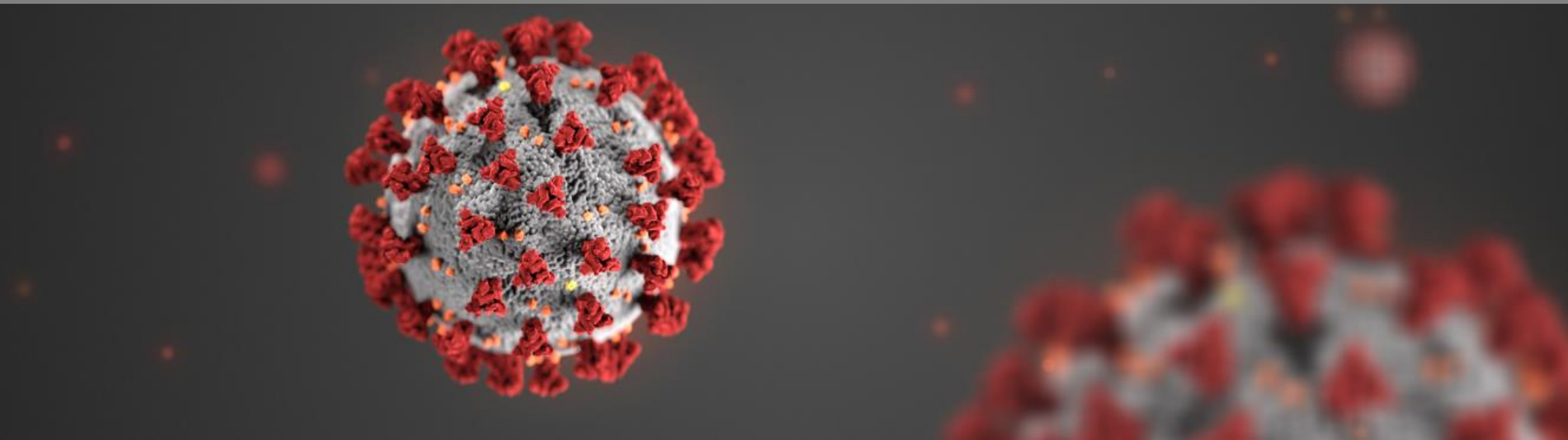
TONY BLAIR INSTITUTE FOR GLOBAL CHANGE

COVID-19: Guide to Procuring Antibody Tests

June 2020



Top considerations for policymakers

1. **Antibody testing will help to refine our knowledge of the virus and estimate its spread in different segments of the population,** especially in low-resource environments where PCR testing supplies and/or capacity is severely constrained. While not a direct substitute for PCR testing, antibody tests can provide rapid and cheaper complementary data points to help policymakers understand transmission chains, and inform the allocation of limited response resources. This can also support scientists by contributing to emerging evidence on the role of different types of antibody in conferring immunity and, in particular, how long immunity is likely to last.

2. **As scientific understanding develops, testing kit performance is refined and global supply increases,** governments can use reliable Covid-19 prevalence information obtained through antibody testing to make decisions around easing restrictions for individuals and different sections of society.

3. **Global demand for reliable antibody tests far outstrips supply.** Most attention is focused on especially promising tests manufactured by major, established biotechnology companies. While these outfits are best positioned to ramp up production, they are unlikely to be able to meet the world's demands alone, especially in the short term. Governments should explore a range of options while ensuring high-quality standards to meet their needs. Different manufacturers' tests can be used simultaneously so long as results are comparable.

4. **In low-resource settings, antibody testing is currently most useful for surveillance and research.** The most practical and valuable tests for carrying out Covid-19 prevalence surveys at scale are likely to be rapid tests with specificity and sensitivity of greater than 95%, which deliver a qualitative result and detect both IgM and IgG antibodies. However, performance of tests should be selected according to intended use.

Roadmap to procurement

Strategise

- Define the **purpose and scope** of your antibody testing regime in the context of your wider testing strategy.

Specify

- Determine the **design** of your test, including **type of antibody** it must detect and **type of patient sample** it requires**.**
- Determine your required **performance specification.**
- Consider **procedural attributes and operating conditions** to maximise ease-of-use.

Procure

- Budget appropriately by considering the full range of costs.
- Estimate the **number of test kits** you will require.
- Choose your **procurement mechanism**.
- Undertake rigorous **scientific and commercial due diligence.**
- **Place your order**.

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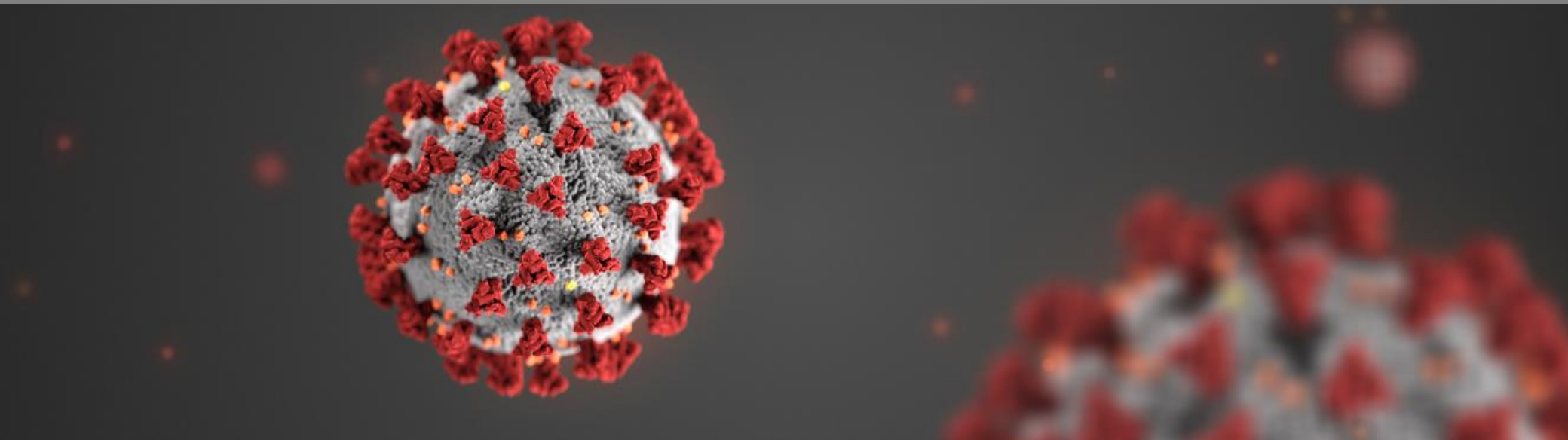
Strategise

- Define the **purpose and scope** of your antibody testing regime in the context of your wider testing strategy.



Define the purpose and scope of your antibody testing regime in the context of your wider testing strategy.

