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# DEVELOPMENT OF A TRANSCRIPTION-MEDIATED AMPLIFICATION BASED ASSAY FOR DETECTION OF SARS CORONAVIRUS

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## Background:

We are developing a highly sensitive assay for the detection of the virus associated with Severe Acute Respiratory Syndrome (SARS). SARS is a highly contagious viral-based infectious disease that emerged in the Guangdong Province of China in November 2002. The high transmission rate from direct contact with infected individuals has lead to thousands of cases world wide, with a concomitant mortality rate of greater than 7%. SARS is caused by a novel coronavirus, referred to as SARS-CoV. Genomic RNA from this virus has been detected in the serum of patients following the acute symptomatic phase of infection. The aim of this study is to develop a sensitive nucleic acid based test for detecting SARS-CoV in human plasma.

## Methods:

The Gen-Probe SARS-CoV assay utilizes magnetic target capture, Transcription-Mediated Amplification (TMA), Hybridization Protection (HPA), and Dual Kinetic Assay (DKA) technologies. The assay is compatible with both a semi-automated and fully automated platform. An Internal Control is simultaneously captured, amplified, and detected along with SARS-CoV target. To assess analytical sensitivity of the assay, we tested serial dilutions of RNA transcript corresponding to the target amplification region ofregion of the SARS-CoV genome. Cross-reactivity studies to evaluate specificity were performed using plasma spiked with virus.

## Results:

Sensitivity data indicate that the assay consistently detects SARS-CoV RNA sequences at a concentration of 100 copies/mL, while simultaneously detecting the internal control. The average signal-to-cutoff value exceeded 15. The assay did not show cross-reactivity with other known blood-borne viral pathogens including HIV-1, HCV, HAV, Parvo-B19, and HBV. The assay showed no cross reactivity with human coronavirus 229E.

## Conclusion:

The results presented demonstrate the feasibility of a sensitive and selective TMA-based nucleic acid amplification test for the detection of SARS-CoV.