


Individual Report	QCMD 2019 Mycobacterium tuberculosis DNA EQA Programme					
	Catalogue Code: QAB014129	Ref Code: MTBDNA19	Challenge: C2	Analysis Type: Qualitative	Dataset: 326450	Report UID: 2677/326450/2344

Intended Results / Panel Composition

Sample Code	Sample Content	Matrix	Sample Relationships ^[1]	Detection Frequency ^[2]	Sample Status ^[3]	Percentage Correct (All) ^[4]	
						(%)	(n)
MTBDNA19C2-01	M. bovis (BCG)	Synthetic Sputum	DS1_1	Frequently Detected	CORE	97.2	145
MTBDNA19C2-02	M. xenopi	Synthetic Sputum		Negative	CORE	93.1	145
MTBDNA19C2-03	M. bovis (BCG)	Synthetic Sputum	DS1_2	Frequently Detected	CORE	96.6	145
MTBDNA19C2-04	Mycobacterium Negative	Synthetic Sputum		Negative	CORE	99.3	145
MTBDNA19C2-05	M. tuberculosis (DR- INH-R)	Synthetic Sputum		Frequently Detected	CORE	100.0	145

[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, DS2_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] **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 from participants within the EQA challenge / distribution.

[3] **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.

[4] **Percentage Correct (All):** Percentage of datasets (%) reporting the correct qualitative result and the total number of datasets (n) reported for each panel member.

For further details please refer to the current participant manual.


Your Summary Results

EQA Assessment Group ^[1]

Commercial

Core Panel Detection (Qualitative) Score ^[2]

0

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Core Panel Members Results

Sample Code	Qualitative Results			Your Quantitative Data (for information only) [3]		
	Percentage Correct (All) [4]	Your Result [5]	Detection Score [6]	Reported Value	Unitage	Cycle Threshold
MTBDNA19C2-01	97.2	Positive	0		N/A	31.5
MTBDNA19C2-02	93.1	Negative	0		N/A	-
MTBDNA19C2-03	96.6	Positive	0		N/A	34.0
MTBDNA19C2-04	99.3	Negative	0		N/A	-
MTBDNA19C2-05	100.0	Positive	0		N/A	23.14

[1] **EQA Assessment Group:** To aid data 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] **Core Panel Detection (Qualitative) Score:** An overall core panel detection score provided per challenge / distribution.

[3] **Quantitative Data (for information only):** This is the quantitative value, unitage and cycle threshold you provided when you submitted your results. For qualitative programmes this information is not used as part of your formal EQA assessment.

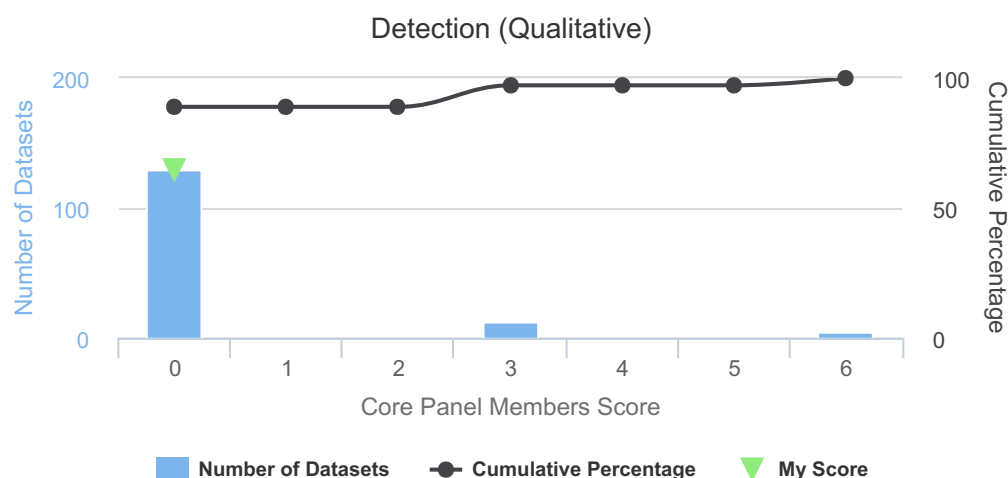
[4] **Percentage Correct (All):** Percentage of datasets (%) reporting the correct qualitative results for each panel member.


