



Health Technology Review	
Technology Ref:	HTA21009
Technology Name:	Look SPOT Covid-19 Antigen Rapid Test
Approvals by International Bodies:	Global Product Certification CE-IVD
Company name:	DAS HOLDING
Agent in UAE:	Yes Healthcare
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Short Description of the Technology:	Look SPOT is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein from SARSCoV-2 in nasal swabs from patients suspected of COVID-19 within the first eight (8) days of symptom onset. Look SPOT can diagnose the SARS-CoV-2 virus detection between 5 to 8 minutes by using AI Look SPOT's AI algorithm has high accuracy and can identify the color response when human eyes cannot identify the low positive cases.
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Health Technology Assessment Team Recommendation:	Disapprove
Summary of Review:	
<p>The technology (rapid antigen test) was approved previously to run a validation test locally at Union71 and the result was reviewed.</p> <p>SEHA Validation Result:</p> <p>Validation result at Union71 cover around 50 samples with previous PCR positive, symptomatic patients without previous PCR positive, and with asymptomatic patients with/without previous PCR positive shows 69.6% sensitivity, 100% specificity and 30.4% false negative</p>	
Advantages	Disadvantages
Fast and rapid (result obtained in 8 minutes)	Local validation was done with INDETERMINATE result
Can be operated by individuals at home	Local validation result shows low sensitivity (69.6%) which is below the required standards set by the FDA for a test seeking to obtain EUA
Portable and easy to use as it does not require any particular skills or devices for the operation	Even in high viral loads, the result was still below the required 80% for the True Positive Rate.
Point of care and non-invasive test which does not require a lab setup	Other antigen tests with higher sensitivity already in Abu Dhabi marker
Already approved by MOH in the UAE	Antigen tests will have more false-negative rate if there is a low or variable viral load in the sample; especially in the early onset of the



	infection
No harm to patients nor healthcare professionals	Using AI Cloud processing
	Relies heavily on the knowledge of its operator in following the steps

We recommend a **disapproval of using this technology**. The applicant may re-apply in case validation with larger samples shows significantly better sensitivity and specificity of the test.

Technology Image

