

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE**

A. 510(k) Number:

K031380

B. Analyte:

Hemoglobin A1c

C. Type of Test:

quantitative

D. Applicant:

Olympus America

E. Proprietary and Established Names:

Olympus Hemoglobin A1c Test

F. Regulatory Information:

1. Regulation section:
21 CFR 864.7470, Glycosylated Hemoglobin Assay
21 CFR 862.1150, Calibrator
21 CFR 862.1660, Quality control material (assayed/unassayed)
2. Classification:
Class II
Control Class I
3. Product Code:
LCP, Glycosylated Hemoglobin
JIS, calibrator, Primary
JJX, Single Analyte Controls (assayed/unassayed)
4. Panel:
Hematology (HE)
Calibrator and Control-Chemistry (CH)

G. Intended Use:

1. Indication(s) for use:
The Olympus Hemoglobin A1c Test is for the quantitative measurement of Hemoglobin A1c in human whole blood on the Olympus system analyzers.
2. Special condition for use statement(s):
N/A
3. Special instrument Requirements:
Olympus AU600, AU400, AU640, AU2700, and AU5400 analyzers

H. Device Description:

The Olympus Hemoglobin A1c Test contains reagents, calibrators and controls used with Olympus analyzers for the quantitative analysis of glycated hemoglobin A1c and total hemoglobin in whole blood. The % hemoglobin A1c is then calculated as the ratio of HbA1c to total hemoglobin.

I. Substantial Equivalence Information:

1. Predicate device name(s):
Roche Unimate HbA1c Reagent
2. Predicate K number(s):
K952337
3. Comparison with predicate:
Same intended use and utility. The predicate device is for use on the Roche COBAS Chemistry systems.

J. Standard/Guidance Document Referenced (if applicable):

N/A

K. Test Principle:

The concentrations of both HbA1c and total hemoglobin are measured separately. The HbA1c/Total Hemoglobin ratio is expressed as %HbA1c. The assay for %HbA1c involves the use of four reagents: total Hemoglobin reagent, HbA1c Agglutinator reagent, HbA1c Antibody reagent and Hemoglobin Denaturant. In a pre-treatment step, whole blood is mixed with Hemoglobin Denaturant in a dilution and incubated for a minimum of five minutes at room temperature. The red cells are lysed and the hemoglobin chain is hydrolysed by the protease present in the reagent.

Total hemoglobin is measured via the conversion of all hemoglobin derivatives into alkaline haematin in the alkaline solution of a nonionic detergent. Addition of the pre-treated blood sample to the Total Hemoglobin reagent results in a green solution, which is measured at 600nm.

HbA1c is measured in a latex agglutination inhibition assay. An agglutinator, consisting of a synthetic polymer containing multiple copies of the immunoreactive portion of HbA1c causes agglutination of latex coated with HbA1c specific mouse monoclonal antibodies. In the absence of HbA1c in the sample, the agglutinator in the HbA1c Agglutinator reagent and the antibody-coated microparticles in the HbA1c antibody will agglutinate. Agglutination leads to an increase in the absorbance of the suspension. The presence of HbA1c in the sample results in agglutination of the HbA1c Antibody reagent R1 and the agglutinator in the HbA1c Agglutinator reagent R2, resulting in an increase in the absorbance measurable at 700nm.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. *Precision/Reproducibility:*

A precision study was conducted, based on NCCLS recommendations from evaluation protocol EP5-A. Three sample pools were run two-fold, twice a day, for twenty days using the AU640, AU400, and AU2700 analyzers. The concentration of the pools were set so that medical decision points and a significant proportion of the assay range were covered. Within run and total CV were calculated. Acceptance criteria for within run precision was less than or equal to 3% and for total precision was less than or equal to 4%.

b. Linearity/assay reportable range:

Linearity was checked according to NCCLS evaluation protocol EP6-P. A series of ten analyte concentrations, covering the linear dynamic range were prepared by dilution of a high pool sample. Each dilution was assayed in quadruplicate and the mean analytical results were plotted versus the relative analyte concentration (% dilution). The best fit line was calculated by linear regression and the deviations were examined to see if they fell within assay specific acceptance which is +/- 10% HbA1c across the linear range.

c. Traceability (controls, calibrators, or method):

Calibrators are traceable to IFCC standard HbA1c reference material.

d. Detection limit:

The lowest detectable level was determined by testing an analyte free sample twenty times. The lowest detectable limit was calculated as the mean plus three times the standard deviation.

e. Analytical specificity:

The effects of bilirubin, lipemia and triglycerides were confirmed by analysis of blood samples spiked with 30 mg/dL bilirubin, 500 mg/dL Intralipid, and 1600 mg/dL triglyceride. The results showed <10% interference for each substance at the levels tested.

f. Assay cut-off:

N/A

2. Comparison studies:

a. Method comparison with predicate device:

Method comparison was performed based on NCCLS evaluation protocol EP9-A. A series of studies were conducted which consisted of running patient serum samples on the Olympus AU600/AU640E analyzer using the proposed Olympus HbA1c Reagent as Method Y and the predicate Roche HbA1c Reagent as Method X. The studies yielded the following data:

AU400E $y = 1.118x - 2.347, r = 0.996, n = 97,$
range = 3.29 – 10.89%

AU640E $y = 1.193x - 2.511, r = 0.995, n = 97,$
range = 3.61 – 11.57%

$$\text{AU2700 } y = 1.216y - 2.618, r = 0.996, n = 97, \\ \text{range} = 3.49 - 11.65\%$$

b. *Matrix comparison:*
N/A

3. Clinical studies:

a. *Clinical sensitivity:*
N/A

b. *Clinical specificity:*
N/A

c. *Other clinical supportive data (when a and b are not applicable):*
N/A

4. Clinical cut-off:

N/A

5. Expected values/Reference range:

Adults: < 3.8% HbA1c(based on IFCC reference method)

M. Conclusion:

Based upon review of the information and labeling provided, this device is SE to 21 CFR 864.7470, 75 LCP, Assay, Glycosylated Hemoglobin, Class II.