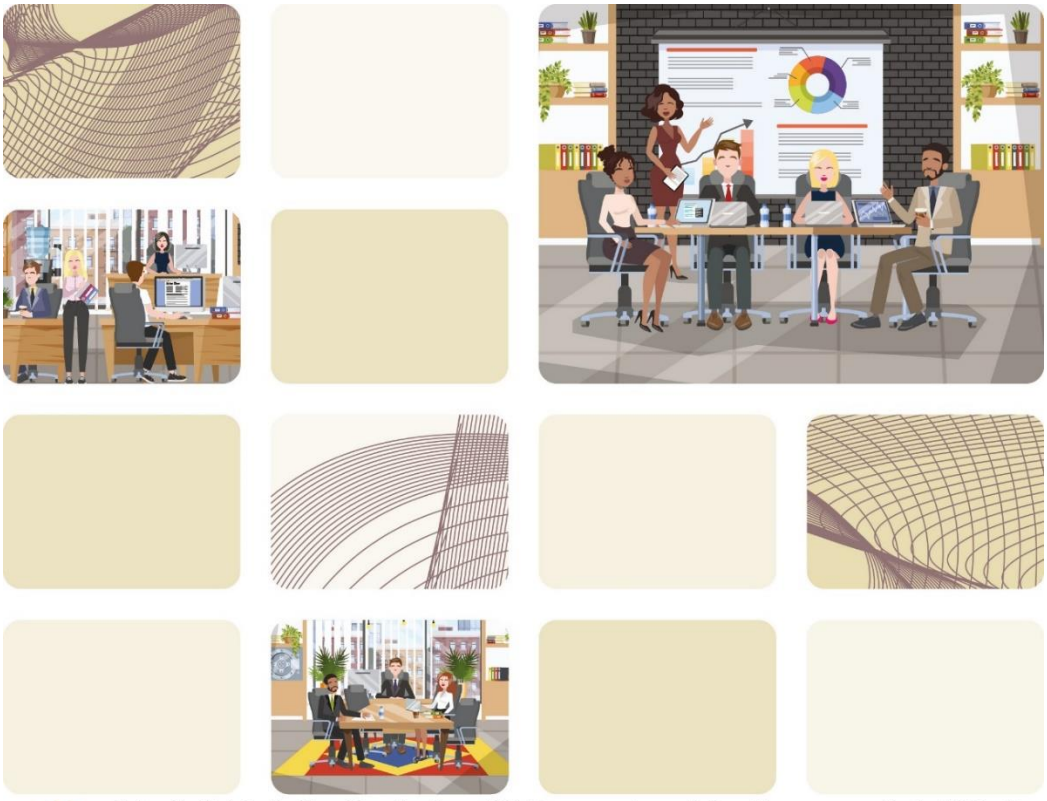
UK Health Security Agency

UK Standards for Microbiology Investigations

Review of users' comments received by

Working group for microbiology standards in clinical virology/serology

V 58 Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) serology



National Institute for Health and Care Excellence (NICE) has renewed accreditation of the process used by the **UK Health Security Agency** to produce **UK Standards for Microbiology Investigations (UK SMIs)**. The renewed accreditation is valid until **30 June 2026** and applies to guidance produced using the processes described in '**UK Standards for Microbiology Investigations Development Process' (2021)**. The original accreditation term began on 1 July 2011.

This publication was created by UK Health Security Agency (UKHSA) in partnership with the partner organisations.

Recommendations are listed as ACCEPT/ PARTIAL ACCEPT/DEFER/ NONE or PENDIN

Issued by the Standards Unit, Specialised Microbiology and Laboratories, UKHSA

1st Consultation: 22/09/2021 – 06/10/2021
Version of document consulted on: V 58 di+

3 Scope of document

Comment number: 1

Date received: 06/10/2021

Laboratory or organisation name: Institute of Biomedical Science

As cardiovascular disease, diabetes, chronic respiratory disease and cancer are more likely to develop serious illness.

It is suggested that immunocompromised is included in this list.