Purposes for carrying out antibody testing

Support diagnosis of suspected cases and conduct surveillance by investigating chains of transmission	Better understand how the virus has affected your population	Understand the state of immunity at individual patient and societal level
Triage suspected symptomatic cases where PCR testing is severely limited, or establish likely stage of infection by comparing PCR and antibody testing of an active case.	Establish what proportion of the population has had the virus and how this differs across demographic groups.	Establish what proportion of your recovered patients have retained antibodies developed during the infection.
Where confirmed case has no immediately obvious source, using rapid antibody testing on larger potential source populations may help – for example, in a specific health facility, school or neighbourhood.	Understand symptoms and clinical outcomes for patients with a milder infection which did not require treatment.	Help individual patients understand if they are likely to be immune from reinfection and can safely return to work in high-exposure environments (e.g. health workers), and would donate convalescent plasma for treatment of other patients.
 **The state of Kerala is using antibody testing** where clusters of cases are reported in the community with an unknown source of infection.	 **England tests 1,000 samples per region stratified by age, to estimate prevalence in different groups**, which may reflect differing behaviour and mixing patterns. Repeated weekly to understand how prevalence is changing over time.	 Institut Pasteur in France tested 160 hospital workers with PCR-confirmed mild cases. **Virtually all patients had antibodies 13 days after the onset of symptoms**. Neutralising activity of antibodies increased over time.

Note: Antibody testing is not a substitute for PCR testing in the early stages of infection. Antibody testing should not be used as a justification to discharge a patient in the absence of a PCR test, for example, as advised by the Africa CDC. Understanding of immunity conferred by antibodies, including its duration, continues to develop and may vary across patients.

Define the purpose and scope of your antibody testing regime in the context of your wider testing strategy.

Scope of surveillance – on whom?

1  **In what population?**	By order of priority: • **People at high risk of exposure to the virus** – e.g. healthcare and public-facing workers such as public transport workers • **People with comorbidities/personal high risk** – to identify if already recovered and immune, especially if they are shielding • **General population** – to understand full extent of the virus's spread • **Disaggregated** by age, gender, ethnicity, symptom severity – to understand how infection has varied across demographics
2  **In which locality?**	• **Focused** on likely hotspots; areas of suspected community transmission; and urban areas where transmission is likely to be rapid, or in border areas. • **Broadly** for a more general picture of transmission, either in a particular region or nationwide.
3  **Selected how?**	• **Sample of individuals/households contacted, followed by voluntary opt-in –** but consider the quality and completeness of population records, and utilise existing records e.g. from community health programmes and registers of cash transfer recipients. • **Voluntary registration, weighted during analysis to reflect characteristics of target locality –** but consider how certain groups, such as people who suspect they have had the virus, or are able to attend testing locations more easily, may skew the data.

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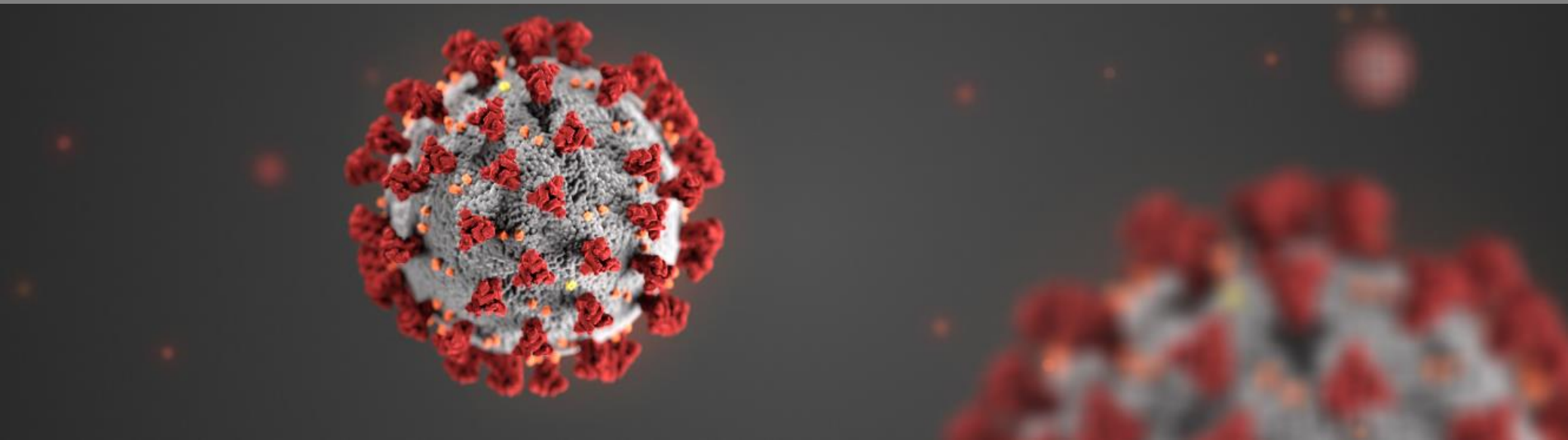
Specify

- Determine the **design** of your test, including **type of antibody** it must detect and **type of patient sample** it requires**,** and identify any **ancillary equipment** needed.
- Determine your required **performance specification.**
- Consider **procedural attributes and operating conditions** to maximise ease-of-use.



Antibody tests vary independently across a wide range of attributes.

Attributes of antibody tests

The most fundamental decisions that will guide procurement are the purpose and scope of the testing regime, which makes certain test attributes essential. Governments must start with and be clear about these decisions.

Design	Performance	Procedure
Result at point-of-care or requires lab analysis	Clinical sensitivity	Storage and operating conditions
Type of antibody the test detects	Clinical specificity	Variation in interpretation of result between readers
Type of human sample it uses and volume it requires	Cross-reactivity with other viruses	
Materials contained in testing kit		

Considerations

Develop a target product profile outlining the minimum and optimal specifications of products you are willing to consider for purchase. This provides a common foundation for all stakeholders to understand your requirements and will form the basis of any invitation to tender documents.

Consider the needs and limitations of your healthcare settings and your financial resources. Trade-offs are likely to be necessary.

- Decide which compromises may be acceptable in order to obtain tests quickly, at an affordable price, and with guaranteed supply.
- Products should achieve as many of the optimal characteristics as feasible while still satisfying minimal criteria for all defined features.
- You may decide a test that does not yet meet all profiles could still have a role in supporting your wider testing strategy.

Design

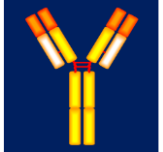
Decide the format of antibody test you will use. You may use both in combination.

