




Detection of SARS-CoV-2 by Use of the Cepheid Xpert Xpress SARS-CoV-2 and Roche cobas SARS-CoV-2 Assays

Angelica Moran,^a Kathleen G. Beavis,^a Scott M. Matushek,^b Carol Ciaglia,^b Nina Francois,^b  Vera Tesic,^a Nedra Love^b

^aDepartment of Pathology, The University of Chicago, Chicago, Illinois, USA

^bClinical Microbiology Laboratory, University of Chicago Medicine, Chicago, Illinois, USA

Angelica Moran and Kathleen G. Beavis contributed equally to this work. Author order was determined in order of increasing seniority.

KEYWORDS COVID-19, Cepheid Xpert Xpress SARS-CoV-2, Roche cobas SARS-CoV-2 assay, SARS-CoV-2

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), a novel coronavirus responsible for a December 2019 outbreak in Wuhan, China, causes a syndrome characterized by fever, cough, and dyspnea progressing to acute respiratory distress syndrome (1). SARS-CoV-2 quickly spread to other countries, with the new coronavirus disease 2019 (COVID-19) declared a pandemic in March 2020 (2–4). Rapid testing for SARS-CoV-2 is important for epidemiological tracking and institution of quarantine procedures (5). The clinical description of COVID-19 continues to evolve; with transmission by asymptomatic individuals reported (6–8), widespread testing is necessary.

Multiple reverse transcription-PCR (RT-PCR) assays have received emergency use authorization from the U.S. Food and Drug Administration. The Roche cobas SARS-CoV-2 assay is a qualitative test that detects SARS-CoV-2-specific ORF1 and part of the E gene, conserved across sarbecoviruses, including SARS-CoV-2 (9). The Cepheid Xpert Xpress SARS-CoV-2 assay also detects the pan-sarbecovirus E gene but detects the N2 region of the N gene as its SARS-CoV-2-specific target (10). This report compares results from specimens tested with both assays.

Eight nasal and 95 nasopharyngeal specimens were collected from inpatients and ambulatory patients at the University of Chicago. Samples were tested by the Roche cobas SARS-CoV-2 assay on the cobas 6800 system (Roche Molecular Systems, Branchburg, NJ) and by the Cepheid Xpert Xpress SARS-CoV-2 assay on the GeneXpert system (Cepheid, Sunnyvale, CA). Of these 103 specimens, 42 tested positive and 60 tested negative with both systems, for an agreement of 99%. Testing was repeated on the single specimen with discrepant results. For this specimen, the Roche assay was repeatedly negative for SARS-CoV-2. The initial Cepheid assay result was positive for SARS-CoV-2, though the cycle threshold (C_T) values for detection of the E gene were 0.0 (negative) and 42.0 (low positivity) for the N gene. Repeat Cepheid testing was negative for both targets. These results suggest that SARS-CoV-2 was present at a very low concentration, near the detection limit of the Cepheid assay.

For the 42 positive samples, C_T values for the E gene ranged from 15.05 to 39.75 (mean, 26.35; standard deviation [SD], 6.69) for the Roche assay and 13.6 to 38.2 (mean, 24.8; SD, 7.1) for the Cepheid assay. By Bland-Altman analysis to assess agreement, C_T values were lower in the Cepheid assay for 37 of 42 samples (mean difference, -1.57; 95% limits of agreement, -5.34, 2.20). This might be due to differences in primer sequences for the E gene, reagents, or amplification conditions.

Limitations of this study include the small sample size of SARS-CoV-2-positive specimens, as testing was limited to patients within our institution. The assays also detect different SARS-CoV-2-specific genes, which may lead to false-negative results if

Citation Moran A, Beavis KG, Matushek SM, Ciaglia C, Francois N, Tesic V, Love N. 2020. Detection of SARS-CoV-2 by use of the Cepheid Xpert Xpress SARS-CoV-2 and Roche cobas SARS-CoV-2 assays. *J Clin Microbiol* 58:e00772-20. <https://doi.org/10.1128/JCM.00772-20>.

Editor Alexander J. McAdam, Boston Children's Hospital

Copyright © 2020 Moran et al. This is an open-access article distributed under the terms of the [Creative Commons Attribution 4.0 International license](https://creativecommons.org/licenses/by/4.0/).

Address correspondence to Kathleen G. Beavis, kbeavis@uchicago.edu.

Accepted manuscript posted online 17 April 2020

Published 23 July 2020

a mutation prevents primer binding. The Cepheid assay is a 45-min random-access assay, with throughput dependent on the number of instrument slots. The Roche platform is batch based, accommodating 90 samples/run every 90 min. As each run requires up to 3 h and 45 min, throughput is approximately 1 result per minute. Overall, the Cepheid Xpert Xpress SARS-CoV-2 and Roche cobas SARS-CoV-2 assays show excellent agreement (>99%), and their combined usage can be tailored to maximize SARS-CoV-2 testing.

