

Specific performance data

Clinical assessment

The Corowell Symptom Screening Test tests subjects for anosmia, typical flu symptoms (fever, cough, shortness of breath, sore throat, muscle pain and unusual fatigue) or a recent disorder of the sense of smell.

The clinical performance of the Corowell Symptom Screening Test for self-testing was evaluated on a total of 200 subjects in two (2) prospective studies at a clinical center in Lausanne, Switzerland.

Of these 200 subjects, symptom screening tests were performed on a first study cohort of 50 subjects, each of which was tested repeatedly once per day on 8 test days, within a total period of two (2) weeks. This study cohort included exclusively adult employees of a clinical center (aged 21 to 65 years) without any specific clinical suspicion of a SARS-CoV-2 infection. The 50 study subjects followed written and illustrated instructions from the official Corowell Symptom Screening Test Instructions for Use (IFU) and conducted the tests themselves. The tests were observed by medical professionals without intervention. RT-PCR tests, using combined nasopharyngeal / oropharyngeal swab samples, were used as a comparison method, for those subjects identified by the symptom screening test as being suspected of a SARS-CoV-2 infection. During the eight (8) test days, a total of 387 symptom screening tests were carried out and a total of 10 subjects were detected as being suspected of a SARS-CoV-2 infection. These subjects were then immediately tested on the same test day with RT-PCR, where 3 of the 10 subjects were tested RT-PCR positive. In this study cohort, no other subjects were tested positive for RT-PCR during the eight test days. All 3 of the 3 RT-PCR positive subjects were initially correctly identified as being suspected of SARS-CoV-2 infection by means of the symptom screening tests.

The symptom screening tests were performed on a second study cohort of 150 subjects. This study cohort also included only adult subjects, however, in this case during initial clinical admission. The entire study cohort was randomly selected without any specific clinical suspicion of a SARS-CoV-2 infection, only based on the initial clinical admission. The 150 study participants followed written and illustrated instructions from the official Corowell Symptom Screening Test Instructions for Use (IFU) to conduct the test themselves. The tests were observed by medical professionals without intervention. RT-PCR tests, using combined nasopharyngeal / oropharyngeal swab samples, were used as a comparison method in all 150 subjects. Based on the 150 symptom screening tests, that were carried out, 16 subjects were detected as being suspected of a SARS-CoV-2 infection. These 16 subjects were then immediately tested on the same test day with RT-PCR, where 5 of the 16 subjects were tested RT-PCR positive. In this study cohort, one (1) further subject was tested RT-PCR positive, which the symptom screening test had previously not detected as being suspected of a SARS-CoV-2 infection. Thus, 5 out of the 6 RT-PCR positive subjects were initially correctly detected as being suspected of a SARS-CoV-2 infection by means of the symptom screening test.

This results in the following pooled performance assessment of the tests from the two study cohorts described above. The Corowell Symptom Screening Test demonstrated a

Sensitivity of 88.8% (8 subjects of the 9 RT-PCR positive subjects were correctly identified by the Corowell symptom screening test) and a

Specificity of 91.1% (174 subjects of the 191 RT-PCR negative subjects were correctly identified by the Corowell symptom screening test).

	RT-PCR positive	RT-PCR negative	Total
Symptom Screening Test suspected of SARS-CoV-2 infection	8	17	25
Symptom Screening Test not suspected of SARS-CoV-2 infection	1	174	175
Total	9	191	200
Sensitivity	88.8 %		
Specificity	91.1 %		