Individual Report	QCMD 2020 Central Nervous System I (Viral Meningitis and Encephalitis) EQA Pilot Study	QCMD Quality Control for Molecular Diagnostics

Catalogue Code:	Ref Code:	Challenge:	Analysis Type:	Dataset:	Report UID:	Laboratory
QAV174195	CNSI20	S	Multiple Pathogen Qualitative	-	0/0/2913	

NOTE: Summary information only.

Panel Composition

Sample Code	Sample Content	Matrix	Sample Relationships[1]	Detected / Determined[2]		Not Detected / Not Determined[2]		Not Tested[2]	
				(%)	*(n)*	*(%)*	*(n)*	*(%)*	*(n)*
CNSI101S-01	Herpes Simplex Virus Type 1	Transport Medium		76.5	62	14.8	12	8.6	7
CNSI101S-02	Parechovirus Type 3	Transport Medium		69.1	56	1.2	1	29.6	24
CNSI101S-03	Varicella-Zoster Virus (9/84)	Transport Medium		88.9	72	2.5	2	8.6	7
CNSI101S-04	Negative	Transport Medium		96.3	78	3.7	3	N/A	0
CNSI101S-05	Enterovirus A71	Transport Medium		90.1	73	6.2	5	3.7	3
CNSI101S-06	Varicella-Zoster Virus (Ellen)	Transport Medium		87.7	71	3.7	3	8.6	7
CNSI101S-07	Herpes Simplex Virus Type 2	Transport Medium		87.7	71	4.9	4	7.4	6
CNSI101S-08	Parechovirus Type 1	Transport Medium		63	51	7.4	6	29.6	24
CNSI101S-09	Echovirus 30	Transport Medium		88.9	72	7.4	6	3.7	3
CNSI101S-10	Herpes Simplex Virus Type 1	Transport Medium		85.2	69	7.4	6	7.4	6

[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] **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 Reported Result[3]			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]			
CNSI101S-01	Positive	Herpes simplex virus	-	-	-	Core	Detected	-
CNSI101S-02	Positive	Parechovirus	-	-	-	Core	Frequently Detected	-
CNSI101S-03	Positive	Varicella-zoster virus	-	-	-	Core	Frequently Detected	-
CNSI101S-04	Negative		-	-	-	Core	Negative	-
CNSI101S-05	Positive	Enterovirus	-	-	-	Core	Detected	-
CNSI101S-06	Positive	Varicella-zoster virus	-	-	-	Core	Frequently Detected	-
CNSI101S-07	Positive	Herpes simplex virus	-	-	-	Core	Detected	-
CNSI101S-08	Positive	Parechovirus	-	-	-	Core	Detected	-
CNSI101S-09	Positive	Enterovirus	-	-	-	Core	Detected	-
CNSI101S-10	Positive	Herpes simplex virus	-	-	-	Core	Detected	-

[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.

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

[6] **Reported Pathogen ID:** The final pathogen(s) identification you reported for each sample within this EQA challenge / distribution.

[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"

For further details please refer to the current participant manual.

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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.

	Laboratory Reported Results						Result Category		Sample Weighting			
Expected Qualitative Result	Positive	Negative	Not Determined	Expected pathogen(s) included in workflow(s)		Expected pathogen(s) not included in workflow(s)			Frequently Detected (>95% positive)	Detected (Between 65 and 95% positive)	Infrequently Detected (Less than 65% positive)	Negative
				Expected pathogen(s) detected	Expected pathogen(s) not detected							
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:

N/A

Further Programme Details

Number of Participants	101
Number of Countries	21
Number of Respondents	80
Number of Datasets Submitted	81

Comments

A number of laboratories who tested the CNSI20S panel using the BioFire FilmArray system returned "not determined" results for some of the samples included in this distribution stating that they had chosen not to test selected samples.

According to the current QCMD scoring system, all results returned as "not determined" are assessed/scored as being incorrect. Therefore please note under the Individual Panel Member Analysis section of this report, the "incorrect" results highlighted within the BioFire FilmArray EQA assessment groups also include these results.

A breakdown of the impacted datasets returned with "not determined" is shown below.

CNSI101S-01 - one dataset

CNSI101S-02 - one dataset

CNSI101S-03 - one dataset

CNSI101S-04 - one dataset

CNSI101S-05 - one dataset

CNSI101S-06 - three datasets

CNSI101S-07 - two datasets

CNSI101S-08 - two datasets

CNSI101S-09 - two datasets

CNSI101S-10 - three datasets

EQA Programme Aims

The central nervous system I (viral) EQA pilot study focuses on the molecular detection and determination of various enterovirus, parechovirus, herpes simplex virus 1/2, Varicella-Zoster virus and JC virus strains.

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.

