



Rapid CoViD-19 RT-LAMP Test

*Developed by Oxford
University*

Introduction

What is Oxsed?

- A Rapid 30 minute Point of Care test for the detection of SARS-Cov-2 [Covid 19]
- Utilizing RT-LAMP (Loop-Mediated Isothermal Amplification) to increase accuracy and reduce testing time over RT-PCR tests.
- Designed and developed by Oxford University
- Produced in the UK, CE marked
- MHRA Approved
- Easy to use and apply across all Organisations

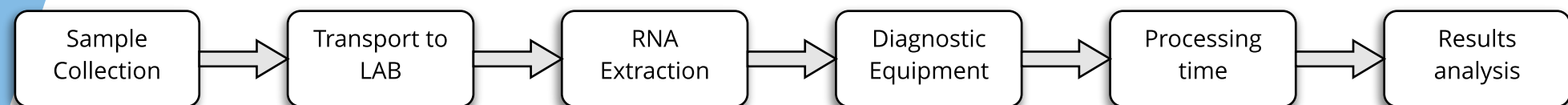
Clinical Performance

- Analytical Sensitivity: 20 copies/reaction (800 copies/ml)
- Analytical Specificity: 100%
- Clinical Evaluation: 30 positive swabs, 39 negative swabs, all clinical samples, compared to Clinical RT-PCR results:
 - Negative Percentage Agreement (NPA): 100%
 - Positive Percentage Agreement (PPA): 92% for samples with CT < 31,
82% for CT < 33,
73% for all samples
 - Overall percentage agreement: 88%
- Limit of Detection: 100 copies per reaction, Equivalent to Ct = 35 using PHE RdRp Assay

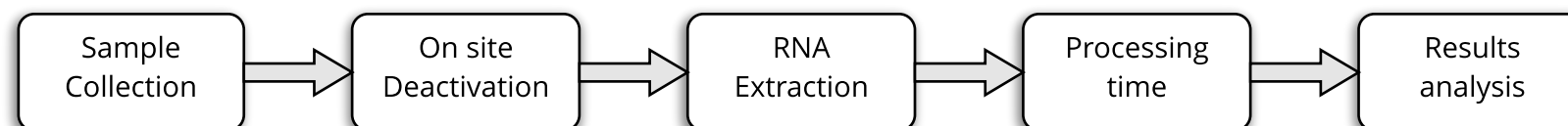
PCR vs LAMP

	RT-qPCR Direct Swab Testing*	RT-LAMP Direct Swap Testing
Total Samples	150 (150 Positive)	69 (30 Positive, 39 Negative)
Positive Agreement Rate / %	91% for Ct < 30	92% for Ct <30
Negative Agreement Rate / %	N/A	100%
Detection Time	90-120 Mins	30 Mins

RT-PCR Testing Process



RT-LAMP Testing Process



* Bruce EA, Huang ML, Perchetti GA, et al. (2020). Direct RT-qPCR Detection of SARS-CoV-2 RNA from patient nasopharyngeal swabs without RNA extraction step

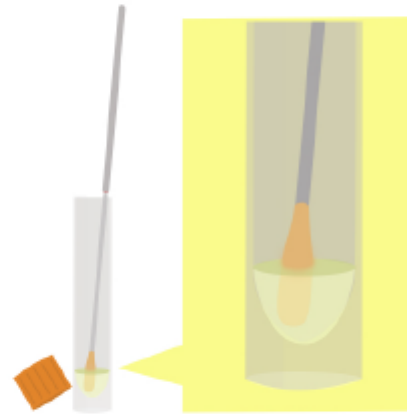
Applications

- **Large scale organisations**, where routine testing of staff is required to maintain business continuity (distribution centres / sports teams / supermarkets)
- **Secondary & primary care environments** (GP clinics / Hospitals / Care Homes / Dentists) to help ensure continuation of care and services
- **Education Centres**, for faculty members as well as pupils to maintain a safe learning and working environment
- **Airports**, for arrival passengers to ensure that we are controlling the virus entering the country from abroad
- **Patient / General population testing**, as a rapid fire test to evaluate the impact and spread of CoViD-19 within communities.

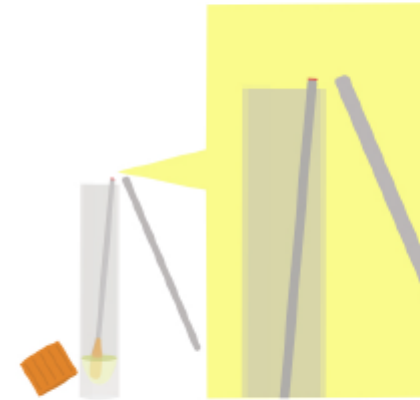
Sample Collection



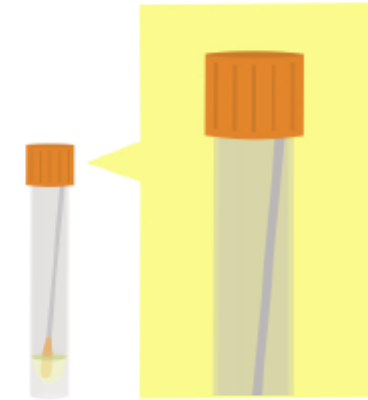
1. Take swab sample with a swab stick.