[5] **Your Result:** The qualitative result you reported for each sample within this EQA challenge / distribution.

[6] **Detection Score:** Your detection (qualitative) scores are based on the assigned detection frequency of each panel members, where 0 (zero) is "highly satisfactory" and 3 (three) is "highly unsatisfactory". Scores are provided for individual panel members.

For further details please refer to the current participant manual.

Core Panel Member Score Breakdown



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Core Panel Member Score Breakdown - Detection: This figure gives you a breakdown of the qualitative detection scores for all qualitative datasets returned within this EQA challenge / distribution independent of the EQA assessment group. Panel detection scores are generated from only those panel members that are defined as "CORE".

For further details please refer to the current participant manual.

My Workflow Details

The details of the workflow(s) used to submit your results for this challenge.

Name	Mycobacterium tuberculosis PCR Kit (v3)
Description	
Targets	B Mycobacterium tuberculosis
Assays	<ul style="list-style-type: none"> DNA <i>Extraction - Manual Extraction Process</i> <ul style="list-style-type: none"> ● Commercial <ul style="list-style-type: none"> ○ Kit Manufacturer: <i>GeneProof</i> ○ Kit Type: <i>PathogenFree DNA Isolation Kit</i> RNA <i>Amplification - GeneProof - croBEE Real-Time PCR System</i> <ul style="list-style-type: none"> ● Commercial <ul style="list-style-type: none"> ○ Kit Manufacturer: <i>GeneProof</i> ○ Kit Type: <i>Mycobacterium tuberculosis PCR Kit</i> ○ Kit Version: <i>ISEX</i>

Further Programme Details

Number of Participants	149
Number of Countries	27
Number of Respondents	132
Number of Datasets Submitted	145
Qualitative Results Returned	145 (100.0%)


EQA Programme Aims

To assess the proficiency of laboratories in the molecular detection of *Mycobacterium tuberculosis*.

Feedback and Enquiries

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

Any queries about this report should be addressed to the QCMD Neutral Office (neutraloffice@qcmd.org).

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

Additional Core Samples Information

The following section has been categorised as shown below:


Core ► Qualitative

Individual Panel Member Analysis (Qualitative)

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. The principal level of assessment is at the individual method level which is defined based on your reported “amplification/detection method” and other laboratories using the same or similar amplification/detection methods.

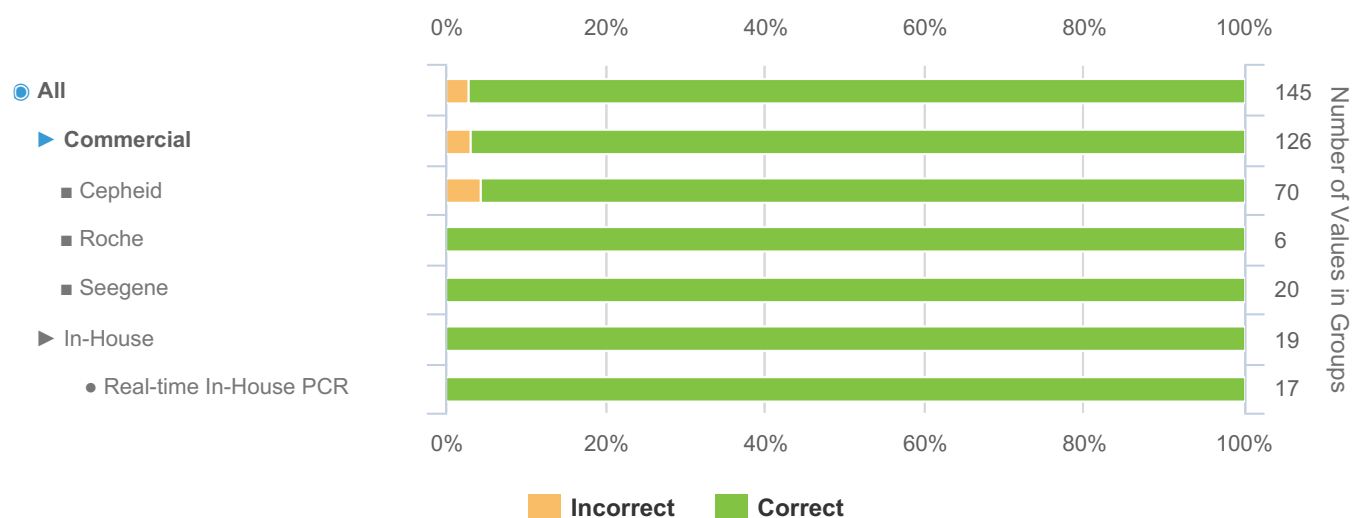
To allow meaningful assessment at the individual method level the EQA assessment group must consist of 5 or more datasets. If there are not sufficient datasets at the individual method level then your results will be included within a higher EQA assessment group based on whether it is a commercial or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