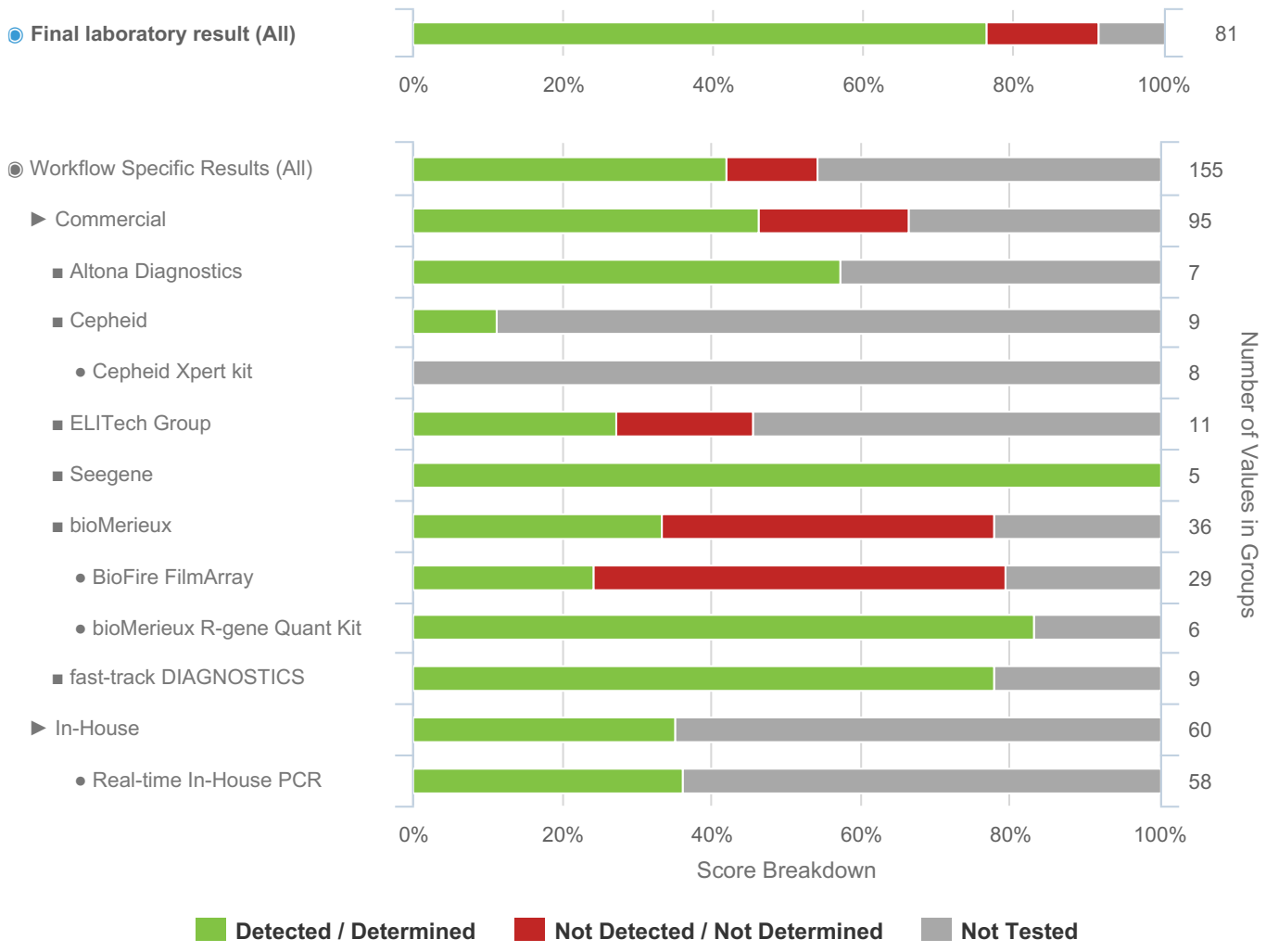
To allow meaningful assessment at the individual method level the EQA assessment group must consist of 5 or more datasets. If there are not sufficient datasets at the individual method level then your results will be included within a higher EQA assessment group based on whether it is a commercial or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

Catalogue Code:	Ref Code:	Challenge:	Analysis Type:	Dataset:	Report UID:	Laboratory
QAV174195	CNSI20	S	Multiple Pathogen Qualitative	-	0/0/2913	

Sample Code	Sample Content	Matrix	Sample Relationships	Expected targets	Detected / Determined		Not Detected / Not Determined		Not Tested	
					(%)	*(n)*	*(%)*	*(n)*	*(%)*	*(n)*
CNSI101S-01	Herpes Simplex Virus Type 1	Transport Medium		Herpes simplex virus	76.5	62	14.8	12	8.6	7



Individual Report

QCMD 2020 Central Nervous System I (Viral Meningitis and Encephalitis) EQA Pilot Study

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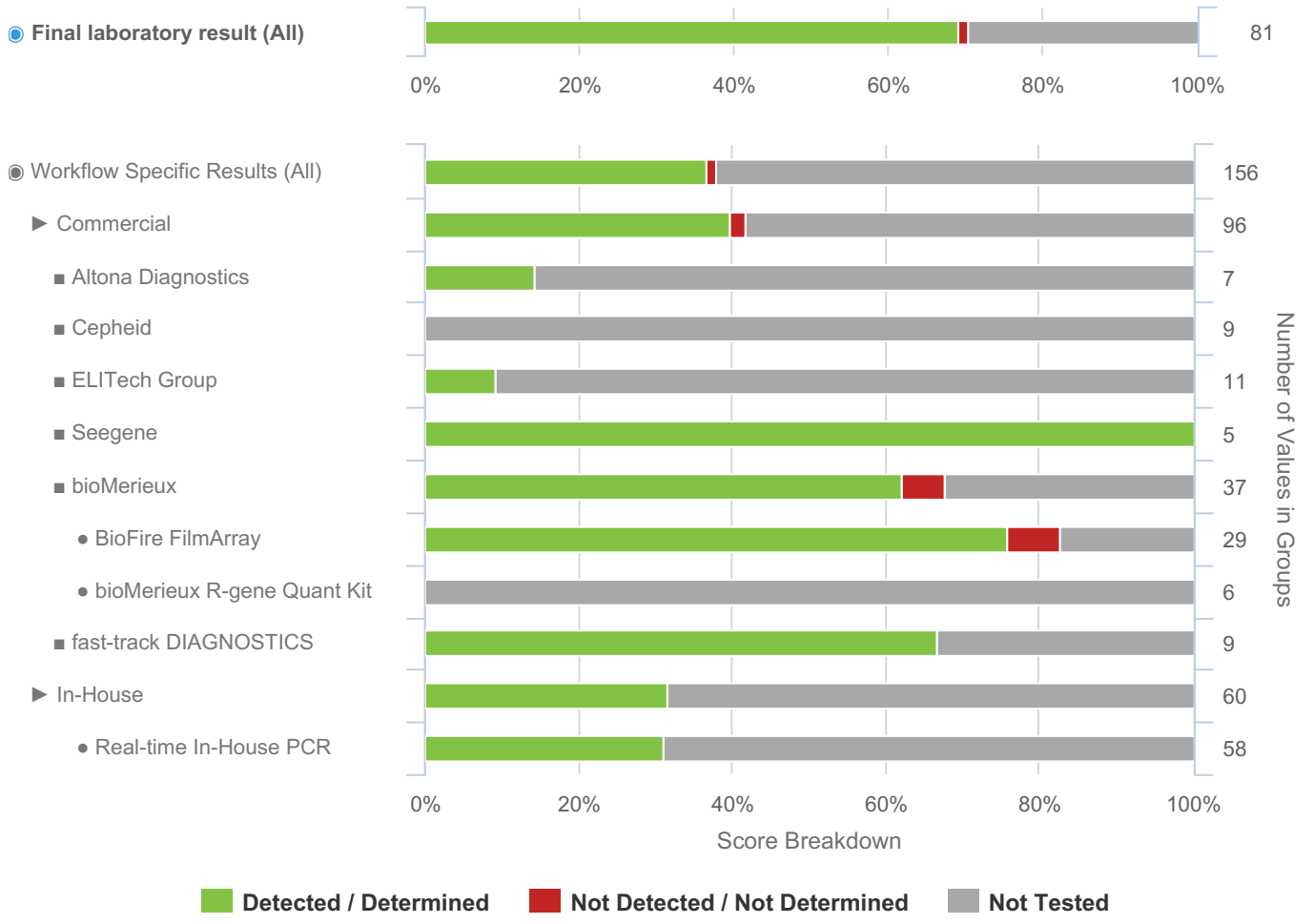
QAV174195	CNSI20	S	Multiple Pathogen Qualitative	-	0/0/2913	

