Summary of Results
Mycobacterium spp. Scheme

External Quality Assessment for Water Microbiology

Distribution Number:	**MY001**
Sample Numbers:	**MY001A and MY001B**

Distribution Date:	**13 May 2019**
Results due:	**2 August 2019**
Report Date:	**21 August 2019**
Samples prepared and quality control tested by:	**Angela Appea** **Isis Asamoah** **Richard Borrill** **Margaret Njenga** **Zak Prior** **Lili Tsegaye**
Data analysed by:	**Nita Patel** **Manchari Rajkumar**
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Overview:
This unique microbiology scheme provides proficiency testing (PT) samples to laboratories that examine endoscope rinse waters for *Mycobacterium* spp. This scheme challenges the detection, accurate enumeration and identification of this organism from this hospital water sample.

Flexible endoscopes are complex reusable instruments that require unique consideration with respect to decontamination. Their external surfaces and internal channels for air, water, aspiration and accessories are all potentially exposed to body fluids and other contaminants. Environmental non-pathogenic mycobacteria present a particular problem when they occur in the final rinse-water of some instruments used for diagnosis.

Procedure for examining samples of endoscope rinse water for *Mycobacterium* spp. is taken from the Health Technical Memorandum 01-06: Decontamination of flexible endoscopes
Part E: Testing methods (page 16) document

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/553303/HTM01-06_PartE.pdf

Guidelines and general advice:
If you experience difficulties with any of the examinations, please refer to section 17.2 of the Scheme Guide
   https://www.gov.uk/government/publications/food-and-water-proficiency-testing-scheme-scheme-guide

FEPTU Quality Control:
For homogeneity of the colony counts a minimum of 10 LENTICULE® discs, selected randomly from the batch, are examined for *Mycobacterium* spp. The FEPTU results are determined using the method in the above HTM-01-06 document.

To demonstrate homogeneity of the sample for enumeration values, a minimum of 10 LENTICULE® discs, selected randomly from a batch, are tested.

To demonstrate stability of the sample for enumeration values, a minimum of six LENTICULE discs, selected randomly from a batch, are examined throughout the distribution period.

The intended results letters provide guidance for participants regarding the assigned values.

Please contact FEPTU staff for advice and information:

Repeat samples	Carmen Gomes or Kermin Daruwalla	Tel: +44 (0)20 8327 7119
Data analysis	Manjhari Rajkumar and Nita Patel	Fax: +44 (0)20 8200 8264
Microbiological advice	Zak Prior or Nita Patel	E-mail: foodeqa@phe.gov.uk
General comments and complaints	Zak Prior or Nita Patel	
Scheme Coordinator	Nita Patel	
Scheme Consultant	Charles Fuller	

Accreditation: PHE will be applying for this scheme to be accredited with the United Kingdom Accreditation Service (UKAS) to ISO/IEC 17043:2010. However, all the quality principles in this standard have been followed to process this distribution.

A total of 33 participants were sent this distribution, of which 30 examined the samples and three did not return a result.

Sample: MY001A

Sample type: Final rinse water from an endoscope

Request: (i) Examine for the presence of *Mycobacterium* spp.
(ii) Quantify the *Mycobacterium* spp.

Contents:
Mycobacterium chelonae (71) (NCTC 946), *Staphylococcus capitis* (35) (wild strain)

All levels are presented as colony forming units (cfu) per 100mL

Expected Results:

	Expected Result
Mycobacterium spp.	Detected
	70 – 4.1×10^2 cfu per 100mL

Your reported result is shown in the table page 6 onwards

Number of participants reported correctly a detected result	29/30 (97%)