A breakdown of qualitative results reported by participants on each of the panel members within this EQA challenge / distribution is provided below. You can compare your results to those within your EQA assessment group and those obtained within other EQA assessment groups or to the overall consensus for each sample within this EQA challenge / distribution.

Individual Report	QCMD 2019 Mycobacterium tuberculosis DNA EQA Programme				 Quality Control for Molecular Diagnostics	
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MTBDNA19C2-01 - Qualitative Results Breakdown

Sample Code	Sample Content	Matrix	Sample Relationships	Detection Frequency	Sample Status	Percentage Correct (All)	
						(%)	(n)
MTBDNA19C2-01	M. bovis (BCG)	Synthetic Sputum	DS1_1	Frequently Detected	CORE	97.2	145



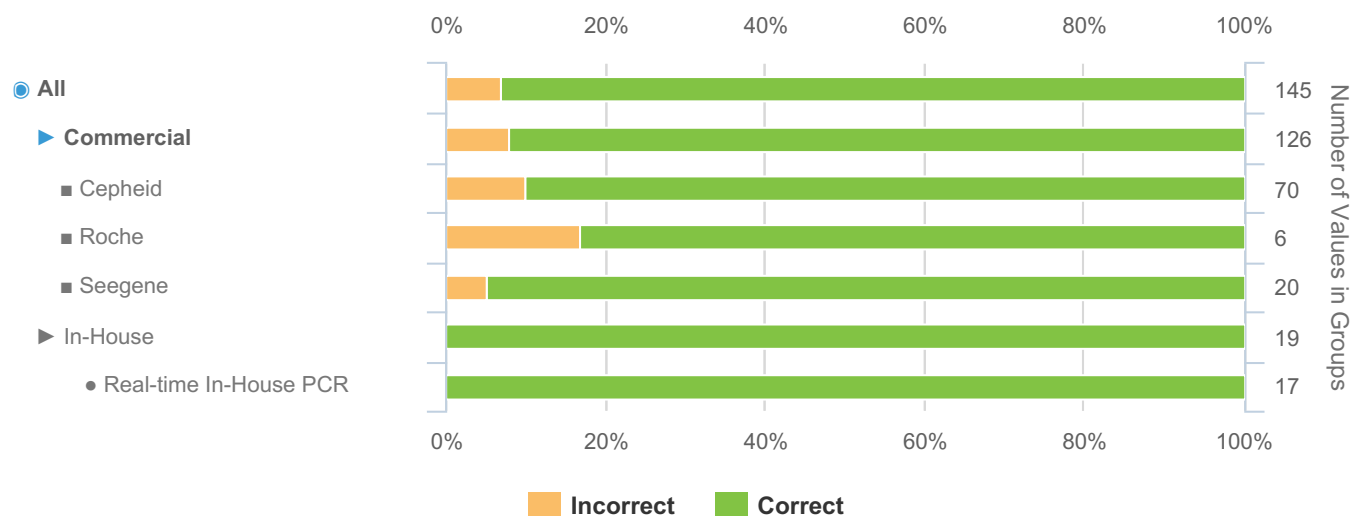
Groups below n=5: AB Analytica (n=2), AB Analytica - AB Analytica REALQUALITY RQ (n=2), ADT Biotech (n=1), ADT Biotech - ADT Biotech LyteStar (n=1), Abbott (n=3), Abbott - Abbott Real Time PCR (n=3), AmpliSens (n=2), AmpliSens - AmpliSens Real Time PCR (n=2), Anatolia Geneworks (n=1), Anatolia Geneworks - Anatolia Geneworks Bosphore (n=1), BD Molecular Diagnostics (n=4), BD Molecular Diagnostics - BD MAX (n=3), BD Molecular Diagnostics - BD ProbeTec (n=1), Diagenode (n=2), Diagenode - Diagenode Real Time kit (n=2), ELITech Group (n=1), ELITech Group - Elitech Elite Real Time kit (n=1), GeneProof (n=2), GeneProof - GeneProof Real Time PCR kit (n=2), Hain Lifescience (n=4), Hain Lifescience - Hain Lifescience FlouroType (n=2), Hain Lifescience - Hain Lifescience GenoType (n=2), Hong Kong CH Gene (n=1), Hong Kong CH Gene - HK CH Gene Real Time PCR (n=1), PathoFinder (n=1), PathoFinder - PathoFinder Real Time PCR (n=1), Progenie Molecular (n=1), Progenie Molecular - Progenie Molecular RealCycler (n=1), QIAGEN (n=4), QIAGEN - QIAGEN Artus Real Time (n=4), Roche - Roche Cobas Amplicor (n=1), Roche - Roche Cobas TaqMan (n=4), Roche - Roche LightCycler (n=1), infopia (n=1), infopia - infopia Real Time PCR (n=1), In-House - Conventional In-House PCR (n=2)

