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Role and utility of COVID-19 laboratory testing in low-income and middle-income countries: protocol for rapid evidence synthesis

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ABSTRACT

Introduction Accurate and affordable laboratory testing is key to timely diagnosis and appropriate management of patients with COVID-19. New laboratory test protocols are released into the market under emergency use authorisation with limited evidence on diagnostic test accuracy. As such, robust evidence on the diagnostic accuracy and the costs of available tests is urgently needed to inform policy and practice especially in resource-limited settings. We aim to determine the diagnostic test accuracy, cost-effectiveness and utility of laboratory test strategies for COVID-19 in low-income and middle-income countries.

Methods and analysis This will be a multistaged, protocol-driven systematic review conducted in line with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines for diagnostic test accuracy studies. We will search for relevant literature in at least six public health databases, including PubMed, Google Scholar, MEDLINE, Scopus, Web of Science and the WHO Global Index Medicus. In addition, we will search Cochrane Library, COVID-END and grey literature databases to identify additional relevant articles before double-screening and abstraction of data. We will conduct a structured narrative and quantitative synthesis of the results guided by the Fryback and Thornbury framework for assessing a diagnostic test. The primary outcome is COVID-19 diagnostic test accuracy. Using the GRADE approach specific to diagnostic accuracy tests, we will appraise the overall quality of evidence and report the results following the original PRISMA statement. The protocol is registered with the International Prospective Register of Systematic Reviews (PROSPERO; https://www.crd.york.ac.uk/prospero/).

Ethics and dissemination Ethical review was done by the School of Biomedical Sciences Research Ethics Committee and the Uganda National Council for Science and Technology. The published article will be accessible to policy and decision makers. The findings of this review will guide clinical practice and policy decisions and highlight areas for future research.

Strengths and limitations of this study

- ► The study will contribute to strengthening the evidence base on the effectiveness of laboratory testing strategies for COVID-19 in hospitals and community populations in low-income and middle-income countries (LMICs).
- ► The protocol has been written following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines.
- ► The GRADE system will be used to ascertain the strength of the evidence base for each outcome and to report data for the primary outcome in a 'Summary of Findings table'.
- ► The review is limited to evidence from LMICs.
- ► Non-English databases will not be searched and this may introduce language bias.

PROSPERO registration number CRD42020209528.

BACKGROUND

COVID-19 is a viral pneumonia caused by a novel coronavirus, initially named 2019 novel coronavirus (2019-nCoV) and subsequently changed to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) by the International Committee on Taxonomy of Viruses.[1] Initial cases of COVID-19 were identified in Wuhan, Hubei Province, China in December 2019. The epidemic later spread to other countries, reaching Egypt and Africa on 14 February 2020. On 11 March 2020, the disease was declared by the WHO a global pandemic.[2]

Proper clinical management and control of this pandemic warrant laboratory diagnosis and testing of appropriate specimens from patients meeting the suspected case

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definition for COVID-19 as a priority.[3] Detection of viral nucleic acid using nucleic acid amplification tests such as reverse transcription-PCR (RT-PCR) is the gold standard for diagnosis of SARS-CoV-2 infection.[1] Real-time RT-PCR assays are characterised by rapid detection and high sensitivity and specificity and hence recommended for diagnosis of early COVID-19 infections.[4]

The RT-PCR assay is complex, time-consuming and associated with risk of eliciting false-negative and false-positive results because it is easily affected by factors such as collection time, sample type and nature of sample preservation.[5 6] Each PCR test may cost hundreds of dollars and requires the use of sophisticated equipment and expensive reagents.[7] According to the Ministry of Health in Uganda, each PCR diagnostic test (WHO-approved) costs approximately $65. This high cost is a potential barrier to majority of the population. Furthermore, this method is unable to meet the principles of early detection, early isolation and early treatment and hence not favourable for prevention and control of the epidemic.[5]

Existing evidence also highlights inconsistencies in the diagnostic accuracy of these assays. More so, most of the evidence on diagnostic accuracy is largely from developed countries, where the COVID-19 curves are flattening. Low-income and middle-income settings are now the epicentre of the pandemic, yet evidence on the diagnostic accuracy of existing tests is largely lacking. This review addresses this knowledge gap on the diagnostic accuracy of available assays to further strengthen the role of testing in the COVID-19 response in these settings.

Rationale

According to a systematic review and meta-analysis of articles on diagnostic accuracy from China, Denmark, Italy, Japan, Spain, Sweden, UK, USA and Germany, the pooled sensitivity of ELISA measuring IgG or IgM was 84.3%, for lateral flow immunoassays was 66.0% and for chemiluminescent immunoassays was 97.8%.[8] In the same study, the pooled specificity ranged from 96.6% to 99.7%.[8] In a similar meta-analysis of studies from North and South America, Europe and China, the average sensitivity of rapid antigen tests was 56.2% and the average specificity was 99.5%.[9] In the same study, the average sensitivity of rapid immunoassays was 95.2% and the specificity was 98.9%.[9] Based on the findings of these review studies, the diagnostic accuracy of these assays varies and remains questionable. Also, these reviews may not be used to depict the diagnostic accuracy of assays in low-income and middle-income countries (LMICs). Therefore, there is a need to review the diagnostic test accuracy of these tests in LMICs as they are key in the fight against the pandemic.

