National Audit of TB Diagnostic Laboratories and Description of Molecular Diagnostic Service Provision

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1. SUMMARY

This audit of TB laboratories in England, Scotland and Wales demonstrates that large numbers of laboratories continue to do TB microbiology, some processing small numbers of samples. Standards for microscopy are well achieved, but standards for culture are less uniformly met. Increasing numbers of laboratories perform molecular diagnostics for TB, with varying approaches and assays. This highlights the need for national guidance and quality control in the use of TB molecular diagnostics.

2. BACKGROUND

TB diagnostic services are an essential part of TB control. Modelling suggests that improvements in diagnosis can have a substantial effect on TB incidence and deaths globally[1]. The US CDC has already identified the number of challenges involved with maintaining a quality TB diagnostic service nationally, including communication, turnaround times, technology adoption, workforce competence, maintaining proficiency and information management[2]. British TB diagnostic services are currently provided by a combination of NHS, public health and private laboratories at a large number of sites, with reference services provided by the HPA and in Scotland commissioned by National Services Scotland through Health Protection Scotland.

In addition to the factors identified in the US, two current developments have the potential to affect UK TB diagnostic services. Firstly, molecular diagnostics tests have become widely available and newer automated platforms such as GeneXpert are accessible to laboratories of all sizes and types. Limited guidance and economic evaluation is available on their implementation, none targeted to high income, low prevalence countries[3]. Existing guidance applicable to the UK from NICE[4] and the Department of Health[5] does not take account of recent developments, although some WHO Europe recommendations have been published[6]. Appendix 1 summarises the current guidance available relating to direct molecular testing.

Secondly, modernization of pathology services is altering the way in which bacteriology is delivered. New commissioning procedures are likely to lead to further changes. It is essential that these factors do not disrupt the diagnosis and surveillance of TB nationally. This is an opportune time to act to maximise service performance, including the appropriate introduction of newer technology. This report describes the provision of TB laboratory services in Britain, audits those services against current best practice standards for routine diagnostic methods, and describes the adoption of molecular technology to date.

3. METHOD

The audit was designed by a team including members from the Health Protection Agency, Association of Clinical Pathologists, Public Health Wales and Health Protection Scotland and approved by the Royal College of Pathologists Microbiology Specialty Advisory Committee. Audit standards were derived from current best practice guidance including the commissioning toolkit[5], NICE[4], ECDC[7] and HSE[8]. Recommendations concerning volume of tests processed and maintaining proficiency were taken from the American Thoracic Society as there is no current British equivalent[9]. Some standards were derived by consensus of expert opinion, either those agreed for a previous HPA London TB audit (personal communication, N. Shetty) or by the members of the study team. Two molecular testing standards were included. Other questions about molecular testing were descriptive only and were agreed by the study team.

An electronic questionnaire was distributed by Keele's National Pathology Benchmarking Service using a contact list held by the Department of Health, targeting the director and laboratory manager at each NHS and HPA microbiology laboratory. Some private providers are included on this list and were contacted; however the intention was to describe NHS and public health laboratory services. Scottish laboratories were contacted through the Scottish Microbiology Forum.

4. RESULTS

A summary of results is provided here. Full numeric results for each question and breakdown by country are provided in Appendix 2.

4.1 Data Return

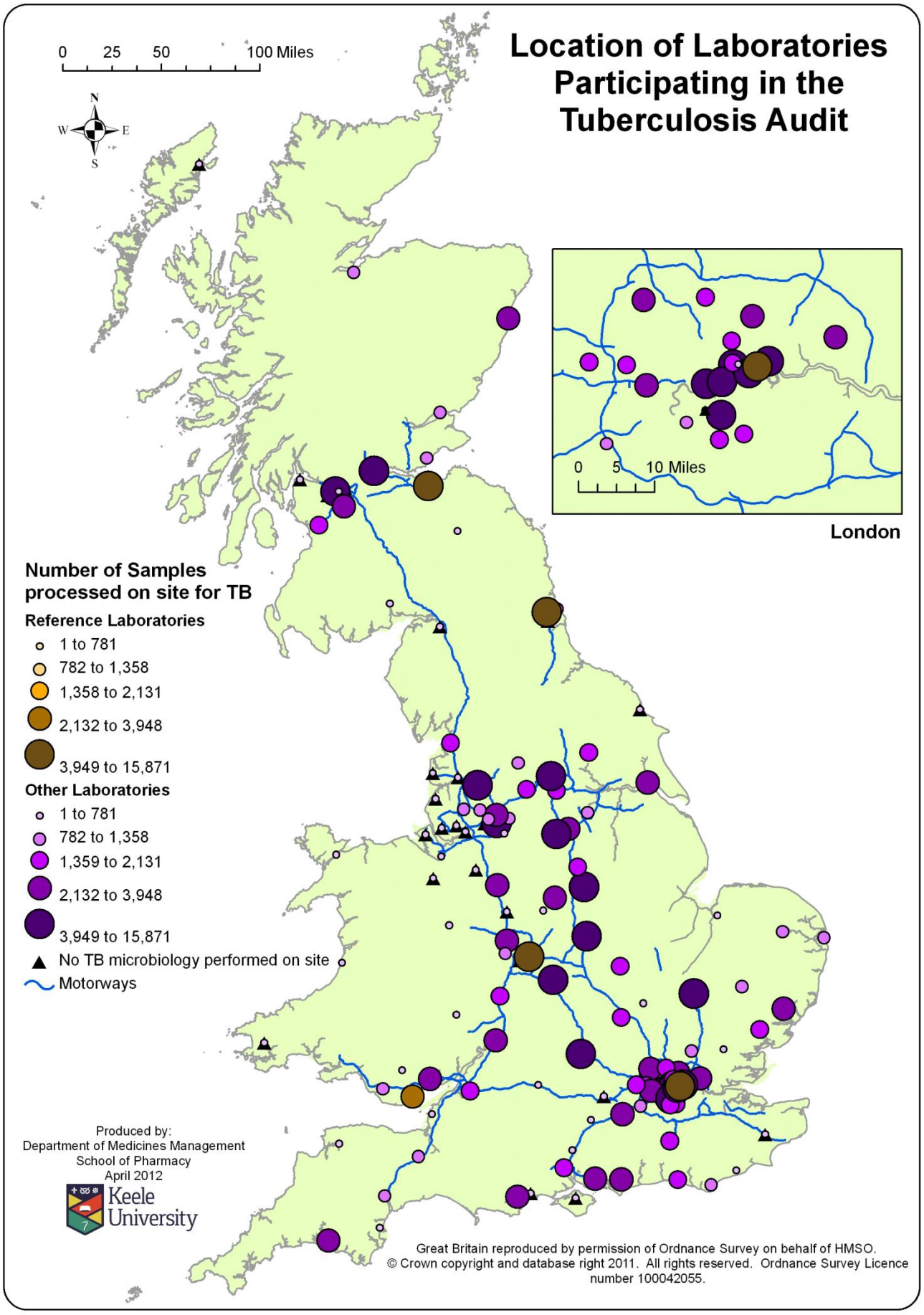
134 returns were received containing data from 149 NHS Trusts or Health Boards in England, Scotland and Wales, including mycobacterial reference laboratories (Figure 1). Good geographical coverage was achieved (Figure 2).

Figure 1: Number of Returns

Country	Number of data returns	Number of NHS Trusts/Health Boards for which data was returned (percentage of total)
England	110	128 (80%)[1]
Scotland	16	14 (100%)
Wales	7	7 (100%)
UK	134	149 (83%)
Non NHS laboratories in England returning data		
HPA specialist microbiology network		7
Private laboratories		3 (excluding those replying on behalf of a single Trust)

[1] *Of the 31 Trusts for which no data was received, 8 provide specialist health services only.*

Figure 2: Geographical Summary of Data Returned



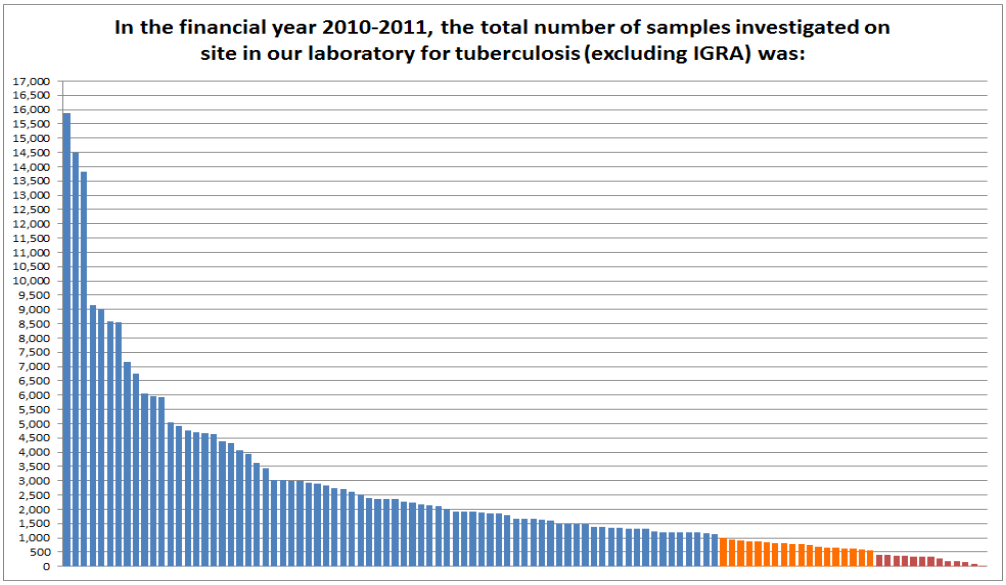
4.2 Workload and Service Provision

In the financial year 2010-11, 305,939 samples were received for TB investigation by responding laboratories (representing 80% of Trusts/Health Boards), including 34,036 to Scottish laboratories and 8253 to Welsh. 36,757 samples for IGRA testing were received.

