


<b>Individual Report</b>	<b>QCMD 2022 Mycobacterium tuberculosis DNA EQA Programme</b>					 <b>QCMD</b> Quality Control for Molecular Diagnostics	
<b>Catalogue Code:</b> QAB014129	<b>Ref Code:</b> MTBDNA22	<b>Challenge:</b> C1	<b>Analysis Type:</b> Qualitative	<b>Dataset:</b> 535208	<b>Report UID:</b> 2677/535208/4489	<b>Laboratory</b> CZ023	

## Intended Results / Panel Composition

Sample Code	Sample Content	Matrix	Sample Relationships <sup>[1]</sup>	Detection Frequency <sup>[2]</sup>	Sample Status <sup>[3]</sup>	Percentage Correct (All) <sup>[4]</sup>	
						(%)	(n)
MTBDNA22C1-01	M. bovis (BCG)	Synthetic CSF	DS1_1	Frequently Detected	CORE	99.1	110
MTBDNA22C1-02	Mycobacterium Negative	Synthetic CSF		Negative	CORE	98.2	110
MTBDNA22C1-03	M. bovis (BCG)	Synthetic CSF	DS1_2	Frequently Detected	CORE	98.2	110
MTBDNA22C1-04	M. tuberculosis (DR- RIF-R)	Synthetic CSF		Frequently Detected	CORE	100.0	110
MTBDNA22C1-05	M. bovis (BCG)	Synthetic CSF	DS1_3	Detected	EDUCATIONAL	88.2	110

[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 <sup>[1]</sup>**

Commercial

**Core Panel Detection (Qualitative) Score <sup>[2]</sup>**

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
MTBDNA22C1-01	99.1	Positive	0		N/A	26.39
MTBDNA22C1-02	98.2	Negative	0		N/A	-
MTBDNA22C1-03	98.2	Positive	0		N/A	29.11
MTBDNA22C1-04	100.0	Positive	0		N/A	19.41

[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.

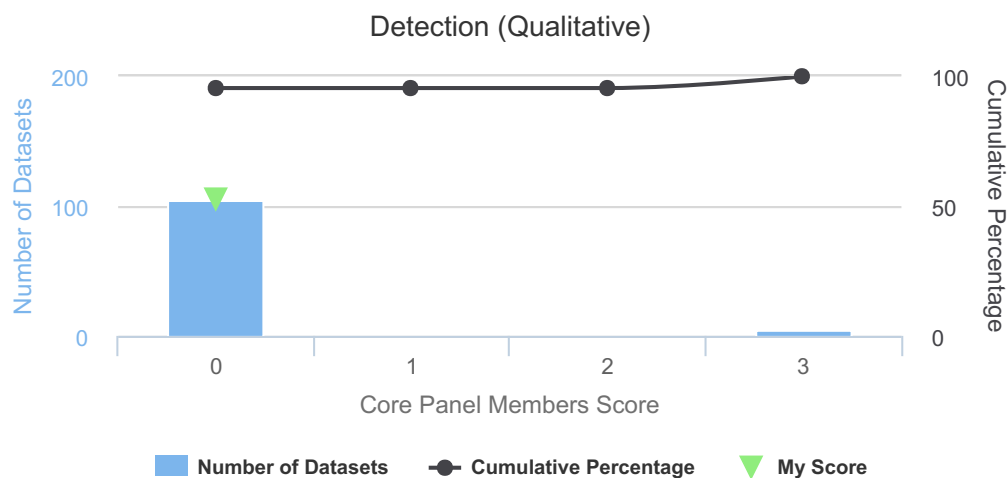
[4] **Percentage Correct (All):** Percentage of datasets (%) reporting the correct qualitative results for each panel member.


[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.

<b>Name</b>	Mycobacterium tuberculosis PCR Kit (v4)
<b>Description</b>	
<b>Targets</b>	<span style="background-color: #90EE90; border-radius: 50%; padding: 2px;">B</span> Mycobacterium tuberculosis
<b>Assays</b>	<div>  <b>Extraction</b> - Manual Extraction Process <ul style="list-style-type: none"> <li>Commercial <ul style="list-style-type: none"> <li>Kit Manufacturer: <i>GeneProof</i></li> <li>Kit Type: <i>PathogenFree DNA Isolation Kit</i></li> </ul> </li> </ul> </div> <div>  <b>Amplification</b> - GeneProof - croBEE Real-Time PCR System <ul style="list-style-type: none"> <li>Commercial <ul style="list-style-type: none"> <li>Kit Manufacturer: <i>GeneProof</i></li> <li>Kit Type: <i>Mycobacterium tuberculosis PCR Kit</i></li> <li>Kit Version: <i>GP</i></li> </ul> </li> </ul> </div>

