United Kingdom Accreditation Service

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ASSESSMENT REPORT

Name & Address of Organisation	Aberdeen Scientific Services Laboratory, Old Aberdeen House, Dunbar Street Aberdeen AB24 3UJ	**Type of Assessment**	Surveillance
		UKAS Reference Number	5464
		Date(s) of Assessment	28/02/2020-19/03/2020
Assessment Location(s)	Aberdeen Scientific Services Laboratory, Old Aberdeen House, Dunbar Street Aberdeen AB24 3UJ	**Project references**	228513-00-01
Assessment Standard / Criteria	ISO/IEC 17025:2017 (Testing)	**Schedule Issue No(s)**	042
Name & Role of UKAS Assessment Team	Eddie Dix (Assessment Manager); Derek Farrington (Technical Assessor); Peter Sleeman (Technical Assessor); Paula Catchpole (Technical Assessor)	**Date(s) of Assessment Plan**	27th January 2020
		No. of (M) Findings: Action Mandatory	14
Name of Organisation Representative(s)		**No. of (M) Findings: Require Evidence to UKAS**	13
Report Issued By	Eddie Dix	**No. of (R) Findings: Action Recommended**	3
Report Issued Date	19th June 2020	**Method of Reviewing Evidence**	Remote
Report Acknowledged By		**Quote for Reviewing Evidence**	0.5 Days Quote to follow
Report Acknowledged Date	As email	**Agreed Action Completion Date**	19th July 2020
Report Acknowledged Method	email	Please return evidence to: customerservices@ukas.com Quoting the UKAS Ref.No in the subject field	

AREAS SAMPLED AT ASSESSMENT (*marked as 'X'*)			
ORGANISATION		*IMPARTIALITY & INTEGRITY*	
Legal Status	x	Independence, Impartiality & Integrity	x
Liability Cover (CB / IB only)	N/A	Confidentiality	x
Management of Finances (CB/IB only)	N/A	**EVALUATION PROCESSES**	
Resources	x	Design & Development of Methods	x
Organisation Structure	x	Enquiries, Tenders, Contracts	x
Responsibility & Authority	x	Planning & Resource Allocation	x
MANAGEMENT		Testing	x
Management System Including Documented Policies & Procedures	x	Reports & Certificates	x
Roles & Responsibilities for Quality	x	Decisions/Opinions	x
Control of Documents and Records		Certification & Maintenance of Certification (CB only)	N/A
Management of Sub Contractors and Purchases		**TECHNICAL COMPETENCE**	
Service to Clients (Test / Cal only)		Personnel	x
Handling of Complaints	x	Methods	x
Control of Non-Conforming Items Dealing with Corrective & Preventive Actions and Improvements	x	Facilities/Equipment/Environmental conditions	x
Internal Audit and Management Review	x	Assurance of Quality of test	x
Supervision & Monitoring of Staff	x	Witnessed Activities	x
Conditions for Granting & Maintaining Certification (CB only)	N/A		

Executive Summary and Recommendation

This was a surveillance assessment of the laboratory at Aberdeen Scientific Services, to assess their continuing competence against the requirements of ISO/IEC 17025:2005 for their testing activities. The assessment also covered the transition to ISO/IEC 170205:2017, which was postponed from 2019. The assessment was carried out as a remote assessment as a result of the Covid-19 outbreak. Due to the everchanging situation it was not possible to carry out all the planned remote method witnessing activities.

The Quality System has been generally well maintained and there is evidence that the changes required as a result of the transition to ISO/IEC 17025:2017 have been considered however there are still some points that need to be addressed and these have been identified within the separate transition report and Improvement Action Report. The laboratory is moving to a more electronic system of records, and these appeared on the whole to be well maintained. Internal audit records are well maintained, and the system appears to be operating well, however due to the remote nature of the assessment a full assessment was not possible. The process for recording non-conforming work has been updated to reflect changes for the transition and the form has been updated accordingly. There had been only one non-conformance logged using the new system and this appeared to have been suitably recorded, however the laboratory may wish to consider documenting the mechanism for how the process is used for identifying risks and opportunities. The laboratory personnel were extremely cooperative and supportive in the remote assessment approach, especially considering the constantly changing nature of the guidance during the early days of the Covid-19 lockdown.

The micro department has done their best to provided documents for review remotely, and several items have been received however due to decision to close the lab it has not been possible to conduct the test witnessing over the live streaming as planned and many items and records are in hard copy form and therefore currently inaccessible to the lab staff at this time. General procedures provided are appropriate and clearly documented giving confidence that good systems are in place, however as paper records in many cases were not able to be reviewed the maintenance in all systems over the last year could not be assessed. The test methods are clearly documented however, some are based on old references and the current standards have not been reviewed.

EQA performance over the year has been good, although where there has been the odd failure, the nonconforming work reports associated lack full details. Other systems to demonstrate test validity such as IQC and MQC have been well maintained and follow appropriate systems.

The remote review of records found the quality assurance systems in the water chemistry area being well maintained across the test methods. Technical record keeping was being maintained to a high standard and both the internal quality control performance and external proficiency testing scheme results over the past 12 months or so were very good (>97% of water chemistry results being *"Satisfactory"*) giving a good confidence in the analytical results being produced.

Decision is that accreditation to ISO/IEC 17025:2005 and the DWTS specification to be maintained for the current scope of accreditation, following satisfactory clearance of findings raised within the agreed timeframe and the outcome of a satisfactory site assessment when the situation permits.

Scope (if not covered elsewhere)

Due to Covid-19 pandemic the assessment was conducted as a remote assessment utilising remote review of documentation provided before the assessment, and additional documentation provided as part of the assessment process. No on site witnessing/assessment activities were undertaken. The remote assessment was carried out following a remote opening meeting on the 19th March 2020.

The plan was for the Technical assessors for food chemistry and food and water microbiology to carry out some remote method witnessing via the use of webcams. The water chemistry technical assessor did an entirely remote assessment, including vertical audit. The remote witnessing was planned for

various dates and times during the week commencing 23rd March 2020. Following the UK Government announcement to cease all unnecessary travel Aberdeen City Council chose to close all none essential services, including the laboratory. As such not all planned witnessing was able to be covered.

Due to challenges in getting access to the local systems, the dates of assessment were extended with the final remote assessment taking place via remote review of records and a vertical audit to address DTWS requirements in the water microbiology section.

Legionella method not assessed; agreed with AM to move to another year within the cycle.

Changes to the Schedule
There appears to be an error on the schedule on page 8. Method 6505 for Enterobacteriaceae in milk and milk products has the reference as ISO 21528-2:2004 when the current method is based on the 2017 version and is correct on page 9 in food and food product matrices. This is to be amended on page 8.

The statement at the beginning of the **WATERS** section *"Examination for the purpose of enforcement of..."* needs the last reference *The Public Water Supplies (Scotland) Regulation 2014* to be updated to **The Public Water Supplies (Scotland) Amended Regulations 2017**.

Organisation

Legal Entity
The laboratory of Aberdeen Scientific Services Laboratory (ASSL) is a department within Aberdeen City Council.

Resources
The laboratory is housed in an old school building, part of the building is still occupied by the school, but there is separation in place between the laboratory and the school. Access to the building is via a secure entry system. Visitors are required to sign into the reception on arrival.

The laboratory is spread over several floors of the building.

There have been some changes in staffing since the last assessment, notably the departure of the Senior Scientist. His role is to be filled internally, a suitable candidate has been identified, but the appointment has not yet taken place. In addition, two staff are on secondment away from the laboratory, one being an Assistant Scientist, post has been back filled on a temporary basis and the other being a member of the laboratory Administration team. This is a job share post, and their secondment has been covered by their job share partner.

The Laboratory Manager is also the Quality Manager and Principal Scientist – Water Chemistry. A business case has been put forward to split this role across two members of staff.

It has also been noted that there are a number of staff approaching retirement age, this is a risk to continuity and has been noted in the laboratory Risk Register. One member of staff is currently actively working towards the MChemA.

The role of the Public Analyst is undertaken by who works part time for the laboratory (3 days a week). He is based remotely but attends the laboratory on a monthly basis. The role of Food Examiner is undertaken by . Training records have been assessed previously for this role.