A number of individual laboratories process small numbers of samples, and do not meet the ATS guidance for volume required to maintain proficiency for either microscopy or culture (Figure 3). The mean audit score is identical (17.4) in laboratories above and below the ATS cut off for number of cultures performed (>20 per week).

Figure 4 shows how diagnostic services are provided at the responding laboratories.

Figure 1: Number of samples investigated for TB on site, excluding IGRA.



Assuming all samples investigated for TB receive smear and culture, laboratories investigating less than 10 samples per week (the minimum to comply with the standard for microscopy) are highlighted in red. Those investigating less than 20 per week (the minimum to comply with the standard for culture) are highlighted in orange.

Figure 4: Provision of TB services at laboratories responding to the survey, corresponding to 149 Trusts/Health Boards in England, Scotland and Wales.

Please indicate how the following mycobacterial laboratory services are provided for patients in your Trust:	By a local laboratory network	By a private provider	By another laboratory which is not a regional mycobacterial reference centre	HPA Birmingham	HPA Newcastle	HPA NMRL London	In our own laboratory	Not provided	Other	PHW Cardiff	Provided by more than one laboratory	SMRL Edinburgh
Direct molecular testing on samples	**1**	**1**	**10**	**16**	**16**	**39**	**23**	**5**		**9**	**1**	**11**
England	1	1	9	16	16	38	21	3		2	1	1
Scotland			1				2	2				10
Wales						1				7		
Genotypic antimicrobial susceptibility testing	**1**	**1**	**5**	**18**	**21**	**46**	**8**	**5**		**12**		**13**
England	1	1	4	18	21	46	7	4		4		1
Scotland			1				1	1				12
Wales										8		
IGRA	**5**	**16**	**38**	**4**	**8**	**7**	**20**	**12**	**5**	**3**	**3**	**6**
England	3	15	37	4	8	7	14	9	4		3	
Scotland		1					6	2				6
Wales	2		1					1	1	3		
Microscopy for AAFB	**1**	**1**	**13**		**2**		**106**	**2**	**1**	**1**	**5**	**1**
England	1	1	12		2		88	1			5	
Scotland			1				11	1	1			1
Wales							7			1		
Molecular identification of isolates	**1**	**1**	**6**	**18**	**20**	**43**	**12**	**3**		**14**	**1**	**13**
England	1	1	5	18	20	43	11	2		6	1	1
Scotland			1				1	1				12
Wales										8		
Mycobacterial culture	**5**	**1**	**19**	**1**	**4**		**92**	**2**		**4**	**1**	**4**
England	5	1	16	1	4		81	1			1	
Scotland			3				7	1				4
Wales							4			4		
Phenotypic antimicrobial susceptibility testing	**1**	**1**	**4**	**19**	**25**	**47**	**4**	**3**		**15**		**13**
England	1	1	3	19	25	47	3	2		7		1
Scotland			1				1	1				12
Wales										8		
VNTR typing	**1**	**1**	**4**	**17**	**19**	**48**	**3**	**11**		**12**		**12**
England	1	1	3	17	19	48	2	8		5		1
Scotland			1				1	2				11
Wales								1		7		

4.3 National Audit Performance

Figure 5 shows the performance of responding laboratories compared to the audit standards.

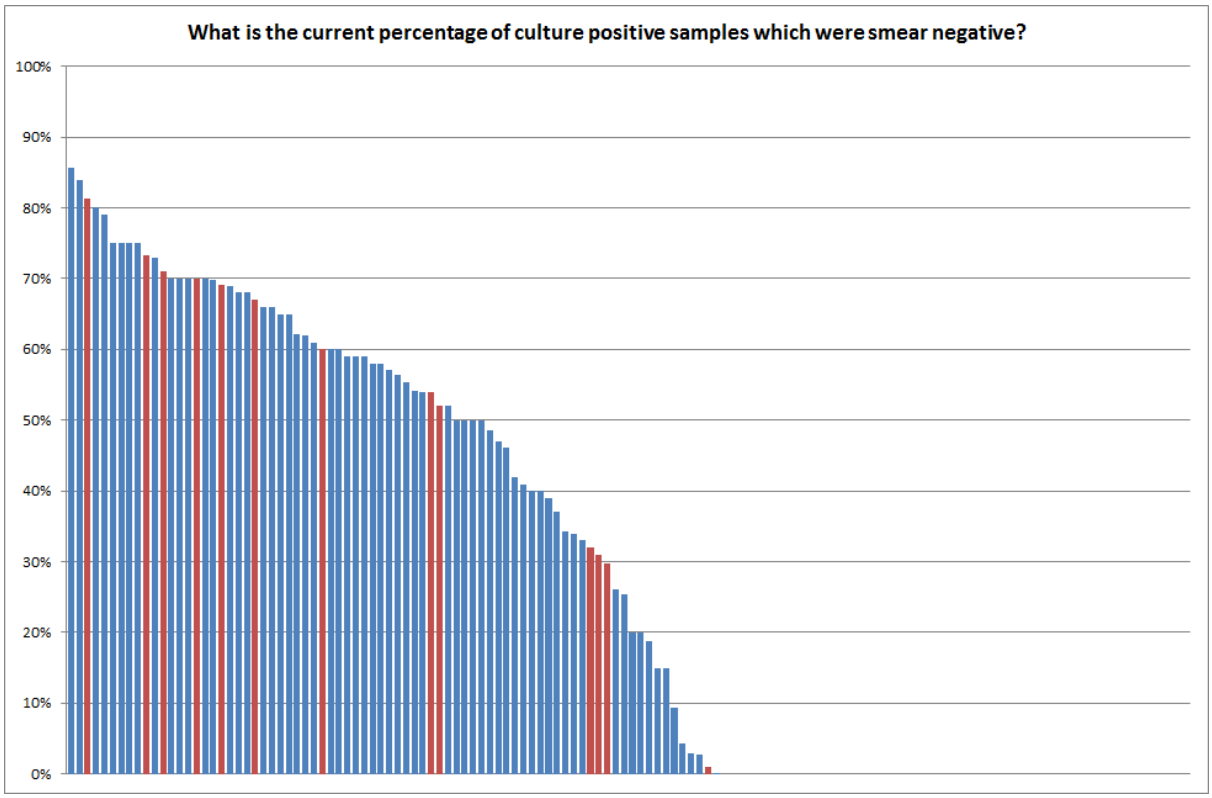
Figure 5: Performance of the England, Scotland and Wales TB diagnostic laboratory service compared to audit standards.

Standard	Source	Percentage of laboratories meeting the standard	Total Number of Responses
Microscopy (Total Number of Laboratories Providing Microscopy = 106)			
Monitor sample time to ensure no more than 48 hours have elapsed between sample collection and arrival at the laboratory	Toolkit	42%	102
AAFB microscopy should be reported within 1 working day of being received	Toolkit	89%	104
Fluorochrome stain should be used	Toolkit	92%	105
6 days per week service minimum for AAFB	Toolkit	50%	105
Positive AAFB telephoned to clinician within 1 working day	Toolkit	98%	105
Positive results communicated to CCDC/TB nurse within 1 working day	Toolkit	89%	102
IQ in place for smear microscopy including positive and negative control slides	Toolkit and Team Consensus	79%	103
Process >10 smears per week in an individual lab	ATS	90%	104
EQA for TB work performed (Microscopy)	ATS	99%	105
Culture (Total Number of Laboratories Providing Culture = 92)			
Automated liquid culture on all samples	NICE, toolkit	78%	91
Solid culture done in addition on all samples	Toolkit (Scottish Action plan does not require this)	38%	90
IQ for culture	Toolkit	47%	91
Culture >20 specimens per week	ATS	77%	89
Contamination rate 3-5%	ECDC	20%	92
EQA for TB work performed (Culture)	Toolkit	97%	89
Actions on positive cultures (Total Number of Laboratories Providing Culture = 92)			
Sent to reference lab within 24 hours (unless MGIT)	Toolkit	74%	90
M. tb identified by molecular testing	Toolkit	98%	91
ID within 1 day if in same lab	Toolkit	21%	43
New culture and ID reported to clinician and CCDC/TB nurse within 1 working day	Toolkit	88%	88
90% M tuberculosis isolates reported within 21 days of sample receipt			
Percentage who meet the standard:	Toolkit	4%	84
Percentage who do not monitor:	Toolkit	70%	
Laboratory facilities (Total Number of Laboratories Providing Microscopy = 106)			
HSE approved CL3	Toolkit	97%	103
CL3 dedicated solely to TB diagnostics	Team Consensus	26%	104
Continuity plan for CL3	Toolkit	75%	102
Reporting (Total Number of Laboratories Providing Culture = 92)			
Report first M. tuberculosis isolates to HPU and CoSURV	Toolkit (cosurv)	95%	90
Histopathologists report positives to the microbiologist	HPA London minimum standards	79%	84
Safety (Total Number of Laboratories Providing Microscopy = 106)			
Employee training to include review of biosafety plan, safety training on aerosol prevention, and medical evaluation after an exposure.	HSE 2001 + HPA consensus	81%	104
Molecular testing (Total Number of Laboratories Providing Molecular Testing = 27)			
Rifampicin susceptibility identified directly on samples from patients with suspected MDR TB.	NICE	63%	27
Molecular assay used to identify M. tuberculosis from positive cultures	Toolkit	63%	27
EQA for TB work performed (Molecular)	Toolkit	67%	18

The percentage refers to the percentage of laboratories performing that service (e.g. culture) and answering that section of the questionnaire.

