


Individual Report	QCMD 2016 Neisseria gonorrhoeae DNA EQA Programme				 <small>Quality Control for Molecular Diagnostics</small>	
Catalogue Code: QAB034126	Ref Code: NgDNA16	Challenge: 1 of 2	Analysis Type: Qualitative	Dataset: 72271	Report UID: 4254/72271/410	Participant: DE182-01

Intended Results / Panel Composition

Sample Code	Sample Content	Matrix	Sample Relationships [1]	Detection Frequency [2]	Sample Status [3]	Percentage Correct (All) [4]	
						(%)	(n)
NgDNA16C1-01	N. gonorrhoeae (St 49226)	Simulated swab	D1	Frequently Detected	CORE	98.4	244
NgDNA16C1-02	N. gonorrhoeae (Lvl Ng PorA)	Urine		Detected	EDUCATIONAL	86.9	244
NgDNA16C1-03	Negative	Urine		Negative	CORE	98.8	244
NgDNA16C1-04	N. gonorrhoeae (St 49226)	Simulated swab	D1	Frequently Detected	CORE	98.8	244
NgDNA16C1-05	Negative	Simulated swab		Negative	CORE	98.8	244

[1] **Sample Relationships:** Indicates the relationships of the samples within this challenge. Dilution series are indicated by 'DS1' with each panel member in the dilution series represented by a number in order of titre, where DS1_1 represents the highest titre within that dilution series. Further dilution series are indicated by 'DS2' 'DS3' 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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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
NgDNA16C1-01	98.4	Positive	0		N/A	30.4
NgDNA16C1-02	86.9	Positive	0		N/A	37.5
NgDNA16C1-03	98.8	Negative	0		N/A	-
NgDNA16C1-04	98.8	Positive	0		N/A	30.4
NgDNA16C1-05	98.8	Negative	0		N/A	-

[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.

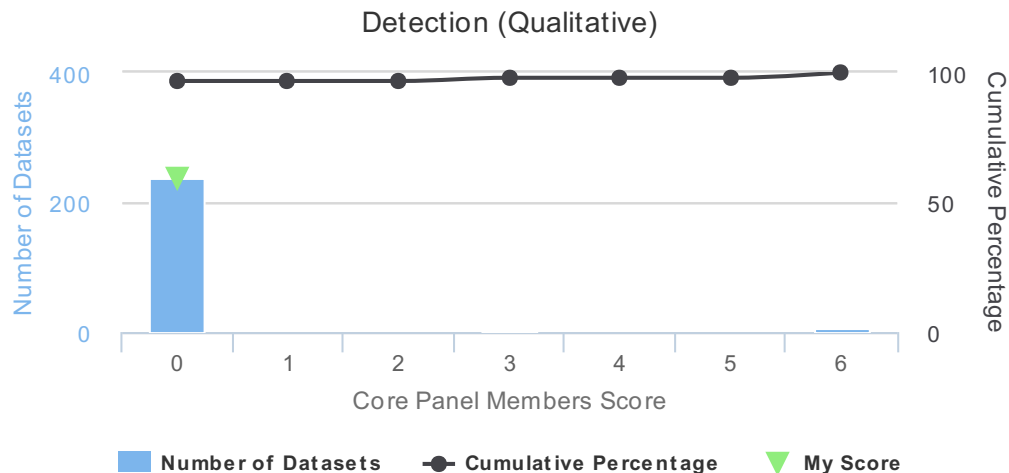
[4] **Percentage Correct (All)** Percentage of datasets (%) reporting the correct qualitative results for each panel member.


[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 used to submit your results for this challenge.