Number of participants enumerating for *Mycobacterium* spp.	25
Number of participants reporting a high censored value considered to be in range	8
Assigned value (participants' median)	1.7×10^2 cfu per 100mL (2.23 $\log_{10}$)
Uncertainty of assigned value ($U(X_{pt})$= $\log_{10}$ cfu per 100mL)	0.06
Number of outlying counts	2 low
Participants mean	1.7×10^2 cfu per 100mL (2.23 $\log_{10}$)
Standard deviation of participants results **	0.19 $\log_{10}$ cfu per 100mL
FEPTU QC median	71 cfu per 100mL (1.85 $\log_{10}$)

cfu – colony forming units

** Robust S* based on median absolute deviation about the participants' median (*MADe*)

Graphical data of the enumeration results is shown on page 5 of this report

Sample: MY001B

Sample type: Final rinse water from an endoscope

Request: (i) Examine for the presence of *Mycobacterium* spp.
(ii) Quantify the *Mycobacterium* spp.

Contents:

Mycobacterium fortuitum (65) (wild strain)

All levels are presented as colony forming units (cfu) per 100mL

Expected Results:

	Expected Result
Mycobacterium spp.	Detected
	53 – 93 cfu per 100mL

Your reported result is shown in the table page 6 onwards

Number of participants reported correctly a detected result	29/30 (93%)

Number of participants enumerating for *Mycobacterium* spp.	26
Number of participants reporting a high censored value considered to be out of range	1
Assigned value (participants' median)	70 cfu per 100mL (1.85 $\log_{10}$)
Uncertainty of assigned value ($U(X_{pt})$= $\log_{10}$ cfu per 100mL)	0.02
Number of outlying counts	5 (4 low, 1 high)
Participants mean	66 cfu per 100mL (1.82 $\log_{10}$)
Standard deviation of participants results **	0.06 $\log_{10}$ cfu per 100mL
FEPTU QC median	65 cfu per 100mL (1.80 $\log_{10}$)