## Educational Panel Members Results

Sample Code	Qualitative Results			Your Quantitative Data (for information only) [1]		
	Percentage Correct (All) [2]	Your Result [3]	Detection Score [4]	Reported Value	Unitage	Cycle Threshold
MTBDNA22C1-05	88.2	Positive	0		N/A	29.67


[1] **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.

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

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

[4] **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.*

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### Further Programme Details

Number of Participants	105
Number of Countries	25
Number of Respondents	100
Number of Datasets Submitted	110
Qualitative Results Returned	110 (100.0%)


### EQA Programme Aims

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

### 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.

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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.

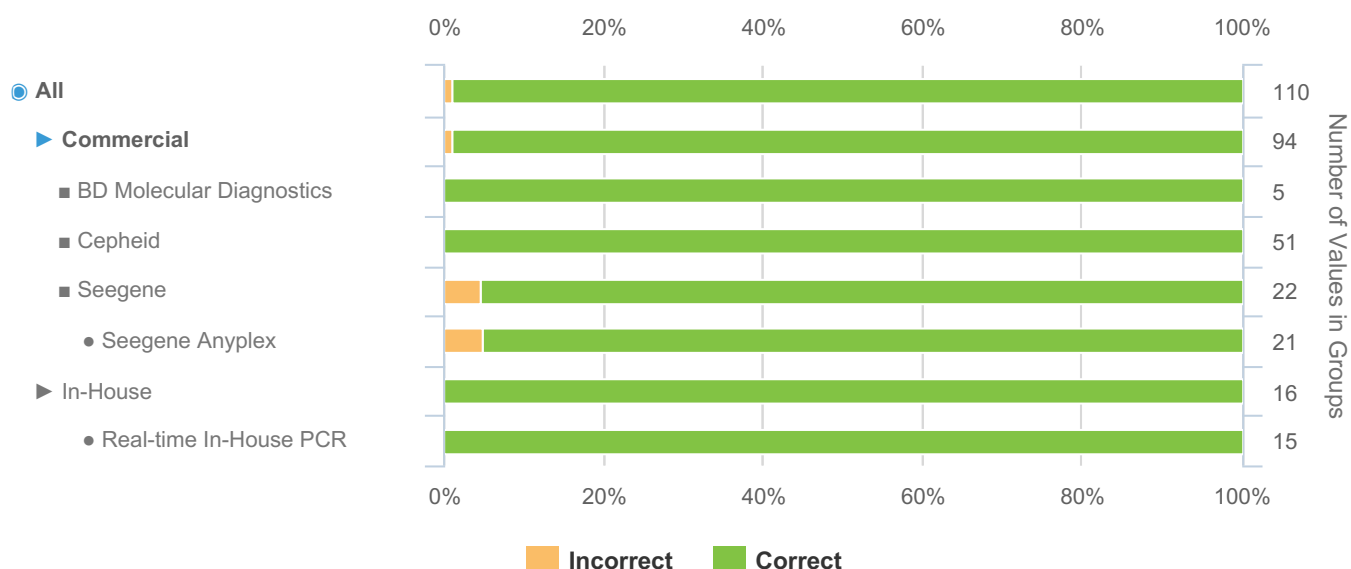
To allow meaningful assessment at the individual method level the EQA assessment group must consist of 5 or more datasets. If there are not sufficient datasets at the individual method level then your results will be included within a higher EQA assessment group based on whether it is a commercial or 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.

