

**New**

**Best of HbA1c Assay!**

# HbA1c **Bulk OEM** Supply

HbA1c (Hemoglobin A1c) is a significant diagnostic marker for diabetes. Our product is for latex immuno-agglutination measurement of Human HbA1c in whole blood and it's the highest quality at the most cost-effective. We supply "R1(75%), R2(25%), Calibrator set(5Levels) and Control set(2Levels)" for HbA1c reagents. \*HDL & LDL are also available!

## Features & Benefits

**Great Latex Immuno-agglutination Test with Ultra-Specificity Monoclonal Antibody**

No interference by labile HbA1c, carbamoylated or acetylated Hemoglobin

**Excellent Precision**

Exceptional correlation with HPLC and No influence by plasma withdrawal

**Available for Whole Blood Directory**

Not necessary to prepare packed red cell

**Works on Wide Variety of General-Purpose Automatic Analyzers**

Hitachi, Toshiba, Beckman, ..., and any your favorite platforms

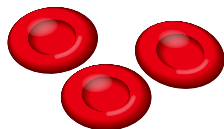
**Directly Read HbA1c Concentration under NGSP%**

Simply read from calibration curve



## Test Procedure (Latex Immunoagglutination on fully automated protocols)

**1 Hemolyzing**



Whole Blood 10 $\mu$ L

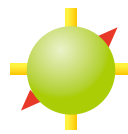


Distilled Water 500 $\mu$ L

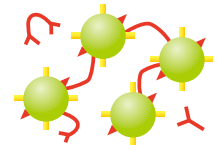
**2 Reaction**



Hemolyzed Sample 6 $\mu$ L



R-1(Latex) [37°C 5min]



R-2(mAb) [37°C 5min]

**3 Measurement**



Measure Turbidity  
660nm/800nm

## Performance

Followings are obtained from runs on Hitachi 7180

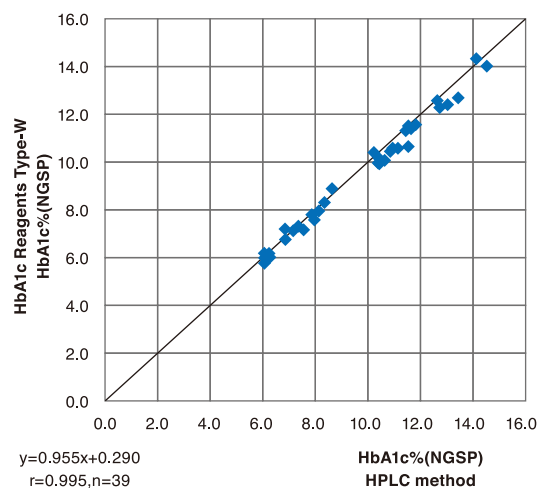
### 1 Reproducibility

| Intra run | Lot 1   |         |         | Lot 2   |         |         | Lot 3   |         |         |
|-----------|---------|---------|---------|---------|---------|---------|---------|---------|---------|
|           | Level 1 | Level 2 | Level 3 | Level 1 | Level 2 | Level 3 | Level 1 | Level 2 | Level 3 |
| Mean      | 5.0     | 9.0     | 12.8    | 5.0     | 9.0     | 12.9    | 5.0     | 9.0     | 12.9    |
| SD        | 0.01    | 0.02    | 0.02    | 0.01    | 0.01    | 0.03    | 0.01    | 0.02    | 0.03    |
| CV(%)     | 0.25    | 0.21    | 0.17    | 0.25    | 0.15    | 0.23    | 0.25    | 0.17    | 0.24    |
| n         | 10      | 10      | 10      | 10      | 10      | 10      | 10      | 10      | 10      |

| Intra run | Lot 1   |         |         | Lot 2   |         |         | Lot 3   |         |         |
|-----------|---------|---------|---------|---------|---------|---------|---------|---------|---------|
|           | Level 1 | Level 2 | Level 3 | Level 1 | Level 2 | Level 3 | Level 1 | Level 2 | Level 3 |
| Mean      | 5.0     | 9.0     | 12.9    | 5.0     | 9.1     | 13.0    | 5.0     | 9.1     | 13.0    |
| SD        | 0.02    | 0.02    | 0.06    | 0.02    | 0.01    | 0.04    | 0.02    | 0.01    | 0.02    |
| CV(%)     | 0.32    | 0.19    | 0.45    | 0.3     | 0.16    | 0.29    | 0.34    | 0.11    | 0.13    |
| n         | 5       | 5       | 5       | 5       | 5       | 5       | 5       | 5       | 5       |

### 2 Correlation

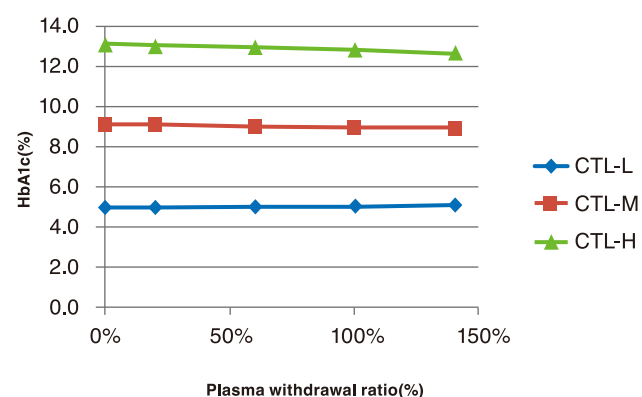
A correlation study showed excellent correlation with HPLC, the standard method.



