Guidance for Food Business Operators:

Getting the Best from Third Party Laboratories

First Edition

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Produced in collaboration with Food Standards Scotland

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Checklist

It is important to note that a laboratory may be accredited for some but not all of the analytical methods it offers to its clients, and that accreditation may not cover usage with specific food matrices.

When carrying out testing for legal purposes, Food Business Operators (FBOs) must carry out sampling correctly, label samples appropriately, ensure a secure and clear chain of custody, receive confirmation from the laboratory that stipulated accredited methods were used, etc.

Best practice for an FBO is to:

- Ensure the laboratory is accredited to ISO 17025 (e.g. by UKAS or equivalent), and separately for the methods that are legally prescribed or recommended by established guidelines
- Verify certification scopes are current and ensure requested analysis has been validated for the sample matrix
- Ensure all samples are fully labelled to enable traceability and make clear the status of the sample, e.g. trial product
- Ensure the laboratory understands any segregation requirements
    - microbiology: RTE or not, raw meat or unwashed produce
    - chemistry: allergens / or any ingredients that may affect the results
- Ensure the laboratory has specifications for all samples submitted and documented instructions for reporting results.
- Ensure a Service Level Agreement has been checked, agreed and reviewed on a regular basis, to include confidentiality, impartiality/conflict of interest, contacts (including emergency contacts), sample specifications, pick up times (including bank holidays), temperature controls, maximum time for sampling, testing and reporting, agreed terms of usage (if any) of subcontracted laboratories.
- Ensure samples are taken, packaged and transported appropriately to the laboratory (See section 4)
- Check the capability of Laboratory Information Management System (LIMS) and the ability of the laboratory to provide data in the required format, e.g. trended, *vs* specification

Elements contributing to a good relationship of FBOs with laboratories include:

- Key contact lists at FBOs and laboratories are kept up to date
- Procedures are in place to enable clear lines of communication of results
- The laboratory welcomes laboratory tours to aid understanding in your business, facilitate unannounced visits by the customer when required, and be able to provide requested information at the time of the visit (e.g. traceability, temperature control, calibration, training records)
- The laboratory ensures a Service Level Agreement is in place, with clear KPIs/Continuous Improvement Indicators (see Table 1)
- The laboratory shares internal non-conforming work issues that may have affected FBO's results, e.g. detection of pathogens from laboratory environmental sampling
- Any issues and / or complaints are investigated, and actions communicated to the client in a timely manner
- The laboratory actively communicates changes in methods (e.g. changes in LOD of allergens), accreditation status and key personnel
- The laboratory notifies the Client in a timely manner in the event of a non-conformance that may affect the Client's results

- The laboratory holds regular KPI (or customer relationship) meetings with the Client and reports on agreed KPIs
- The laboratory keeps in regular contact with key staff regarding issues, customer services and encourages a good relationship
- The laboratory notifies the client when experiencing increased volume (e.g. increased number of FBO samples), or decreased laboratory capacity, and discusses to agree on solutions
- The laboratory shares, on request, results from Internal Quality Assurance (IQA) and External Quality Assurance (EQA) covering test methods and laboratory analyst performance, monitoring and investigating in line with documented procedures any which fall outside the acceptable criteria. Laboratories should ideally present results in graphical form to allow trends and biases to be identified
    - The laboratory should have a schedule to ensure all laboratory analysts, food matrices and tests are covered within a given time period.
    - Results are reviewed at regular intervals to enable trends and biases to be identified for test methods, matrices and analysts, and actions arising from the identification of trends or biases to be investigated, actioned, verified and documented.

