Fujirebio Europe expands its portfolio with introduction of the innovative PreCursor-M AnoGYN assay (RUO) for methylation testing in anal specimens

Gent, Belgium and Amsterdam, The Netherlands – March 5th, 2024: Fujirebio Europe and Self-screen B.V. today announced an expansion of their commercial collaboration with the distribution of the PreCursor-M AnoGYN methylation-specific molecular assay from Self-screen B.V. The test is intended for the detection of promoter hypermethylation of the genes *ASCL1* and *ZNF582* and is used to test the methylations status of anal specimens for research use only (RUO). It complements Fujirebio's HPV-associated molecular test portfolio.

"The Human Papilloma Virus (HPV) test panel of Fujirebio Europe continues to grow with effective and accurate testing solutions , and we are pleased to add this new RUO methylation-based assay to our molecular testing toolbox", says Christiaan De Wilde, CEO at Fujirebio Europe *"With its unmatched accuracy and reliability, this innovative PreCursor-M AnoGYN assay represents a significant advancement for research studies in the field of anal cancer prevention. We wanted our customers to have access to this valuable research tool as soon as possible, ultimately catalyzing advancements in elimination of HPV-related diseases."*

We are very happy with the continued partnership with Fujirebio in the distribution of Self-screen's HPV tests and -methylation tests, says Michelle Meijer, Chief Commercial Officer at Self-screen B.V. *The PreCursor-M AnoGYN extends our offering of HPV products into the field of anal cancer. Also in this HPV-related cancer, methylation appears to be promising for future use as an accurate biomarker for objective risk stratification of anal lesions. The growing medical need for better and more supportive diagnostics tools for HPV related cancers such as anal cancer drove us to the development of the PreCursor-M AnoGYN RUO assay which is now available through Fujirebio."*

About host cell DNA methylation and anal cancer

Incidence of anal cancer is increasing worldwide. The majority of anal cancers are squamous cell carcinoma (SCC) and are, like cervical cancer, mainly caused by a persistent high-risk HPV infection and preceded by high-grade squamous intraepithelial lesion (HSIL). In analogy with cervical cancer screening, the screening and treatment of HSIL to prevent anal cancer in high-risk groups are under debate. Host cell DNA methylation is an epigenetic hallmark of HPV-induced carcinogenesis. The PreCursor-M AnoGYN assay is a robust and reliable tool to further investigate host cell DNA methylation in anal carcinogenesis and study it's potential as valuable biomarker for the detection of anal (pre-)cancer.[1-4]

Please contact Fujirebio for further information about the local availability of the test.

About Self-screen B.V.

Self-screen B.V. is a company highly experienced in translational HPV related research, assay development and commercialization of *In Vitro* Diagnostics (IVD).

Our dedication is towards the development and clinical application of molecular assays for the early detection of anogenital and head&neck (pre)cancers, to the benefit of patients and health care programs around the world.

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Our main focus is on cervical (pre)cancer screening and prevention. Self-screen markets two clinically validated CE-IVD assays. The HPV-Risk-Assay and the PreCursor-M+ Methylation Test, for screening and triage respectively, to support full molecular cervical screening and to assist the clinician in management of women with high-grade CIN. Recently PreCursor-M AnoGYN RUO is added.

About Fujirebio

Fujirebio is a global leader in the field of high-quality IVD testing. We have more than 50 years' accumulated experience in the conception, development, production, and worldwide commercialization of robust IVD products.

Fujirebio has a long-lasting tradition for developing high-quality routine and truly novel biomarkers. Our IVD product lines span the range from specialized manual and automated testing to fully automated routine clinical laboratory testing solutions covering a variety of disease states.

Our global presence includes offices in the United States, Latin America, Europe and Asia as well as a vast international distribution network.

References:

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