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Seegene's Allplex RV Master assay receives Australian TGA approval, European CE-IVD mark

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Test detects 21 targets for 19 respiratory viruses in single tube, including COVID-19 and flu

Seegene Inc., South Korea's leading molecular diagnostics (MDx) company, announced that its Allplex RV Master Assay has received approval from Australia's Therapeutic Goods Administration and achieved the European CE-IVD marking.

Therapeutic goods must be entered in the Australian Register of Therapeutic Goods before they can be supplied in the country. The CE-IVD marking is a legal requirement for marketing medical devices in the European Union.

Seegene's Allplex RV Master Assay can distinguish 21 targets for 19 different respiratory viruses, including COVID-19, flu, and common colds. Specifically, the assay can identify three genes of COVID-19, Flu A, Flu B, metapneumovirus, two types of respiratory syncytial virus, four types of parainfluenza virus, six types of adenovirus and three types of human rhinovirus (see table 1).

The Allplex RV Master Assay was developed based on Seegene's decades-long know-how and applies patent technologies, like DPO, TOCE and MuDT. The syndromic test allows medical specialists to swiftly find out which viruses are making the patient sick with a single sample.