In addition, dependent upon expertise, Laboratories may be able to provide the following:

- advice on testing schedules, swab points and sampling
- consultancy on site-based microbiological issues, such as troubleshooting to identify the potential source of a problem
- advise on changes to legislation or guidance, e.g. legislation, PHE Guidance for assessing the microbiological safety of ready-to-eat foods placed on the market, or the IFST Handbook of Microbiological Criteria for Foods
- provide training courses

Criteria recommended for a purchasing organisation to use when employing the services of a laboratory/analytical service are[1]:

1. Accreditation to ISO 17025 by a suitable body (e.g. UKAS, CLAS) for the performance of tests using legally recognised methods (section 3)
2. Compliance with the requirements of Customers e.g. Retailer Supplementary Audit (RSA) scheme compliance / specific method requirements.
3. Suitably trained, qualified and knowledgeable staff who keep up to date in their areas of work and can provide flexibility to cover roles professionally
4. Sufficient staff to undertake the work required, including at peak times and during holiday periods
5. Sample temperatures controlled and not subjected to temperature abuse, and auditable from receipt, storage and analysis.
6. An appropriate track record in providing such services to industry
7. Check the UKAS website or RSA[2] to check accreditation status. If necessary, consult their local Regulatory Services or their local Public Analyst regarding the *bona fides* of an organisation they wish to employ.

[1] https://www.gov.uk/government/publications/elliott-review-into-the-integrity-and-assurance-of-food-supply-networks-final-report
[2] https://www.campdenbri.co.uk/services/rsa.php

1. Background and Guidance Aims

Industry has legal responsibilities, under both domestic and EU law, to ensure that food is safe, accurately described and labelled, and does not mislead the consumer. Where industry uses laboratory testing to help it meet those responsibilities, for validation or verification, it must ensure that the testing is fit for purpose and able to withstand legal scrutiny in the case of challenge.

Whilst this document is focused on microbiological analysis, the general principles apply to all analytical services.

This guidance aims to raise awareness of the need to use analytical laboratories with the right expertise, accreditations, using appropriate methods and facilitate development of partnerships between such third-party laboratories and their customers in the food industry, moving away from purely transactional arrangements. To achieve this, greater transparency is needed from both companies and laboratories, with greater understanding of each other's needs and impacts on business and working to agreed Key Performance/Continuous Improvement Indicators (see Table 1) regarding resilience, reliability, relevance and sustainability of analytical services.

2. Scope

Analytical services provided by a third party to a food business operator, with focus on microbiology.

3. Fitness for Purpose – Laboratories and Methods

It is important to understand that accreditation is awarded for a specific method for the specific type of sample, and not for the laboratory overall. Accreditation encompasses all aspects of the laboratory's quality management system including the handling of complaints and non-conforming work.

The onus is on industry to demonstrate due diligence and to only use appropriately accredited methods for the specific issue in question.

Fitness for purpose can also comprise compliance with any particular voluntary proficiency scheme when used as part of a voluntary national surveillance programme, e.g. *Campylobacter*.

Note that CFA's Best Practice Guidelines for the Production of Chilled Foods (4th ed, 2006)[3], compliance with which is a prerequisite of CFA membership, requires for third party laboratories that *"These services must work to a documented quality management system and use competent personnel and laboratories must be proven to be competent in the tests carried out and must use official methods or validated alternatives".*

A culture of continuous improvement should be seen and be supported by data confirming corrective actions taken and issues closed out (see Table 1).