Recommended action

1. ACCEPT: link to COVID-19: the green book, chapter 14a added to the scope of the document

4 Background

Comment number: 2

Date received: 06/10/2021

Laboratory or organisation name: Institute of Biomedical Science

1. First paragraph: *The serological differentiation between different viral targets such as nucleocapsid or spike antigen might help*. The highlighted phrase is vague, is this sufficient justification for deployment? A more considered phrase may work better.
2. Second paragraph: *A longitudinal study has reported that patients who recovered from mild COVID-19infection developed SARS-CoV-2-specific IgG antibodies, neutralising plasma, and memory B and memory T cells that persisted for at least 3 months (8). While there is Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) an increase in evidence to suggest memory T cells develop post SARS-CoV-2 infection correlates of immunity are not yet well defined(9)*. The combination of wording and punctuation in the above sentences do not read well. The following changes are suggested: *evidence to suggest that memory T cells develop post SARS-CoV-2 infection, correlates of immunity are not yet well defined*. or *develop following SARS-CoV-2 infection*.
3. Third paragraph: *epidemiological and public health control measures by providing information of the level and length of the immune response following SARS-CoV-2 viral infection. This information will be useful to determine reinfection and how the virus spreads across the country*. The IBMS is happy with the wording above

however, given the high community transmission & repeat exposures plus vaccination, is not sure meaningful data will result. The SMI panel may wish to review this based on timeframes for waning antibody levels.

Recommended action

1. ACCEPT: words ‘might help’ removed from the paragraph
2. ACCEPT: necessary amendment made to the second paragraph
3. ACCEPT: necessary amendment made to the third paragraph

Comment number: 3

Date received: 22/09/2021

Laboratory or organisation name: PHE South West Regional Laboratory

In addition to the reasons given for SARS-CoV-2 antibody testing (page 6, second paragraph), it is worth also noting that following the approval of Ronapreve for therapy of selected SARS-CoV-2 positive, spike antibody negative in-patients, and prophylaxis of high-risk spike antibody negative patients (https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=103175) this has become the main reason for SARS-CoV-2 spike antibody testing.

Recommended action

1. ACCEPT: information on Ronapreve and SARS-CoV-2 spike antibody testing added to the document

Comment number: 4

Date received: 05/10/2021

Laboratory or organisation name: Public Health Wales Virology Cardiff

Serological assays are currently being used to guide treatment

Recommended action

1. ACCEPT: information on serological assay added to the document

Comment number: 5

Date received: 05/10/2021

Laboratory or organisation name: Public Health Wales Virology Cardiff

Do assays pick up S1 RBD and S2? do different assays pick up different targets? what is the role of the nibsc or other standard?

Recommended action

1. NONE, UK SMI will not define what each commercial company is producing, our advice will be to follow manufacturing instructions

7 Investigation detection of SARS-CoV-2 antibodies and 8 Interpreting and reporting laboratory results

Comment number: 6

Date received: 05/10/2021

Laboratory or organisation name: Public Health Wales Virology Cardiff

Should this include the reporting for equivocal results what impact will the reporting section have if any, on patients who may be eligible for treatment

Recommended action

1. ACCEPT: appropriate wording added to section 7.1 and 8

7.1 Footnotes relating to investigation of SARS-CoV-2 antibodies algorithm

Comment number: 7

Date received: 06/10/2021

Laboratory or organisation name: Institute of Biomedical Science

1. Footnote b) *Data not currently available to support the use of a reactive result to exclude the possibility of re-infection*. Should be: *Data is not currently available*
2. Footnote c) *Data not currently available on how IgG correlates to functional immunity* Should be: *Data is currently not available* to keep it consistent with sequence of wording on the in the point above.