According to Fryback and Thornbury,[10] it is necessary to assure the efficacy of a diagnostic technique at six levels. This involves determining the technical quality (does the test measure what it purports to measure?), diagnostic accuracy (sensitivity and specificity of the test), diagnostic thinking efficacy (does the test help clinicians come to a diagnosis?), therapeutic efficacy (does it aid in planning treatment?), whether patients benefit from the use of the test, and the societal efficacy (cost–benefit and cost-effectiveness).[11] This review therefore seeks to generate evidence-based recommendations that support the effectiveness of testing strategies and the utility of testing in the control and management of COVID-19 in LMICs through a rapid review.

Table 1 The PICOST model for the review question

PICOST element	Description
Population/setting	Adults (18 years and above) in LMIC settings as defined by the World Bank.
Intervention/exposure	New index laboratory test; peripheral laboratory testing strategy or mass testing (pooling).
Comparator	Reference tests for COVID-19 (gold standard) and the current standard of testing strategy (centralised and individualised).
Outcome	Types of tests available; diagnostic test accuracy (sensitivity, specificity, predictive values); costs and cost–effectiveness of the tests; relative risk of testing strategy.
Study design	Diagnostic accuracy studies of observational design (cross-sectional, case–control and cohort studies), and diagnostic strategy studies of experimental design or randomised trials on COVID-19 laboratory testing.
Timing of outcome assessment	72 hours.

LMIC, low-income and middle-income country.

METHODS

The evidence synthesis will be protocol-driven. The protocol is registered with the International Prospective Register of Systematic Reviews (PROSPERO; https://www.crd.york.ac.uk/prospero/) and will be published in a peer-reviewed journal after further development following the statement of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines for diagnostic test accuracy studies (PRISMA-DTA).[12]

Review question

The review question is: what is the effectiveness of laboratory testing strategy for COVID-19 in hospitals and community populations in LMICs?

Our review will be guided by the following elements of PICOST (population/setting, intervention/exposure, comparator, outcome, study design, timing of outcome assessment) (table 1).

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Outcomes

The primary outcome is the diagnostic test accuracy (sensitivity and specificity) of COVID-19 laboratory test methods in LMICs. The secondary outcomes are the types of COVID-19 tests that are available in LMICs, the effect (relative risk) of the testing strategy, and the cost and cost-effectiveness (incremental cost-effectiveness ratio, ICER) of the various COVID-19 testing algorithms.

Eligibility and selection of studies

Studies will be included if they are published in peer-reviewed journals from January 2020 to present; are studies about PCR assay tests for COVID-19 and rapid point-of-care diagnostic tests; studies conducted on adults (18 years and above) in LMIC settings; and observational studies (cross-sectional, case–control and cohort studies), systematic reviews and randomised controlled trials on COVID-19 laboratory testing.

We intend to exclude studies about index COVID-19 tests without a reference standard; clinical COVID-19 diagnosis alone without verification with any laboratory test; modelling studies on COVID-19 testing; manufacturers' brochures on COVID-19 testing; studies on children <18 years as they are an unlikely source of transmission; or COVID-19 laboratory tests not recommended by the WHO.

Data sources

Article search will be performed on the following databases: PubMed, Google Scholar, MEDLINE, Scopus, Web of Science and the WHO Global Index Medicus. Manual searches will be conducted in websites of organisations championing COVID-19 management for grey literature, including but not limited to manufacturers of COVID-19 laboratory tests; Centers for Disease Control and Prevention in Africa, China, Europe and the USA; the WHO; specialised research institutions in Africa, such as the Uganda Virus Research Institute and Kenya Medical Research Institute; and departments of health such as the Ministry of Health in Uganda, South Africa (Southern Africa), Nigeria (West Africa), and Rwanda and Kenya (Eastern Africa). A list of key experts in diagnosis and testing will be developed and contacted to obtain more information on this subject matter.

Search strategy

The search strategy was developed by our information science specialist (AAK). This search strategy was piloted in PubMed to test for precision of appropriate articles retrieved. We will identify additional relevant articles by manually searching the reference list of selected articles, consulting experts in this field, and searching targeted libraries and websites such as Cochrane and COVID-END.

Search terms

We will use the following search terms: COVID-19, 2019-nCOV, novel corona virus disease, Wuhan pneumonia, severe acute respiratory syndrome related corona virus-2, SARS-CoV-2 and corona virus disease-19. We will also use the following Medical Subject Heading (MeSH) terms to identify the tests: testing, tests, diagnosis, diagnostics, COVID-19 'point of care tests', Wuhan corona virus tests, laboratory test, corona virus tests and corona virus testing. The search will be limited to LMICs and the search terms will be combined using Boolean operators (AND, OR, NOT) in the electronic search engines.[13] This search string from PubMed will be adapted to the syntax of other targeted databases for this review (online supplemental file 1).