[3] www.tsoshop.co.uk/chilledfoods

Table 1: Industrywide Continuous Improvement Indicators for Laboratories

Indicator	Rationale and notes
Does the laboratory identify non-compliances (NCs), document and address their root cause?	Overall performance measure indicating the laboratory is picking up its own (NCs) and addressing them prior to complaints being raised by customers
Does the laboratory document and minimise the risk of recurrence of customer complaints? See section 6	
Have any changes been made to methods, e.g. from the scope	Relates to amendment without approval of ISO and other standard methods, invalidating testing done under e.g. Regulation (EC) 2073/2005, to absence of UKAS certification or equivalent for each method-material combination.
The laboratory has a procedure to keep abreast of necessary changes to methods from scope and other changes and notifies customers in advance of the method being used.	
The laboratory must have validated and verified the disciplined segregation procedures in place to prevent cross contamination including from transport (where it is in the control of the laboratory) to analysis according to microbial risk, e.g. cooked components, raw RTE, raw ready to cook.	
Samples are tested and results reported to the customer to agreed timescales	Relates to adherence to agreed timescales: • whether a sample is tested on the agreed date • for couriering samples including between laboratories. Transport issues resulting in delays to receipt to be addressed immediately and customers advised. • QC failures causing the results of testing to be invalidated or delayed Efficacy of communication to customers monitored and non-compliances (NCs) flagged and acted on
EQA proficiency testing carried out covers all methods, matrices and staff on a yearly basis. Any trends or bias are actioned.	Customers advised of any failures potentially impacting on the quality of test results
Outcomes of any audits carried out are shared on request with customers– including NCs (majors, minors), rectification progress, closeouts	Internal – carried out by whom and at what time (e.g. out of hours) - and external. Customers advised of any failures potentially impacting on the quality of test results
Results of internal hygiene swabbing of laboratory for indicators and pathogens e.g. *Listeria monocytogenes* and Salmonella spp during laboratory operation, any non-conformances to be immediately followed up (root cause identification and rectification, and advising customers of any potential for impact on their results)	Customers advised in a timely manner of any failures potentially impacting on the quality of test results, in particular regarding pathogens
Changes to staff/staff turnover, hours, overtime and absence worked are monitored and systems in place to notify any changes to the customer	Relates to training and cross-contamination. Senior staff changes and rate of general staff turnover to be notified to customers. Hours worked relate to scheduling and capacity
A procedure must be in place for reporting of any temperature exceedances outside of the specification	Any laboratory or transport exceedances that potentially affect results of tests. Laboratories must notify customers
A procedure to notify the customer beforehand of any outsourcing/subcontracting of services – must be in place. The outsourced/subcontracted laboratory must meet the requirements of this guidance and be approved by the Client.	Relates to sending of samples to other laboratories. Extent of outsourcing to be communicated to customers as an indicator of lab capacity issues. Notify customers in advance of any proposed outsourcing. Notify customers in advance if samples are proposed to be sent to another lab for testing.
Share outcomes of internal audits and management reviews with customers	

This table provides a means of assessing performance. Consistent failure to meet continuous improvement indicators may result in a laboratory being put into special measures by a customer. See Section 8.

4. Provision of Samples to Laboratories

NOTE: Great care must be taken during sampling and handling of samples to ensure that they do not become contaminated and/or cross-contaminated.

Samples are taken for a variety of reasons such as to verify process safety, to validate and/or verify shelf life, to monitor production controls.

Samples must:

- Be representative of the full process and taken at the appropriate stage, e.g. for final product after blast chill and in final packaging, be stored according to the recommended storage temperature or abuse temperature at all stages from sample collection to analysis. An additional sample should be placed in with a batch of samples for temperature checking upon receipt at the laboratory.
- Be labelled to ensure full traceability. This must include sample description (e.g. trial product), date and time of sampling as a minimum.
- Be sent in leak-proof containers and appropriate transport and storage in the laboratory used to ensure no cross contamination occurs between different samples.
- Any consumables supplied by laboratories to FBOs must be appropriate to the type of sample to be taken (e.g. neutralisers for environmental swabbing[4]).
- Samples should be taken to the laboratory with the minimum delay, and tested within 24 hours of samples being taken, and where this is not possible, this should be agreed with the food business operator.
- Appropriate clean, new, sterile containers must be used.
- The sample container should be labelled prior to sampling (nature of the sample, date and time of sampling, location, who took the sample) to enable it to be traced and for appropriate testing to be done (e.g. raw/cooked).
- Samples taken must be delivered as soon as possible to a holding fridge where the temperature is monitored and maintained at 1-5°C, or appropriate to the sample type, or as otherwise agreed. The temperature of the sample must always be maintained.
- Unless otherwise agreed samples delivered to the laboratory by the Client must be stored at 1-5°C at all times and delivered in a cool box/mobile refrigerator pre-cooled to 1-5°C (or appropriate to the sample type) as soon as practicable.
- Chilled food samples must not be frozen prior to testing.
- The chill chain to the point of testing must be monitored and auditable.