cfu – colony forming units

** Robust S^* based on median absolute deviation about the participants' median (*MADe*)

Graphical data of the enumeration results is shown on page 5 of this report
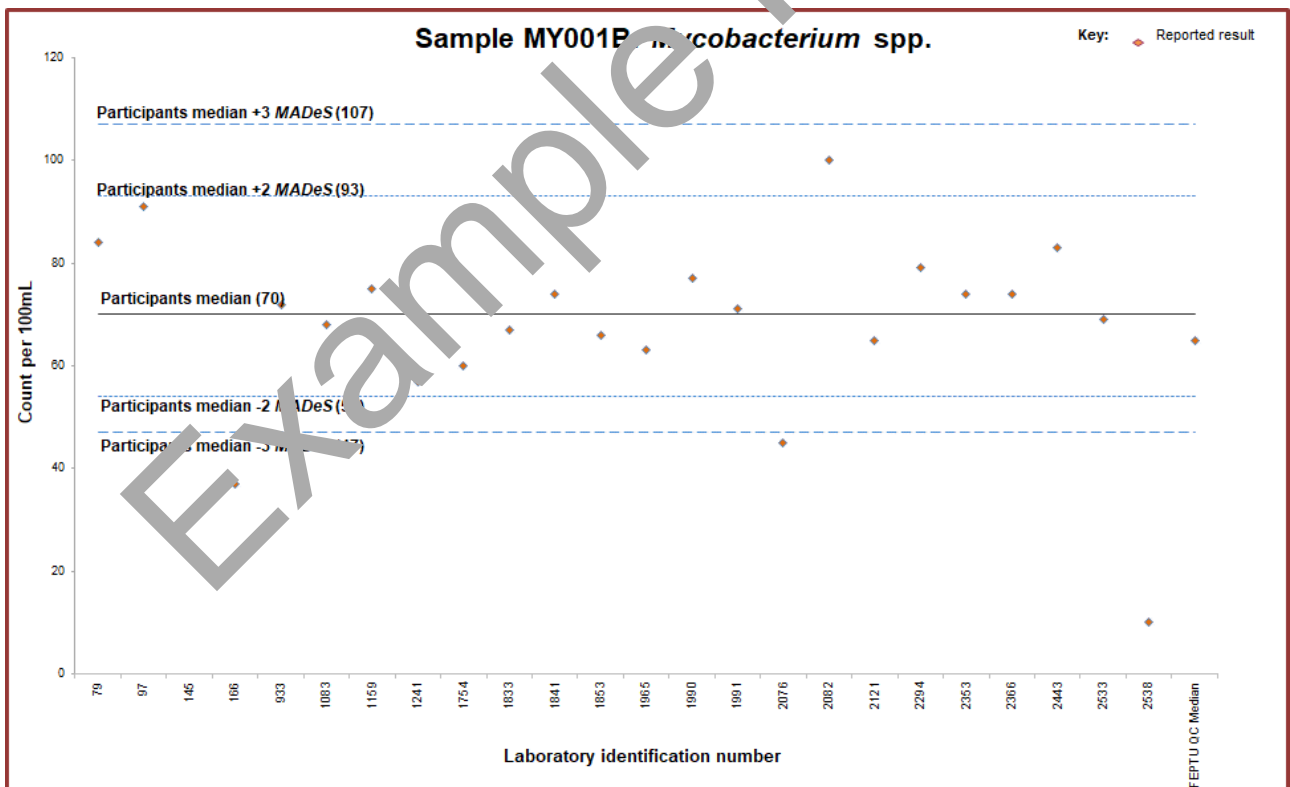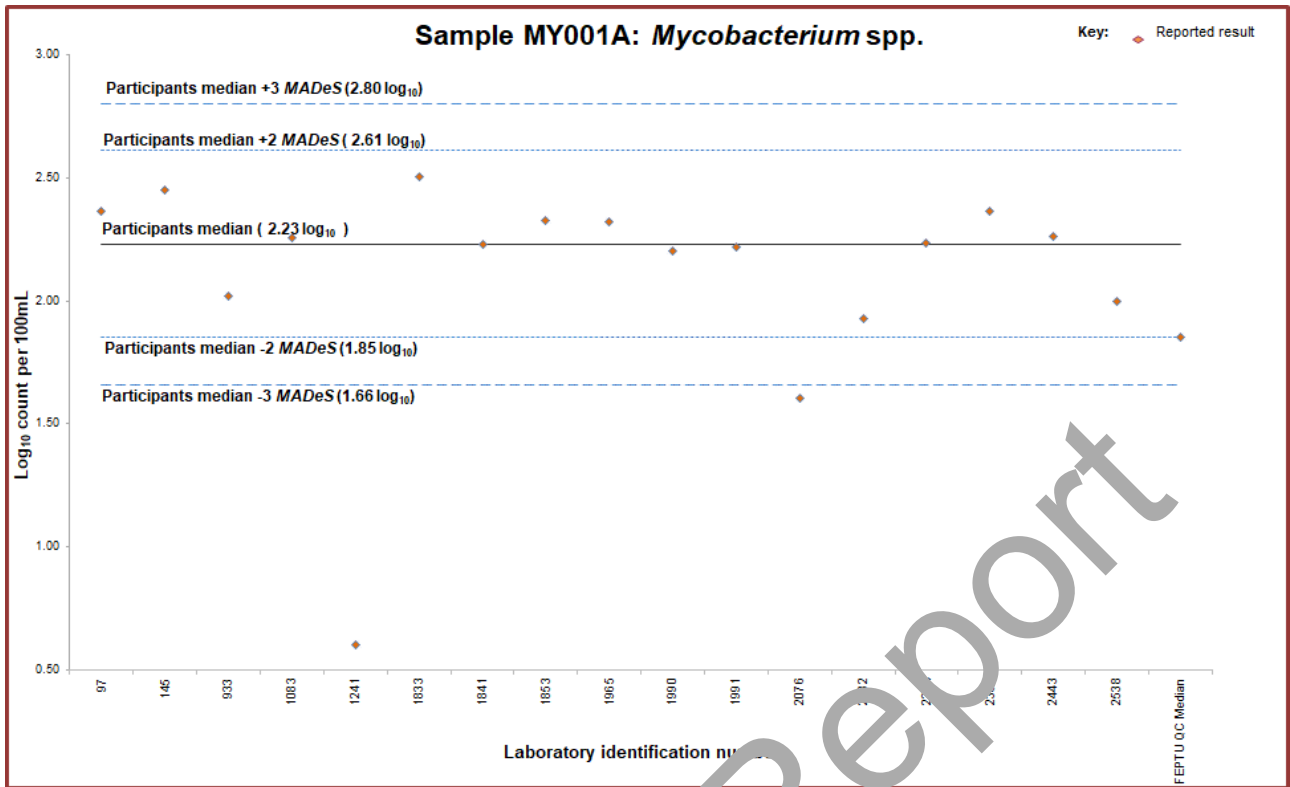
Sample MY001A: *Mycobacterium* spp.