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#### MTBDNA22C1-01 - Qualitative Results Breakdown

Sample Code	Sample Content	Matrix	Sample Relationships	Detection Frequency	Sample Status	Percentage Correct (All)	
						(%)	(n)
MTBDNA22C1-01	M. bovis (BCG)	Synthetic CSF	DS1_1	Frequently Detected	CORE	99.1	110



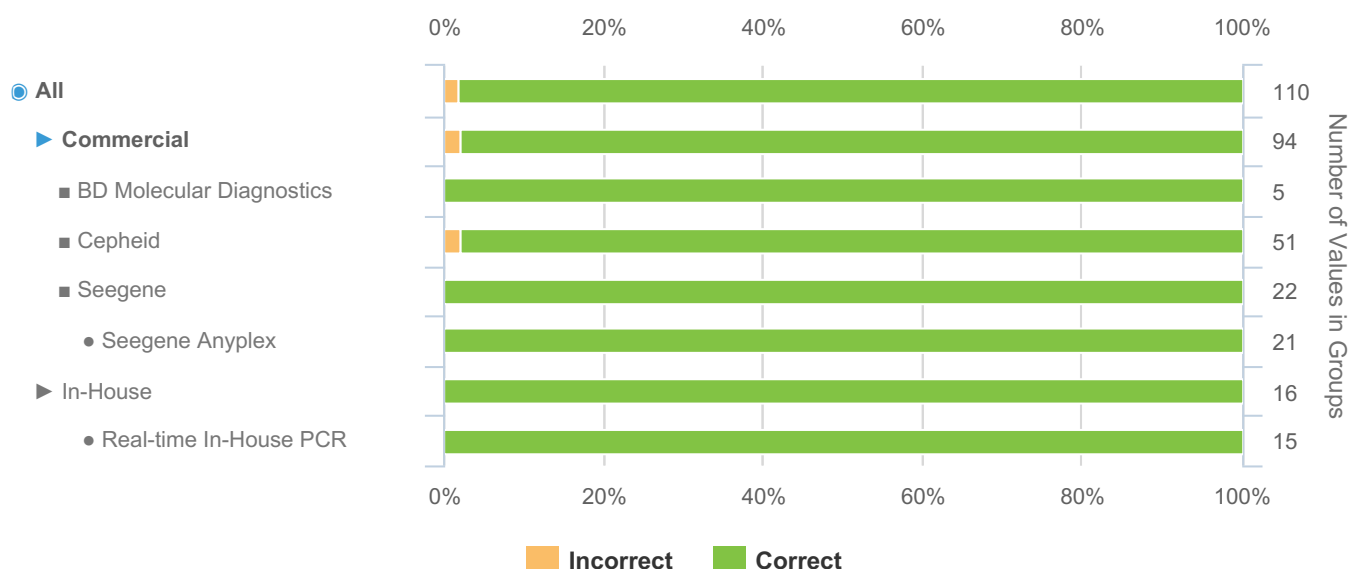
**Groups below n=5:** AB Analitica (n=2), AB Analitica - AB Analitica REALQUALITY RQ (n=2), Amplisens (n=1), Amplisens - AmpliSens Real Time PCR (n=1), AusDiagnostics (n=1), AusDiagnostics - AusDiagnostics TandemPlex (n=1), ELITech Group (n=2), ELITech Group - Elitech Elite Real Time kit (n=2), GeneProof (n=3), GeneProof - GeneProof Real Time PCR kit (n=3), Hain Lifescience (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), Master Diagnostica (n=1), Master Diagnostica - Master Diagnostica Flow Chip (n=1), PathoFinder (n=1), PathoFinder - PathoFinder Real Time PCR (n=1), QIAGEN (n=1), QIAGEN - QIAGEN Artus Real Time (n=1), Seegene - Seegene Allplex (n=1), in-house real-time PCR (n=1), in-house real-time PCR - in-house real-time PCR (n=1), In-House - Conventional In-House PCR (n=1)

**Groups Rolled Up:** BD Molecular Diagnostics - BD MAX (n=5), Cepheid - Cepheid Xpert kit (n=51)

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#### MTBDNA22C1-02 - Qualitative Results Breakdown

Sample Code	Sample Content	Matrix	Sample Relationships	Detection Frequency	Sample Status	Percentage Correct (All)	
						(%)	(n)
MTBDNA22C1-02	Mycobacterium Negative	Synthetic CSF		Negative	CORE	98.2	110