Answers to some numerical questions showed wide variation and suggest variation in practice or proficiency. Examples of these are shown in Figure 6 (percentage of cultures positive samples which were smear negative on initial microscopy), Figure 7 (contamination rate for liquid culture of sputum) and Figure 8 (percentage of cultures reported with identification within 21 days of receipt).

Figure 6: Percentage of culture positive samples which are smear negative on initial microscopy



Laboratories which are processing less than the recommended volume for maintaining proficiency at culture are shown in red.

Figure 7: Contamination rate for liquid culture of sputum

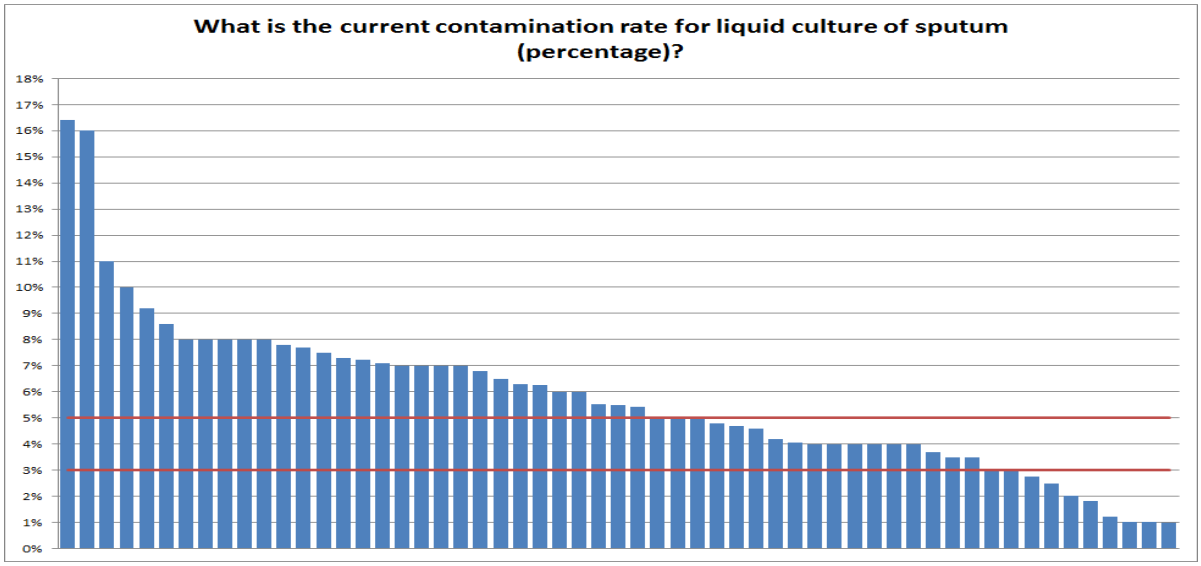
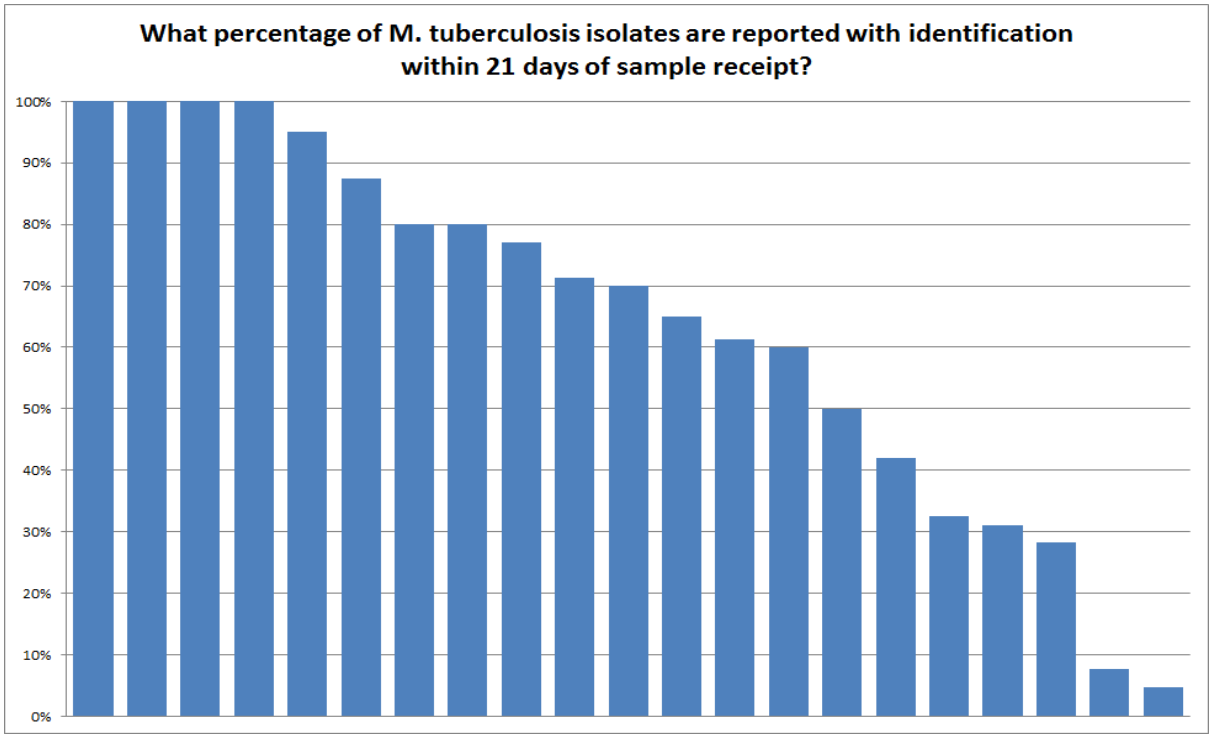


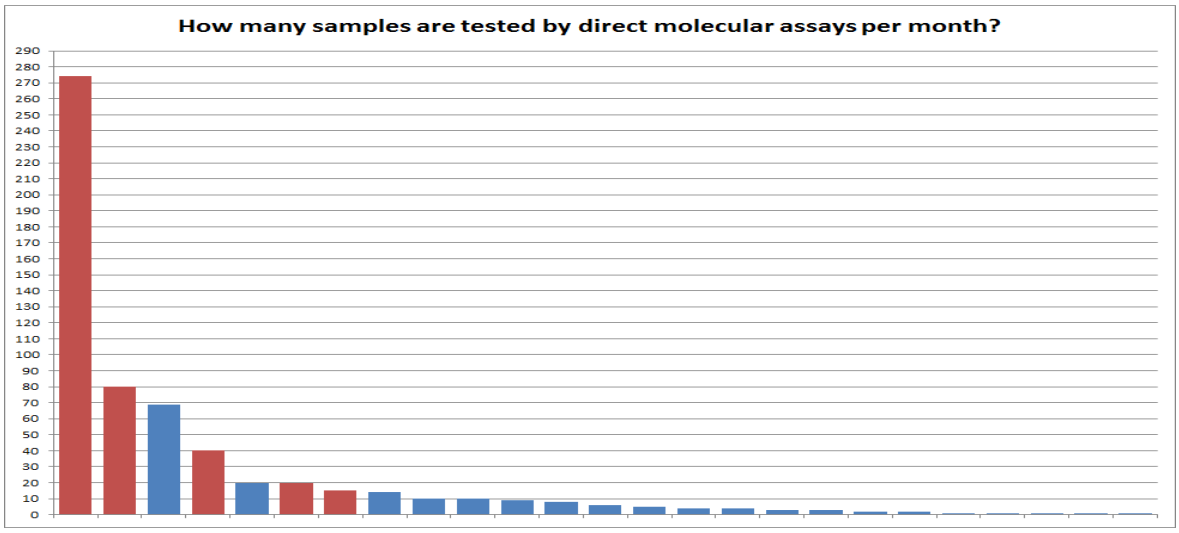
Figure 8: Percentage of cultures reported with identification within 21 days of receipt



4.4 Molecular Testing Directly on Samples

27 laboratories perform direct molecular testing in house, of which 16 use Cepheid GeneXpert MTB/RIF, 11 use HAIN Genotype, 5 use assays developed in house and a number use other assays including Anyplex Segene and Nanogen assays. 7 laboratories use more than one assay. Most non reference laboratories which use direct molecular tests perform small numbers (Figure 9). The algorithm used to choose samples for direct molecular testing is variable (Figure 10), including 5 laboratories testing all patients suspected of having TB. Direct testing for detection of antimicrobial resistance is also performed at most of these laboratories, with 14 testing for rifampicin only. 8 laboratories test all smear positive samples, 9 only test suspected MDR TB and 10 use another algorithm.

