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## **Evaluation of a rapid diagnostic assay for detection of SARS CoV-2 antigen in nasopharyngeal swab**

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1 **Evaluation of a rapid diagnostic assay for detection of SARS CoV-2 antigen in**  
2 **nasopharyngeal swab**

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6 behalf of the AP-HP/Universities/Inserm COVID-19 research collaboration

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19 Severe Acute Respiratory Syndrome coronavirus 2 (SARS-CoV-2), the virus causing causing Coronavirus  
20 disease 2019 (COVID-19) was reported for the first time in Wuhan (Hubei, China) in December 2019  
21 (1, 2) and has become a major public health concern all over the world. Early diagnosis is crucial for  
22 patient management and outbreak control. Most tests currently used for detection of SARS-CoV-2 rely  
23 on viral RNA amplification by using RT-PCR and require a few hours before results release. Hence,  
24 highly sensitive immunological diagnostic methods that directly detect viral antigens in clinical samples  
25 would be very helpful for rapid and accurate diagnosis of COVID-19.

26 Here, we evaluated a rapid diagnostic test, COVID-19 Ag Respi-Strip CORIS (BioConcept®, Gembloux,  
27 Belgium), for detection of the SARS-CoV-2 antigen in nasopharyngeal secretions. The assay is ready to  
28 use and based on a nitrocellulose membrane technology with colloidal gold nanoparticles sensitized  
29 with monoclonal antibodies directed against highly conserved SARS-CoV-2 nucleoprotein antigens. We  
30 compared this test with RT-PCR, the current reference assay in virology laboratories of three university

[Texte]

31 hospital groups from Assistance-Publique-Hôpitaux de Paris (APHP), (Saint-Antoine-Tenon-Trousseau,  
32 Saint-Louis-Lariboisière and Kremlin Bicêtre-Paul Brousse). Different RT-PCR methods were used  
33 (RealStar Altona®, Anatolia®, Cobas 6800 Roche®, Allplex™ 2019-nCoV Assay Seegene®). All assays  
34 amplify SARSCoV2 E gene. Cycle threshold (Ct) values were recorded. Nasopharyngeal samples were  
35 tested prospectively within a few hours after collection and without any cooling or freezing step, from  
36 April 1<sup>st</sup> to April 15<sup>th</sup> 2020. Swabs were collected in various transport media (COPAN UTM 3ml, Virocult  
37 1 ml, Eswab Amies 1 ml, 4MRT 3 ml, 0.9% NaCl buffer and COBAS ROCHE). The first four samples  
38 collected in COBAS medium tested gave invalid results. We therefore excluded such samples from the  
39 study. Analysis included 138 nasopharyngeal samples of which 94 (68.8%) were positive for SARS-CoV-  
40 2 by RT-PCR. Compared to RT-PCR, the specificity of the test was 100% (CI 95%: 91.8-100). Among the  
41 94 RT-PCR positive samples, the rapid test only detected 47 specimens, resulting in a sensitivity of  
42 50.0% (95 CI: 39.5-60.5). In nine positive and eight negative tests, control lines were barely visible.  
43 Median of E gene Ct values differed significantly between positives (median =21, Interquartile range  
44 (IQR) [17.0-23.0]) and negatives (28.3, IQR:[25.6-33.0]) antigenic test results ( $p<0.0001$ ) (Figure 1). A  
45 study conducted by the manufacturer mentioned a sensitivity of 76.7% for samples positive with a Ct  
46 value under 25 (3). In our study, the test would have a sensitivity of 82.2 % for Ct values under 25.  
47 In our study, the COVID-19 Ag Respi-Strip CORIS® had a sensitivity of 50% compare to RT-PCR. The test  
48 was more sensitive for high viral loads and could perhaps be used for patients within a few days after  
49 symptoms onset when the load in upper respiratory tract is at its peak. Considering current low COVID  
50 19's prevalence of 0.19 % in France, prospective studies should be conducted to determine the best  
51 settings for its implementation.

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56 **References**

[Texte]

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69 Development and Potential Usefulness of the COVID-19 Ag Respi-Strip Diagnostic Assay in a Pandemic  
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73 [=&journalName=Frontiers\\_in\\_Medicine&id=551560](https://www.frontiersin.org/articles/10.3389/fmed.2020.00225/full?utm_source=Email_to_author&utm_medium=Email&utm_content=T1_11.5e1_author&utm_campaign=Email_publication&field=&journalName=Frontiers_in_Medicine&id=551560)

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76 **Figure 1.** COVID-19 Ag Respi-Strip CORIS results according to real-time PCR Ct values. All cycle  
77 threshold values of E gene real-time PCR positive assays are shown for positive and negative COVID-  
78 19 Ag Respi-Strip CORIS assay results. Results gathering Ct values for all real-time PCR positive assays  
79 are depicted by squares. Ct values between samples positive or negative for the antigenic assay are  
80 significantly different (\* indicates a p-value < 0.0001). Ct values corresponding to the Cobas 6800,  
81 Allplex, Anatolia, and RealStar assays are depicted by triangles, diamonds, circles and reversed  
82 triangles respectively.

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