### 3 No influence of Plasma mixture

Plasma withdrawal ratio is described as the ratio of plasma to packed red cell.

The ratio of 100% means the mixture ratio between plasma and packed red cell is 1:1.



## Interference

High lipid(hormagine concentration of 2,700 degrees) or bilirubin(conjugated type 20mg/mL, free type 20mg/mL) in blood sample did not affect the test results.

## Measuring Range

3.3 – 14.5% (NGSP%)

## Reference Range

4.6 - 6.2% (NGSP%)

## Product description

| Component                | Product Code | Reagent Type                     |
|--------------------------|--------------|----------------------------------|
| Reagent 1(R-1)           | A1c-F R1W    | Latex (liquid)                   |
| Resgent 2(R-2)           | A1c-F R2W    | Closs-linked Anti-HbA1c (liquid) |
| Associated Reagent       | Contents     | Reagent Type                     |
| Calibrator set(5 levels) | 5×0.5mL      | lyophilized                      |
| Control set(2 levels)    | 2×0.5mL      | lyophilized                      |

# *HbA1c Latex Reagent*

Although there are several methods for measuring HbA1c, Latex reagents have high repeatability and specificity and are suitable for large-scale simultaneous processing. In addition, it has been continuously adopted at test sites.

***NGSP  
Certified***

***No  
centrifugation  
of blood cells  
needed***

***Resistant  
to freezing***

***Correlate  
with HPLC  
perfectly***

**Reproducibility**

|         | Measurand (HbA1c; NGSP %) |             |
|---------|---------------------------|-------------|
|         | Sample-Low                | Sample-High |
| 1       | 5.73                      | 13.16       |
| 2       | 5.70                      | 13.31       |
| 3       | 5.70                      | 13.24       |
| 4       | 5.73                      | 13.28       |
| 5       | 5.70                      | 13.30       |
| 6       | 5.71                      | 13.32       |
| 7       | 5.71                      | 13.28       |
| 8       | 5.73                      | 13.27       |
| 9       | 5.72                      | 13.30       |
| 10      | 5.75                      | 13.28       |
| Average | 5.72                      | 13.27       |
| S.D.    | 0.02                      | 0.05        |
| C.V.(%) | 0.29                      | 0.35        |
| MAX.    | 5.75                      | 13.32       |
| MIN.    | 5.70                      | 13.16       |
| RANGE   | 0.05                      | 0.16        |

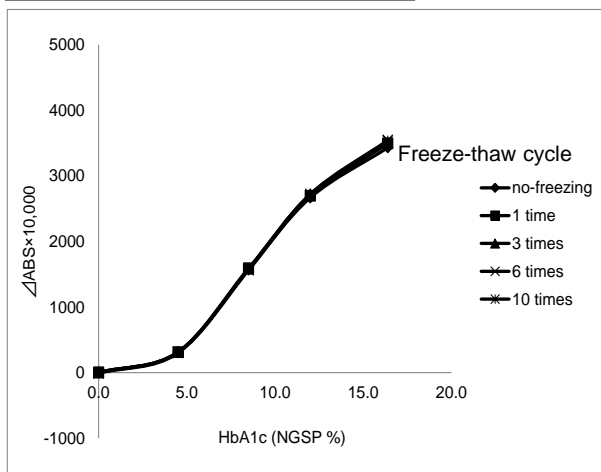
**Measurement of CRM**

| JCCRM 411-3 (JDS Lot5) |   |                             |
|------------------------|---|-----------------------------|
| Level                  | HbA1c (NGSP)%<br>and expanded uncertainty % | Measurand<br>HbA1c (NGSP %) |
| Level 1                | 5.10 ±0.13                                  | 5.09                        |
| Level 2                | 5.77 ±0.14                                  | 5.76                        |
| Level 3                | 7.39 ±0.19                                  | 7.35                        |
| Level 4                | 9.60 ±0.23                                  | 9.47                        |
| Level 5                | 11.98 ±0.28                                 | 11.89                       |

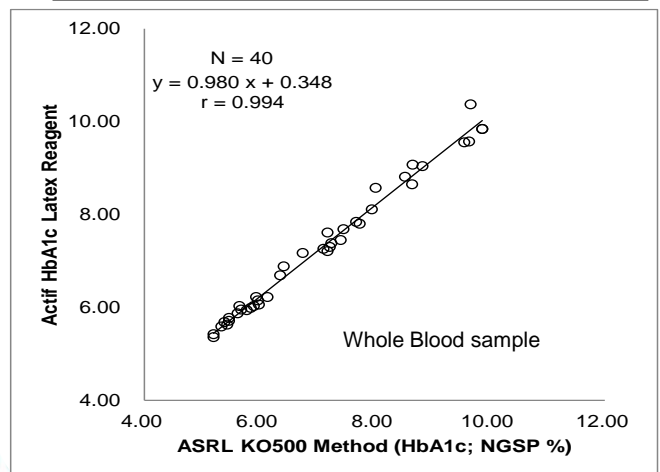
**Measurement range**

HbA1c (NGSP %) ; 3% - 16%

**Freeze-thaw resistance**



**Correlation with standard method**



**Interference testing**

Interference substance up to the following concentrations does not affect the test result.

| Interference substance | Concentration |
|------------------------|---------------|
| Bilirubin F            | 19.6mg/dL     |
| Bilirubin C            | 20.6mg/dL     |
| Chyle                  | 1590FTU       |
| Hemolytic hemoglobin   | 500mg/dL      |
| Reumatoid factor       | 1100IU/mL     |
| Ascorbic acid          | 50mg/dL       |

**ACTIF**

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