Figure 9: Number of samples tested by direct molecular assays for the presence of *M. tuberculosis*, per month.



Bars in red represent reference laboratories.

Figure 10: Algorithm used to choose which samples receive direct molecular testing for the detection of *M. tuberculosis* DNA.

Algorithm	Number of laboratories
All smear positive samples	4
Selected smear positive samples	16
Smear positive samples by physician request	17
All sputa from patients clinically suspected of TB	5
Selected smear negative samples	10
Smear negative samples by physician request	15
Other	5

These were not mutually exclusive categories.

Figure 11: Satisfactory Performance in an EQA Scheme

Does the laboratory have a satisfactory performance in the last 12 months in an EQA scheme for every level for service provided for TB?	Not participating in EQA	Participating but not currently satisfactorily	Yes
Molecular Diagnostics	**3**		**9**
England	3		8
Scotland			1

4.5 Molecular Testing on Isolates

17 laboratories are doing their own molecular identification of isolates, of which the majority (12) use the HAIN Genotype assay whilst 3 use sequencing based techniques. 15 laboratories do their own genotypic antimicrobial susceptibility testing on isolates, of which 15 use one of the HAIN Genotype assays, 7 Cepheid and 1 an in-house assay.

4.6 Clinical Advice

Clinical advice is still provided most commonly by microbiologists and chest physicians. Figure 12 shows responses. These answers were not mutually exclusive.

Figure 12: Provision of clinical advice on diagnosis and management of TB cases

Provider	Number of laboratories
Microbiologist with responsibility for TB	43
Duty microbiologist	97
Infectious diseases physician	39
Chest physician	109
Provided from outside the Trust	9
Other	4

5. COMMENTARY

The data return was good and is an improvement on previous similar audits. This methodology could be employed for future audits. The principal messages from the data are as follows:

5.1 Large numbers of laboratories continue to do TB work, some processing small numbers of samples

The majority of laboratories do their own smear testing and many do mycobacterial culture, though few do their own susceptibility testing. For those laboratories which send microscopy and culture elsewhere, use of a non-reference laboratory predominates, perhaps reflecting the increase in laboratory networks. However, the majority of identification of isolates and susceptibility testing is done at HPA or Scottish reference laboratories. A number of laboratories process small volumes of work, and almost one quarter do not meet the standard for number of cultures processed per week. Many laboratories do not maintain separate containment level 3 facilities for TB. However the data from this audit does not suggest that very low sample numbers (under the ATS threshold) affect the quality of service.

5.2 There is variable achievement of the standards for culture processes

The performance in standards relating to smear microscopy is good, although only 50% of laboratories provide the 6 day service required by the DH commissioning toolkit. The achievement of culture standards was much more variable, particularly regarding turnaround times. A large number of laboratories are not monitoring the 21 day turnaround standard on complete reporting.

Many of the audit criteria relate to the provision of an adequate service rather than operator proficiency. However, the percentage of culture positive samples which are found smear negative on initial investigation can be an indicator of the operator microscopy skill and an optimised smear and culture set up process. This indicator showed variation between laboratories [Figure 3].

5.3 Increasing numbers of laboratories perform direct molecular diagnostics

Adoption of direct molecular testing is underway. One quarter of responding laboratories which have a TB service provide molecular diagnostics and almost every other laboratory has a referral arrangement in place. Laboratories using molecular assays are not exclusively in centres with academic microbiology or in high TB prevalence areas. New diagnostic models are being introduced, such as one laboratory which performs on-site direct PCR on samples from any patient suspected of TB and sends the samples on for culture elsewhere. Most of these laboratories also do direct antimicrobial resistance testing (in many cases this refers to the use of the Cepheid GeneXpert combined identification/rifampicin resistance test). For those labs referring samples away, the HPA and Scottish and Welsh reference laboratories are the major providers.

5.4 The approach to using direct molecular diagnostics is variable and may affect diagnostic performance

Most laboratories using direct molecular diagnostics test selected smear positive samples and/or smear positive samples by physician request, but one third have more inclusive algorithms (e.g. all sputa from patients suspected of TB, all smear positive sputa). Despite this, the majority of laboratories test under 25 samples a month with a direct molecular test and this is of potential significance in maintaining adequate expertise to perform and interpret the test. Some laboratories also have inclusive algorithms for direct resistance testing, (in many cases this refers to the rifampicin resistance result in the combined Cepheid GeneXpert test) and in areas of low resistance prevalence this may produce false positive results. For these reasons, the WHO recommends that all such samples are tested for resistance by another methodology.

The growing number of laboratories providing these services, and apparent diversity of approach, assay and providers, highlights the need for guidance and quality control for this aspect of the service.

5.5 Clinical advice

Despite the changing infection workforce, the majority of TB clinical advice within Trusts is still provided by microbiologists and chest physicians. Information and guidance on diagnostics will need to be disseminated appropriately to reach physicians as well as laboratories.

6. NEXT STEPS

The findings of the audit were discussed by the HPA TB Delivery Board, including representatives from Scotland and Wales. All members agreed the need for UK specific guidance on implementation of molecular tests for TB diagnosis, and an associated quality control scheme.

In order to take this forward, the HPA will shortly invite representatives from relevant stakeholders to form a working party to develop this guidance. The working party will also consider the optimal service configuration for delivery of TB microbiology in England, with a view to providing information to support commissioning. Proceedings of the working party will be published.

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APPENDICES

Appendix 1: Guidance Relating to Direct Molecular Testing

Figure 13: Direct Molecular Testing Guidance

Organisation	Document	Principal recommendations	Implication: Who should receive direct molecular tests?
Documents applicable to the UK			
ECDC	Mastering the basics of TB control 2011	[Molecular tests] do not/should not replace the currently endorsed standard methods of detecting mycobacteria and determining drug-susceptibility patterns, but rather be used as a support to the diagnostic work-up	Not specified
WHO Europe	Recommended standards for modern tuberculosis laboratory services in Europe 2006	Laboratories should aim to identify *M. tuberculosis* and rifampicin resistance in 90% of cases from smear-positive sputum directly where resources are available for this (this will require an investment in new methodological techniques).	All smear positive samples
WHO	Rapid implementation of Xpert MTB/RIF and STAG 2011	Xpert MTB/RIF should be used as the initial diagnostic test in individuals suspected of having MDR-TB or HIV-associated TB; Xpert MTB/RIF may be considered as a follow-on test to microscopy in settings where MDR-TB or HIV is of lesser concern, especially in further testing of smear-negative specimens. Consider for use in patients with abnormal chest X ray or smear negative but still suspected of having TB.	As primary test: All risk of MDR or HIV positive. After microscopy: Any patient with suspicion of TB, especially if smear negative .
NICE	NICE guideline, updated 2011	Rapid diagnostic tests for *M. tuberculosis* complex on primary specimens should be used only if rapid confirmation of a TB diagnosis in a sputum smear-positive person would alter their care, or before conducting a large contact-tracing initiative. Clinicians should still consider a diagnosis of non-respiratory TB if rapid diagnostic tests are negative, for example in pleural fluid, CSF and urine. R24 Before conducting a large contact-tracing initiative (for example, in a school or hospital), the species of *Mycobacterium* should be confirmed to be *M. tuberculosis* complex by rapid diagnostic tests on microscopy- or culture-positive material. Clinical judgement should be used if tests are inconclusive or delayed. D(GPP 2006 If a risk assessment suggests a patient has MDR TB rapid diagnostic tests should be conducted for rifampicin resistance	Individual assessment: Those where it would alter care or public health activity. Rifampicin direct test if risk of MDR.