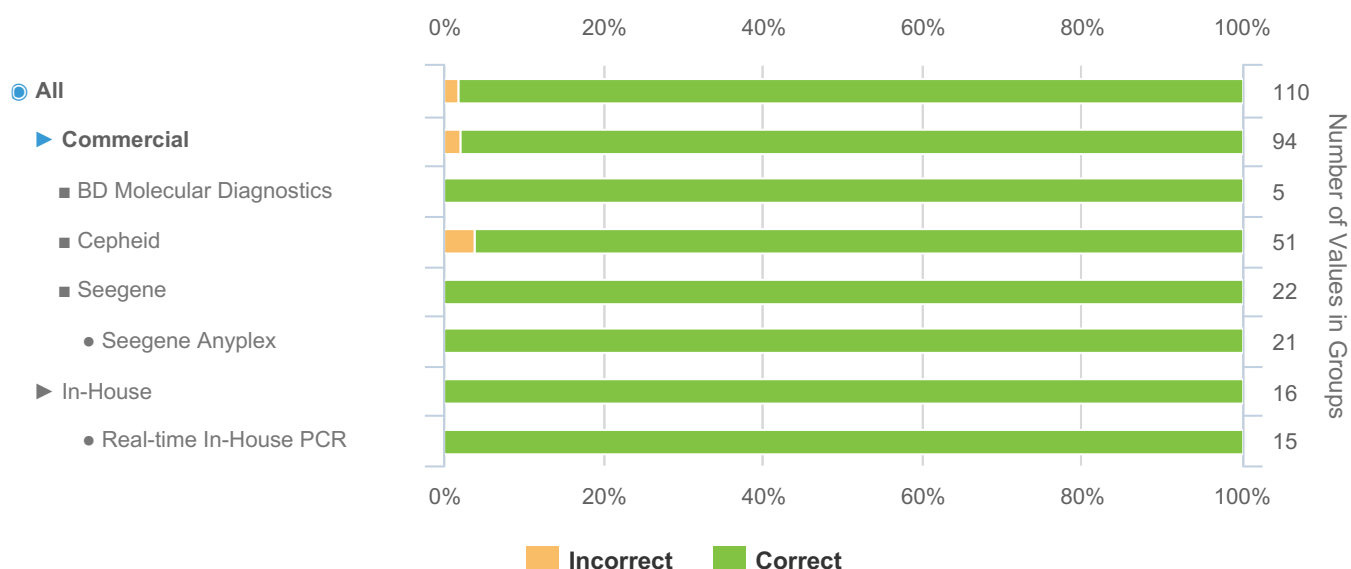
**Groups below n=5:** AB Analitica (n=2), AB Analitica - AB Analitica REALQUALITY RQ (n=2), Amplisens (n=1), Amplisens - AmpliSens Real Time PCR (n=1), AusDiagnostics (n=1), AusDiagnostics - AusDiagnostics TandemPlex (n=1), ELITech Group (n=2), ELITech Group - Elitech Elite Real Time kit (n=2), GeneProof (n=3), GeneProof - GeneProof Real Time PCR kit (n=3), Hain Lifescience (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), Master Diagnostica (n=1), Master Diagnostica - Master Diagnostica Flow Chip (n=1), PathoFinder (n=1), PathoFinder - PathoFinder Real Time PCR (n=1), QIAGEN (n=1), QIAGEN - QIAGEN Artus Real Time (n=1), Seegene - Seegene Allplex (n=1), in-house real-time PCR (n=1), in-house real-time PCR - in-house real-time PCR (n=1), In-House - Conventional In-House PCR (n=1)

**Groups Rolled Up:** BD Molecular Diagnostics - BD MAX (n=5), Cepheid - Cepheid Xpert kit (n=51)

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#### MTBDNA22C1-03 - Qualitative Results Breakdown


Sample Code	Sample Content	Matrix	Sample Relationships	Detection Frequency	Sample Status	Percentage Correct (All)	
						(%)	(n)
MTBDNA22C1-03	M. bovis (BCG)	Synthetic CSF	DS1_2	Frequently Detected	CORE	98.2	110



**Groups below n=5:** AB Analitica (n=2), AB Analitica - AB Analitica REALQUALITY RQ (n=2), Amplisens (n=1), Amplisens - AmpliSens Real Time PCR (n=1), AusDiagnostics (n=1), AusDiagnostics - AusDiagnostics TandemPlex (n=1), ELITech Group (n=2), ELITech Group - Elitech Elite Real Time kit (n=2), GeneProof (n=3), GeneProof - GeneProof Real Time PCR kit (n=3), Hain Lifescience (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), Master Diagnostica (n=1), Master Diagnostica - Master Diagnostica Flow Chip (n=1), PathoFinder (n=1), PathoFinder - PathoFinder Real Time PCR (n=1), QIAGEN (n=1), QIAGEN - QIAGEN Artus Real Time (n=1), Seegene - Seegene Allplex (n=1), in-house real-time PCR (n=1), in-house real-time PCR - in-house real-time PCR (n=1), In-House - Conventional In-House PCR (n=1)

