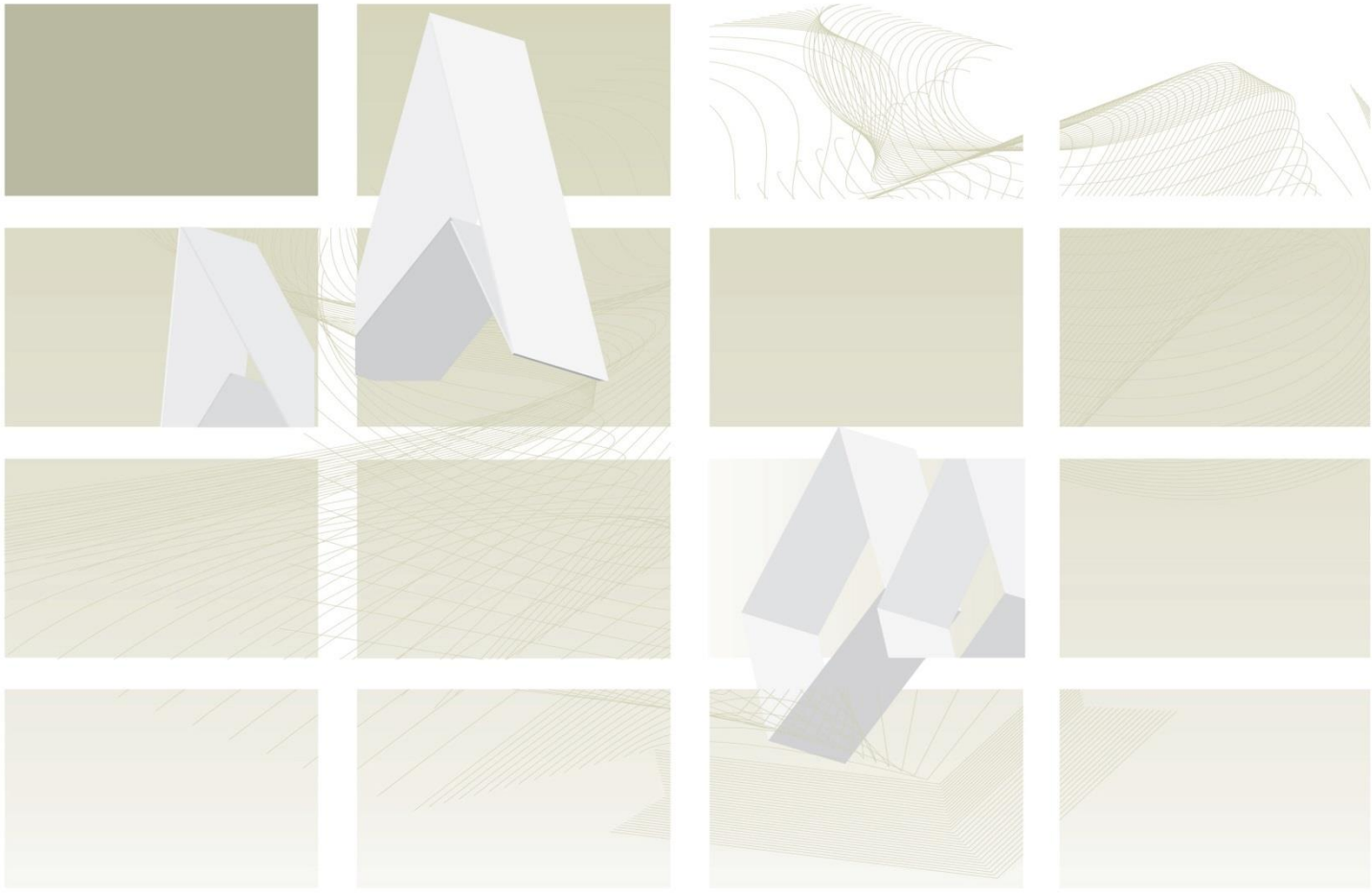
UK Standards for Microbiology Investigations

Review of users' comments received by
Working group for microbiology standards in clinical virology/serology

Q 2 Quality assurance in the diagnostic infection sciences laboratory



NICE accredited
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"NICE has renewed accreditation of the process used by **Public Health England (PHE)** to produce **UK Standards for Microbiology Investigations**. The renewed accreditation is valid until **30 June 2021** and applies to guidance produced using the processes described in **UK standards for microbiology investigations (UKSMIs) Development process, S9365', 2016**. The original accreditation term began in **July 2011.**"