	Rapid Diagnostic Tests (RDT)	Lab Analysed Tests
Attributes	Provides a binary result on presence of antibodies. Can be administered in a range of healthcare settings and potentially at home by the patient themselves. Can provide a rapid result (between 15 and 40 minutes after administering specimen). Relatively easy to store. Many come in self-contained tests with most equipment required included.	More accurate than rapid tests and some can provide insight to the number and neutralising power of a patient's antibodies. Require more expertise for both obtaining and analysing specimens. Require more equipment that needs to be purchased separately. Some tests can be automatically analysed in large batches using standard laboratory analyser equipment, others require proprietary analysers produced by same company that manufactures the test reagents.
Types	Most common type is a **lateral flow assay** contained inside a plastic cassette.	Most common type is **enzyme-linked immunosorbent assay (ELISA)**, but other types with different analytical processes are emerging and include neutralisation assay and chemiluminescence immunoassay (CLIA).
Suitability	Most suitable for general understanding of transmission and tracing live chains of transmission.	Essential for understanding individual immunity.

Design

Determine the type of antibody your test must be able to detect.

Types of antibodies

	Indicates	First appears	Peaks
 IgM	First antibodies to be produced by immune system. If detected without IgG, the person has or recently had the virus.	5–7 days after infection	Around 21 days, then declines and becomes undetectable Essential for population studies of virus prevalence
 IgG	More numerous than IgM. If detected without IgM, infection was more than a month ago.	10–14 days after infection	Around 21–28 days and believed to remain detectable in blood to confer immunity Essential for aiding diagnosis

Considerations

- **Antibody response to respiratory viruses is very complex.** IgA antibodies and other cellular mechanisms are likely to play a role but scientific understanding is still emerging.
- Relatively few commercial tests can detect IgA antibodies and existing seroprevalence protocols emphasise IgG and IgM.

- **An increasing number of rapid tests combine IgG and IgM.** While this can help to improve detection rates, the performance of a single test may not necessarily be the same for each type of antibody it claims to detect.
- Sensitivity of a test may vary across patients with different severity of symptoms. Check claims for each type of antibody and establish the severity of patients included in validations.

Indicative only. Data on the production and retention of antibodies continues to evolve.
Source: ScienceDaily

Test format and antibody requirements for different uses

Purpose	Support diagnosis of suspected cases	Better understand how the virus has affected your population	Understand the state of immunity at individual patient and societal level
Format of Test	• **Rapid test acceptable** but lab-analysed tests desirable. • Must be approved for **diagnostic purposes.** • **Must supplement rather than substitute for PCR test.**	• **Rapid test most feasible** for larger sample sizes or general population. • Tests **must be approved for research and surveillance purposes** but not necessarily for diagnostic use.	• **Lab-analysed test essential** to obtain data on number and neutralising power of antibodies produced. • **Tests approved for research and surveillance purposes** but not for diagnostic use acceptable.
Type of Antibody	• **Ideally IgM and IgG**. • **IgM essential** as it is present from earliest stage of infection, during which PCR tests are most likely to return false negatives – but without IgM the likely stage of infection cannot be inferred. • **IgG alone unacceptable** as not detectable until later stages of infection.	• **Ideally IgM and IgG.** • **IgG essential** as it is key indicator that a person has had the disease even after recovery – but without IgM the survey will miss out people in early stage of infection and slightly underestimate prevalence. • **IgM alone unacceptable** as will be undetectable in recovered patients and will hugely underestimate prevalence.	• **Ideally total antibody**. • **IgG essential** as it known to remain in the blood after recovery and is likely to play a key role in immunity. • **IgA desirable** as more research is needed on its role in the immune response to Covid-19. • **IgM alone unacceptable** as will not be detectable in blood after patient is recovered.

Design

Consider how the sample for your selected test type will be obtained.

Sample type

	RDT	ELISA
Method for obtaining sample	 Capillary finger-prick	 Drawn from vein
Person obtaining sample	Healthcare professional including community health workers, and potentially patient for home use.	Healthcare professional trained in phlebotomy
Type of sample required for analysis	 Whole blood	 Plasma or serum
Quantity of sample required for analysis	One or two drops inserted directly into well on rapid-test cassette	Small amount as specified by manufacturer, plus enough for test to be repeated if necessary, stored in blood collection tubes

Considerations

Generally easier to obtain good quality samples for antibody testing (in comparison to PCR testing) but **extraction can still cause discomfort and some patients may seek to avoid diagnostics for this reason.**

Patient specimens should be used as soon as possible after collection and typically immediately for RDT tests. **Consult Clinical and Laboratory Standards Institute and national guidance on transport and storage conditions for samples** that require laboratory analysis.

Rapid testing at home is feasible, though the UK suspended retail of test kits directly to consumers after concerns that improper sample collection by patients may produce unreliable results.

Research is ongoing to understand whether antibody presence varies by sample type and extraction method.

Indicative only of typical tests currently available. Sample requirements may vary by manufacturer and may change as science evolves.

Design

Seek complete, self-contained kits and source any necessary ancillary equipment.

Materials required for obtaining samples and conducting test

	RDT	ELISA
Included in typical test kit	• Test cassette with in-built conjugate pad, negative and positive controls • Sample buffer (ideally in dropper bottle)	• Precoated microplate • Sample dilution buffer • Washing buffer • Substrate solution • Stop solution • Positive control • Negative control • Conjugate
Sometimes included in test kit	• Lancets • Alcohol swabs	• Cover for microplate
Not included – separate purchase necessary	• Gloves • Gauze • Plasters • Sharps box	• Blood-drawing needles • Tourniquet • Plasters • Alcohol swabs • Sharps box • Blood collection tubes • Pipettes • Microplate washer • Microplate reader • Distilled/deionised water • Incubator

Considerations

Self-contained kits with all reagents and controls in a single package simplify procurement, distribution and administration processes. Equipment required for obtaining samples are less likely to be included in kits but are essential.

Kit components **should not be removed from packaging or sealed pouches until they are to be used.** This ensures stability and accurate results.

Components from test kits produced by different manufacturers should not be mixed or substituted.

Controls of human origin included in test kits are a potential infection risk. Identify that they have been tested negative for antigens from diseases such as hepatitis B, hepatitis C and HIV by manufacturer.

Indicative only. Materials provided and required for different tests will vary by manufacturer.

Determine your required performance specification.

Specificity and sensitivity

Many countries are only considering tests with at least 90% sensitivity and 95% specificity. But optimal thresholds of accuracy can be tuned depending on local virus prevalence and intended use.

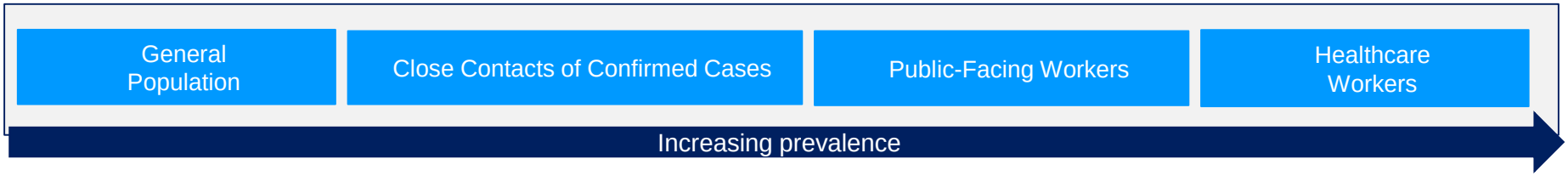
- For general serological studies, especially where there is reason to expect high prevalence of infection in a particular target population, lower-performing tests might be considered. Statistical adjustments can be made for imperfect sensitivity and specificity/test kit error.
- If individual use is to inform patient management, especially where tests are used to determine an individual's immunity, near-perfect specificity is required to maximise positive predictive value.

