

# Summary of Results *Mycobacterium* spp. Scheme

### **External Quality Assessment for Water Microbiology**

Distribution Number: Sample Numbers:	MY013 MY013A and MY013B
Distribution Date:	October 2022
Results due:	23 December 2022
Report Date:	4 January 2023
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#### **Overview:**

This unique 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: <u>Health Technical Memorandum 01-06: Decontamination of flexible endoscopes. Part E: Testing methods (england.nhs.uk)</u>

#### Guidelines and general advice:

If you experience difficulties with any of the examinations, please refer to section 17.0 of the Scheme Guide <a href="https://www.gov.uk/government/publications/food-and-water-proficiency-testing-scheme-scheme-guide">https://www.gov.uk/government/publications/food-and-water-proficiency-testing-scheme-scheme-guide</a>

#### 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	Nita Patel	
Microbiological advice	Zak Prior or Nita Patel	E-mail: foodeqa@ukhsa.gov.uk
General comments and complaints	Zak Prior or Nita Patel	
Scheme Co-ordinator	Nita Patel	
Scheme Consultant	Caroline Willis	

**Accreditation:** UK Health Security Agency EQA Scheme for *Mycobacterium* spp. in waters is accredited by the United Kingdom Accreditation Service (UKAS) to ISO/IEC 17043:2010



A total of 35 participants were sent this distribution, of which 30 examined the samples, four did not return a result and one did not examine any of the samples.

Participants reported results and scores are shown on page 5 and 6 of this report.

#### Sample: MY013A

Sample type: Final rinse water from an endoscope

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

Contents: Mycobacterium avium complex (17) (wild strain) and Kocuria kristinae (26) (NCTC 11038)

All levels are presented as colony forming units (cfu) per 100mL **Expected Results:** 

	Expected Result			
	Detected			
<i>Mycobacterium</i> spp.	Counts too variable to determine			

Number of participants reporting correctly a detected result	24/30 (80%)				
Number of participants enumerating for <i>Mycobacterium</i> spp.	22				
Number of participants reporting a high censored value or too numerous to count	10				
Assigned value (participants' median)					
Uncertainty of assigned value ( $U(X_{pt})$ = log <sub>10</sub> cfu per 100mL)					
Number of outlying counts	Counts too variable to determine –				
Participants mean	see comment below				
Standard deviation of participants results *					
FEPTU QC median					

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

#### Comment

This sample contained a strain of *Mycobacterium avium* complex. In the FEPTU laboratory this organism grew as tiny opaque colonies on Middlebrook 7H10 agar after 14 days. The counts reported by the participants for this organism was extremely variable, the range reported was 22 – 780 colony forming units per 100mL, in addition 10 laboratories reported a high censored value of >100.

The reasons for the variable results could be multifactorial from the quality of media used, the very slow growth pattern of this organism in addition, the colonies were very small and opaque and could easily have been missed when reading the culture plates. The homogeneity test done in the FEPTU laboratory confirmed that the sample was homogenous. Based on the findings, all enumeration results have been scored as being correct and all not detected results have been excluded from scoring.

#### Sample: MY013B

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 (36) (wild strain), Staphylococcus epidermidis (15) (wild strain)

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

#### **Expected Results:**

	Expected Result
	Detected
Mycobacterium spp.	17 - 28 cfu per 100mL

Number of participants reporting correctly a detected result	28/30 (93%)
Number of participants enumerating for Mycobacterium spp.	25
Assigned value (participants' median)	22 cfu per 100mL (1.34 log <sub>10</sub> )
Uncertainty of assigned value ( $U(X_{pt})$ = log <sub>10</sub> cfu per 100mL)	0.01
Number of outlying counts	4 (2 low, 2 high)
Participants mean	22 cfu per 100mL (1.34 log <sub>10</sub> )
Standard deviation of participants results *	0.06 log <sub>10</sub> cfu per 100mL
FEPTU QC median	32 cfu per 100mL (1.51 log <sub>10</sub> )

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

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1.50 -	Par	ticipa	nts m	edian ·	+2 M/	ADeS (	1.451	og <sub>10</sub> )			•															•	
1.40 -	Part •	ticipa	nts me	edian (	(1.34	og <sub>10</sub> )	•	•		•			•	•	•	•				•	•	•		•	•		
				•								•						•									
u 1.20 -	1.20 - Participants median -2 MADeS (1.23 log 10)																										
- 1.10 - Conut Fog10 - Conut 1.00 -	Par	ticipa	nts m	edian	-3 MA	ADeS (	1.17 k	)g <sub>10</sub> )	•																		
0.90 -																											
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0.70 -	29	97	123	145	166	329	1159	1241	1754	1773	1841	1853	1958	1965	1990	1991	2121	2129	2294	2353	2366	2443	2533	2615	2617	FEPTU	
	Laboratory identification number																										

## Table 1: Summary of participant's results for MY013A (incorrect results are shown in red and outlying enumeration results in green).

