



Public Health
England

Protecting and improving the nation's health

PHE Food and Water PT Schemes:

A guide to the use of the PHE proficiency testing schemes for food and water microbiology



Public Health England
Food and Environmental Proficiency Testing Unit (FEPTU)
61 Colindale Avenue
London
NW9 5EQ
Tel: +44 (0) 20 8327 7119
Fax: +44 (0) 20 8200 8264
Email: foodeqa@phe.gov.uk
Website: www.gov.uk/government/collections/external-quality-assessment-eqa-and-proficiency-testing-pt-for-food-water-and-environmental-microbiology

Index

	Page
Introduction	4
Section	
1.0 Organisation	4
2.0 Quality systems	4
3.0 Management issues	5
4.0 Scheme participation	5
5.0 Registration fees	6
6.0 Confidentiality	6
7.0 Sample dispatch	6
8.0 PT samples	6
9.0 Non-conforming products	7
10.0 Sample examinations	7
11.0 Reporting results	7
12.0 Notification of intended results	7
13.0 Establishing assigned values (intended results)	7
14.0 Allocation of scores and performance assessments	8
15.0 Reports	8
16.0 Trend analysis and performance data: uses	8
17.0 Response to incorrect results	9
18.0 Complaints and comments	10
19.0 Conferences	10
20.0 Scheme consultants	10

Website links for scheme-specific information

Food Microbiology Schemes	Water Microbiology Schemes
<u>Standard Scheme</u>	<u>Legionella Isolation Scheme</u>
<u>European Food Microbiology Legislation Scheme</u>	<u>Legionella Molecular Scheme</u>
<u>Non-Pathogen Scheme</u>	<u>Recreational and Surface Water Scheme</u>
<u>Shellfish Scheme</u>	<u>Drinking Water Scheme</u>
<u>Pathogenic <i>Vibrio</i> Scheme</u>	<u>Bottled and Mineral Water Scheme</u>
<u><i>Staphylococcus aureus</i> enterotoxin Scheme</u>	<u>Endoscope Rinse Water Scheme</u>
<u>Environmental Swab Scheme</u>	<u><i>Mycobacterium</i> spp. in Water Scheme (non-accredited)</u>
<u>Shiga Toxin-producing <i>Escherichia coli</i> Scheme</u>	<u>Dialysis Water Scheme</u>
<u>Norovirus and Hepatitis A Virus Scheme (non-accredited)</u>	<u>Hospital Tap Water Scheme</u>

Introduction

This guide is designed to help participants gain maximum benefit from Public Health England's (PHE) proficiency testing schemes (external quality assessment (EQA) schemes) for food, water and environmental microbiology.

1.0 Organisation

The schemes are organised by the Food and Environmental Proficiency Testing Unit (FEPTU) based at Colindale. FEPTU is part of the External Quality Assurance Department (eQAD) which also has responsibility for providing the UK NEQAS (United Kingdom National External Quality Assessment Service) EQA schemes for clinical microbiology. Further information is available from the website: www.gov.uk/government/collections/external-quality-assessment-ega-and-proficiency-testing-pt-for-food-water-and-environmental-microbiology

The organisers within FEPTU are supported by a Steering Group for Food and Water Microbiology Schemes, which includes participant representatives, scheme consultants with expertise in specific aspects of food and/or water microbiology and representatives from the food and water industries. The Steering Group meets twice every year; participants are contacted by email prior to each meeting and invited to submit queries and comments regarding scheme development and strategy for consideration by the Group. The remit of the Steering Group is available on request.

FEPTU is accredited to ISO/IEC ISO 17043:2010 (Conformity assessment – General requirements for proficiency testing) by the United Kingdom Accreditation Service (UKAS) for the provision of all the PHE food and water microbiology PT schemes. The scope of accreditation is available from the UKAS website (link below). Copies of the UKAS accreditation certificate are available on request. www.ukas.com/services/accreditation-services/proficiency-testing-scheme-provider-accreditation/.asp

2.0 Quality systems

Proficiency testing (PT) is also referred to as external quality assessment (EQA), particularly in the clinical field, and is only one component of a quality system. The following definitions may help to define the relationships between the components:

- *Quality assurance* is the total process whereby the quality of laboratory results can be guaranteed.
- The *quality control (QC)* programme comprises the processes undertaken to check that media, reagents and equipment are performing within specifications
- *Proficiency testing or external quality assessment* is the challenge of the effectiveness of a laboratory's quality system with samples of known but undisclosed content.