Groups below n=5: AITbiotech (n=1), AITbiotech - AITbiotech Real Time PCR (n=1), Amplex (n=1), Amplex - Amplex Easy-Plex (n=1), AusDiagnostics (n=1), AusDiagnostics - AusDiagnostics Easy-Plex (n=1), Cepheid - Cepheid SmartCycler (n=1), Certest (n=1), Certest - Certest Real Time PCR (n=1), Diagenode (n=2), Diagenode - Diagenode Real Time kit (n=2), Diasorin (n=2), Diasorin - DiaSorin Simplexa (n=2), InterLabService (n=1), InterLabService - InterLabService AmpliSens (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 (n=1), Roche - Roche Cobas 4800 (n=1), Sacace (n=1), Sacace - Sacace Real TM (n=1), Seegene - Seegene Real Time PCR (n=4), Seegene - Seegene Seeplex (n=1), TIB MOLBIOL (n=1), TIB MOLBIOL - TIB-MolBiol LightMix (n=1), bioMerieux - bioMerieux R-gene Kit (n=1), In-House - Conventional In-House PCR (n=2)

Groups Rolled Up: Altona Diagnostics - Altona Diagnostics RealStar (n=7), ELITech Group - Elitech Elite Real Time kit (n=11), fast-track DIAGNOSTICS - FTD real time PCR (n=9)

Sample Code	Sample Content	Matrix	Sample Relationships	Expected targets	Detected / Determined		Not Detected / Not Determined		Not Tested	
					(%)	*(n)*	*(%)*	*(n)*	*(%)*	*(n)*
CNSI101S-02	Parechovirus Type 3	Transport Medium		Parechovirus	69.1	56	1.2	1	29.6	24



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QAV174195	CNSI20	S	Multiple Pathogen Qualitative	-	0/0/2913	

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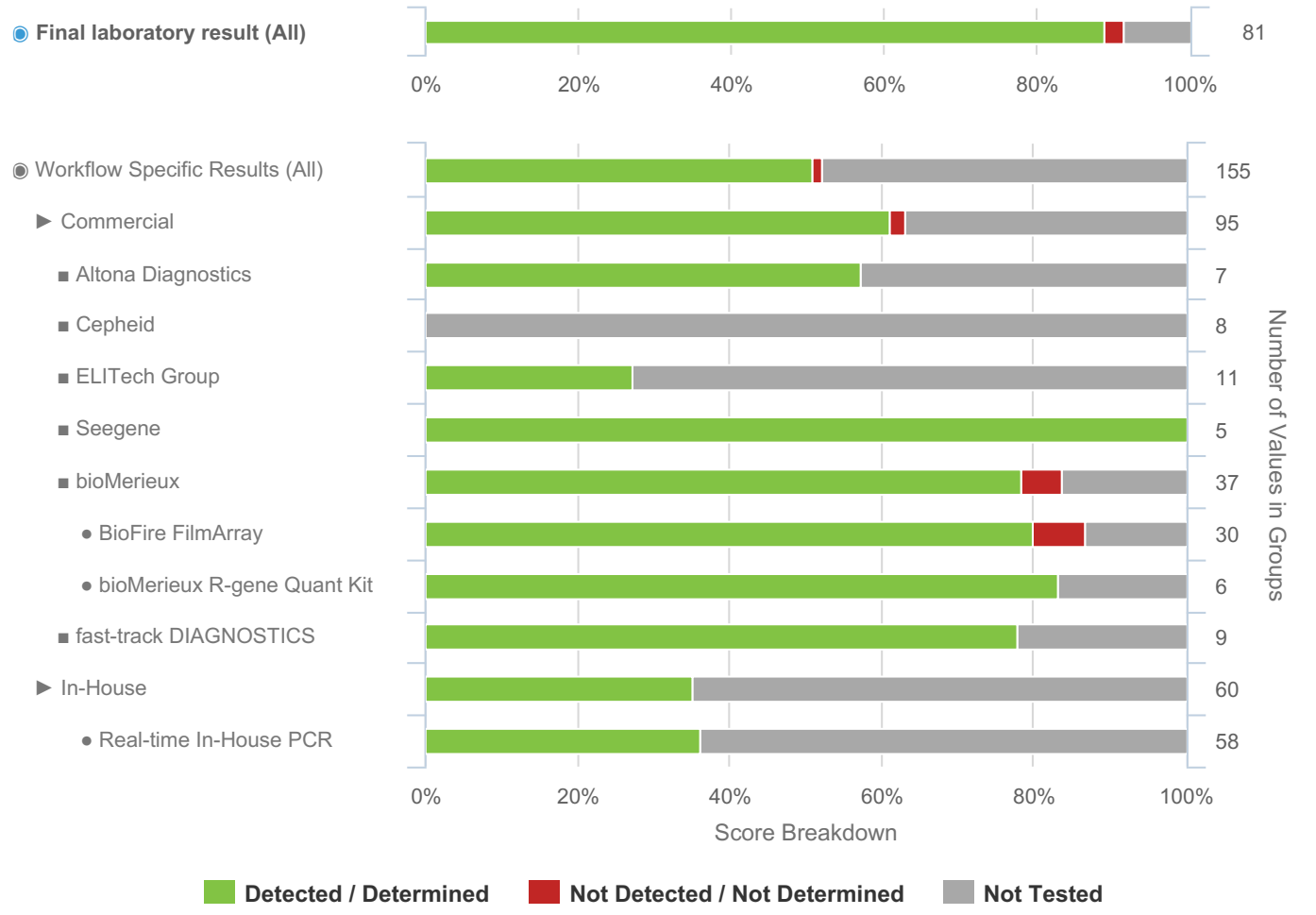
Groups Rolled Up: Altona Diagnostics - Altona Diagnostics RealStar (n=7), Cepheid - Cepheid Xpert kit (n=9), ELITech Group - Elitech Elite Real Time kit (n=11), fast-track DIAGNOSTICS - FTD real time PCR (n=9)