Key: Reported result

Participants median +3 *MADeS* (2.80 log₁₀)

Participants median +2 *MADeS* (2.61 log₁₀)

Participants median (2.23 log₁₀)

Participants median -2 *MADeS* (1.85 log₁₀)

Participants median -3 *MADeS* (1.66 log₁₀)

Log₁₀ count per 100mL

Laboratory identification number

(x-axis labels: 97, 145, 933, 1083, 1241, 1833, 1841, 1853, 1965, 1990, 1991, 2076, ..., ..., ..., 2443, 2538, FEPTU QC Median)

Sample MY001B: *Mycobacterium* spp.

Key: Reported result

Participants median +3 *MADeS* (107)

Participants median +2 *MADeS* (93)

Participants median (70)

Participants median -2 *MADeS* (...)

Participants median -3 *MADeS* (...)

Count per 100mL

Laboratory identification number

(x-axis labels: 79, 97, 145, 166, 933, 1083, 1159, 1241, 1754, 1833, 1841, 1853, 1965, 1990, 1991, 2076, 2082, 2121, 2294, 2353, 2366, 2443, 2533, 2538, FEPTU QC Median)

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Table 1: Summary of participant's results for MY001 (incorrect results are shown in red and outlying quantification results in green).

Lab	Results MY001A	Enumeration result for MY001A	Results MY001B	Enumeration result for MY001B
	Not detected		Detected	84
	Detected	232	Detected	91
	Detected	>100	Detected	>100
	Detected	Not examined	Detected	Not examined
	Detected	280	Detected	31
	Not detected		Not detected	
	Detected	>100	Detected	37
	Detected	104	Detected	72
	Not detected	Not applicable	Detected	NE
	Detected		Detected	
	Detected	181	Detected	68
	Non-return of results			

Lab	Results MY001A	Enumeration result for MY001A	Results MY001B	Enumeration result for MY001B
	Detected	>100	Detected	75
	Detected	>100	Not detected	<1
	Detected	4	Detected	57
	Detected	>100	Detected	60
	Non-return of results			
	Detected	320	Detected	67
	Detected	70	Detected	74
	Detected	213	Detected	66
	Non-return of results			
	Detected	210	Detected	63
	Detected	159	Detected	77
	Detected	166	Detected	71
	Detected	40	Detected	45

Lab	Results MY001A	Enumeration result for MY001A	Results MY001B	Enumeration result for MY001B
	Detected	85	Detected	100
	Detected	>100	Detected	65
	Detected	171	Detected	79
	Detected	>130	Detected	74
	Detected	230	Detected	74
	Detected	182	Detected	83
	Not detected	>100	Detected	69
	Detected	100	Detected	10

General comments

This is the first distribution since this scheme was launched April 2019. FEPTU will be applying for this scheme to be accredited once we have gathered more performance data.