Organisation Structure
There is a documented organisational chart detailed in Appendix 2 of the Quality Manual (PA/POL/001). The structure defines the reporting lines within the laboratory.

Responsibility & Authority
The Laboratory Manager ( ) has overall responsibility for the day to day running of the laboratory. He is also the Quality Manager and Principal Scientist for the Water Chemistry department. There are Principal Scientists for each of the other two departments. The Principal Scientist for the Food Chemistry is ; and for Microbiology is .

Job Profiles are in place for all of the staff. Which detail the key roles and responsibilities.

Management
Management System Including Documented Policies & Procedures
The system consists of the Quality Manual (PA/POL/001). This has been updated to capture the changes as a result of the transition to ISO/IEC 17025:2017. The Quality Manual details the policies as well as providing some procedural details. The Quality Manual is supported by a series of other documents, that are referenced within the Quality Manual. Hyperlinks are also in place to provide direct links to specific forms or procedures.

The Quality System is managed through the laboratory server, with records held electronically.

Roles & Responsibilities for Quality
The Laboratory Manager undertakes the role of Quality Manager for the Laboratory. The Public Analyst is identified as the Technical Manager, however specific responsibility for the individual departments lies with the Principal Scientists for each department.

Management of Sub Contractors and Purchases
The laboratory holds a list of approved suppliers, the list includes and expiry date and a date for when the record was updated. There is a section for recording comments which is generally where the details of the approvals held is recorded. The process for approval and review of suppliers was not fully assessed due to the current situation.

Service to Clients
The laboratory saves emails associated with customer feedback and reviews these as part of the Management Review. The overwhelming majority are compliments and thanks. A selection of the emails was reviewed, and no negative responses were noted.

A feedback survey was carried out with data collated into a report. The overall responses indicated that Aberdeen Scientific Services Laboratory provides a very good level of service, there appeared to be one customer that score "very dissatisfied" across all of the questions. This had been noted in the Management Review and a similar issue had been noted on a previous survey. The respondent did not however provide any details as the reason for the dissatisfaction.

Handling of Complaints
The laboratory has written a new complaints procedure PA/IHP/1071 as part of the transition to ISO/IEC 17025:2017. The procedure captures all of the requirements as set out in the standard. Complaints are investigated using the Anomaly Investigation report used for other types of non-conformance.

No complaints have been received by the laboratory in the last year.

Control of Non-Conforming Items Dealing with Corrective & Preventive Actions and Improvements

The process for handling non-conforming work is detailed in Section 17 of the Quality Manual (PA/POL/001). The procedure covers the process for non-conforming work arising from all sources, including IQC failures, EQA failures, internal audit, complaints and that arising from other sources. All non-conformances are recorded on the Anomaly Investigation Form.

The form includes a section for recording a unique identification number based on the year followed by a sequential number, starting at 1 each year, e.g. 2019-03. The form includes a section for recording the nature of the abnormality e.g. complaint, non-conformance, preventive action or other anomaly. There is a section for recording the source e.g. Internal audit. There is a section for recording the details of the root cause, whether other related anomalies exist and whether a further investigation is required. The form includes a section for Impact/Significance, a section for recording any corrective actions as well as any risks arising from the non-conformance. There are sign offs for Name of the person completing the investigation, Signature of Principal Scientist and Laboratory/Quality Manager. Each sign off includes the requirement to record the date that each was completed. The form had been updated as a result of changes required for the transition and issued in March 2020.

There was only one instance where the new form had been used. The form appeared to have been completed appropriately however, it was noted that the lab had recorded that no risk or opportunity had been identified, looking at the impact/significance the lab had recorded "Being Short Staffed and Heavy Workload". This could be perceived as a risk. The laboratory will need to consider whether procedures should include any guidance on how risks arising from non-conforming work are identified, this has been raised as a recommended finding.

It was noted that although the Anomaly Investigation Form includes a section for recording dates at the end of the form, there is no where on the form to record the date that the Non-conformance was identified (See Finding E01490-008).

On review of records of anomalies for 2019 it was noted that there were a number of anomalies that appear to have been raised throughout 2019 that had not been fully signed off until January 2020 (See Finding E01490-009). It appears that the investigations were completed promptly, however the fomrs not updated at the time with the dates.

All records of non-conforming work are held electronically.

Internal Audit

The laboratory has an audit schedule in place that covers the Quality System and Method Audits. The plan also includes vertical audits, audits covering DWTS for both microbiology and chemistry and an audit of the Generic Protocol.

Audits are recorded on an audit checklist, where the detail of the audit is recorded, audit findings are then recorded on an Audit Summary which lists all of the findings alongside an audit report number. The audit report is the mechanism for capturing the audit findings and documenting the corrective actions. The records associated with each individual audit are saved into individual folders for each separate audit. This includes the Audit Summary Form, the Audit Checklist and Audit Reports along with supporting information as applicable.

There is a team of auditors who undertake system and method audits. Competence records for the auditors were not covered at this remote assessment and will be covered at next years assessment.

Audit reports are generally very well detailed and include objective evidence, providing traceability back to the activity being audited. The majority of audits performed raised findings, on review of the findings raised, they are all minor in nature and provide confidence in the audit process.

As part of the overall review of the system the laboratory undertakes an annual audit review. This is documented in minutes along with a summary of audits performed, number and type of audit findings being raised. The minutes are well detailed and provide a good summary of the audit status. It was noted from the review that the laboratory had identified that there are some challenges with maintaining the audit schedule, but the labs has, on the whole been able to maintain the schedule. Any audits that are not carried out in the audit year are carried over into the next year to be completed at the earliest opportunity.

The current audit appears to be robust and on the whole well maintained.

Management Review
The Management Review was held in March 2020 and was attended by the Public Analyst and Quality Manager/Laboratory Manager. A draft of the minutes has been prepared that includes section covering all of the points outlined in ISO/IEC 17025:2017, however the minutes have not been fully completed to demonstrate how the new areas have been addressed, this has been raised as a finding against the transition.

Some of the sections of the minutes have been completed and provide a good summary of those areas under discussion. The minutes included a section covering use of the Generic Protocol, however as identified, not all of the sections had been completed.

Impartiality & Integrity

Independence, Impartiality & Integrity
The laboratory is part of Aberdeen City Council. There are a range of policies and procedures in place covering impartiality, conflicts of interest and integrity.

The laboratory is intending to use the Senior Staff meetings as the mechanism for identifying risks to impartiality associated with laboratory operations. As this is a new system, there have not yet been any meetings where this has taken place, this has been raised as a finding via the transition.
Whilst no risks have been formally documented, the current Public Analyst ( ) has his own business working as a Public Analyst for other local authorities. This has been identified and controls are in place to ensure that this does not pose a risk to impartiality, specifically where he may act as the Public Analyst for a customer of Aberdeen Scientific Services Laboratory.

Confidentiality
Contracts of employment include a clause covering confidentiality. This covers the release of confidential information during the period of employment and after employment has ceased.

Evaluation Processes

Flexible Scope
The laboratory operates a flexible scope, which is detailed in procedure PA/IHP/0030 which details the process for how the flexible scope is applied, and PA/IHT/3000 which describes the procedure for how a new method is developed. The two procedures are to be read in conjunction with each other.

PA/IHP/0030 details the Matrices which are covered by the flexible scope, these are Foods and Animal Feeds. This is typical of the Public Analyst Laboratory service, as there is a recognised requirement that they should hold accreditation for as many tests as possible, however it is impracticable to have all tests accredited, particularly if only used occasionally. The procedure also details the techniques covered by the Generic Protocol. The authorisations for each of the different stages of the process are also defined. The Public Analyst has overall responsibility for the use and approval of the process. They are responsible for appointing a Responsible Analyst, this is one of the Principal Scientists who will responsible for developing the analytical approach based on PA/IHT/3000 as well as the target

performance criteria to be met. Once these have been approved, the Principal Scientist will oversee the validation and analytical process. The analysis will be undertaken by a member of staff who has documented competence in the technique to be operated. The names and justification for authorisations are recorded on the Generic Protocol Checklist. The names are also recorded on the Generic File Index. The Generic File Index acts as the register of usage.

