Attachment 4

Summary of Safety and Effectiveness
Bio-Rad Laboratories, Inc.

Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: <u>K_____</u>.

Submitter:

Bio-Rad Laboratories, Inc.
Clinical System Division
4000 Alfred Nobel Drive,
Hercules, California 94547
Phone: (510) 741-5309
FAX: (510) 741-6471

Contact Person:

Jackie Buckley
Regulatory Affairs Representative

Date of Summary Preparation:

December 30, 2005

Device Name:

Bio-Rad D-10™ Dual Program
Bio-Rad D-10™ Hemoglobin A1c Program
on the D-10 Hemoglobin System with D-10 Rack Loader

Classification Name:

HbA_{1c}: Assay, Glycosylated Hemoglobin
[21CFR 864.7470 / Prod. Code LCP] and

HbA_2: Hemoglobin A_2 Quantitation
[21CFR 864.7400 / Prod. Code: JPD]

Predicate Devices:

D-10 Hemoglobin A1c Program
Bio-Rad Laboratories, Inc.
[K031043, August 27, 2003]

D-10 Dual Program
Bio-Rad Laboratories, Inc
[K041444, June 9, 2004]

Indications for Use Statements and Intended Uses:

The D-10™ Hemoglobin A1c Program is intended for the percent determination of hemoglobin A1c in human whole blood using ion-exchange high performance liquid chromatography (HPLC).

The D-10 Hemoglobin A1c Program is intended for use only with the Bio-Rad D-10 Hemoglobin Testing System. For In Vitro Diagnostic Use.

The Bio-Rad D-10™ Dual Program system is intended for the percent determination of hemoglobins A1c, A2 and F, and for the detection of abnormal hemoglobins in human whole blood using ion-exchange high performance liquid chromatography (HPLC).

The Bio-Rad D-10™ Dual Program is intended for Professional Use Only. For in vitro diagnostic use.

Measurement of the percent hemoglobin A_{1c} is effective in monitoring long-term glucose control in individuals with diabetes mellitus, and measurement of the percent HbA_2 and HbF are effective in screening of β–thalassemias (i.e., hereditary hemolytic anemias characterized by decreased synthesis of one or more types of abnormal hemoglobin polypeptide chains).

Detection of hemoglobin variants such as hemoglobins S, C, D and E by HPLC is effective in presumptive identification of these variants.

New Device Description

The Bio-Rad Hemoglobin Testing System is a fully automated analyzer consisting of a single module that provides an integrated method for sample preparation, separation, and determination of specific hemoglobins in whole blood. The Bio-Rad Hemoglobin Testing System provides an integrated method for the separation and determination of the relative percent of specific hemoglobins (e.g. A2, F and A1c in whole blood). The separation is based on the principles of high performance liquid chromatography. The system can accommodate 1 to 10 samples per run using a single rack currently.

The new feature in this submission is the optional D-10 Rack Loader which will be available for use with the D-10 Hemoglobin Testing System. The D-10 Rack Loader accommodates 5 racks and automatically transports each rack into and out of the D-10 System. The D-10 Rack Loader offers continuous loading, allowing the operator to insert or remove racks during a run.

Technical Characteristics Compared to Predicate

The Bio-Rad D-10™ Hemoglobin A1c Program and the D-10 Dual Program run on the D-10 Hemoglobin Testing System with D-10 Rack Loader have the same basic technical characteristics as the predicates D-10 Hemoglobin A1c Program (k) 031043 and D-10 Dual Program (k)041444 run on the D-10 Hemoglobin Testing System. There are three main differences between the D-10 Hemoglobin Testing System with the new D-10 Rack Loader. The technical characteristics are summarized in the following tables:

D-10™ Hemoglobin A1c (k)031043

Summary of Technological Characteristic Similarities in Comparison to Predicate Device		
Characteristics	New Device: D-10™ Hemoglobin A1c Program run on the D-10 Hemoglobin Testing System <u>with</u> D-10 Rack Loader	Predicate Device: D-10™ Hemoglobin A1c Program run on the D-10 Hemoglobin Testing System <u>without</u> the D-10 Rack Loader
Intended Use(s)	The Bio-Rad Hemoglobin A1c Program is intended for the percent determination of hemoglobin A1c in human whole blood using ion-exchange high-performance liquid chromatography (HPLC). The D-10 Hemoglobin A1c Program is intended for use only with the Bio-Rad D-10 Hemoglobin Testing System. For In Vitro Diagnostic Use.	The Bio-Rad Hemoglobin A1c Program is intended for the percent determination of hemoglobin A1c in human whole blood using ion-exchange high-performance liquid chromatography (HPLC). The D-10 Hemoglobin A1c Program is intended for use only with the Bio-Rad D-10 Hemoglobin Testing System. For In Vitro Diagnostic Use.
Indication(s) for Use	Measurement of the percent hemoglobin A_{1c} is effective in monitoring long-term glucose control in individuals with diabetes mellitus.	Measurement of the percent hemoglobin A_{1c} is effective n monitoring long-term glucose control in individuals with diabetes mellitus.
Assay Principle	Cation exchange high performance liquid chromatography	Cation exchange high performance liquid chromatography
Sample Type	Human anticoagulated whole blood (EDTA)	Human anticoagulated whole blood (EDTA)
Visible Detection	415 nm	415 nm
Standardization	Traceable to the Diabetes Control and Complications Trial (DCCT) reference method and IFCC. Certified via the National Glycohemoglobin Standardization Program (NGSP) for HbA_{1c}.	Traceable to the Diabetes Control and Complications Trial (DCCT) reference method and IFCC. Certified via the National Glycohemoglobin Standardization Program (NGSP) for HbA_{1c}.
Results	Quantitative Area % HbA_{1c}	Quantitative Area % HbA_{1c}
Time to process sample	3.0 minutes	3.0 minutes

D-10™ Hemoglobin A1c (k)031043

Summary of Technological Characteristic Differences in Comparison to Predicate Device		
Characteristics	New Device: D-10™ Hemoglobin A1c Program run on the D-10 Hemoglobin Testing System <u>with</u> D-10 Rack Loader	Predicate Device: D-10™ Hemoglobin A1c Program run on the D-10 Hemoglobin Testing System <u>without</u> the D-10 Rack Loader
Software version	3.5	3.00
Number of Racks that can be run.	5 Racks of 10 EDTA whole blood tubes	1 rack of 10 EDTA whole blood tubes
Rack insertion into D-10 Hemoglobin Testing System	Automated	Manual