Recommended action

1. ACCEPT: wording amended

2. ACCEPT: wording amended

Comment number: 8

Date received: 04/10/2021

Laboratory or organisation name: UK Health Security Agency

1. There needs to be something to say that if recently vaccinated, i.e 1st dose less than 56 days ago as per the gov UK antibody interpretation document for GPs, not a cause for concern or that it may take up to 56 days to develop antibodies to S. A person may be N detected and S not but might have been vaccinated recently and thus no S yet. Again, with N not detected and S not detected but have been vaccinated 3 days ago. https://www.gov.uk/government/publications/antibody-testing-for-sars-cov-2-information-for-general-practitioners/antibody-testing-for-sars-cov-2-information-for-general-practitioners
   Link to GP interpretation document. I guess we should try to send a consistent message as all same organisation.
2. N negative, S positive: Suggestive of response to spike targeted SARS-CoV-2 vaccination if administered recently 'Recently' needs clarifying. Secondly, this seems to go against the gov.uk interpretation for GPs which says 'a negative result after one dose of vaccination should not be cause for concern, particularly if vaccine was administered fewer than 56 days ago.

Recommended action

1. NONE
2. ACCEPT wording amended

Comment number: 9

Date received: 06/10/2021

Laboratory or organisation name: UK Health Security Agency

1. N negative, S positive: it could either indicate false positive IgG or IgG generated against spike protein outlasting the IgG generated against nucleocapsid following natural infection I was glad to see them include subtleties of false positives, and the document mentions, in footnote a, the likelihood of false reactivity depends on local seroprevalence. However, I think this will cause confusion if the statement isn't quantified. Suggest give example of false positive rate where local prevalence is 100/100K to guide interpretation.
2. N not tested, S positive 'consistent with SARS-CoV-2 infection or vaccination at some time' This doesn't really fit with 'Suggestive of response to spike targeted SARS-CoV-2 vaccination if administered recently'. These need to be made consistent once the first bullet point is addressed.

Recommended action

1. ACCEPT: wording amended
2. ACCEPT: wording amended

Comment number: 10

Date received: 07/10/2021

Laboratory or organisation name: South West Regional Laboratory

1. Algorithm- I can see why you chose to squeeze it into one but it doesn't work well, in fact, it would probably be best as just the table of result patterns. For example, you have chosen to start with ant-N but actually most sites will do anti-s first now it is required pre-antibody therapy.
2. Suggest mention indeterminate results are not included in the algorithm.
3. Footnote a needs adjusting. The likelihood of false reactivity depends on lots of stuff, not just the local seroprevalence. If the test was truly 100% specific, the local prevalence wouldn't matter at all.

Recommended action

1. ACCEPT: algorithm amended
2. ACCEPT: appropriate wording added to section 7.1 and 8
3. NONE

8 Interpreting and reporting laboratory results

Comment number: 11

Date received: 22/09/2021

Laboratory or organisation name: University Hospitals of North Midlands NHS Trust (UHNM), Stoke-on-Trent

The sentence "It is important to follow current guidelines on protection from SARS-CoV-2 for the latest advice" is not an interpretative comment and hence not appropriate; please delete. Some of the text in the other Interpretative Comments is woolly and not very helpful. For the interpretative comments that we implemented at our NHS Trust since synthetic monoclonal antibodies for the treatment of COVID-19 became available in the UK, see uploaded MS-Word file. Please note that the Roche anti-S test result can be "equivocal".

Recommended action

1. NONE: it was decided by the working group to keep sentence “It is important to follow current guidelines on protection from SARS-CoV-2 for the latest advice". This sentence is important for guidance on antibody testing and other information for SARS-CoV-2.

Comment number: 12

Date received: 07/10/2021

Laboratory or organisation name: South West Regional Laboratory

1) Report comments- not internally consistent with respect to ‘suggestive of’ or ‘consistent with’. ‘Consistent with’ is better for antibody detection. I would simplify the report comments. Omit the ‘it is important to follow current guidelines on protection from SARS-CoV-2’. This type of advice is not put on any other report, e.g. VZV IgG negative (avoid primary infection), HCV antibody positive (avoid reinfection).
2) N pos, S pos- why mention possible subsequent spike IgG boost? It provides no help to the service user or the patient, and might even be misleading.
3) N neg, S pos- wordy, and what is ‘recent’? Could just report consistent with vaccine response, past infection, or false positive anti-spike IgG.