The laboratory is active in the use of the Generic Protocol, having used it 27 times since it was first used in 1998. It was noted that the laboratory has started to record the analysis for which the Generic Protocol was used onto the File Index, this has been recorded in the margin of the form. There is a new version which is held as appendix 3 of the procedure PA/IHP/0030 which has been updated to include the Test Parameter within one of the columns. The laboratory will need to ensure that when starting a new register, that the new form as detailed in Appendix 3 is implemented (Recommended Finding)

The Laboratory has used the Generic Protocol once in 2019, this was for the development of a method for sugar, by Luff-Schoorl, which is a titration method. The sample matrix was a Dry Pet Dog Food. The bounds of the flexible scope include Animal Feeds and Titration techniques. The process as documented has been followed. The use was numbered as G/0027 in line with the other instances and all information was recorded on the Generic Protocol Checklist, the form was signed by as Public Analyst approving the use of the Generic Protocol. The responsible Analyst was ., with the analysis being undertaken by and . There are approvals in place to demonstrate that the staff are all competent. For each use of the Generic Protocol, a Quality Control Sheet is generated, this details the target criteria and that achieved by the validation.

The procedure appears to meet the requirements as set out in GEN 4.

Technical Competence - Food Chemistry (Derek Farrington)

Use of Generic Protocol – Review of Technical Records as applicable.
The protocol is to be used at least once a year to maintain competence. The laboratory has applied their Generic Protocol once in the past year, for Total sugars in pet food by Luff-Schoorl titration.

PA/IHP/0030 provides an overall generic approach to the selection of a suitable method for the analysis. PA/IHT/3000 is used when developing or modifying an analytical procedure for generic purposes. Together these documents set out the procedures to be followed. Individual Generic Protocol applications are summarised in PA/IHT/3000; Generic Protocol Checklist.

The laboratory provided a completed Generic Protocol Checklist. For Generic Method No: G/0027. Sample Ref No:10200961-10200980. Description: Dry pet dog food. Parameter(s) to be determined: Total sugars by Luff-Schoorl. This falls within the boundaries of the accredited protocol as Animal Feedingstuffs, Classical techniques.

The G/0027 Checklist provided evidence that the use of the Generic Protocol had been appropriately authorised. The approach to the method including reference to a Regulatory procedure (Luff-Schoorl method prescribed by Section J of Annex III of Commission Regulation (EC) No 152/2009). This was proposed by the Principal Scientist and approved by the appropriate signatory. Staff designated to undertake the analysis were identified and and their Similar Method Training Record(s) References confirmed appropriate competence. Training records for these analysts were also provided. Procedure and approach has also been discussed with members of staff ensuring that the procedures to be used are fully understood (Signed off on Check list).

APPENDIX 2 – The Generic Method Quality Control Sheet had been completed. This sets the Validation parameters. Generically it lists Target Criteria and Achieved Criteria for the following: L.O.D.;

Recovery; Repeatability; Range on Linearity of response; Estimation of Uncertainty; Chromatography/Spectrometry Acceptability Criteria and Others (Specify). The laboratory considered these criteria and selected those shown below, which also lists the criteria achieved.

	Target Criteria	Achieved Criteria
Repeatability	5%	1.86%
Estimation of Uncertainty	10%	4.55%

These target criteria had been approved and there was approval of Acceptance by a designated signatory.

The report to the customer identified that the procedure had been carried out under the laboratory's flexible scope of accreditation.

The laboratory also provided the following documentation.

- Completed and signed Generic Protocol File including G/0027.
- Completed Generic Scope Lab Book detailing preparation of Luff-Schoorl Reagents and raw data on titrations, also showing that this had been checked and signed appropriately.
- Full details of the Regulatory method Section J of Annex III of Commission Regulation (EC) No 152/2009.
- FAPAS data sheet for T20161, Chocolate cake mix. Total sugars assigned 54.5 g/100g; Range |z| <2 49.5-59.5g/100g. (NOTE: Although this is not a Pet Food it is an appropriate QC as the principle of the method covers both Pet foods and human food.)
- The customer request that triggered the requirement.
- Worksheet W19A0492. This detailed all of the raw data and calculations leading to the final results of the replicate (n = 20) total sugar results on the dried dog food. It also demonstrated compliance with the acceptance criteria in the T20161 Reference Material (n=3) and CRM 020 (n = 2)
- Full details of the derivation of the Method Uncertainty
- Details of the derivation of repeatability precision. (NOTE: Taking these (2x10) results overall across all the batches analysed equates to a $Horrat_R$ value of 0.8, this is good precision for Luff Schoorl)
- A completed validation procedure document.

In conclusion this submission provides good evidence of adherence of the procedure to the parent Generic Protocols; an excellent level of traceability to raw data and their approval; and a good standard of professional competence in achieving the final set of results meeting customer requirements.

Personnel (training and on-going competence)
Practical demonstration was restricted to a remote assessment of PA/VEM/0216. This was well demonstrated by a very experienced analyst who showed a good understanding of the procedures and principles of the equipment involved. There have been no new staff, or new significant training given since the last visit.

Training records are maintained electronically within the LIMS system, detailing the training that has been received in the analytical procedures. Training records viewed at the last visit were acceptable. Appropriate Training Records provided for and in respect of competence to undertake Generic Protocol work.

Methods (including uncertainty of measurement and validation)
The test methods are all available as controlled hard copy documents in the laboratory; they are readily available to the staff and were referred to by the staff demonstrating the procedures. The methods are

clearly written and detailed with good associated procedures detailing the use and calibration of the equipment. The laboratory does have a documented Infrequent test method which requires escalation of the quality assurance of the method if it has not been undertaken for 24 months. Competence is maintained through participation in relevant proficiency testing, which is to a high standard. No new test methods or equipment procedures have been implemented since the last visit.

Method Uncertainty is estimated using a spreadsheet which is common to a number of Public Analyst laboratories. This calculates uncertainty of measurement using a combination of precision from repeatability data and bias from proficiency test performance.

The laboratory has a schedule to review the Uncertainty budgets of its accredited tests. Less frequent tests are reviewed over a 5-year cycle, but the more common tests, e.g. nutrition analyses, are subject to annual review. The latest version of the Uncertainty Calculations program confirmed that this procedure is being kept up to date.

Facilities and equipment (maintenance, calibration)
The laboratory provided appropriate Equipment servicing and calibration details for the following;
Six Analytical balances; certificates all in date.
Details of successful calibration of two autopipettes, in date.
Balance check records for 4 analytical balances in daily use.
External service records for ICP-OES and microwave digestor.
In house maintenance records for the HPLC in use for aflatoxin analysis.
In house maintenance records for the GC in use for butyric acid analysis
In house maintenance records for the ICP-OES and Microwave digestor.

Environmental conditions
Accommodation is fit for purpose with appropriate segregation of tests where required. There were no significant changes in environmental conditions since the last visit.

Sample handling
There have been no significant changes in sample handling procedures since the last visit.

Internal and external quality control
Internal Quality Control

Batch-wise IQC relies mainly on a combination of reference material (in-house or FAPAS) analysis supplemented by duplicate analysis of a sample within the batch. Typical batch sizes are quite small. In cases where results were found to be outside acceptance limits appropriate action is taken. Shewhart charts are set up in accordance with standard acceptance rules and were provided for all the methods on the Visit Plan including Remote review methods. The charts viewed reflected acceptable precision (see individual method reviews below). Charts are subject to periodic review in accordance with a documented procedure. Individual details provided for individual methods in the Visit Plan. In cases where results are found to be outside acceptance limits appropriate action is taken.

External Proficiency Testing

The laboratory participated in FAPAS Series 01, 04, 08,10,14,15,18,21, 27,& 28; together with LGC QDCS over the past year. This comprised a total of 62 tests of these 61 (98%), returned satisfactory z-scores representing very good performance. The one test in the set not returning a satisfactory z-score was for nitrate in meat (FAPAS 15128). This overlapped with the non-conforming work report presented at the previous visit. The laboratory had undertaken an extensive re-testing of this sample by HPLC and colorimetry. They were unable to ascertain any definite root cause, but the report demonstrated a good approach to resolving quality failures.

