




	National Public Health Laboratory	Version No. 1
	COVID-19 SOP	Copy no: 01
	NPHL/ C19/SOP/11/ML	Date of issue: 8/10/2020
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**PathoDetect™ Coronavirus (COVID-19)- Qualitative PCR kit in
Humans**

By My Lab discovery solutions

**Standard Operating procedure
of
National Public Health Laboratory
Tripura Marg, Kathmandu
Nepal**

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I. INTRODUCTION

Corona viruses (CoV) are a large family of viruses that cause illness ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS-COV) and Severe Acute Respiratory Syndrome (SARS-CoV).

A novel coronavirus (nCoV) identified in China as COVID 19 or SARS-CoV-2 is a new strain that has not been previously identified in humans. Since then COVID-19 has spread to many more countries – cases have been reported in all over the world. Coronaviruses are zoonotic and are transmitted between animals and people. Common signs of infection include respiratory symptoms, fever, cough, shortness of breath and breathing difficulties. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome, kidney failure and even death.

At present, there is no cure for COVID-19. Standard recommendations to prevent infection spread include regular hand washing, covering mouth and nose when coughing and sneezing, thoroughly cooking meat and eggs. Avoid close contact with anyone showing symptoms of respiratory illness such as coughing and sneezing. Early detection is very crucial for clinical management and disease spread. Real time PCR technology is recommended for early detection by CDC.




II. INTENDED USE:

Mylab Discovery Solutions PathoDetect™ COVID-19 qualitative PCR kit is an in vitro RT PCR (rT-PCR) assays for the in vitro qualitative detection of 2019-Novel Coronavirus (2019-nCoV) in respiratory specimens and sera

III. PRODUCT DESCRIPTION:

Mylab Discovery Solutions PathoDetect™ COVID-19 qualitative PCR kit is an in vitro RT PCR (rT-PCR) assays for the in vitro qualitative detection and discrimination of 2019-Novel Coronavirus (2019-nCoV) in respiratory specimens and sera. The 2019-nCoV primer and probe sets are designed for the universal detection of SARS-like coronaviruses and for specific detection of 2019-nCoV using E gene for screening and RdRP gene for conformation based on Berlin protocol in a single test.

The assay includes positive controls, Internal Control to identify possible PCR inhibition, and to confirm the integrity of the reagents of the kit.

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