Sample Code	Sample Content	Matrix	Sample Relationships	Expected targets	Detected / Determined		Not Detected / Not Determined		Not Tested	
					(%)	*(n)*	*(%)*	*(n)*	*(%)*	*(n)*
CNSI101S-03	Varicella-Zoster Virus (9/84)	Transport Medium		Varicella-zoster virus	88.9	72	2.5	2	8.6	7



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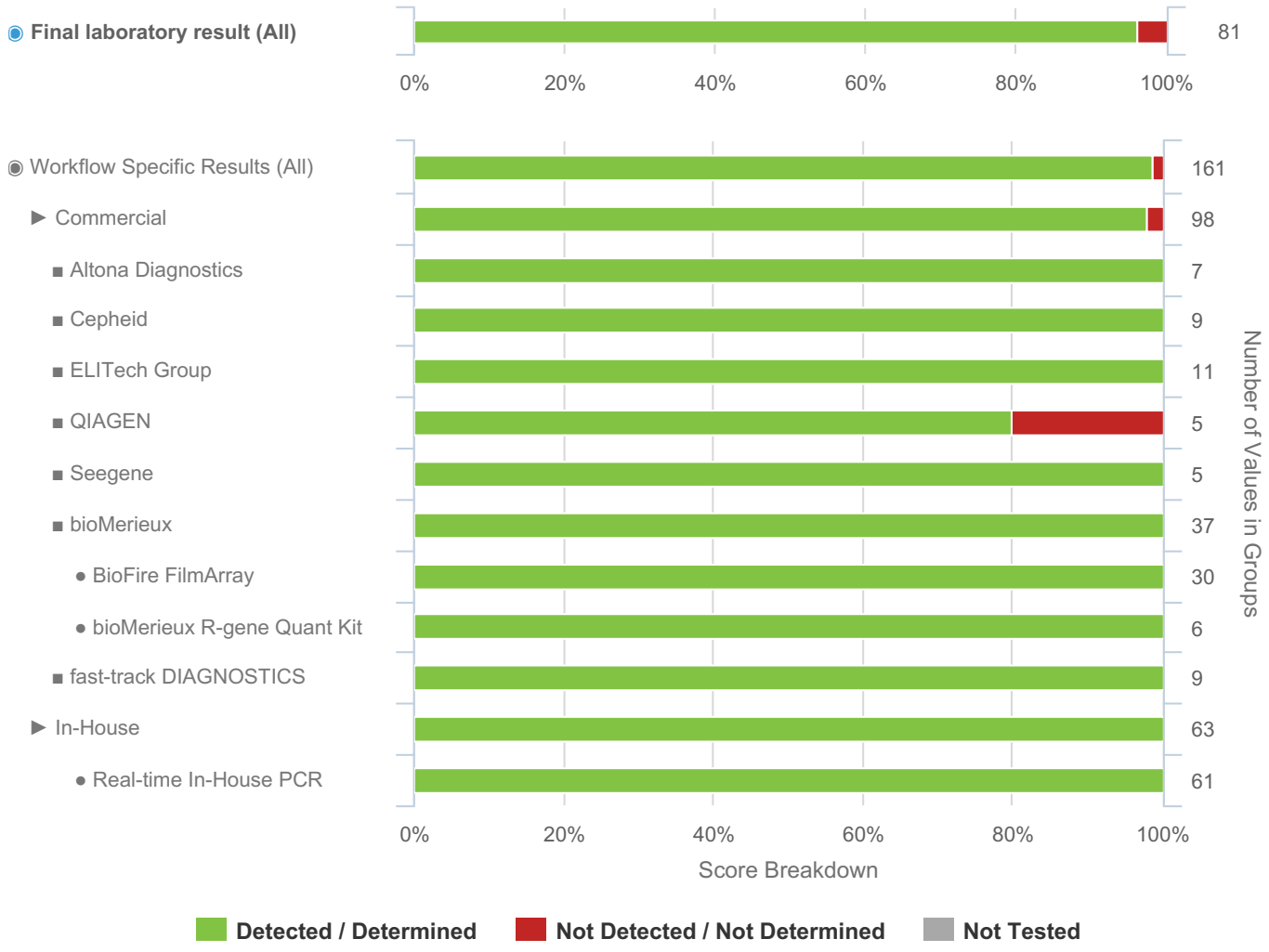
Groups Rolled Up: Altona Diagnostics - Altona Diagnostics RealStar (n=7), Cepheid - Cepheid Xpert kit (n=8), ELITech Group - Elitech Elite Real Time kit (n=11), fast-track DIAGNOSTICS - FTD real time PCR (n=9)

