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Company: KYORIN Pharmaceutical Co., Ltd.  
Representative: Yutaka Ogihara  
Representative Director, President and CEO  
(Security Code: 4569, TSE Prime.)  
Contact: Shota Kikuchi  
Director, Corporate Planning  
Telephone: 03-6374-9702

## KYORIN Receives Regulatory Approval for Influenza Virus Nucleic Acid Kit, "GeneSoC® FluA/B Detection Kit"

KYORIN Pharmaceutical Co., Ltd. announced today that it has obtained regulatory approval and received the approval certificate from Ministry of Health, Labour and Welfare (MHLW) for influenza virus nucleic acid kit, the "GeneSoC FluA/B Detection Kit" (hereinafter referred to as "the Product"), as an in vitro diagnostic (IVD). The Product is scheduled to be launched in the first half of fiscal year 2026.

The Product is an IVD designed to assist in the diagnosis of influenza virus infections. When used in conjunction with "Genetic Analyzers GeneSoC mini 2" or "Genetic Analyzers GeneSoC mini", it can differentiate and detect Influenza A and B viruses in approximately 15 minutes. Compared to currently marketed "GeneSoC Influenza Virus A/B Detection Kit," the Product offers enhanced detection sensitivity and a shorter measurement time. It has been reported that nucleic acid amplification tests (NAAT) allow for diagnosis in the early stages of onset. The Product is expected to contribute to the rapid and accurate diagnosis of influenza virus infections.

KYORIN remains committed to advancing the development and launch of IVD and research reagents dedicated to the GeneSoC in the areas of respiratory etc. Through these efforts, KYORIN aims to contribute to the diagnosis, prevention, and treatment of infectious diseases.

The impact on business performance for the fiscal year ending March 31, 2026 is expected to be negligible.

### Product Overview

- Product name: GeneSoC FluA/B Detection Kit
- Product category: IVD
- General name: Influenza virus nucleic acid kit
- Approval number: 30800EZX00003000

[Reference]

### About "Genetic analyzers GeneSoC mini 2" or "Genetic analyzers GeneSoC mini"

GeneSoC is a lightweight, compact medical device capable of analyzing target genes in samples within a short timeframe (approximately 5 to 15 minutes). This is achieved through proprietary microfluidic thermal cycling technology based on real-time PCR<sup>1</sup>. As a device supporting POCT<sup>2</sup>, it aims to enhance the quality of medical care, improve patient quality of life (QOL), and increase overall patient satisfaction.

- 1) PCR (Polymerase Chain Reaction): A technology used to amplify and simultaneously detect specific DNA sequences
- 2) POCT (Stands for Point-of-Care Testing): Medical testing performed at or near the site of patient care, allowing for immediate clinical decision-making.

<Currently marketed Medical devices>

#### **Genetic Analyzers GeneSoC mini 2**

Marketing Authorization Number: 13B3X10356000002

Dimensions: Diameter 105 mm x Height 173 mm

Weight: Approx. 650g (excluding AC adapter)



#### **Genetic Analyzers GeneSoC mini**

Marketing Authorization Number: 13B3X10356000001

Dimensions: Diameter 105 mm x Height 155 mm

Weight: Approx. 650g (excluding AC adapter)



<Currently marketed IVD>

#### **GeneSoC Bordetella pertussis Detection Kit**

General name: Bordetella pertussis nucleic acid detection kit

Marketing Authorization Number: 30500EZX00053000



#### **GeneSoC SARS-CoV-2 N2 Detection Kit**

General name: SARS-CovV-2 nucleic acid kit

Marketing Authorization Number: 30400EZX00018000



#### **GeneSoC Influenza virus A/B Detection Kit**

General name: Influenza virus nucleic acid kit

Marketing Authorization Number: 30400EZX00056000

\*This is a different product from "GeneSoC® FluA/B Detection Kit" announced in this release.



For more information, please visit the following page: <https://genesoc.jp/>