

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

A. 510(k) Number:

k071675

B. Purpose for Submission:

New Device

C. Measurand:

Alpha-Fetoprotein (AFP), Beta-2-Microglobulin (B2-M), CA 15-3, CA 19-9, CA 27-29, CA 125, Carcinoembryonic antigen (CEA), Ferritin, hCG/Beta hCG (human chorionic gonadotropin), Insulin growth factor-1 (IGF-1), Prostate acid phosphatase (PAP), Prolactin, Prostate specific antigen (PSA), Prostate specific antigen-free (Free PSA), Thyroglobulin.

D. Type of Test:

Quality Control Material

E. Applicant:

Bio-Rad Laboratories

F. Proprietary and Established Names:

Liquichek Tumor Marker Control Levels 1, 2 and 3

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JJY	Class I	21 CFR 862.1660 Quality control material (assayed and unassayed)	Chemistry 75

H. Intended Use:

1. Intended use(s):
Liquichek Tumor Markers 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.
2. Indication(s) for use:
Same as above
3. Special conditions for use statement(s):
Prescription use
4. Special instrument requirements:
Not applicable

I. Device Description:

Liquichek Tumor Markers Control is prepared from human source material with added constituents of human and animal origin, chemicals, stabilizers, and preservatives (cocktail of preservatives in which the concentration of any one ingredient does not exceed 0.1%). The controls are provided in ready-to-use liquid form.

J. Substantial Equivalence Information:

Liquichek Tumor Markers Control claims substantial equivalence to the Lyphocheck Tumor Markers Control (k011579).

Similarities		
Item	Device	Predicate
Intended Use	Liquichek Tumor Markers Control is intended as an assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.	Lyphochek Tumor Markers Control is intended as an assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.
Differences		
Item	Device	Predicate
Analytes	Alpha-Fetoprotein (AFP), Beta-2-Microglobulin (B2-M), CA 15-3, CA 19-9, CA 27-29, CA 125, Carcinoembryonic antigen (CEA), Ferritin, hCG/Beta hCG (human chorionic gonadotropin), Insulin growth factor-1 (IGF-1) , Prostate acid phosphatase (PAP), Prolactin, Prostate specific antigen (PSA), Prostate specific antigen-free (Free PSA), Thyroglobulin	ACTH, Aldosterone, Alpha-Fetoprotein (AFP), Beta-2-Microglobulin (B2-M), CA 15-3, CA 19-9, CA 27-29, CA 50, CA 125, CASA, Calcitonin, Carcinoembryonic antigen (CEA), Ferritin, hCG/Beta hCG (human chorionic gonadotropin), Neuron specific enolase, Prostate acid phosphatase (PAP), Prolactin, Prostate specific antigen (PSA), Prostate specific antigen-free (Free PSA).
Levels	Level 1, 2 and 3	Level 1 and 2
Reagent Preparation	Liquid	Lyophilized
Matrix	Human and animal serum albumin	Human serum
Preservatives	Contains preservatives	Does not contain preservatives
Storage	-20°C to -70°C	2°C to 8°C; -10°C to -20°C for 30 days after reconstitution
Stability, open	IGF-1: 15 days; All other analytes 30 days at 2°C to 8°C.	Ferritin and CA 27-29: 6 days; ACTH, Calcitonin, Free PSA, PSA immediately; all other analytes 14 days at 2°C to 8°C

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

None 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):*

Traceability: there are no claims for traceability made.

Stability:

Open vial stability: All analytes are stable for 30 days at 2°C to 8°C with the following exception: Insulin-like growth factor (IGF-1) is stable for 15 days.

Shelf life: two-years.

Expected values: Value assignments for each lot are performed by independent manufacturers and laboratories using FDA

exempt/cleared/approved tests. Mean values for the three levels are derived from replicate analysis. It is recommended that each laboratory establish its own values and acceptable range. Values and ranges are lot specific.

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.