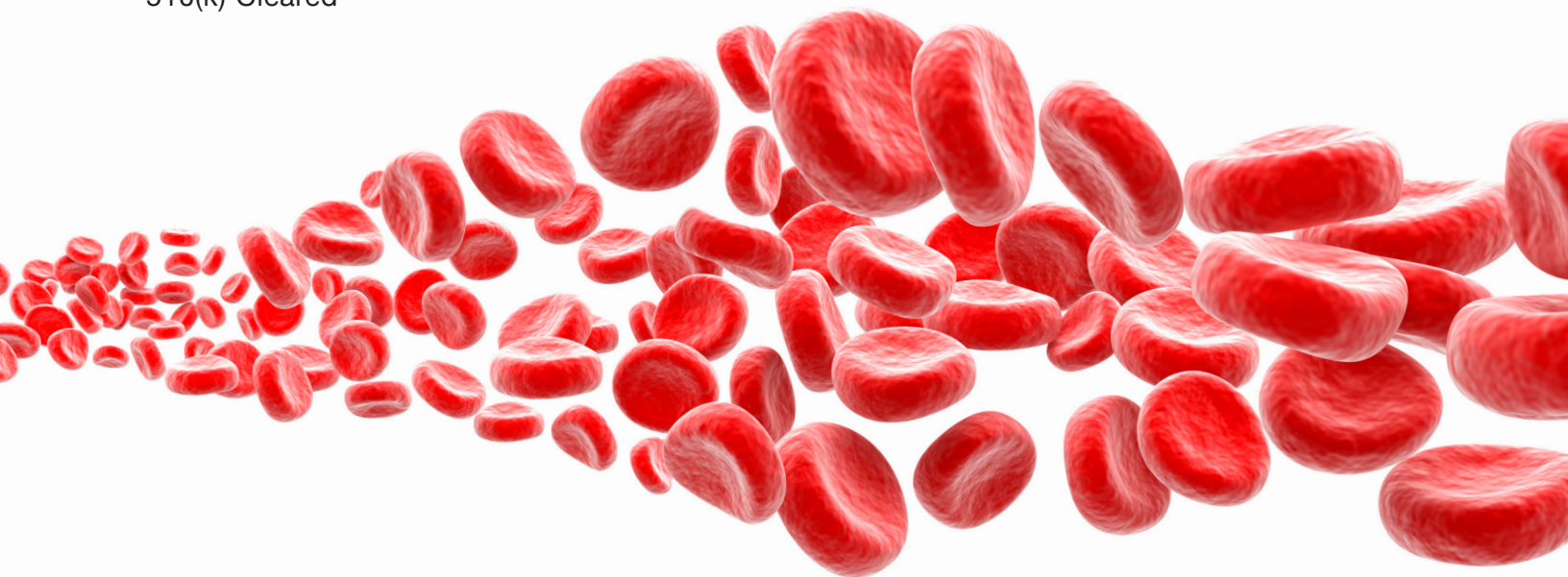


## **DIAZYME 1,5-AG ASSAY ADVANTAGES**

- 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



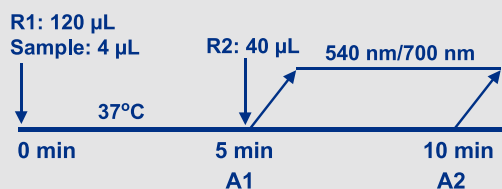
# 1,5-ANHYDROGLUCITOL (1,5-AG) ASSAY

Dual Vial  
Liquid Stable

## ASSAY SPECIFICATIONS

|                                                    |                                                                                                                                                                                                     |
|----------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Method</b>                                      | Enzymatic Assay                                                                                                                                                                                     |
| <b>Sample Type &amp; Volume</b>                    | <ul style="list-style-type: none"> <li>Serum</li> <li>Plasma                             <ul style="list-style-type: none"> <li>- EDTA</li> <li>- Heparin</li> </ul> </li> </ul> Sample Volume 4 µL |
| <b>Analytical Sensitivity</b><br><b>*Linearity</b> | 0.6 - 110 µg/mL<br>0 - 110 µg/mL                                                                                                                                                                    |
| <b>LOB</b>                                         | 0.3 µg/mL                                                                                                                                                                                           |
| <b>LOD</b>                                         | 0.5 µg/dL                                                                                                                                                                                           |
| <b>LOQ</b>                                         | 0.6 µg/dL                                                                                                                                                                                           |
| <b>Interferences</b>                               | The following substances do not interfere:<br>Hemoglobin<br>- Up to 125 mg/dL<br>Triglycerides<br>- Up to 1000 mg/dL<br>Bilirubin<br>- 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](mailto: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<br>2.0%      | 0.05<br>1.4%       | 0.03<br>0.7%       | 0.09<br>2.5%       | 0.09<br>2.5% |
| Con H      | 12.30              | 0.09<br>0.8%      | 0.10<br>0.8%       | 0.03<br>0.3%       | 0.14<br>1.1%       | 0.14<br>1.1% |
| Calibrator | 21.15              | 0.12<br>0.6%      | 0.11<br>0.5%       | 0.09<br>0.4%       | 0.18<br>0.9%       | 0.19<br>0.9% |
| S1         | 3.07               | 0.07<br>2.3%      | 0.07<br>2.3%       | 0.11<br>3.5%       | 0.14<br>4.7%       | 0.15<br>4.8% |
| S2         | 5.70               | 0.07<br>1.3%      | 0.08<br>1.4%       | 0.07<br>1.2%       | 0.13<br>2.2%       | 0.13<br>2.2% |
| S3         | 11.56              | 0.09<br>0.8%      | 0.11<br>1.0%       | 0.05<br>0.5%       | 0.15<br>1.3%       | 0.15<br>1.3% |
| S4         | 23.17              | 0.14<br>0.6%      | 0.15<br>0.6%       | 0.07<br>0.3%       | 0.22<br>0.9%       | 0.22<br>0.9% |
| S5         | 61.84              | 0.32<br>0.5%      | 0.36<br>0.6%       | 0.42<br>0.7%       | 0.63<br>1.0%       | 0.64<br>1.0% |
| S6         | 97.26              | 0.48<br>0.5%      | 0.51<br>0.5%       | 0.62<br>0.6%       | 0.93<br>1.0%       | 0.94<br>1.0% |

## DIAZYME LABORATORIES, INC.

12889 Gregg Court, Poway, CA 92064 USA  
 PO Box 85608, San Diego, CA 92186 USA  
 Tel: +1-858-455-4768 +1-888-DIAZYME  
[www.diazyme.com](http://www.diazyme.com) [sales@diazyme.com](mailto:sales@diazyme.com)

## DIAZYME EUROPE GMBH

Zum Windkanal 21, 01109 Dresden, Germany  
 Tel: +49-351-886-3300 Fax: +49-351-886-3366  
[sales@diazyme.de](mailto:sales@diazyme.de)

## SHANGHAI DIAZYME CO., LTD.

Building 8, 3879 Dongchuan Road  
 Minhang District, Shanghai, 200245  
 Tel: +86-21-54843802 Fax: +86-21-51320663  
[www.lanyuanbio.com](http://www.lanyuanbio.com) [service@lanyuanbio.com](mailto:service@lanyuanbio.com)