Name	CT/NG Workflow double Kit (v2)
Description	Verwendung RealLine Chlamydia trachomatis / Neisseria gonorrhoeae REF VBD0457
Targets	<ul style="list-style-type: none"> B Chlamydia trachomatis B Neisseria gonorrhoeae
Assays	<ul style="list-style-type: none">  Extraction - Manual Extraction Process <ul style="list-style-type: none"> • Commercial <ul style="list-style-type: none"> ◦ Kit Manufacturer: <i>BIORON Diagnostics GmbH</i> ◦ Kit Type: <i>RealLine DNA Express REF VBC8899</i>  Amplification - DNA Technology - DTlite Real-Time PCR System <ul style="list-style-type: none"> • Commercial <ul style="list-style-type: none"> ◦ Kit Manufacturer: <i>BIORON Diagnostics GmbH</i> ◦ Kit Type: <i>RealLine Chlamydia trachomatis / Neisseria gonorrhoeae REF VBD0457</i> ◦ Kit Version: <i>not applicable</i>

Further Programme Details

Number of Participants	220
Number of Countries	32
Number of Respondents	208
Number of Datasets Submitted	244
Qualitative Results Returned	244 (100.0%)

EQA Programme Aims

To determine the qualitative performance of participants' testing for *Neisseria gonorrhoeae* using molecular technologies.

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

Additional Information: 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.

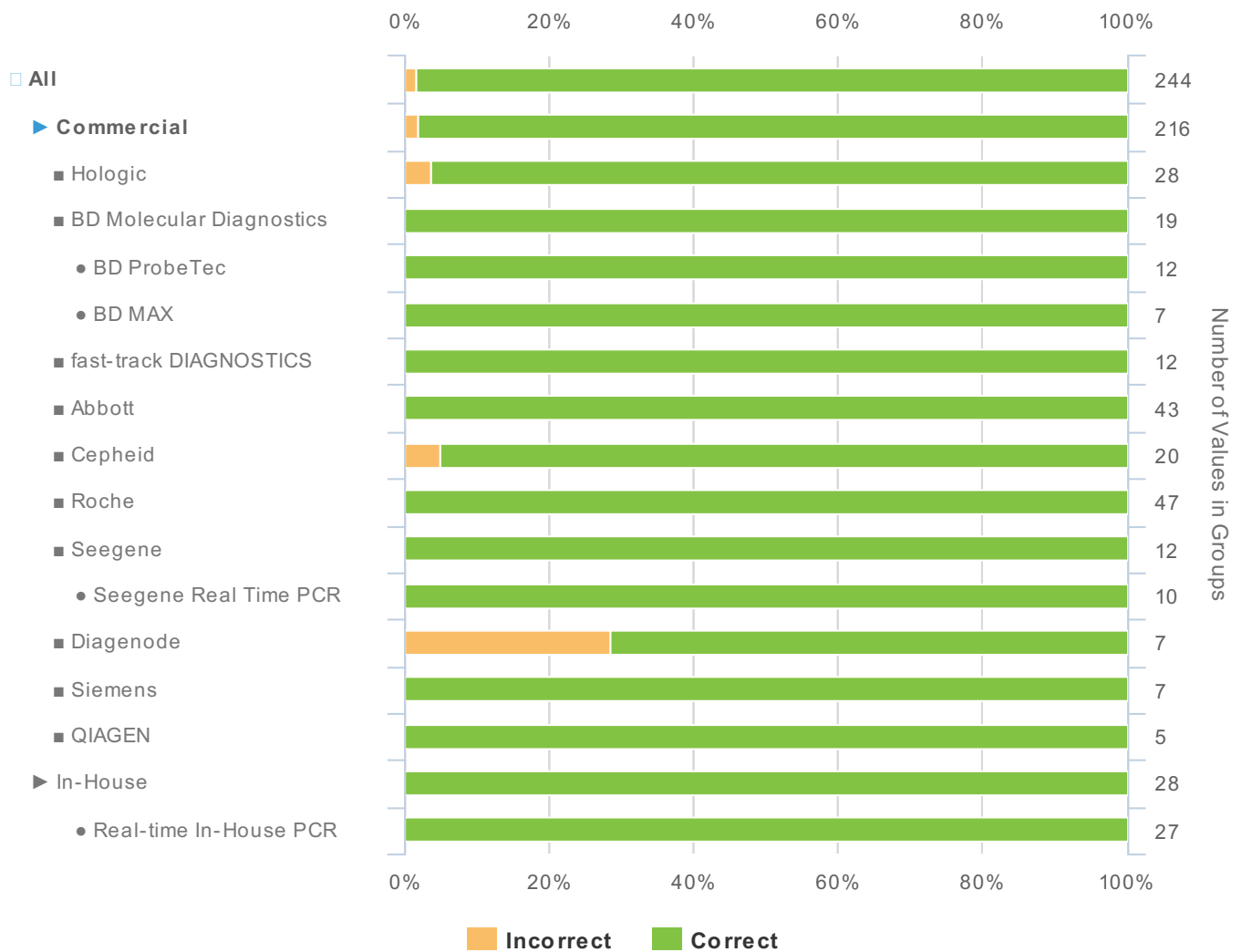
To allow meaningful assessment at the individual method level the EQA assessment group must consist of 5 or more datasets. If there are not sufficient datasets at the individual method level then your results will be included within a higher EQA assessment group based on whether it is a commercial or 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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NgDNA16C1-01 - Qualitative Results Breakdown