Groups Rolled Up: Cepheid - Cepheid Xpert kit (n=70), Seegene - Seegene Real Time PCR (n=20)

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MTBDNA19C2-02 - Qualitative Results Breakdown

Sample Code	Sample Content	Matrix	Sample Relationships	Detection Frequency	Sample Status	Percentage Correct (All)	
						(%)	(n)
MTBDNA19C2-02	M. xenopi	Synthetic Sputum		Negative	CORE	93.1	145



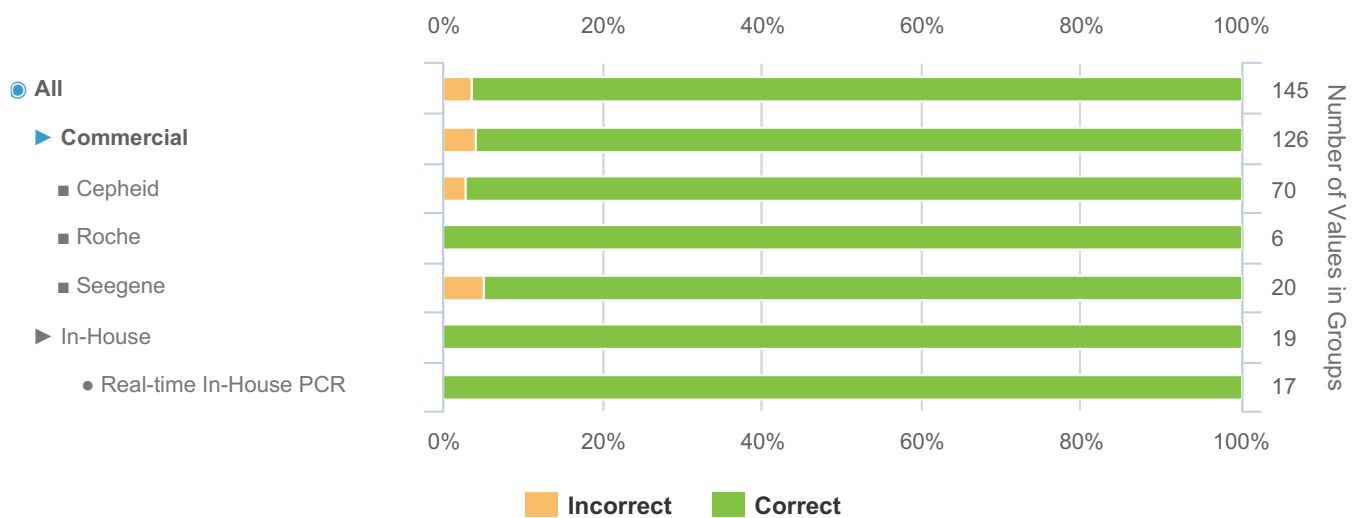
Groups below n=5: AB Analytica (n=2), AB Analytica - AB Analytica REALQUALITY RQ (n=2), ADT Biotech (n=1), ADT Biotech - ADT Biotech LyteStar (n=1), Abbott (n=3), Abbott - Abbott Real Time PCR (n=3), AmpliSens (n=2), AmpliSens - AmpliSens Real Time PCR (n=2), Anatolia Geneworks (n=1), Anatolia Geneworks - Anatolia Geneworks Bosphore (n=1), BD Molecular Diagnostics (n=4), BD Molecular Diagnostics - BD MAX (n=3), BD Molecular Diagnostics - BD ProbeTec (n=1), Diagenode (n=2), Diagenode - Diagenode Real Time kit (n=2), ELITech Group (n=1), ELITech Group - Elitech Elite Real Time kit (n=1), GeneProof (n=2), GeneProof - GeneProof Real Time PCR kit (n=2), Hain Lifescience (n=4), Hain Lifescience - Hain Lifescience FlouroType (n=2), Hain Lifescience - Hain Lifescience GenoType (n=2), Hong Kong CH Gene (n=1), Hong Kong CH Gene - HK CH Gene Real Time PCR (n=1), PathoFinder (n=1), PathoFinder - PathoFinder Real Time PCR (n=1), Progenie Molecular (n=1), Progenie Molecular - Progenie Molecular RealCycler (n=1), QIAGEN (n=4), QIAGEN - QIAGEN Artus Real Time (n=4), Roche - Roche Cobas Amplicor (n=1), Roche - Roche Cobas TaqMan (n=4), Roche - Roche LightCycler (n=1), infopia (n=1), infopia - infopia Real Time PCR (n=1), In-House - Conventional In-House PCR (n=2)

