SIEMENS Healthineers

Press

Luxembourg, March 28, 2018

Fast Track Diagnostics releases CE-labelled,[1] real-time PCR kit for the detection of 14 HPV High-Risk subtypes

Fast Track Diagnostics (FTD), a Siemens Healthineers company, has expanded its comprehensive sexually transmitted infections portfolio by adding an array of human papillomavirus (HPV) tests.[1] By providing solutions for the detection of multiple strains of the virus, the company's portfolio helps to enable the utilization of precision medicine in the field of molecular diagnostics.

Real-time Polymerase Chain Reaction (PCR) and Reverse Transcription PCR kits amplify nucleic acids, DNA and RNA respectively, from laboratory samples, allowing clinicians to diagnose infections with just a small sample from patients. FTD's multiplex real-time PCR kit detects human papillomavirus 16, human papillomavirus 18, and a pool of 12 other High-Risk human papillomavirus subtypes, including an endogenous control.

"The FTD HPV High-Risk assay was especially designed to meet the high-quality requirements of all laboratories to deliver accurate and specific diagnoses for precision medicine," says Dr. Miriam Steimer, General Manager of Fast Track Diagnostics. "Genotyping of HPV 16 and HPV 18 can provide valuable support in the appropriate diagnosis and follow-up testing of women at risk to develop cervical cancer."

The human papillomavirus is a double-stranded circular DNA virus that can be easily transmitted through sexual contact. HPV infection is one of the most common viral infections of the reproductive tract and is the major risk factor for the development of cervical carcinoma. From over 150 subtypes of HPV being identified, 14 High-Risk subtypes are responsible for nearly all cervical cancers, with HPV type 16 and 18 alone accounting for over 70% of cases.[2]

Siemens Healthcare GmbH (Siemens Medical Solutions USA)
Communications
Dr. Matthias Krämer

Henkestr. 127
91052 Erlangen
Germany

Reference number: PR-20180328011HC

"In offering a comprehensive portfolio of platform-agnostic assays, including those for sexually transmitted infections, FTD—now a Siemens Healthineers company—provides customers with the flexibility to diagnose a broad range of diseases, such as the many strains of HPV," says Fernando Beils, Head of Siemens Healthineers Molecular Diagnostics. "This new assay provides a new precision medicine solution that can enable clinicians to better diagnose and treat these High-Risk strains of HPV."

Although over 90% of HPV infections are resolved within two years, a small proportion of infections from any of the 14 High-Risk HPV subtypes can persist and progress into neoplastic lesions. Cervical cancer screening based on cytology, despite being specific, has a high rate of false negatives and often fails to prevent adenocarcinoma of the cervix.[3]

The human papillomavirus assay is based on multiplex real-time PCR.

[1] Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

[2] Groves et al, Journal of Pathology, 2015; 235: 527–538, Published online 20 January 2015.

[3] Cuzick et al, Int. J. Cancer: 119, 1095–1101 (2006).

Contact for journalists

Theresa Gombar, Siemens Healthineers

Phone: +1 610-448-6370; Email: Theresa.Gombar@siemens-healthineers.com

Siemens Healthineers enables healthcare providers worldwide to increase value by empowering them on their journey towards expanding precision medicine, transforming care delivery, improving patient experience and digitalizing healthcare. A leader in medical technology, Siemens Healthineers is constantly innovating its portfolio of products and services in its core areas of diagnostic and therapeutic imaging and in laboratory diagnostics and molecular medicine. Siemens Healthineers is also actively developing its digital health services and enterprise services.
In fiscal 2017, which ended on September 30, 2017, Siemens Healthineers generated revenue of €13.8 billion and profit of €2.5 billion and has about 48,000 employees worldwide. Further information is available at www.siemens-healthineers.com.

Founded in 2006, **Fast Track Diagnostics (FTD)**, a Siemens Healthineers company, is the leading global suppliers of real-time PCR multiplexing kits, covering all the major infectious disease groups based on the syndromic approach (respiratory infections, gastroenteritis, meningitis, etc.).

Today FTD exports over seventy different kits validated on real clinical samples (including lyophilised kits) and detecting over 140 viruses, bacteria, parasites and fungi to eighty countries. FTD kits are used in hundreds of public and private hospitals and laboratories around the world, and in global surveillance studies by organisations such as the Fondation Mérieux, the Bill and Melinda Gates Foundation and the US Centre for Disease Control and Prevention (CDC).