

SURVEILLANCE TESTING USING SALIVARY RT-PCR FOR SARS-COV-2 IN MANAGED QUARANTINE FACILITIES IN AUSTRALIA: A LABORATORY VALIDATION AND IMPLEMENTATION STUDY

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Background: Regular repeat surveillance testing is a strategy to identify SARS-CoV-2 infectious asymptomatic individuals in high-risk work settings to prevent onward community transmission. Saliva sampling is less invasive compared to nasal/oropharyngeal sampling, thus making it suitable for regular testing. In this multi-centre evaluation, we aimed to validate salivary RT-PCR testing of SARS-CoV-2 for large-scale surveillance testing and assess implementation amongst staff working in the hotel quarantine system in Victoria, Australia.

Methods: A multi-centre laboratory evaluation study was conducted to systematically validate the *in vitro* and clinical performance of salivary RT-PCR for implementation of SARS-CoV-2 surveillance testing. Analytical sensitivity for multiple RT-PCR platforms was assessed using a dilution series of known SARS-CoV-2 viral loads, and assay specificity was examined using a panel of viral pathogens other than SARS-CoV-2. Regular self-collected saliva swab RT-PCR testing was implemented for staff across fourteen quarantine hotels. Samples were tested at three diagnostic laboratories validated in this study, and results were provided back to staff in real-time.

Results: The agreement of self-collected saliva swabs for RT-PCR was 72.6% (95% CI 60.3 to 82.2) compared to RT-PCR using nasal/oropharyngeal swab samples collected by a healthcare practitioner. Sensitivity increased to 82.5% (95% CI 67.7 to 91.6) when saliva samples were collected within seven days of symptom onset. Between 7th December 2020 and 17th December 2021, almost 500,000 RT-PCR tests were performed on saliva swabs self-collected by staff working in quarantine hotels in Melbourne. The majority of staff that tested positive occurred during periods of community transmission of the SARS-CoV-2 Delta variant.

Conclusion: Salivary RT-PCR had an acceptable level of agreement compared to standard nasal/oropharyngeal swab RT-PCR within early symptom onset. The scalability, tolerability and ease of self-collection highlights utility for frequent or repeated testing in high risk settings, such as quarantine or healthcare environments.

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