Groups Rolled Up: Cepheid - Cepheid Xpert kit (n=70), Seegene - Seegene Real Time PCR (n=20)

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MTBDNA19C2-03 - Qualitative Results Breakdown

Sample Code	Sample Content	Matrix	Sample Relationships	Detection Frequency	Sample Status	Percentage Correct (All)	
						(%)	(n)
MTBDNA19C2-03	M. bovis (BCG)	Synthetic Sputum	DS1_2	Frequently Detected	CORE	96.6	145



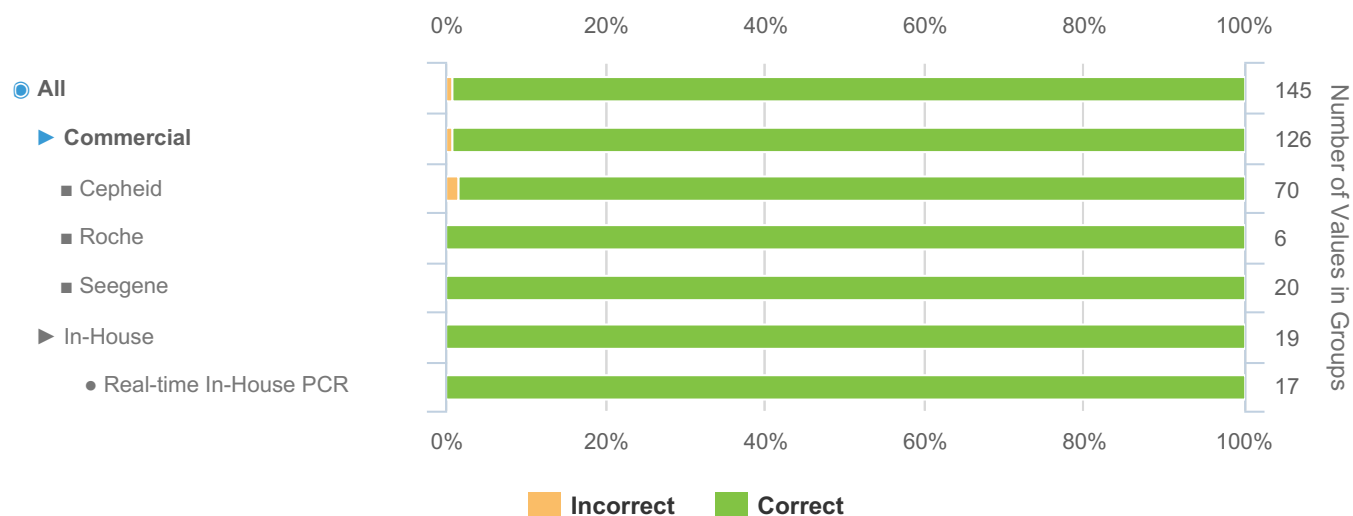
Groups below n=5: AB Analytica (n=2), AB Analytica - AB Analytica REALQUALITY RQ (n=2), ADT Biotech (n=1), ADT Biotech - ADT Biotech LyteStar (n=1), Abbott (n=3), Abbott - Abbott Real Time PCR (n=3), AmpliSens (n=2), AmpliSens - AmpliSens Real Time PCR (n=2), Anatolia Geneworks (n=1), Anatolia Geneworks - Anatolia Geneworks Bosphore (n=1), BD Molecular Diagnostics (n=4), BD Molecular Diagnostics - BD MAX (n=3), BD Molecular Diagnostics - BD ProbeTec (n=1), Diagenode (n=2), Diagenode - Diagenode Real Time kit (n=2), ELITech Group (n=1), ELITech Group - Elitech Elite Real Time kit (n=1), GeneProof (n=2), GeneProof - GeneProof Real Time PCR kit (n=2), Hain Lifescience (n=4), Hain Lifescience - Hain Lifescience FlouroType (n=2), Hain Lifescience - Hain Lifescience GenoType (n=2), Hong Kong CH Gene (n=1), Hong Kong CH Gene - HK CH Gene Real Time PCR (n=1), PathoFinder (n=1), PathoFinder - PathoFinder Real Time PCR (n=1), Progenie Molecular (n=1), Progenie Molecular - Progenie Molecular RealCycler (n=1), QIAGEN (n=4), QIAGEN - QIAGEN Artus Real Time (n=4), Roche - Roche Cobas Amplicor (n=1), Roche - Roche Cobas TaqMan (n=4), Roche - Roche LightCycler (n=1), infopia (n=1), infopia - infopia Real Time PCR (n=1), In-House - Conventional In-House PCR (n=2)