Key principles of scheduling sample despatch:

- Companies must advise laboratories in advance of launches/other peaks to aid laboratory planning
- Routine vs development samples should where possible be scheduled to avoid logjams and to allow laboratories to resource appropriately

[4] EU Reference Laboratory for *L. monocytogenes*. "Guidelines on sampling the food processing area and equipment for the detection of *Listeria monocytogenes*." Version 3–20/08/2012. https://eurl-listeria.anses.fr/en/system/files/LIS-Cr-201213D1.pdf

5. Reporting Results

Care must be taken to clearly identify the stage at which the result is regarded as suspect, presumptive and confirmed, and define at which stage results require direct reporting by telephone to the client and which require immediate action by the laboratory and/or client, out of hours contacts (see Table 2).

Laboratories must present results clearly, for example stating that a negative result does not mean that the organism was not present, but that it was not detected and giving the limits of detection and/or quantification applicable.

Table 2: Findings, Laboratory Action and Communication of Results

Finding	Action by Laboratory	Communication and Action
Presumptive*/Suspect*	Confirmation testing required according to the internal methodology or as agreed with the Client	From the laboratory to the manufacturer, in line with written agreement. Suspect colonies will require further confirmation and are usually not required to be reported to Retailer. The manufacturer may advise the customer of the findings according to risk and Retailer requirements.
Presumptive*/ Confirmed	These are the final results reported and will not require further testing by the laboratory	From the laboratory to the manufacturer, in line with written agreement. A presumptive result may require further confirmatory testing if a food safety issue is indicated. The manufacturer must risk assess and advise the customer of the findings.
Counts exceeding the Report level or set by legislation	**Advise manufacturer of exceedance, in line with written agreement** Carry out additional testing as agreed with the manufacturer	Manufacturer to report to Customer according to their requirements and take appropriate actions.
Presence of target organism (e.g. Lm)	**Advise manufacturer of exceedance, in line with written agreement.** Report enumeration with the detection result. Carry out additional testing as agreed with the manufacturer	From the laboratory to the manufacturer, in line with written agreement. Manufacturer to ensure Legislation is complied with**.
Counts exceeding the food safety criteria set out in the MCFR (2073/2005 Annex I, Chapter 1)	**Advise manufacturer immediately of exceedance, in line with written agreement.** Carry out additional testing as agreed with the manufacturer or customer	Laboratory to Inform manufacturer immediately. Retailer own label product: Manufacturer to advise brand owner of exceedance. Brand owner to advise Competent Authorities of exceedance. Branded product: Brand owner to advise Competent Authorities of exceedance.
Counts exceeding the process hygiene criteria set out in 2073/2005 (Annex I, Chapter 2)	**Advise manufacturer immediately of exceedance, in line with written agreement.** Carry out additional testing as agreed with the manufacturer or customer	From the laboratory to the manufacturer, in line with written agreement. Manufacturer to investigate and take effective corrective action.

See CFA's Microbiological Testing and Interpretation Guidance (2nd ed, 2016). For further details

*Laboratories use the terms presumptive and suspect interchangeably. Most third-party laboratories do not use the term suspect. This can cause confusion as this suspect stage may also be reported as presumptive by the laboratory. For clarification the two terms have been separated above. Ensure you are clear at what stage the test is at and whether any further testing is being carried out. The laboratory must specify whether any further testing is being done to confirm results. A suspect result must not appear on a final report. A true presumptive is the reported result when **no** further testing is routinely carried out by the laboratory. See Terminology (Appendix 1).

**** Note that presence of *L. monocytogenes* is not an automatic breach of Regulation (EC) 2073/2005**

6. Complaints Procedure

Manufacturing sites should define their procedure for raising laboratory issues, which should include the laboratory formally logging complaints, the company collating complaints within the group and reviewing actions taken by the laboratory.