Data management, screening and selection

The EndNote software will be used for the initial management of references of the search results. These will later be exported to online open access review management software for screening, coding and analysis. The retrieved articles will be exported to EndNote and duplicates will be removed. The studies will then be screened in duplicate following a priori criteria for eligibility (online supplemental file 2). The screening will be performed independently by two review team pairs (OKO, KE, NL and EN), and any disagreements between the reviewers will be resolved by consensus, with further disagreements referred to a tie breaker (EAO or MO).

Data abstraction and coding

The data abstraction form will be developed in an Excel 2007 spreadsheet. The coding process will be performed independently by two research team members (OKO, KE, NL and EN), whose results will be reconciled. Disagreements will be resolved through discussion, and later independent senior reviewers (EAO and MO) will validate the results for quality control and assurance to ensure completeness and correctness.

The following data will be extracted from the articles in a table format: author, year of publication, author affiliation, study design, funding source and other PICOST items, as shown in table 1. The outcome data items are the types of tests available, diagnostic test accuracy (sensitivity, specificity, predictive values), costs and cost-effectiveness of the tests, and relative risk of the testing strategy (online supplemental file 3).

Framework for review synthesis

Our review will be guided by the Fryback and Thornbury[10] framework to establish diagnostic test efficacy, focusing on three levels. These are 'technical efficacy', 'diagnostic accuracy efficacy' and 'societal efficacy'. This six-tiered model is a continuum for diagnostic test efficacy and assesses the effectiveness of laboratory testing strategy for COVID-19 among hospitals and community populations in LMICs. The other levels are 'diagnostic thinking efficacy', 'therapeutic efficacy' and 'patient outcome efficacy' and are less applicable to this review.

Briefly, the following are the three levels of interest: (1) Technical efficacy concerns physical parameters describing the technical quality of a diagnostic test. These are derived under optimal laboratory conditions

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and are prerequisites to consideration of efficacy at all subsequent levels. These include the turnaround time, type of the sample and diagnostic test algorithm, that is, single test or series of tests. (2) Diagnostic accuracy efficacy is characterised by the yield of abnormal or normal diagnoses in a case series. This will be measured as a percentage of the correct diagnoses in the case series, the positive and negative predictive values, and the sensitivity and specificity of a given COVID-19 laboratory diagnostic test. (3) Societal efficacy goes beyond the individual risk and benefit of a given COVID-19 test and denotes the cost borne by the society as whole for the diagnostic test to be acceptable for use regardless of the efficacy of the test on individual patient application at any other level. We will estimate whether a given COVID-19 laboratory test is efficacious to an extent that it is an efficient use of resources and provides medical benefits to the society given the low-income and middle-income setting. We will calculate the cost per unit output (measures from level 1 to 6) of a given COVID-19 diagnostic test and the cost-effectiveness by calculating the ICER as a difference between the costs of two given COVID-19 laboratory tests divided by the difference in their effects (measures from level 2).

To determine the relative risk/effect of the testing strategy, we will conduct regression analysis with a random effects model and estimate the relative risk ratios to identify the types of strategies which are associated with optimal strategies associated with optimal specificity and sensitivity cut-offs. Relative risk ratios and CIs will be reported.

Data synthesis

The syntheses will be in the form of summary of findings tables, simple graphs and forest plots, as applicable, using STATA V.15. The Fryback and Thornbury framework[10] will guide this synthesis. First, a structured narrative synthesis of the results will be conducted. This will describe the types of data available, including the tests and the study design. Second, the quantitative synthesis will be outcome-based considering the primary outcome (diagnostic test accuracy of COVID-19 laboratory tests) and the secondary outcomes (costs, cost-effectiveness, turnaround times and the diagnostic testing strategy: centralised versus peripheral; and targeted individual testing versus pooling of samples for scale-up). We will use mixed effects model with the Duckworth-Lewis-Stern method to calculate the overall target score for accuracy. Reporting of these findings will be in line with the PRISMA-DTA statement.[12]

Risk of bias assessment

Two reviewers (EN, OKO, NL or KE) will independently evaluate the methodological quality using the Quality Assessment of Diagnostic Accuracy Studies approach (QUADAS-2 tool).[14] Bias will be assessed by making judgements (high, low and unclear) on individual elements from five domains (selection bias, attrition bias, performance bias, reporting bias, detection bias and other biases, ie, conflict of interest). Any disagreements will be resolved through discussion and involvement of a senior reviewer (MO or EAO).

