

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

A. 510(k) Number:

k040273

B. Analyte:

Quality control material (assayed & unassayed)

C. Type of Test:

Quantitative

D. Applicant:

Bio-Rad Laboratories, Inc.

E. Proprietary and Established Names:

Lyphochek® Assayed Chemistry Control

F. Regulatory Information:

1. Regulation section:
21 CFR 862.1660
2. Classification:
Class I
3. Product Code:
JJY
4. Panel:
75

G. Intended Use:

1. Intended use(s):
Lyphochek Assayed Chemistry 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.
2. Indication(s) for use:
Lyphochek Assayed Chemistry Control is for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.
3. Special condition for use statement(s):
Prescription use
4. Special instrument Requirements:
See instruments listed in the package insert.

H. Device Description:

Lyphochek Assayed Chemistry Control is a human serum based product containing constituents of purified biochemicals (tissue extracts of human and animal origin), chemicals, therapeutic drugs, preservatives, and stabilizers. The control is provided in lyophilized form at two levels, each consisting of twelve (12) 5-mL vials.

I. Substantial Equivalence Information:

1. Predicate device name(s):
Lyphochek Assayed Chemistry Control
2. Predicate K number(s):
k874280
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Monitor precision of laboratory testing procedures for various analytes	Monitor precision of laboratory testing procedures for various analytes
Matrix	Serum	Serum
Form	Lyophilized	Lyophilized
Levels	Two	Two
Differences		
Item	Device	Predicate
Constituents	<p>Same as the predicate device (72 analytes) with the following exceptions:</p> <p>Does not contain claims for aldolase and folate</p> <p>Contains claims for the following analytes: calcium (ionized), copper, glutamate dehydrogenase (GLDH), globulin, cholesterol (LDL), iron-binding capacity, total (TIBC), iron-binding capacity, unsaturated (UIBC), T3 free, T4 free, transferrin, vitamin B12, and zinc</p>	<p>Contains claims for aldolase and folate</p> <p>Does not contain claims for the following analytes listed to the left</p>

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

None referenced

K. Test Principle:

Not applicable

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):*

None referenced

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:

The mean values printed in the insert were derived from replicate analyses and are lot specific. The tests listed were performed by the reagent manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this lot of control.

M. Conclusion:

The Lyphochek Assayed Chemistry Control is similar to the predicate device with the exception of sixteen (16) constituents. However, the difference in these constituents does not raise new issues of safety and effectiveness. Additionally, the value

assignment and stability information provided for the calibrator were adequate. Therefore, a substantial equivalence determination is recommended for the Lyphochek Assayed Chemistry Control.