PPV
NPV

Across a range of sensitivities and prevalence thresholds, negative predictive value remains relatively high – so test performance in this respect is of relatively small concern.

Positive predictive value is significantly more variable. Even where test performance is high, positive predictive value will be low in populations with low virus prevalence, leading to false positives.

Anticipated prevalence by population type



For more information on predictive value based on test performance and virus prevalence in population, click here.
For more information on adjusting prevalence estimates for laboratory test kit errors, click here. Source: Foundation for Innovative Diagnostics, Science: Immunology

Procedure

Consider ease-of-use when selecting testing kits, especially RDTs, for efficiency and accuracy.

RDT considerations

- Length of time that result signal remains visible, especially important in busy testing environments.
- Minimising variation in how result signal is interpreted by different users (with clarity over what constitutes an inconclusive test)
- Number of manual operator steps between obtaining sample and reading result. Ideally reagents will not be added manually.
- Inclusion of job sheet/instructions for use in RDT package, including diagrams
- Mechanism (for example, paper strip) or space for recording patient details on RDT unit

Lab-analysed tests considerations

- Type of analyser required (proprietary variety developed by same manufacturer as test less likely to be widely installed in low-resource settings and more difficult to acquire)
- Throughput (number of tests analyser can process in an hour)
- Capability of linking to hospital information systems for automated reporting of test results

Procedure

Consider how you will always appropriately store testing materials to ensure stability.

Conditions for stability of test kits

	RDT	ELISA
 Temperature	2–30 °C (Storage) 15–30°C (Use)	2–8 °C (Storage) 18–25 °C (Preparation and Use)
 Shelf Life	Between 12 and 24 months from date of manufacture. Must use by expiry date	Within 12 months of date of manufacture. Must use by expiry date

Considerations

- Ensure **all stages in the chain of distribution have appropriate storage conditions** (international and domestic to final mile – at ports, in central and regional storage warehouses, at point-of-use and in laboratories).
- Ensure packaging is **appropriately labelled with ISO standard symbols for medical devices** and all personnel handling them understand their meaning.
- **Discard tests that have not been stored properly** to safeguard against inaccurate results. The costs of potentially inaccurate tests are greater than of discarded units.
- Consult manufacturers on **results of simulations of transport conditions** they may have undertaken.

All ranges indicative. Will vary by manufacturer.. Sources: Cellex, Biopanda, Epitope Diagnostics, NovaTec, Euroimmun

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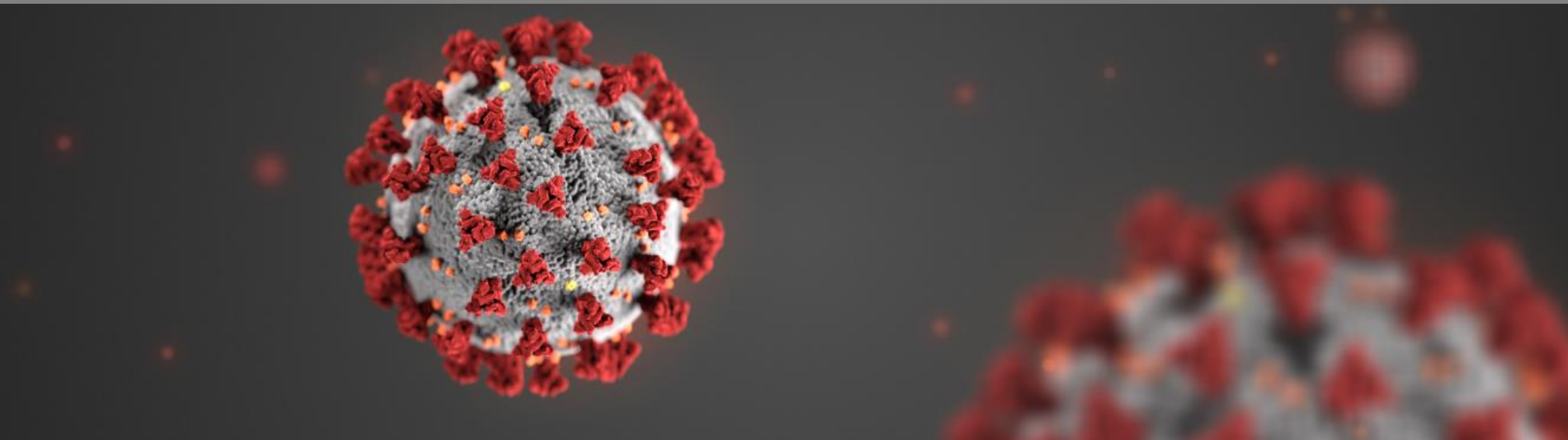
Procure

- Budget appropriately by considering the full range of costs.
- Estimate the **number of test kits** you will require.
- Choose your **procurement mechanism.**
- Undertake rigorous **scientific and commercial due diligence.**



Consider the range of direct and indirect costs to budget appropriately.

Procurement & Quality Assurance

Cost of coordinating procurement process, carrying out due diligence and quality assurance processes such as independent validation and possibly lot testing.

Storage & Transport

International transport from manufacturer to central warehouse in-country. Onward distribution to point of care and return of samples to laboratories for ELISA tests.

Staff & Patient Sensitisation

Cost of educating staff in administering tests, building community awareness of antibody testing.

Test Unit

Cost of the testing units as sold by the manufacturer.

Ancillary Items

Sterile swab sticks, alcohol swabs, gloves and sharp boxes for safe administration and disposal. Standard laboratory equipment including pipettes, glass tubes, distilled water, microplate reader, incubator, repeating dispenser.

Test Processing

Staff time, use of laboratory space and overheads for ELISA tests. Any proprietary equipment produced by test manufacturer for automated processing of ELISA tests.

Test Unit Cost Range
$5 - $15

- **Best prices can be obtained through pooled procurement mechanisms.**
- **ELISA test kits are more expensive to purchase than RDTs and entail costs in storage, transport, administration and analysis.**

Source: Cost data from World Health Organization allocations and ShARE analyses

Estimate the number of test kits you will require.

Considerations for seroprevalence studies

Sample Size

Most prevalence surveys will use population sampling techniques. In general, the larger the sample size, the more reflective the results will be of the actual prevalence.