A comprehensive quality assurance system will cover such areas as provision and control of standard operating procedures, education and training, planned maintenance and calibration of equipment, monitoring of response times, monitoring of suppliers etc. There is also a growing trend towards formal accreditation of laboratories for food, water and environmental examinations to acknowledge conformance with defined and objective quality standards, in particular those contained in ISO/IEC 17025:2005 (General requirements for the competence of testing and calibration laboratories) and ISO 15189:2012 (Medical laboratories - Requirements for quality and competence).

Laboratories may expect to report results of a consistently good quality only after all the components of the quality system are in place. It is important to consider the following limitations when designing a quality system for a laboratory:

- PT is not a substitute for other components of the quality system and cannot replace the QC programme.
- PT is of limited value without at least some of the other quality components such as adequate documentation, training of staff and the QC programme.
- PT helps to identify problems with testing; it does not solve the problems.

3.0 Management issues

PT schemes aim to provide the laboratory management with an insight into the quality of the routine work of their laboratories. The following qualifying factors apply:

- PT results will only provide an effective insight into routine results if the PT samples are treated in the same way as routine samples.
- If PT samples are treated differently from routine samples then the PT results may be excellent but nothing will be learnt about the quality of the routine service.

There are several ways in which PT samples may be given 'special' treatment. They may be handled by more experienced staff than those who examine typical routine samples, subjected to more rigorous checking procedures than normal, or results and information from other participants (collusion) may be sought before reporting. These practices must be discouraged by laboratory management. If the scheme organisers suspect collusion then the laboratories concerned will be contacted.

To help to prevent malpractice and in order to gain maximum benefit from PT, management are advised to deal with situations where results for PT samples are incorrect in a sensitive manner. Problems may result from general failures in the quality system rather than from errors by individual staff. If incorrect PT results are not handled with sensitivity, staff may become defensive and will make more effort with PT samples in future to avoid further criticism. It is essential to involve staff closely in the process of quality system development. A positive approach to PT will help to reassure staff; guidance for helping to investigate incorrect results is provided in **17.0**.

4.0 Scheme participation

PHE PT samples are grouped into schemes; each scheme is described on the website www.gov.uk/government/collections/external-quality-assessment-ega-and-proficiency-testing-pt-for-food-water-and-environmental-microbiology (the correct website URLs for each scheme is listed on page 3 of this document). The schedules for each scheme are also available from the web-site and a booklet summarising all the schedules (Ref. FEPTU483) is sent to all participants at the beginning of each distribution year. FEPTU staff are able to provide advice regarding the most appropriate scheme for laboratories.

The schemes are open to microbiology laboratories that can provide assurance that their facilities and expertise are adequate to ensure the safe handling and disposal of the samples. The terms and conditions of participation are available from the website: www.gov.uk/government/publications/external-quality-assessment-ega-and-proficiency-testing-pt-scheme-registration-form-and-terms-of-conditions-of-participation.

Laboratories are encouraged to participate in all distributions (rounds) of a scheme, although some flexibility is allowed for some of the schemes. On some occasions, other bodies such as retail groups or accreditation bodies may advise on frequency of participation. Further guidance may also be sought from the scheme organisers.

5.0 Registration fees

The fees for participating in the PT schemes are reviewed annually; participants are advised, in advance, of any changes to registration fees. Price lists are also available from the scheme organisers on request, or from distributors in some countries outside the United Kingdom. Listed prices include PT samples, reports, repeat samples and advice as required. They do not include dispatch fees for laboratories outside the United Kingdom.

6.0 Confidentiality

All participants are allocated a unique laboratory identification number when they register for a PHE PT scheme. The same laboratory identification number will be used for participation in multiple PHE food and water microbiology schemes. The laboratory identification numbers are known only to the participating laboratory and the relevant PHE staff. This system enables results to be reported without divulging participant identity. Participants may reveal their identification number to other bodies if they choose to do so; PHE will never reveal identification numbers to any other organisations unless expressly instructed to, in writing, by the participant. If either a participant or a member of PHE staff has any concerns that anonymity has been compromised then a new laboratory identification number will be issued. If a participant wants to submit more than one result per sample, for example in order to challenge two different methods, then they must register for a second laboratory identification number.

