510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:

K163015

B. Purpose for Submission:

Modification of previously cleared control (K071675) to add Her-2/neu and Human Epididymis Protein (HE4)

C. Measurand:

Multi-analyte quality control materials

D. Type of Test:

Not applicable

E. Applicant:

Bio-Rad Laboratories

F. Proprietary and Established Names:

Liquichek Tumor Marker Control – Level 1
Liquichek Tumor Marker Control – Level 2
Liquichek Tumor Marker Control – Level 3
Liquichek Tumor Marker Control – Trilevel Minipak

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1660, Quality control material (assayed and unassayed)

2. Classification:

   Class I, Reserved

3. Product code:

   JJY

4. Panel:

   Chemistry (75)

H. Intended Use:

1. Intended use:

   Liquichek Tumor Marker Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in this package insert.

   The following analytes are listed in the package insert:

   Alpha Fetoprotein (AFP)
   Beta-2-Microglobulin (B2-M)
   CA 15-3
   CA 19-9
   CA 27.29
   CA 125
   Carcinoembryonic Antigen (CEA)
   Ferritin
   Her-2/neu
   Human Chorionic Gonadotropin (hCG)/(β-hCG, Total hCG, Intact hCG)
   Human Epididymis Protein (HE4)
   Insulin-like Growth Factor-I (IGF-1)
   Prostatic Acid Phosphatase (PAP)
   Prolactin
   Prostate Specific Antigen, Total (Total PSA)
   Prostate Specific Antigen, Free (Free PSA)
   Thyroglobulin (Tg)

2. Indication(s) for use:

   See Intended use above.

3. Special conditions for use statement(s):

   For prescription use only.

4. Special instrument requirements:

   See product insert for instruments' requirements.

I. Device Description:

Liquichek Tumor Marker Control is prepared from human serum with added constituents of

human and animal origin, stabilizers and preservatives. This product is provided in liquid form for convenience in the following configurations:

Description	Configuration
Liquichek Tumor Marker Control, Level 1	6 x 2 mL
Liquichek Tumor Marker Control, Level 2	6 x 2 mL
Liquichek Tumor Marker Control, Level 3	6 x 2 mL
Liquichek Tumor Marker Control, Trilevel MiniPak	3 x 2 mL (1 per level)

The sponsor has the following caution statement in their labeling: "The human source material 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." The labeling also includes the standard precaution about proper handling of human-sourced material cautions.

J. Substantial Equivalence Information:

1. Predicate device name and 510(k) number:

   Liquichek Tumor Marker Control, K071675

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Liquichek Tumor Marker Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in this package insert.	Same
Form	Liquid	Same
Base Matrix	Human source material and constituents of animal origin	Same
Thawed and Open Stability	All analytes at 60 days at 2–8°C Except: • IGF-1, PAP: 35 days at 2–8°C • Free PSA: 30 days at 2–8°C	Same

Similarities		
Item	Device	Predicate
	• CA 125: 14 days at 2–8°C	
Frozen Aliquot Stability	30 days at −20–−70ºC	Same
Shelf Life	36 months at −20–−70°C	Same

Differences		
Item	Device	Predicate
Frozen aliquot	30 days at −20–−70 ºC	No claim
Analytes	Contains:	Contains:
	• Alpha Fetoprotein (AFP) • Beta-2-Microglobulin (B2-M) • CA 15-3 • CA 19-9 • CA 27.29 • CA 125 • Carcinoembryonic Antigen (CEA) • Ferritin • Her-2/neu • Human Chorionic Gonadotropin (hCG)/(β-hCG, Total hCG, Intact hCG) • Human Epididymis Protein (HE4) • Insulin-like Growth Factor-I (IGF-1) • Prostatic Acid Phosphatase (PAP) • Prolactin • Prostate Specific Antigen, Total (Total PSA) • Prostate Specific Antigen, Free (Free PSA) • Thyroglobulin (Tg)	• Alpha Fetoprotein (AFP) • Beta-2-Microglobulin (B2-M) • CA 15-3 • CA 19-9 • CA 27.29 • CA 125 • Carcinoembryonic Antigen (CEA) • Ferritin • Human Chorionic Gonadotropin (hCG)/(β-hCG, Total hCG, Intact hCG) • Insulin-like Growth Factor-I (IGF-1) • Prostatic Acid Phosphatase (PAP) • Prolactin • Prostate Specific Antigen, Total (Total PSA) • Prostate Specific Antigen, Free (Free PSA) • Thyroglobulin (Tg) **Does not contain Her-2/neu and HE4**

K. Standard/Guidance Document Referenced:

Not applicable

L. Test Principle:

Not applicable

M. Performance Characteristics:

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 and corresponding ± 3 standard deviation ranges in the Assignment of Values Data Charts were derived from replicate analyses by different clinical laboratories using Bio-Rad's protocol or by manufacturers' using their own value assignment protocols; each value is specific for this lot of product and clinical analyzer. The tests listed were performed by the manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this lot of product. It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides.

Stability Studies:

Real-time stability studies were performed to establish thawed stability claims. Thawed and open-vial stability when stored at 2ºC–8ºC is as follows: IGF-1 is 15 days, CA 125 is 10 days, and all other analytes are 30 days.

Thawed and unopened-vial stability when stored at 2ºC–8ºC is as follows: IGF-1 is 35 days, free PSA is 30 days, CA 125 is 14 days, and all other analytes are 60 days.

Frozen aliquot stability is 30 days when stored at −20ºC–−70ºC for all analytes.

Accelerated stability studies were performed for establishing the shelf life claim of 28 months from the date of manufacture when stored at −20ºC–−70ºC. Real time studies are ongoing, and support 10 months stability at this writing.

Shelf-life and open-vial stability studies protocols and acceptance criteria were reviewed and found to be acceptable.

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 and Specificity:

Not applicable

b. Other clinical supportive data (when a. 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.