

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

A. 510(k) Number:

K143379

B. Purpose for Submission:

New device

C. Measurand:

AFP (Alpha Fetoprotein)
hCG (human Chorionic Gonadotropin)
Unconjugated (free) Estriol (uE3)
Inhibin A

D. Type of Test:

Not applicable

E. Applicant:

Bio-Rad Laboratories

F. Proprietary and Established Names:

Liquichek Maternal Serum II Control

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:

Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

See Indications for use below.

2. Indication(s) for use:

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

Analytes are: AFP, hCG, unconjugated Estriol, and Inhibin A

3. Special conditions for use statement(s):

For Prescription use only.

4. Special instrument requirements:

None.

I. Device Description:

Liquichek Maternal Serum II Control is prepared from defibrinated human plasma with added human constituents, chemicals, stabilizers and preservatives. Controls are provided in liquid form in the following configurations:

Level	Configuration
Liquichek Maternal Serum II Control Level 1	6 x 2.5 mL
Liquichek Maternal Serum II Control Level 2	6 x 2.5 mL
Liquichek Maternal Serum II Control Level 3	6 x 2.5 mL
Liquichek Maternal Serum II Control Trilevel MiniPak	3 x 2.5 mL (1 vial per level)

Each human 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):

Lyphocheck Material Serum Control

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

k984594

3. Comparison with predicate:

Similarities		
Item	Candidate Device Liquichek Maternal Serum II Control	Predicate Device Lyphocheck Maternal Serum Control
Intended Use	Liquichek Maternal Serum II Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.	Same
Number of Levels	3	Same
Matrix	Defibrinated Human Plasma	Same

Differences		
Item	Candidate Device Liquichek Maternal Serum II Control	Predicate Device Lyphocheck Maternal Serum Control
Form	Liquid	Lyophilized
Fill Size	2.5	5 mL
Open Vial Stability	30 days at 2 – 8 °C	10 days at 2 – 8 °C
Shelf Life / Storage (Unopened)	-20 to -70 °C, until the expiration date	2 – 8 °C, until the expiration date
Analytes	AFP, hCG, unconjugated Estriol, Inhibin A	AFP, hCG, unconjugated Estriol

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

Not applicable.

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:

The analytes contained in the Liquichek Maternal Serum II Control are obtained from commercially available sources, except for Inhibin A which is internally sourced.

Value Assignments:

The mean values and the corresponding $\pm 3SD$ ranges are printed in the package insert for each analyte and level of the control material, for a number of instrument systems. Values in the package insert are derived from replicate analyses and are specific for each lot of the product. Tests for value assignment were performed by the manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sample of each lot of product. The labeling recommends that each laboratory establish its own acceptable ranges and use those provided in the labeling as guides only.

Stability Studies:

Real time stability studies were performed to establish thawed (opened and unopened vial) stability claims. Accelerated stability studies were performed to establish the shelf life stability claims, with real-time stability ongoing. Protocols and acceptance criteria were reviewed and deemed acceptable. The following stabilities for Liquichek Maternal Serum II Control are supported:

Thawed and Unopened Stability:	40 days at 2 to 8°C
Thawed and opened Stability:	30 days at 2 to 8°C
Shelf Life Stability:	40 months 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.