Sample Code	Sample Content	Matrix	Sample Relationships	Detection Frequency	Sample Status	Percentage Correct All	
						(%)	(n)
NgDNA16C1-01	N. gonorrhoeae (St 49226)	Simulated swab	D1	Frequently Detected	CORE	98.4	244



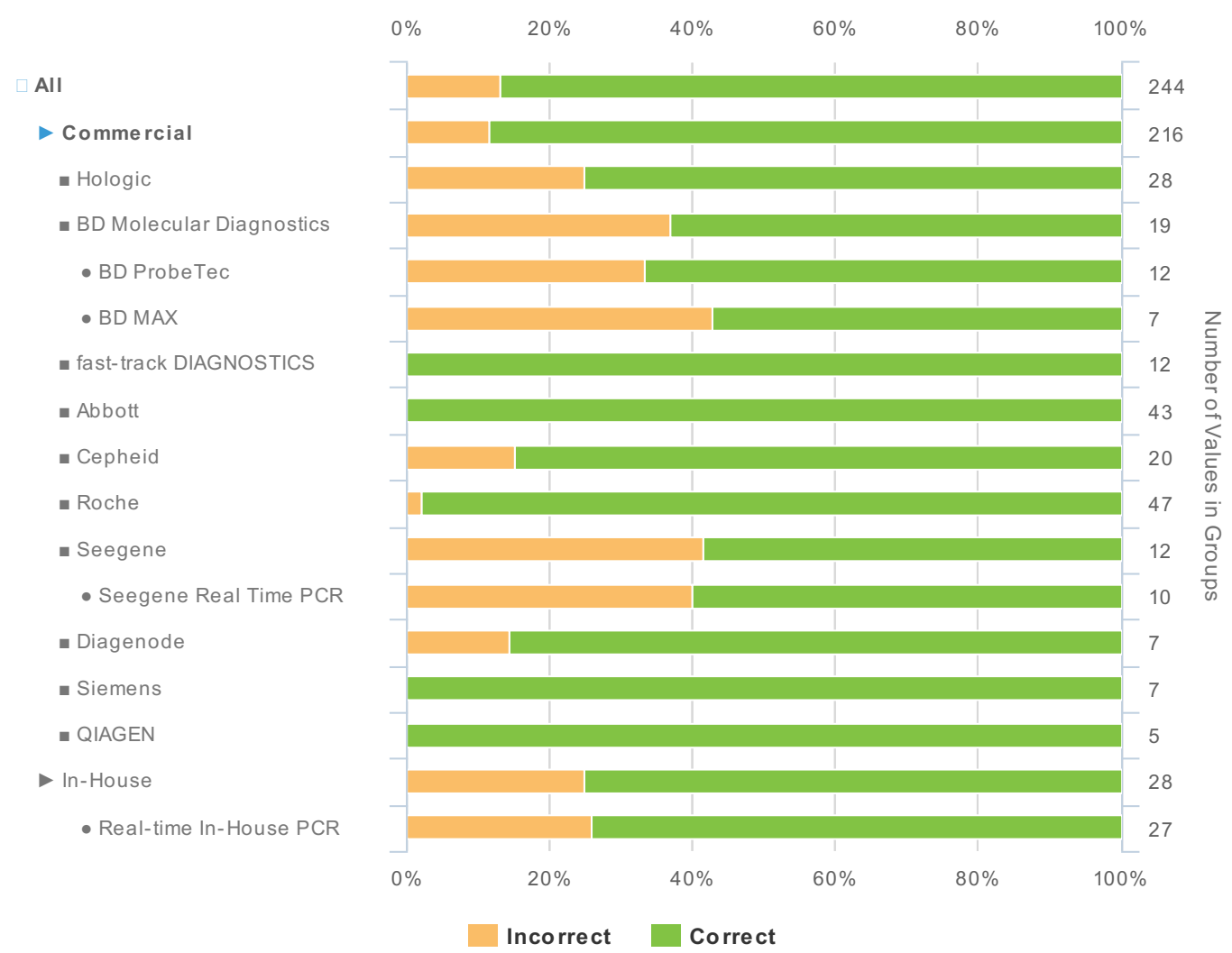
Groups below n=5: Seegene - Seegene Seeplex (n=2), BIORON (n=1), BIORON - BIORON RealLine (n=1), AB Analytica (n=3), AB Analytica - AB Analytica REALQUALITY RQ (n=3), EuroClone Diagnostica (n=2), EuroClone Diagnostica - EuroClone Duplica Real-time (n=2), Goffin Molecular Technologies (n=2), Goffin Molecular Technologies - Goffin Molecular Technologies Presto (n=2), Sacace (n=2), Sacace - Sacace Real TM (n=2), InterLabService (n=1), InterLabService - InterLabService AmpliSens (n=1), TIB MOLBIOL (n=2), TIB MOLBIOL - TIB-MolBioL LightMix (n=2), Randox (n=1), Randox - Randox Multiplex Array (n=1), GeneProof (n=2), GeneProof - GeneProof Real Time PCR kit (n=2), In-House - Conventional In-House PCR (n=1)


