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

A. 510(k) Number:
k101809

B. Purpose for Submission:
New device

C. Measurand:
Controls for AFP (Alpha Fetoprotein), CA 15-3, CA 19-9, CA 125, CEA (Carcinoembryonic Antigen), Ferritin, HE4 (Human Epididymis Protein 4), PSA (Prostate Specific Antigen), Free PSA

D. Type of Test:
Assayed Quality control material

E. Applicant:
Fujirebio Diagnostics, AB

F. Proprietary and Established Names:
Fujirebio Diagnostics Tumor Marker 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)
4. Panel:
   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):
   For In Vitro Diagnostic Use Only.
   Fujirebio Diagnostics Tumor Marker Control is intended for use as an assayed control serum to monitor the precision of laboratory testing procedures for the analysis of AFP, CA15-3, CA19-9, CA125, CEA, Ferritin, HE4, PSA and Free PSA.
2. Indication(s) for use:
   Same as intended use
3. Special conditions for use statement(s):
   For prescription use only
4. Special instrument requirements:
   This device may be used as an assayed quality control material only for the instrument specified in the package insert supplied with the kit.

I. Device Description:
The Fujirebio Diagnostics Tumor Marker Controls is prepared from human serum, purified biochemical materials, preservative and stabilizer chemicals. The kit includes 6 bottles of lyophilized material, 3 of each level (Level 1-low control, and Level 2-high control). The table below shows an example of typical range values for the two control levels:

Analyte	Typical Range Level 1	Typical Range Level 2	Assay Unit	SI Unit
AFP	15.4 – 28.6	193 - 344	ng/mL	µg/L
CA 15-3	11.9 – 22.1	105 - 195	U/mL	kU/L
CA 19-9	39.2 – 72.8	431 – 800**	U/mL	kU/L
CA 125	17.5 – 32.5	280 - 520	U/mL	kU/L
CEA	3.5 – 6.5	42.0 – 78.0	ng/mL	µg/L
HE4	50.0 - 100.0	450 - 850	pM	pmol/L
FERRITIN	31.5 – 75.0	280 - 520	ng/mL	µg/L
FREE PSA	≥ 1.0	7.0 – 19.0	ng/mL	µg/L
PSA	2.3 – 4.2	21.0 – 39.0	ng/mL	µg/L

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Bio-Rad Lyphochek® Tumor Marker Plus Control
2. Predicate 510(k) number(s):
   k082036
3. Comparison with predicate:

	New Device	Predicate
Item	Fujirebio Diagnostics Tumor Marker Control	Bio-Rad Lyphochek® Device
Similarities		
Intended Use	For In Vitro Diagnostic Use Only. Fujirebio Diagnostics Tumor Marker Control is intended for use as an assayed control serum to monitor the precision of laboratory testing procedures for the analysis of AFP, CA15-3, CA19-9, CA125, CEA, Ferritin, HE4, PSA and Free PSA.	Same
Matrix	Human Serum	same
Form	Lyophilized	same
Differences		
Number of Levels	2	3
Reconstitution Volume	3.0 mLs	2.0 mLs
Controls for the following Analytes	AFP, CA 15-3, CA 19-9, CA 125, CEA, Ferritin, PSA, Free PSA, HE4	AFP, CA 15-3, CA 19-9, CA 125, CEA, Ferritin, PSA, Free PSA ACTH, Aldosterone, Beta-2-Microglobulin, CA 27.29, Calcitonin, hCG, Prolactin, Prostatic Acid

		Phosphatase, and Thyroglobulin
Stability - Reconstituted at 2-8˚C	14 days at 2-8˚C, except Free PSA - 7 days	14 days at 2-8˚C, except Total PSA – 7 days Free PSA – 7 days CEA - 11 days
Stability – Reconstituted at ≤-20˚C	60 days when stored at ≤-20˚C	30 days when stored at ≤-20˚C
Stability (unopened)	18 months at 2 to 8°C	3 years at 2 to 8°C
Stability – Freeze/thaw	May be frozen and thawed repeatedly for up to 9 cycles	No claim made for freeze/thaw stability

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

EN 13640 - Stability Testing of In Vitro Diagnostic Reagents

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 - The stability studies were performed in compliance to the CEN standard, 13640 – Stability Testing of *In Vitro* Diagnostic Reagents. The studies were performed on the ARCHITECT *i*2000 analyzer. The respective ARCHITECT Controls are tested for assay validity.

ARCHITECT AFP	ARCHITECT CA15-3
ARCHITECT CEA	ARCHITECT CA19-9XR
ARCHITECT CA125II	ARCHITECT Ferritin
ARCHITECT Total PSA	ARCHITECT HE4
ARCHITECT Free PSA	

Accelerated stability & Real time Stability:
Two lots of lyophilized Fujirebio Diagnostics Tumor Marker Controls were tested. The vials were stored at 2-8°C (reference), ambient temperature (room temperature) and 37°C. The test and reference were reconstituted and run in duplicate at different time points and compared.
Real-time stability study is ongoing. The shelf life stability is based on the accelerated stability study and the real-time stability studies done so far.

The claimed shelf life stability is 18 months at 2°C to 8°C.
Open bottle stability at 2-*8°*: Two lots of Fujirebio Diagnostics Tumor Marker Controls were used for the study. Reconstituted vials are stored at 2-8°C (test). Lyophilized vials are stored at 2-8°C (reference). The test and reference (after reconstitution) were run in duplicate at the following time points: day 3, 8, 15, and 30 and compared. The claimed stability, once the control is reconstituted, is 14 days when stored tightly capped at 2-8°C with the following exception: Free PSA is stable for 7 days.
Open bottle stability at ≤ -20°C :
Two lots of Fujirebio Diagnostics Tumor Markers were used for the study. Reconstituted vials are stored at ≤ -20°C (test). Lyophilized vials are stored at 2-8°C (reference). The test and reference (after reconstitution) were run in duplicate at day 30 and 61 and compared. The claimed open vial stability is for 60 days when stored at ≤ -20°C after reconstitution.
Freeze / Thaw Stability study:
Vials were reconstituted at the start of the study and then frozen and thawed without opening the vial between the freeze/thaw cycles. The sponsor claims that controls may be frozen and thawed repeatedly for up to 9 cycles.
Transport Stability Simulation Study – Lyophilized: Transport stability study is currently ongoing.
Expected/assigned values:
Value assignments for each lot are performed by independent manufacturers of laboratory tests and CAP and/or CLIA certified laboratories. Mean values for each level of each analyte on each analyzer/manual method are determined by running a minimum of 20 replicates. It is recommended that each laboratory establish its own means and acceptable ranges and use the printed ranges as guidance only. Values and ranges are lot specific.

Acceptance ranges for the target-setting reference system,
Abbott ARCHITECT:

Analyte	Design Goal Target Mean Level 1	Design Goal Target Mean Level 2
AFP ng/mL	22.0	275
CA 15-3 U/mL	17.0	150
CA 19-9 U/mL	56.0	615
CA 125 U/mL	25.0	400
CEA ng/mL	5.0	60
Ferritin ng/mL	45.0	400
Total PSA ng/mL	3.25	30.0
fPSA ng/mL	1.3	13.0

Acceptance ranges for the target-setting reference system, EIA from Fujirebio

Diagnostics:

Analyte	Design Goal Target Mean Level 1	Design Goal Target Mean Level 2
HE4 pM	75.0	650

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.