Records
The standard of record keeping at the laboratory is good, as demonstrated by the comprehensive records available to demonstrate use of the Generic Protocol.

Reporting of results
Reports viewed met the requirements of LAB 1.

Reference material/standards
Covered by data provided for individual methods.

Methods intended for Practical Witnessing on the Visit Plan

PA/IHT/2308: Aflatoxins using High Performance Liquid Chromatography (HPLC)

The Scope of this method is testing groundnuts and groundnut products (e.g. peanut butter), maize, soya, cotton seed, palm kernel and some compound feeding stuffs. This method is not suitable for the determination of aflatoxins in fruit and fruit products.

The limits of detection specified in the SOP Performance characteristics are fit for purpose for monitoring compliance with the lowest Regulatory MRLs associated with the matrices in the accredited SOP Scope.

Mycotoxin	LOD µg/kg	Mycotoxin	LOD µg/kg
Aflatoxin B1	0.08	Aflatoxin B2	0,13
Aflatoxin G1	0.40	Aflatoxin G2	0.20
Total Aflatoxins	0.81		
Food. Commission Regulation 165/2010 lowest MRL Cereals, 2 µg/kg for B1; 4 µg/kg total aflatoxins			
Feeds. Commission Regulation 574/2011 lowest MRL Compound feed 5 µg/kg for B1.			

A chromatogram of the working standard, equivalent to 1.25ng/ml aflatoxins served to demonstrate that the laboratory can routinely achieve the sensitivity claimed in the method.

A typical chromatogram of a representative matrix served to demonstrate that typical real sample matrices do not give rise to significant interferences in the vicinity of the aflatoxin peaks.

IQC Performance
Repeatability check a duplicate is run with each batch of samples and the results must conform to those specified in 14.1.3

Action Limits ±	n	% n>3sd	Comments
B1 20 % of mean	19	0	Chart reflects routine performance well. RSD_r within Regulation 519/2014 RSD_r performance criteria
B2 20 % of mean	13	0	Chart reflects routine performance well. RSD_r within Regulation 519/2014 RSD_r performance criteria
G1 17 % of mean	11	0	Chart reflects routine performance well. RSD_r within Regulation 519/2014 RSD_r performance criteria

G2 30 % of mean	7	0	Chart reflects routine performance well. RSD_r within Regulation 519/2014 RSD_r performance criteria

The recovery data for spiked samples for each toxin 100µg/kg show few points outside limits. They demonstrate routinely achieved $\%RSD_R$ values which are within the performance criteria stated in Commission Regulation (EU) 519/2014.

Aflatoxin	**Mean%**	**Action Limits µg/kg**	**$\%RSD_R$**	**519/2014 RSD_R (1 Horrat)**
B1	96	55-140	10	22.6
B2	96	60-130	10	22.6
G1	96	60-140	10	22.6
G2	75	20-140	20	22.6
Reg 519/2014		50-120		

The correlation coefficient of each calibration graph should be at least 0.9985. Confirmed by calibration run 04/03/2020.

External Quality Assurance
The latest PT associated with aflatoxin analysis was FAPAS 04340, aflatoxins & ochratoxin A in paprika (satisfactory z-score) . This covers SOP PA/IHT/2327. The last PT associated with SOP PA/IHT/2308 was undertaken in 2015. Aflatoxins and ochratoxin A in hazelnut slurry is scheduled for dispatch from FAPAS on 06/07/20. The laboratory intends to analyse this by both methods.

Reference materials
In date R-BioPharm Certificate of Analysis provided for 250ng/ml aflatoxin standard. R-BioPharm is accredited to ISO 17034.

PA/IHT/0007: Moisture oven drying
The Scope of this method is foods and animal feeding stuffs, not applicable to cheese or honey samples. The referenced standard methods are; for Feeds The Animal Feed (Scotland) Regulations 2010.For food; BS4401: Part 5: 1996 Current, BS 6049: Part 2: 1981 Tea Current.

IQC Performance
At least 1 in every 50 samples should be analysed in duplicate and the difference between the results should conform to the performance characteristics quoted in 14.1.3.

Action Limits ±	**n**	**% n>3sd**	**Comments**
2.1%	510	2	No recent >3sd. Chart reflects routine performance well

Each batch of samples should include analysis of a standard control material (either an In-House Control or CRM). The results must conform to the performance data quoted in 14.1.2 (see PA/LOG/0216 and LIMS). The standards control used is CRM 037 Canned Meat

Mean g/100g	$\%RSD_R$	$Horrat_R$	n for 2019/20	Out of spec.
61.25*	0.8	0.4	12	0

*The control material used is FAPAS T0193QC, Canned meat. The assigned mean value is 60.82g/100g with a range set ($|z| \leq 2$) at 59.97-61.68g/100g.

External Quality Assurance
FAPAS 01120 (z-score -0.8); 01129 (z-score 0.1); 10156 (z-score -0.1)

Equipment
The laboratory provided details of oven calibration, both daily and annual temperature profiles. Evidence of calibration of thermometers used, vs reference thermometer, was also provided

PA/IHT/2062: Crude Fibre using Fibretec system
The Scope of this method is Feeding stuffs and bread and bread products. The method is based on that referred to in The Feed (Sampling and Analysis and Specified Undesirable Substances) (Scotland)) Regulations 2010.

IQC Performance
For statutory purposes, the difference between two parallel determinations carried out on the same sample must not exceed 0.3 in absolute value for fibre contents lower than 10%. 3% relative to the higher result, for fibre contents equal to or greater than 10%.

Statutory Sample 10202799 Prime Beef 1 animal feed. Declared at 5.0%. Duplicate results 5.17g/100g and 5.27 g/100g therefore absolute difference of 0.1g/100g i.e. < 0.3 for fibre declaration of <10%. Supported by raw data worksheet and registration details for a formal sample.

Each batch of samples must contain a duplicate and the difference between the results is to conform to the precision data 14.1.3

Action Limits ±	n	% n>3sd	Comments
14% of mean	80	0	

Each batch of samples must include a standard control material or a certified reference material (8.24). The IHRM used is AQC IHC 013.

Mean g/100g	$\%RSD_R$	$Horrat_R$	n for 2019/20	Out of spec.
14.1	3.5	1.3	2	0

External Quality Assurance
FAPAS 10156 (z-score 0.5).

Equipment
In-house Fibretec maintenance evidence provided. Details of oven calibration, both daily and annual temperature profiles. Evidence of calibration of thermometers used, vs reference thermometer, was also provided

PA/VEM/0216: Fat in Cream using Gerber Method

The Scope of this method is cream It is referenced to BS ISO 2446:2008 (Current).

IQC Performance
Each batch of samples must contain a duplicate and the difference between the results is to conform to the precision data 14.1.3
difference between the results is to conform to the precision data 14.1.3

Action Limits ±	n	% n>3sd	Comments

4% of the mean	11	0	

Each batch must include an in-house standard control material

Mean g/100g	Limits	n for 2019/20	Out of spec.
12.1	11.5-12.5	1	0

External Quality Assurance
LGC QDCS 264, fat in milk by Gerber, z-score 1.60.

Equipment
Covered by Method witnessing evidence

Reference materials
Covered by Method witnessing evidence.

PA/IHT/0101: Nitrite in Meat using Spectrophotometry
The Scope of this method is meat and meat products It is referenced to BS 4401: Part 8:1976 (Current).

IQC Performance
Obtain the calibration curve by plotting the measured absorbance of the standard solutions (8.6.1) against amount of sodium nitrite. This can be done electronically using Excel. The correlation coefficient for the curve must be ≥ 0.9985. Confirmed by routine calibration run.

Each batch of samples must contain a duplicate analysis and the difference between the results must conform to the performance characteristics quoted in 14.1.3. For reference purposes each sample must be analysed in duplicate and the difference between the results must conform to the performance characteristics quoted in 14.1.3

Action Limits ±	**n**	**% n>3sd**	**Comments**
15 % of mean	11	0	Chart reflects routine performance well

Each batch of samples must include a recovery check (8.8) and (8.9) and the results must conform to the performance characteristics quoted in 14.1

Each batch of samples must include a standard control material or a certified reference material (8.24)

Mean %	%RSD	% Limits	n for 2019/20	Out of spec.
100	5	85-115	0	0

Last batch: Spike recovery 104.5% and duplicate 6.70%.