Sample Code	Sample Content	Matrix	Sample Relationships	Expected targets	Detected / Determined		Not Detected / Not Determined		Not Tested	
					(%)	*(n)*	*(%)*	*(n)*	*(%)*	*(n)*
CNSI101S-04	Negative	Transport Medium			96.3	78	3.7	3	N/A	0



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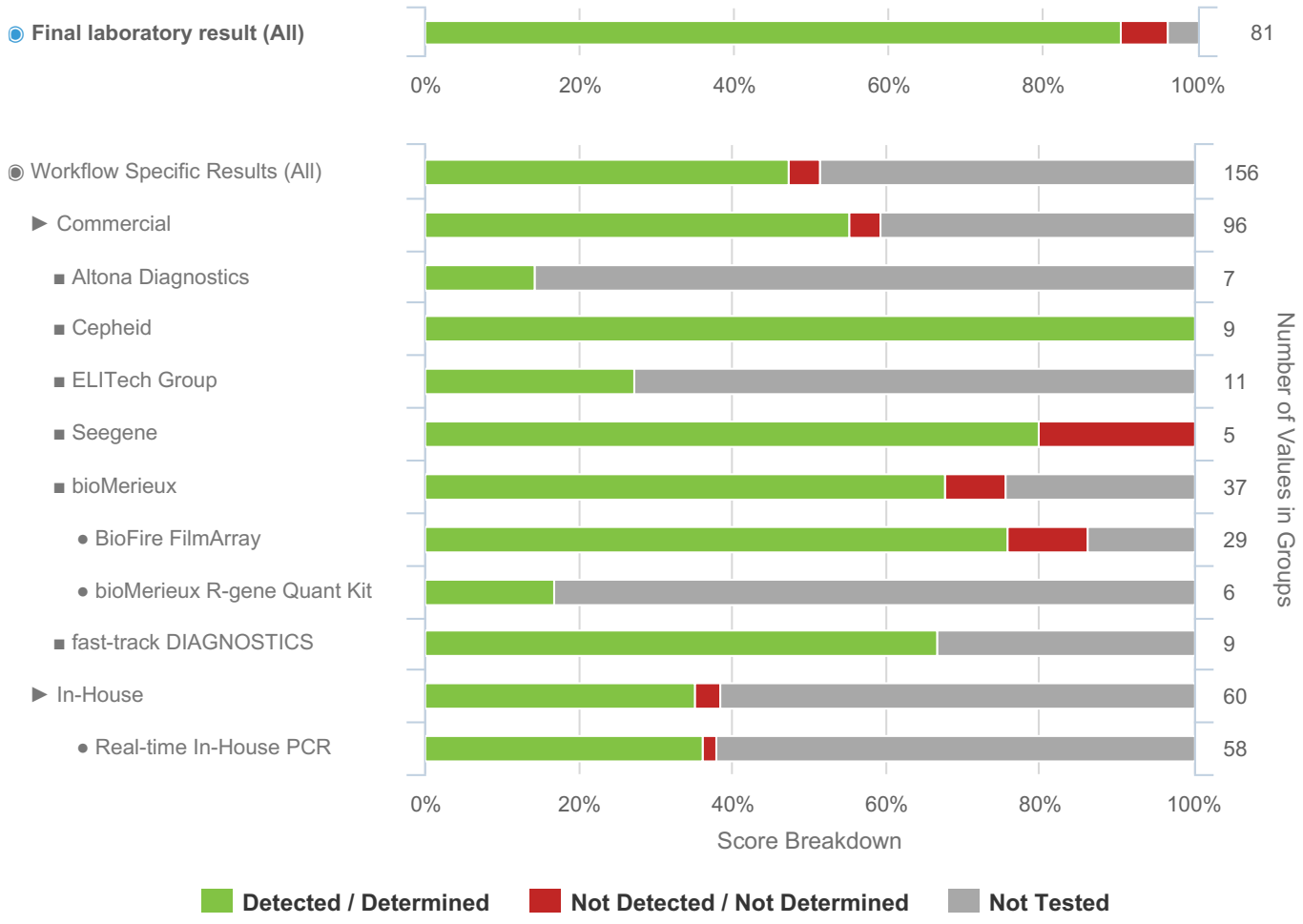
Groups Rolled Up: Altona Diagnostics - Altona Diagnostics RealStar (n=7), Cepheid - Cepheid Xpert kit (n=9), ELITech Group - Elitech Elite Real Time kit (n=11), QIAGEN - QIAGEN Artus Real Time (n=5), fast-track DIAGNOSTICS - FTD real time PCR (n=9)

Sample Code	Sample Content	Matrix	Sample Relationships	Expected targets	Detected / Determined		Not Detected / Not Determined		Not Tested	
					(%)	*(n)*	*(%)*	*(n)*	*(%)*	*(n)*
CNSI101S-05	Enterovirus A71	Transport Medium		Enterovirus	90.1	73	6.2	5	3.7	3