Recommended action

1. NONE
2. ACCEPT: wording amended
3. ACCEPT: wording amended

General Comments

Comment number: 13

Date received: 06/10/2021

Laboratory or organisation name: UK Health Security Agency

There are several national level initiatives about guidance on interpretation of serology that have already been gathered together and consolidated

(a) Into the guidance that has been issued for GPs which was done through CMO office, but with coordination with NHS E, RCPath and PHE. This is what people are referring to at present, though it may not be as detailed as necessary for complex patient groups

(b) There was a general agreement with DHSC that a more detailed guidance might be needed, to be produced through NHS E, which there is a working group operating,

and as it happens UKHSA is deeply involved in that with meetings scheduled over the last few weeks. UKHSA can give an update. This more detailed guidance is also intended to be consistent with what has already been issued, but also underpin testing programmes to support MAbs and any other interventions

(c) anything that SMI are doing on reporting of antibody test results should fit/be consistent within this landscape, as multiple divergent guidance documents from different organisations are not what is needed at the present time. Would also suggest that definitive interpretation is a bit tricky, given the state of understanding of COVID serology profiles over time, so an SMI in this area might be a little premature

Recommended action

1. NONE: It is the remit of UK SMI and approved by the governing Steering Committee

Comment number: 14

Date received: 06/10/2021

Laboratory or organisation name: UK Health Security Agency

This document from the standards unit is highly duplicative of the existing guidance for GPs (issued by NHS T&T) and of the more detailed guidance targeted at specialists, lab managers and doctors managing special groups currently being drafted by DHSC in consultation with UKHSA (me, and therefore virology cell), RCPath and the operational leads for serology testing at NHS England (who are currently creating a pathway for non-responders to vaccine). This more detailed guidance is aiming to cover everything in the standards unit's document and more. I am not sure what this additional guidance from the standards unit adds, particularly as there is little in the document about standardising the procedures used. I think the next step is to contact the standards unit to let them know about the DHSC guidance that is being written, and invite them to contribute to that.

Recommended action

1. NONE

Comment number: 15

Date received: 10/10/2021

Laboratory or organisation name: GP

1. Re covid testing UKSMI from GPs 1. Thanks! I'm struck that they mention false positives (without a specificity) but not false negatives (and no sensitivity) which are the major problem to my mind. Per our CDC https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html. A negative antibody test does not

preclude previous infection. A proportion of persons who are infected with SARS-CoV-2 might not develop measurable antibodies, thereby limiting the sensitivity of any antibody test to detect previous infection in these individuals. In addition, measurable antibodies also might wane over time, and the extent to which seroreversion occurs could vary according to the antibody test used.
2. And the IDSA: https://www.idsociety.org/covid-19-real-time-learning-network/diagnostics/antibody-testing/ Due to the time it takes for antibodies to become detectable, serologic tests are not useful early in the course of illness for diagnosing COVID-19. In addition, most but not all patients with SARS-CoV-2 infection develop an antibody response, and so a negative serologic result does not exclude past infection.
3. And JAMA (older but still relevant) https://jamanetwork.com/journals/jama/fullarticle/2764954

Recommended action

1. ACCEPT: information on specificity and sensitivity of antibody test added
2. ACCEPT: general comment to say refer to local validation data and use validated kit added

Comment number: 16

Date received: 10/10/2021

Laboratory or organisation name: GP

The doc lacks a stated purpose and should include a section

‘Purpose. To provide guidance on the interpretation and reporting of SARS-CoV-2 anti N and anti S testing laboratory results’, or similar words

Recommended action

1. NONE: scope of the document provides sufficient information on the purpose of the document

Comment number: 17

Date received: 10/10/2021

Laboratory or organisation name: GP

Interesting to read through

Biobank sent me an Ab test after my first vaccination - negative - so wonder what this means! Generally the document is clear, useful, and well written; pathway diagram very good

Areas to improve:

1. My (personal) findings are also an occasional dilemma in GP land so - guidance should consider how to interpret intermediate results such as this
2. Graph of test results v time: this looks similar to one that was published early in the pandemic (updated for antibody tests?) but is based around a median incubation period of 7days. This is no longer felt to be true (due to quicker effect of the delta variant?). Could they also extend the timescale to show what happens to IgG over a longer period?
3. Could they also do a simpleton's version of the explanation of -N and -S tests?

