

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

A. 510(k) Number:

k082036

B. Purpose for Submission:

New device

C. Measurand:

Adrenocorticotrophic Hormone (ACTH), Alpha Fetoprotein (AFP), Aldosterone, Beta-2-Microglobulin, CA 15-3, CA 19-9, CA 27.29, CA 125, Calcitonin, Carcinoembryonic Antigen (CEA), Ferritin, hCG Beta Subunit (β -hCG)/ hCG, Prostatic Acid Phosphatase (PAP), Prolactin, Prostate Specific Antigen, Total (PSA), Prostate Specific Antigen, Free (Free PSA), Thyroglobulin (Tg)

D. Type of Test:

Quality control material

E. Applicant:

Bio-Rad Laboratories

F. Proprietary and Established Names:

Lyphocheck Tumor Marker Plus 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, Multi-analyte controls, all kinds (assayed and unassayed)
4. Panel:
Chemistry (75)

H. Intended Use:

1. Intended use(s):
See Indications for Use below.
2. Indication(s) for use:
Lyphocheck Tumor Marker Plus 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:

Domestic Analytes Listed

- Adrenocorticotrophic Hormone (ACTH)
- Alpha Fetoprotein (AFP)
- Aldosterone
- Beta-2-Microglobulin (B2M)
- CA 15-3
- CA 19-9
- CA 27.29
- CA 125
- Calcitonin
- Carcinoembryonic Antigen (CEA)
- Ferritin
- hCG Beta Subunit (β -hCG)/ hCG
- Prostatic Acid Phosphatase (PAP)
- Prolactin
- Prostate Specific Antigen, Total (PSA)
- Prostate Specific Antigen, Free (Free PSA)
- Thyroglobulin (Tg)

3. Special conditions for use statement(s):
For prescription use only.
4. Special instrument requirements:
Values for each lot are listed in the package insert for several analyzers.

I. Device Description:

Lyophilized Lyphocheck Tumor Marker Plus Controls (Level 1, 2, and 3) are provided in vials to be reconstituted by the user. They are prepared from human source material with added constituents of human and animal origin, chemicals, stabilizers, and preservatives.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Lyphocheck Tumor Marker Control
2. Predicate K number(s):
k011579
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Lyphocheck Tumor Marker Plus Control is intended as an assayed quality control material to	Lyphocheck Tumor Marker Control is intended as an assayed quality control material

Similarities		
Item	Device	Predicate
	monitor the precision of laboratory testing procedures for the analytes listed in the package insert.	to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.
Storage (unopened)	3 years at 2 to 8°C	3 years at 2 to 8°C
Form	Lyophilized	Lyophilized
Matrix	Human Serum	Human Serum

Differences		
Item	Device	Predicate
Levels	3	2
Analytes	No claims for: CA 50 CA 72-4 CASA Cyfra 21-1 Neuron Specific Enolase (NSE)	Includes proposed device claims and additional analytes. Does not claim thyroglobulin (Tg)

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 made for traceability.

Stability:

An accelerated stability study suggested that lyophilized (unreconstituted) vials stored under recommended conditions were stable for 3 years. Real time stability studies demonstrated that lyophilized vials were stable for a minimum of 12 months.

Reconstituted vial stability stored at 2°C to 8°C: All analytes are stable for 14 days with the following exceptions:

Carcinoembryonic Antigen (CEA) is stable for 11 days

Free and Total PSA is stable for 7 days.
Thyroglobulin (Tg) is stable for 5 days.
ACTH and calcitonin should be assayed immediately.

Reconstituted vials stored at -20°C to -70°C are stable for 30 days with the following exceptions: there are no stability claims at -20°C to -70°C for ACTH and calcitonin.

Expected values:

Value assignments for each lot are performed by independent manufacturers and laboratories using FDA-exempt, cleared, or approved tests. Mean values for the three levels are derived from repeated analysis of each analyte. 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.