**Summary of validation studies**

**Analytical characteristics**

**Analytical sensitivity**

Conclusion: Experiment 1: BIONOTE® Rapid MERS-CoV Ag Test Kit (BKM kit) detected up to 1250 mg/ml of recombinant nucleocapsid antigen of MERS-CoV.

Experiment 2: Negative camel nasal swabs, collected from Central Veterinary Research Laboratory (CVRIL) in Dubai, UAE, and MERS-CoV Culture Fluid were used for the Limit of detection test. The MERS-CoV Culture Fluid was diluted into 2-fold steps and tested simultaneously with the UOII and OII test and RT-PCR (Corman et al. 2012) in the experiments performed using MERS-CoV Culture Fluid. BKM kit can detect up to 1.6 x 10^5 TCD50/mL, corresponding to an LOP at CT value of 32.51 and ORP at CT value of 34.93 according to molecular analysis performed concurrently.

**Analytical specificity**

The BKM kit does not have cross-reactivity with camel coronaviruses (EcCoV-UAE-MU0223), COVID-19 (SARS-CoV-2), and other coronaviruses (HCoV-229E, HCoV-NL63, HCoV-OC43, RbCoV HKU14, Ty-Bat CoV HKU4).

**Target species**

MERS-CoV / Middle East Respiratory Syndrome Coronavirus (MERS-Cov)

**Evaluation and validation**

- **Analytical reproducibility**
  - **Analytical sensitivity**
  - **Analytical specificity**
  - **Analytical stability**
  - **Analytical precision**

**Summary**

**Conclusions**

**Interpretation of the Result**

1) **Negative result**: Only one control (C) band appears.
2) **Positive result**: 2(C) bands appear.
3) **Invalid**: Control (C) fails to appear.

If the control band is not visible within the result window after performing the test, the result is considered invalid. It is recommended that the sample be re-tested using a new test kit.

**Limitations of the Test**

1) Although the BIONOTE® Rapid MERS-CoV Ag Test Kit is very accurate in detecting MERS-CoV antigens, a low incidence of false results can occur. Other clinical or laboratory tests may be required if questionable results are obtained.
2) As other diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should be based on a thorough examination after all laboratory findings and evaluations have been completed.
3) The reading window may show a light pink background coloration; this will not affect the accuracy of the results.
4) There has been no assessment of anal site testing under a range of extreme temperature conditions.
5) Biohit and its distributors cannot be held responsible for the consequences of misuse or misinterpretation of the results given by the test.

**References**

2. Interim Guidelines for MERS-CoV Version 2.0 in CO 017/10.
4. Laboratory Testing for Middle East Respiratory Syndrome Coronavirus : WHO Interim guidance, June 2015
**Conclusion**

The BIM kit is shown to be less sensitive than the real-time PCR assay. Samples with viral load below the detection limit of the BIM kit are likely to test negative in the BIM kit. It is a common observation that antigen tests can be markedly less sensitive than real-time PCR tests. MERS-CoV-2 infected camels can shed a low level of viral RNA for an extended period (several weeks). Nonetheless, infectious virus can only be detected mainly in the first week after infection (Adney et al., EID 2014).

**References**

**WOART Terrestrial Manual (2021)**


**Acknowledgement**

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### Diagnostic Algorithm for MERS CoV

**Methods of Sample Collection**

<table>
<thead>
<tr>
<th>Sample No.</th>
<th>Test Procedure</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Dispense 100 μl of the extracted sample into a test tube.</td>
<td>No further action is required</td>
</tr>
<tr>
<td>2</td>
<td>Add 200 μl of the extracted sample into the same test tube.</td>
<td>Rapid MERS-CoV Ag Test with re-testing (2-3 days) or RT-PCR targeting two regions</td>
</tr>
</tbody>
</table>

**Test Procedure**

1. Dispense 100 μl of the extracts into a test tube.
2. Add 200 μl of the extracted sample into the same test tube.
3. After 10-15 min.
4. Read the result.

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