Health Technology Review	
Technology Ref.:	HTA22055
Technology Name:	Xpert Xpress SARS-CoV-2/Flu/RSV
Approvals by International Bodies:	FDA (EUA)
Company name:	AL Zahrawi medical group
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Short Description of the Technology:	The Xpert Xpress SARS-CoV-2/Flu/RSV test includes reagents for the detection of RNA from Flu A, Flu B, RSV and SARSCoV-2 virus in either nasopharyngeal swab, nasal swab, or nasal wash/aspirate specimens. A Sample Processing Control (SPC) and a Probe Check Control (PCC) are also included in the cartridge utilized by the GeneXpert instrument. The SPC is present to control for adequate processing of the sample and to monitor for the presence of potential inhibitor(s) in the RT-PCR reaction. The SPC also ensures that the RT-PCR reaction conditions (temperature and time) are appropriate for the amplification reaction and that the RT-PCR reagents are functional. The PCC verifies reagent rehydration, PCR tube filling, and confirms that all reaction components are present in the cartridge including monitoring for probe integrity and dye stability. The nasopharyngeal swab, nasal swab, or nasal wash/ aspirate specimen is collected and placed into a transport tube containing 3 mL of viral transport medium. The specimen is briefly mixed by rapidly inverting the collection tube 5 times. Using the supplied transfer pipette, the sample is transferred to the sample chamber of the Xpert Xpress SARS-CoV-2/Flu/RSV cartridge. The GeneXpert cartridge is loaded onto the GeneXpert Instrument System platform, which performs hands-off, automated sample processing, and real-time RT-PCR for detection of viral RNA.

Health Technology Assessment Team Recommendation:	**Approve**

Summary of Review:

The test is a comprehensive assay for detecting SARS-CoV-2/Flu/RSV, it a rapid, real-time RT-PCR test It gives the results in 25 minutes, the samples could be either nasopharyngeal swab, nasal swab, or nasal wash/aspirate specimens. The test kit has been validated at Union 71 with total of 38 nasopharyngeal samples, it shows 83.3% sensitivity & 100% specificity for COVID19 testing.

Advantages	Disadvantages
FDA approved	For professional use only

Rapid Real-time RT-PCR test, Short time Actionable detection of SARS-CoV-2, Flu A, Flu B, and RSV in as little as 25 minutes	The results of the test are just for clinical reference. The test should not be used as sole criteria for diagnosis. Results should be considered in conjunction with the clinical information and other data available to the physician
No risk to healthcare professional & patients	
Good Performance (83.3% sensitivity & 100% specificity for COVID19 testing)	

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

1. Using Xpert Xpress SARS-CoV-2/Flu/RSV for symptomatic patients.
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 "Xpert Xpress SARS-CoV-2/Flu/RSV"

- **Population/ Intended User**;
  - Using Xpert Xpress SARS-CoV-2/Flu/RSV for symptomatic patients.
- **To be performed by**:
  - By Healthcare Professionals
- **Clinical Setting:**
  - Point of care
- **Condition of use:**
  - As per the manufacturer instruction
- **Exclusion criteria:**
  - Other conflicting medical issues