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Groups Rolled Up: Hologic - Hologic Aptima (n=28), fast-track DIAGNOSTICS - FTD Real Time PCR (n=12), Abbott - Abbott Realtime (n=43), Cepheid - Cepheid Xpert kit (n=20), Roche - Roche Cobas 4800 (n=47), Diagenode - Diagenode Real Time kit (n=7), Siemens - Siemens Versant (n=7), QIAGEN - Qiagen Artus Real Time (n=5)

NgDNA16C1-02 - Qualitative Results Breakdown


Sample Code	Sample Content	Matrix	Sample Relationships	Detection Frequency	Sample Status	Percentage Correct All	
						(%)	(n)
NgDNA16C1-02	N. gonorrhoeae (Lvl Ng PorA)	Urine		Detected	EDUCATIONAL	86.9	244



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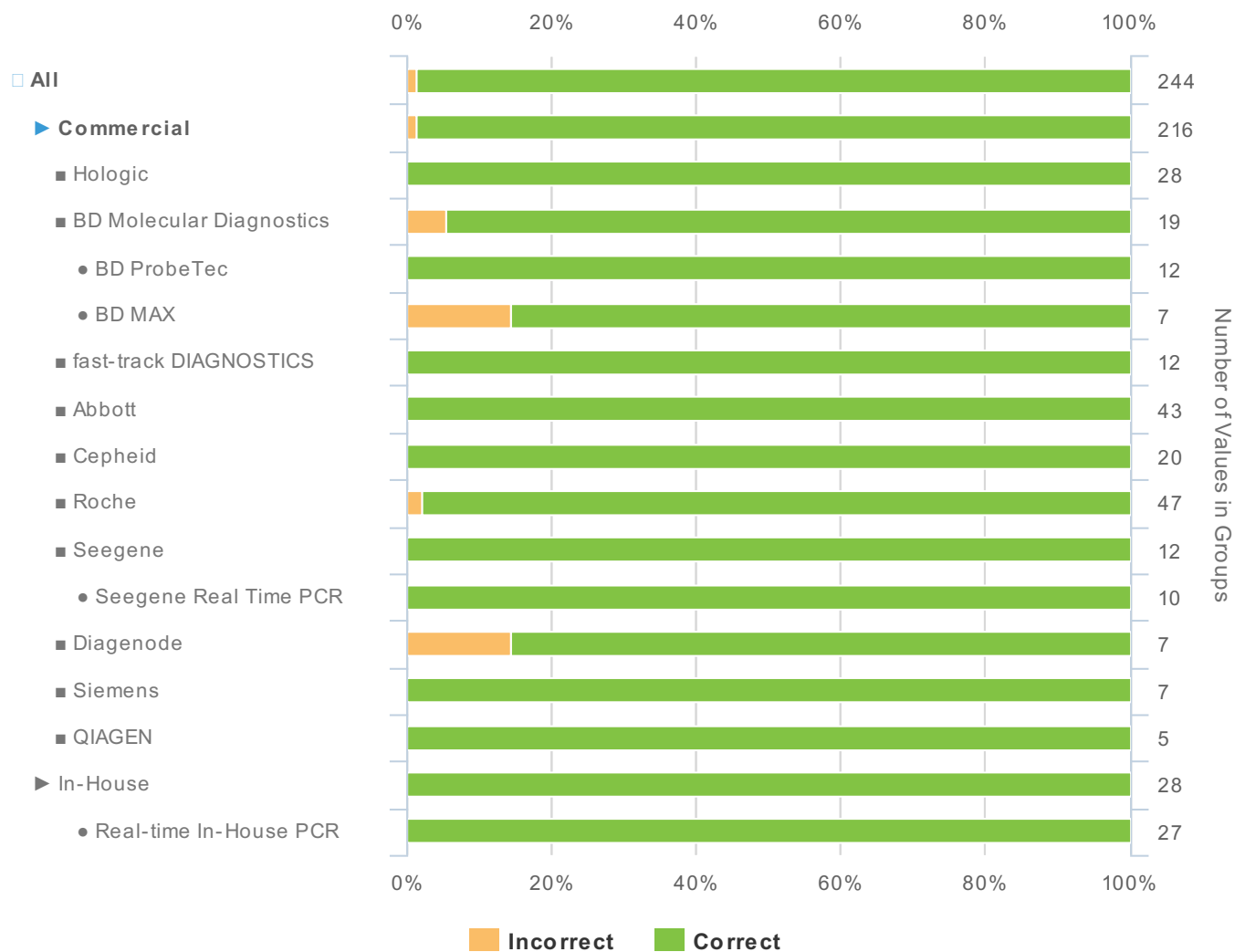
Groups below n=5: Seegene - Seegene Seeplex (n=2), BIORON (n=1), BIORON - BIORON RealLine (n=1), AB Analytica (n=3), AB Analytica - AB Analytica REALQUALITY RQ (n=3), EuroClone Diagnostica (n=2), EuroClone Diagnostica - EuroClone Duplica Real-time (n=2), Goffin Molecular Technologies (n=2), Goffin Molecular Technologies - Goffin Molecular Technologies Presto (n=2), Sacace (n=2), Sacace - Sacace Real TM (n=2), InterLabService (n=1), InterLabService - InterLabService AmpliSens (n=1), TIB MOLBIOL (n=2), TIB MOLBIOL - TIB-MolBioI LightMix (n=2), Randox (n=1), Randox - Randox Multiplex Array (n=1), GeneProof (n=2), GeneProof - GeneProof Real Time PCR kit (n=2), In-House - Conventional In-House PCR (n=1)

Groups Rolled Up: Hologic - Hologic Aptima (n=28), fast-track DIAGNOSTICS - FTD Real Time PCR (n=12), Abbott - Abbott Realtime (n=43), Cepheid - Cepheid Xpert kit (n=20), Roche - Roche Cobas 4800 (n=47), Diagenode - Diagenode Real Time kit (n=7), Siemens - Siemens Versant (n=7), QIAGEN - Qiagen Artus Real Time (n=5)


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NgDNA16C1-03 - Qualitative Results Breakdown

