



Health Technology Review	
Technology Ref.:	HTA21005
Technology Name:	RASSED – Portable device for rapid COVID-19 testing using RT-LAMP
Approvals by International Bodies:	Not yet approved as testing tool
Company name:	Khalifa University
Agent in UAE:	Dr. Anas Alazzam & Dr. Habiba Alsafar
Email:	anas.alazzam@ku.ac.ae & habiba.alsafar@ku.ac.ae

Short Description of the Technology:	<p>It is a portable all-in-one device “RASSED” to perform Reverse – Transcription Loop Mediated Isothermal Amplification (RT-LAMP) in order to facilitate rapid screening of COVID–19 at the point-of-care using nasopharyngeal swab. The device which is powered using only a 5-Volt AC-DC adapter, is capable of performing 16 simultaneous RT-LAMP reactions, and can be used multiple times. The experimental protocol is devised to obviate the need of separate equipment for the RNA extraction and ensure minimum evaporation of the sample during heating. The complete process on RASSED from sample preparation to the qualitative assessment of COVID-19 test takes only 45 minutes. The completion of amplification reaction yields a fuchsia color for the negative samples and either yellow or orange color for all the positive samples, based on a pH indicator dye. The sensitivity and specificity of the device are at par with the commercial RT-PCR method. Thus, the device can be used as an effective tool for molecular diagnostics of COVID–19 at the point-of-care or in remote settings where access to a lab is difficult or the results are urgently required.</p>
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Health Technology Assessment Team Recommendation:	Approved with limitation
Summary of Review:	
<p>RASSED is a device developed at Khalifa University using the RT-LAMP for rapid detection of COVID-19. It does not require any RNA extraction. One of the steps requires adding a silicon oil to prevent sample evaporation. It is useful to be used in areas where a rapid result is needed like airports, schools and universities.</p>	
Advantages	Disadvantages
Fast (result obtained in only 45 minutes for 16 samples in one run)	It does not have any approval as a testing tool
Sensitivity and specificity same as RT-PCR	It was tested in a university not on real patients
Point of care device and no need for a lab setup	More validation is required on larger scale
Very accurate	
Cheaper than RT-PCR (~40 AED per test)	
Portable and easy to use as it does not require any particular skills for the operation	

Use of silicon oil increase the accuracy more than other RT-LAMP tests

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

1. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
2. Use of the product is initially limited under the supervision of SEHA for validation purpose until the final approval is given.
3. Provision of regular updates and reports about the product to DOH upon request.
4. Any other documents or information requested regarding the product and cost to finalize the approval process.
5. The final approval for using the technology will be under the decision of Abu Dhabi Public Health Center.

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

