

Anti-PSA staining results with HAM18 are consistant with singular expression of PSA in prostatic derived cells. PSA positivity of non-PSA expressing tissues seen with other antibodies points to cross-reactivity.

All Gleason Grades stain with high sensitivity.

True negative staining of extraprostatic carcinoma tissues.

Validation performed by



Whitepaper

Cancer tissue study of anti-PSA antibody clone HAM18 on FFPE tissues and comparison with common anti-PSA antibodies

Anti-PSA (Prostate specific antigen) clone HAM18 stands out among more than 1,000 commercially available PSA antibodies because of its documented high specificity and sensitivity for recognition of prostatic cancer. Although PSA is solely expressed in prostatic epithelial cells, studies utilizing various different other antibodies have described PSA expression in 9%-60% of breast cancers ¹⁻⁸, in 55% of malignant melanomas ⁷, 3%-9% of male breast cancers ^{8, 9}, 3 of 3 acinar pancreatic cancers ¹⁰, various salivary gland carcinomas (including 6 of 11 pleomorphic adenomas, 1 of 6 mucoepidermoid carcinomas, and 1 of 2 adenocarcinomas not otherwise specified) ¹¹⁻¹³. Multiple case reports have also described PSA expression in at least 4 cases of paraurethral adenocarcinoma ¹⁴⁻¹⁸ and in a urinary bladder cancer ¹⁹. Moreover PSA expression was described to occur in normal salivary glands, 60% of salivary gland adenomas, and in normal pancreatic epithelium ¹². Using Anti-PSA clone HAM18, PSA positivity was not seen in any of these normal and neoplastic tissues.

Performance Characteristics

The validation of Anti-PSA clone HAM18 on more than 20,000 cancers using the protocol recommended by Oncodianova (Hamburg, Germany) at an antibody dilution of 1:800 enabled a precise documentation of the sensitivity and specificity of this antibody. The key figures on the performance of the HAM18 Anti-PSA antibody are as follows.

Sensitivity

Prostate Cancer Subset	Samples analyzed (n)	PSA positive (n)	Sensitivity at 1:800 (1:100) dilution
Gleason 3+3=6	2,439	2,437	99.92%
Gleason 3+4=7	7,470	7,461	99.87%
Gleason 4+3=7	2,213	2,205	99.64%
Gleason 8	112	111	99.15%
Gleason 9-10:	628	618	98.41%
Recurrent prostate cancer after therapy (Gleason ≥8)	392	387	99.72%
Small cell carcinoma of the prostate	13	1	7.69%

Specificity

Tumor type	Samples analyzed (n)	PSA positive (n)	Sensitivity at 1:800 dilution
Adenocarcinoma, extraprostatic	877	1*	99.89%
Squamous cell carcinoma, extraprostatic	319	0	100%
Small cell carcinoma, extraprostatic	46	0	100%
Other extraprostatic carcinomas	1,603	0	100%
All extraprostatic malignancies	2,845	1	99.96%

HAM18 has been developed for high-contrast detection of prostate specific antigen (PSA) in routine formalin-fixed paraffin-embedded prostate tissue specimen. HAM18 can be used in brightfield immunohistochemistry and for multicolor immunofluorescence. More data on HAM818 are presented on PSA-antibody.com.

chemovo

Extensive antibody validation on tissues is a prerequisite for diangostic accuracy of IHC antibodies.

Primary Reference

Bonk S. et al. Prognostic and diagnostic role of PSA immunohistochemistry: A tissue microarray

study on 21,000 normal and

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cancerous tissues. Oncotarget

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www.psa-antibody.com

Conclusion

The use of extensively validated antibodies is highly recommended for certified and accredited pathology laboratories.

In diagnostic routine, PSA (HAM18) immunohistochemistry can be used in the following applications:

- Carcinoma of unknown origin: Proof or rule out origin from prostatic cancer.
- Bladder tumor of male patients without unequivocal urothelial precursor lesion suggesting urothelial origin: Rule out origin from a prostate cancer.
- Advanced high-grade prostate cancer with rather low (or unknown) serum PSA levels: Low PSA expression in poorly differentiated cancer suggest that serum PSA levels may "underestimate" total tumor mass of the patient.

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