Sample Code	Sample Content	Matrix	Sample Relationships	Detection Frequency	Sample Status	Percentage Correct All	
						(%)	(n)
NgDNA16C1-03	Negative	Urine		Negative	CORE	98.8	244



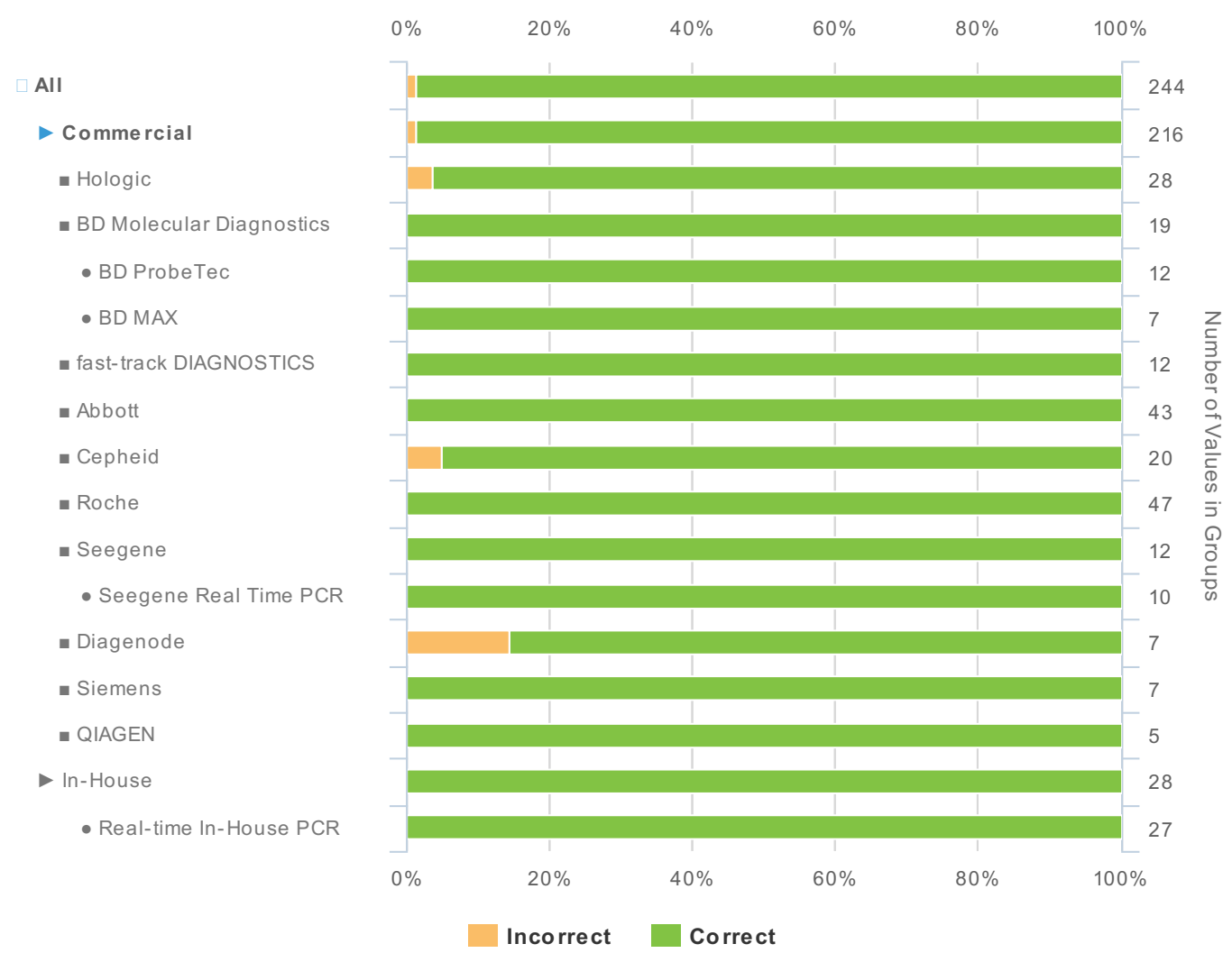
Groups below n=5: Seegene - Seegene Seeplex (n=2), BIORON (n=1), BIORON - BIORON RealLine (n=1), AB Analytica (n=3), AB Analytica - AB Analytica REALQUALITY RQ (n=3), EuroClone Diagnostica (n=2), EuroClone Diagnostica - EuroClone Duplica Real-time (n=2), Goffin Molecular Technologies (n=2), Goffin Molecular Technologies - Goffin Molecular Technologies Presto (n=2), Sacace (n=2), Sacace - Sacace Real TM (n=2), InterLabService (n=1), InterLabService - InterLabService AmpliSens (n=1), TIB MOLBIOL (n=2), TIB MOLBIOL - TIB-MolBiol LightMix (n=2), Randox (n=1), Randox - Randox Multiplex Array (n=1), GeneProof (n=2), GeneProof - GeneProof Real Time PCR kit (n=2), In-House - Conventional In-House PCR (n=1)