Scheme specific comment for MY001A and MY001B

There are number of incorrect detection or outlying enumeration results reported, these participants are encouraged to investigate the reason for this by requesting a repeat sample from FEPTU.

Statistical analysis used for this scheme:

The samples in this distribution have not been scored.

The PHE criteria below has been used to calculate the expected range for this distribution. More data needs to be gathered before a final decision is made on how scoring will be applied for this scheme.

Median absolute deviation from the median (*MADeS*) values has been used as there are less than 50 data sets. The use of *MADeS* values provides a statistically robust method for calculating the acceptable range using an analysis that requires calculation of the median difference from the median for every participant's result, which is then multiplied by a constant (1.4826) to obtain a robust estimate of the standard deviation (*MADeS* value).

The expected range for each enumeration result reported is calculated using the median absolute deviation from the median (*MADe*) values which are determined from the median result reported by participants' and take into account the following criteria:

(1) median ± 2 *MADeS*
(2) median ± 3 *MADeS*

Questionnaire results:

Please note that not all participants provided the relevant information.

FEPTU are aware that processes are different and therefore have not attempted to categorise the information into specific groups for comparing data.

The data shown below is for information only. It does not evaluate or associate the data with a failure with PT to a method/process used nor does it attempt to compare performance of the various methods used with each other.

A total of seven countries participated in this distribution (Graph 1). The majority of which were in the United Kingdom.

Graph 1: Countries
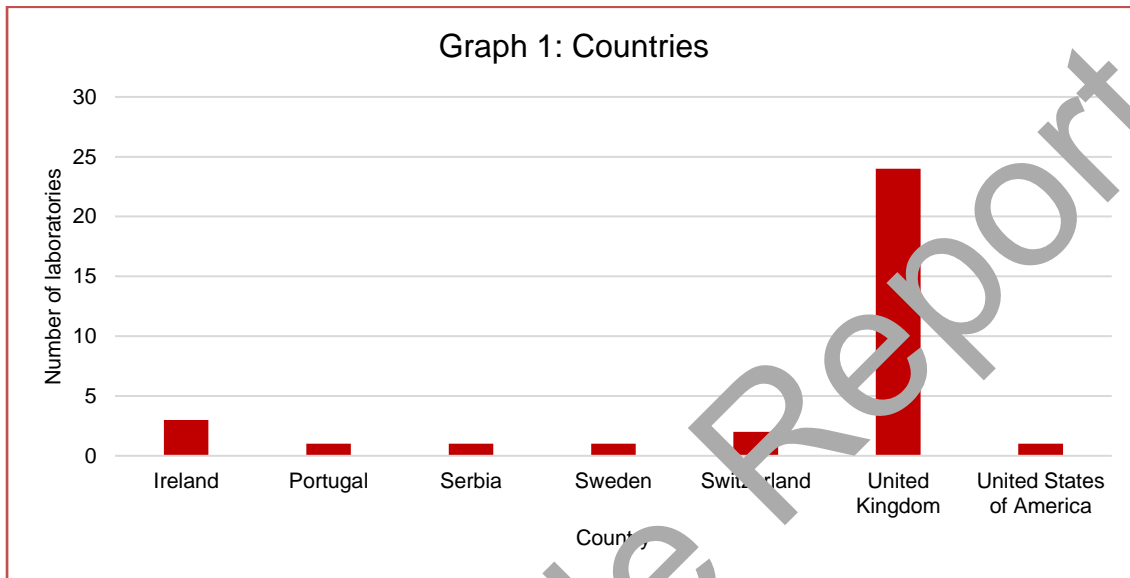
1. **Standard and or guideline used for the sample examination**
   - Of the 27 responses received the majority used the Health Technical Memorandum 01-06 (graph 2).

