Health Technology Review	
Technology Ref.:	HTA23005
Technology Name:	ID NOW Instrument Flu, Strep A & RSV
Approvals by International Bodies:	FDA, CE Mark and SFDA
Company name:	Abbott
Agent in UAE:	Wisam Haddadin
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Short Description of the Technology:	The ID NOW™ test system comprises a rapid molecular in vitro point of care diagnostic testing device and assay components meant for qualitative detection of specific nucleic acid sequences via isothermal NAAT from individuals suspected by their healthcare provider of infection by the following microorganisms. Available ID NOW™ assays are: 1. COVID-19 2. Influenza A & B 2 3. RSV 4. Strep A 2 The ID NOW™ Instrument has a small footprint and easy to use graphical user interface for convenience within busy hospital or near patient testing environments. ID NOW™ test kits contain all components required to carry out an assay on the ID NOW™ Instrument.

SME Speciality	Chief Medical Officer
SME Workplace	Chief Executive Officer Office - Union71
SME comments	No objection from my end

SME Speciality	Senior Specialist Medical Products Regulation
SME Workplace	DOH
SME comments	Reference to ID NOW™ assay, kindly note the application is approved – no objection

SME Speciality	Reference Laboratory Officer

SME Workplace	ADPHC
SME comments	No further concerns to be highlighted from my end.

Health Technology Assessment Team Recommendation:	**Approve**

Summary of Review:

IDNOW™ is Molecular Platform for Point of Care detecting COVID-19, influenza A and B, RSV, and group A Streptococcus that gives the results in 13 minutes. the samples could be direct nasal or nasopharyngeal swabs and nasal or nasopharyngeal swabs eluted in viral transport media from patients with signs and symptoms of respiratory infection.

Advantages	**Disadvantages**
FDA approved, CE Mark and SFDA	For professional use only
Reduction in the time to result 15 mins	Waived tests are determined by CDC or FDA to be so simple that there is little risk of error
No risk to healthcare professional & patients	Rapid test can't detect small amounts of the virus or asymptomatic cases as accurately as the PCR test
Good Performance (96.3 % sensitivity& 97.4 % specificity for Influenza A & B), (98.6% sensitivity & 98.0% specificity for RSV) and (98.5% sensitivity & 93.4% specificity for Strep A)	
Rapid and accurate POCT enables timely clinical management decisions, as well as appropriate disease control measures	

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

1. Approval on the device version IDNOW 2.0
2. To be use as Point of Care testing by health care professional.
3. Using IDNOW influenza A and B / Strep A /RSV for symptomatic patients.
4. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
5. Provision of regular updates and reports about the product to DOH upon request.
6. 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 IDNOW influenza A and B / Strep A /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