Publication bias

All included articles will be assessed for publication bias based on the asymmetry of the funnel plot and/or Egger's test,[15] as appropriate; these are simple rank-based data augmentation techniques which have been proven to be accurate in assessing publication bias due to missing studies.[16] We will plot funnel plots and use the symmetry of the plots to detect the likelihood of publication bias among the articles included in the review. Graphically, in the absence of missing studies, the shape of the scatter plot resembles a symmetrical inverted funnel with a wide base and a narrow top. The presence of large 'holes'—most often seen close to the bottom—or asymmetry in the plot indicates publication bias, but could also be explained by other factors such as study heterogeneity.

Heterogeneity

To assess the level of statistical heterogeneity in the articles, I^2 statistics will be used.[22 17] The I^2 statistics will indicate percentage (%) heterogeneity that can be attributed to between-study variance. An I^2 of 25% indicates low heterogeneity, I^2 of 50% moderate heterogeneity and I^2 of 75% high heterogeneity. Subgroup analysis will be done on articles with low and moderate heterogeneity.

Quality assessment

To assess the quality of evidence from the reviews, we will use AMSTAR 2 (A Measurement Tool to Assess Systematic Reviews), which is a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions or both.[18] The tool contains 10 domains against which the articles are assessed for quality. The overall quality of evidence will be assessed using a modified Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach, where we will assign certainty of evidence ratings for the outcome variables listed above based on an approach developed by the GRADE Working Group[19] and will be done in duplicate, with any disagreements resolved by consensus.

Ethics approval and consent to participate

The review protocol was reviewed and approved by the Makerere University School of Biomedical Sciences Institutional Review Board and the Uganda National Council for Science and Technology.

Patient and public involvement

There was no patient and public engagement in the design, interpretation or dissemination of the findings nor will it be required in this review since it will use already published data.

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Contributors Conception of the work: MO, EAO and NS. Acquisition of data: OKO, KE, NL, EN, FN, RN, RNW, BAK, TK, AEO, RA, DS, AL, AAK, NS, SNB, MO and EAO. Drafting the work: EN, NL, OKO and KE. Final approval: all authors. OKO, KE, NL, NE, FN, RN, RNW, BAK, TK, AEO, RA, DS, AL, AAK, NS, SNB, MO and EAO reviewed and approved the final manuscript.

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Electronic Search Strategy In PubMed: https://pubmed.ncbi.nlm.nih.gov/

Search #1: Corona Virus

(Coronavirus OR Corona virus OR Coronavirus-2 OR Corona virus-2 OR Novel coronavirus OR Novel corona virus OR Coronavirus Infection* OR Corona virus Infection* OR Coronavirus disease OR Corona virus disease OR Coronavirus disease 2019 OR Corona virus disease 2019 OR Coronavirus disease-19 OR Corona virus disease-19 OR 2019 novel coronavirus OR 2019 novel corona virus OR 2019 novel coronavirus disease OR 2019 novel corona virus disease OR 2019 novel coronavirus disease OR 2019 novel coronavirus infection* OR 2019 novel corona virus infection* OR Novel Respiratory 2019 OR Coronavirus OR Novel Respiratory 2019 Corona virus OR 2019-nCoV infection* OR 2019-nCoV OR COVID-19 OR COVID19 OR COVID-19 virus infection* OR COVID-19 pandemic OR SARS-Cov-2 OR SARS-CoV-2 infection* OR SARS-COV2 OR Wuhan pneumonia)[Text Word])

AND

Search #2: Testing

((Test*[Mesh Terms] OR (Test* OR Diagnos* OR Point of care test* OR Laboratory test* OR Antibod* OR Diagnostic kit OR Antigen test* OR Antigen detect* OR Antigen reagent OR Antigen strip* OR Rapid test* OR Rapid kit* OR IgM OR IgG OR IgA OR Serological OR ELISA)[Title/Abstract]))