2. Insert the swab into a swab tube (containing 1 mL of saline solution).



3. Break the swab handle at the breakpoint.



4. Close the cap.

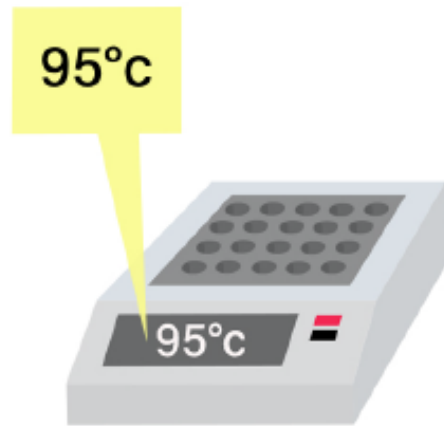


5. Label with the appropriate patient information.

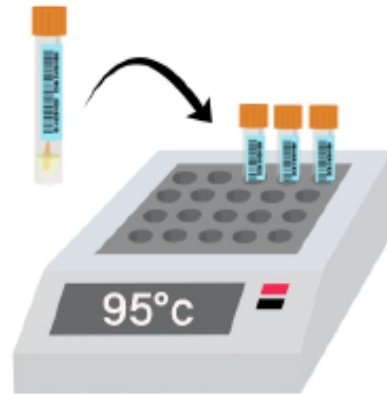


6. Sample is ready for testing.

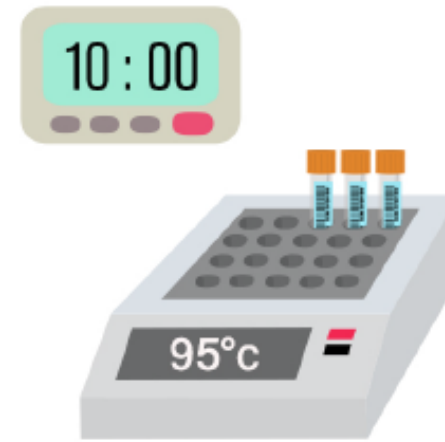
Deactivation



1. Preheat a big heat block (compatible with 15 mL falcon tubes) to 95°C.



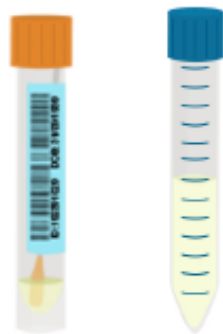
2. Once the heat block reaches 95°C, insert the patient sample tubes.



3. Heat the sample tubes in the heat block for 10 minutes.



4. Safely remove the hot sample tubes from the heat block with heat-proof gloves.



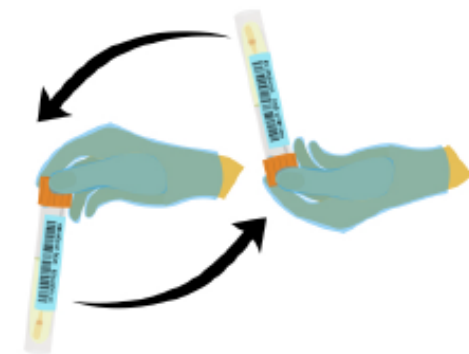
5. Take a swab sample tube and a blue-capped falcon tube (containing 9 mL of solution).



6. Carefully empty the solution in the blue-capped falcon tube into the sample tube.

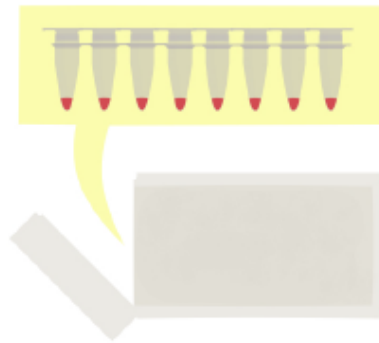


7. Close the cap of the sample tube securely.

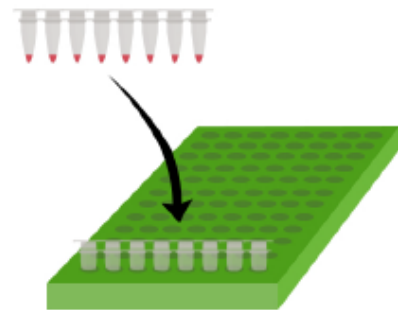


8. Mix the solution in the sample tube by inverting it for 3 times.

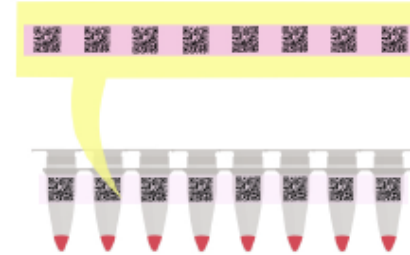
Testing



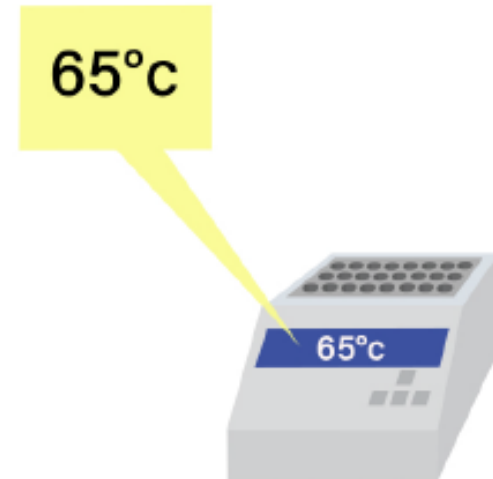
1. Unwrap one unit of OXSED test kit strip.



