QCMD 2020 Sexually Transmitted Infections I EQA Programme



Catalogue Code: QAB154177

Ref Code: STI_I20 Challenge:

C1

Analysis Type:

Multiple Pathogen Qualitative

Dataset: 363368

Report UID: 2677/29470/2774

Laboratory CZ023

Panel Composition

Sample Code	Sample Content	Matrix	Sample Relationships ^[1]	Detected / Determined ^[2]		Not Detect Determined		Not Tested ^[2]	
				(%)	(n)	(%)	(n)	(%)	(n)
STI_I101C1-01	Mycoplasma hominis	Transport Medium		80.5	33	4.9	2	14.6	6
STI_I101C1-02	Trichomonas vaginalis	Transport Medium	DS1_2	70.7	29	22	9	7.3	3
STI_I101C1-03	Negative	Transport Medium		97.6	40	2.4	1	N/A	0
STI_I101C1-04	Mycoplasma genitalium (wild type)	Transport Medium		95.1	39	4.9	2	N/A	0
STI_I101C1-05	Trichomonas vaginalis	Transport Medium	DS1_1	85.4	35	7.3	3	7.3	3

[1] Sample Relationships: Indicates the relationships of the samples within this challenge. The highest titre member of dilution series DS1 is indicated by DS1_1 and further members of the series as DS1_2, DS1_3 etc. in order of reducing titre. Additional dilution series are indicated by DS2 (e.g DS2_1, DS3_2 etc.), DS3 (e.g. DS3_1, DS3_2 etc.). If one duplicate pair is present this is indicated by 'D1'. Further duplicate pairs are indicated by 'D2', 'D3' etc. [2] Detected / Determined; Not Detected / Not Determined; Not Tested: The percentage (%) of datasets reported by all participants in relation to the assigned status of the panel member i.e. 'positive' or 'negative' and the expected pathogen type as defined through pre-testing and the total number of datasets (n) for each panel member.

For further details please refer to the current participant manual.

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EQA Assessment Group^[1]

N/A (Refer to My Workflow details section below)

Your Summary Results (Core Samples)

Sample Code	Expected Result ^[2]		Your Final Laboratory Re	Sample Status ^[7]	Detection Frequency ^[8]	Detection Score ^[9]		
	Qualitative	Pathogen ID	Pathogen included in workflow(s) ^[4] Yes/No	Qualitative ^[5]	Reported Pathogen ID ^[6]		,	
STI_I101C1-01	Positive	Mycoplasma hominis	Yes	Positive	Mycoplasma hominis	Core	Detected	0
STI_I101C1-03	Negative		N/A	Negative		Core	Negative	0
STI_I101C1-04	Positive	Mycoplasma genitalium	Yes	Positive	Mycoplasma genitalium	Core	Frequently Detected	0
STI_I101C1-05	Positive	Trichomonas vaginalis	Yes	Positive	Trichomonas vaginalis	Core	Detected	0

- [1] **EQA Assessment Group:** To aid analysis participant results are grouped according to the molecular amplification/ detection method specified within their molecular workflow for this challenge/ distribution. For further details refer to the Additional Information: Individual Panel Member Analysis section of this report.
- [2] **Expected Result:** positive / negative result and the specific pathogen present within each panel member.
- [3] Your Final Laboratory Reported Result: the final reported result which may be based on one or more workflows used to test each panel member.
- [4] Pathogen included in workflow(s): Yes / No answer to whether the expected pathogen was tested for.
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- [7] Sample Status: Sample Status: EQA samples are defined as "CORE" or "EDUCATIONAL". Core proficiency samples are reviewed by the QCMD Scientific Expert(s). This is on the basis of scientific information, clinical relevance, current literature and, where appropriate, professional clinical guidelines. Participating laboratories are expected to report core proficiency samples correctly within the EQA challenge / distribution.
- [8] **Detection Frequency:** To aid qualitative analysis each panel member is assigned a frequency of detection. This is based on the peer group consensus of all qualitative results returned by participants within the EQA challenge/distribution. Note that the detection frequency is assigned using only datasets submitted using workflows including the target pathogen.
- [9] **Detection Score:** Your detection scores are based on the assigned detection frequency of each panel member, where 0 is "highly satisfactory" and 3 (three) is "highly unsatisfactory"

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Multiple Pathogen Programme - Qualitative Assessment of Results

Results are categorised based on the workflow used and the pathogen(s) targeted as shown in the table below.