Recommended action

1. ACCEPT
2. ACCEPT: a line added to say ‘there may be differences depending on the dominant variant circulating at the time’.
3. NONE

Comment number: 18

Date received: 07/10/2021

Laboratory or organisation name: South West Regional Laboratory

1. A necessary document. P6 ‘Therefore, at present, positive serological assays cannot be used to infer protective immunity against SARS-CoV-2 *or as a sole method for the diagnosis’* That last bit is not because of the lack of knowledge of correlates of immunity, it is about test performance, so the ‘therefore’ doesn’t apply.
2. I am not bothered, but passively acquired antibody is rarely mentioned in any serology SMI, but now that almost all of the population are either N or S positive, it will be passively acquired.

Recommended action

1. ACCEPT: word ‘therefore’ removed
2. ACEPT: information on passively acquired antibody added to the document

Financial barriers

Respondents were asked: 'Are there any potential organisational and financial barriers in applying the recommendations or conflict of interest?'.

Comment number: 19

Date received: 22/09/2021

Laboratory or organisation name: PHE South West Regional Laboratory

SARS-CoV-2 spike antibody testing is being provided through NHS Pathology networks.

Comment number: 20

Date received: 30/09/2021

Laboratory or organisation name: Healthcare Infection Society

no

Comment number: 21

Date received: 05/10/2021

Laboratory or organisation name: public health wales virology Cardiff

no

Comment number: 22

Date received: 22/09/2021

Laboratory or organisation name: University Hospitals of North Midlands NHS Trust (UHNM), Stoke-on-Trent

No

Health benefits

Respondents were asked: 'Are you aware of any health benefits, side effects and risks that might affect the development of this UK SMI?'.

Comment number: 23

Date received: 22/09/2021

Laboratory or organisation name: PHE South West Regional Laboratory

No.

Comment number: 24

Date received: 30/09/2021

Laboratory or organisation name: Healthcare Infection Society

no

Comment number: 25

Date received: 05/10/2021

Laboratory or organisation name: public health wales virology Cardiff

1. Availability of treatment and development of treatment algorithms

Recommended action

1. ACCEPT

Comment number: 26

Date received: 22/09/2021

Laboratory or organisation name: University Hospitals of North Midlands NHS Trust (UHNM), Stoke-on-Trent

No

Interested parties

Respondents were asked: 'Are you aware of any interested parties we should consider consulting with on the development of this document?'

Comment number: 27

Date received: 22/09/2021

Laboratory or organisation name: PHE South West Regional Laboratory

Emergency medicine consultants and intensivists

Comment number: 28

Date received: 30/09/2021

Laboratory or organisation name: Healthcare Infection Society

no

Respondents indicating they were happy with the contents of the document

Overall number of comments: 1			
Date received	30/09/2021	**Lab name/Professional body (delete as applicable)**	Healthcare Infection Society
Health benefits			
No			

2nd Consultation: 17/12/2021 – 07/01/2022
Version of document consulted on: V 58 ds+

3 Scope of document

Comment number: 1

Date received: 20/12/2021

Laboratory or organisation name: UKHSA SW/ Severn Infection Sciences

'Vaccines targeting the S protein elicits an immune response in vaccinated individuals.'- this line is unnecessary

Recommended action

1. ACCEPT: sentence removed

Comment number: 2

Date received: 06/01/2021

Laboratory or organisation name: IBMS

1. *Vaccines targeting the S protein elicits an immune response in vaccinated individuals*. Replace ‘elicits’ with ‘elicit’.
2. *These antibody testing programmes have aimed to provide information on the prevalence of COVID 19 in different regions of the country*. This should be reworded, so it is a little clearer. Seroprevalence will not solely provide information on the prevalence of COVID-19, as some individuals may have already had a dose of the vaccination.

