510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k070546

B. Purpose for Submission:

New Device

C. Measurand:

Quality control materials for hemoglobin (A1C, A1, F, Total and Total Glycated)

D. Type of Test:

Not Applicable (N/A)

E. Applicant:

Bio-Rad Laboratories

F. Proprietary and Established Names:

Lyphochek® Diabetes Control

Lyphochek® Diabetes Control (MiniPak)

G. Regulatory Information:

1. Regulation section:

   21 CFR 864.8625

2. Classification:

   II

3. Product code:

   GGM

4. Panel:

81 Hematology

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

   Lyphochek® Diabetes Control is intended for use an as assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.

3. Special conditions for use statement(s):

   For professional use only

4. Special instrument requirements:

   The specific instruments are listed in the package insert.

I. Device Description:

This is a lyophilized product containing two distinct levels of assayed values prepared from human whole blood. It also contains preservatives and stabilizers.

The labeling for this material states “Each whole blood donor unit used to manufacture this control was tested by FDA accepted methods and found non-reactive for Hepatitis B Surface Antigen (HBsAg), antibody to Hepatitis C (HCV) and antibody to HIV-1/HIV 2.”

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Lyphochek® Diabetes Control

2. Predicate 510(k) number(s):

   k862186

3. Comparison with predicate:

   The submission is seeking to add total hemoglobin to the Lyphochek Diabetes Control.

Similarities		
Item	Device	Predicate
Intended Use	Lyphochek Diabetes Control is intended for the use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.	Same.
Matrix	Human Whole Blood	Same
Preservatives	Contains Preservatives	Same
Form	Lyophilized	Same
Open Vial Claim	7 days at 2-8° C	Same

Differences		
Item	Device	Predicate
Analytes	Hemoglobin A1C Hemoglobin A1 Hemoglobin F Total Glycated Hemoglobin Total Hemoglobin	Hemoglobin AIC Hemoglobin A1 Hemoglobin F Total Glycated Hemoglobin

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

No standards or guidance documents were referenced.

L. Test Principle:

Not applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. Precision/Reproducibility:

   Not applicable

   b. Linearity/assay reportable range:

   Not applicable

   c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Value assignment for the Lyphochek® Diabetes Control Material was conducted by assaying 20 replicates per level per analyte over a period of 10 days using various lots of reagents. The values listed in the package insert are the average values from three reference laboratories specific for the product lot. The ranges vary and are set at +/- 20% of the average values.

Open vial stability study time is defined to be at least 20% longer than the claimed open vial stability for the product and is determined at a minimum of three time points (T_{zero}, T_{final} and $T_{final+20\%}$). Controls are assayed to ensure the accuracy and precision of the testing methods. The sponsors' failure criteria are defined as the T_{final} being +/- 10% of the T_{zero}. The sponsors open vial stability claim is 7 days when stored tightly capped at 2-8 C.

The sponsor conducted accelerated stability testing on pilot lots at elevated temperatures (i.e. 41°C, 47°C and 56°C) in order to observe changes in product performance more rapidly than would be seen under normal storage conditions of 2-8°C. Controls are assayed to ensure the accuracy and precision of the testing methods at several time points for each temperature to predict shelf life using a stability model with activation energy of the 20 –kCal/mol or Arrhenius Model predictions. The sponsors' shelf life claim is 3 years when stored tightly capped at 2-8°C.

The sponsors real time stability testing is determined by storing the product under the recommended storage conditions (2-8°C) for the life of the product. These studies are conducted on production lots and are long-term studies. Several vials of each level are tested at each time point and the results of the real time samples are compared to the results of reference vials store at -70°C. Failure is assumed to have taken place when the product's analyte concentration has changed by greater than or equal to the established acceptance recovery criteria. Real time stability studies are ongoing.

d. Detection limit:

Not applicable

e. Analytical specificity:

Not applicable

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

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

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

The package insert contains a table with the mean value and acceptable ranges for each analyte/instrument. Also contained in the package insert is the recommendation by the manufacturer that each laboratory establish its own mean value and acceptable range.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.