			Labora	atory Reporte	d Results													
Expected					pathogen(s) workflow(s)	Expected	Posult Co	Result Category		Sample Weighting								
Qualitative Result	Positive	Negative	Not Determined	Expected pathogen(s) detected	Expected pathogen(s) not detected	pathogen(s) not included in workflow(s)	resuit Category		Result Sategory						Frequently Detected (>95% positive)	Detected (Between 65 and 95% positive)	Infrequently Detected (Less than 65% positive)	Negative
Positive	~			~			Expected Pathogen Reported	Detected / Determined	0	0	0	N/A						
Negative		~					No pathogen reported	Detected / Determined	N/A	N/A	N/A	0						
Negative	~						False Positive	False Positive	3	3	3	N/A						
Positive	~					~	Reported Pathogen(s) not as expected	False Positive	3	3	3	N/A						
Positive	•				~		Reported Pathogen(s) not as expected	False Positive	3	3	3	N/A						
Positive or Negative			~				Result reported as not determined	Not Determined	3	2	1	N/A						
Positive		~			~		No pathogen reported	False Negative	3	2	1	N/A						
Positive		~				~	Expected pathogen not tested for	Not Tested	Not Scored	Not Scored	Not Scored	N/A						

My Workflow Details:

Name	Gardnerella vaginalis (v2)
Description	
Targets	B Gardnerella vaginalis

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Assays

Extraction - Manual Extraction Process

Commercial

- o Kit Manufacturer: GeneProof
- Kit Type: PathogenFree DNA Isolation Kit

Amplification - GeneProof - croBEE Real-Time PCR System

Commercial

o Kit Manufacturer: GeneProof

o Kit Type: Gardnerella vaginalis PCR Kit

o Kit Version: ISEX

Used to test samples:

STI 1101C1-01, STI 1101C1-02, STI 1101C1-03, STI 1101C1-04, STI 1101C1-05

Name	GeneProof Mycoplasma genitalium/hominis PCR Kit (v2)
Description	
Targets	B Mycoplasma genitalium B Mycoplasma hominis
Assays	 Extraction - Manual Extraction Process Commercial Kit Manufacturer: GeneProof Kit Type: PathogenFree DNA Isolation Kit Amplification - GeneProof - croBEE Real-Time PCR System Multiplex Commercial Kit Manufacturer: GeneProof Kit Type: Mycoplasma genitalium/hominis PCR Kit Kit Version: ISEX

STI_I101C1-01, STI_I101C1-02, STI_I101C1-03, STI_I101C1-04, STI_I101C1-05 Used to test samples:

Name	Trichomonas vaginalis PCR Kit (v2)					
Description						
Targets	B Trichomonas vaginalis					

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Laboratory CZ023

Assays

A

Extraction - Manual Extraction Process

- Commercial
 - o Kit Manufacturer: GeneProof
 - Kit Type: PathogenFree DNA Isolation Kit

Amplification - GeneProof - croBEE Real-Time PCR System

- Multiplex
- Commercial
 - o Kit Manufacturer: GeneProof
 - o Kit Type: Trichomonas vaginalis PCR Kit
 - o Kit Version: ISEX

Used to test samples:

STI_I101C1-01, STI_I101C1-02, STI_I101C1-03, STI_I101C1-04, STI_I101C1-05

Name	STI-CNMX (v3)
Description	
Targets	B Mycoplasma genitalium B Neisseria gonorrhoeae B Chlamydia trachomatis
Assays	 Extraction - Manual Extraction Process Commercial Kit Manufacturer: GeneProof Kit Type: PathogenFree DNA Isolation Kit
	 Amplification - GeneProof - croBEE Real-Time PCR System Multiplex Commercial Kit Manufacturer: GeneProof Kit Type: GeneProof CT/NG/MG Multiplex PCR Kit Kit Version: ISEX

Used to test samples: | STI_I101C1-01, STI_I101C1-02, STI_I101C1-03, STI_I101C1-04, STI_I101C1-05

Name	Ureaplasma PCR Kit (v3)
Description	
Targets	B Ureaplasma parvum B Ureaplasma urealyticum

