FASPIT ™ SARS-CoV-2 Antigen Saliva Test

Diagnostic Sensitivity and Specificity Study Report

Final report date: **2021-11-12**

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Study Director Signature and Verification Dates

This study meets with the technical requirements of the protocol. The study also meets with technical specification for the test.

Study Director: **Wei Yang**

Signature: 

Company: **Atlas Link Technology Co.,Ltd**

Position: **Head of R & D Department**

Verification Dates:2021-11-12

Study Summary

The purpose of this study was to obtain diagnostic sensitivity and specificity of the FASPIT™SARS-CoV-2 Antigen Saliva Test. A total of 260 samples were tested by using TaqPath™ COVID-19 Fast PCR Combo Kit produced by Life Technologies Corporation as control reagents, of which the diagnostic sensitivity of antigen detection is 96.2%; diagnostic specificity is 97.7%; overall agreement is 96.9%.

1. Purpose

To validate the diagnostic sensitivity and specificity of FASPIT^{TM}SARS-CoV-2 Antigen Saliva Test.

2. Reference and Compliance

FDA guidance for In vitro diagnostic medical device
NMPA guidance
The present study conformed to all applicable laws and regulations

3. Materials

- Saliva specimens collected from local volunteer by laboratory.
- FASPIT^{TM}SARS-CoV-2 Antigen Saliva Test, Lot. No: 20210316, Production Date: 2021-03-16
- TaqPath^{TM} COVID-19 Fast PCR Combo Kit. (Lot No.:WSC200189)

4. Study Design:

4.1 **Making evaluation for patient saliva collected by central laboratory synevo, Poland.**

Subject was a patient admitted to the local hospital due to a respiratory virus infection, about 260 samples in total were collected.

4.2 **Examiner and clinical laboratories**

- Central laboratory synevo, Poland

4.3 **Sample requirement**:

All the samples were confirmed.
Samples were to be randomly chosen and double-blind labeled.

4.4 **Test conduction:**

All tests were performed by the clinical technicians in each clinical laboratory according to the manufacturer's instructions using the confirmed samples.
Visual interpretations of the results of FASPIT^{TM}SARS-CoV-2 Antigen Saliva Test were made independently by the clinical technician.
The testing center was responsible to summarize the result and send to Atlas Link.

5. Evaluation Criteria

Negative

If only the C band is present, the absence of any burgundy color in the test band indicates that no SARS-CoV-2 antigen is detected in the specimen. The result is negative.

Positive

In addition to the presence of C band, if test band is developed, the test indicates for the presence of SARS-CoV-2 antigen. The result is positive.

Invalid

If no C band is developed, the assay is invalid regardless of any burgundy color in the test band as indicated below. Repeat the assay with a new device.

6. Results

260 samples were collected from selected subjects, all samples were tested with FASPIT^{TM}SARS-CoV-2 Antigen Saliva Test and TaqPath^{TM} COVID-19 Fast PCR Combo Kit produced by Life Technologies Corporation. Calculated the specificity and sensitivity, the results are as follows:

RNA Test	FASPIT^{TM}SARS-CoV-2 Antigen Saliva Test		Total
	Positive	Negative	
Positive	125	5	130
Negative	3	127	130
Total	128	132	260

Diagnostic Sensitivity:

125/(5+125)×100%=96.2% 95%CI(91.3%~98.3%)

Diagnostic Specificity:

127/(3+127)×100%=97.7% 95%CI(93.4%~99.2%)

Overall Agreement:

(125+127)/260×100%=96.9% 95%CI(94.0%~98.4%)

7. Conclusion

The clinical evaluation was carried out for the clinical performance of FASPIT^{TM}SARS-CoV-2 Antigen Saliva Test. Total 260 samples were tested, of which the diagnostic sensitivity of antigen detection is 96.2%, diagnostic specificity is 97.7%; overall agreement is 96.9%.

8. Report

8.1 Original raw data is archived at Quality Control Department

8.2 The original final report is archived in Quality Control Department.