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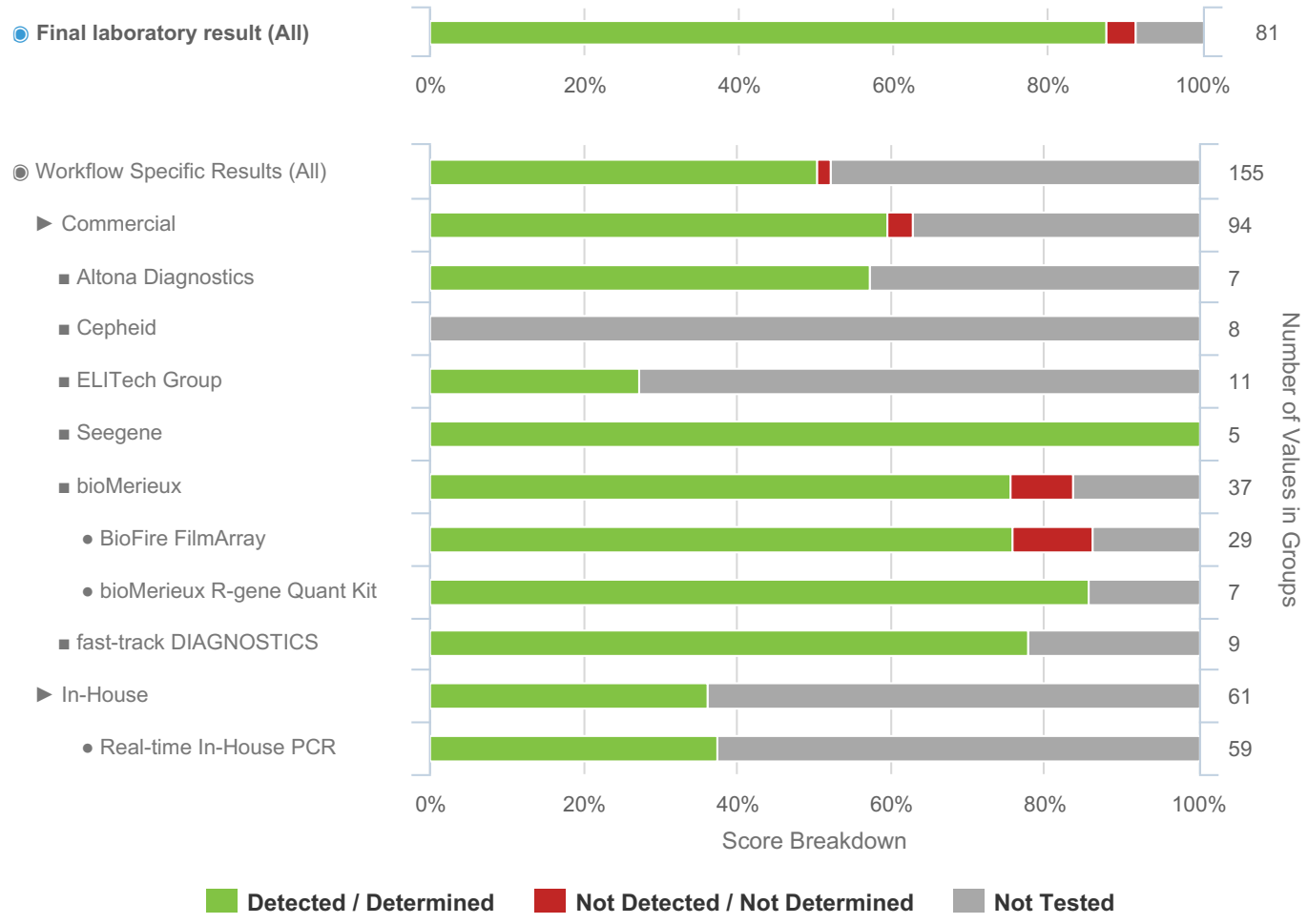
Groups Rolled Up: Altona Diagnostics - Altona Diagnostics RealStar (n=7), Cepheid - Cepheid Xpert kit (n=9), ELITech Group - Elitech Elite Real Time kit (n=11), fast-track DIAGNOSTICS - FTD real time PCR (n=9)

Sample Code	Sample Content	Matrix	Sample Relationships	Expected targets	Detected / Determined		Not Detected / Not Determined		Not Tested	
					(%)	*(n)*	*(%)*	*(n)*	*(%)*	*(n)*
CNSI101S-06	Varicella-Zoster Virus (Ellen)	Transport Medium		Varicella-zoster virus	87.7	71	3.7	3	8.6	7



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Groups Rolled Up: Altona Diagnostics - Altona Diagnostics RealStar (n=7), Cepheid - Cepheid Xpert kit (n=8), ELITech Group - Elitech Elite Real Time kit (n=11), fast-track DIAGNOSTICS - FTD real time PCR (n=9)

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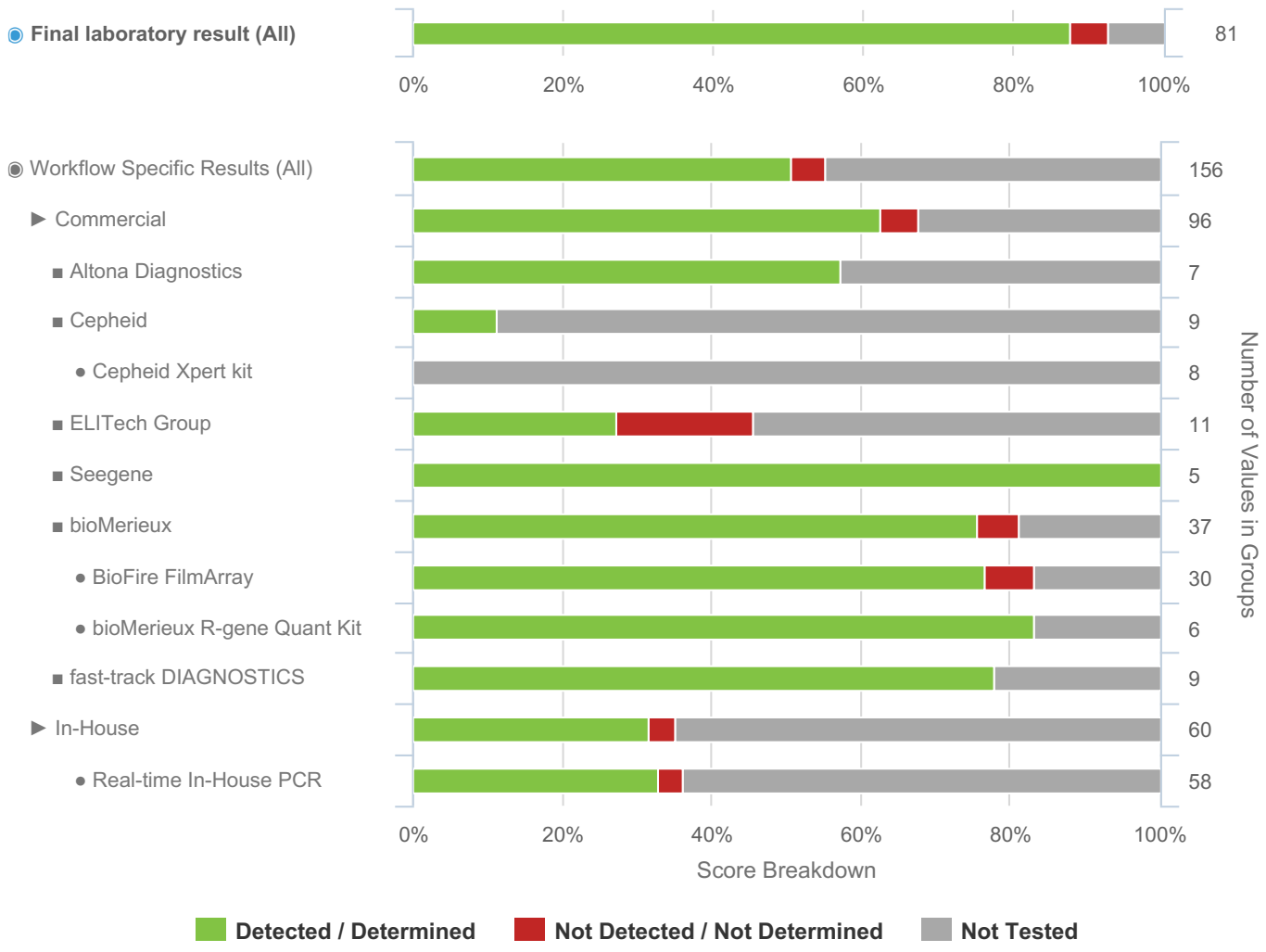
QAV174195	CNSI20	S	Multiple Pathogen Qualitative	-	0/0/2913	