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Laboratory CZ023

Assays

Extraction - Manual Extraction Process

- Commercial
 - o Kit Manufacturer: GeneProof
 - Kit Type: PathogenFree DNA Isolation Kit

Amplification - GeneProof - croBEE Real-Time PCR System

- Multiplex
- Commercial

o Kit Manufacturer: GeneProof o Kit Type: Ureaplasma PCR Kit

o Kit Version: ISEX

Used to test samples:

STI 1101C1-01, STI 1101C1-02, STI 1101C1-03, STI 1101C1-04, STI 1101C1-05

Name	MH/UU/UP Multiplex PCR Kit (v2)
Description	
Targets	B Ureaplasma parvum B Ureaplasma urealyticum B Mycoplasma hominis
Assays	 Extraction - Manual Extraction Process Commercial Kit Manufacturer: GeneProof Kit Type: PathogenFree DNA Isolation Kit
	 Amplification - GeneProof - croBEE Real-Time PCR System Multiplex Commercial Kit Manufacturer: GeneProof Kit Type: GeneProof MH/UU/UP Multiplex PCR Kit Kit Version: ISEX

Used to test samples:

STI I101C1-01, STI I101C1-02, STI I101C1-03, STI I101C1-04, STI I101C1-05

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Your Summary Results (Educational Samples)

Sample Code	Expected Result ^[2]		Your Final Laboratory Rep	Sample Status ^[7]	Detection Frequency ^[8]	Detection Score ^[9]		
	Qualitative	Pathogen ID	Pathogen included in workflow(s) ^[4] Yes/No	Qualitative ^[5]	Reported Pathogen ID ^[6]			
STI_I101C1-02	Positive	Trichomonas vaginalis	Yes	Positive	Trichomonas vaginalis	Educational	Detected	0

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- [2] Expected Result: positive / negative result and the specific pathogen present within each panel member.
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For further details please refer to the current participant manual.

Further Programme Details

Number of Participants	46
Number of Countries	19
Number of Respondents	38
Number of Datasets Submitted	41

EQA Programme Aims

The aim of the Sexually Transmitted Infection I (STI_I) EQA is to assess the laboratories' ability to detect a range of sexually transmitted infections known to cause disease using their routine molecular diagnostic platform and procedures.

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Feedback and Enquiries

Participants are encouraged to read the QCMD Participants' Manual, which can be downloaded from the QCMD website.

Any enquiries should be submitted through the 'Contact Us' form that you can find in the 'Help' section of your QCMD (ITEMS) Participant Profile Area.

Panel member analysis is separated into CORE samples followed by EDUCATIONAL samples.

Individual Panel Member Analysis (Core Samples)

Qualitative analysis for each panel member is provided in relation to your EQA assessment group. EQA assessment groups are established using the molecular workflow information reported by all participants within this EQA challenge / distribution.

To allow meaningful assessment at the individual method level the EQA assessment group must consist of 5 or more datasets. If there are not sufficient datasets at the individual method level then your results will be included within a higher EQA assessment group based on whether it is a commercial or in house technology/method. The highest level assessment grouping is "All" participant reported qualitative results.

A breakdown of qualitative results reported for all workflows used by participants on each of the panel members within this EQA challenge / distribution is provided below. Note: participants may use multiple workflows for each sample.

The final laboratory result indicates the final reported result which may be based on one or more workflows used to test each panel member.

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Groups below n=5: Abbott (n=1), Abbott - Abbott Alinity m (n=1), Applied Biosystems (n=1), Applied Biosystems - Applied Biosystems Real Time PCR (n=1), AusDiagnostics (n=1), AusDiagnostics - AusDiagnostics Easy-Plex (n=1), BD Molecular Diagnostics (n=2), BD Molecular Diagnostics - BD MAX (n=1), BD Molecular Diagnostics - BD ProbeTec (n=1), BIORON (n=3), BIORON - BIORON RealLine (n=3), BioGX (n=1), BioGX - BioGX Sample-Ready (n=1), Cepheid (n=1), Cepheid - Cepheid Xpert kit (n=1), Randox (n=1), Randox - Randox Multiplex Array (n=1), Roche (n=1), Roche - Roche Cobas 6800/8800 (n=1), Seegene - Seegene Seeplex (n=2), SpeeDx (n=1), SpeeDx - SpeeDx Real Time PCR (n=1), TIB MOLBIOL (n=1), TIB MOLBIOL - TIB-MolBiol LightMix (n=1), In-House - Conventional In-House PCR (n=4), In-House - Real-time In-House PCR (n=3)