7.0 Sample dispatch

The PT samples are dispatched in compliance with the relevant international regulations. Instructions for storage of samples on receipt are printed on the request/report forms and outside of the boxes; the dispatch boxes are not intended for reuse. Request/report forms that describe the examinations required and provide the links to the website for the instruction sheets, videos on sample handling and safety data sheets are included with the samples; these forms will show the laboratory identification number (which must be checked by the participant on receipt) and should be referred to for the final date for returning results.

The dispatch dates are included in the booklet summarising all the schedules (Ref FEPTU483). Forwarding laboratories are used in some countries outside the United Kingdom to reduce the cost of dispatch; those laboratories receive all the samples for a country in a single over-pack for onward dispatch using the most appropriate local system. All participants are advised that if they do not receive their samples within seven days of the dispatch date then they should contact FEPTU so an investigation can be initiated. If PT samples are damaged or lost in transit then they are normally replaced without further cost to the participant. Contact the organisers for advice if you receive damaged samples.

8.0 PT samples

There are two sample formats for the PT samples: freeze-dried micro-organisms in evacuated glass vials and LENTICULE® discs. The sample format used depends on the purpose of the individual scheme. Instructions for rehydration of the samples prior to testing are available from the website under the relevant scheme information:

www.gov.uk/government/collections/external-quality-assessment-eqa-and-proficiency-testing-pt-for-food-water-and-environmental-microbiology.

Instruction sheets are available in a number of European languages.

The samples are prepared in advance and are subjected to an array of control tests prior to dispatch. The sample contents are designed to ensure that participating laboratories will receive a wide range of different target micro-organisms; where enumerations are required, the samples will be designed in such a way as to ensure that participation over a distribution year will allow a challenge to a laboratory's accuracy with a range of different levels.

The samples are mostly straightforward; they are not designed to be 'tricky' or to 'catch people out'. On most occasions, the samples will reflect what is likely to be found in routine samples submitted to food, water and environmental microbiology laboratories, although the proportion of positive results is

significantly greater with the PT samples. Occasionally, a sample will be included that contains unusual micro-organisms to give participants the opportunity to gain experience.

9. Non-conforming products

Despite the rigorous quality control tests that are undertaken, there may be rare occasions when a sample does not meet the required specifications; this may be identified after dispatch. Participants will be informed as soon as possible if such a situation arises, with an explanation of how or if their results will be analysed. The outcome will be dependent on the specific situation.

10.0 Sample examinations

Participants are advised to read the instruction sheets for sample reconstitution for every distribution of samples in case there are any changes from previous distributions. After the samples have been reconstituted participants should use their routine methods. PT results will only provide an effective insight into routine results if the PT samples are treated in the same way as routine samples. Some schemes, such as the Shellfish and European Food Microbiology Legislation schemes, are designed for processes where a particular method may be stipulated in EU legislation. In most cases participants should use the method they believe to be most appropriate; method analyses are undertaken on some occasions to provide background information. The FEPTU senior microbiologists are sufficiently experienced to be able to provide advice about the impact of different methods on participant results. Comments will be included in the distribution reports if this is a sample-specific effect; more general advice for individual participants will be provided on request.

There is sufficient reconstituted sample material for some of the schemes for at least two/three members of staff to perform all the tests required. However, one result must be nominated for statistical calculations.

11.0 Reporting results

Results must be reported to FEPTU by the deadline date noted on the request/report form. Sample contents will not normally be revealed to any participants before the deadline date to prevent collusion. Extensions to the deadline dates cannot normally be accommodated; late results (results received after the deadline date) will not be included in the reports.

For some schemes, more than one set of results may be reported. However, one result for each test must be nominated and reported to FEPTU for statistical calculations. One of the reasons for this is to prevent multiple results from a single laboratory skewing the statistical calculations. If more than one member of staff (or staff team) examines a sample it should be decided in advance which set of results will be submitted. The sets of results should not be combined as this may mask an individual's poor performance.