Organisation	Document	Principal recommendations	Implication: Who should receive direct molecular tests?
UK Department of Health	DH Commissioning Toolkit 2007	[Direct molecular testing] is not part of the routine investigation of samples for *M. tuberculosis* but may be considered where there is a high suspicion of infection and a definitive diagnosis of *M. tuberculosis* is deemed urgent in clinical terms or for health protection purposes.	Individual assessment: Those where it would alter care or public health activity.
	Health Technology Assessment	Our findings indicate that for pulmonary, smear positive TB, NAAT tests should be used regardless of degree of clinical suspicion, to distinguish between *M. TB* and NTM or to identify the NTM in question, or to identify MDR-TB. For smear negative disease, appropriate use of a NAAT test will depend on the associated degree of clinical suspicion.	All smear positive samples. Test smear negative samples if clinically suspicious.
HPA	National Standard Method	Equivalent to NICE	If would alter care.
Documents not applicable to the UK			
CDC	Updated Guidelines for the Use of Nucleic Acid Amplification Tests in the Diagnosis of Tuberculosis 2009	The panel recommended that NAA testing become a standard practice in the United States to aid in the initial diagnosis of patients suspected to have TB, rather than just being a reasonable approach, as suggested in previously published guidelines…NAA testing should be performed on at least one respiratory specimen from each patient with signs and symptoms of pulmonary TB for whom a diagnosis of TB is being considered but has not yet been established, and for whom the test result would alter case management or TB control activities	

Appendix 2: Complete Results and Breakdown by Country

2.1 Transport and Microscopy

Figure 14: Microscopy Specimens

	No	Yes
Do you monitor sample delivery time to ensure no more than 48 hours have elapsed between speciment collection and arrival at the laboratory?	**67**	**52**
England	59	41
Scotland	4	9
Wales	4	2
Do you process and report microscopy for acid fast bacilli within one working day?	**11**	**103**
England	7	88
Scotland	2	11
Wales	2	4
Do you use a fluorochrome (auramine) stain as the primary technique for direct microscopy of specimens?	**7**	**107**
England	4	92
Scotland	1	11
Wales	2	4

Figure 15: Number of Days per Week AAFB Smear Microscopy Serviced is Offered

	5 Days	6 Days	7 Days
How many days per week do you offer an AAFB smear microscopy service?	**56**	**18**	**40**
England	47	17	32
Scotland	5		7
Wales	4	1	1

Figure 16: Communication of Positive Smear Results to Referring Clinician

Are positive smear results communicated to the referring clinician within one working day? Method:	No	Yes
By Email:	**67**	**30**
England	56	28
Scotland	9	2
By Telephone:	**1**	**113**
England	1	95
Scotland		12
Wales		6
By Another Method:	**40**	**45**
England	31	43
Scotland	9	1
Wales		1

Figure 17: Communication of Positive Smear Results to CCDC/CPHM/Local Specialist Nurse

	No	Yes
Are positive smear results communicated to the CCDC/CPHM/local specialist nurse with responsibility for contact tracing within one working day?	**8**	**101**
England	8	83
Scotland		12
Wales		6

Figure 18: Out-of-Hours Smear Testing

	No	Yes
Do you offer out-of-hours smear testing?	**37**	**76**
England	34	61
Scotland	2	10
Wales	1	5

Figure 19: Communication of Positive Smear Results to Trust's Respiratory Medical Team

	No	Yes for all samples	Yes for selected samples
Are positive smear results communicated to the Trust's respiratory medical team?	**3**	**78**	**23**
England	3	66	19
Scotland		9	2
Wales		3	2

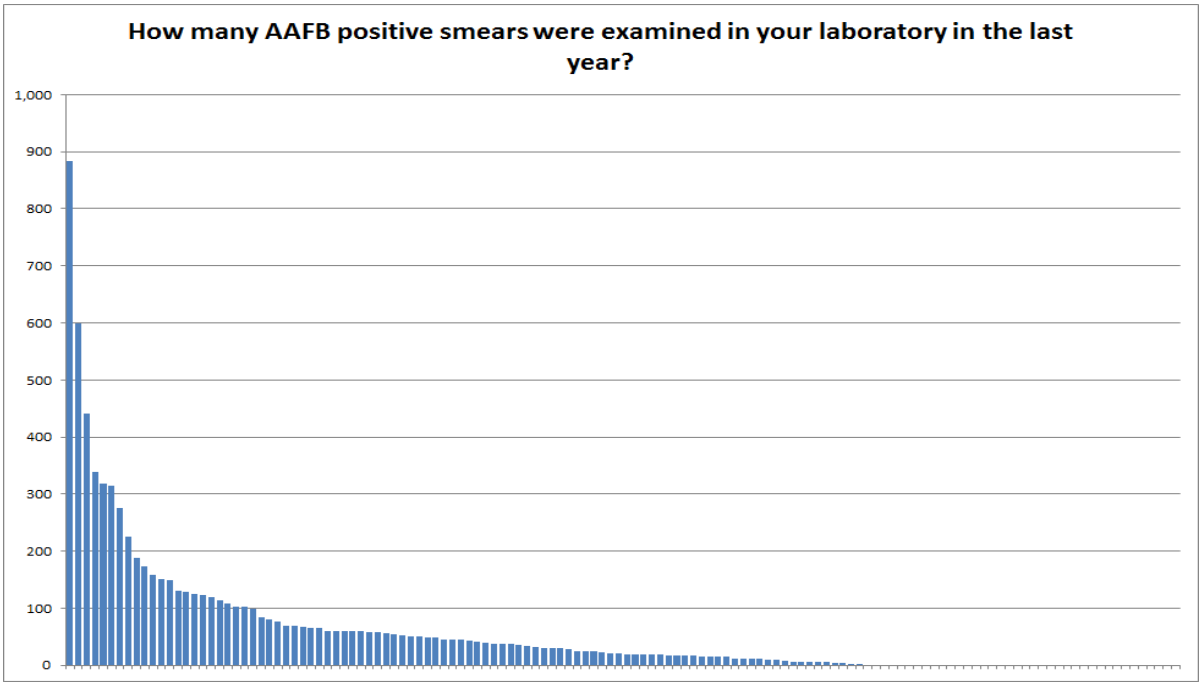
Figure 20: Internal Quality Control Programme

	No	Yes
Do you have a documented internal quality control programme in place for smear microscopy, including daily positive and negative control slides?	**20**	**90**
England	18	75
Scotland	2	10
Wales		5

Figure 21: Preparation and Examination of >10 Smears per Week

	No	Yes
Does your laboratory prepare and examine >10 smears per week?	**15**	**98**
England	11	85
Scotland	3	9
Wales	1	4

Figure 22: AAFB Positive Smears Examined in your Laboratory



2.2. Culture

Figure 23: Samples for TB Investigation Set Up for Culture

	No	Yes
Are all samples for TB investigation set up for culture within one day of receipt?	**42**	**47**
England	37	41
Scotland	2	5
Wales	3	1

Figure 24: Automated Liquid Culture Done on all Samples for Culture of Mycobacterial Species

	No	Yes
Is automated liquid culture done on all samples for culture of mycobacterial species?	**19**	**72**
England	14	66
Scotland	4	3
Wales	1	3

Figure 25: Conventional Solid Culture Done on all Samples for Culture of Mycobacterial Species

	No	Yes
Is conventional solid culture done on all samples for culture of mycobacterial species?	**55**	**35**
England	51	28
Scotland	2	5
Wales	2	2

Figure 26: Internal Quality Control Programme

	No	Yes
Do you have a documented internal quality control programme in place for culture?	**48**	**43**
England	45	35
Scotland	2	5
Wales	1	3

