

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

A. 510(k) Number:

k040822

B. Analyte:

ToRCH Plus panel IgM antibodies

C. Type of Test:

Precision controls

D. Applicant:

Bio-Rad Laboratories

E. Proprietary and Established Names:

Liquichek™ ToRCH Plus IgM Control

F. 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, all kinds (assayed and unassayed)
4. Panel:
Chemistry (75)

G. Intended Use:

1. Intended use(s):

Liquichek™ ToRCH Plus IgM Control is intended for use as an unassayed quality control serum to monitor precision of IgM laboratory testing procedures for the analytes listed in this package insert. This product is not intended for use in blood donor screening assays. Analytes listed: *Toxoplasma gondii* IgM, Rubella Virus IgM, Cytomegalovirus (CMV) IgM, Herpes Simplex Virus Type 1/2 (HSV-1/2) IgM, Epstein-Barr Virus (EBV) Viral Capsid Antigen (VCA) IgM, and Lyme (*Borrelia burgdorferi*) IgM.

2. Indication(s) for use:

Liquichek™ ToRCH Plus IgM Control is intended for use as an unassayed quality control serum to monitor precision of IgM laboratory testing procedures for the analytes listed in this package insert. This product is not intended for use in blood donor screening assays. Analytes listed: *Toxoplasma gondii* IgM, Rubella Virus IgM, Cytomegalovirus (CMV) IgM, Herpes Simplex Virus Type 1/2 (HSV-1/2) IgM, Epstein-Barr Virus (EBV) Viral Capsid Antigen (VCA) IgM, and Lyme (*Borrelia burgdorferi*) IgM.

3. Special condition for use statement(s):
Prescription use
4. Special instrument Requirements:
Not applicable

H. Device Description:

These are unassayed IgM controls for the ToRCH panel (Toxoplasma, Rubella, CMV, and Herpes 1/2,) plus EBV VCA and Lyme (*Borrelia burgdorferi*) group of assays. Both positive and negative controls are part of the kit. The control materials are made of negative human sera and monoclonal antibodies as analytes. The controls are to be processed the same way as patient specimens.

I. Substantial Equivalence Information:

1. Predicate device name(s):
VIROTROL ToRCH
2. Predicate K number(s):
k942295
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Procedure	Unassayed controls, positive and negative	Unassayed controls, positive and negative
Matrix	Serum based	Serum based
Form	Liquid	Liquid
Differences		
Item	Device	Predicate
Analytes tested	IgM antibodies to: CMV,EBV VCA,HSV-1/2, Lyme (<i>B. burgdorferi</i>), and <i>Toxoplasma gondii</i>	IgM & IgG antibodies to: CMV,EBV VCA,and HSV- 1/2
Analyte composition	Mouse IgM monoclonals conjugated to human IgM	Native IgM human antibodies

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

Not applicable

K. Test Principle:

Analyte specific EIA

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. *Precision/Reproducibility:*
Not applicable
 - b. *Linearity/assay reportable range:*
Not applicable

- c. Traceability (controls, calibrators, or method):*
Not applicable
 - 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

M. Conclusion:

The descriptive characteristics reported here for the device indicates that it is comparable to other such test kits currently in the market.