AND

Search #3: Low and Middle Income Countries

(afghan[Text Word] OR afghans[Text Word] OR afghani[Text Word] OR albanian[Text Word] OR albanians[Text Word] OR algerian[Text Word] OR algerians[Text Word] OR american samoan[Text Word] OR american samoans[Text Word] OR angolan[Text Word] OR angolans[Text Word] OR antiguan[Text Word] OR antiguans[Text Word] OR barbudan[Text Word] OR berbudans[Text Word] OR argentine[Text Word] OR argentines[Text Word] OR argentinian[Text Word] OR argentinians[Text Word] OR argentinean[Text Word] OR argentineans[Text Word] OR armenian[Text Word] OR armenians[Text Word] OR aruban[Text Word] OR arubans[Text Word] OR azerbaijani[Text Word] OR azerbaijanis[Text Word] OR bahraini[Text Word] OR bahrainis[Text Word] OR bangladeshi[Text Word] OR bangladeshis[Text Word] OR bangalees[Text Word] OR bajan[Text Word] OR bajans[Text Word] OR belarusian[Text Word] OR belarusians[Text Word] OR byelorussian[Text Word] OR byelorussians[Text Word] OR belizean[Text Word] OR belizeans[Text Word] OR beninese[Text Word] OR benineses[Text Word] OR bhutanese[Text Word] OR bolivian[Text Word] OR bolivians[Text Word] OR bosnian[Text Word] OR bosnians[Text Word] OR botswana[Text Word] OR batswana[Text Word] OR brazilian[Text Word] OR brazilians[Text Word] OR brasilian[Text Word] OR brasilians[Text Word] OR bulgarian[Text Word] OR bulgarians[Text Word] OR burkinabe[Text Word] OR burkinese[Text Word] OR burundian[Text Word] OR burundians[Text Word] OR cape verdean[Text Word] OR cape verdeans[Text Word] OR cabo verdean[Text Word] OR cabo verdeans[Text Word] OR cambodian[Text Word] OR cambodians[Text Word] OR khmer[Text Word] OR cameroonian[Text Word] OR cameroonians[Text Word] OR central african[Text Word] OR central africans[Text Word] OR chadian[Text Word] OR chadians[Text Word] OR chilean[Text Word] OR chileans[Text Word] OR chinese[Text Word] OR colombian[Text Word] OR colombians[Text Word] OR comorian[Text Word] OR comorians[Text Word] OR congolese[Text Word] OR costa rican[Text Word] OR costa ricans[Text Word] OR ivorian[Text Word] OR ivorians[Text Word] OR croatian[Text Word] OR croatians[Text

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Word] OR cuban[Text Word] OR cubans[Text Word] OR cypriot[Text Word] OR cypriots[Text Word] OR czech[Text Word] OR czechs[Text Word] OR djiboutian[Text Word] OR djiboutians[Text Word] OR dominican[Text Word] OR dominicans[Text Word] OR ecuadorian[Text Word] OR ecuadorians[Text Word] OR egyptian[Text Word] OR egyptians[Text Word] OR salvadoran[Text Word] OR salvadorans[Text Word] OR equatorial guinean[Text Word] OR equatorial guineans[Text Word] OR equatoguinean[Text Word] OR equatoguineans[Text Word] OR eritrean[Text Word] OR eritreans[Text Word] OR estonian[Text Word] OR estonians[Text Word] OR swazi[Text Word] OR swazis[Text Word] OR swati[Text Word] OR swatis[Text Word] OR ethiopian[Text Word] OR ethiopians[Text Word] OR fijian[Text Word] OR fijians[Text Word] OR gabonese[Text Word] OR gabonaise[Text Word] OR gambian[Text Word] OR gambians[Text Word] OR georgian[Text Word] OR georgians[Text Word] OR ghanaian[Text Word] OR ghanaians[Text Word] OR gibraltarian[Text Word] OR gibraltarians[Text Word] OR greek[Text Word] OR greeks[Text Word] OR grenadian[Text Word] OR grenadians[Text Word] OR guamanian[Text Word] OR guamanians[Text Word] OR guatemalan[Text Word] OR guatemalans[Text Word] OR guinean[Text Word] OR guineans[Text Word] OR bissau guinean[Text Word] OR bissau guineans[Text Word] OR guyanese[Text Word] OR haitian[Text Word] OR haitians[Text Word] OR honduran[Text Word] OR hondurans[Text Word] OR hungarian[Text Word] OR hungarians[Text Word] OR indian[Text Word] OR indians[Text Word] OR indonesian[Text Word] OR indonesians[Text Word] OR iranian[Text Word] OR iranians[Text Word] OR iraqian[Text Word] OR iraqians[Text Word] OR iraqi[Text Word] OR iraqis[Text Word] OR manx[Text Word] OR jamaican[Text Word] OR jamaicans[Text Word] OR jordanian[Text Word] OR jordanians[Text Word] OR kazakhstani[Text Word] OR kazakhstanis[Text Word] OR kenyan[Text Word] OR kenyans[Text Word] OR kirabati[Text Word] OR kirabatian[Text Word] OR kirabatians[Text Word] OR korean[Text Word] OR koreans[Text Word] OR kosovar[Text Word] OR kosovars[Text Word] OR kosovan[Text Word] OR kosovans[Text Word] OR kyrgyzstani[Text Word] OR kyrgyzstanis[Text Word] OR kyrgyz[Text Word] OR lao[Text Word] OR laotian[Text Word] OR laotians[Text Word] OR latvian[Text Word] OR latvians[Text Word] OR lebanese[Text Word] OR lesothan[Text Word] OR lesothans[Text Word] OR lesothonian[Text Word] OR lesothonians[Text Word] OR mosotho[Text Word] OR basotho[Text Word] OR liberian[Text Word] OR liberians[Text Word] OR libyan[Text Word] OR libyans[Text Word] OR lithuanian[Text Word] OR lithuanians[Text Word] OR macanese[Text Word] OR macedonian[Text Word] OR macedonians[Text Word] OR malagasy[Text Word] OR madagascan[Text Word] OR madagascans[Text Word] OR malawian[Text Word] OR malawians[Text Word] OR malaysian[Text Word] OR malaysians[Text Word] OR maldivian[Text Word] OR maldivians[Text Word] OR malian[Text Word] OR malians[Text Word] OR maltese[Text Word] OR marshallese[Text Word] OR marshalleses[Text Word] OR mauritanian[Text Word] OR mauritanians[Text Word] OR mauritian[Text Word] OR mauritians[Text Word] OR mexican[Text Word] OR mexicans[Text Word] OR micronesian[Text Word] OR micronesians[Text Word] OR moldovan[Text Word] OR moldovans[Text Word] OR mongolian[Text Word] OR mongolians[Text Word] OR mongol[Text Word] OR montenegrin[Text Word] OR montenegrins[Text Word] OR moroccan[Text Word] OR moroccans[Text Word] OR mozambican[Text Word] OR mozambicans[Text Word] OR burmese[Text Word] OR myanma[Text Word] OR namibian[Text Word] OR namibians[Text Word] OR nauruan[Text Word] OR nauruans[Text Word] OR nepali[Text Word] OR nepalese[Text Word] OR netherlands antillean[Text Word] OR netherlands antilleans[Text Word] OR nicaraguan[Text Word] OR nicaraguans[Text Word] OR nigerien[Text Word] OR nigeriens[Text Word] OR nigerian[Text Word] OR nigerians[Text Word] OR northern mariana islander[Text Word] OR northern mariana islanders[Text Word] OR mariana[Text Word] OR marianas[Text Word] OR omani[Text Word] OR omanis[Text Word] OR pakistani[Text Word] OR pakistanis[Text Word] OR palauan[Text Word] OR palauans[Text Word] OR panamanian[Text Word] OR panamanians[Text Word] OR papua new guinean[Text Word] OR papua