The laboratory must have a complaints procedure which is agreed with the food business operator.

It should be clearly stated in the procedure:

a. What the complaint resolution procedure should comprise, i.e.
    i. Which results have been affected
    ii. Immediate actions taken
    iii. Root cause analysis completion within an agreed period
    iv. Identifying systemic measures to address any and all deficiencies identified through root cause analysis
    v. Confirmation of closeouts within an agreed timescale to permanently address issues
b. How to monitor efficacy of preventative actions, including
    i. Trending complaints to identify new or repeat issues
    ii. Further corrective action – when it is required and monitoring to determine efficacy (feedback loop)

7. Selecting a laboratory through tender

Consider all of the above points and, in addition:

1. Commercial aspects: pricing structure transparency taking into consideration additional costs such as:
    - temperature checks on receipt, gas checks
    - transfer of samples between different storage temperatures
    - multiple dilutions
    - duplicate plating
    - confirmatory testing - price per colony versus price per plate or sample
    - checking the rate of high level of suspects not confirming
    - use of different methodologies for the same organism
    - charges for consumables supplied e.g. swabs, bags, bottles
2. Risk assess capacity including at peak periods
3. Trial to test capability
4. Dilutions appropriate to methods
5. Ensure appropriate scope of validation e.g. for different food matrices

8. Special measures for laboratories

A laboratory may be put into special measures by a customer on consistent failure to meet continuous improvement indicators.

Special measures can include adoption of an action plan to an agreed timescale for improvements such as laboratory meeting with customer monthly, reporting on progress to address any deficiencies identified.

Escalation can include measures such as sharing KPI performance information through trade associations and raising issues with the relevant certification body, e.g. UKAS, through trade associations.

9. Contracts

There should only be one contract between a laboratory and a company, which must be signed by all parties, either at group level if a multisite company, or at (local) site level if a single site company. The contract should include the legal terms and conditions and could include the Service Level Agreement (SLA).

The SLA could be a standalone written agreement owned by the local FBO site, but must not contain legal terms and conditions. It should cover:

- Sample receipt procedure
- Agreed test methods
- Shelf life protocols
- Specifications
- Exception protocols
- Subcontracting instructions
- Advice provision including approach to sampling, trending and analysis of results by the laboratory
- The laboratory's communication of findings to the FBO, including any requested group level contacts, and to any agreed third party
- Results reporting including out of specification notifications or suspect pathogens
- Sample retention, e.g. in the case of a retest or further examination of the samples being required
- Retest requirements
- Test reports
- Consumable requirements
- Charging and invoicing
- Consultation
- Complaints
- UKAS and RSA visits
- Laboratory communication to advise the FBO if analysis will be delayed and if so, by how long
- Confidentiality
- Impartiality
- Requirement for contracts to be signed and reviewed annually

Appendix 1: Terminology

Results:

- **Confirmed**: All tests have been completed, confirming the identity of the organism or substance.
- **Presumptive**: Tests indicate with a high probability the identity of the organism or substance. Depending upon risk to food safety, further confirmation may not be required. If a food safety issue is identified further confirmation will be required.
- **Suspect**: Further characterisation tests need to be done to determine the identity of the organism or substance. Suspects must not be reported on a final report.

