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Emergency use authorization of *In-Vitro* diagnostics for infectious disease in Korea

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The Emergency Use Authorization(EUA) is a tool for temporarily use of unapproved diagnostic products as one of the rapid countermeasures to infectious disease.

In Korea, the need of emergency use of unapproved diagnostic products was brought up during the response to the 2015 MERS. Since then, enforcement regulations of the *Medical Device Act* amended the article 10 and 32 to establish the EUA system in 2016. The first EUA granted by enforcement regulations of the *Medical Device Act* had been issued to response to Zika and MERS in 2016. As the first process of EUA, Korean Center for Disease Control &Prevention (KCDC) had assessed the international and domestic situation about threat of Zika and MERS and had determined the issuing of EUA. Next, KCDC assessed the molecular diagnostics devices of Zika and MERS in collaboration with Ministry of Food and Drug Safety (MFDS). Assessment procedure has three key steps; review of documentation relating performance (e.g. analytical and clinical evidence, stability data) and manufacturer's systems (e.g. GMP, max output per day, production flow including quality management); laboratory evaluation for product's performance; review of the KCDC assessment results by committee. Finally, two devices for each Zika and MERS had gained EUAs for 1 year.

These devices had been used by 21 civil hospitals and 12 clinical examination centers, these institutions were certified by the Korean Laboratory Accreditation Program and KCDC.
Since Public Health laboratory (KCDC, Institute of Health & Environment, and national quarantine station) have examining suspected patients exposed by epidemiological hazard and showed appropriate symptoms, civil medical institute have examining to patient who want to get the test without appropriate symptoms.

KCDC had monitored EUA products and medical institutions using EUA products. To improve test quality of the 33 medical institutions, KCDC and Korean Association of External Quality Assessment Service had performed and external quality assessment (EQA) and "Quality Improvement Workshop"

Interestingly, All of EUA products were licensed by MFDS in EUA period. It looks like manufacturers were motivated by EUA to get MFDS license. And it was thought another positive function of EUA. Because of the licensed devices, KCDC terminated EUA without additional prolongation at August 2017.

KCDC found several points to be improved by using EUA for the first time. KCDC give strenuous efforts to upgrade the EUA system. Institutional Regulations to enhance proper procedure and policy was already established in last July and detailed guideline will be prepared for stakeholders. Furthermore, there are plans to start the "pre-EUA activity" with MFDS and expert for preemptive preparedness for diagnostics of infectious disease. KCDC will advertise policy implications of EUA to people.