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AND

Search #4: Time limits at the time COVID-19 was described to date

Filters: From 2019-2021

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PRISMA-P 2015 Checklist

This checklist has been adapted for use with protocol submissions to *Systematic Reviews* from Table 3 in Moher D et al: Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Systematic Reviews* 2015 **4**:1

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
ADMINISTRATIVE INFORMATION					
Title					
Identification	1a	Identify the report as a protocol of a systematic review	☒	☐	1-3
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	☐	☐	Not applicable
Registration	2	If registered, provide the name of the registry (e.g., PROSPERO) and registration number in the	☒	☐	83, 145-146 CRD42020209528

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
		Abstract			
Authors					
Contact	3a	Provide name, institutional affiliation, and e-mail address of all protocol authors; provide physical mailing address of corresponding author	☒	☐	11-42 Names: Ojiambo Kevin Ouma[1,2], Kisangala Ephraim[1,3], Eve Namisango[1,4], Nakalembe Loyce[1,5], Nalugoda Fred[1, 6], Regina Ndagire[1,3], Rachel Nante Wangi[1,3], Brenda Allen Kawala[1,7] Thomas Katairo[1,8], Allen Eva Okullo[1,2], Robert Apunyo[1], Daniel Semakula[1, 10]Ash Luwambo[1,11], Alison A. Kinengyere[1,10], Nelson K. Sewankambo[1,2,6,], Sheila N. Balinda[12,] Moses Ocan[1,2,13], Ekwaro A. Obuku[1,2,14] Author Affiliations pages 400-422 1. Africa Centre for Systematic Reviews and Knowledge Translation, College of Health Sciences, Makerere University, Kampala, Uganda 2. Clinical Epidemiology Unit, Department of Medicine, College of Health Sciences, Makerere University, Kampala, Uganda 3. Kairos Hospital, Namuwongo, Kampala, Uganda 4. Cicely Saunders Institute, King's College London 5. Department of pharmacology, College of Medicine, Health and Life sciences, King Ceasor University, Kampala, Uganda 6. Rakai Health Sciences Program (RHSP), School of Public Health, College of Health Sciences, Makerere University, Kampala, Uganda. 7. Section for Epidemiology and Social Medicine, Department of Public Health, Institute of Medicine. The Sahlgrenska Academy at University of Gothenburg, Gothenburg, Sweden 8. Infectious Diseases Research Collaboration (IDRC), Kampala, Uganda 9. Regional East African Community Health (REACH) Policy Initiative, College of Health Sciences, Makerere University, Kampala,

