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EVALUATION OF RAPID MOLECULAR POCT (POCT X) FOR DETECTION OF INFLUENZA A/B VIRUS AND RESPIRATORY SYNCYTIAL VIRUS IN COMPARISON TO MULTIPLEX PCR

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ABSTRACT

BACKGROUND: Influenza A, B and Respiratory Syncytial Virus are highly infectious and are the most prevalent infective agents of acute respiratory infection. Morbidity and mortality are high in young children, the elderly and those who are immunocompromised. Antiviral treatment for influenza infection is beneficial if it is given within 48 hours of symptoms, while antiviral treatment for Respiratory Syncytial Virus infection is reserved for severe disease and transplant patients. However, as early clinical symptoms are non-specific flu-like illness, initial presentations to the primary care clinic will not be able to confirm the diagnosis without sending patient's specimen to the bigger laboratory, which will take time and delay antiviral commencement and patient isolation. The development of a sensitive, specific and easy to use point-of-care testing will enable clinician to perform the test in the clinic, confirm the diagnosis early and allow early treatment, avoid disease progression and further complications, as well as advise patient isolation to limit spread of infection.

OBJECTIVE: This study aims to evaluate the performance (sensitivity and specificity) of a rapid molecular point-of-care testing for Influenza A virus, Influenza B virus and RSV, using a multiplex PCR as the method of reference.

METHODS: A cross sectional study on the evaluation of a rapid molecular POCT (POCT X) in comparison to multiplex PCR was conducted for the detection of Influenza A, B and RSV viruses. 120 nasopharyngeal swabs were recruited from Microbiology Laboratory, Department of Pathology, Hospital Sungai Buloh, and Quantum Diagnostic Gribbles Pathology Laboratory, Petaling Jaya Selangor, Malaysia from November 2019 to October 2020. 31 specimens out of 120 were served as control and all these had none of the above stated three viruses detected. The inclusion criteria for the specimens to be processed includes nasopharyngeal swabs that was tested positive for influenza viruses and RSV. Meanwhile the exclusion criteria were insufficient volume of viral transport media and specimens other than nasopharyngeal swabs. Demographic data that are age and gender were collected. The specimens were tested using both method; rapid molecular POCT X and multiplex PCR. Descriptive analysis was performed for the demographic data, while specificity, sensitivity, positive predictive value and negative

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1. 1 INTRODUCTION

Influenza has been recognized as highly infectious respiratory disease with symptoms ranging from moderate to high in severity. During an epidemic, influenza-associated mortality and rate of hospitalization is exceptionally high, which increase the disease burden for influenza [1]. On the other hand, although Respiratory Syncytial Virus (RSV) infection is more common in children and has been associated to cause higher morbidity to those under the age of two especially premature infants, the infection has also known to cause high morbidity to older adults especially those with underlying lung disease and those who are immunocompromised.

The Centre for Disease Control and Prevention (CDC) recommended the use of molecular techniques specifically reverse transcriptase polymerase chain reaction (RT-PCR) [2] as the method of reference for diagnosis of influenza. The Polymerase Chain Reaction (PCR) is a fast and reliable technique with a turn-around-time of two to four hours. Nevertheless, it is crucial to note that such advanced molecular technique is not widely available throughout Malaysia due to its high technicality and cost. Taking Hospital Sungai Buloh as an example as the national infectious disease hospital; before the pandemic of SARS-CoV-2 virus, laboratory test for respiratory pathogen that includes influenza virus and RSV by PCR was only offered to in-hospital patients. In addition, the molecular testing for respiratory pathogen was not routinely done but rather they were processed in batch. Thus, in reality, such investigation is not available in every centre nationwide, and even in the hospitals where it is offered; the timing from sampling to result may take up to a week.

Molecular technology had evolved and enabled multiple pathogen detection in a single test; also known as multiplex PCR. This technology will reduce the cost of performing multiple tests for one sample, as well as aiding the detection of a wider range of pathogens. However, such multiplex PCR still require the initial process of decontamination and extraction. Well-trained personnel are needed to perform the