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Groups Rolled Up: Hologic - Hologic Aptima (n=28), fast-track DIAGNOSTICS - FTD Real Time PCR (n=12), Abbott - Abbott Realtime (n=43), Cepheid - Cepheid Xpert kit (n=20), Roche - Roche Cobas 4800 (n=47), Diagenode - Diagenode Real Time kit (n=7), Siemens - Siemens Versant (n=7), QIAGEN - Qiagen Artus Real Time (n=5)

NgDNA16C1-04 - Qualitative Results Breakdown


Sample Code	Sample Content	Matrix	Sample Relationships	Detection Frequency	Sample Status	Percentage Correct All	
						(%)	(n)
NgDNA16C1-04	N. gonorrhoeae (St 49226)	Simulated swab	D1	Frequently Detected	CORE	98.8	244



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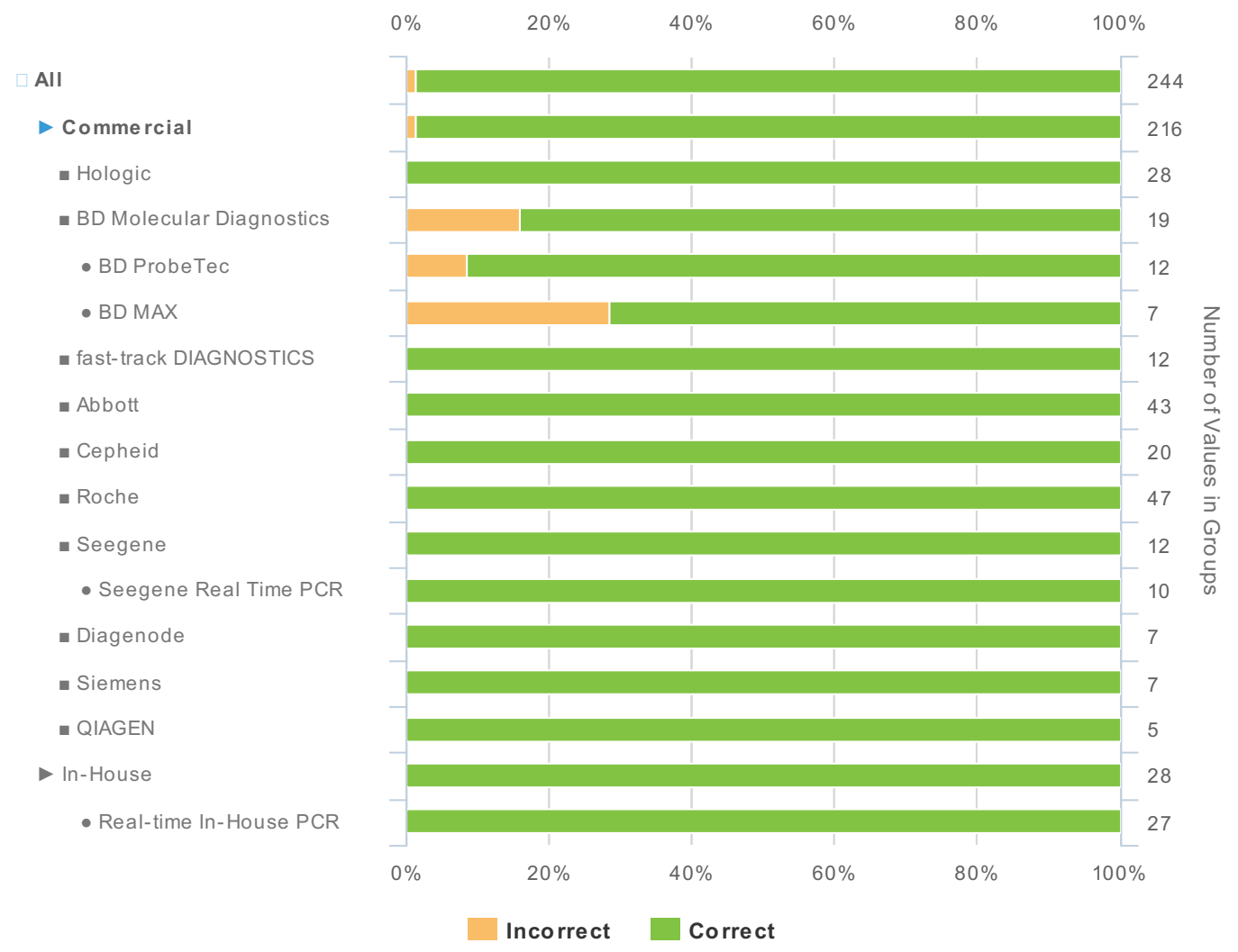
Groups below n=5: Seegene - Seegene Seeplex (n=2), BIORON (n=1), BIORON - BIORON RealLine (n=1), AB Analytica (n=3), AB Analytica - AB Analytica REALQUALITY RQ (n=3), EuroClone Diagnostica (n=2), EuroClone Diagnostica - EuroClone Duplica Real-time (n=2), Goffin Molecular Technologies (n=2), Goffin Molecular Technologies - Goffin Molecular Technologies Presto (n=2), Sacace (n=2), Sacace - Sacace Real TM (n=2), InterLabService (n=1), InterLabService - InterLabService AmpliSens (n=1), TIB MOLBIOL (n=2), TIB MOLBIOL - TIB-MolBioI LightMix (n=2), Randox (n=1), Randox - Randox Multiplex Array (n=1), GeneProof (n=2), GeneProof - GeneProof Real Time PCR kit (n=2), In-House - Conventional In-House PCR (n=1)