Graph 2: Standard or guideline followed
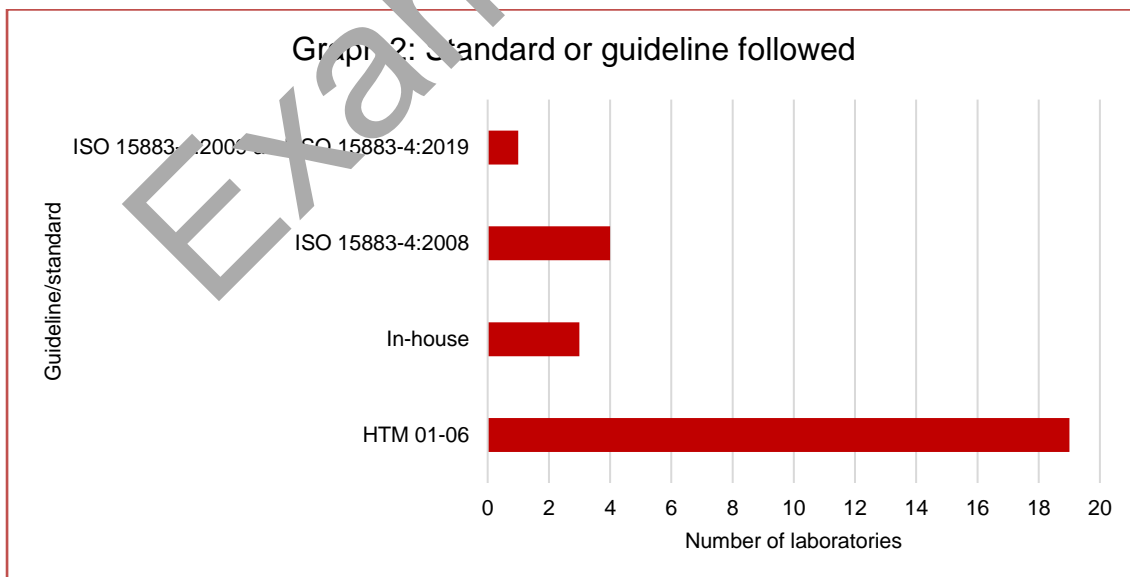
2. **Duplication**
   - 17/30 (57%) of the laboratories examined the samples in duplication.

3. **Details of the media used is shown in the table below:**

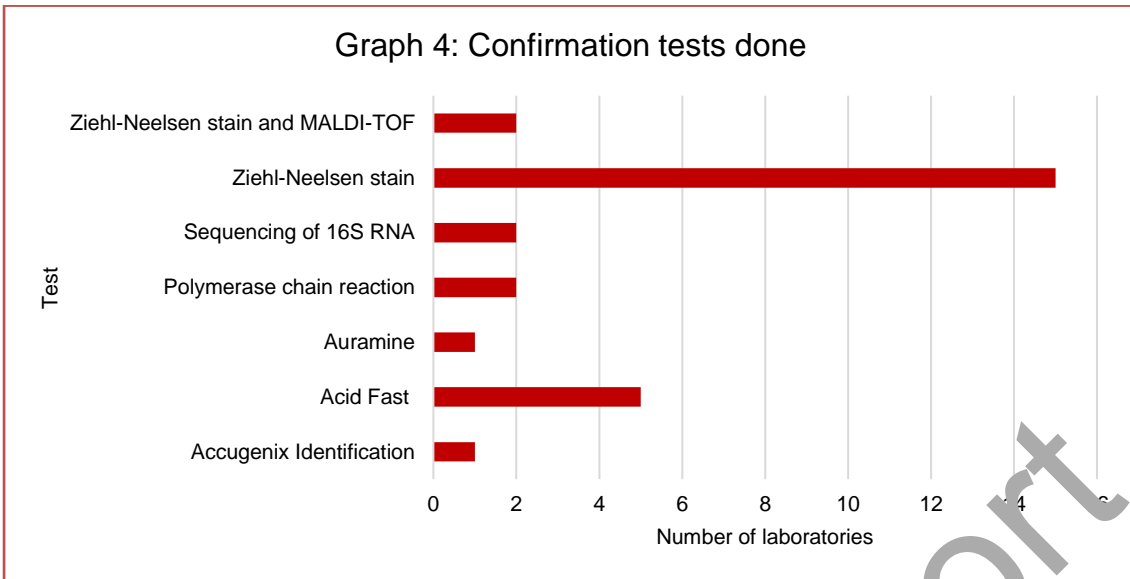| Media	Number of users	% of users
Middlebrook 7H10	19	65
Middlebrook 7H11	7	24
Middlebrook 7H9	1	3
Middlebrooks 7H	1	3
Mycobacteria Growth Indicator Tube - BD MGIT	1	3