This publication was created by Public Health England (PHE) in partnership with the NHS.
Recommendations are listed as ACCEPT/ PARTIAL ACCEPT/DEFER/ NONE or PENDING

Consultation: 01/04/2021 – 15/04/2021

Version of document consulted on: Q 2 do+

Section for comments: General

Comment number: 1

Date received: 12/04/2021
Laboratory/organisation name: NHS Fife Medical Microbiology

The use of the word 'should' implies it is considered optional. The word 'must' indicates the such an expectation is intended to be acted upon

Recommended action

1. NONE: The UK SMIs use “must” where applicable, such as when referring to health and safety requirements and statutory notifications

Comment number: 2

Date received: 14/04/2021
Laboratory/organisation name: Severn Infection Sciences/ Bristol PHL

This a very well written and useful document. I will be recommending it as reading for microbiology/virology/ID clinical trainees. A potential improvement would be to mention how error investigation plays a key role in improving laboratory quality- it is implied but not stated separately.

Recommended action

1. NONE: error investigation is covered in section 10 “management of non-conforming work”. This is also briefly mentioned in section 4 “background” in the paragraph commencing “Quality assurance can only be undertaken effectively…”

Comment number: 3

Date received: 15/04/2021
Laboratory/organisation name: PHE Diagnostic Developments and Evaluations Unit

Suggest that the overall document title is changed e.g. to 'Quality assurance in the diagnostic laboratory'. This appears to be a general QA document and it's confusing to refer to Diagnostic Virology and Serology at the same time (diagnostic virology includes molecular assays, and the subject matter also applies to other lab disciplines).

Recommended action

1. PARTIAL ACCEPT: title has been amended to “quality assurance in the diagnostic infection sciences laboratory” to reflect a broader scope

Comment number: 4

Date received: 15/04/2021
Laboratory/organisation name: Insitute of Biomedical Science

The documents covers all of the steps systematically and it appears to provides enough information for each one.

Recommended action

2. NONE: thank you for your comment

Section for comments: Scope of document

Comment number: 5

Date received: 14/04/2021
Laboratory/organisation name: Severn Infection Sciences/ Bristol PHL

Mentions in the absence of reference methods or standards, laboratories must carry out their own validation. This has potential to be confusing as validation is typically required in the setting of assay introduction even if there are standards.

Recommended action

1. ACCEPT: reference to “reference methods” has been removed as these are uncommon in virology. The note that laboratories must carry out their own validation where reference materials are unavailable has been removed from scope of document, and is instead expanded on with the discussion of tertiary standards in section 6: Internal quality control

Section for comments: Section 6 Internal quality control

Comment number: 6

Date received: 15/04/2021
Laboratory/organisation name: PHE Diagnostic Developments and Evaluations Unit

It would be useful to indicate the level of reactivity for controls e.g. within the assay's dynamic range

Recommended action

1. NONE: this is covered in section 6.2 “For example, in an ELISA the OD value of the control should lie within the linear part of the dose response curve. Control material that is strongly positive and therefore saturates the assay should not be used. Control material that is close to the limit of detection (e.g. <2S.D) should not be used in isolation as this may cause assays to be invalid”

Comment number: 7

Date received: 15/04/2021
Laboratory/organisation name: PHE Diagnostic Developments and Evaluations Unit

Identify which are warning rules and which are mandatory rules. Also provide actions to take where Westgard rules are not followed. It is known that some laboratories do not strictly follow the rules when they have frequent run failures and may then follow a 3-standard deviation rule and ignore other rules (e.g. when reporting a qualitative result from a numerical value)

Recommended action

1. NONE: Westgard rules are defined as “mandatory” or “warning” rules; however, it is for laboratories to decide which rules to apply locally, and to justify their approach. The wording of section 6.3.2 Westgard rules has been slightly amended to emphasise this

Section for comments: Section 8 Audit

Comment number: 8

Date received: 15/04/2021
Laboratory/organisation name: PHE Diagnostic Developments and Evaluations Unit

One of the bullet point states ''independent - if possible''. Please expand on this point, explaining whether the 'if possible' comment is for laboratories with small numbers of staff that won't be able to do independent audit.

