ZET Medical Co Ltd

SOFTEC Sars Cov-2 (COVID-19) Antigen Rapid Test
Clinical Sensitivity and Specificity Study Report

1. Objective

The Softec Sars Cov-2 COVID-19 Antigen Rapid Test (hereinafter referred to as the SOFTEC Device) manufactured by ZET medical textile Foreign trade Co., Ltd. is a lateral flow immunoassay intended for the qualitative detection SARS-CoV-2 nucleocapsid antigens in nasopharyngeal swab and oropharyngeal swab from individuals who are suspected of COVID-19 by their healthcare provider.

This study is intended to evaluate the clinical performance, between the SOFTEC Device and the comparator RT-PCR assay.

2. Method

A study of 1224 direct nasopharyngeal swabs was performed. The specimens were collected from symptomatic patients suspected of COVID-19 at 3 locations and tested at a single central laboratory.

Two nasopharyngeal swabs were collected from individual symptomatic patients (within 7 days of onset) who were suspected of COVID-19. At all locations, one nasopharyngeal swab was immediately frozen at -70℃ for later testing, and the other swab was eluted in 3 mL viral transport media and tested with RT-PCR assay for detection of SARS-CoV-2. A total of 1224 retrospective nasopharyngeal swab specimens within a pre-specified date range were selected and then tested by the SOFTEC Device in a blinded fashion. The operators were blinded to the RT-PCR test results.

The positive percent agreement (PPA) (Sensitivity) was calculated as 100% x (True Positive/[True Positive+False Negative]). The negative percent agreement (NPA) (Specificity)was calculated as 100% x (True Negative / [True Negative + False Positive]). The 95% (two-sided) confidence interval (CI) was calculated using the Wilson Score Method.

3. Comparator method

Real-Time Fluorescent RT-PCR Kit for Detecting SARS-CoV-2, manufactured by BGI Genomics Co. Ltd. This product has got CE, NMPA certification and FDA Emergency Use Authorized. A specimen is positive for SARS-CoV-2 if the Ct value of ORF1ab gene is not higher than 37.

4. Enrollment criteria (inclusion/exclusion criteria)

4.1 Inclusion criteria

Individual symptomatic patients (within 7 days of onset) who were suspected of COVID-19.

4.2 Exclusion criteria

Unable to obtain samples of information needed for the experiment
Samples that have been contaminated or contaminated during sample storage
Samples with inappropriate storage conditions

5. Result

The results are summarized in the following table.

COVID-19 Antigen		RT-PCR		Total
		Positive	Negative	
softec	Positive	480	6	486
	Negative	18	720	738
Total		498	726	1224

Positive Percent Agreement (PPA) (Sensitivity) = 96,38 % (480/498), (95%CI: 89.8%～99.2%)
Negative Percent Agreement (NPA) (Specificity) =99,17 % (720/726), (95%CI: 95.5%～99.9%)
The PPA is 98.3% (1200/1224) (95%CI: 95.1 %～99.5%) with specimens of a Ct count ≤33.

6. Conclusion

Taken together, the SOFTEC Antigen Rapid Test had a positive percent agreement (sensitivity) of 96,38 % (480/498), (95%CI: 89.8%～99.2%) and negative percent agreement (specificity) of 99,17 % (720/726), (95%CI: 95.5%～99.9%)with specimens of a Ct count ≤33.