Sample Code	Sample Content	Matrix	Sample Relationships	Expected targets	Detected / Determined		Not Detected / Not Determined		Not Tested	
					(%)	*(n)*	*(%)*	*(n)*	*(%)*	*(n)*
CNSI101S-07	Herpes Simplex Virus Type 2	Transport Medium		Herpes simplex virus	87.7	71	4.9	4	7.4	6



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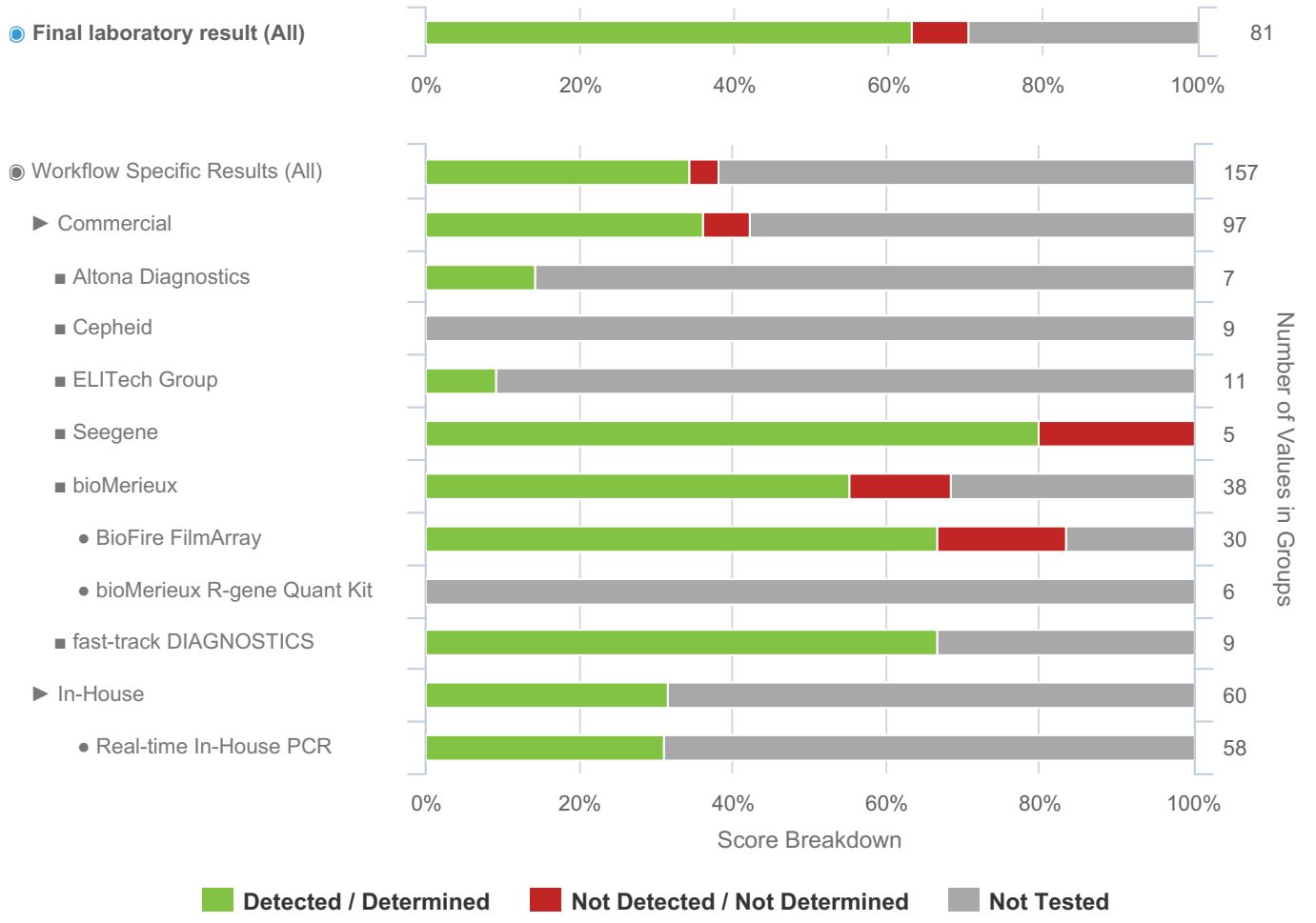
Groups below n=5: AITbiotech (n=1), AITbiotech - AITbiotech Real Time PCR (n=1), Amplex (n=1), Amplex - Amplex Easy-Plex (n=1), AusDiagnostics (n=1), AusDiagnostics - AusDiagnostics Easy-Plex (n=1), Cepheid - Cepheid SmartCycler (n=1), Certest (n=1), Certest - Certest Real Time PCR (n=1), Diagenode (n=2), Diagenode - Diagenode Real Time kit (n=2), Diasorin (n=2), Diasorin - DiaSorin Simplexa (n=2), InterLabService (n=1), InterLabService - InterLabService AmpliSens (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 (n=1), Roche - Roche Cobas 4800 (n=1), Sacace (n=1), Sacace - Sacace Real TM (n=1), Seegene - Seegene Real Time PCR (n=4), Seegene - Seegene Seeplex (n=1), TIB MOLBIOL (n=1), TIB MOLBIOL - TIB-MolBiol LightMix (n=1), bioMerieux - bioMerieux R-gene Kit (n=1), In-House - Conventional In-House PCR (n=2)

