

September 20, 2014

Bioneer expands MDx portfolio with new CE-IVD marked kits

Bioneer said today that the CE-IVD mark has been applied to 14 new qPCR-based MDx kits this year, bringing their portfolio of such kits to 36. This enables the South Korea-based firm to offer these tests in markets accepting the CE mark.

Kits receiving the CE mark include 11 for infectious disease detection and 3 for genotyping. The infectious disease kits encompass tests for enterovirus, norovirus, human herpesvirus, human papillomavirus 16 and 18 in duplex, and sexually transmitted infections, including *Neisseria gonorrhoeae* (NG), in 4-plex or single-plex. The genotyping tests target ApoE associated with alzheimer disease, Factor V Leiden, and JAK2 V617F.

The line-up of CE marked IVD kits also covers detection of Tuberculosis, Multi-drug resistant tuberculosis, Pneumonia, Respiratory viruses, malaria, Gastrointestinal pathogens, and viral load tests for EBV and BKV.

Bioneer's founder and CEO, Han-Oh Park, Ph.D. said, the company has a proprietary MDx system, ExiStation™ which is the universal molecular diagnostic system consisting of ExiPrep™ 16 Dx (automatic nucleic acid extraction and reaction prep instrument), ExiCycler 96 (realtime qPCR instrument and analysis software), and a broad menu of MDx kits. With these additional CE-IVD marked MDx kits, Bioneer's ExiStation™ is able to expand its capacity to cover the largest MDx menus in a global space accepting CE-IVD mark.

Bioneer MDx kits which obtained CE-IVD marking in 2014.

No.	Product Name	Remark	DATE
1	AccuPower® ApoE Real-Time PCR Kit	Genotyping	Feb 2014
2	AccuPower® Factor V Leiden Real-Time PCR Kit	Genotyping	May 2014
3	AccuPower® JAK2 V617F Quantitative PCR Kit	Genotyping	May 2014
4	AccuPower® MG Real-Time PCR Kit	STD, <i>Mycoplasma genitalium</i>	Feb 2014
5	AccuPower® MH Real-Time PCR Kit	STD, <i>Mycoplasma hominis</i>	Feb 2014
6	AccuPower® NG Real-Time PCR Kit	STD, <i>Neisseria gonorrhoeae</i>	Feb 2014
7	AccuPower® STI8B-Plex Real-Time PCR Kit	STD, MH, TV, HSV1, HSV2	Feb 2014
8	AccuPower® TG Real-Time PCR Kit	Toxoplasma gondii	Jul 2014
9	AccuPower® Enterovirus71 Real-Time RT-PCR kit	Enterovirus71	Mar 2014
10	AccuPower® EV Real-Time RT-PCR kit	Enterovirus	Mar 2014
11	AccuPower® HHV6 Real-Time PCR Kit	human herpesvirus 6	Jul 2014
12	AccuPower® HHV8 Real-Time PCR Kit	human herpesvirus 8	Jul 2014
13	AccuPower® Norovirus Real-Time RT-PCR Kit	Norovirus	Jul 2014
14	AccuPower® HPV16&18 Real-Time PCR Kit	Cervical Cancer, human papillomavirus 16, 18	Feb 2014