

Tumor Marker Control

Look closer. Perform better. Deliver more.

Tumor Marker Analytes

HE4	CA 125	Total PSA	CA 27.29*
CA 15-3	AFP	Free PSA	CA 242*
CA 19-9	CEA	Ferritin	

* Non-spiked analytes. No claim is made for performance or stability.

Fujirebio Diagnostics, Inc.'s Tumor Marker Control, the only multi-constituent control to contain the novel biomarker HE4¹, is an assayed, bi-level tumor marker panel containing clinically relevant proportions of Free PSA and PSA-ACT^{2,3}, as well as excellent reconstitution stability. Manufactured to the highest quality standards, the Tumor Marker Control ensures accurate precision monitoring of *in-vitro* diagnostic laboratory testing procedures and techniques.

Typical values

These values are provided solely for the convenience of the laboratory prior to the assessment of the control. Values were obtained from testing performed on the Abbott ARCHITECT and AxSYM Immunoassay systems except for HE4 (Fujirebio Diagnostics EIA).



Reference and Typical Values

Analyte	Reference Ranges*	Typical Range Level 1	Typical Range Level 2	Units
HE4	≤150 pM ⁴	50.0 - 100.0	450 - 850	pM
CA 15-3	<30 U/mL ⁵	11.9 - 22.1	105 - 195	U/mL
CA 125	<35 U/mL ⁵	17.5 - 32.5	280 - 520	U/mL
CA 19-9	<37 U/mL ⁵	39.2 - 72.8	431 - 800 ⁶	U/mL
AFP	<10.0 ng/mL ⁵	15.4 - 28.6	193 - 344	ng/mL
CEA	Non-Smokers <3.0 ng/mL ⁵ & Smokers <5.0 ng/mL ⁵	3.5 - 6.5	42.0 - 78.0	ng/mL
Total PSA	<4.0 ng/mL ⁵	2.3 - 4.2	21.0 - 39.0	ng/mL
Free PSA	≤25% of Total PSA ⁵	≥1.0	7.0 - 19.0	ng/mL
Ferritin	Male 20-250 ng/mL ⁵ Female 10-120 ng/mL ⁵	31.5 - 75.0	280 - 520	ng/mL

*It is recommended that each laboratory establish its own reference ranges for the population of interest.



Tumor Marker Control

Kit components

Item	
Tumor Marker Control 100% Human Sera Matrix	P/N 108-20
Tumor Marker Control Level 1 (lyophilized)	3 x 3 mL
Tumor Marker Control Level 2 (lyophilized)	3 x 3 mL
Stability (unopened vial): 36 months at 2-8°C (from the Date of Manufacture)	
Reconstituted: All analytes will be stable for 60 days when stored at ≤-20°C, 14 days at 2-8°C for most analytes with the following exception: Free PSA will be stable for 7 days. Sustains 9 freeze/thaw cycles.	

Please refer to current lot number package inserts for assigned values and stability claims.

References:

1. Fujirebio Diagnostics, Inc. HE4 EIA
2. Lilja H, Christensson A, Dahlén U, Matikainen M-T, Nilsson O, Pettersson K, Lövgren T. (1991). Prostatic-specific antigen in serum occurs predominately in complex with α_1 -antichymotrypsin. *Clin Chem* 37:1618-1625.
3. Lilja H, Ulmert D, Vickers AJ. Prostatic specific antigen and prostate cancer: prediction, detection, and monitoring. *Nature Reviews Cancer* 2008;8:268-278.
4. Fujirebio Diagnostics AB Göteborg, Sweden. HE4 EIA Assay Insert, 404-10, 2008-09, F5907, r1.
5. Wu A. Tietz Clinical Guide To Laboratory Tests. St. Louis: W. B. Saunders Company, 2006. Print.
6. Higher values as seen with Abbott ARCHITECT assay.

For more information please visit: www.fujirebio-us.com



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