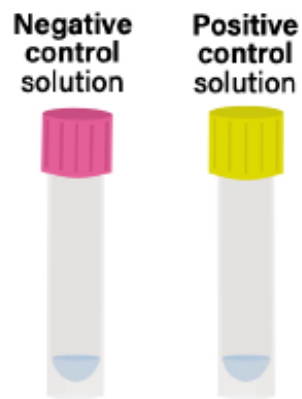
2. Place the test kit strip on a test kit holder.



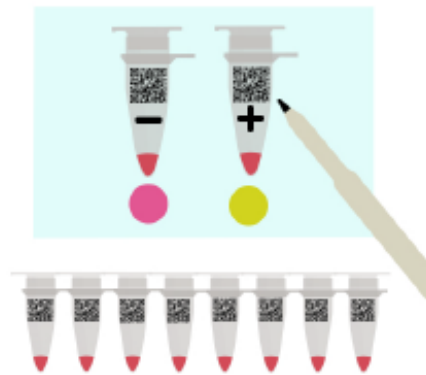
3. Affix the QR code sticker to the body (not lid) of the test kit strip.
*** this step is only applicable to sites with compatible QR code scanning system.



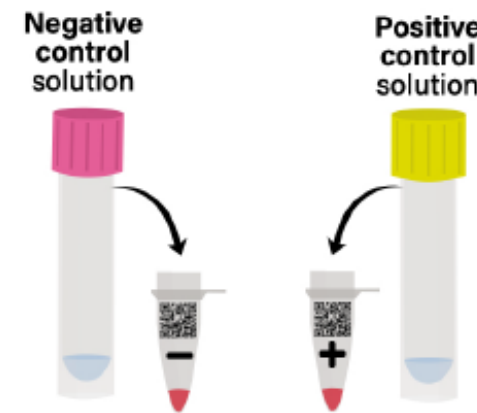
4. Preheat a heating block to 65°C.



5.i. Both negative and positive control solutions are provided.



ii. Using any test kit from the strip, label a negative and a positive (on the body not lid).
*** **optional:** affix pink sticker for negative and yellow sticker for positive control.

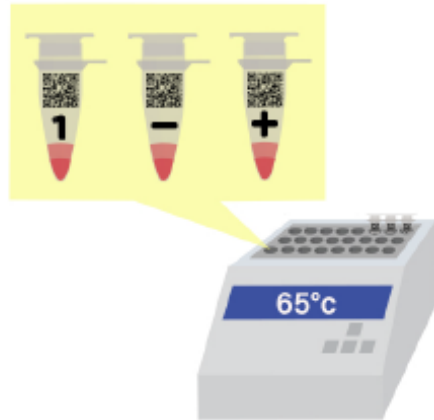


iii. Transfer one drop or 25 μ L of control solution to its corresponding test kit.

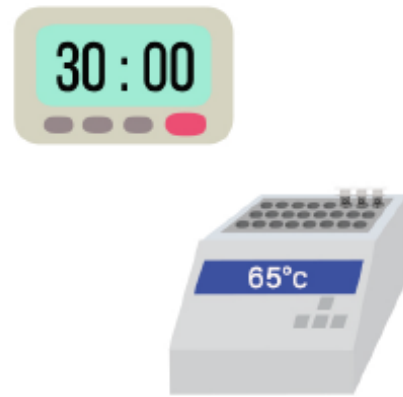


iv. Close the lid and proceed to steps 6 to 9.

Testing



6. Immediately transfer the test kits to the small heat block preheated to 65°C.



7. Incubate the test kits in the small heat block at 65°C for 30 minutes.


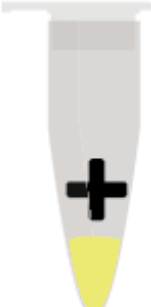



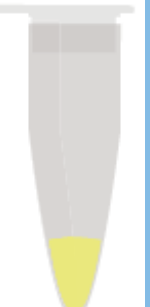


8. Safely remove the test kits from the heat block with heat-proof gloves.



9. Allow the test kits to cool down to room temperature.

Results

CONTROL		RESULTS			
NEGATIVE	POSITIVE	NEGATIVE	POSITIVE		
					
The negative control (test kit labelled as pink) should remain pink.	The positive control (test kit labelled as yellow) should turn yellow.	The sample is considered SARS-CoV-2 negative if the OXSED test kit shows pink.	The sample is considered SARS-CoV-2 positive if the OXSED test kit shows orange or yellow.		