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Letter to the editor

AusDiagnostics SARS-CoV-2 kits shown to be more sensitive than reference laboratory test



To the editor.

In a recent article published in this journal by Rahman et al. [1] one of the multiplexed panels detecting SARS-CoV-2 that is manufactured by AusDiagnostics was compared with the results obtained by the reference virology laboratory in Sydney. The authors claimed that the commercial kit, which is based on a two step PCR process, created false positives because 4 out of 9 positives could not be confirmed by the single step PCR used in their laboratory. No attempt was made to corroborate this allegation.

We have now sequenced a positive sample that was not detected by this laboratory and shown that it contains SARS-CoV-2 sequence. The simpler conclusion therefore is that the lack of concordance was caused by the low sensitivity of the test used by the reference laboratory.

In addition to this finding two other Australian laboratories have submitted publications showing that AusDiagnostics kits can detect SARS-CoV-2 positives than cannot be detected by the local public health reference laboratories using published primers and a single step PCR. In one case these additional positives have been sequenced and shown to be correct [2].

Australia has been remarkably successful in combating the COVID-19 pandemic, reducing the case load from over 400 new cases a day in late March to less than 20 new cases a day in late April using a combination of sensitive testing, contact tracing and social isolation. Tests for SARS-CoV-2 that can give a false negative result could have a devastating impact on the case load by allowing low positive individuals, who might well be asymptomatic, to escape detection and pass on the

virus to members of the community. This will be especially important as countries ease social distancing policies.

Our recommendation is therefore that reference laboratories, who have the status of "gold standard" should use sensitive tests, like those supplied by AusDiagnostics. In preparation for the southern hemisphere winter season AusDiagnostics has modified all its multiplexed respiratory panels to include one or more targets for SARS-CoV-2. Combining all respiratory targets into one panel saves a laboratory time and cost.

Declaration of Competing Interest

Keith Stanley is Managing Director of AusDiagnostics Pty Ltd.

References

- H. Rahman, I. Carter, K. Basile, et al., Interpret with caution: an evaluation of the commercial AusDiagnostics versus in-house developed assays for the detection of SARS-CoV-2 virus, J. Clin. Virol. 127 (2020) 104374.
- [2] Lucy Attwood, Michelle Francis, John Hamblin, Tony Korman, Julian Druce, Maryza Graham, Clinical evaluation of AusDiagnostics SARS-CoV-2 multiplex tandem PCR assay, J. Clin. Virol. 128 (2020) 104448.

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