Figure 27: Contamination Rate for Liquid Culture of Sputum

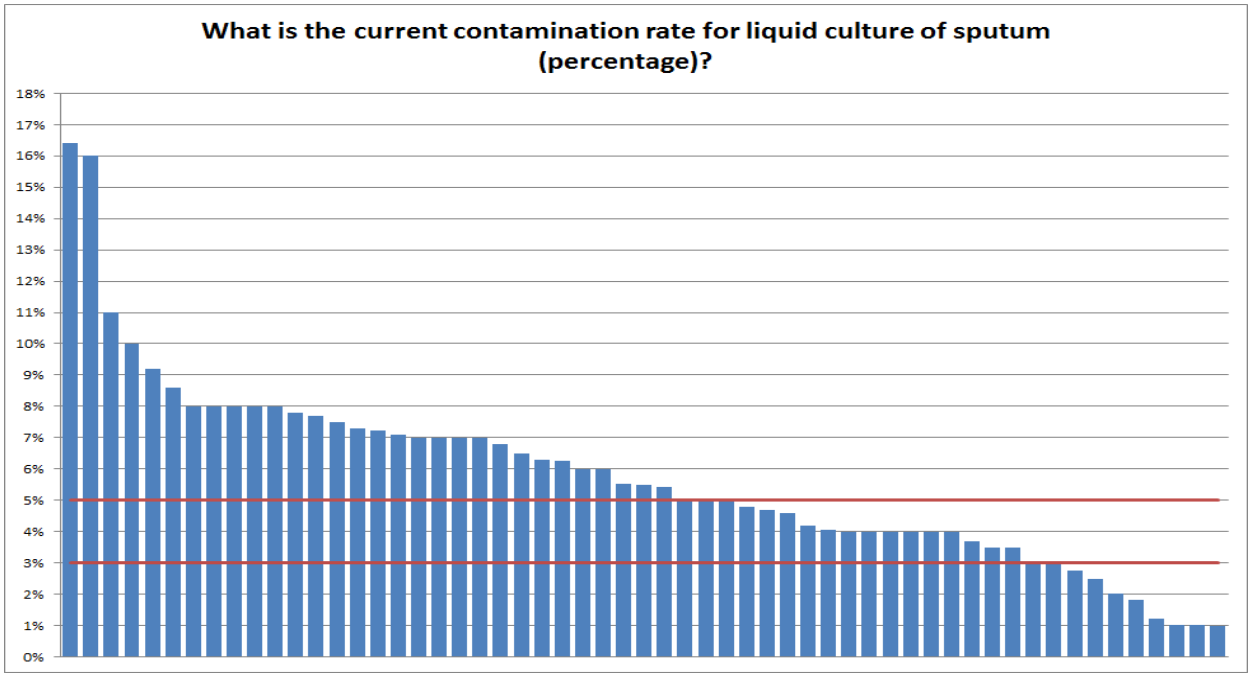


Figure 28: Number of Positive Mycobacterial Cultures per Year

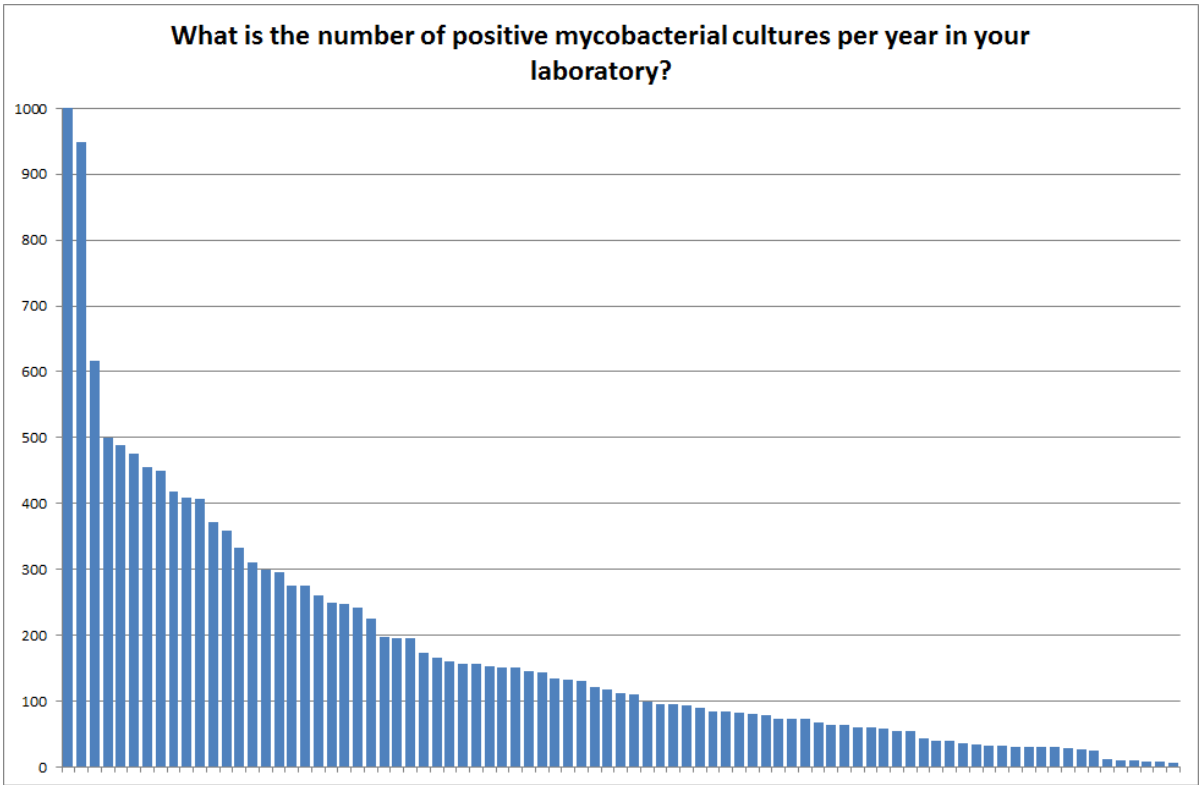


Figure 29: Current Percentage of Culture Positive Samples which were Smear Negative

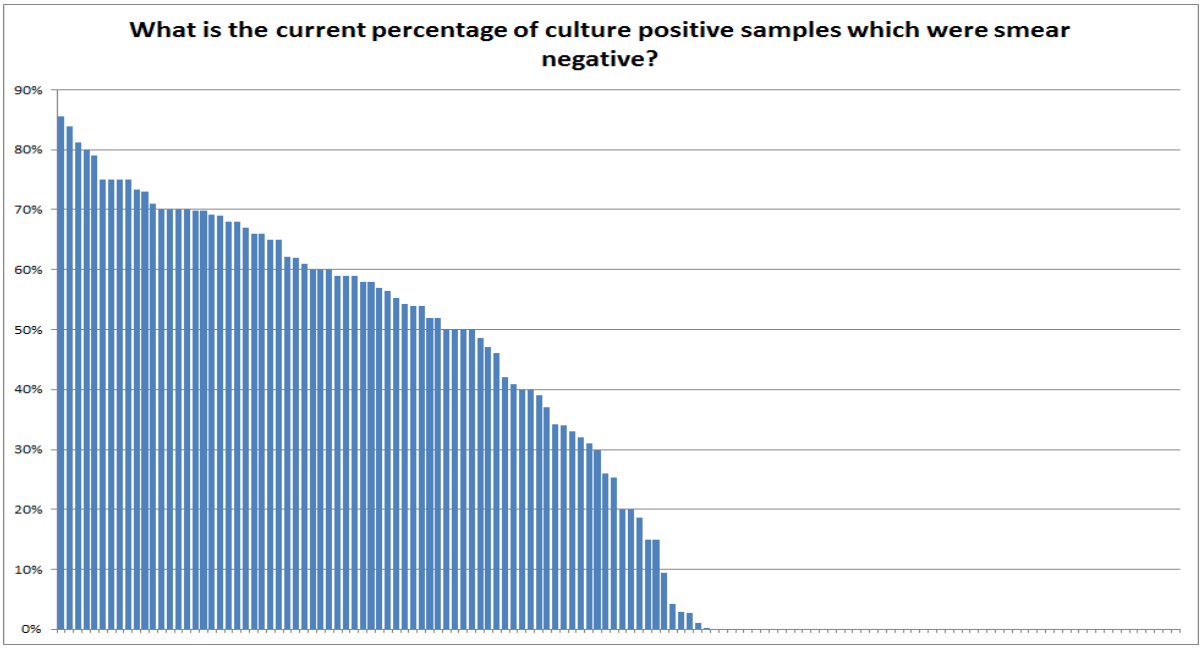


Figure 30: Respiratory Samples that are Cultured for Mycobacteria

	All respiratory samples received by the laboratory	Only those where mycobacteriology is requested by the physician	Samples selected by a laboratory algorithm
Which respiratory samples are cultured for mycobacteria?	**5**	**54**	**33**
England	5	47	29
Scotland		5	2
Wales		2	2

2.4 Action on Positive Cultures

Figure 31: Positive Cultures Dispatched to a Regional Reference Centre

	No	Yes
Are positive cultures dispatched within 24 hours to a regional reference centre?	**22**	**70**
England	19	63
Scotland	3	4
Wales		3

Figure 32: How is M. Tuberculosis Identified from Positive Cultures

	By molecular testing at a reference laboratory	By molecular testing in your own laboratory	By non-molecular testing in your own laboratory
How is M. tuberculosis identified from positive cultures?	**82**	**11**	**1**
England	72	10	1
Scotland	6	1	
Wales	4		

Figure 33: Availability of Identification Result for Positive Cultures

	Yes
If performing identification in your own laboratory, is the result available within one working day of the culture becoming positive?	**11**
England	10
Scotland	
Wales	1

