Editorial

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Laboratory Diagnosis of Monkeypox in South Korea: Continuing the Collaboration With the Public Sector

Monkeypox is a zoonotic infectious disease caused by the monkeypox virus. Since the first human case of monkeypox was identified in a child in the Democratic Republic of the Congo in 1970, human cases have been continuously reported in Central and West Africa over several decades [1, 2]. Given the sudden and unexpectedly frequent cases of monkeypox in many non-endemic countries since May 2022, the WHO declared the monkeypox global outbreak a public health emergency of international concern on July 23, 2022 [3]. As of September 16, 2022, there were 60,703 confirmed cases and 10 deaths due to monkeypox in 97 non-endemic countries [4].

Korea took an immediate action on the overseas monkeypox outbreak. On June 8, the Korean government designated monkeypox as a second-degree infectious disease based on a four-tier system and strengthened infection surveillance [5]. For accurate and rapid laboratory testing, the Korean Society for Laboratory Medicine (KSLM) and the Korea Centers for Disease Control and Prevention Agency (KDCA) published Guidelines for the Laboratory Diagnosis of Monkeypox on June 22 [6]. As of September 1, 2022, there were two confirmed cases but no deaths in Korea [4, 7].

Monkeypox virus transmission, either animal-to-human or human-to-human, has predominantly occurred through very close contact with respiratory secretions or skin lesions of an infected person or recently contaminated objects, sexual transmission, direct contact with blood, body fluids, or cutaneous or mucosal lesions of infected animals [1, 2]. There are two genetic clades of monkeypox virus that can infect humans; the Central African clade has a high fatality rate (~10%), whereas the West African clade has a low fatality rate (<1%) [8, 9]. The 2022 monkeypox outbreak is a mild, self-limiting disease caused by the West African virus clade [10-12].

This issue of *Annals of Laboratory Medicine* timely presents guidelines for the laboratory diagnosis of monkeypox [13]. Laboratory diagnosis is essential for defining cases, managing patients, especially those who need prompt treatment, determining quarantine release, and investigating contact traces, as well as for differential diagnosis from similar clinical features.

The US Food & Drug Administration approved emergency use authorization (EUA) for a commercial real-time PCR-based *in-vitro* diagnostic medical device on September 15, 2022 [14]. Korea's Ministry of Food and Drug Safety and the KDCA have not yet determined the need for the activation of an EUA program for monkeypox. Accordingly, *in-vitro* diagnostic medical devices developed for monkeypox should submit all files for authorization with complete clinical evaluation for use on the domestic market. Therefore, there is no authorized *in-vitro* diagnostic product for monkeypox in Korea, except one for the export market [15]. Recent reports of a downward trend in the global incidence of monkeypox [4, 16] reduce the likelihood of an EUA program for *in-vitro* diagnostic products for monkeypox being launched for the moment. However, the characteristics of the

infectious disease may change at any time. Korea's efficient response to COVID-19, especially the early detection of SARS-CoV-2 through diagnostic testing, has been highly appraised globally [17, 18]. As cooperation between the public and private sectors is established, KSLM, as a counterpart of the private sector, plans to cooperate with the KDCA for efficient monkeypox virus detection and for providing resources and education programs for qualified testing for sentinel laboratories whenever needed.

AUTHOR CONTRIBUTIONS

Kim N and Shin S wrote and revised the manuscript. Both authors approved the final manuscript.

CONFLICTS OF INTEREST

None declared.

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