Recommended action

1. ACCEPT: sentence removed
2. ACCEPT: sentence amended

4 Background

Comment number: 3

Date received: 20/12/2021

Laboratory or organisation name: UKHSA SW/ Severn Infection Sciences

1. *'antibody tests help to determine that an individual has been exposed to the virus immunologically regardless of symptom presentation.*' Not always exposed to the virus, but instead vaccine component- which is one point of this SMI (distinguishing natural infection from vacccine induced).
2. '*The monoclonal antibody combination bids specifically*'- should be 'binds'?
3. Top of p7- '*Sequence homology of the nucleocapsid and spike proteins of SARS-CoV-1 to other Betacoronaviruses is 33 to 47% and 29% respectively (18). SARS-CoV-2 is similar to SARS-CoV-1, showing sequence homology of 90% in the nucleocapsid and 76% in the spike protein (19)*.' This sentence is left hanging without a purpose, e.g. this means the assays do not cross-react....
4. '*Impact of variant strains on serology tests is not understood just yet, but likely to be limited in commercial test kits and assays which are looking for broad antibody response with diverse antibody repertoire*.' Is this still true, surely we know something now? 'Limited' is imprecise in meaning, how about 'unlikely to be significant'.

Recommended action

1. ACCEPT: word ‘vaccine’ added to the sentence
2. ACCEPT
3. ACCEPT: appropriate wording added with the reference
4. ACCEPT

Comment number: 4

Date received: 29/12/2021

Laboratory or organisation name: Surrey and Sussex Healthcare NHS Trust

Paragraph 3: The monoclonal antibody combination bids specifically to two different sites on the spike protein of the SARS-CoV-2 virus particle,- Presumed spelling error: 'Binds' instead of 'Bids'.

Recommended action

1. ACCEPT

Comment number: 5

Date received: 06/01/2021

Laboratory or organisation name: IBMS

1. *While there is an increase in evidence to suggest memory T cells develop post SARS-CoV-2 infection correlates of immunity are not yet well defined*. This sentence would benefit from revision.
2. Third paragraph replace ‘bids’ with ‘binds’

Recommended action

1. ACCEPT: sentence revised
2. ACCEPT

Comment number: 6

Date received: 06/01/2021

Laboratory or organisation name: ACB

Page 6, paragraph 2 TYPO - The monoclonal antibody combination binds specifically to two different sites.

Recommended action

1. ACCEPT

6.1 Specimen Type

Comment number: 7

Date received: 30/12/2021

Laboratory or organisation name: Keith Shuttleworth and Associates Ltd

It might be helpful if people are told how and where to find the Manufacturers' Specification. Provide the Link

Recommended action

1. NONE: information on manufacturers' instructions are assay kit specific and widely available on the internet.

6.2 Specimen Transport and Storage Conditions

Comment number: 8

Date received: 30/12/2021

Laboratory or organisation name: Keith Shuttleworth and Associates Ltd

We have too many references and appears confusing. Such as: UK Regulations (should have all relevant instructions and guidelines), Local Validation data (will gather

information from UK Regulations/Manufacturer's/ The Royal College of Pathologist to create their own guidelines), Manufacturer's Instructions (Instructions never complete anyway), The Royal College of Pathologist Guidelines (should have all relevant instructions and guidelines). Could we just refer to only one of these?

Recommended action

1. NONE: it is decided by the working group to keep these references for guidance

7 Investigation of SARS-CoV-2 antibodies

Comment number: 9

Date received: 30/12/2021

Laboratory or organisation name: Microbiology, St George's Hospital, London

As well as testing for anti-S and then proceeding to anti-N, laboratories that have access to both assays via automated methods could test both simultaneously and report both markers with an overall interpretation, as in the later table. This would improve turnaround time.

