INPLASY PROTOCOL

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Support: **No.**

Review Stage at time of this submission: **The review has not yet started.**

Conflicts of interest: **No.**

Accuracy of rapid IgM and IgG Antibody Test for SARS-CoV-2 Infection Diagnosis: a systematic review and meta analysis

Rosa, MI[1]; Prestes, GS[2]; Macedo, ACL[3]; Colonetti, T[4]; Uggioni, MLR[5]; Grande, AJ[6].

Review question / Objective: **Evaluate the accuracy of rapid IgM and IgG Antibody Test for SARS-CoV-2 Infection Diagnosis comparing with RT-PCR.**
Condition being studied: **Currently, there is a crisis in public health that threatens the world population due to the emergence and spread of COVID-19. Its transmission occurs through inhalation or contact with infected droplets. The main symptoms involved fever, cough, sore throat and malaise, even more severe symptoms such as breathing difficulties. n the general population, symptoms are considered mild, however, patients who belong to the so-called risk group such as the elderly and patients with comorbidities such as type II diabetes mellitus seem to develop more severe forms of this disease, such as progressing to pneumonia, acute respiratory distress syndrome and multiple organ dysfunction. It is also known that many patients can present the asymptomatic form of the disease, which creates a difficulty in containing the spread of the disease. The diagnosis occurs through the evaluation of respiratory secretions by molecular tests, with RT-PCR being the gold standard, however, molecular tests are time-consuming and require trained professionals to perform them. Rapid tests such as IgM and IgG Antibody Test for SARS-CoV-2 Infection have been used for the rapid screening of patients with SARS-CoV-2, symptomatic or asymptomatic, aiming to streamline the care of patients with COVID-19 and reduce the spread of disease.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 16 April 2020 and was last updated on 16 April 2020 (registration number INPLASY202040099).

INTRODUCTION

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METHODS

Participant or population: Patients tested by RT-PCR for SARS-CoV-2 and by a serologic test.

Intervention: Diagnostics tests of interest (rapid IgM and IgG Antibody Test for SARS-CoV-2 Infection) with the reference results (RT-PCR) for confirmation of COVID-19.

Comparator: Results of rapid IgM and IgG Antibody Test for SARS-CoV-2 Infection Diagnosis (index test) will be compared to results of RT-PCR (reference test).

Study designs to be included: Cross-sectional, Cohort or Case-control.

Eligibility criteria: Patients who tested positive for COVID-19 using RT-PCR and who were evaluated using the rapid IgM and IgG Antibody Test for SARS-CoV-2 Infection.

Information sources: We will search MEDLINE, EMBASE, Cochrane Library, Web of Science and Cumulative Index to Nursing and Allied Health Literature (CINAHL Database). We will use the following terms, both as text words and, as appropriate, Medical Subjects Heading (MeSH) or equivalent subject heading / thesaurus terms: "SARS-CoV" OR "COVID-19" OR "COVID" OR "COVID-19 diagnostic testing"AND "test". Reference lists of all available primary studies will be evaluated to identify additional relevant citations.

Main outcome(s): SARS-CoV-2 Infection.

Quality assessment / Risk of bias analysis: All studies will be assessed for their methodological quality using the QUADAS 2 (Quality Assessment of Diagnostic Accuracy Studies) criteria (Whiting et al.2011). This will be performed independently by two reviewers (TC and ALM).

Strategy of data synthesis: Two reviewers (ALM, GSP) will initially screen the titles and abstracts for relevance in Rayyan (rayyan.qcri.org). The full texts of each potentially eligible study will be retrieved and reviewed independently by the two reviewers (ALM , GSP). Data from all studies will be independently extracted by two reviewers, and combined to construct a definitive dataset. Data will be extracted on pre-piloted data extraction tables for study characteristics, and on a 2x2 table for study results. However, when this is not possible, corresponding authors will be contacted in order to obtain this data. Disagreements during the study identification, data extraction and methodological quality assessment process will be resolved through consensus discussion between the two reviewers. If agreement can not be met, conflict will be resolved by a third reviewer (TC) who will act as an adjudicator.

Subgroup analysis: None.

Sensibility analysis: In sensitivity analysis results will be described by technique, country and, if possible, by manufacturer.

Country(ies) involved: Brazil.

Keywords: Systematic review, SARS-CoV, COVID-19, COVID-19 diagnostic testing.

Contributions of each author:
Author 1 - Project coordinator, project writing, writing of the manuscrip.
Author 2 - Project writing, selection of included studies, data extraction, analysis of the quality of studies, writing of the manuscript.
Author 3 - Project writing, selection of included studies, data extraction, analysis of the quality of studies, writing of the manuscript.
Author 4 - Project writing, search strategy, article selection, data extraction, data analysis, study quality analysis, manuscript writing.
Author 5 - Article selection, data extraction, manuscript writing.
Author 6 - Project writing, search strategy, article selection, data extraction, data analysis, study quality analysis, manuscript writing.