- In low-resource settings, governments should consider how best to deploy limited testing resources according to the intended purpose identified, while ensuring their sample size is not too small as to render studies limited in value.

Number of Testing Rounds

A single prevalence study can provide a baseline but data will age rapidly, especially where there is a high growth rate in cases. Repeated studies at regular intervals are necessary and this should be considered when placing orders.

- England has undertaken **weekly prevalence testing** in a small sample for rapid and repeat snapshots, while many others are scheduling **twelve-month projects with three or four rounds of testing.**
- Ordering several studies' worth of kits in one order may allow governments to obtain them at better prices but storage capacity and expiry dates must be considered.

Other considerations

Wider Testing Policy/Strategy

- **Any commitments made on access to testing for specific segments of the population** (for example, number of people who work in high-risk environments, others who have previously had Covid-19-like symptoms but were unable to access PCR testing).

Buffer Supply

Any additional tests required beyond initial estimates to account for:

- Spoilage of some batches in transit.
- Need to repeat a test where result is inconclusive.

Choose a procurement mechanism according to national regulations and resources available.

Options for outsourced/pooled procurement

Procuring antibody tests should now be possible through the Africa Medical Supplies Platform established by the AU and Africa CDC and the WHO-led pooled procurement system. The African Pandemic Response Alliance (APRA) brokers partnerships and provide procurement and logistics advice.

Commercial supply chain organisations may be able to offer support in negotiation, quality-assurance and logistics.

Research institutes and universities may be able to obtain a small supply of validated tests from partners in other countries to conduct baseline prevalence studies but will need to identify other options for larger or repeat studies.

Options for in-house procurement

TENDER	**Open Tender** *Any supplier can submit an offer*	**Not Recommended** *Likely to receive large volume of unsuitable offers. Time consuming to process and unlikely to offer any additional negotiating leverage.*
TENDER	**Restricted Tender** *Prequalified suppliers can submit offers*	**Possible** *Opportunity to identify multiple suitable options in a single round of procurement. Can be used to obtain wide-ranging survey of the market.*
APPROACH	**Negotiation** *Buyer approaches limited number of pre-approved suppliers*	**Best Option** *Directly pursue most promising options, identified through publicly-available data and testimonials. Establish ongoing dialogue with different suppliers.*
APPROACH	**Direct Procurement** *Purchase made at quoted price from single supplier*	**Possible** *Significantly limits negotiating leverage. Inefficient repetition of process needed. Single supplier unlikely to be able to meet need.*

Considerations

- Is a particular procurement process mandated by existing law or regulations?
- Can certain rules be waived or processes expedited under the current circumstances where potential benefits outweigh potential risks?
- Do diagnostic tools need to be approved for use before they can be imported?

Undertake rigorous due diligence.

Scientific Due Diligence

Ensure scientific staff fully evaluate the data available in journals and on pre-print surveys before placing an order. **Use online searchable databases of independent validations** and compare against evidence presented by the manufacturer. **Validate claims about CE marks and Emergency Use Authorisation.**

Consider **purchasing a smaller batch for initial accuracy validation** before purchasing a larger batch and scaling up testing.

Consider payment terms through which **release of funds is staggered depending on performance criteria** being met.

Commercial Due Diligence

Establish whether manufacturing, marketing and distribution is handled by **one or a number of companies.** Identify what part of the value chain is your point-of-contact and what kinds of questions they are qualified to answer.

Check **appropriate manufacturing, operating and export licenses for the appropriate jurisdictions.** Consider verifying authenticity with issuing authority.

Consider requesting overseas diplomatic staff carry out a **visit of the manufacturer's premises** to verify production capacity claims.

Evaluate whether the manufacturer has a **demonstrated history of providing quality healthcare products** and diagnostic tools by reference to web presence, date of company registration, financial accounts and source verifiable testimonials from other clients.

Understand the **length and geographies of their supply chain** – from sourcing materials and components, to manufacturing kits and packaging/labelling. Identify if any stage likely to be disrupted by constraints on domestic or international logistics.

Note: Pooled procurement mechanisms carry out vetting and quality assurance processes before approving manufacturers to sell through their platforms.

Effective planning, including effective cooperation between agencies, and due diligence will enable governments to avoid challenges experienced elsewhere.

Disagreements and delays over protocols

- Israel sourced its tests from reputable US and Italian suppliers.
- But health ministry **disagreements over the sample size and recruitment process** for serological testing caused delays of more than a month. 250,000 tests in storage are **reported to expire by early July.**

Lack of coordination of testing initiatives

- Food and Drug Administration initially allows commercialisation of antibody tests without pre-approval and **many inaccurate tests flooded the market**.
- Range of testing protocols and manufacturers at local and state level **undermines data comparability.** National Institutes of Health eventually announces its own national, coordinated study.

Large orders of inaccurate kits and/or disputed independent validation processes

- In April, reported that GBP millions spent on home testing kits from Chinese manufacturers, AllTest and Wondfo, later found to be **insufficiently accurate**.
- Widespread scientific and media speculation about **efficacy of UK's test validation process**.
- In May, Public Health England **stops home testing after concerns about accuracy of test results based on samples patients obtain themselves.**

- Denmark sought to return batch of quarter of a million antibody tests obtained from Chinese manufacturer Livzon, after **sensitivity deviation was found to be too high in independent validations.** Accuracy was inadequate even for the intended surveillance use.
- Spain sought to return 58,000 rapid tests from total of 640,000 purchased through a Spanish distributor on behalf of Chinese manufacturer BioEasy, after **sensitivity found to be only 30%.**

Sources: The Times of Israel, The New York Times, Science Media Centre, Reuters, El Pais

Resources for policymakers.

African Centres for Disease Control and Prevention – Interim Guidance on Use of Rapid Antibody Tests
Advice on selection and use of rapid tests.

