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

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

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

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: Yes	Information reported: No	Line number(s)
		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.

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

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)			