External Quality Assurance
FAPAS 15112 (z-score 0.1), 15128 was (z-score 1.4).

Equipment
In-house spectrophotometer calibration records provided.

Reference materials
Fisher Chemical sodium nitrite Certificate of Analysis provided. Opened September 2016 and expires September 2020. Fisher Chemical is accredited to ISO 17034.

PA/IHT/2101: n-Butyric Acid using GC

The Scope of this method is n-butyric acid in fat It is referenced to the Phillips and Sanders method; JAPA 1968, 6 89-95.

IQC Performance
The correlation coefficient of the calibration graph in 8.3.5 should be > 0.9985. Confirmed by routine calibration run.

Repeatability check At least one sample in every batch is to be analysed in duplicate. The difference between the results must conform to 14.1.3.

Action Limits ±	n	% n>3sd	Comments
10% of mean	55	2	

An in-house control is run with each batch. IHC 090, Butter

Mean g/100g	SD	% Limits	n for 2019/20	Out of spec.
3.45	0.1	3.15-3.75	1 (7 back to 2018)	0

External Quality Assurance
FAPAS 14209 (z-score 0.8) 14181 (z-score 0.8).

Equipment
In house maintenance records for the GC in use for butyric acid analysis provided.

Reference materials
Butyric acid (Acros Organics) and iso-butyric (Thermo Fisher) certificates of Analysis provided. Iso-butyric acid opened February 2015 and expired February 2020. No samples for butyric acid in the system currently and the laboratory would order new standards as and when required for analysis.

PA/VEM/0381: Energy by Calculation

The Scope of this method is food It is referenced to Commission Regulation EU 1169/2011. All of the conversion factors align with the Regulation factors.

The laboratory provided a worked example for Laboratory No. 10172734 (mince pie) derived from LIMS with a manual calculation alongside. This cross check confirmed the LIMS calculation.

A report to a customer including Energy to demonstrated that LIMS correctly assigned the accreditation status to each of the components that go into the final energy result.

PA/IHT/0005: Ingredients using Gravimetry

Details of raw data and associated Reports for two samples (10131445 & 10198195) were provided to illustrate this method in action.
This method is required occasionally and has been on the laboratory schedule for over 20 years.

There are difficulties in assessing this procedure as a desk exercise, and it was not considered worth using valuable remote video resource to demonstrate it. The method needs to be included in the next Surveillance visit.

PA/IHT/2319: Vitamin C using HPLC

The Scope of this method is foodstuffs. It is referenced to BS EN 14130:2003 (Foodstuffs - Determination of vitamin C by HPLC) which has since been withdrawn.

IQC Performance
Instrument calibration: Correlation coefficient R^2 0.9999 achieved for analysis of Vitamin C in baby food. Repeatability check at least one sample per batch must be analysed in duplicate; the difference between the results should conform to the precision data in 14.1.3.

Action Limits ±	n	% n>3sd	Comments
9.5 % of mean	10	0	Chart reflects routine performance well

Recovery check a recovery check (see 8.10) must be carried out with each batch of samples; the results should be within two standard deviations of the mean value quoted in 14.1.2.

Mean %	%RSD	% Limits	n for 2018/19	Out of spec.
100	10	70-130	3	0

External Quality Assurance
FAPAS 21111 (z-score 0.2).

Equipment
In house maintenance records for the HPLC in use for Vitamin C analysis provided.

Reference materials
(Thermo Fisher) certificate of Analysis for ascorbic acid._Opened Jun 2018 and expires Jun 2020.

PA/IHT/2540: Sodium (salt by calculation) using ICP-OES

The Scope of this method is foodstuffs. It has been developed in-house.

The Limit of detection stated in the SOP (0.001 g/100g) is fit for purpose for monitoring compliance with Sodium Free or Salt Free claims made under Commission Regulation 1924/2006. The laboratory has noted that this method was amended to cover a more appropriate range of standards more suitable for the sodium content of foods the laboratory is usually requested to test but it previously used the same set of standards as the non-potable water method. It previously included a wider range of standards and included a 10 µg/L standard which can be re-instated to the method to cover the claims above if required.

IQC Performance
Instrument calibration Confirmed by routine calibration run, Calibration coefficient 0.9999.

Repeatability check every batch must contain a duplicate analysis, the results of which must conform to the performance characteristics in 14.1.3.

Action Limits ±	n	% n>3sd	Comments
4.7% of mean	21	0	

Reference material check A certified reference materials or in-house control, if available, is used to monitor method performance. CRM 037, Canned Meat

Mean g/100g	%RSD_R	$Horrat_R$	n for 2019/20	Out of spec.
0.98	3	0.7	12	0

External Quality Assurance
FAPAS 01120 (z-score 0.3) & 1895 (z-score 0.8).

Equipment
External service records for ICP-OES and microwave digestor, and In-house maintenance records for the ICP-OES and Microwave digestor provided.

Reference materials
Sigma Aldrich 1000mg/L sodium standard Certificate of Analysis. Expiry date September 2018. The laboratory has noted that this standard used is out of date according to the CoA but an independent 5.0 mg/L CCV is run using reagent 6.6 of method PA/IHT/4524 (water laboratory non-potable method which is used regularly) as a standard control check and this passed and was within the specified tolerance justifying its use. This provides an acceptable independent check on this standard.

Remote review of IQC/EQA Performance

PA/IHT/0081: Acidity using titrimetry
Scope; Determination of acidity of wine.

Meeting SOP IQC requirements
Repeatability Check; At least every tenth sample is to be analysed in duplicate and the difference between the results is to conform to the precision data quoted in 14.1.3.

Action Limits ±	n	% n>3sd	Comments
1.5 % of mean	5	0	Chart reflects routine performance well.

EQA participation
FAPAS 0872, pineapple juice; z-score -0.9.

PA/VEM/0222: Moisture on Bread using Gravimetry
Scope; Determination of the moisture content of bread and bread rolls. VEMS method.

Meeting SOP IQC requirements
Repeatability check each batch must contain a duplicate and the difference is to conform to the quoted performance data quoted in LIMS

Action Limits ±	n	% n>3sd	Comments
4.6% of mean	22	5	No fail since 2001

This analysis has not been carried out since 2006 except for a batch run in February 2020. CRM026 was run with this batch and was satisfactory. Two sets of duplicate samples were also run with the batch and were also satisfactory.

EQA participation
Moisture carried out on 2 FAPAS rounds (food and feed) but not specifically bread. FAPAS 01129 (canned meat) z-score 0.1. FAPAS 10156 (dairy ration) z-score -0.1.

PA/IHT/0216: Fat in Ice Cream using Gerber Method

Scope; Fat content of an ice cream in. Based on BS ISO 2446 2008. (Current).

Meeting SOP IQC requirements
Repeatability check each batch must contain a duplicate and the difference is to conform to the quoted performance data quoted in LIMS

Action Limits ±	n	% n>3sd	Comments
13% of mean	37	5	No recent >3sd.?

Standard control each batch must include an in-house standard control material. The results must conform to the performance data quoted in LIMS.

- The QC chart covers 2005-2019, total 31 points with one point in 2019 and no points outside acceptance limits. The reference material is AQC IHC 076 Ice Cream. Mean 12.1 g/100g RSD_R, 1.6%, $Horrat_R$ 0.6. This demonstrates acceptable batchwise precision.

EQA participation
LGC QDCS 264 is fat in milk by Gerber, z-score 1.60.

PA/IHT/2324: Histamine in Fish and Fish Products using HPLC

Scope; Histamine in canned and fresh fish

Meeting SOP IQC requirements
Repeatability a duplicate is run with each batch of samples and the results must is to conform to those specified in 14.1.3 (LIMS)

Action Limits ±	n	% n>3sd	Comments
6.5 % of mean	19	0	Chart reflects routine performance well. No results since 2018

Recovery Check; see 8.6; a recovery determination should be carried out with each batch of samples; the result must conform to data in LIMS

- The QC chart covers 2009-2019, total 59 points with four points in 2019 and no points outside acceptance limits. The spike level is 100mg/kg, with acceptance levels set at 70-130%.