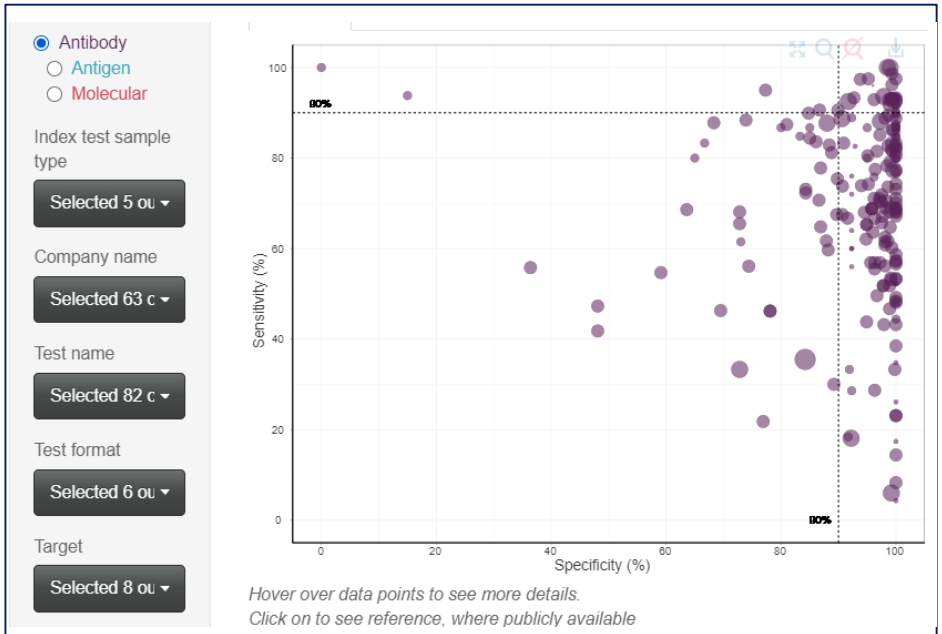
Foundation for Innovative Diagnostics – Immunoassay Dashboard
Dashboard and database of published, independent validations of commercially-available antibody tests. Updated on a rolling basis.

US Food and Drug Administration – Emergency Use Authorisation
List of all diagnostic tools with Emergency Use Authorisation in the United States. For antibody tests, filter 'Technology' heading for 'Total Antibody' or 'Serology'. Updated on a rolling basis.

Medicines and Healthcare Products Regulatory Agency - Target Product Profile
Model target product profile for Covid-19 antibody tests for use in the United Kingdom.

African Medical Supplies Platform
African Union-led initiative with single online marketplace for supply of critical medical equipment from vetted manufacturers.

African Pandemic Response Alliance
Alliance of organisations with procurement, logistics and service delivery advice.



Foundation for Innovative Diagnostics – Immunoassay Dashboard

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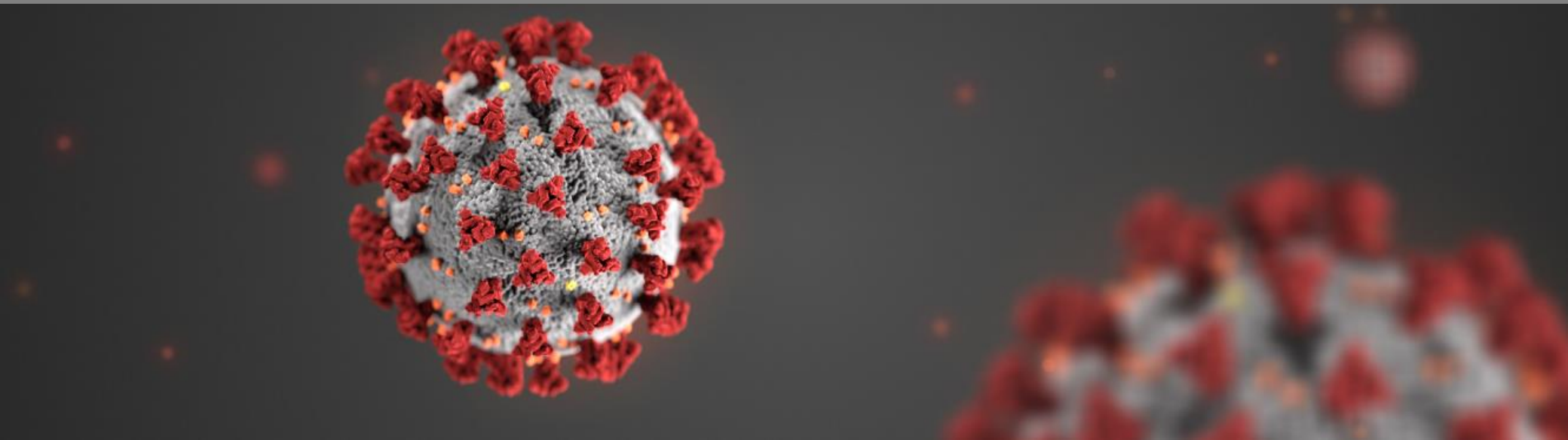
Annex 1: Snapshot of commercially available tests



Tests with emergency approval in the United States

	RDT	ELISA/other lab-based
Authorised for emergency use to support diagnosis by Food and Drug Administration	**Cellex,** USA (IgG/IgM) **ChemBio,** USA (IgG/IgM) **Autobio,** USA (IgG/IgM)	**Ortho-Clinical Diagnostics,** USA (IgG) **Roche,** Switzerland (IgG/IgM) **Mount Sinai,** USA (IgG) **DiaSorin,** USA (IgG) **Bio-Rad,** USA (IgM, IgG, IgA)
Approved for purchase by research labs and healthcare providers for surveillance and research purposes only	**BioEasy,** China (Unclear) (*See note 1*) **PharmACT,** Germany (IgG/IgM) **Sanuo Biotech,** China (IgG/IgM) **BioTime,** China (IgG/IgM) **GenBody,** Korea (IgG/IgM)	**Creative Diagnostics,** USA (IgG) **Eagle Biosciences,** USA (IgG) and (IgM) **BioEasy,** China (IgG/IgM) **Euroimmun,** Germany (IgG)

1. Spanish government sought to return 64,000 tests from this manufacturer after low sensitivity was found during use in hospitals. Sources: Johns Hopkins University

Examples of suppliers to national governments

Country	Test Manufacturer
 United Kingdom	**Roche** (Switzerland, IgM/IgG), **Abbott Laboratories** (United States, IgG)
 France	**Roche** (Switzerland, IgM/IgG)
 Spain	**Zhejiang Orient Gene/Healgen** (China, IgM/IgG)
 Germany	**Roche** (Switzerland, IgM/IgG)
 Italy	**Abbott Laboratories** (United States, IgG)
 Israel	**Abbott Laboratories** (United States, IgG), **DiaSorin** (Italy, IgG)

Sources: Financial Times, The Connexion, The Scientist, Al Jazeera, Hamodia

Foundation for Innovative Diagnostics is undertaking its own independent validations on some of the most promising tests.

Selected for validation on basis of regulatory status and probable time to market, manufacturing and distribution capacity of the supplier, high claimed clinical and analytical performance. Findings not yet published and no statement of efficacy can be made.