Quality:

- **Accreditation/Certification**: Confirmation that the laboratory has been audited against a British standard (ISO17025 for testing and calibration laboratories) or Retailer Supplementary Audit (RSA) scheme and is compliant with the requirements
- **Accuracy:** The closeness of agreement between a test result or measurement result and a reference value.
- **Applicability:** the analytes, matrices, and concentrations for which a method of analysis may be used satisfactorily.
- **Bias:** Any deviation of results that are one-sided or systematic variations in measurement from the true value (systematic error)
- **Uncertainty of measurement:** Impact on results of testing from differences in methods, analysts, techniques, equipment, sampling and calibration
- **EQA - External Quality Assurance:** The term external quality assessment (EQA) is used to describe a method that allows for comparison of a laboratory's testing to a source outside the laboratory. This comparison can be made to the performance of a peer group of laboratories or to the performance of a reference laboratory. The term EQA is sometimes used interchangeably with proficiency testing; however, EQA can also be carried out using other processes. E.g. EQA Ring trials with other laboratories
- **IQA - Internal Quality Assurance:** Samples are prepared in house using stock cultures purchased through an accredited supplier. Results are internally compared to expected values.
- **Precision:** The closeness of agreement between independent test/measurement results obtained under stipulated conditions.
- **PT - Proficiency testing (part of EQA)**: Proficiency testing is the most commonly employed type of EQA, as it is able to address many laboratory methods. Proficiency testing is available for most of the commonly performed laboratory tests and covers a range of chemistry and microbiology immunology testing. Samples are purchased through an accredited proficiency testing provider and tested using the appropriate routine laboratory methods, results are submitted to the provider and a report is issued detailing sample content alongside statistical analysis in relation to expected values. Proficiency tests are essential for demonstrating the performance of a laboratory to third parties (e.g. to customers, to accreditation bodies or to other supervisory bodies).
- **Repeatability**: The variation that occurs when repeated analysis is carried out on the same sample using identical conditions: same technician, procedure, method, environment, and equipment – the ability to repeat the same results
- **Reproducibility:** The variation that occurs when different conditions are used for the same analysis: Different technicians, procedures, methods, environments and equipment – the ability to reproduce the same results
- **Sensitivity:** Measure of the ability of the analytical method to detect a change in the value of the quantity being measured. True positive rate
- **Specificity:** Measure of the ability of the analytical method to identify the organism being tested for. False positive rate

Appendix 2. Microbiology

A2.1 Legally Recognised Methods

For results to be valid in law, methods specified in relevant legislation including EU Regulations 2073/2005 and 853/2004 (as amended) must be used otherwise alternative methods to those prescribed in the Regulation may be used as long as those methods provide equivalent results validated against the reference method given in Annex I of the 2073/2005 (see Table 3):

Table 3: Microbiological Methods - Specified by EU Regulation 2073/2005

Organism	Method	
	Detection	Enumeration
ACC	ISO 4833	
Campylobacter	EN ISO 10272-2	
E. coli	EN/ISO 16649-3 (Criterion 1.25) ISO 16649-1 or 2 (Criterion 2.1.6) ISO 21528-1 (Criterion 2.2.9)	
Enterobacteriaceae	ISO 21528-2 ISO 21528-1 (Criterion 2.210)	
Listeria monocytogenes	EN/ISO 11290-1	EN/ISO 11290-2
Salmonella	EN/ISO 6579 for detection (typing: White- Kaufmann-Le Minor scheme)	
Staphylococci - Coagulase-positive	EN/ISO 6888-2 (Criterion 2.23) EN/ISO 6888-1 or 2 (Criterion 2.24)	
STEC	CEN/ISO TS 13136	

Table 4 below gives key information regarding expected turnaround times for common tests. The total test time is the primary indicator, but it should be expected that additional time is required to determine, analyse and interpret the results.

Table 4: Typical Expected Turnaround of Microbiological Tests if Compliant with Standard Methods