Recommended action

1. NONE: the guidance is available to use in both situations either simultaneously and anti-S or anti-N testing

Comment number: 10

Date received: 23/12/2021

Laboratory or organisation name: Immunology, University Hospitals Birmingham

Previous treatment with SARS-CoV-2 neutralising monoclonal antibodies (currently Ronapreve or sotrovimab) will also result in positive Spike antibody testing, which may last for many months (especially with sotrovimab). While only applying to a minority of vulnerable individuals currently, it may become more widely used, including for prophylaxis. Consider including this in interpretative guidance.

Recommended action

1. ACCEPT information on therapeutic neutralising monoclonal antibodies added to the document.

Comment number: 11

Date received: 06/01/2021

Laboratory or organisation name: ACB

Page 9, bottom row, box 1: 'Suggestive of previous SARS-CoV-2 infection and if there was any recent SARS-CoV-2 vaccination.' I'm not sure about the second part of the sentence. Presence of anti-N-Ab suggests previous infection, but so could anti-spike. What does 'recent' mean? Maybe 'Suggestive of previous SARS-CoV-2 infection. The presence of anti-spike antibody could also result from previous vaccination'

Recommended action

1. ACCEPT: wording in the flowchart amended

Comment number: 12

Date received: 20/12/2021

Laboratory or organisation name: UKHSA SW/ Severn Infection Sciences

Algorithm- the SMI only works if testing is done for anti-Spike and anti-nucleocapsid, which isn't necessarily what every laboratory does. This should at least be commented upon.

Recommended action

1. NONE: it was the view of the working group that guidance is provided for laboratories undertaking anti-S and anti-N testing

7.1 Footnotes relating to investigation of SARS-CoV-2 antibodies algorithm

Comment number: 13

Date received: 20/12/2021

Laboratory or organisation name: UKHSA SW/ Severn Infection Sciences

1. Footnote b- I suggest not including therapeutic consideration around the low level antibody detection result- this SI is about diagnostics, not potentially evolving treatment decisions.
2. Footnote c- 'Consideration should be given to the possibility of a false positive result. The likelihood of false reactivity depends on local seroprevalence'. The possibility of a false positive result depends on assay performance, the interpretation of the meaning or predictive value depends on the seropevalence.
3. Unusual that d appears after e on the algorithm.
4. General- comments are too long and not suitable for a standard report. Suggest it is made clear which aspects of the interpretative comment are expected to be reported to the service user/ patient.

Recommended action

1. ACCEPT: wording amended
2. ACCPT: reference added to support footnote ‘c’
3. ACCEPT
4. NONE: it is the view of the working group that interpretative comments are clearer as they stand

Comment number: 14

Date received: 23/12/2021

Laboratory or organisation name: Immunology, University Hospitals Birmingham

Footnote ‘b’"..bottom 10% of the assays positive range" is not meaningful. The upper limit of our Abbott S1 IgG assay is 40,000, so the lower 10% of that would be 4000. That would include over 70% of all the results we have reported since April 2021, which is probably not the intention of the guidance.
It is also possible to extend the reportable range by dilution (because many samples test as >40,000) which would result in an even higher 10% threshold.

Recommended action

1. ACCEPT: Footnote ‘b’ amended

8 Interpreting and reporting laboratory results

Comment number: 15

Date received: 30/12/2021

Laboratory or organisation name: Microbiology, St George's Hospital, London

1. In the interpretation comments, references to IgG should be replaced by antibody as many commercial assays in use are total antibody assays.
2. In the interpretation comments, where antibody is detected there is a rider comment regarding immunoglobulin. Whilst accurate, this seems odd to include, as such would apply to all serological tests that detect IgG, but we do not normally include such a comment. If the intent is specifically regarding SARS-CoV-2 therapeutic nMABs (e.g. Sotrovimab, Ronapreve), this should be explicitly stated.
3. In the interpretation comments, the references to government guidance seem redundant and given web addresses change, would be hard to maintain. I recommend these be removed.
4. The interpretation comment for situation number 2 (anti-S detected, anti-N not detected) whilst plausible is likely to confuse. Why not have the same comment

as scenario number 3? We do not yet have clear evidence that antibody to one marker persists any longer than another to my knowledge. This would be far simpler and not really any less accurate.