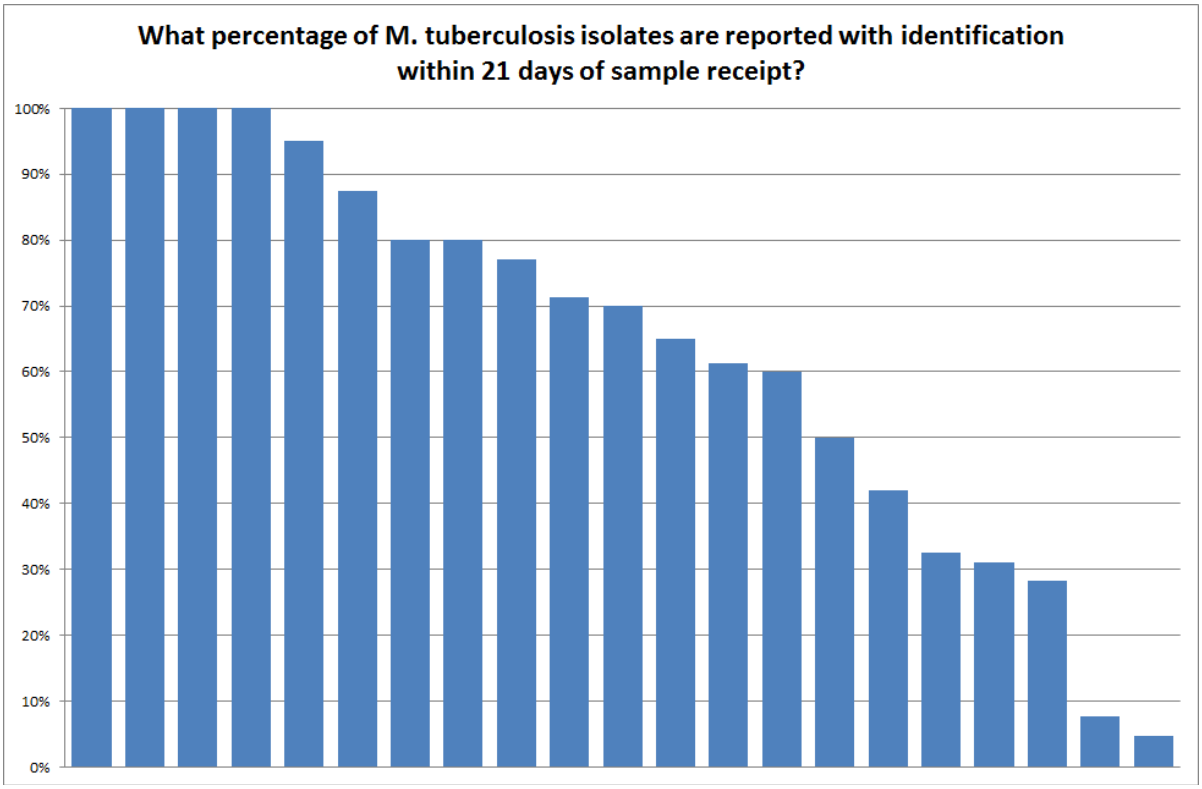
Figure 34: Communication of New Culture/ID Results to Referring Clinician

Are new culture/ID results communicated to the referring clinician within one working day? Method:	No	Yes
By Email:	**53**	**23**
England	47	22
Scotland	6	1
By Telephone:	**6**	**86**
England	5	76
Scotland	1	6
Wales		4
By Another Method:	**30**	**44**
England	25	41
Scotland	5	2
Wales		1

Figure 35: Communication of New Culture/ID Results to Trust's Respiratory Medical Team

	No	Yes
Are all new culture/ID results communicated to the Trust's respiratory medical team?	**8**	**78**
England	8	68
Scotland		6
Wales		4
Are new culture/ID results communicated to the CCDC/CPHM/local specialist nurse within one working day?	**7**	**82**
England	6	72
Scotland	1	6
Wales		4

Figure 36: Percentage of M. Tuberculosis Isolates Reported with Identification within 21 Days of Receipt



2.5 Laboratory Facilities

Figure 37: CPA Accreditation

	No	Yes
Is your laboratory CPA accredited?	**2**	**122**
England	2	102
Scotland		13
Wales		7

Figure 38: Category 3 Containment Facility Inspected and Approved by HSE

	Never	Yes in the last 12 months	Yes in the last 5 years
Has your Category 3 Containment Facility been inspected and approved by HSE?	**1**	**66**	**54**
England	1	53	48
Scotland		9	4
Wales		4	2

Figure 39: Category 3 Containment Facility Dedicated Solely to TB Diagnostics

	No	Yes
Do you have a Category 3 Containment Facility dedicated solely to TB diagnostics?	**93**	**29**
England	76	26
Scotland	11	2
Wales	6	1

Figure 40: Continuity Plan for Service Support in case of Category 3 Laboratory Closure

	Yes
Does the laboratory have a continuity plan for service support in case of Category 3 laboratory closure, which is agreed with another laboratory?	**94**
England	78
Scotland	11
Wales	5

Figure 41: Satisfactory Performance in an EQA Scheme

Does the laboratory have a satisfactory performance in the last 12 months in an EQA scheme for every level for service provided for TB?	Not participating in EQA	Participating but not currently satisfactory	Yes
Culture		**2**	**89**
England		2	78
Scotland			7
Wales			4
Microscopy			**105**
England			88
Scotland			11
Wales			6
Molecular Diagnostics	**3**		**9**
England	3		8
Scotland			1
Wales			

2.6 Reporting

Figure 42: Q7-1 & Q7-2 Reporting of First Isolates

	No	Yes
Do you report the first isolates of M. tuberculosis from each individual patient to the local Health Protection Unit/CPHM?	**10**	**79**
England	10	68
Scotland		7
Wales		4
Do you report the first isolates of M. tuberculosis from each individual patient via CoSURV, or if in Scotland via ECOSS?	**3**	**87**
England	3	76
Scotland		7
Wales		4

Figure 43: Q7-3 Reporting of Specimens Containing Mycobacteria by Histopathologists

	Never	Routinely	Sometimes
Do histopathologists in your pathology service report specimens containing mycobacteria to the consultant microbiologist?	**11**	**30**	**43**
England	10	23	40
Scotland	1	5	1
Wales		2	2

2.7 Safety

Figure 44: Q8-1 Employee Training and Support

Do all employees receive the following training and support?	No	Yes
Medical evaluation, counselling and follow up for any known exposure event	**1**	**109**
England	1	92
Scotland		13
Wales		4
Review of biosafety plan during induction	**7**	**112**
England	7	93
Scotland		13
Wales		6
Safety training on aerosol prevention techniques before commencing work in the mycobacterial lab	**3**	**114**
England	3	95
Scotland		13
Wales		6

2.8 Direct Molecular Testing

Figure 45: Molecular Testing Performed Directly on Clinical Samples for Detection of M. Tuberculosis Complex DNA or RNA

	No	Yes
Do you perform molecular testing directly on clinical samples for the detection of M. tuberculosis complex DNA or RNA?	**18**	**27**
England	15	24
Scotland	2	2
Wales	1	1

Figure 46: If Yes Assays Used

If yes, which assay(s) do you use?	Number of Responses:
Assay developed in house	**5**
England	4
Scotland	1
Wales	
Cepheid GeneXpert MTB/RIF	**16**
England	15
Scotland	1
Wales	
HAIN Genotype	**11**
England	10
Scotland	
Wales	1
INNOLiPA	**1**
England	1
Scotland	
Wales	
Other	**3**
England	2
Wales	1

These are not mutually exclusive categories. 5 laboratories used 2 assays and 2 used 3 assays.

Figure 47: If Yes Samples this Test is Performed On

If yes, which samples do you perform this test on?	Number of Responses:
All smear positive samples	**4**
England	4
Scotland	
Wales	
Selected smear positive samples	**16**
England	14
Scotland	1
Wales	1
Smear positive samples by physician request	**17**
England	15
Scotland	1
Wales	1
All sputa from patients clinically suspected of TB	**5**
England	4
Scotland	1
Wales	
Selected smear negative samples	**10**
England	9
Scotland	1
Wales	
Smear negative samples by physician request	**15**
England	14
Scotland	1
Wales	
Other (please specify)	**5**
England	4
Wales	1

These were not exclusive categories.

Figure 48: Molecular Testing Performed Directly on Clinical Samples for Detection of Antimicrobial Resistance

	Yes for rifampicin and other drugs	Yes for rifampicin only
Do you perform molecular testing directly on clinical samples for the detection of antimicrobial resistance?	**12**	**14**
England	10	13
Scotland	1	1
Wales	1	

Figure 49: Selection of Samples that are Tested Directly for Antimicrobial Resistance

	Test all positive smear samples	Test cases of suspected MDR TB	Other
How do you select which samples are tested directly for antimicrobial resistance?	**8**	**9**	**10**
England	8	8	8
Scotland			2
Wales		1	

Figure 50: Molecular Assay Used to Identify M. Tuberculosis from Positive Mycobacterial Cultures

	No	Yes
Do you use a molecular assay to identify M. tuberculosis from positive mycobacterial cultures in your own laboratory?	**16**	**17**
England	14	15
Scotland	2	1
Wales		1