EQA participation
FAPAS 27234, z-score 0.6

PA/VEM/0247: Soluble Solids using refractometry

Scope: The method is applicable to preserves, drinks (including fruit juice and soft drinks), fruit curds, mincemeat, and honey. The method is based on EC Commission Implementing Regulation (EU) No 974/2014.

Meeting SOP IQC requirements
Repeatability check each batch must contain a duplicate and the difference is to conform to the quoted performance data quoted in LIMS

Action Limits ±	n	% n>3sd	Comments
2 % of mean	37	3	No fail since 2003. No results since 2017

Standard control each batch must include an in-house standard control material. The results must conform to the performance data quoted in LIMS (60% sucrose)

- The QC chart covers 2013-2017, total 36 points, there are no points after 2017, and no points outside acceptance limits. The AQC is 60% sucrose, mean set at 60.0% with acceptance levels set at 59.25 to 60.75%,

EQA participation
Last analysed in November 2017 but the laboratory has analysed FAPAS homogeneity testing samples for Brix in tomato paste in November/December 2019 but not accredited for Brix. (Brix involves additional steps and different calculations from the refractometry method).

PA/IHT/2303: Chloride (Salt as NaCl by calculation) using IC
Scope; Determination of chloride in foodstuffs. This method describes a procedure for the determination of chloride in foodstuffs. It is noted in the Scope that it is not suitable for calculation of salt for nutritional labelling purposes.

Meeting SOP IQC requirements
Repeatability check each batch must contain a duplicate and the difference is to conform to the quoted performance data quoted in LIMS

Action Limits ±	n	% n>3sd	Comments
8% of mean	81	0	No fails

Standard control each batch must include an in-house standard control material. The results must conform to the performance data quoted in LIMS

- The QC chart covers 2016-2019, total 14 points, one point 2019 and no points outside acceptance limits. The AQC is CRM 037, Canned Meat. (Target 1.26 g/100g; Acceptable range 1.16-1.36 g/100g for warning limits). Laboratory mean of1.25 g/100g, falls within the range. Routine performance 1.25 g/100g RSD_R, 4%, $Horrat_R$ 1.0. This demonstrates acceptable batchwise precision.

EQA participation
FAPAS 01120 z-score -0.5

PA/IHT/0215: Total Fat using Acid Digestion and Soxhlet Extraction
Scope; Determination of total fat in foods and animal feeding stuffs

Meeting SOP IQC requirements
For statutory purposes for animal feeding stuffs repeatability data is quoted in 8.6.
- 0.2% in absolute value, for contents of crude oils and fats lower than 5%
- 4.0% relative to the higher result for contents at 5 – 10%
- 0.4% in absolute value, for contents above 10%

Informal feed 10203014 had an action limit for oil but both results conformed with statutory statement, so results accepted, and reason entered in audit trail. Laboratory also carried out FAPAS homogeneity testing for oil on dry dog food in November 2019.

Each batch should contain a duplicate analysis and the difference between results should conform to the performance characteristics quoted in 14.1.3.

Action Limits ±	n	% n>3sd	Comments
10% of mean	81	1	Most recent point, 2020 is >3sd.

			Sample 10203014 audit trail attached separately. Statutory statement declaration states, "Crude oil and fats 2.9%" and duplicate results were 2.91 g/100g and 3.24 g/100g which both complied with tolerance for statutory statement. CRM 037 also gave satisfactory result for fat and as all the samples in the batch complied with the relative statutory statements the results were accepted, and no further action was required.

Each batch of samples should include analysis of a standard control material. The results must conform to the performance data quoted in 14.1.2.

- The QC chart covers 2016-2020 total 13 points, three points 2019/20 and no points outside acceptance limits. The AQC is CRM 037 Canned meat. Mean 22.3g/100g RSD_R,3.1% $Horrat_R$ 1.2 This demonstrates acceptable batchwise precision

EQA participation
Total fat FAPAS 01120 (food) z-score 0.0, FAPAS 01129 (food) z-score -0.3 and Oil in FAPAS 10156 (animal feed) z-score -0.4.

PA/VEM/0282: pH by meter
Scope; pH value of foods. Based on the British Standard Methods BS 4401: Part 9: 1975 and BS 5086: Part 7: 1991.

Meeting SOP IQC requirements
Repeatability check each batch must contain a duplicate and the difference is to conform to the quoted performance data quoted in LIMS

Action Limits ±	n	% n>3sd	Comments
1%	115	2	No fail since 2011.

Standard control the high ionic strength solution used in the water laboratory is used as a standard control

- The QC chart covers 2009-2020 total 88 points, three points 2019/20 and no points outside acceptance limits. The AQC is High standard Mean pH 6.90 Sd 0.5 pH Units

EQA participation
Covered by FAPAS 0872 z-score -0.4

PA/IHT/2510; Method to be withdrawn. Iron, Copper, Manganese and Zinc using AAS
Scope; Determination of the trace elements iron, copper, manganese and zinc in foods and animal feeding stuffs

Meeting SOP IQC requirements
For statutory purposes for feeding stuffs:
The difference between the results of two parallel determinations carried out on the same sample by the same analyst should not exceed:

- 5mg/kg, in absolute value, for trace element levels up to 50 mg/kg.
- 10% of the higher result for trace element levels from 50 – 100 mg/kg.
- 10mg/kg, in absolute value, for trace element levels from 100 – 200 mg/kg.
- 5% of the higher result for trace element levels above 200 mg/kg

Two animal feed samples for copper received in December 2017. 10177996 2.2% difference in results, allowance is 10% for statutory declarations of 50-100 mg/kg 10177998 3.2% difference in results, allowance is 5% for statutory declarations > 2000 mg/kg

Repeatability check each batch must contain a duplicate and the difference is to conform to the quoted performance data quoted in LIMS

Action Limits ±	n	% n>3sd	Comments
Cu 16% of mean	72	1	Chart reflects routine performance well. Last "Fail" was in 2005
Fe 12% of mean	55	0	Chart reflects routine performance well
Mn 10% of mean	51	2	Chart reflects routine performance well. Last "Fail" was in 2003
Zn 15% of mean	65	1	Chart reflects routine performance well. Last "Fail" was in 2004

Standard controls. Each batch must include a spiked sample or a reference material. See 8.19. The result must conform to Bias data quoted in 14.1.2.

- The QC chart uses IHC 085 Animal Feed. Overall for the 4 elements the period covered was 2014 up to 2018 when the method was withdrawn. During this period none of the data points fell outside the acceptance limits for any of the elements (Cu n =21; Fe n = 14; Mn n = 21; Zn m =19). This reflects acceptable control up until the method was taken of the Schedule. The performance criteria for the elements were: Copper; 495 mg/Kg RSD_R, 3 %, $Horrat_R$ 0.5. Iron 1640 mg/Kg RSD_R, 5%, $Horrat_R$ 1.0; Manganese 2000 mg/Kg RSD_R, 4%, $Horrat_R$ 1.0.; Zinc 1296 mg/Kg RSD_R, 4%, $Horrat_R$ 0.8. This demonstrates acceptable batchwise precision

EQA participation
FAPAS Rounds

	10111	10112	10117	10136	10156	1895	07258
Mn			0.0	-0.6	-0.5		
Fe			0.1	-2.4	-0.6	-0.3	-1.2
Zn		0.5				-1.2	-1.5
Cu	-0.3					-1.0	

Practical witnessing
Mainly a Remote assessment due to Covid-19 emergency measures.

