



European Community Reference laboratory
for monitoring bacteriological and
contamination of bivalve molluscs

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Community Reference Laboratory (CRL) guidance on performance assessment in proficiency testing and follow-up activities

Introduction

Article 33 of Regulation (EC) No 882/2004 of the European Parliament and of the Council on Official Controls performed to ensure the verification of compliance with feed and food law (Anon 2004) sets out the remit of European National Reference laboratories (NRLs). This article specifies that where appropriate, NRLs should organise comparative tests, also known as proficiency testing (PT), between official laboratories and ensure an appropriate follow-up of such comparative testing.

All laboratories undertaking Official Controls on live bivalve molluscs should participate in a relevant PT scheme organised by their NRL or another designated programme (e.g. those organised by the CRL). Proficiency testing enables both an independent assessment of laboratory performance and comparative performance assessments with other participants. The frequency of such participation should be at least biannual to enable identification of poor performance over a realistic timescale. Laboratory performance should be monitored by the NRL on a regular basis. Poor performance should be investigated and reasons for failures identified. Laboratories that continually or persistently fail in proficiency tests may be suspended from Official Control testing by the relevant authorities.

Frequently PT schemes utilise statistical approaches to assess participant's performance and assign acceptability criteria. The following document describes an approach to assessing performance in comparative testing based upon allocation of numerical scores. Examples of follow-up procedures and suggested courses of action in the event of continual or persistence poor performance are provided.

The use of scoring

Allocation of scores in proficiency testing schemes enables measurement of performance based on empirical data. The bullets listed below set out the advantages of the use of scoring in proficiency testing.

- Scoring systems are used to help assess participants' results in proficiency testing schemes. Allocation of scores helps participants', and other entities (CRL, NRL, Accreditation bodies), assess their performance.
- Scores can be used to assess performance in a single distribution (or sample) and to monitor ongoing performance over time with assessments on cumulative scores over a specified timeframe or number of distributions.
- Scores help scheme organisers recognise those participants' who experience problems and thus enable provision of additional help, advice and support.
- Scores are usually allocated following statistical analysis of participants' results. It is important that scoring procedures are reviewed frequently to ensure continued fitness for purpose.

An example of a scoring system appropriate for use for *Escherichia coli* MPN/100g is given in Table 1; this approach is used in the CRL/HPA shellfish scheme (for further details <http://www.hpa.org.uk>)

Table 1. Allocation of scores in the CRL/HPA shellfish scheme

Results	Points allocated
Return of results	2
All replicate MPN results within the expected range	10
Or	
One replicate MPN result reported is outside the expected range and falls between the median $\pm 3SD$ and the median $\pm 5SD$ value	7
Or	
Both replicate MPN results reported are outside the expected range and fall between the median $\pm 3SD$ and the median $\pm 5SD$ value	4
Or	
One replicate MPN result reported is outside the median $\pm 5SD$ value	5
Or	
Both replicate MPN results reported are outside the median $\pm 5SD$ value	0
Or	
Single MPN result reported only	5
Or	
Tube combination inconsistent with MPN reported (one replicate)	7
Or	
Tube combination inconsistent with MPN reported (both replicates)	5
Or	
Sample not examined or results returned late- no explanation received	0
Or	
High censored result (e.g. MPN=>18,000 per 100g)	Score not allocated

In the CRL/HPA shellfish scheme the cumulative scores are calculated for each participant for the current and previous two distributions resulting in an individual distribution and rolling performance score. Preset performance measures are set to trigger follow-up procedures. In the CRL/HPA shellfish scheme these performance measures are set by the scheme steering group as follows:

- *E. coli* – Participant's who achieve <40% for single distribution or <70% over the three consecutive distributions
- *Salmonella* spp.– Participant's those who achieve <70% over three consecutive distributions

It is important to note that the efficacy of scoring systems should be reviewed regularly, the CRL/HPA scoring scheme is subject to formal review annually.

Monitoring of laboratory performance

Laboratory performance should be monitored frequently and according to a defined schedule. Where poor performance is noted certain procedures should be instigated. When scoring systems are utilised failures may be identified by participants' scores that fall outside of defined performance criteria. Such occurrences should trigger follow-up activities by NRLs, all PT failures should be examined by the NRL. Follow-up procedures should be fit for purpose and regularly reviewed.

In the first instance it is recommended that the laboratory experiencing a failure in a proficiency test should be contacted and reasons for failure identified. This will enable the laboratory to conduct an investigation under their quality procedures into the nature of the failure and if available repeat the test.

The NRL should be aware of the performance of Official Control laboratories under their supervision. If the NRL does not organise the PT directly a method of dissemination of this information should be agreed in advance with the scheme organisers.

It is anticipated that unless otherwise agreed the NRL should undertake proactive checks covering Official Control Laboratory performance in proficiency testing on at least an annual basis.

Example follow-up procedures

- Follow-up procedures can include:
 - Examination of methodology in use, through for example, scrutiny of the laboratories standard operating procedures and result interpretation/reporting protocols.
 - For culture based methods in microbiology e.g. ISO TS 16649-3 and EN/ISO 6579, quality control information of media should be scrutinised to ensure that media is performing adequately.
 - Equipment records for equipment used in the procedures (e.g. incubators, measuring instruments, refrigerators) should be checked to ensure appropriate calibration, maintenance and performance.
 - Staff training records should be examined to ensure that staff are adequately trained; familiar with procedures and that ongoing checks of staff competence are in place.
 - Clerical procedures should be scrutinised to ensure that sample receipt, sample labelling, laboratory numbering and supporting clerical procedures are in place. It is worthy of note that frequently failures in proficiency testing can stem from failure to return results within a specified time frame. Laboratory systems should be in place to ensure that results are reported accurately and on time.
 - Accreditation records should be checked to ensure that staff adhere the laboratory quality policy at all times.
 - The use of, type and relevance of internal quality controls should be examined.
 - Laboratory quality procedures for reacting to internal/external quality control failures.
 - Onsite observation of practices in the poorly performing laboratories.

Corrective Actions

If a laboratory continues to fail in a proficiency test (or series of tests), or fails to provide adequate justification for the responsible authorities should be notified.

Continued failure in proficiency testing may result in the formal removal of the laboratory from Official Control testing.

References

Anon 2004. European Communities 2004. Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. Off. J. Eur. Communities L 165, 30.4.04 : 1-141.