

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

A. 510(k) Number:

k052838

B. Purpose for Submission:

Notification of intent to manufacture and market the device: Bio-Rad Laboratories Liquichek™ Diabetes Control

C. Measurand:

Hemoglobin A1C and Total Hemoglobin Control Material

D. Type of Test:

Not applicable

E. Applicant:

Bio-Rad Laboratories

F. Proprietary and Established Names:

Proprietary Name – Bio-Rad Laboratories Liquichek™ Diabetes Control
Established Name – Quality Control

G. Regulatory Information:

1. Regulation section:

21 CFR 864.8625

2. Classification:

Class II

3. Product code:

GGM

4. Panel:

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

Liquichek Diabetes control is intended for use as an 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 liquid product containing three distinct levels of assayed values prepared from human whole blood containing 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, antibody to Hepatitis C (HCV) and antibody to HIV-1/HIV-2”.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Bio-Rad Lyphochek Diabetes Control

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

k862186

3. Comparison with predicate:

Characteristics	Bio-Rad Laboratories Liquichek™ Diabetes Control	Bio-Rad Laboratories Lyphochek Diabetes Control k862186
Similarities		
Intended Use	Liquichek Diabetes control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.	Lyphochek Diabetes control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.
Matrix	Human Whole Blood Based	Human Whole Blood Based
Preservatives	Contains Preservatives	Contains Preservatives
Differences		
Form	Liquid	Lyophilized
Storage (unopened)	-10°C to -70°C Until Expiration date or 2°C to 8°C for 6 months	2°C to 8°C until expiration date
Open Vial Claim	14 days at 2°C to 8°C	7 days at 2°C to 8°C
Analytes	Contains: Hemoglobin A1C Total Hemoglobin	Contains: Hemoglobin A1C Hemoglobin A1 Hemoglobin F Total Glycolated Hemoglobin

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

No standards or guidances 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):*

The controls are manufactured by processing human whole blood and extracting purified A1C concentrate. Level 1 is made entirely from base material (hemolysate). Levels 2 and 3 are made with base blood material blended with purified A1C until the HbA1C value of the blend is within the target ranges for %HbA1c listed below (as assayed on the Bio-Rad Variant II):

Level 1 4.6 - 6.0
 Level 2 9.5 - 11.0
 Level 3 14.0 - 16.0

Total hemoglobin values are endogenous. Values for both analytes are assigned by replicate analyses.

Open vial stability study time is defined to be at least 20% longer than the claimed open vial stability for the product and 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. Failure criterion is defined as the T_{final} being $\pm 10\%$ of the T_{zero} . Claim: 14 days when stored tightly capped at 2 °C to 8 °C.

Liquichek Diabetes Control Open Vial Stability Data						
Test Day	Level 1		Level 2		Level 3	
	Mean (%)	Change (%)	Mean (%)	Change (%)	Mean (%)	Change (%)
A1C						
0 (T_{zero})	5.7	0.00	10.3	0.00	16.1	0.00
7	5.7	-0.58	10.3	0.32	16.2	0.62
14	5.7	-0.58	10.3	0.32	16.2	0.21
21(T_{final})	5.7	-0.58	10.3	0.32	16.2	0.41
Total Hemoglobin						
0 (T_{zero})	11.7	0.00	7.3	0.00	8.2	0.00
7	11.8	0.57	7.4	1.36	8.2	-0.41
14	11.8	0.57	7.5	1.82	8.1	-1.22
21(T_{final})	11.8	0.57	7.4	0.91	8.1	-1.22

Accelerated stability testing studies are performed on pilot lots at elevated temperatures (ie 47 °C, 41 °C, 35 °C, etc.) in order to observe changes in product performance more rapidly than would be seen under normal conditions of -10 to -70 °C. Controls are assayed to

ensure the accuracy and precision of the testing methods. Several time points (T_{zero} and other regular interval points) are generated for each temperature to predict shelf life using a stability model with activation energy of the 20-kCal/mol or Arrhenius Model predictions. Claim: 3 years when stored tightly capped at -10 to -70 °C or 6 months when stored tightly capped at 2 °C to 8 °C.

Real time stability testing is determined by storing the product under the recommended storage conditions (-10 to -70 °C and 2 °C to 8 °C) for the life of the product. These studies are conducted on production lots and are long term studies. Several vials of each lot are tested at each time point and the results of the real time samples are compared to the results of several reference vials stored 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 recovery criteria.

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:

Not applicable

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.