



July 13, 2018

Dear Sirs

Company Precision System Science Co., Ltd.

Representative Hideji Tajima,

President and Representative Director

(Code number: 7707 TSE Mothers)

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Notice on commercial launch of geneLEAD VIII, fully automated molecular diagnostic system

Precision System Science Co., Ltd. (PSS) will start selling geneLEAD VIII, a small fully automated genetic molecular diagnostic system (real-time PCR diagnostic instrument) developed by PSS together with an expanding menu of PCR assays.

geneLEAD VIII is a geneLEAD series product following geneLEAD XII plus, a medium-sized fully automated molecular diagnostic system. The feature of this system is that it is possible to perform from nucleic acid extraction to real-time PCR analysis in approximately 90 minutes by using compact pre-filled reagent setting and button operation.

By using this system, molecular testing will be possible even in small and medium-sized hospitals. Combined with PSS's nucleic acid extraction reagent (MagDEA Dx SV) and PCR assays developed by Diagenode Diagnostics, it can deal with various specimen types and can perform 8 different PCR analyses. It is extremely competitive in cost and accuracy as it is a fully automated system capable of high gene diagnosis by using automated measurement technology for multiplex fluorescence detection of up to six colors.

From September 2018, four real-time CE-IVD PCR assays will be launched on the geneLEAD VIII and sold in France, BENELUX (Belgium, the Netherlands, Luxembourg), Portugal and Spain. (Please see annexed the list of PCR assays which will be launched from September 2018 and March 2019).

Mr. Ikeda, Senior Managing Director, who has been in charge of development says, "geneLEAD VIII is an innovative fully automated molecular diagnostic system integrating automatic DNA extraction and quantitative measurement system. These pre-packed diagnostic reagents are optimized for geneLEAD VIII and can provide convenient, rapid and accurate clinical diagnosis results at the clinical diagnostic site."

Mr. Tajima, President is commenting, "We are starting from Europe and planning to expand our business in Asia and worldwide. For that, it is important to line up clinical diagnostic items and clinical standard compliant with each country. We believe that geneLEAD VIII will have the possibility to change the concept of future genetic testing with technologies and methods that are easy to adapt to, and we recommend that you use it in the fields of bacteria, virus, infectious disease, cancer gene mutation, constitution measurement."

Reference: PSS website product introduction

http://www.pss.co.jp/english/product/genelead/lead8.html

[geneLEAD VIII] Fully automated molecular diagnostic system



Up to 6 geneLEAD VIII can be analyzed by controlling one PC



Product specifications

Product name	geneLEAD VII (Fully automated molecular diagnostic system)
Instrument shape	Bench top type
Dimensions	W350×D700×H770mm
Weight	About 80kg
Number of specimen erection	1-8 Sample / Batch
Temperature control function	PCR unit 40 to 99 °C (8 channel independent control) Extraction unit 65 ~ 80 °C
Extracted sample liquid volume	200μL/400μL/1000μL
PCR reaction volume	20~50μL
Detection system	6 color fluorescence detection

PCR reagents available from September

Mycobacterium tuberculosis complex	
Influenza A/B + RSV	
Legionella species and pneumophila	
Adenovirus	

PCR reagents available from March 2019

Bordetella
Norovirus I/II + Rotavirus
Mycoplasma pneumoniae