Lab	Results MY013A	UKKSA score	Z- score	Enumeration result	UKHSA score	Z-score
9	Detected	2	0			
79	Detected	2	0	TNTC	2	0
97	Detected	2	0	94	2	0
123	Detected	2	0	>100	2	0
126	Detected	2	0			
145	Detected	2	0	107	2	0
166	Not detected	N/A	N/A			
329	Detected	2	0	>200	2	0
991	Non-return	0	4			
1010	Non-return	0	4			
1041	Not examined	N/A	N/A			
1063	Detected	2	0			
1159	Not detected	N/A	N/A			
1241	Detected	2	0	>100	2	0
1647	Non-return	0	4			
1754	Detected	2	0	40	2	0
1773	Detected	2	0	183	2	0
1841	Detected	2	0	>100	2	0
1853	Detected	2	0	780	2	0
1958	Not detected	N/A	N/A			
1965	Detected	2	0	>100	2	0
1990	Detected	2	0	>100	2	0
1991	Detected	2	0	45	2	0
2076	Non-return	0	4			
2082	Detected	2	0	22	2	0
2121	Detected	2	0	>100	2	0
2129	Not detected	N/A	N/A			
2294	Detected	2	0	188	2	0
2353	Detected	2	0	>160	2	0
2366	Not detected	N/A	N/A			
2443	Detected	2	0	>100	2	0
2533	Not detected	N/A	N/A	36	2	0
2583	Detected	2	0	53	2	0
2615	Detected	2	0	45	2	0
2617	Detected	2	0	30	2	0

N/A=Not applicable

## Table 2: Summary of participant's results for MY013B (incorrect results are shown in red and outlying enumeration results in green).

Lab	Results MY013B	UKKSA score	Z- score Enumeration result		UKHSA score	Z-score
9	Not detected	0	4			
79	Detected	2	0	23	2	0.06
97	Detected	2	0	22	2	0.01
123	Detected	2	0	6	0	-1.61
126	Detected	2	0			
145	Detected	2	0	19	2	-0.17
166	Detected	2	0	22	2	0.01
329	Detected	2	0	23	2	0.06
991	Non-return	0	4			
1010	Non-return	0	4			
1041	Not examined	N/A	N/A			
1063	Detected	2	0			
1159	Detected	2	0	28	2	0.31
1241	Detected	2	0	22	2	0.01
1647	Non-return	0	4			
1754	Detected	2	0	9	0	-1.10
1773	Detected	2	0	22	2	0.01
1841	Detected	2	0	30	1	0.39
1853	Detected	2	0	18	2	-0.24
1958	Detected	2	0	22	2	0.01
1965	Detected	2	0	22	2	0.01
1990	Detected	2	0	25	2	0.17
1991	Detected	2	0	24	2	0.11
2076	Non-return	0	4			
2082	Detected	2	0			
2121	Detected	2	0	17	2	-0.31
2129	Detected	2	0	19	2	-0.17
2294	Detected	2	0	35	0	0.58
2353	Detected	2	0	24	2	0.11
2366	Detected	2	0	24	2	0.11
2443	Detected	2	0	26	2	0.21
2533	Detected	2	0	17	2	-0.31
2583	Not detected	0	4			
2615	Detected	2	0	22	2	0.01
2617	Detected	2	0	22	2	0.01

N/A=Not applicable

#### **General comments**

#### Scoring of this scheme:

The expected range for the results reported will be calculated using the median absolute deviation from the median (*MADe*<sup>\*\*</sup>) values in whole numbers, which are determined from the median result reported by participants' and take into account the following criteria:

(1) median  $\pm 2 MADeS^*$ (2) median  $\pm 3 MADeS^*$ 

\*\*The median absolute deviation from the median value is a robust estimate of the standard deviation (S\*).

It is only possible to calculate a precise estimate of the  $S^*$  if more than 20 participants report enumeration results.

#### Score

Expected range	Poisson 95% Confidence Interval or within the range according to criteria (1)	2
Outlying results (1)	Within the range of criteria (2) but not within criteria (1)	1
Outlying results (2)	Poisson 95% Confidence Interval or outside the range of criteria (2)	0

Depending on the sample contents and the level of organisms in the sample, the 95% confidence interval around the participants' or FEPTU's median may be applied. However, if the median is >=4 and the lower end starts at 0 this will be changed to 1.

Participants who do not return a result by the specified date are allocated a UKHSA score of zero main tests.

#### **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 20/29 (69%).



#### 1. Standard and or guideline used for the sample examination

• Of the 29 responses received, the majority used the Health Technical Memorandum (HTM) 01-06 20/29 (69%) (Graph 2).



#### 2. Duplication

• 22/28 (79%) of the laboratories examined the samples in duplication.

#### 3. Details of the culture media used is shown in the table below (n=29):

Media	Number of users	% of users
Becton Dickinson BACTEC™ MGIT™	1	3
Middlebrook 7H10, Löwenstein–Jensen medium and MGHI	1	3
Middlebrook 7H10	19	66
Middlebrook 7H10 and 7H11	1	3
Middlebrook 7H11	7	24

#### 4. Filter size used

Of the 27 responses received, 22/27 (81%) of laboratories used 0.45µm filter size and 5/27 (19%) of laboratories used 0.2µm filter size.

#### 5. Temperature used to incubate agar plate/s

• Of the 28 responses received 25/28 (89%) of the laboratories incubated their culture plates at 30°C, 2/28 (7%) at 35°C and 1/28 (4%) at both 30 and 37°C.

#### 6. Incubation period is shown in the table below

• Of the 29 responses received 22/26 (85%) of the laboratories incubate their growth media for 28 days.

Incubation period (days)	Number of users
21	2
28	22
42	3
56	2

#### 7. Confirmation test

• 28/29 (97%) of the laboratories performed a confirmation test on presumptive *Mycobacterium* spp. isolates grown. Tests done are shown in graph 3 (to note - some laboratories did a combination of tests).



21/29 (72%) of the laboratories would send the isolate off to a reference laboratory.

9/29 (31%) of the laboratories would provide a comment or a conclusion of the results obtained.

#### End of report.