D-10™ Dual Program (k)0414444

Summary of Technological Characteristic Similarities in Comparison to Predicate Device		
Characteristics	New Device: Bio-Rad D-10™ Dual Program run on the D-10 Hemoglobin Testing System with D-10 Rack Loader	Predicate Device: Bio-Rad D-10™ Dual Program run on the D-10 Hemoglobin Testing System without D-10 Rack Loader
Intended Uses	The Bio-Rad D-10 Dual Program system is intended for the percent determination of hemoglobins A_{1c}, A_2 and F, and for the detection of abnormal hemoglobins in human whole blood using ion-exchange high performance liquid chromatography (HPLC). The Bio-Rad D-10 Dual Program is intended for Professional Use Only. For in vitro diagnostic use.	The Bio-Rad D-10 Dual Program system is intended for the percent determination of hemoglobins A_{1c}, A_2 and F, and for the detection of abnormal hemoglobins in human whole blood using ion-exchange high performance liquid chromatography (HPLC). The Bio-Rad D-10 Dual Program is intended for Professional Use Only. For in vitro diagnostic use.
Indication(s) for Use	Measurement of the percent hemoglobin A_{1c} is effective in monitoring long-term glucose control in individuals with diabetes mellitus, and measurement of the percent HbA_2 and HbF are effective in monitoring of ß-thalassemia (i.e., hereditary hemolytic anemias characterized by decreased synthesis of one or more types of abnormal hemoglobin polypeptide chains). Detection of hemoglobin variants such as hemoglobins S, C, D and E by HPLC is effective in presumptive identification of these variants.	Measurement of the percent hemoglobin A_{1c} is effective in monitoring long-term glucose control in individuals with diabetes mellitus, and measurement of the percent HbA_2 and HbF are effective in monitoring of ß-thalassemia (i.e., hereditary hemolytic anemias characterized by decreased synthesis of one or more types of abnormal hemoglobin polypeptide chains). Detection of hemoglobin variants such as hemoglobins S, C, D and E by HPLC is effective in presumptive identification of these variants.
Assay Principle	Cation exchange high performance liquid chromatography	Cation exchange high performance liquid chromatography
Sample Type	Human anticoagulated whole blood (EDTA)	Human anticoagulated whole blood (EDTA)
Visible Detection	415 nm	415 nm
Standardization	Traceable to the Diabetes Control and Complications Trial (DCCT) reference method and IFCC. Certified via the National Glycohemoglobin Standardization Program (NGSP) for HbA1c. The Joint Committee on Traceability in Laboratory Medicine has not identified a higher order reference method or reference material for the quantitation of HbA2 and HbF	Traceable to the Diabetes Control and Complications Trial (DCCT) reference method and IFCC. Certified via the National Glycohemoglobin Standardization Program (NGSP) for HbA1c. The Joint Committee on Traceability in Laboratory Medicine has not identified a higher order reference method or reference material for the quantitation of HbA2 and HbF
Results	Quantitative Area % HbA2, F and A1c	Quantitative Area % HbA2, F and A1c
Time to process sample	6.5 minutes	6.5 minutes

Bio-Rad Laboratories, Inc.   4-A-6

D-10™ Dual Program (k)0414444

Summary of Technological Characteristic Differences in Comparison to Predicate Device		
Characteristics	New Device: D-10™ Hemoglobin A1c Program run on the D-10 Hemoglobin Testing System <u>with</u> D-10 Rack Loader	Predicate Device: D-10™ Hemoglobin A1c Program run on the D-10 Hemoglobin Testing System <u>without</u> the D-10 Rack Loader
Software version	3.5	3.00
Number of Racks that can be run.	5 Racks of 10 EDTA whole blood tubes	1 rack of 10 EDTA whole blood tubes
Rack insertion into D-10 Hemoglobin Testing System	Automated	Manual

Testing To Establish Substantial Equivalence:

Note: The D-10 Hemoglobin Testing System currently contains one rack for 10 EDTA Whole Blood Tubes for small laboratories. Throughout this document the text will indicate either the D-10 Hemoglobin A1c Program or D-10 Dual Program are run <u>with</u> or <u>without</u> the D-10 Rack Loader on the D-10 Hemoglobin Testing System. The D-10 Rack Loader is an optional accessory item to the D-10 Hemoglobin Testing System that allows for 5 racks of 10 EDTA Whole Blood Tubes to be run automatically while the system is running in mid size laboratories.

Accuracy:

D-10 Hemoglobin HbA1c Program (3 minute)

Method correlation between Bio-Rad D-10 Hemoglobin A1c Program <u>with</u> D-10 Rack Loader and D-10 Hemoglobin A1c Program <u>without</u> D-10 Rack Loader was evaluated using 40 EDTA whole blood samples ranging from 5.1% -14.3% HbA1c. The results are presented in the following table:

D-10 Hemoglobin A1c Program Correlation for HbA1c

Regression Method	n	r^2	Slope	Intercept
Least Squares	40	0.9950	0.9415	0.2714

D-10 Dual Program -Hemoglobin A1c (6.5 minute)

Method correlation between Bio-Rad D-10 Dual Program <u>with</u> D-10 Rack Loader and D-10 Dual Program <u>without</u> D-10 Rack was evaluated using 40 EDTA whole blood samples ranging from 5.1% to 14.3% HbA_{1c}. The results are presented in the following table:

D-10 Dual Program Correlation for HbA1c

Regression Method	n	r^2	Slope	Intercept
Least Squares	40	0.9956	0.9827	0.1208

D-10 Dual Program – Hemoglobin A2 (6.5 minute)

Method correlation between Bio-Rad D-10 Dual Program <u>with</u> D-10 Rack Loader and D-10 Dual Program <u>without</u> Rack Loader was evaluated with 39 EDTA whole blood samples ranging from 2.1% – 11.8% HbA2. The results are presented in the following table:

D-10 Dual Program Correlation for HbA2

Regression Method	n	r^2	Slope	Intercept
Least Squares	39	0.9975	0.9902	0.2476

D-10 Dual Program – Hemoglobin F (6.5 minute)

Method correlation between Bio-Rad D-10 Dual Program <u>with</u> D-10 Rack Loader and D-10 Dual Program <u>without</u> D-10 Rack Loader was evaluated with 39 EDTA whole blood samples ranging from 0.8% – 17.3% HbF. The results are presented in the following table:

D-10™ Dual Program Correlation for HbF

Regression Method	n	r^2	Slope	Intercept
Least Squares	39	0.9956	1.0188	-0.3863

Precision:

D-10 Hemoglobin A1c Program (3 minute)

The following precision table provides comparison data on the precision between D-10 Hemoglobin A1c Program with the D-10 and Rack Loader and the D-10 Hemoglobin A1c Program without the D-10 Rack Loader, each utilizing EDTA whole blood patient samples.

Method precision was performed using a protocol based on the NCCLS Evaluation protocol, EP5-A2 for the D-10 Hemoglobin A1c Program with D-10 Rack Loader and NCCLS Evaluation protocol EP5-T2 for the D-10 Hemoglobin A_{1c} Program without Rack Loader. The protocols for both the D-10 Hemoglobin A1c Program with D-10 Rack Loader and D-10 Hemoglobin A_{1c} Programs without D-10 Rack Loader are similar. Using these protocols, two samples were run on one rack, twice a day over 20 working days on one D-10 Hemoglobin Testing System without D-10 Rack Loader. On the D-10 Hemoglobin Testing System with D-10 Rack Loader, the protocol requires two samples run on each of five racks, twice a day over 20 working days. In each duplicate daily run for both verification studies, duplicate aliquots of normal HbA1c and diabetic HbA1c patient samples were each analyzed per run. Although the precision samples are different, since they were run at different time periods, the precision results between the D-10 Hemoglobin A1c Program with D-10 Rack Loader and the D-10 Hemoglobin A1c Program without D-10 Rack Loader are equivalent. A summary of combined comparative precision results is presented in the following precision table.

D-10 HbA1c with D-10 Rack Loader vs. D-10 HbA1c without D-10 Rack Loader - Precision

	D-10 HbA1c with D-10 Rack Loader		D-10 HbA1c without D-10 Rack Loader	
	Normal Sample	Diabetic Sample	Normal Sample	Diabetic Sample
n= (number of samples)	400	400	80	80
Mean (%HbA1c)	5.6	11.0	5.9	13.1
Within run (%CV)	0.6	0.6	0.8	0.3
Total Precision (%CV)	1.5	1.4	1.8	0.9

D-10 Dual Program - HbA1c (6.5 minutes)

The following precision table provides comparison data on the precision between D-10 Dual Program (HbA1c) with Rack Loader and the D-10 Dual Program (HbA1c) without the D-10 Rack Loader, each utilizing EDTA whole blood patient samples.

