| Health Technology Review | |
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| **Technology Ref.:** | **HTA21055** |
| **Technology Name** | **cobas® Liat System** |
| **Approvals by International Bodies:** | **FDA & CE marked** |
| **Company name:** | **Roche Diagnostics** |
| **Agent in UAE:** | **Pharmatrade LLC** |
| **Email:** | **mahmoud.moawad@roche.com** |

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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.<br>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.<br>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).<br>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:** | **Approved** |
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| **Summary of Review:** | |
| Cobas® Liat System has been granted conditional approval based on their submitted local validation test at Union71 that covered 50 samples and only 4 samples above ct-value 35 were included (3 were concordance and 1 was not). Based on the new provided evidence and the 2nd validation conducted in U71 the test passes in Performance for low and very low viral load samples.<br>**2nd Local Validation Result:**<br>Validation result at Union71covered 69 samples from 69 samples with a ct-value between 35 and | |

40 (i.e., very low viral load) were selected from SARS-2 positive patients shows 100% the sensitivity and specificity

| Advantages | Disadvantages |
|---|---|
| **Excellent sensitivity and specificity** as per the validation result at Union71 for low and very low viral load samples | 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. |
| **Rapid** in producing the results within minutes | |
| **Multiple uses**; Can be used for different and combined tests including COVID-19 with influenza A/B | |
| **Easy to use**: Point of care device and can be used at physician office, emergency department and primary care | |
| **Can detect all variants listed of COVID-19** | |
| **Can be used for any individuals including without symptoms** | |

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

1. Using the technology as a point of care at authorized healthcare provider for COVID-19 testing for both symptomatic and asymptomatic patients.
2. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
3. Use of the product is initially limited under the supervision of authorized COVID-19 laboratory.
4. Provision of regular updates and reports about the product to DOH upon request.
5. 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 “cobas® Liat System”

- **Population/ Intended User**;
  - COVID 19 cases for both symptomatic and asymptomatic patients
  - influenza A/B ± RSV and SARS-COV-2 + influenza A/B
- **To be ordered by**:
  - By physicians
- **Clinical Setting:**
  - Point of care
- **Condition of use:**
  - To be used in for SARS-COV-2, influenza A/B combined tests
- **Exclusion criteria:**
  - Other conflicting health issues