RDT

Beijing Tigsun, China (IgM/IgG)

Beijing Wantai, China (Total Ig)

BioMedomics, USA (IgM/IgG)

Boditech, Korea (IgM/IgG)

BTNX, China (IgM/IgG)

Changsha Sinocare, China (IgM/IgG)

Core Technology Co, China (IgM/IgG)

Dynmiker Biotech, China (IgM/IgG)

GenBody, Korea (IgM/IgG)

Guangzhou Wondfo, China (IgM/IgG) (*See note 1*)

Hangzhou AllTest, China (IgM/IgG) (*See note 1*)

Hangzhou Biotest, China (IgM/IgG)

Innovita, China (IgM/IgG)

InTec Products, China (IgM/IgG)

Jiangsu Bioperfectus, China (IgM/IgG)

Qingdao Hightop, China (IgM/IgG)

RapiGEN, Korea (IgM/IgG)

SD Bionsesor, Korea (IgM/IgG)

Shanghai Kehua, China (IgM/IgG)

Shenzhen Bioeasy, China (IgM/IgG) and (Total Ig)

VivaChek Biotech, China (IgM/IgG)

Zhuhai Livzon, China (IgG) and (IgM)

ELISA

Beijing Wantai, China (IgM) and (Total Ig)

Epitope Diagnostics, USA (IgG) and (IgM)

Euroimmun, Germany (IgA) and (IgG)

Guangzhou Darui, China (IgG) and (IgM)

1. UK government sought to return tests from these manufacturers after deemed to be insufficiently accurate. Sources: Foundation for Innovative Diagnostics

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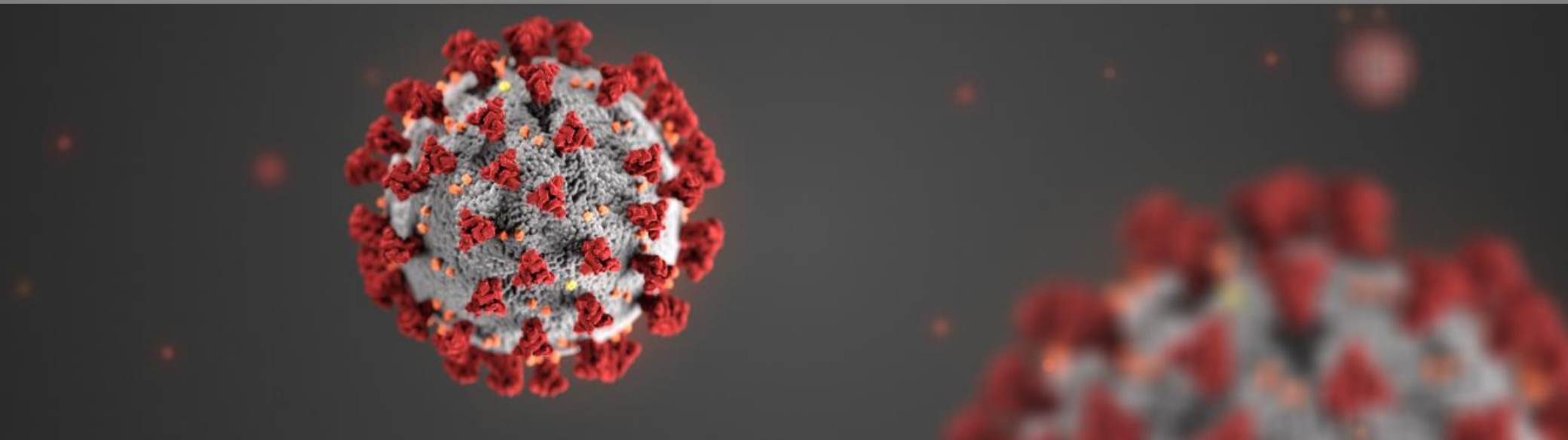
Annex 2: Summary of seroprevalence study protocols by country



Protocol Snapshot: Ghana

Testing Body/Location	West African Center for Cell Biology of Infectious Pathogens (Accra)
Test Type & Manufacturer	RDT obtained from University of Edinburgh. ELISA developed by researchers using proteins from University of California, San Francisco.
Test Accuracy	Unknown.
Population and Sample	• Focussed in Accra, where majority of confirmed cases are located. • 2,000 people using RDT tests, sampled from the general population using latest available census data as well as among groups particularly exposed, including frontline workers and lorry drivers. • 5,000 people using ELISA to undertake quantitative measurement of antibodies in patients with their case confirmed through PCR/molecular testing who have since recovered, as well as the general population.
Findings	No results yet published – still seeking funding.

Sources: TBI interviews

Protocol Snapshot: Ireland

Testing Body/Location	SCOPI: Covid-19 Antibody Research Project, Health Service Executive (Dublin and Sligo initially)
Test Type & Manufacturer	ELISA.
Test Accuracy	Unknown.
Population and Sample	• 5,000 people to be invited to participate through letter, from capital city Dublin and sea-port town of Sligo, randomly selected from primary care reimbursement scheme database. • Study to be repeated in other areas over 2020. • Participants will complete short questionnaire by phone, including date of birth, sex, occupation, ethnicity and any reported symptoms. Will also participate in follow-up study with three more blood tests over 12-month period. • Phlebotomist will take blood sample at local testing centre. • Results will be provided to individuals but they will be advised not to use it as basis for clinical decisions about diagnosis or management.
Findings	First results expected in August.

Sources: Government of Ireland, The Journal

Protocol Snapshot: Israel

Testing Body/Location	Health Ministry of Israel and Tel Aviv University School of Public Health	Health Ministry of Israel (Bnei Brak pilot, followed by high prevalence areas and Israel-wide)
Test Type & Manufacturer	Unknown.	Abbott Laboratories and DiaSorin. ELISA.
Test Accuracy	"Between 95 and 98% accurate".	100% Sensitivity, 99.5% Specificity (Abbott Laboratories). 97.4% Sensitivity, 98.5% Specificity (DiaSorin).
Population and Sample	• 1,700 blood samples, some from healthy people who donated to blood banks and others collected randomly as part of routine, non-Covid-19 monitoring. • Representative of age, gender and place of residence carried out in June.	• To be trialled in Bnei Brak on 3,000 patients, one of the worst affected Israeli cities, then into 'red cities' with high death rates and then across the country. Around 2.4m kits reportedly purchased. • Pilot will include three groups: families confirmed to have had cases of the virus, symptom-free families living in a building where there was a confirmed case, and random sampling of households. • Patients visiting clinics for standard blood tests will be asked if their sample can also be used for Covid-19 antibody testing. • Patients will be asked to complete questionnaire about symptoms experienced, whether they were isolated at home or hospitalised. • Patients whose blood tests show presence of antibodies will be called back for PCR test to establish if patient is still an active case.
Findings	• 2.5% prevalence, ten times higher than confirmed number of patients and 1.5% higher than Health Ministry estimates. • Higher exposure rate for men than women. Highest infection rate among age group 40-59.	No results yet published.

Sources: The Times of Israel, The New York Times, Hamodia

Protocol Snapshot: The Netherlands

Testing Body/Location	Sanquin – Netherlands Blood Supply Agency	PIENTER Corona Study (Nationwide)
Test Type & Manufacturer	Unknown.	ELISA.
Test Accuracy	Unknown.	Unknown.
Population and Sample	• Testing 7,000 samples from those donated to blood banks between specific ten day periods in both April and May. • Not representative of the Dutch population as a whole.	• Personal invitation sent to participants, information obtained through Dutch Personal Records Database, followed by voluntary opt-in. • Self-sampling at home using fingerpick, between 3-6 times over period of 1.5 years. 0.5ml, about 10-20 drops collected. Kit for obtaining and returning sample sent to participant's home by mail. • Questionnaire used to collect data about patient.
Findings	• 5.5% prevalence in May; 3% in April. • Prevalence was higher among older donors.	No results yet published.