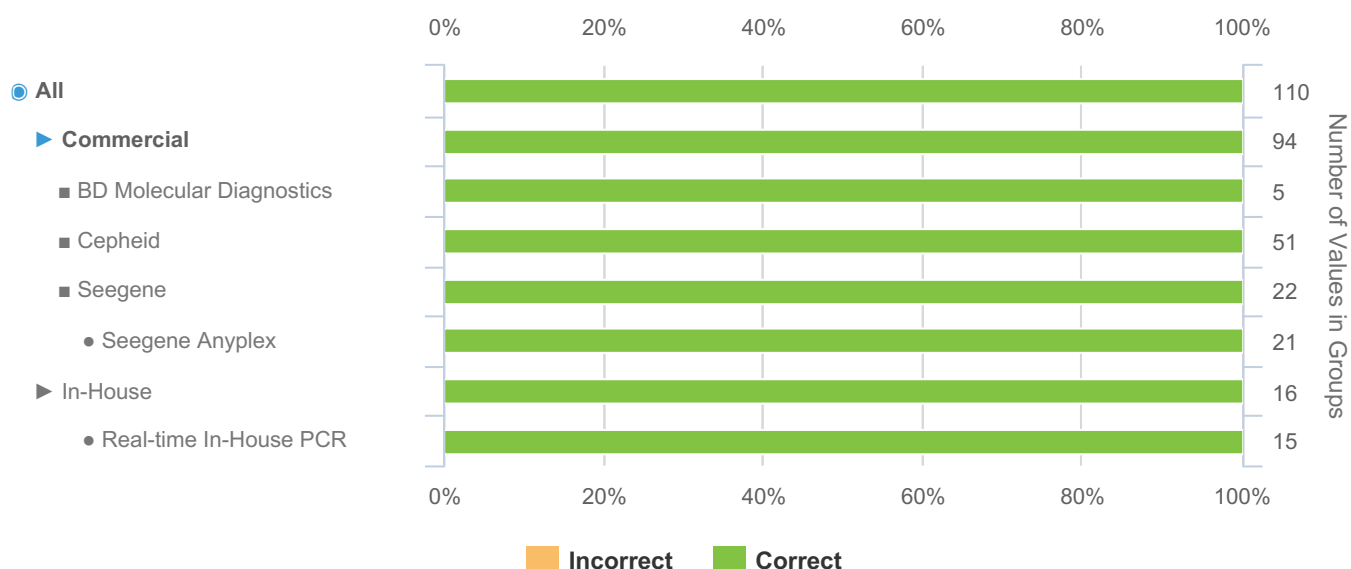
**Groups Rolled Up:** BD Molecular Diagnostics - BD MAX (n=5), Cepheid - Cepheid Xpert kit (n=51)



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#### MTBDNA22C1-04 - Qualitative Results Breakdown

Sample Code	Sample Content	Matrix	Sample Relationships	Detection Frequency	Sample Status	Percentage Correct (All)	
						(%)	(n)
MTBDNA22C1-04	M. tuberculosis (DR-RIF-R)	Synthetic CSF		Frequently Detected	CORE	100.0	110



**Groups below n=5:** AB Analitica (n=2), AB Analitica - AB Analitica REALQUALITY RQ (n=2), Amplisens (n=1), Amplisens - AmpliSens Real Time PCR (n=1), AusDiagnostics (n=1), AusDiagnostics - AusDiagnostics TandemPlex (n=1), ELITech Group (n=2), ELITech Group - Elitech Elite Real Time kit (n=2), GeneProof (n=3), GeneProof - GeneProof Real Time PCR kit (n=3), Hain Lifescience (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), Master Diagnostica (n=1), Master Diagnostica - Master Diagnostica Flow Chip (n=1), PathoFinder (n=1), PathoFinder - PathoFinder Real Time PCR (n=1), QIAGEN (n=1), QIAGEN - QIAGEN Artus Real Time (n=1), Seegene - Seegene Allplex (n=1), in-house real-time PCR (n=1), in-house real-time PCR - in-house real-time PCR (n=1), In-House - Conventional In-House PCR (n=1)

