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Korea Leads Development of International Standard for Infectious Disease Diagnostics

Draft international standard (DIS) confirmed for gene amplification testing technique proposed by Korea

☐ **South Korea is leading the development of an international standard for gene-amplification-based diagnostics for infectious diseases** applied to in vitro diagnostic testing devices.

○ The Ministry of Food and Drug Safety (Minister Lee Eui-Kyung) and the Ministry of Trade, Industry and Energy's Korean Agency for Technology and Standards (head: Lee Seung-woo) have announced that a "**gene amplification diagnostics for the detection of microbial pathogens"**, for which international standardization has been promoted by South Korea, has been **approved as a draft international standard (DIS)*** by a medical device technical committee (ISO/TC/212) at the International Organization for Standardization.

※ International standard establishment process (refer to attachment): new work item proposal (NP)→working draft (WD)→committee draft (CD)→**Draft International Standard (DIS)**→Final Draft International Standard (FDIS)→International Standard (IS)

○ Following the process for establishing international standards, **the only stage left for this proposal is for it to receive final approval from all the member nations**. It is predicted that **it will complete its establishment as an international standard within the year**.

* When compared to the legislative process, being approved as a Draft International Standard (DIS) is comparable to having passed the screening of the Legislation and Judiciary Committee of the National Assembly and only having the step of being introduced at a plenary session remaining.

☐ This gene amplification testing technique for the detection of microbial pathogens which was approved as a draft international standard* defines **the overall procedures and methods to use for nucleic acid amplification** in vitro testing utilized in various types of infectious disease testing.

○ It is a standard that can be applied to various types of nucleic acid amplification testing, such as the **real time gene amplification technique (Real Time Polymerase Chain Reaction)** applied in testing kits used domestically for COVID-19 diagnoses.

* Name of standard: In vitro diagnostic test systems— Nucleic acid amplification-based examination procedures for detection and identification of microbial pathogens—Part 2: Laboratory quality practice guide (ISO/DIS 17822-2)

☐ This standard passed review by our country's national standard expert committee (representative member: Park Ae-ja) and was proposed to ISO as a draft international standard in 2016.

○ Since then, we have cooperated closely with ISO technical committee members from various countries including the USA/Europe/Japan and through this, as a result of successfully leading discussion on international standardization, the proposal **received unanimous approval from all member nations in a draft international standard vote in February 2020.**

○ This example of international standardization is being viewed as being highly meaningful in the sense that it signifies that diagnostic kits developed using domestic technology will enter into markets successfully and establish themselves as a global standard in the future.

☐ Representatives from KATS and the MFDS stated that the approval of the draft international standard is the result of cooperation between the MFDS and KATS aimed at **leading the way in the developments of infectious disease diagnostics and international standardization**, and also

○ that, in the midst of the circumstances lately where South Korea's COVID-19 testing capabilities are receiving attention from many countries around the world, it is also expected to **help raise the level of faith international society has in our infectious disease testing devices and assist domestic business to enter foreign markets**.