

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

A. 510(k) Number:

k031042

B. Analyte:

Hemoglobin A1c

C. Type of Test:

Quantitative

D. Applicant:

Clinical Data, Inc. (formerly Elan Diagnostics)

E. Proprietary and Established Names:

ATAC Hemoglobin A1c Reagent Kit

F. Regulatory Information:

1. Regulation section:
21 CFR 864.7470, Glycosylated Hemoglobin Assay
2. Classification:
Class II
3. Product Code:
LCP, Assay, Glycosylated Hemoglobin
4. Panel:
81 Hematology (HE)

G. Intended Use:

1. Indication(s) for use:
The ATAC Hemoglobin A1c Reagent Kit is intended for use with the ATAC 8000 Random Access Chemistry System as a system for the quantitative determination of Hemoglobin A1c in blood. Hemoglobin A1c results are used to assess the level of control of a patient's diabetes.

This reagent is intended to be used by trained personnel in a professional setting and is not intended for home use.

2. Special condition for use statement(s):
N/A
3. Special instrument Requirements:
ATAC 8000 Random Access Chemistry System

H. Device Description:

The ATAC Hemoglobin A1c Reagent Kit contains reagents used with the ATAC 8000 Random Access Chemistry System as a system for the quantitative analysis of glycated hemoglobin A1c and total hemoglobin in whole blood. The % Hemoglobin A1c is then calculated using the results obtained from these two quantitative measurements.

I. Substantial Equivalence Information:

1. Predicate device name(s):
Bayer Hemoglobin A1c Reagent
2. Predicate K number(s):
K955087
3. Comparison with predicate:
Same intended use, utility and reagent formulation. The predicate device is for use on the Technicon RA-500, RA-000, RA-XT, and RA-2000 systems.

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

NCCLS publication EP5-T; NCCLS publication EP-6P

K. Test Principle:

The concentration of total hemoglobin and Hemoglobin A1c (HbA1c) are measured separately. In the pretreatment step, whole blood is mixed with Hemoglobin Denaturant Reagent (1:41 dilution) and incubated at room temperature for 5 minutes. During this incubation, the red cells are lysed and hemoglobin is hydrolyzed by protease in the reagent.

The measurement of total hemoglobin is based on the conversion of all hemoglobin derivatives into alkaline hematin using the total hemoglobin reagent. The addition of the pretreated blood sample to the reagent, followed by a 5 minute incubation, results in the conversion of all hemoglobin species to form a green colored solution of hematin with one defined absorption spectrum at 578 and 700 nm.

The measurement of HbA1c uses a latex agglutination inhibition assay. The HbA1c antibody reagent contains synthetic polymers comprised of multiple copies of the immunoreactive portion of HbA1c. The antibody reagent contains latex particles coated with mouse monoclonal antibodies that react with the immunoreactive portion of HbA1c. In the absence of HbA1c in a sample, the agglutinator and antibody coated latex particles will agglutinate, resulting in an increased absorbance monitored at 700 nm. HbA1c in samples will compete with the reaction between agglutinator and antibody reagents slowing the agglutination rate. The ratio of HbA1c to total hemoglobin is reported as % Hemoglobin A1c.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. *Precision/Reproducibility:*
Two controls and a patient sample were run twice per day in duplicate over a twelve day period. Estimates of within run and total

imprecision were calculated as described in NCCLS publication EP5-T.

		Within Run			Total	
Sample	n	mean	1SD	%CV	1SD	%CV
Control 1	32	5.581	0.189	3.38	0.265	4.74
Control 2	31	10.345	0.254	2.46	0.318	3.08
Patient	31	6.777	0.176	2.60	0.316	4.66

b. Linearity/assay reportable range:

The analytical range of the total hemoglobin test is limited to 7-23 mg/dL. The analytical range of HbA1c is limited to the range covered by the HbA1c standards, typically 1.8 – 7.8 umol/L. The analytical range of %HbA1c is from 1.8% to a %HbA1c level given by the upper limit of HbA1c for a sample with total hemoglobin of 14 g/dL. A whole blood hemolysate was prepared to yield a total hemoglobin level greater than 23 mg/dL. Dilutions of the hemolysate were prepared to yield hemoglobin levels covering the upper limit of the claimed linear range. Additionally, dilutions of the calibrator (18 g dL) were made to obtain target levels of 18, 14.4, 10.8, 7.2, 3.6, and 1.8 g/dL and analyzed 10 times. The results of analysis of these samples are compared with expected values by least squares linear regression according to NCCLS EP-6P.

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

The firm chooses not to apply for certification by the National Glycohemoglobin Standardization Program (NGSP).

d. Detection limit:

No detection limit is claimed for this product.

e. Analytical specificity:

The effects of two major potential interfering substances were confirmed by analysis of blood samples spiked with bilirubin and triglycerides, up to 30 mg/dL and 1600 mg/dL respectively. The results showed that bilirubin up to 30 mg/dL and triglycerides up to 1600 mg/dL do not interfere with this assay. Also tested, with no resulting interference were rheumatoid factor (up to 2000 IU/ml), acetylsalicylic acid (up to 60 mg/dL), sodium cyanate (up to 50 mg/dL), and urea (up to 500 mg/dL).

f. Assay cut-off:

N/A

2. Comparison studies:
 - a. *Method comparison with predicate device:*

Whole blood specimens from 104 adults were assayed using the ATAC device and a Tosoh method. Results were compared by least squares linear regression and the following statistics were obtained:
 $y = 0.637 + 0.972X$, $R^2 = 0.95$, range = 4.6 – 11.7% HbA1c
 - 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:

non diabetics 4-6%
controlled diabetics 6-8%
uncontrolled diabetics up to 20%
- referenced from Tietz Textbook of Clinical Chemistry, 2nd Edition

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.