Method name	Test type	Sample Type		Incubation Temp °C	Incubation Time (hours)	Total Test Time from receipt by lab	Incubation Atmosphere	Confirmation (time)
TVC	Enumeration	Food or swabs	Plate Count Agar	30 ± 1	48 ± 4	~ 2 days	Aerobic	None
TVC 22°C	Enumeration	Water	Yeast Extract Agar	22 ± 1	68 ± 4	~ 3 days	Aerobic	None
TVC 37°C	Enumeration	Water	Yeast Extract Agar	37 ± 1	44 ± 4	~2 days	Aerobic	None
Coliforms	Enumeration	Food or swabs	Violet red bile Agar	37 ± 1	24 ± 2	~1 day	Aerobic	None
Enterobacteriaceae	Enumeration	Food and swabs	Violet red bile glucose Agar	37 ± 1	24 ± 2	~1 day	Aerobic	None
E. coli	Enumeration	Food and swabs	Tryptone Bile - X Glucoronide Agar	37 ± 1	4 ± 1	~1 day	Aerobic	None
				44 ± 1	18-24	~2 days	Aerobic	None
Yeast and Moulds	Enumeration	Food and swabs	Dichloran Rose- Bengal Chloramphenicol Agar	25 ± 1	72 ± 4	~3 days	Aerobic	None
Presumptive *Pseudomonas*	Enumeration	Food and swabs	Pseudomonas CFC Agar	25 ± 1	44 ± 4	~4 days	Aerobic	Required (same day)
Coliform and *E. coli*	Detection	Water	Colilert	37 ± 1	26 ± 2	~2 days	Aerobic	None
S. aureus	Enumeration	Food and swabs	Baird Parker Agar	37 ± 1	48 ± 4	~4 days	Aerobic	Required (2 days)
Presumptive *B. cereus*	Enumeration	Food and swabs	Bacillus cereus MYP Agar	30 ± 1	48 ± 4	~4 days	Aerobic	Required (1 day)
Listeria spp	Enumeration	Food and swabs	ALOA	37 ± 1	48 ± 4	~4 days	Aerobic	Required (4 days)
	Detection	Food and swabs	ELISA - enrichment	30 ± 1	22-26	2d for ND. Further 4d to confirm (dependent on method)	Aerobic	
			ELISA - selective enrichment	30 ± 1	22-26			
		Food and swabs	Selective plating - ALOA	37 ± 1	48 ± 4		Aerobic	Required (4 days)
			Selective plating - PALCAM	30 ± 1	48 ± 4		Aerobic	Required (4 days)
Salmonella spp	Detection	Food and swabs	ELISA - enrichment	37 ± 1	16-20	2d for ND. Further 4d to confirm (dependent on method)	Aerobic	
			ELISA - selective enrichment	41.5±1	21-27		Aerobic	
			Selective plating	37 ± 1	21-27		Aerobic	Required (4 days)
C. perfringens	Enumeration	Food	TSC Agar	37 ± 1	18-22	~1 day	Anaerobic	None

Regulation (EC) 2073/2005 states that alternative methods must be:

a. validated against the reference method, and if a commercial kit, certified by a third party using an internationally accepted protocol, i.e. ISO 16140 or

b. validated by an internationally accepted protocol and authorised by the Competent Authority.

The scope of any validation must be confirmed to cover the range of food matrices being tested.

Laboratories must verify that they can use the method correctly.

Proprietary kits must be accredited to ISO 17025 and confirmed to meet customer requirements.

See CFA's Microbiological Testing and Interpretation Guidance (2nd ed, 2016). For further details

A2.2 What other Microbiological Tests are Relevant for Various Food Materials

Testing for pathogens is stipulated by law (Regulation (EC) 2073/2005) and/or by customers. Consideration must also be given to the toxins formed by *B. cereus*, *S. aureus, C. botulinum* and *C. perfringens* if not controlled by, e.g. hygiene measures and/or thermal processes.

Pathogen growth and survival data must be consulted to determine whether it is valid to test specific products on the basis of their formulation/processing. What testing is recommended by CFA is given in its Microbiological Testing & Interpretation Guidance, 2nd ed) and is legally required under Regulation (EC) 2073/2005.

The timescales set out in Table 4 are those expected when analysis is carried out according to accredited methods. Shortening turnaround times raises potential for methods to be compromised which may affect reliability and, where the method is specified by law, the ability to use the results in the case of legal proceedings. Shortened turnaround times must therefore be questioned by the food business and verified by the laboratory and food business to not compromise the resultant data.