

Health Protection Agency: Guidance on the development and validation of diagnostic tests that depend on nucleic acid amplification and detection

EVIDENCE SUBMITTED BY THE SOCIETY FOR GENERAL MICROBIOLOGY

Introduction

The Society for General Microbiology (SGM), founded in 1945, is an independent learned and professional scientific body dedicated to promoting modern microbial science. It has established itself as one of the two major societies in its field globally, with some 5,000 members in the UK and abroad. Further information about SGM is provided in Appendix 1.

General comments

All pertinent issues have been covered in this document, mostly in great detail, although navigation through the document is difficult.

Although the title of the document is ‘development and validation’, section 4.0, Purpose and Scope, implies that the primary focus of the document is on the validation of diagnostic tests. However, the core of the report covers the design of new tests, with the development and validation added on to this as a necessary adjunct. Section 7, Planning and Inception, reinforces this view, and refers to new tests.

There are a number of abbreviations throughout the document that are not initially expanded.

Specific comments

Section 7.2 provided no explanation of how ‘high-level management agreement for the work to proceed and approval of any necessary funding’ was to be sought.

In places the requirements for the development of the tests is extremely prescriptive, with what appears to be policy embedded in the development protocols. For example, the requirements in section 8.5 regarding the results on the day of sample receipt; this is clearly a worthy objective, but should not necessarily drive the development of a better assay.

Section 9.1.1 on the design of primers appears very detailed, and gives the impression of having been written apart from the rest of the report as a separate document.

It is unclear who section 11 is aimed at. Assuming that most of the end users of this documentation should be extremely familiar with the concepts of sensitivity, specificity,

precision and accuracy, the inclusion of such definitions here extends an already lengthy document.

The requirement to consider 'all possible conditions' in regard of shelf life in section 11.19.1, is unrealistic.

The term 'risk assessment' is used in two different contexts – correctly in section 12.0 in relation to the hazards to staff associated with the reagents and methodologies, but again on page 30 relating to the risks to patient care of false positive or false negative results.

In Annex A, Table I 'General Levels of Assurance' the terms shown seem subjective, and there is no obvious published source cited for the use of these.

Sources

This response is based on evidence submitted by Dr Jonathan Fletcher, University of Bradford.

Appendix 1

The Society for General Microbiology (SGM) was founded in 1944/1945 and is now the largest microbiological society in Europe. It has over 4,500 individual members of whom 75% are resident in the UK. The remainder is located in more than 60 countries throughout the world. More than 700 schools and a number of companies are corporate members.

The Society provides a common meeting ground for scientists working in academic centres and in a number of fields with applications in microbiology (medicine, dentistry, veterinary medicine, pharmaceuticals, numerous industries, agriculture, food and beverages, the environment and education). The majority of Society members are employees of universities, research institutes, health services, government agencies and small to multinational companies.

The science of microbiology covers a great diversity of life forms: disease-related molecular structures such as prions and viruses, archaea, bacteria, fungi, protozoa and algae. Microbes are of crucial importance in a number of processes affecting all life on Earth: the cause and control of disease, fertility of soils and aquatic environments, fermentation, biodegradation of waste materials and dead biomass, bioprocessing steps in drug and antibiotic production, and molecular biotechnology.

The Society's objective is to advance the art and science of microbiology. It does this by:

- Organizing regular scientific meetings at centres throughout the UK and abroad, where microbiologists meet to hear and discuss the latest research findings. The largest meetings last 4 days and involve up to 1400 participants.
- Publishing four major international learned journals: *Microbiology*, *Journal of General Virology*, *Journal of Medical Microbiology* and *International Journal of Systematic and Evolutionary Microbiology*. The journals are available on-line through HighWire Press (www.sgmjournals.org).
- Representing the science and profession of microbiology to policy-makers and the media. The Society is represented on a number of biological and biomedical committees and organizations, in the UK and internationally, thereby exerting influence on science policy and education, regulatory affairs and international collaboration.
- Promoting microbiology as a career for young people, by increasing awareness of microbiology in schools and aiding the development of teaching resources. The Society also provides grants for young scientists to attend scientific meetings and training courses.
- Keeping members informed of current developments in professional and scientific matters in microbiology, through publication of the magazine *Microbiology Today* and other means.

The Society is a Charity registered in England and Wales (No. 264017) and in Scotland (No. SC039250) and a Company Limited by Guarantee, registered in England and Wales (No. 1039582). It is governed by a Council drawn and elected from the membership. The Society employs a staff of over 30 at its headquarters.

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