July 6, 2022

Bio-Techne Announces Launch of the CE-IVD RNAscope™ ISH Probe High Risk HPV Assay for Head and Neck Cancer

A highly accurate new tool for the direct detection of HPV mRNA in FFPE tissue specimens

MINNEAPOLIS, July 6, 2022 /PRNewswire/ -- Bio-Techne (NASDAQ: TECH), a global life sciences company providing innovative tools and bioactive reagents for the research and clinical diagnostic communities today announced the European launch of the CE-IVD marked RNAscope ISH Probe High Risk HPV, intended for use in patients diagnosed with oropharyngeal squamous cell carcinoma (OPSCC) to aid in the identification of high-risk human papillomavirus (HPV).

HPV is a major cause of OPSCC, and HPV has emerged as a valuable diagnostic marker that significantly impacts clinical management.[1,2] Immunohistochemistry (IHC) for p16 protein, a surrogate marker, is widely used for HPV detection in OPSCC; however, misdiagnosis rates of 5-20% have been reported when using p16.[3] The presence of E6/E7 mRNA is considered the gold standard for diagnosing HPV-related OPSCC.[4] RNAscope offers a superior method for detection of E6/E7 mRNA when assessing HPV status in OPSCC patients, enabling clinicians to provide a more accurate diagnosis and improve patient management.[5]

"Bio-Techne's innovative tissue diagnostic solutions empower our customers to serve patients and improve lives," said Kim Kelderman, President, Diagnostics and Genomics Segment of Bio-Techne. "We are excited to launch the new CE-IVD RNAscope ISH Probe High Risk HPV, which provides pathologists a highly accurate tool for the direct detection of HPV mRNA to inform treatment selection in oropharyngeal squamous cell carcinoma patients."

RNAscope *in situ* hybridization (ISH) is a highly sensitive and specific spatial biology technology. Its double Z probe design enables an exceptional signal-to-noise ratio when staining formalin-fixed paraffin-embedded (FFPE) tissue specimens. RNAscope ISH allows users to visualize and localize biomarker expression patterns by light microscopy. Over the past 10 years, RNAscope ISH has proven its reliability, reproducibility, and robustness with more than 6000 peer reviewed publications, making it a powerful solution for anatomic pathologists.

RNAscope ISH Probe High Risk HPV is used in an RNAscope ISH assay for the qualitative detection of HPV E6/E7 mRNA in FFPE tissue specimens. RNAscope ISH Probe High Risk HPV is for use in clinical laboratories with the CE-IVD marked BOND RNAscope Brown Detection kit on the automated Leica Biosystems BOND-III stainer. The assay detects high-risk HPV types 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 73, and 82.

To learn more about RNAscope ISH Probe High Risk HPV, please visitwww.bio-techne.com/rnascope-hpv

About Bio-Techne Corporation (NASDAQ: TECH)

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