

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY**

A. 510(k) Number:

k043108

B. Purpose for Submission:

This is a new device.

C. Measurand:

Quality Control material for the following:

Anti-TG

Anti-TPO

C-peptide

Erythropoietin (EPO)

Intact PTH (iPTH)

IGF-1

Osteocalcin

25-OH Vitamin D

D. Type of Test:

Not applicable

E. Applicant:

Bio-Rad Laboratories

F. Proprietary and Established Names:

Liquichek™ Specialty Immunoassay Control

G. Regulatory Information:

1. Regulation section:

21CFR § 862.1660 Quality Control Material (Assayed and Unassayed)

2. Classification:

Class I

3. Product code:

JJY Multi-analyte controls

4. Panel:

Chemistry (75)

H. Intended Use:

1. Intended use(s):

Liquichek™ Specialty Immunoassay Control is intended for use as a quality control serum to monitor the precision of laboratory testing procedures listed in the package insert

2. Indication(s) for use:
Same as above
3. Special conditions for use statement(s):
For prescription use only
4. Special instrument requirements:
Not Applicable

I. Device Description:

This product is prepared from human serum with added constituents, chemicals, stabilizers, and preservatives. Three levels of control are available and are provided ready to use.

Substantial Equivalence Information:

1. Predicate device name(s):
Lypocheck Immunoassay Plus Control
2. Predicate 510(k) number(s):
k981532
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
	Liquichek™ Specialty Immunoassay Control	Lypocheck Immunoassay Plus Control
Intended Use	For use as quality control serum to monitor the precision of laboratory testing procedures listed in the package insert.	Same
Matrix	Human serum	Same

Differences		
Item	Device	Predicate
Form	Liquid	Lyophilized
Preservatives	Contains Preservatives (5-chloro-2-methyl-2H-isothiazol-3-1	None
Analytes	Contains only the following analytes: 1. Anti-TG 2. Anti-TPO 3. C-peptide 4. Erythropoietin (EPO)	Contains the following analytes: 1. 25-OH Vitamin D 2. C-peptide 3. Intact PTH Does not contain: 1. Anti-TG

Differences		
Item	Device	Predicate
	5. Intact PTH (iPTH)	2. Anti-TPO
	6. Insulin like Growth Factor (IGF-1)	3. Erythropoietin (EPO)
	7. Osteocalcin	4. Insulin like Growth Factor (IGF-1)
	8. 25-OH Vitamin D	5. Osteocalcin

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

None referenced.

L. Test Principle:

Not applicable. This submission is for clearance of control material.

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 mean values printed in the insert were derived from replicate analyses and are specific for a particular lot. The material is analyzed by the reagent manufacturer and/or independent laboratories using manufacturer supported reagents. For value assignment, a minimum of 20 replicates per level per analyte over a period of 10 days are run. Means established by individual laboratory should fall within the corresponding acceptable range. Refer to the package insert for the assigned values and ranges. It is recommended that each laboratory establish its own means and acceptable ranges and use those provided only as guides.

Stability studies were performed as follows:

- Open Vial: At least six time points (time 0 and five additional time points at regular interval during the study period) per temperature, per analyte, per level are assayed using three vials in singlicate. The study time is defined to be at least 20% longer than the claimed open vial stability
- Shelf Life:
 1. Accelerated Stability: At least six time points (time 0 and five additional time points at regular interval during the study period) per temperature, per analyte, per level are assayed using three

vials in singlicate. The study time is defined to be at least 20% longer than the claimed shelf life stability.

2. Real Time Stability: At least eight time points (i.e. time 0, 6, 9, 12, 24, 27, 36 and 40 months) per analyte, per level are assayed using at least four vials to obtain a total of eight replicates. The study time is defined to be at least 20% longer than the claimed shelf life stability.

The results are as follows:

Open vial stability is 30 days at 2° C to 8° C with the following exceptions:

Anti-Tg and Anti-TPO will be stable for 21 days.

Shelf Life Stability is 2 years at -20° to -70° C.

- 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 based upon a Tier I review.