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Purpose: Despite the rollout of several vaccines targeting SARS-CoV-2, attainment of near-universal vaccination is a challenging task, particularly for low- and middle-income nations such as Sri Lanka. Rapid, reliable diagnostics for the detection of the virus is of vital importance for the predominantly export- and tourism-based economy of the country. Herein, we report the development of a RT-LAMP assay as an alternative to the gold-standard RT-qPCR method for diagnostic laboratories in Sri Lanka in a cost-effective and highly reliable manner.

Methods & Materials: About 313 nasopharyngeal and oropharyngeal samples from the community were collected and subjected to RNA purification and subjected to simultaneous RT-qPCR and RT-LAMP experiments by using previously published primers in a thermocycler. Duplex (containing N and E gene primers) and multiplex (containing N, E and ORF1ab gene primers) RT-LAMP assay results were compared with standard RT-qPCR results using an agreement attribute statistical test. The effect of guanidine hydrochloride was also analyzed.

Results: The limit of detection for the duplex assay was found to be 10 copies μ L⁻¹ at a constant temperature of 63°C, and 5 copies μ L⁻¹ for multiplex assays at 66.4°C. Both types of RT-LAMP assay were specific only for the SARS-CoV-2 virus, successfully distinguishing it from multiple other human viruses. Attribute agreement analysis between duplex- and multiplex RT-LAMP vs RT-qPCR yielded 93% and 96.5% scores, respectively. Moreover, both RT-LAMP assays showed 100% agreement with RT-qPCR when Ct was <25 in positive samples and showed 100% (duplex) or 97.22% (multiplex) at 35 \geq Ct \geq 25. The discrepancy between agreements at higher Ct values was attributed to the higher sensitivity of the multiplex RT-LAMP assay. The addition of guanidine hydrochloride increased the sensitivity and decreased detection time significantly for both the duplex and multiplex assays.

Conclusion: Overall, we have demonstrated a potentially rapidly deployable diagnostic test kit not only for widespread community use but particularly for high-risk locations such as ports of entry or manufacturing facilities to mitigate the effects of the SARS-CoV-2 virus in Sri Lanka.

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Treatment with Ivermectin Is Associated with Decreased Mortality in COVID-19 Patients: Analysis of a National Federated Database

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Purpose: To evaluate the difference in mortality of patients treated with ivermectin vs patients treated with remdesivir with

COVID-19 in United States using TriNetX Research network, a federated EMR network of over 44 healthcare organizations and 68 million patients from US, from 2009–2021.

Methods & Materials: We retrospectively identified adults (\geq 18 years) with a recorded COVID-19 infection between January 1, 2020 and July 11, 2021. We compared those with recorded use of ivermectin, but not remdesivir, against those with recorded use of remdesivir, but not ivermectin. We controlled for the following demographics, comorbidities, and treatments that may affect COVID-19 survival outcomes: age, gender, race, ethnicity, nicotine use, diabetes mellitus, obesity, chronic lower respiratory disease, ischemic heart diseases, tocilizumab, glucocorticoids, or ventilator use. We measured association with mortality as the primary outcome, with significance assessed at $p < 0.05$.

Results: There were a total of 1,761,060 possible COVID-19 patients based on ICD-10 diagnostic terms and confirmatory lab results. Prior to controlling, our analysis yielded 41,608 patients who had COVID-19 resulting in two unique cohorts that were treated with either ivermectin (1,072) or remdesivir (40,536). Within the ivermectin cohort, average age was 51.9 + 17.8 years, 43% were male, 60% had glucocorticoids and 1% required ventilator support. In the remdesivir cohort, average age was 62.0 + 16.0 years, 54% were male, 64% had glucocorticoids and 2% required ventilator support. After using propensity score matching and adjusting for potential confounders, ivermectin was associated with reduced mortality vs remdesivir (OR 0.308, 95% CI (0.198,0.479)), Risk Difference -5.224%, CI (-7.079%,-3.369%), $p < 0.0001$.

Conclusion: Ivermectin use was associated with decreased mortality in patients with COVID-19 compared to remdesivir. To our knowledge, this is the largest association study of patients with COVID-19, mortality and ivermectin. Further double-blinded placebo-controlled RCTs with large samples are required for definite conclusion. In the future, if more publications are published with the similar result to the current analyses, the certainty of evidence will increase.

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Surveillance of Immunological Status after Vaccination by two Serological Assays based on SARS-CoV-2 Spike Protein

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Purpose: Two serological assays, an Enzyme-Linked Immunosorbent Assay (ELISA) and a Lateral Flow Assay (LFA), have been developed based on the SARS-CoV-2 recombinant Receptor Binding Domain (RBD-ELISA) and the combination of Trimeric Spike (S) and Nucleoprotein (N), S-LFA and N-LFA, respectively, as