Recommended action

1. ACCEPT: IgG replaced with antibody
2. ACCEPT: sentence amended
3. ACCEPT: hyperlink to the government guidance removed
4. ACCEPT: wording amended

General Comments

Comment number: 16

Date received: 20/12/2021

Laboratory or organisation name: UKHSA SW/ Severn Infection Sciences

Ran out of time to go through algorithm and decodes in the table- please ensure it aligns with the very recently published serology document https://www.gov.uk/government/publications/antibody-testing-for-sars-cov-2-extended-information

Recommended action

1. ACCEPT

Financial barriers

Respondents were asked: 'Are there any potential organisational and financial barriers in applying the recommendations or conflict of interest?'.

Comment number: 17

Date received: 20/12/2021

Laboratory or organisation name: UKHSA SW/ Severn Infection Sciences

only if the intention is to always test for anti-s and anti-n as a set.

Comment number: 18

Date received: 23/12/2021

Laboratory or organisation name: Immunology, University Hospitals Birmingham

none

Comment number: 19

Date received: 29/12/2021

Laboratory or organisation name: Surrey and Sussex Healthcare NHS Trust

n/a

Comment number: 20

Date received: 30/12/2021

Laboratory or organisation name: member of the public

No

Comment number: 21

Date received: 30/12/2021

Laboratory or organisation name: Keith Shuttleworth and Associates Ltd

None to my knowledge

Comment number: 22

Date received: 30/12/2021

Laboratory or organisation name: Microbiology, St George's Hospital, London

None

Comment number: 23

Date received: 06/01/2022

Laboratory or organisation name: Institute of Biomedical Science

No

Comment number: 24

Date received: 06/01/2022

Laboratory or organisation name: ACB

No

Health benefits

Respondents were asked: 'Are you aware of any health benefits, side effects and risks that might affect the development of this UK SMI?'.

Comment number: 25

Date received: 20/12/2021

Laboratory or organisation name: UKHSA SW/ Severn Infection Sciences

Never understood what this question means. We expect health benefits, that's why they are written.

Comment number: 26

Date received: 23/12/2021

Laboratory or organisation name: Immunology, University Hospitals Birmingham

Attempts to cohort or otherwise risk-stratify patients on the basis of serology results is not evidence-based. Consider including this in the interpretation guidance. Any such use of serology should only occur in the context of a controlled clinical trial.

Recommended action

1. NONE

Comment number: 27

Date received: 29/12/2021

Laboratory or organisation name: Surrey and Sussex Healthcare NHS Trust

n/a

Comment number: 28

Date received: 30/12/2021

Laboratory or organisation name: member of the public

Yes

Comment number: 29

Date received: 30/12/2021

Laboratory or organisation name: Keith Shuttleworth and Associates Ltd

Yes

Comment number: 30

Date received: 30/12/2021

Laboratory or organisation name: Microbiology, St George's Hospital, London

None

Comment number: 31

Date received: 06/01/2022

Laboratory or organisation name: Institute of Biomedical Science

No

Comment number: 32

Date received: 06/01/2022

Laboratory or organisation name: ACB

No

Interested parties

Respondents were asked: 'Are you aware of any interested parties we should consider consulting with on the development of this document?'

Comment number: 33

Date received: 20/12/2021

Laboratory or organisation name: UKHSA SW/ Severn Infection Sciences

DHSC

Comment number: 34

Date received: 30/12/2021

Laboratory or organisation name: member of the public

Yes

Comment number: 35

Date received: 30/12/2021

Laboratory or organisation name: Keith Shuttleworth and Associates Ltd

not sure

Comment number: 36

Date received: 30/12/2021

Laboratory or organisation name: Microbiology, St George's Hospital, London

None

Respondents indicating they were happy with the contents of the document

Overall number of comments: 1			
Date received	06/01/2022	**Lab name/Professional body (delete as applicable)**	Institute of Biomedical Science
Health benefits			
None			