Figure 51: If Yes Assay Used

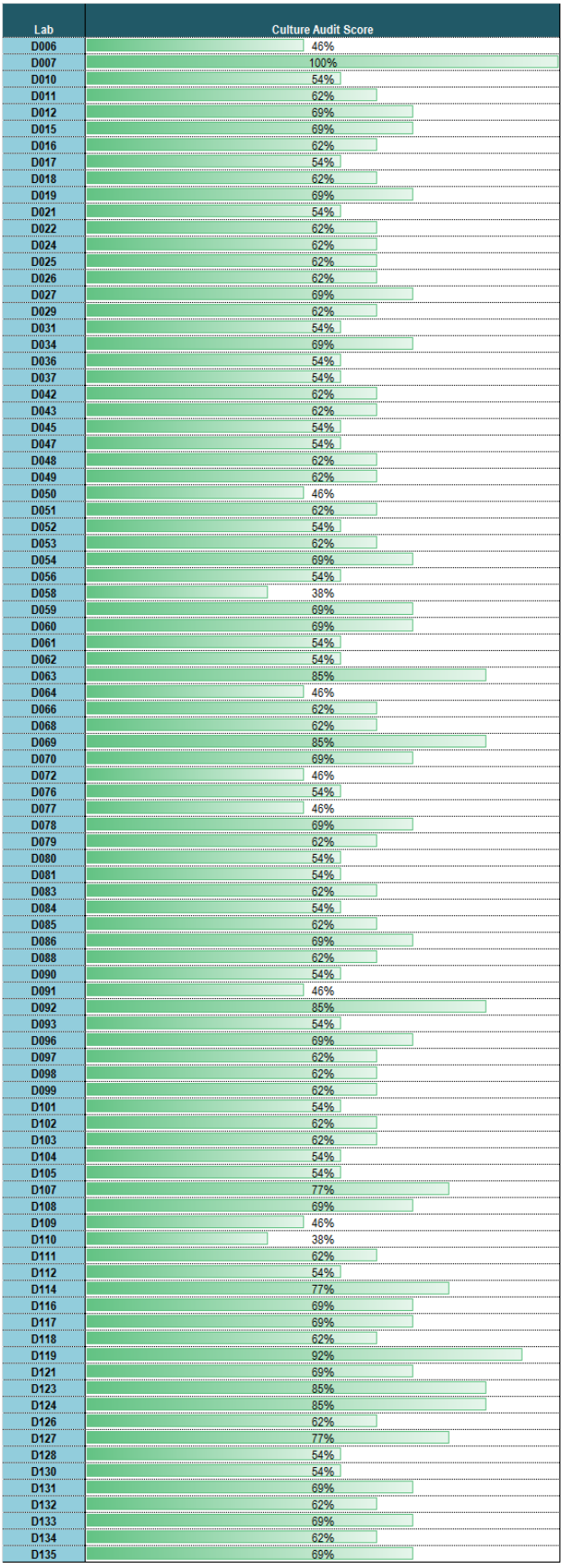
If yes, which assay do you use?	No	Yes
DNA sequencing	**8**	**3**
England	7	2
Scotland		1
Wales	1	
HAIN Genotype	**3**	**12**
England	3	10
Scotland		1
Wales		1
Not done	**5**	**1**
England	5	1
Other	**5**	**5**
England	5	5

Figure 52: Main Providers of Clinical Advice Regarding Diagnosis, Management and Infection Control of TB

Who are the main providers of clinical advice regarding diagnosis, management and infection control of TB in your Trust?	No	Yes
Microbiologist with responsibility for TB	**39**	**43**
England	31	36
Scotland	6	4
Wales	2	3
Duty microbiologist	**10**	**97**
England	6	83
Scotland	3	10
Wales	1	4
Infectious disease physician	**38**	**39**
England	33	28
Scotland	2	9
Wales	3	2
Chest physician	**2**	**109**
England	2	91
Scotland		13
Wales		5
Provided from outside the Trust (please specify below)	**59**	**9**
England	51	6
Scotland	6	3
Wales	2	
Other (please specify below)	**36**	**4**
England	32	2
Scotland	3	1
Wales	1	1

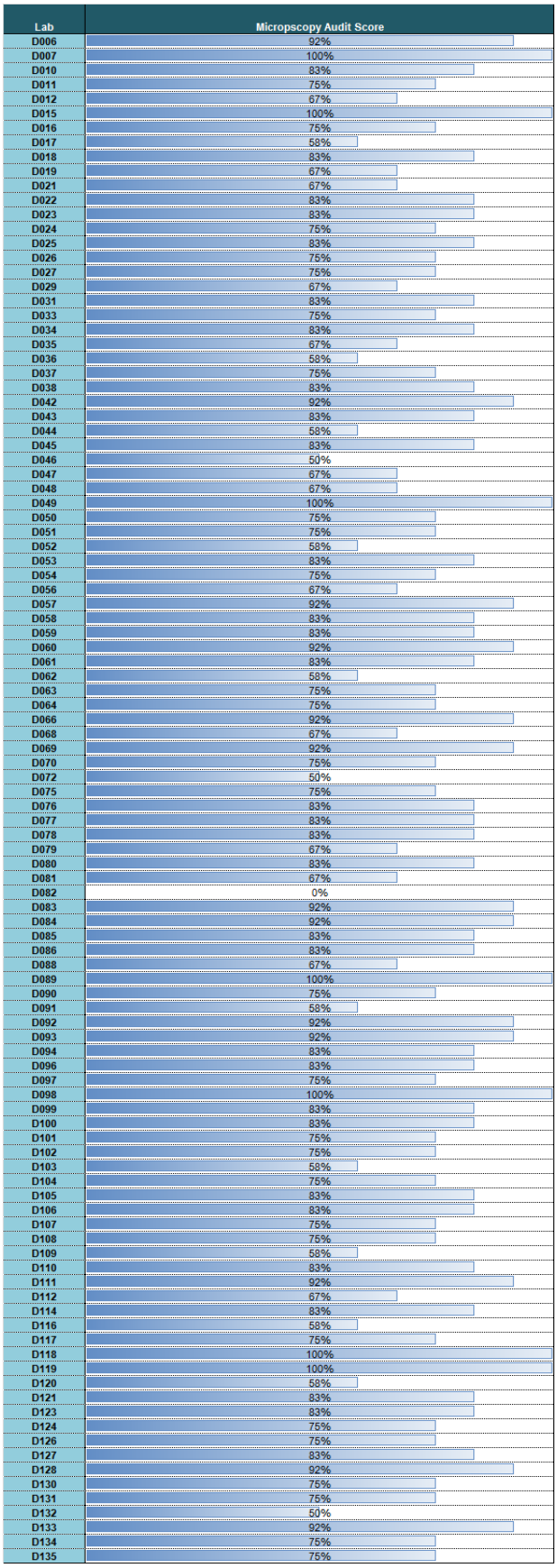
Appendix 3: Anonymised Individual Laboratory Results
(Code Numbers Supplied to Participants)

Figure 53: Culture Audit Score for the 92 Individual Laboratories who Perform Culture



Lab	Culture Audit Score
D006	46%
D007	100%
D010	54%
D011	62%
D012	69%
D015	69%
D016	62%
D017	54%
D018	62%
D019	69%
D021	54%
D022	62%
D024	62%
D025	62%
D026	62%
D027	69%
D029	62%
D031	54%
D034	69%
D036	54%
D037	54%
D042	62%
D043	62%
D045	54%
D047	54%
D048	62%
D049	62%
D050	46%
D051	62%
D052	54%
D053	62%
D054	69%
D056	54%
D058	38%
D059	69%
D060	69%
D061	54%
D062	54%
D063	85%
D064	46%
D066	62%
D068	62%
D069	85%
D070	69%
D072	46%
D076	54%
D077	46%
D078	69%
D079	62%
D080	54%
D081	54%
D083	62%
D084	54%
D085	62%
D086	69%
D088	62%
D090	54%
D091	46%
D092	85%
D093	54%
D096	69%
D097	62%
D098	62%
D099	62%
D101	54%
D102	62%
D103	62%
D104	54%
D105	54%
D107	77%
D108	69%
D109	46%
D110	38%
D111	62%
D112	54%
D114	77%
D116	69%
D117	69%
D118	62%
D119	92%
D121	69%
D123	85%
D124	85%
D126	62%
D127	77%
D128	54%
D130	54%
D131	69%
D132	62%
D133	69%
D134	62%
D135	69%

Figure 54: Micropscopy Audit Score for the 106 Laboratories Providing Microscopy



Lab	Micropscopy Audit Score
D006	92%
D007	100%
D010	83%
D011	75%
D012	67%
D015	100%
D016	75%
D017	58%
D018	83%
D019	67%
D021	67%
D022	83%
D023	83%
D024	75%
D025	83%
D026	75%
D027	75%
D029	67%
D031	83%
D033	75%
D034	83%
D035	67%
D036	58%
D037	75%
D038	83%
D042	92%
D043	83%
D044	58%
D045	83%
D046	50%
D047	67%
D048	67%
D049	100%
D050	75%
D051	75%
D052	58%
D053	83%
D054	75%
D056	67%
D057	92%
D058	83%
D059	83%
D060	92%
D061	83%
D062	58%
D063	75%
D064	75%
D066	92%
D068	67%
D069	92%
D070	75%
D072	50%
D075	75%
D076	83%
D077	83%
D078	83%
D079	67%
D080	83%
D081	67%
D082	0%
D083	92%
D084	92%
D085	83%
D086	83%
D088	67%
D089	100%
D090	75%
D091	58%
D092	92%
D093	92%
D094	83%
D096	83%
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D103	58%
D104	75%
D105	83%
D106	83%
D107	75%
D108	75%
D109	58%
D110	83%
D111	92%
D112	67%
D114	83%
D116	58%
D117	75%
D118	100%
D119	100%
D120	58%
D121	83%
D123	83%
D124	75%
D126	75%
D127	83%
D128	92%
D130	75%
D131	75%
D132	50%
D133	92%
D134	75%
D135	75%