**Groups Rolled Up:** BD Molecular Diagnostics - BD MAX (n=5), Cepheid - Cepheid Xpert kit (n=51)

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## Additional Educational Samples Information

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Educational ► Qualitative

## Individual Panel Member Analysis (Qualitative)

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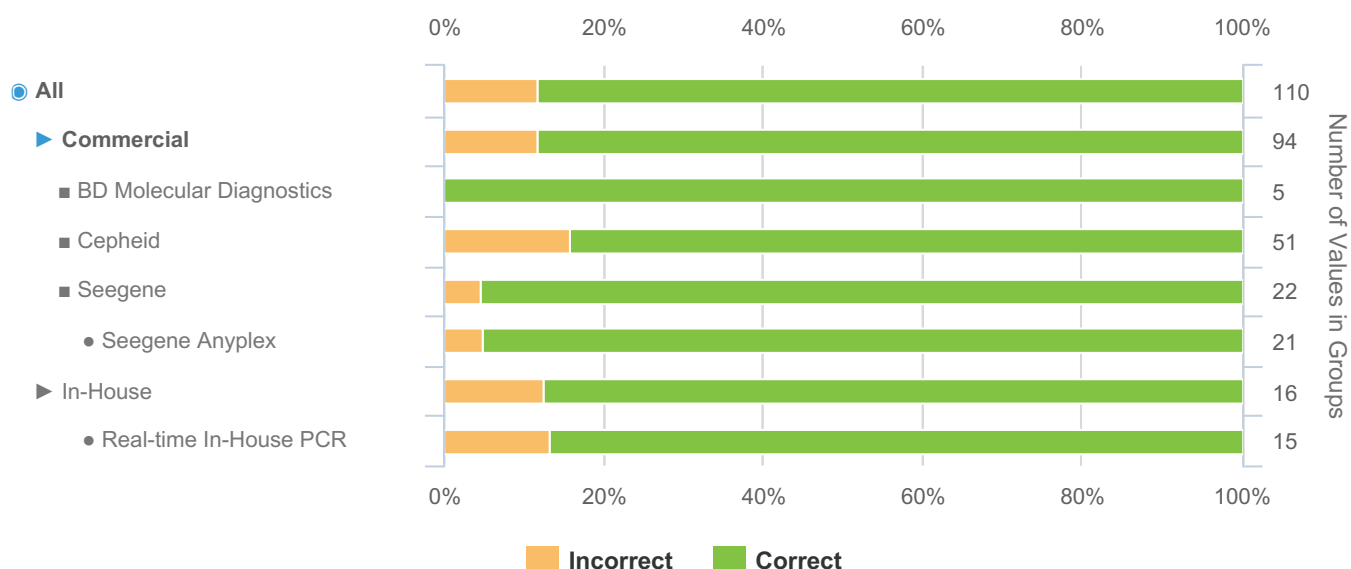
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#### MTBDNA22C1-05 - Qualitative Results Breakdown

Sample Code	Sample Content	Matrix	Sample Relationships	Detection Frequency	Sample Status	Percentage Correct (All)	
						(%)	(n)
MTBDNA22C1-05	M. bovis (BCG)	Synthetic CSF	DS1_3	Detected	EDUCATIONAL	88.2	110



**Groups below n=5:** AB Analitica (n=2), AB Analitica - AB Analitica REALQUALITY RQ (n=2), Amplisens (n=1), Amplisens - AmpliSens Real Time PCR (n=1), AusDiagnostics (n=1), AusDiagnostics - AusDiagnostics TandemPlex (n=1), ELITech Group (n=2), ELITech Group - Elitech Elite Real Time kit (n=2), GeneProof (n=3), GeneProof - GeneProof Real Time PCR kit (n=3), Hain Lifescience (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), Master Diagnostica (n=1), Master Diagnostica - Master Diagnostica Flow Chip (n=1), PathoFinder (n=1), PathoFinder - PathoFinder Real Time PCR (n=1), QIAGEN (n=1), QIAGEN - QIAGEN Artus Real Time (n=1), Seegene - Seegene Allplex (n=1), in-house real-time PCR (n=1), in-house real-time PCR - in-house real-time PCR (n=1), In-House - Conventional In-House PCR (n=1)

**Groups Rolled Up:** BD Molecular Diagnostics - BD MAX (n=5), Cepheid - Cepheid Xpert kit (n=51)

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