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
					Uganda 10. Albert Cook Library, College of Health Sciences, Makerere University, Kampala, Uganda 11. Communications Section, Makerere University College of Health Sciences, Kampala Uganda. 12. Medical Research Council, Uganda Virus Research Institute, Entebbe, Uganda 13. Department of Pharmacology, School of Biomedical Sciences, College of Health Sciences, Makerere University, Kampala, Uganda 14. Faculty of Epidemiology and Population Health, London School of Hygiene and Tropical Medicine, London, United Kingdom Email address Pages 310-318 [1,2]Kevin.O.Ouma,ojambok@gmail.com;[1,3]EphraimKisangala,ephraimkis@gmail.com;[1,4]EveNamisango,enamisango@gmail.com;[1,5]Loyce,Nakalembe,nakaloy2011@gmail.com,[1,6]FredNalugoda,fnalugoda@rhsp.org;[1,2]ReginaNdagire,ndaginar@gmail.com;[1,2]RachelN.Wangi,wangirachel@gmail.com;[7]BrendaA.Kawala,brendakawala@gmail.com,[1,8]ThomasKatairo,katairothomas@gmail.com;[1]RobertApunyo,rapuny@gmail.com;[1,2,6,9]DanielSemakula,semakuladaniel@gmail.com,[1,10]AlisonA.Kinengyere,alison.kine@gmail.com,[1],[11]AshLuwambo,[1,2,6,9]Sewankambo,sewankam@infocom.co.ug,[12]Sheila N.Balinda,sbalinda@gmail.com, [1,13]MosesOcan,ocanmoses@gmail.com, [1,3,14] Ekwaro A. Obuku, ekwaro@gmail.com
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the	☒	☐	294-298 MO, EAO and KOO developed the idea into a concept. KOO, EK, EN and LN wrote the initial protocol and AAK developed the search strategy, which was then piloted by the study team. MO and EAO appraised the draft protocol, reviewed and approved final version for publication. All authors read, critiqued and approved the final version of the protocol.

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
		review			
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	☐	☐	Not applicable
Support					
Sources	5a	Indicate sources of financial or other support for the review	☒	☐	289-291 This study is funded by Makerere University Research and Innovation Fund, (MakRIF-COVID-19 fund).
Sponsor	5b	Provide name for the review	☒	☐	289-291

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
		funder and/or sponsor			This study is funded by Makerere University Research and Innovation Fund, (MakRIF-COVID-19 fund). The funder had no role in developing the protocol.
Role of sponsor/funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	☒	☐	291 The funder/sponsor had no role in developing the protocol
INTRODUCTION					
Rationale	6	Describe the rationale for the review in the context of what is already known	☒	☐	132-143
Objectives	7	Provide an explicit statement of the question(s) the review will address with	☒	☐	149-151 What is the effectiveness of laboratory testing strategy for COVID-19 among hospital and community populations in LMICs?

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
		reference to participants, interventions, comparators, and outcomes (PICO)			
METHODS					
Eligibility criteria	8	Specify the study characteristics (e.g., PICO, study design, setting, time frame) and report characteristics (e.g., years considered, language, publication status) to be used as criteria for eligibility for the review	☒	☐	152-154, 161-170 *Inclusion criteria* Articles published in peer reviewed journals from January 2020 -to-date Articles on polymerase chain reaction (PCR) assay tests for COVID-19, Rapid/ point of care diagnostic tests, and serology tests (IgG, IgM) in LMICs Articles of studies conducted on Adults (18 years and above) in LMIC settings Article of observational studies (cross sectional, case control and cohort studies), systematic reviews and Randomized Control Trials on COVID-19 laboratory testing *Exclusion criteria* Articles on index COVID-19 tests without a reference standard Articles on clinical COVID-19 diagnosis alone without verification with any laboratory test

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
					Articles of Modeling studies on COVID-19 testing Manufacturers brochures on COVID-19 testing Articles done in children <18 years as they are an unlikely source of transmission Articles on COVID-19 laboratory tests not recommended by WHO
Information sources	9	Describe all intended information sources (e.g., electronic databases, contact with study authors, trial registers, or other grey literature sources) with planned dates of coverage	☒	☐	171-181 Search will be performed on the following databases; PubMed, Google Scholar, MEDLINE , SCOPUS, Web of Science and the WHO Global Index Medicus. Manual searches will be conducted in websites of organizations championing COVID-19 management for grey literature including but not limited to; Manufacturers of COVID-19 laboratory tests, Centers for disease control and prevention (CDC) in Africa, China, Europe and the USA, World Health Organization (WHO), Specialized research institutions in Africa such as the Uganda Virus Research Institute (UVRI) and Kenya medical research institute (KEMRI) and Departments of Health in Uganda such as the Ministry of Health Uganda, South Africa, Nigeria, Rwanda and Kenya. A list of key Experts in diagnosis and testing was also developed and contacted to get more information on this subject matter.
Search strategy	10	Present draft of search strategy to	☒	☐	155-164 SN | DATABASE | SEARCH STRATEGY | RESULTS

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Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
		be used for at least one electronic database, including planned limits, such that it could be repeated			

1	PUBMED-SEARCHED 5 JULY 2020	In Text Word: Coronavirus Corona virus Coronavirus-2 Corona virus-2 Novel coronavirus Novel corona virus Coronavirus Infection* Corona virus Infection* Coronavirus disease Corona virus disease Coronavirus disease 2019 Corona virus disease 2019 Coronavirus disease-19 Corona virus disease-19 2019 novel coronavirus 2019 novel corona virus 2019 novel coronavirus disease	43,741

