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Editorial

Racing Towards the Development of Diagnostics for a Novel Coronavirus (2019-nCoV)

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In December 2019, a mysterious viral illness causing pneumonia broke out in the city of Wuhan, in Hubei Province in China. A proportion of the earlier cases were associated with a seafood market in the city, where exotic animals were also sold for food *(1)*. Since then, this illness has been shown to be caused by a novel coronavirus (nCoV) that is named 2019-nCoV, and the disease named as coronavirus disease 2019 (COVID-19). As of February 26, 2020, the disease has been confirmed in over 80 900 cases, with over 2760 deaths. Geographically, the disease has spread beyond China to close to 40 other countries.

The sensitive and specific detection of this virus is an important part of the global healthcare response to this outbreak. In this issue of the journal, Chu et al. *(2)* reported the development of two one-step real-time reverse transcription polymerase chain reaction assays for detecting 2019-nCoV. The 2 assays target the Orf1b and the N region of the viral genome. Due to the relative paucity of positive control materials when the authors developed these assays, the authors had designed the primers and probes such that they would also cross-react with the Severe Acute Respiratory Syndrome (SARS)-CoV. The authors then use SARS-CoV as one of their positive controls. The authors argued that this cross-reactivity would not cause any diagnostic ambiguity as SARS-CoV was no longer seen clinically following the resolution of the SARS epidemic in 2004.

The authors found that the N assay was more sensitive than that targeting the Orf1b. The authors proposed using the former as a screening assay, and the latter as a diagnostic assay. On the basis of the data presented by the authors, one can perhaps argue that this two-tier test arrangement should be considered provisional. Further validation of this approach using a much larger sample cohort would be necessary.

When the authors designed their assays, only one 2019-nCoV sequence was publicly available. However, since then, several other 2019-nCoV sequences became available *(3)*. It will be essential to reassess the specificity of the authors' primers and probes as the sequence database and biobank for 2019-nCoV grow. It also will be important to compare the performance of the authors' assays versus those developed by other workers in the field *(1)*.

Additionally, it will be necessary to assess the quantitative performance of the authors' assays in a clinical context, using serial samples. Exploration of the viral kinetics in various sample types and looking for correlations with clinical outcome will be valuable. Viral kinetics studies will be beneficial in identifying treatment modalities that may be effective in inhibiting viral replication.

Viral diagnostics is one important part of our armamentarium against COVID-19. Public health measures, such as decisions to place a person and his or her close contacts under medical isolation, surveillance, or quarantine are intimately related to whether a suspected case has been confirmed to be infected with 2019-nCoV. To combat an epidemic, time is of the essence and hence the rapid development of sensitive and specific diagnostic tests is crucial. It is hoped that new therapies and even vaccines might eventually become available for this disease. The emergence of such viral zoonoses is indeed testing modern global healthcare and collaboration to the extreme.

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