Diagnostic Performance Accuracy

Clinical Performance:

The study enrolled 256 subjects in a single center study with collection of saliva sample. The performance of the RapiX Saliva™ One Step COVID-19 Antigen Test was established with 236 direct saliva sample prospectively collected and enrolled from individual symptomatic patients within 5 days of onset and 20 asymptomatic patients who were suspected of COVID-19. The performance of the RapiX Saliva™ One Step COVID-19 Antigen Test was compared to results of a nasopharyngeal swab stored in 3 mL viral transport media tested with an Emergency Use Authorized molecular (RT-PCR) test for detection of COVID-19.

The study enrolled 236 subjects in a single center randomized blinded study with collection of nasal swabs and a saliva sample. The performance of RapiX Saliva™ One Step COVID-19 Antigen Test was established with 236 Saliva samples collected from individual symptomatic patients (within 5 days of onset) who were suspected of COVID-19. Performance of the RapiX Saliva™ One Step COVID-19 Antigen Test (on Saliva specimens), was compared to the authorized Thermo Fisher Scientific TaqPath RT-PCR COVID-19 combo kit by testing nasopharyngeal samples. Nasopharyngeal swabs and saliva were collected from patients in the Pioneer Research Solutions Inc, Houston, TX. Saliva was collected in sterile urine cups without addition of any preservatives. Nasopharyngeal swab was collected in 3 mL viral transport media. These NP and saliva specimens were tested in parallel with the EUA-authorized TaqPath COVID-19 combo kit (on NP specimens) and the RapiX Saliva™ One Step COVID-19 Antigen Test (on saliva specimens). For RT-PCR testing (on NP specimens), the EUA-authorized Thermo Fisher Scientific TaqPath RT-PCR COVID-19 combo kit, and Applied Biosystems™ QuantStudio™ 12K Flex Real-Time PCR System instrument were utilized. The Thermo Fisher Scientific TaqPath COVID19 combo kit combines RNA extraction using the MagMax Viral/Pathogen Nucleic Acid Isolation Kit with a multiplex RT-PCR diagnostic assay targeting 3 regions of the SARS-CoV-2 genome. `For antigen testing (on saliva specimens), the RapiX Saliva™ One Step COVID-19 Antigen Test was directly used according to product instructions. The TaqPath RT-PCR testing (on NP specimens), results from these 130 specimens were used as the comparator for the RapiX Saliva™ One Step COVID-19 Antigen Test when evaluating

positive percent agreement (PPA). The 56 TaqPath negative NP specimens were used as the comparator for the RapiX Saliva™ One Step COVID-19 Antigen Test when evaluating negative percent agreement (NPA). The results from this paired study are described below:

RapiX Saliva™ One Step COVID-19 Antigen Test Performance within 5 days of symptom onset against the Reference RT-PCR Assay (N=256, First round 180 , second round 76)

Saliva One Step COVID-19 Antigen Test	Reference RT-PCR Assay		
	Positive	Negative	Total
Positive	186	0	186
Negative	14	56	70
Total	200	56	256
Positive Agreement: 186/200			93%(95%CI:83%-95%)
Negative Agreement: 56/56			100%(95%CI:93%-100%)