

Carbonic anhydrase IX automated IHC kit, 11/15

Nuclea Biotechnologies has met the requirements from the FDA for its Carbonic Anhydrase IX Automated immunohistochemistry kit as a class I in vitro diagnostic device for use on a Ventana Benchmark XT instrument.

Carbonic anhydrase IX, as a well-known marker of the tumor hypoxic environment, can provide information along with other clinical medical data for a variety of cancers. Of particular interest is use of the assay concerning the impact of carbonic anhydrase IX expression on the pathological evaluation of head and neck squamous cell carcinomas. This information may be used, together with other clinically relevant information, in the determination of tumor aggressiveness. A correlation has also been shown between carbonic anhydrase IX expression and decreased survival in human papilloma virus p16 head and neck tumors. A benefit of obtaining carbonic anhydrase IX results includes providing physicians with additional data that can be used in conjunction with other clinical information to design and optimize personalized treatment strategies for patients.

The kit uses a proprietary antibody to measure carbonic anhydrase IX in tissue samples with excellent lot-to-lot reproducibility and performance and has been validated on Ventana Medical Systems' Immunohistochemistry assay instrument.

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