Groups Rolled Up: Cepheid - Cepheid Xpert kit (n=70), Seegene - Seegene Real Time PCR (n=20)

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MTBDNA19C2-04 - Qualitative Results Breakdown

Sample Code	Sample Content	Matrix	Sample Relationships	Detection Frequency	Sample Status	Percentage Correct (All)	
						(%)	(n)
MTBDNA19C2-04	Mycobacterium Negative	Synthetic Sputum		Negative	CORE	99.3	145



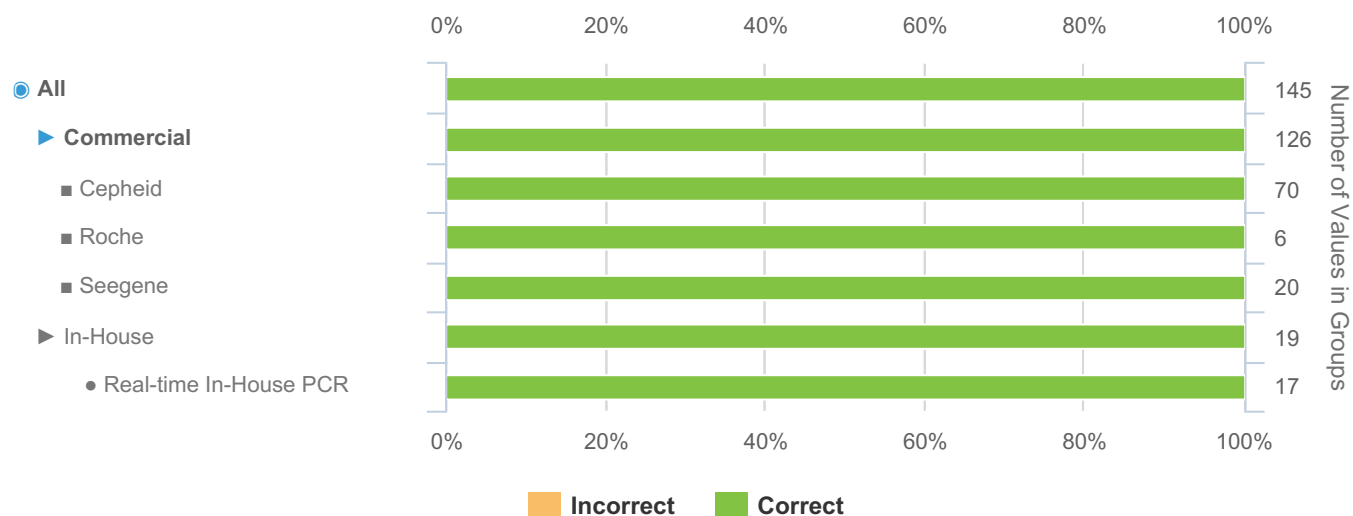
Groups below n=5: AB Analytica (n=2), AB Analytica - AB Analytica REALQUALITY RQ (n=2), ADT Biotech (n=1), ADT Biotech - ADT Biotech LyteStar (n=1), Abbott (n=3), Abbott - Abbott Real Time PCR (n=3), AmpliSens (n=2), AmpliSens - AmpliSens Real Time PCR (n=2), Anatolia Geneworks (n=1), Anatolia Geneworks - Anatolia Geneworks Bosphore (n=1), BD Molecular Diagnostics (n=4), BD Molecular Diagnostics - BD MAX (n=3), BD Molecular Diagnostics - BD ProbeTec (n=1), Diagenode (n=2), Diagenode - Diagenode Real Time kit (n=2), ELITech Group (n=1), ELITech Group - Elitech Elite Real Time kit (n=1), GeneProof (n=2), GeneProof - GeneProof Real Time PCR kit (n=2), Hain Lifescience (n=4), Hain Lifescience - Hain Lifescience FlouroType (n=2), Hain Lifescience - Hain Lifescience GenoType (n=2), Hong Kong CH Gene (n=1), Hong Kong CH Gene - HK CH Gene Real Time PCR (n=1), PathoFinder (n=1), PathoFinder - PathoFinder Real Time PCR (n=1), Progenie Molecular (n=1), Progenie Molecular - Progenie Molecular RealCycler (n=1), QIAGEN (n=4), QIAGEN - QIAGEN Artus Real Time (n=4), Roche - Roche Cobas Amplicor (n=1), Roche - Roche Cobas TaqMan (n=4), Roche - Roche LightCycler (n=1), infopia (n=1), infopia - infopia Real Time PCR (n=1), In-House - Conventional In-House PCR (n=2)

