Health Technology Review	
Technology Ref.:	**HTA21055**
Technology Name	**cobas® Liat System**
Approvals by International Bodies:	**FDA & CE marked**
Company name:	**Roche Diagnostics**
Agent in UAE:	**Pharmatrade LLC**
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Short Description of the Technology:	The cobas® Liat® analyzer is small (length 24.1 cm, width 11.4 cm) and light weight (3.76 kg) so occupies minimal space within a doctor's office, primary care clinic, ER or inpatient ward. It also requires minimal training and "hands-on" time and is therefore suitable for use by personnel without highly specialist laboratory training. The cobas® Liat® System effectively combines the speed of rapid antigen tests with the diagnostic accuracy of central laboratory-based methods, thereby providing accurate diagnostic information at the PoC and negating the need for further confirmatory testing. The cobas® Liat® analyzer accommodates one sample at a time (compared with central laboratory methods such as PCR, which are frequently run only in batches and therefore the operator may wait until multiple samples require analysis before performing a batch analysis). Each sample requires approximately 1 minute of hands-on time, which involves pipetting an aliquot from a throat swab sample in Amies media for the Group A Streptococcus (GAS) test and an aliquot from a nasopharyngeal swab in universal transport media1 for the influenza A/B ± RSV test(s) and the SARS-COV-2 + influenza A/B using the transfer pipette provided. All sample preparation, processing and the PCR reaction steps are fully automated and the result of the assay is provided on the Liat analyzer screen in a timeframe of 15 minutes for GAS and 20 minutes for influenza A/B ± RSV and SARS-COV-2 + influenza A/B

Health Technology Assessment Team Recommendation:	**Conditional Approval**
Summary of Review:	
Cobas® Liat System can be used for different tests such as Group A Streptococcus, SARS-COV-2 and SARS-COV-2 + influenza A/B combined. FDA has reported an issue with the device and false positive results. False positive results could lead to improper patient management. they may also lead to unnecessary isolation and additional health monitoring, delayed diagnosis and treatment, and mis-allocation of resources used for surveillance and prevention for other infections or health conditions. This requires monitoring for unexpected clusters of the positive results when tested in the device,	

repeating the tests and stop using the device and contact the company.

Local Validation Result:

Validation result at Union71covered 50 samples from inpatients and outpatients shows 100% sensitivity and 88.9% (SARS-COV-2 + influenza A/B combined test) and 100% (SARS-COV-2 test) specificity.

Advantages	Disadvantages
Rapid in producing the results within minutes	The device can produce false positive results due to tubes may sporadically leak, causing an obstructed optical path in the Liat analyser or other multiple factors happening at the same time, such as hardware positioning, volume movement, and curve interpretation.
Point of care device and can be used at physician office, emergency department and primary care	
Can be used for different and combined tests including COVID-19 with influenza A/B	
Excellent sensitivity and specificity as per the validation result at Union71 but did not cover the higher CT value	
Can detect all variants listed of COVID-19	
Can be used for any individuals including without symptoms	

We recommend a **conditional approval of using this technology** only with the following conditions:

1. The conditional approval is subjected only to complete 200 samples to have higher CT value (above 35) and sharing the data/report to DoH – HTA Team for the complete evaluation.
2. Using the technology as a point of care at authorized healthcare provider for COVID-19 testing.
3. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
4. Use of the product is initially limited under the supervision of authorized COVID-19 laboratory.
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.

Issue with false positive results corrective action and control measures is required to be submitted to HTA Team.

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