4. **Filter size used**

   - Of the 30 responses received, 27/30 (90%) of laboratories used 0.45µm filter size

5. **Temperature used to incubate agar plate/s is shown in graph 3. 19/29 (66%) incubated the plates for 28 days**

Graph 3: Temperature
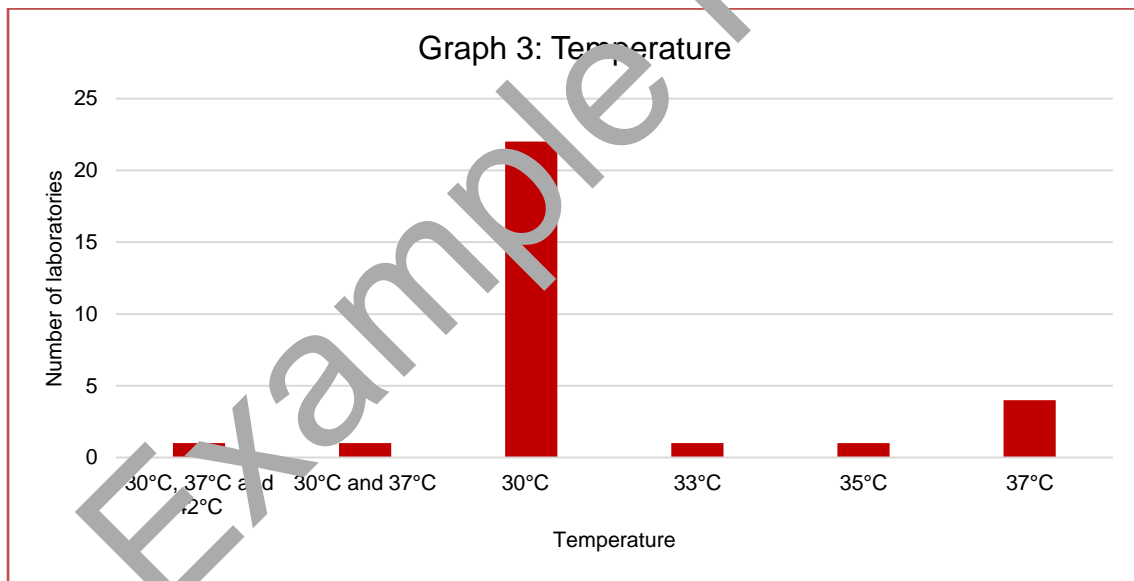
6. 28/29 (97%) of the laboratories would perform a confirmation test on presumptive *Mycobacterium* **spp. isolates grown. Tests done are shown in graph 4:**

Graph 4: Confirmation tests done

Test	Number of laboratories
Ziehl-Neelsen stain and MALDI-TOF	2
Ziehl-Neelsen stain	14
Sequencing of 16S RNA	2
Polymerase chain reaction	2
Auramine	1
Acid Fast	5
Accugenix Identification	1

18/30 (60%) of the laboratories would send the isolate off to a reference laboratory.

8/30 (27%) of the laboratories would provide a comment or a conclusion of the results obtained.

End of report.