Witnessed Activity (test/ calibration/ inspection/ audit*)	Performed By	Technical Assessor	Comments
PA/IHT/2308: Aflatoxins using High Performance Liquid Chromatography (HPLC)	Document review	Derek Farrington	
PA/IHT/0007: Moisture oven drying	Document review		

PA/IHT/2062: Crude Fibre using Fibretec system	Document review		
PA/VEM/0216: Fat in Cream using Gerber Method	Remote Assessment via Microsoft Teams		Duplicate analysis of a retail cream sample, declared at 19.1g/100g. The analyst followed the SOP well demonstrating good practical technique. The balance used had been checked at 1g and 100g on the day of analysis with results within acceptable tolerance limits. Appropriate checks were made to check the 65°C water bath, which was within tolerance. The Gerber centrifuge had been checked for compliance with acceptance specifications on 17/03/2020. The Timer had been appropriately calibrated. Raw data records of all calibration checks were presented. The duplicate cream analysis, at 20.0g/100g and 20.0g/100g fell within the duplicate tolerance limit. On repeat of water bath/centrifuge stages the readings obtained were identical.
PA/IHT/0101: Nitrite in Meat using Spectrophotometry	Document review		
PA/IHT/2101: n-Butyric Acid using GC	Document review		
PA/VEM/0381: Energy by Calculation	Document review		
PA/IHT/0005: Ingredients using Gravimetry	Document review		
PA/IHT/2319: Vitamin C using HPLC	Document review		
PA/IHT/2540: Sodium (salt by calculation) using ICP-OES	Document review		

Technical Competence – Food and Water Microbiology (Paula Catchpole)

Documents reviewed

Example test reports
EQA trend plots
IHP 1030 Cleaning procedure
IHP 0015 QC procedures
IHP 1031 Environmental monitoring
IHP 1032 Maintenance of working cultures
IHP 1066 Sample receipt procedure
And IQC data
Documented Methods for tests initially on VP with the exception of the legionella which was agreed with AM to move to another year.
NCW 2020 -02 Environmental monitoring
Autoclave calibration records
Media production and QC records
(QA-M-03-19) 7602 SRC and Cl.perf in waters
(QA-M-04-19) 7604 Enteros
(QA-M-05-19) 6510 Listeria enumeration

Personnel

There have been no new starters in the micro lab in the last year. One existing team member has changed roles and is now involved in preparation of food samples. The lab has confirmed that training has been conducted using spiked samples, although the records are in hard copy form and not currently available for review. Staff already trained take part in IQC and EQA which has been demonstrated.

Methods

Methods on the schedule are generally based on standard ISO methods or MoDW. Documented procedures are clearly written with suitable levels of detail included. There are several references however on the schedule which are not the most current and the lab has not documented a review of the current update or version, there are no formal justifications for basing methods on older versions. (Finding raised). For example, 6507 Coagulase positive staphylococci ISO6888-1:1999+Amd 2:2018, 6402 β-glucuronidase positive *Escherichia coli* ISO16649-3:2015 and 6408 *Escherichia coli* O157 ISO 16654: 2017.

Facilities and Environmental conditions

The lab has supplied their cleaning and environmental monitoring procedures which are both appropriate and inclusive of relevant areas and equipment. Environmental monitoring procedure covers all areas around the lab using general exposure plates (airplates/ contact plates) testing for bacterial and fungi contamination. Pathogen swabs testing for Listeria, salmonella and legionella monthly and O157 when samples are tested. There are limits defined and suitable actions are taken where these are exceeded. The records are kept in hard copy form so were unable to be reviewed although the lab management has confirmed that there have been no incidences of pathogen detection in the environment in the last year.

One nonconforming work related to environmental monitoring was provided, which is the only one that has been raised during the year. This was regarding some missed swabbing and that has been documented suitably with appropriate action taken.

Equipment

The lab has confirmed that there have been no new pieces of equipment in the micro department in the last year. Records are kept for all current items and frequencies of calibration both internal and external are included. The records for the autoclave used in media production have been provided and

these demonstrate that a suitable ISO/IEC 17025 calibration agent has been used and that senior staff review the certificates on receipt.

Records for internal daily checks are maintained for pipettes and balances etc. however these are in hard copy form and therefore unable to be provided at this time.

Example media production records have been provided which are clear and good traceability is maintained for batches made. QC procedures are based around ISO11133 and percentage recoveries for recent batches reviewed have shown good results. Suitable control organisms are used, and records are signed with a pass or fail overall. The media generally appears to be meeting all internal requirements and no recent batches have failed QC testing for the media types reviewed.

Cultures

The lab purchases its control organisms from recognised culture collections (NCTC/ ATCC) in the format of freeze-dried ampules from which working stocks are hydrated harvested and stored on frozen beads. The procedure for this is suitable and clearly describes the preparation stages, authenticity checks are done on receipt of new batches.

Some organisms are also purchased as cultiloops (traceable to recognised collections, however number of subcultures unclear) which are used directly for spiking for QC purposes. The lab acknowledges that the number of acceptable passages for the cultures could therefore be exceeded and to this effect have additional checks for these particular organisms. The records for these are in hard copy form in the lab so this will need to be followed up at the site visit.

Sample handling

Procedure has been received which appears to be suitable. Indication is that water samples would be tested within suitable time frames although it is not clear the action to be taken where deviations occur. To be followed up (see also section on Test Reports).

Test Validity

The lab uses LGC PT provider and the PHE provider for waters. Results and trend plots have been provided for all methods. Coverage is good across all the accredited tests and the lab seems to take part in at least two or three samples per year. The majority of samples have achieved good results and performance within the defined acceptable ranges.

There doesn't appear to be any bias or trends for any methods for the plots reviewed and the lab has indicated that this is their conclusion based on their own internal assessment.

The lab has noted 5 failures in micro EQA schemes; this was indicated on the pre visit questionnaire received, although it was noted that two of these where prior to the UKAS visit last year and have already been reviewed by UKAS. Therefore, the remaining three Proficiency Testing Failure nonconforming work reports only have been reviewed; QA-M-03-19, QA-M-04-19 and QA-M-05-19. These were for different methods and were for false positive results, false negative results and one under recovery for an enumeration test. The reports contain potential root causes for the errors and where mainly explained to be due to reporting, calculation errors or misinterpretation of results otherwise. However, there is a lack of detail as to how these errors occurred and there are no further actions indicated beyond staff being informed. In particular it is not recorded if there is any impact from the non-conformity, to ongoing work and no indication that this was considered. (See finding).

There is an IQC programme in place and this seems appropriate from a review of the procedure provided. Duplicate samples and spiked samples are used, and the sample matrices varied to cover a range of samples presumably fitting with the those received. The lab reviews results obtained for precision and recovery and the results seen have been good. Spreadsheets for the methods on the

initial visit plan have been provided and it can be seen that staff participation is also varied between trained staff.

The above data is used for method uncertainty calculations and the values seen show method uncertainties to be at a reasonable level.

Reporting Results

The lab has provided a range of Test Reports covering methods on the intial visit plan. These present results clearly and Test Reports contain all aspects as required by ISO/IEC17025, the UKAS symbol is used appropriately and in line with UKAS publication Lab 1 and the BEIS document. There is a clear mechanism to disclaim tests outside accreditation. Water reports contain sampling dates, and for the examples provided the samples have been analysed within suitable sample stability times.
The lab makes statements of conformity on test reports and the specifications on which these are based are clear on the Test Reports. It is not clear how the decision rules are agreed and how this agreement is documented (see transition assessment by AM).

DWTS Vertical Audit

Supplement Assessment 18/06/20

On return to work, the lab subsequently provided documentation to enable a vertical audit for the purposes of DWTS work. Sample number selected was 10193447submitted to the lab on 01/04/2019. Date and time of sampling was detailed on sample submission paperwork (01/04/19, 10:15), type of testing needed was clearly stated. Sample was tested for Coliforms/E.coli, aerobic colony count, Clostridium perfringens and Enterococcus.

Worksheets were provided for all tests, these contained good information for the purposes of traceability. Media batches and other consumable batches have been recorded as well as equipment such as incubators used. Incubation times have been recorded and these were in line with methodologies. Controls also recorded and results cross checked with Test Report. Staff performing stages of testing have signed.

Confirmation records were provided for Clostridium perfringens, these were suitable completed with the relevant information, again batch numbers for confirmation media have been recorded and equipment nos. for incubators used.

Media QC records demonstrate appropriate checks on all batches used. Temperature monitoring records show equipment to be within range on the day of testing and profiling information for incubators demonstrate equipment to have been checked.

Training records and EQA associated with the tests were assessed as part of the assessment conducted earlier in the year. Records of training for staff mentioned above who has changed roles have now been provided and these are appropriate.

Test Report for the sample number 10193447 meets with requirements of ISO17025 and demonstrate results to have been reported promptly to the customer. Statement of conformity are clear and regulation on which they are based stated.