Groups Rolled Up: Hologic - Hologic Aptima (n=28), fast-track DIAGNOSTICS - FTD Real Time PCR (n=12), Abbott - Abbott Realtime (n=43), Cepheid - Cepheid Xpert kit (n=20), Roche - Roche Cobas 4800 (n=47), Diagenode - Diagenode Real Time kit (n=7), Siemens - Siemens Versant (n=7), QIAGEN - Qiagen Artus Real Time (n=5)


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NgDNA16C1-05 - Qualitative Results Breakdown

Sample Code	Sample Content	Matrix	Sample Relationships	Detection Frequency	Sample Status	Percentage Correct All	
						(%)	(n)
NgDNA16C1-05	Negative	Simulated swab		Negative	CORE	98.8	244



Groups below n=5: Seegene - Seegene Seeplex (n=2), BIORON (n=1), BIORON - BIORON RealLine (n=1), AB Analytica (n=3), AB Analytica - AB Analytica REALQUALITY RQ (n=3), EuroClone Diagnostica (n=2), EuroClone Diagnostica - EuroClone Duplica Real-time (n=2), Goffin Molecular Technologies (n=2), Goffin Molecular Technologies - Goffin Molecular Technologies Presto (n=2), Sacace (n=2), Sacace - Sacace Real TM (n=2), InterLabService (n=1), InterLabService - InterLabService AmpliSens (n=1), TIB MOLBIOL (n=2), TIB MOLBIOL - TIB-MolBioI LightMix (n=2), Randox (n=1), Randox - Randox Multiplex Array (n=1), GeneProof (n=2), GeneProof - GeneProof Real Time PCR kit (n=2), In-House - Conventional In-House PCR (n=1)

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