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Section/topic	#	Checklist item	Information reported		Line number(s)			
			Yes	No				
							2019 novel corona virus disease 2019 novel coronavirus disease 2019 novel coronavirus infection* 2019 novel corona virus infection* Novel Respiratory 2019 Coronavirus Novel Respiratory 2019 Corona virus 2019-nCoV infection* 2019-nCoV disease COVID-19 COVID19 COVID-19 virus infection* COVID-19 pandemic SARS-Cov-2 SARS-CoV-2 infection* SARS-COV2 Wuhan pneumonia)	
							Test*[Mesh Terms]	6,073,060

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Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
					In TiAb: Test* Diagnos* Point of care test* Laboratory test* Antibod* Diagnostic kit Antigen test* Antigen detect* Antigen reagent Antigen strip* Rapid test* Rapid kit* IgM IgG IgA Serological ELISA

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
					1 AND 2 — 11,120 LMICs (see filter below) — 1,984,565 1 AND 2 AND 3 — 3,126 "2020"[Date - Publication]) — 1,707 Relevant studies after pilot screening of 100 articles — 13
STUDY RECORDS					
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	☒	☐	210-213
Selection process	11b	State the process that will be used for selecting studies (e.g., two independent reviewers) through each	☒	☐	197-204 The retrieved articles will be exported to Endnote and duplicates removed. The studies shall then be screened in duplicate following *a priori* criteria and the PRISMA guidelines. The screening will be performed independently by two review team pairs (KOO, EK, LN and EN), any disagreements between the reviewers will be resolved by consensus and further disagreements referred to the tie breaker (EAO or OM).

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
		phase of the review (i.e., screening, eligibility, and inclusion in meta-analysis)			
Data collection process	11c	Describe planned method of extracting data from reports (e.g., piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	☒	☐	219-238
Data items	12	List and define all variables for which	☒	☐	152-154

PICOST element	Description

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
		data will be sought (e.g., PICO items, funding sources), any pre-planned data assumptions and simplifications			Population: Adults (18 years and above) in LMIC settings Intervention/ Exposure: New index laboratory test; peripheral laboratory testing strategy or mass testing (pooling) Comparator: Reference tests for COVID-19 (gold standard); current standard of testing strategy (centralized and individualized) Outcome: Types of tests available; diagnostic test accuracy (sensitivity, specificity, predictive values); costs and cost–effectiveness of tests; relative risk of testing strategy Study designs: Observational studies (cross sectional, case control and cohort studies), and Randomized Control Trials on COVID-19 laboratory testing Setting: Low- and middle-income countries (LMIC) Timing of outcome assessment: Jan 2020 to date
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with	☒	☐	232-241 1) Primary outcome: The primary outcome of this review will be the Diagnostic test accuracy of COVID-19 laboratory test methods in LMICs. Given that these tests are being issued under emergency authorization, a dearth of evidence for their accuracy exists in resource limited settings, and hence the prioritization. 2) Secondary outcomes: The secondary outcomes of this review shall be the types of COVID-19 tests that are available in low- and middle-income countries; the cost of each type of COVID-19 test available in low- and middle-income countries; the utility of testing for control of COVID-19 in low- and middle-income countries; relative risk / effect of the testing strategy and costs and cost-effectiveness (ICER) of the various COVID-19 testing algorithms.

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Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
		rationale			
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	☒	☐	255-270
DATA					
Synthesis	15a	Describe criteria under which study data will be	☒	☐	244-254

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
		quantitatively synthesized			
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data, and methods of combining data from studies, including any planned exploration of consistency (e.g., I^2, Kendall's tau)	☒	☐	270-274
	15c	Describe any proposed additional analyses	☐	☒	Not applicable

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
		(e.g., sensitivity or subgroup analyses, meta-regression)			
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	☐	☐	
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (e.g., publication bias across studies, selective reporting within studies)	☒	☐	262-270
Confidence	17	Describe how the	☒	☐	280-283

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Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
in cumulative evidence		strength of the body of evidence will be assessed (e.g., GRADE)			

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Study ID	Lead author	Type of reference (journal article, WHO document	Publication year

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Year of data collection	Country(tries) where study was done	Citation	Funder

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ethical approval obtained?	Name of ethics approving body	Design	Median age	study population or partcipants

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Severity of disease	Type of test	setting for the testing	sample size	sample size - cases

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Sample size-control arm	Response rate	Details of the test	Matrix used	samples tested onsite

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sample transported and tested off site	Cost of test	Funder for the test (self and funded)	TAT	measure for covid detection under PCR

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measure for covid detection	Positives - PCR	Positives - point of care test	positives cuture test	Negatives - PCR	Negatives- point of care test

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Sensitivity - PCR	Sensitivity - point of care test	Specificity - PCR	Specificity- point of care test	Test side-effects	PPV FOR PCR

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PPV FOR POC TEST	NPV-PCR	NPV-POC TEST	Total positive cases	Total negative cases	Total positive (prevalence) %

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Total negative %	cost effectiveness	other comments

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