Method precision was performed using a protocol based on the NCCLS Evaluation protocol EP5-A2 for the D-10 Dual Program with D-10 Rack Loader and NCCLS Evaluation protocol EP5-A for the D-10 Dual Program without Rack Loader. The protocols for both the D-10™ Dual Program with D-10 Rack Loader and D-10 Dual Program without D-10 Rack Loader are similar. Using these protocols, two samples were run on one rack, twice a day over 20 working days on one D-10 Hemoglobin Testing System. On the D-10 Hemoglobin Testing System with D-10 Rack Loader, the protocol requires two samples run on each of five racks, twice a day over 20 working days. In each duplicate daily run for both verification studies, duplicate aliquots of normal HbA_{1c} and diabetic HbA1c patient samples were each analyzed per run. Although the precision samples are different, since they were run at different time periods, the precision results between the D-10

Dual Program with D-10 Rack Loader and the D-10 Dual Program without D-10 Rack Loader are equivalent. A summary of combined comparative precision results is presented in the following precision table.

D-10 Dual Program (HbA1c) <u>with</u> D-10 Rack Loader vs. D-10 Dual Program (HbA1c) <u>without</u> D-10 Rack Loader - Precision

	D-10 Dual (6.5 Minutes) HbA1c Program with D-10 Rack Loader		D-10 Dual (6.5 Minutes) HbA1c Program without D-10 Rack Loader	
	Normal Sample	Diabetic Sample	Normal Sample	Diabetic Sample
n= (number of samples)	400	400	80	80
Mean (%HbA$_{1c}$)	5.5	10.6	5.9	13.1
Within run (%CV)	0.7	0.4	0.8	0.3
Total Precision (%CV)	1.5	1.2	1.8	0.9

D-10 Dual Program HbA2 (6.5 minutes)

The following precision table provides comparison data on the precision between D-10 Dual Program (HbA2) <u>with</u> D-10 Rack Loader and D-10 Dual Programs (HbA2) <u>without</u> D-10 Rack Loader, each utilizing EDTA whole blood patient samples.

Method precision was performed using a protocol based on the NCCLS Evaluation protocol EP5-A2 for the D-10 Dual Program with D-10 Rack Loader and NCCLS Evaluation protocol EP5-A for the D-10 Dual Program without Rack Loader. The protocols for both the D-10 Dual Program with D-10 Rack Loader and D-10 Dual Program without D-10 Rack Loader are similar. Using these protocols, two samples were run on one rack, twice a day 40 runs over 20 working days were performed on one D-10 Hemoglobin Testing System. On the D-10 Hemoglobin Testing System with D-10 Rack Loader, the protocol requires two samples run on each of five racks, twice a day over 20 working days. In each duplicate daily run for both verification studies, duplicate aliquots of low HbA2 and high HbA2 patient samples were each analyzed per run. Although the precision samples are different, since they were run at different time periods, the precision results between the D-10 Dual Program with D-10 Rack Loader and the D-10 Dual Program without D-10 Rack Loader are equivalent. A summary of combined comparative precision results is presented in the following precision table.

Precision: (continued)

D-10 Dual Program (HbA2) <u>with</u> D-10 Rack Loader vs. D-10 Dual Program (HbA2) <u>without</u> D-10 Rack Loader - Precision

	D-10 Dual Program (6.5 Minutes) HbA2 run with D-10 Rack Loader		VARIANT II β-thalassemia Short HbA2 run without D-10 Rack Loader	
	Low Sample	High Sample	Low Sample	High Sample
n= (number of samples)	400	400	80	80
Mean (%HbA$_2$)	2.9	4.9	2.2	5.4
Within run (%CV)	1.8	1.2	4.5	1.7
Total Precision (%CV)	3.6	3.6	5.3	3.1

D-10 Dual Program – HbF (6.5 minutes)

The following precision table provides comparison data on the precision between D-10 Dual Program (HbF) <u>with</u> the D-10 Rack Loader and the D-10 Dual Program (HbF) <u>without</u> D-10 Rack Loader, each utilizing EDTA whole blood patient samples.