12.0 Notification of intended results

Intended results are published on the website on the first working day following the close of each distribution (unless otherwise advised usually through an email). Email notification of the intended results is sent to participants who have supplied their email address. The intended results are derived from the results obtained in the FEPTU laboratory and are provided for guidance. The results for detection of micro-organisms are very unlikely to change prior to the final report, although the expected ranges for enumeration results in the reports are derived from participant consensus data so may show minor differences from the initial intended results. Participants should compare their results with the intended results and decide if any repeat samples need to be ordered to investigate discrepancies. They should decide whether immediate action is necessary or whether investigations should wait until the distribution summary report is received (usually within three weeks). Generally, it is advisable to perform an initial investigation as soon as possible.

13.0 Establishing assigned values (intended results)

The assigned values for qualitative examinations (detection or presence/absence examinations) are derived from the sample contents; the samples are designed in such a manner that it is statistically unlikely that a participant will report an incorrect result for a qualitative examination by chance.

The assigned values for quantitative examinations (enumerations) are derived from participants' results using robust statistical methods including calculation of the median, calculation of the median absolute deviation from the median, percentile ranges and standard deviations from the median values. The median is used in preference to the mean because the median is less affected by extreme outlying results. In practice the two values are usually very similar. The methods used are dependent on factors such as the purpose of the scheme, the levels of micro-organisms to be enumerated and the number of participants reporting enumeration results for a particular parameter. A description of the statistical methods used for each scheme is provided on the web-site: www.gov.uk/government/publications/food-and-water-proficiency-testing-schemes-scoring-systems-and-statistics

14.0 Allocation of scores and performance assessments

The allocation of scores is a means of drawing attention to differences between a participant's result and what has been designated as the intended result or the 'assigned value'. Scores may help participants to identify whether there is a problem with their testing, although low scores do not always mean that this is the case. There will always be differences in laboratory practice; this means that the score allocated for the PT results may not be totally applicable to a particular situation. For example, a participant may report an outlying result for an enumeration because they use a method that results in a higher recovery than methods used in most other laboratories. In this situation, the low score does not indicate a problem but this should be documented, indicating that no corrective actions are required.

Participants are advised that if they report outlying results for enumerations and are allocated low scores on single occasions only then they should not be unduly alarmed, although they should still assess the reason(s) for the outlying result. This is particularly important for samples that are likely to contain very low levels of micro-organisms, such as for the Drinking Water, Bottled and Mineral Water, Endoscope Rinse Water, Dialysis Water and Hospital Tap Water Schemes.

The allocation of scores is provided as a management tool to help assess performance; it cannot replace assessment of PT results in the context of the individual laboratory. Methods should never be amended for the sole purpose of achieving better scores with PT samples.

15.0 Reports

Distribution scheme reports are provided after every distribution, normally within three weeks of the deadline date (depending on the scheme) for return of results, and include the expected results for each sample and a comparison of an individual participant's results together with those of all the other laboratories that participated in the distribution. Note that enumeration results are often converted to log₁₀ values.

Sample-specific comments are often included in reports, as appropriate. Scores and an overarching assessment of performance over time, using the scoring system, are also included, together with statistical data, and bar charts or scatter graphs to demonstrate the range of enumeration results reported. FEPTU contact details, the names of the FEPTU staff who contributed to the distribution and the person who authorised the report are provided for all reports.

16.0 Trend analysis and performance data: Uses

Although the distribution scheme reports provide information about performance over an extended period of time, participants are also advised to monitor their own results to identify trends that may not be apparent from the reports. Trend analysis charts are available from the website with the relevant scheme information to help with this www.gov.uk/government/collections/external-quality-assessment-ega-and-proficiency-testing-pt-for-food-water-and-environmental-microbiology. The on-line reporting system also provides trending information. Trend charts allow the laboratory to plot its own result for an enumeration test against the participants' median result. The ensuing graph can then be examined for the presence of any trends or bias. The laboratory should investigate the reasons if these are found.

It should be noted that participation in proficiency testing schemes is one of the few ways that the laboratory's bias can be determined.