Witnessed Activity (test)	Performed By	Technical Assessor	Comments
To be followed up at the site visit			

Technical Competence – Water Chemistry (Peter Sleeman)

This remote surveillance assessment was based on discussions with the Laboratory Manager (JD) following the review of records supplied as listed below...

Analyst training table detailing current records for environment methods
Training spreadsheet for the analyst who has most recently completed all training in the section
On-going competence spreadsheet with Aquacheck PT Z-scores for each analyst
Balance calibration certificates, Hach system calibration certificates, in-house calibration spreadsheets for pipettes/dispensers
ICPOES instrument annual service documentation & Metrohm IC service documentation
System suitability & calibration data spreadsheets for ICPAES instrument (PA/IHT/4523)
System suitability spreadsheet for Metrohm IC
Charts for monitoring absorbances in UV methods
pH electrode "slope" chart (PA/IHT/4203)
GFAAS absorbance chart (PA/IHT/4005)
AQC charts for COD & nitrogen dioxide
12-monthly AQC charts for DWTS parameters
AQC charts for in-house standards for all DWTS parameters
DWTS parameter annual performance summary for 2019
Uncertainty spreadsheets for all DWTS parameters based on 2019 data
Copy of original SCA spreadsheet for uncertainty calculation
Aquacheck PT reports since last UKAS visit (Rounds 561 to 581)
Analyst individual Z-scores for all Aquacheck rounds
PT "failure" investigations since last UKAS visit (4 *"Questionable"*)

General

Analysts were "signed off" as competent in the AIS LIMS against competence data.

Senior staff and analysts (e.g.) involved in DWTS testing had appropriate CPDs in place. On-going competence is monitored analysts running proficiency samples and recording the results by analyst on a spreadsheet.

Test method documentation was fit for purpose, detailed and easy to follow with only minor amendments, required to ensure consistency of application.

Availability of validation data was not checked at this surveillance visit.

For the major instruments (e.g. ICPAES and Metrohm IC systems), there were annual preventative maintenance reports showing equipment was fit for purpose.

It was noted that the laboratory plans to move to another site (James Hutton Institute) over the next year or so.

Balances were calibrated by an appropriate external accredited company, Precisa UKAS No. 0428, in Jan 2019. Balance calibration certificates were supplied and there is a system in place to review certificates to ensure they are fit for purpose.

Mechanical pipettes are calibration checked quarterly with both precision and accuracy checked against defined targets across the range of volumes used. Records were readily available for each pipette checked.

It was noted that the COD LT200 digestion block had been serviced by Hach in the past 12 months but there are no traceability records available to show that the temperature checks at 100 & 148°C were traceable to national standards.

The standards used for ICPAES instrument calibrations are sourced from Inorganic Ventures via Esslab and are traceable to national standards being ISO 17034 accredited products. However, the traceable standard in use for conductivity was a "Reagecon" standard, but this product was not an ISO17034 accredited product to ensure the calibration is fully traceable to national standards.

All surveillance test methods had appropriate instrument system suitability checks (e.g. ICPAES intensities across wavelength range and spectrometry absorbance values for a calibration standard with appropriate acceptance thresholds in place.

The AQC system is via the AIS LIMS system with AQC (CCV) checks run at an appropriate level. AQC charts were supplied for all surveillance parameters with instrument system suitability check data also charted via LIMS so that trends could be observed.

Test method parameter AQC control limits are regularly reviewed every 60 points or on a 3-monthly basis by the Laboratory Manager (JD).
The AQC precision performance for all DWTS parameters, except for lead (RSD 5.14% c.f. 5%) at PCV level met the specification.

Proficiency scheme results were available for all accredited water chemistry methods with all parameters. The overall performance for water chemistry methods over the past year or so has been very good >97% results being *"Satisfactory"* with no *"Unsatisfactory"* results. The four *"Questionable"* results (TOC, nitrite, arsenic x2) had been investigated and the root cause found. The two arsenic *"Questionable"* results were values close to the reporting limit. Copies of investigations were supplied.

The CAB participates in the LGC Air scheme to cover nitrogen dioxide in air samples and 19 of the 20 results submitted were *"Satisfactory"* with only one "*Questionable*" result.

Uncertainty of Measurement estimates are re-assessed annually and the values recorded in a spreadsheet so that trends can be identified.

Test report (Lab Ref: 10201158) chosen for the DWTS vertical audit appeared to comply with 17025 requirements with appropriate use of the logo and any comments made clearly identified as outside accreditation scope.

The test report did include statements that parameter values exceeded prescribed concentration values but no reference in the report was made to the uncertainty associated with the result
(see Decision Rules: ISO/IEC 17025:2017).

DWTS Performance Summary
Earlier in the year, the laboratory re-evaluated DWTS performance validation data against the new LoQ and UoM Water Directive specification but has not evaluated the 2019 AQC performance data against the specification changes to show on-going performance into 2020 meets the new UoM specification.

The individual DWTS 2019 parameter performance spreadsheets supplied include precision data from the control chart but no bias component and thus there is no on-going uncertainty assessment to show performance meets Directive and DWI/DWQR requirements.

There were appropriate training records and CPDs in place for senior staff (e.g.) and other analysts involved it potable waters analysis.

For the DWTS parameters, the QC charts were all running with well within the Bias and RSD targets for all parameters except for 10ug/l lead by GFAAS that is running with a RSD of 5.14% c.f. target 5%. The laboratory now has an additional performance check at 1ug/l lead with appropriate acceptance tolerances in place further control low-level lead determinations.

Aquacheck proficiency scheme results have been very good over the past year or so for DWTS parameters with only arsenic generating two "Questionable" results. There was an appropriate non-conforming work investigation in place covering arsenic where the level of arsenic in the PT sample was close to the reporting limit value in both cases.

A vertical audit was carried out on a Potable Private Water sample (Lab Ref: 102011158) for a selection of results including two parameters that had breached a PCV threshold (Mn & Ni).
The audit found that the laboratory record system was working well with the results traceable back to worksheets and instrument results via the AIS LIMS.

Test Method Remote Reviews	Discussion with	Technical Assessor	Comments
PA/IHT/4204 - Conductivity of potable waters (DWTS)		Peter Sleeman	This was a remote assessment - no methods were witnessed. Analyst competence, equipment checks, instrument system suitability checks, calibration traceability, AQC and PT performance checked via records supplied & discussions with JD.
PA/IHT/4104 - Nitrite in potable waters by spectrophotometry (DWTS)			
PA/IHT/4523 - Metals in potable waters by ICPAES (DWTS)			
PA/IHT/4519 - COD in surface, ground waters & landfill leachates by "sealed tube" digestion methodology & spectrophotometry			
PA/IHT/4222 - TDS & TS of waters by gravimetry			
PA/IHT/8001 - Nitrogen dioxide in air by spectrophotometry			

Next Step
Submission of evidence to address the mandatory findings raised within the agreed timescale. Objective evidence to demonstrate that the mandatory findings requiring close out action have been suitably addressed is to be submitted electronically by email to UKAS at customerservices@ukas.com both your UKAS reference number(s) and the project number within the subject field. You should receive notification from UKAS that this evidence has been received within three working days of submission. NB: If this notification is not received, please contact UKAS. In order to ensure reliable delivery we request that all emails to be kept below approximately 5MB, if a large amount of data is to be submitted we request that multiple emails are used marked 1 of x, 2 of x to x of x etc. Where no evidence has been requested please indicate the action taken on the Improvement Action Summary form (IASF). Please use a separate form for each assessor.

Note: the laboratory is advised that if corrective action evidence supplied does not clear the nonconformities raised within two submissions of evidence, a review will be carried out with the expectation that an extra visit will be necessary to review actions taken and their implementation with the organisation.

References (if applicable)
ISO/IEC 17025:2017 – General Requirements for the competence of testing and calibration laboratories

ISO/IEC 17025:2005 – General Requirements for the competence of testing and calibration laboratories
LAB 37 - DWTS specification
The Water Intended for Human Consumption (Private Supplies) (Scotland) Regulations 2017
The Public Water Supplies (Scotland) Amended Regulations 2017

Appendices (if applicable)
Improvement Action Report
Transition Template (ISO/IEC 17025:2017 Transition)