Health Technology Review	
Technology Ref.:	HTA22031
Technology Name:	Allplex SARS COV2/FLU A/FLU B/ RSV Assay
Approvals by International Bodies:	CE IVD
Company name:	Seegene Medical Equipment Trading LLC
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Short Description of the Technology:	a multiplex real-time PCR assay designed to detect N gene, RdRP gene and S gene for SARS-CoV-2, influenza A, influenza B and respiratory syncytial virus (RSV) A/B in a single tube, the Results within two hours

Health Technology Assessment Team Recommendation:	**Approve**

Summary of Review:

The test is CE Marked, it enables simultaneous amplification and differentiation of respiratory symptoms. In a single test, it can distinguish among Influenza A, B, RSV, and COVID-19. The test allows Reporting individual Ct value of multiple targets in a single channel all-in-One automated platform. By using this kit, the symptomatic people can know if they are positive for covid or Flu.
The validation conducted in SKMC with total of 19 samples, it shows high sensitivity and specificity. And the validation conducted in Union 71 for SARS-COV-2 Accuracy is 96.55% Sensitivity and100%. Specificity.

Advantages	Disadvantages
CE- Marked	To be conducted by healthcare professional
Accurate results; high sensitivity and specificity	Requires a Laboratory set up
Fast: real-time PCR assay & Result within 2 hours after extraction	
Distinguish between Influenza A & B, RSV and COVID 19 in symptomatic patients which helps in faster treatment decisions; Simultaneous detection of 3 different target genes of SARS-CoV-2 to complement genetic variations, which allows high accuracy	
Safety; Safe to use by healthcare professionals & patients	

We recommend an **approval of using this technology** with the following conditions:

1. Using the technology for SARS-COV-2, Flu A and Flu B, and RSV testing for symptomatic cases at the authorized laboratories.
2. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
3. Use of the product is initially limited under the supervision of authorized COVID-19

laboratory.

4. Provision of regular updates and reports about the product to DOH upon request.
5. Any other documents or information requested regarding the product and cost to finalize the approval process.

Moreover, DOH has the right to stop the product at any stage if deemed necessary, initial conditions and any subsequent conditions must be satisfied before obtaining final approval. Failure to do so will reflect in provoking the approval.

Technology Image

Population, setting and intended user for Technology "Allplex SARS COV2/FLU A/FLU B/ RSV Assay"

- **Population/ Intended User**;
  - For SARS-COV-2, Flu A and Flu B, and RSV testing in Symptomatic cases.
- **To be performed by**:
  - By healthcare professional.
- **Clinical Setting:**
  - Point of care.
- **Condition of use:**
  - For COVID 19 suspected cases, Flu A and Flu B, and RSV testing
- **Exclusion criteria:**
  - Other conflicting medical issues