Clinical evaluation of the GRIP influenza and SARS-CoV-2 point-of-care assays using fresh patient nasal swab samples

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General Study Information

Principal Investigator: Matthew Binnicker, Ph.D.

Study Title: **Clinical evaluation of the GRIP influenza and SARS-CoV-2 point-of-care assays using fresh patient nasal swab samples**

Protocol version number and date: V1 11/9/22

Research Question and Aims

Hypothesis:

Aims, purpose, or objectives:

1. Compare the performance of a novel, graphene-based, point-of-care device to routine laboratory-based nucleic acid amplification tests (NAATs) for detection of respiratory viruses, such as COVID-19 and influenza.
2. Determine if the novel, graphene-based assay provides enhanced sensitivity for detecting respiratory viruses compared to point-of-care antigen tests.

Background:
GRIP Molecular has developed a novel, graphene-based point-of-care device for detection of respiratory viruses (e.g., COVID-19 and influenza) from a nasal swab. This study is designed to compare the performance of this novel device to standard, laboratory-based molecular tests (i.e., PCR) for detection of these viruses.

Study Design and Methods

Methods:

Clinical evaluation experiments will be carried out at the Mayo Clinic in the Advanced Diagnostics Lab using freshly collected patient samples collected at the clinic in Rochester, MN. Two nasal swab samples from each patient will be collected by a trained healthcare provider; one sample (solely for study purposes) will be diluted into 3 mL of (0.9% wt/vol) phosphate buffered saline for GRIP graphene field effect transistor (GFET) analysis) and the second (for routine clinical testing) will be diluted into viral transport media (i.e., Remel M4RT) for routine PCR analysis (e.g., Roche cobas SARS-CoV-2 or influenza A/B). The sample for routine clinical testing will be collected prior to the study sample. Upon sample collection, the patient sample collected solely for study purposes will be given a unique identifier that will allow the result to be matched to that of the routine clinical test. No patient identifiable information will used during the data analysis. The only information available from the samples is the test result (+/- and PCR cycle threshold, if positive) and the test date. For GFET testing, 10 µL of the sample in saline will be added directly to the GFET well and data collected. Sample analyses conducted on the GFET chips will be done with a 48-h 1x PBS 0.5-mM $MgCl_2$ incubation step in the functionalization process.

Subject Information

Target accrual: 200

Subject population (children, adults, groups): 18 and older

Inclusion Criteria: Patients being tested for COVID 19 or Influenza

Exclusion Criteria:

Data Analysis

Data Analysis Plan:

To determine the positive percent agreement (PPA) and negative percent agreement (NPA), the results of the GRIP device will be compared to that of routine clinical testing. GRIP results will be compared to NAAT, with positive results requiring a Ct value ≤35 to be included in the comparison. Patient samples will be collected during a period of time when influenza rates are ≥10% in the local community. A total of 200 patients will be enrolled, with at least 50 negative patient samples, and up to 50 SARS-CoV-2 positive and 50 Influenza A positive samples. We will compare GRIP GFET results with the PCR results, obtained in parallel, by calculating the percent agreement between the GRIP test results and those of the PCR.

The known RT-qPCR–negative data will be used to set the sensor response threshold value with 99.7% CI using ±3σ analysis to predict negative patient samples. During the clinical testing, the sensor response value above the mean +3σ will be assigned as positive for the respective test.