Recommended action

1. ACCEPT: additional clarification in line with ISO 9000:2015 has been added

Section for comments: Section 9 Internal Quality Assurance

Comment number: 9

Date received: 15/04/2021
Laboratory/organisation name: PHE Diagnostic Developments and Evaluations Unit

When comparing the 'routine result' with the 'IQA result' recommend that the person comparing results is independent from the person who issued the original result report.

Recommended action

1. ACCEPT: suggested note has been added to section 9

Comment number: 10

Date received: 12/04/2021
Laboratory/organisation name: Public Health Wales, Microbiology Cardiff

We have found that blindly repeating serology samples as IQA is no longer useful, where high levels of automation exists. For example, a blood sample submitted for

qualitative antibody detection is only subject to manual processing at the pre-examination stages, where the sample suitability checks are undertaken. Once the sample is barcoded and registered in LIMS, the rest of the processes are automated (including test selection and result interpretation on the analysers). Therefore, repeating a negative antibody result is not providing much assurance regarding the majority of the processes, that isn't already covered by EQA/IQA processes. At the Wales Specialist Virology Centre, in Cardiff, we have moved to a more audit-based approach for these assays (similar to how our bacteriology colleagues perform IQA), where we choose a sample at random and review the pre/post examination procedures - labelling, coding, data entry, form scanning, result entry (including manual transcription checks where appropriate), authorisation & transmission to external result portals. This has been examined at UKAS assessment and favourably received by our assessors. Quantitative assays are also subjected to this audit-style IQA method, but with the additional step of repeating samples of varying levels to ensure the values are repeatable. Manually-interpreted assays have an additional step of the IQA samples being checked by a second member of staff to help identify any unusual subjectivity. IQA results are recorded in a basic Microsoft Access database (screenshot attached), which can be used to extract reports of the findings.

Recommended action

1. ACCEPT: An additional paragraph has been added to section 9: internal quality assurance to cover local adaptation of traditional IQA methods

Section for comments: References

Comment number: 11

Date received: 15/04/2021
Laboratory/organisation name: PHE Diagnostic Developments and Evaluations Unit

Consider adding a reference to the WHO document on biological standardisation https://www.who.int/biologicals/WHO_TRS_1004_web.pdf, including preparation of secondary standards (Annex 6, p389), and consider whether any parts of this need to be mentioned in the main document

Recommended action

1. ACCEPT: reference has been added to the document, and further information covering usage of secondary/tertiary standards has been included

Section for comments: Financial barriers

Respondents were asked “are there any potential organisational and financial barriers in applying the recommendations or conflict of interest?”.

Comment number: 12

Date received: 12/04/2021
Laboratory/organisation name: Public Health Wales, Microbiology Cardiff

No

Comment number: 13

Date received: 12/04/2021
Laboratory/organisation name: NHS Fife Medical Microbiology

None

Comment number: 14

Date received: 14/04/2021
Laboratory/organisation name: Severn Infection Sciences/ Bristol PHL

No

Comment number: 15

Date received: 15/04/2021
Laboratory/organisation name: PHE Diagnostic Developments and Evaluations Unit

None

Comment number: 16

Date received: 15/04/2021
Laboratory/organisation name: Institute of Biomedical Science

None identified

Section for comments: 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: 17

Date received: 12/04/2021
Laboratory/organisation name: Public Health Wales, Microbiology Cardiff

No

Comment number: 18

Date received: 12/04/2021
Laboratory/organisation name: NHS Fife Medical Microbiology

None

Comment number: 19

Date received: 14/04/2021
Laboratory/organisation name: Severn Infection Sciences/ Bristol PHL

Well, a high quality laboratory means better patient outcome, and that is the point of the document.

Comment number: 20

Date received: 15/04/2021
Laboratory/organisation name: PHE Diagnostic Developments and Evaluations Unit

None

Comment number: 21

Date received: 15/04/2021
Laboratory/organisation name: Institute of Biomedical Science

No

Section for comments: 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: 22

Date received: 12/04/2021
Laboratory/organisation name: Public Health Wales, Microbiology Cardiff

No response given

Comment number: 23

Date received: 12/04/2021
Laboratory/organisation name: NHS Fife Medical Microbiology

None

Comment number: 24

Date received: 14/04/2021
Laboratory/organisation name: Severn Infection Sciences/ Bristol PHL

UK NEQAS

Comment number: 25

Date received: 15/04/2021
Laboratory/organisation name: PHE Diagnostic Developments and Evaluations Unit

None

Comment number: 26

Date received: 15/04/2021
Laboratory/organisation name: Institute of Biomedical Science

None