REFERENCES

- Chen N, Zhou M, Dong X, Qu J, Gong F, Han Y, Qiu Y, Wang J, Liu Y, Wei Y, Xia J, Yu T, Zhang X, Zhang L. 2020. Epidemiological and clinical characteristics of 99 cases of 2019 novel coronavirus pneumonia in Wuhan, China: a descriptive study. *Lancet* 395:507–513. [https://doi.org/10.1016/S0140-6736\(20\)30211-7](https://doi.org/10.1016/S0140-6736(20)30211-7).
- Ki M, Task Force for 2019-nCoV. 2020. Epidemiologic characteristics of early cases with 2019 novel coronavirus (2019-nCoV) disease in Korea. *Epidemiol Health* 42:e2020007. <https://doi.org/10.4178/epih.e2020007>.
- Spiteri G, Fielding J, Diercke M, Campese C, Enouf V, Gaymard A, Bella A, Sognamiglio P, Sierra Moros MJ, Riutort AN, Demina YV, Mahieu R, Broas M, Bengner M, Buda S, Schilling J, Filleul L, Lepoutre A, Saura C, Mailles A, Levy-Bruhl D, Coignard B, Bernard-Stoecklin S, Behillil S, van der Werf S, Valette M, Lina B, Riccardo F, Nicastrì E, Casas I, Larrauri A, Salom Castell M, Pozo F, Maksyutov RA, Martin C, Van Ranst M, Bossuyt N, Siira L, Sane J, Tegmark-Wisell K, Palmerus M, Broberg EK, Beaute J, Jorgensen P, Bundle N, Pereyaslov D, Adlhoch C, Pukkila J, Pebody R, Olsen S, Ciancio BC. 2020. First cases of coronavirus disease 2019 (COVID-19) in the WHO European Region, 24 January to 21 February 2020. *Euro Surveill* 25:2000178. <https://doi.org/10.2807/1560-7917.ES.2020.25.9.2000178>.
- Holshue ML, DeBolt C, Lindquist S, Lofy KH, Wiesman J, Bruce H, Spitters C, Ericson K, Wilkerson S, Tural A, Diaz G, Cohn A, Fox L, Patel A, Gerber SI, Kim L, Tong S, Lu X, Lindstrom S, Pallansch MA, Weldon WC, Biggs HM, Uyeki TM, Pillai SK, Washington State 2019-nCoV Case Investigation Team. 2020. First case of 2019 novel coronavirus in the United States. *N Engl J Med* 382:929–936. <https://doi.org/10.1056/NEJMoa2001191>.
- Deng SQ, Peng HJ. 2020. Characteristics of and public health responses to the coronavirus disease 2019 outbreak in China. *J Clin Med* 9:E575. <https://doi.org/10.3390/jcm9020575>.
- Bai Y, Yao L, Wei T, Tian F, Jin DY, Chen L, Wang M. 2020. Presumed asymptomatic carrier transmission of COVID-19. *JAMA* 323:1406. <https://doi.org/10.1001/jama.2020.2565>.
- Rothe C, Schunk M, Sothmann P, Bretzel G, Froeschl G, Wallrauch C, Zimmer T, Thiel V, Janke C, Guggemos W, Seilmaier M, Drosten C, Vollmar P, Zwirgmaier K, Zange S, Wolfel R, Hoelscher M. 2020. Transmission of 2019-nCoV infection from an asymptomatic contact in Germany. *N Engl J Med* 382:970–971. <https://doi.org/10.1056/NEJMc2001468>.
- Borges do Nascimento IJ, Cacic N, Abdulazeem HM, von Groote TC, Jayarajah U, Weerasekera I, Esfahani MA, Civile VT, Marusic A, Jeroncic A, Carvas Junior N, Pericic TP, Zakarija-Grkovic I, Meirelles Guimaraes SM, Luigi Bragazzi N, Bjorklund M, Sofi-Mahmudi A, Altujjar M, Tian M, Arcani DMC, O'Mathuna DP, Marcolino MS. 2020. Novel coronavirus infection (COVID-19) in humans: a scoping review and meta-analysis. *J Clin Med* 9:E941. <https://doi.org/10.3390/jcm9040941>.
- Roche Molecular Systems. 2020. cobas SARS-CoV-2. (Package insert.) US Food and Drug Administration, Silver Spring, MD. <https://www.fda.gov/media/136049/download>. Accessed 8 April 2020.
- Cepheid. 2020. Xpert Xpress SARS-CoV-2. (Package insert.) US Food and Drug Administration, Silver Spring, MD. <https://www.fda.gov/media/136314/download>. Accessed 8 April 2020.