Groups Rolled Up: AmpliSens - AmpliSens Real Time PCR (n=5), Hologic - Hologic Aptima (n=5), fast-track DIAGNOSTICS - FTD real time PCR (n=5)

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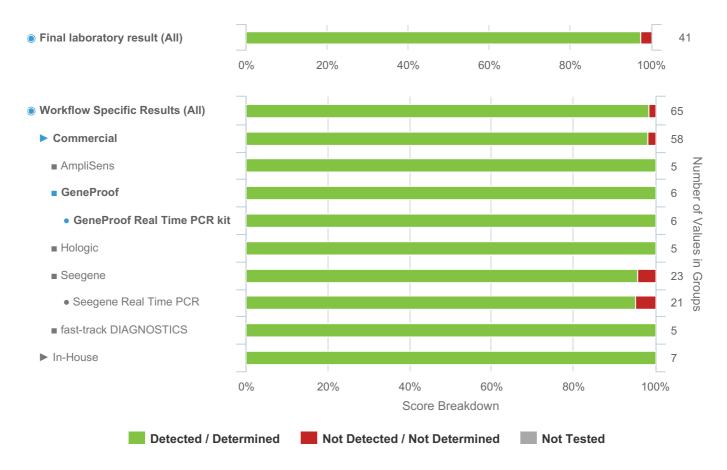


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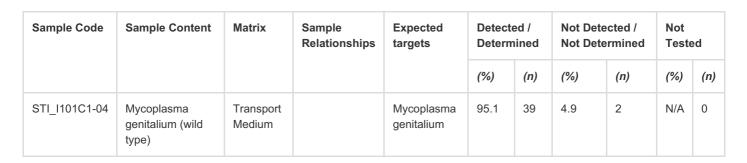


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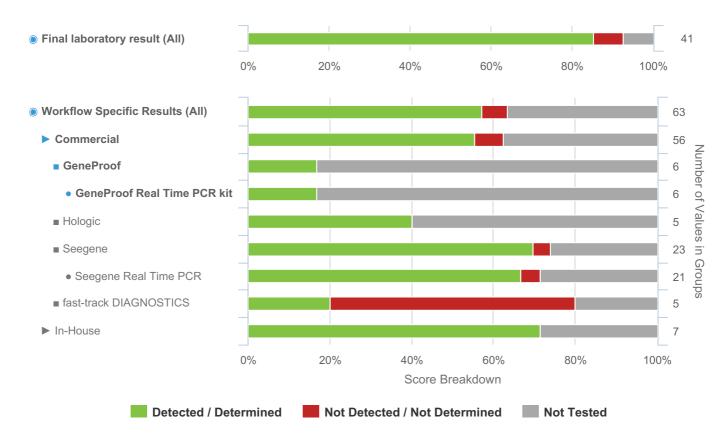
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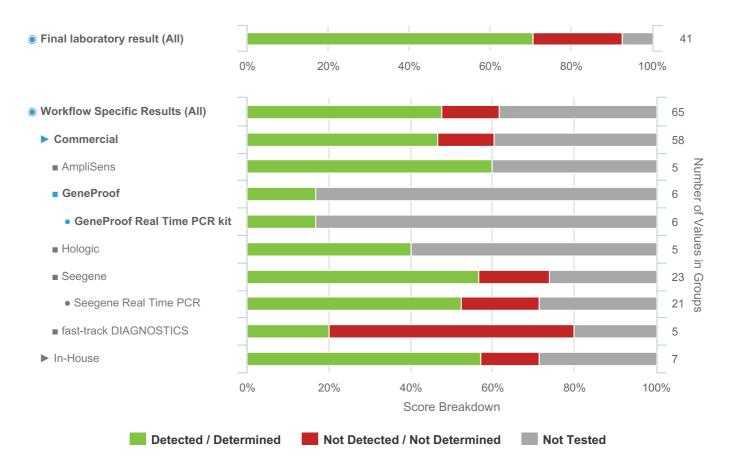
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