The PHE schemes always publish the number of colony forming units per gram or per litre for detection (presence/absence) tests such as *Salmonella*. This information can be used by the laboratory when compiling performance data including its **lower limit of detection** for each detection method.

17.0 Response to incorrect results

A common initial response to incorrect results with a PT sample may be that 'there was probably something wrong with the sample'. While it not possible to demonstrate that every single sample of a PT batch is representative, stringent manufacturing practices, past experience, homogeneity and stability testing, and general sampling of the batch by the FEPTU laboratory provides good assurance that it is unlikely that a participant will receive an unrepresentative sample. If a participant does receive such a sample by chance, it is statistically extremely unlikely that they will receive a series of them.

Where incorrect results have been identified, it is advisable to consider, at an early stage, whether any actions are necessary. Repeat PT samples are normally available after every distribution, on request, and are provided free of charge. Appropriate actions following incorrect results may include:

- i) **Assessing methods:** *Is the laboratory using standard or validated, clearly documented methods for isolation, identification and enumeration?*
- ii) **Assessing QC procedures:** *Are there sufficient and appropriate QC procedures in place?*
- iii) **Assessing equipment:** *Is all the equipment used for the procedures (incubators, refrigerators, measuring instruments, spiral platers etc.) calibrated and monitored regularly?*
- iv) **Assessing staff training:** *Are the staff who perform the examinations fully trained and familiar with all the procedural steps?*
- v) **Assessing laboratory practice:** *Do staff adhere to good laboratory practice (GLP) at all times?*
- vi) **Assessing clerical procedures:** *Are the laboratory numbering and clerical procedures adequate?*

Participants must note that a single PT sample is not fully representative of the materials that are examined routinely in a food, water and environmental laboratory; also individual bacterial strains vary in factors such as growth requirements, antigenic structure and biochemical characteristics. For these reasons, it is inadvisable to make major changes, such as to suppliers or use of culture media, on the basis of results with single PT samples. Such changes may give better results with an individual PT sample but worse results with the majority of the routine food, water and environmental samples. Therefore, it is necessary to confirm that the problem revealed is general in nature, and this will require further investigation with real samples, before such changes are made.

It is important also to remember the impact of incorrect results if they arise with routine samples. Some examples are provided below:

False negative results: where a laboratory does not report micro-organisms that are present in a sample; this may have serious public health implications.

False positive results: where a laboratory reports incorrectly the presence of micro-organisms that are not present in a sample; this may result in unnecessary product withdrawal for a foodstuff, or inappropriate treatment of a water system, with serious financial implications.

Incorrect results for enumerations: where a laboratory reports results that are consistently higher or lower than would be expected; this may result in a misleading impression of hygiene conditions, or of the severity of the risk associated with the sample.

18.0 Complaints and comments

Complaints arise when a participant expresses dissatisfaction about one or more aspects of the PT service. Participants can appeal if they are not satisfied with the evaluation of their performance in the PT service.

Complaints are always documented and investigated; participants are advised of the outcome. The FEPTU management monitors and assesses all complaints to determine the underlying causes and whether any changes to the quality system are required to improve the service.

General comments, feedback and suggestions for change are always welcomed; participants are encouraged to submit these by email, fax, mail or telephone; wherever possible, written responses will be sent within two working days.

FEPTU may distribute questionnaires, on occasion, to solicit participants' opinions about proposed changes to a service, or to assess whether the service provided continues to be fit for purpose.

19.0 Conferences

Open scientific conferences that cover aspects of the PT schemes and also provide updates about new and emerging issues in food and water microbiology are organised regularly (approximately every 18 months). The conferences allow further opportunity for participants to meet FEPTU staff and other colleagues working in their field to discuss the schemes and other food and water microbiology issues.

20.0 Scheme consultants

The PHE food and water PT schemes are supported by a number of consultants who are experts, with many years of experience, in the relevant field of proficiency testing, food microbiology and/or water microbiology. Most of the consultants are, or were, employed by the PHE and are internationally recognised; they are all members of the Steering Group on Food and Water Microbiology Schemes. The consultants not only provide advice for the scheme organisers but are also able to respond to participant queries that are submitted via FEPTU, as required.