Method precision was performed using a protocol based on the NCCLS Evaluation protocol EP5-A2 for the D-10 Dual Program with D-10 Rack Loader and NCCLS Evaluation protocol EP5-A for the D-10 Dual Program without Rack Loader. The protocols for both the D-10 Dual Program with D-10 Rack Loader and D-10 Dual Program without D-10 Rack Loader are similar. Using these protocols, two samples were run on one rack, twice a day over 20 working days on one D-10 Hemoglobin Testing System. On the D-10 Hemoglobin Testing System with D-10 Rack Loader, the protocol requires two samples run on each of five racks, twice a day over 20 working days. In each duplicate daily run for both verification studies, duplicate aliquots of low HbF and high HbF patient samples were each analyzed per run. Although the precision samples are different, since they were run at different time periods, the precision results between the D-10 Dual Program with D-10 Rack Loader and the D-10 Dual Program without D-10 Rack Loader are equivalent. A summary of combined comparative precision results is presented in the following precision table.

D-10 Dual Program (HbF) <u>with</u> D-10 Rack Loader vs. D-10 Dual Program (HbF) <u>without</u> D-10 Rack Loader - Precision

	D-10 Dual Program (6.5 minutes) HbF with D-10 Rack Loader		D-10 Dual Program (6.5 minutes) HbF without D-10 Rack Loader	
	Low Sample	High Sample	Low Sample	High Sample
n= (number of samples)	400	400	80	80
Mean (%HbF)	1.4	6.6	2.1	8.7
Within run (%CV)	2.1	0.8	1.7	1.4
Total Precision (%CV)	2.9	1.8	3.3	2.0

Conclusion:

The similarities of the intended use and the general performance characteristics and results of the newly described and evaluated **D-10 Hemoglobin A1c Program and D-10 Dual Program with D-10 Rack Loader on the D-10 Hemoglobin Testing** system are nearly identical to or logical extensions of those for the two cleared predicate program systems [i.e., the Bio-Rad D-10 Hemoglobin A_{1c} Program and the Bio-Rad Dual Program]. Thus, one may conclude, based on the use of the same HPLC technology, and the nearly equivalent results obtained for the correlation and precision versus the corresponding results obtained with the two predicate systems that the new **D-10 Hemoglobin A1c Program and D-10 Dual Program with D-10 Rack Loader on the D-10 Hemoglobin Testing** system is substantially equivalent to these 2 cleared and currently marketed predicate systems.

Ms. Jackie Buckley
Regulatory Affairs Representative
Bio-Rad Laboratories, Inc.
Clinical Systems Division
4000 Alfred Nobel Dr.
Hercules, CA 94547

JAN 2 0 2006

Re: k060001
        Trade/Device Name: Bio-Rad D-10™ Dual Program and D-10
                            Hemoglobin A1c Program run on the D-10
                            Hemoglobin Testing System with D-10 Rack Loader
        Regulation Number: 21 CFR§864.7470
        Regulation Name: Glycosylated hemoglobin assay
        Regulatory Class: Class II
        Product Code: LCP, JPD
        Dated: December 30, 2005
        Received: January 3, 2006

Dear: Ms. Buckley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.
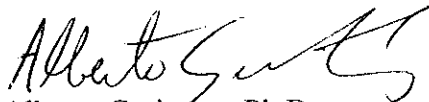
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
    Evaluation and Safety
Center for Devices and
    Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): __K060001__

Device Name: Bio-Rad D-10^{TM} Dual Program and D-10 Hemoglobin A$_{1c}$ Program run on the D-10 Hemoglobin Testing System with D-10 Rack Loader

Indications For Use: Measurements of percent HbA$_{1c}$ are effective in monitoring long-term glucose control in individuals with diabetes mellitus.

Measurement of percent HbA$_2$ and HbF are used for evaluation β – thalassemia, a hereditary hemolytic anemia.

Detection of hemoglobin variants such as S, C, D and E are effective in presumptive identification.

Prescription Use __✓__   AND/OR   Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)   (21 CFR 801 Subpart C)

 (PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Ann Chopper
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

Page 1 of ____

K060001