Groups Rolled Up: Cepheid - Cepheid Xpert kit (n=70), Seegene - Seegene Real Time PCR (n=20)

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MTBDNA19C2-05 - Qualitative Results Breakdown

Sample Code	Sample Content	Matrix	Sample Relationships	Detection Frequency	Sample Status	Percentage Correct (All)	
						(%)	(n)
MTBDNA19C2-05	M. tuberculosis (DR-INH-R)	Synthetic Sputum		Frequently Detected	CORE	100.0	145



Groups below n=5: AB Analytica (n=2), AB Analytica - AB Analytica REALQUALITY RQ (n=2), ADT Biotech (n=1), ADT Biotech - ADT Biotech LyteStar (n=1), Abbott (n=3), Abbott - Abbott Real Time PCR (n=3), AmpliSens (n=2), AmpliSens - AmpliSens Real Time PCR (n=2), Anatolia Geneworks (n=1), Anatolia Geneworks - Anatolia Geneworks Bosphore (n=1), BD Molecular Diagnostics (n=4), BD Molecular Diagnostics - BD MAX (n=3), BD Molecular Diagnostics - BD ProbeTec (n=1), Diagenode (n=2), Diagenode - Diagenode Real Time kit (n=2), ELITech Group (n=1), ELITech Group - Elitech Elite Real Time kit (n=1), GeneProof (n=2), GeneProof - GeneProof Real Time PCR kit (n=2), Hain Lifescience (n=4), Hain Lifescience - Hain Lifescience FlouroType (n=2), Hain Lifescience - Hain Lifescience GenoType (n=2), Hong Kong CH Gene (n=1), Hong Kong CH Gene - HK CH Gene Real Time PCR (n=1), PathoFinder (n=1), PathoFinder - PathoFinder Real Time PCR (n=1), Progenie Molecular (n=1), Progenie Molecular - Progenie Molecular RealCycler (n=1), QIAGEN (n=4), QIAGEN - QIAGEN Artus Real Time (n=4), Roche - Roche Cobas Amplicor (n=1), Roche - Roche Cobas TaqMan (n=4), Roche - Roche LightCycler (n=1), infopia (n=1), infopia - infopia Real Time PCR (n=1), In-House - Conventional In-House PCR (n=2)

Groups Rolled Up: Cepheid - Cepheid Xpert kit (n=70), Seegene - Seegene Real Time PCR (n=20)

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