Sources: Sanquin, Netherlands National Institute for Public Health and the Environment

Protocol Snapshot: United Kingdom

Testing Body/Location	Public Health England Seroprevalence Survey (England only)	Oxford University and Office of National Statistics (UK-wide)	Statistics Jersey (Crown Dependency of the UK)
Test Type & Manufacturer	Euroimmun.	IgG/IgM, ELISA. Developed by researchers.	IgG/IgM, RDT. Healgen.
Test Accuracy	79% Sensitivity. 99% Specificity.	Unknown.	83.33% Sensitivity. 100% Specificity.
Population and Sample	• Tests 1,000 samples from each of England's regions, each week. Obtained from blood donor banks and stratified by age, to estimate prevalence in different groups, which may reflect differing behaviour and mixing patterns. Repeated weekly to understand how prevalence is changing over time. • Forms part of the fourth pillar in the UK's testing strategy.	• Of 25,000 people from 20,000 households in pilot study who provide a molecular/PCR testing sample, 1,000 will additionally have blood sample taken by trained medical professional and give further samples monthly for next twelve months. • Representative sample of UK population by age and geography. Questionnaire of each patient will identify their symptomatic status, whether they had been in contact with a confirmed case, their gender, ethnicity and occupation.	• Repeated studies, conducted end of April and end of May. • Administered by medical professional at a testing centre. • List of 1,000 addresses randomly drawn from land and property register to form representative sample. Total of 629 households and 1,062 individuals took part. Compensation for non-response through household and individual-level weighting of results.
Findings	• Highest prevalence found among adolescent and young adult age group in all regions. • Prevalence in London increased from 1% to 15% over 5 weeks.	• No results yet published.	• 4.2% prevalence for May average, 4.3% prevalence for 16–34 year olds and 6.7% for those over 65. • Proportion of positive tests more than 1.5x higher for men than women.

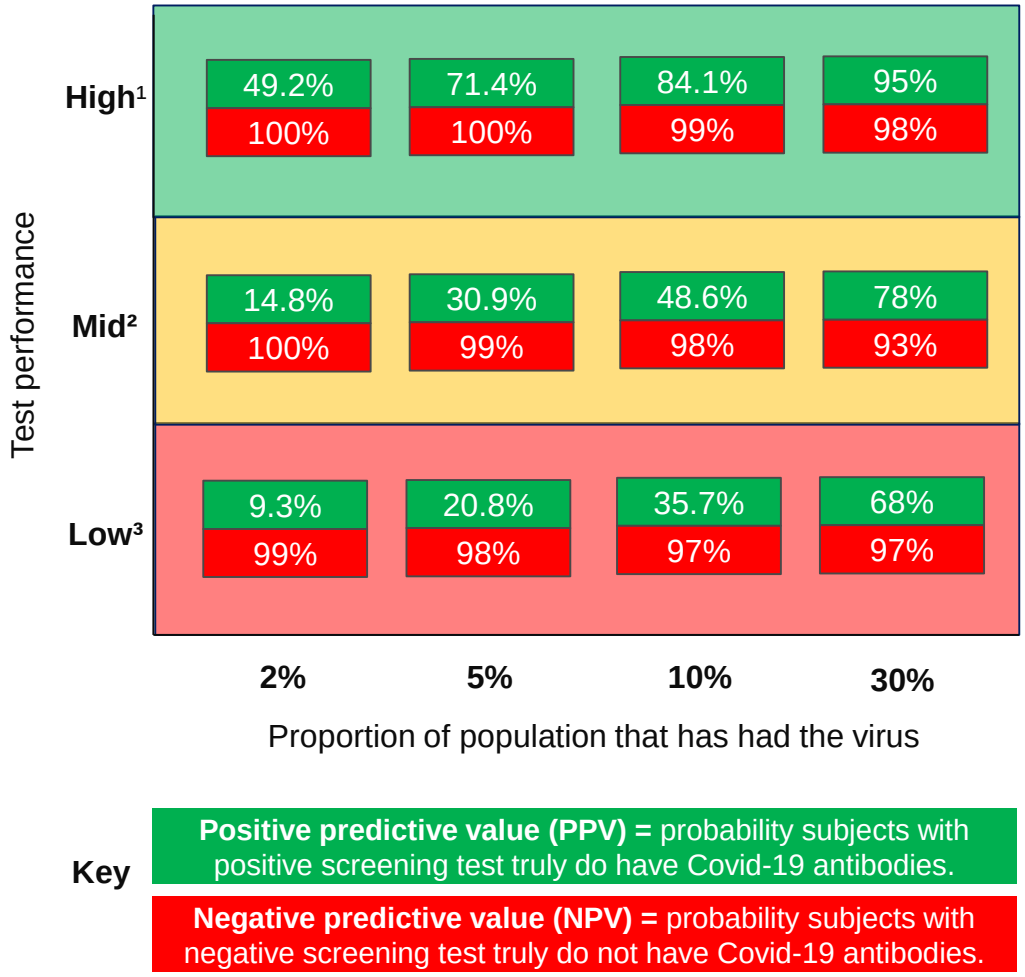
Sources: Public Health England, University of Oxford, Government of Jersey

Protocol Snapshot: United States

Testing Body/Location	Santa Clara County, California	Los Angeles County, California
Test Type & Manufacturer	IgM and IgG, ELISA. Premier Biotech.	IgM and IgG, RDT. Premier Biotech.
Test Accuracy	99.5% Specificity. 82.2% Sensitivity.	99.5% Specificity. 82.7% Sensitivity.
Population and Sample	• 3,330 adults from general population. • Recruited via Facebook ads targeted to Santa Clara County, likely to have led to over-representation of people who believe they previously had Covid-19. • Attended drive-through testing centre, disproportionate representation of people who had access to and time to visit testing centre.	• 1,952 invited from general population, 836 adults tested. • Random sample from market research database, with quotas based on age, sex, race, ethnicity distribution of Los Angeles County. • Attended drive-through testing centre, disproportionate representation of people who had access to and time to visit testing centre.
Findings	2.8% prevalence.	4.65% prevalence.

Sources: Stanford University, University of Southern California

Predictive value based on test performance and virus prevalence in population.



[1]High Performance: 95% Sensitivity, 98% Specificity; [2]Mid Performance: 85% Sensitivity, 90% Specificity; [3]Low Performance: 75% Sensitivity, 85% Specificity

Source: Foundation for Innovative Diagnostics, Science: Immunology