Groups Rolled Up: Altona Diagnostics - Altona Diagnostics RealStar (n=7), ELITech Group - Elitech Elite Real Time kit (n=11), fast-track DIAGNOSTICS - FTD real time PCR (n=9)

Sample Code	Sample Content	Matrix	Sample Relationships	Expected targets	Detected / Determined		Not Detected / Not Determined		Not Tested	
					(%)	*(n)*	*(%)*	*(n)*	*(%)*	*(n)*
CNSI101S-08	Parechovirus Type 1	Transport Medium		Parechovirus	63	51	7.4	6	29.6	24

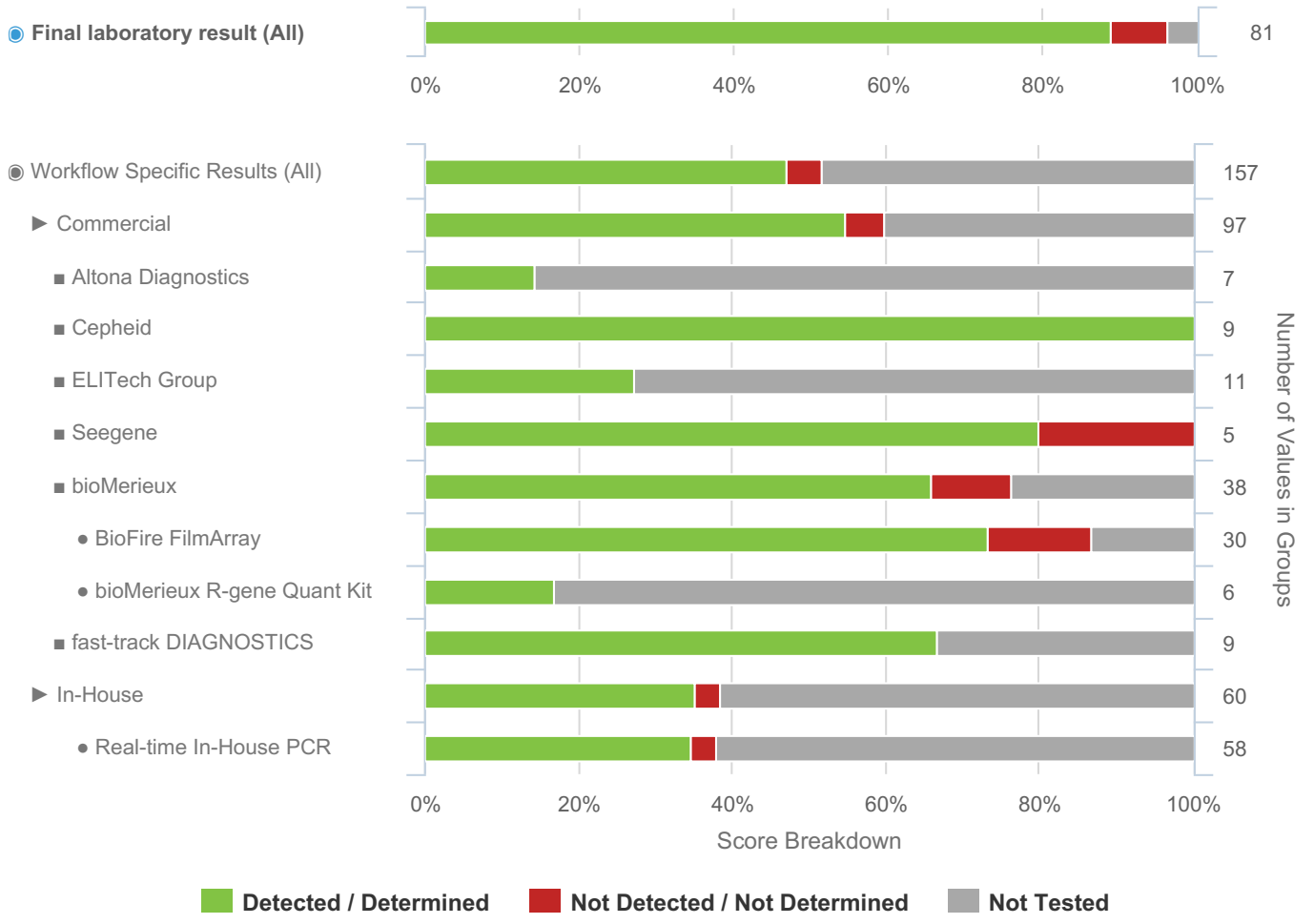


Catalogue Code:	Ref Code:	Challenge:	Analysis Type:	Dataset:	Report UID:	Laboratory
QAV174195	CNSI20	S	Multiple Pathogen Qualitative	-	0/0/2913	

Groups below n=5: AITbiotech (n=1), AITbiotech - AITbiotech Real Time PCR (n=1), Amplex (n=1), Amplex - Amplex Easy-Plex (n=1), AusDiagnostics (n=1), AusDiagnostics - AusDiagnostics Easy-Plex (n=1), Certest (n=1), Certest - Certest Real Time PCR (n=1), Diagenode (n=2), Diagenode - Diagenode Real Time kit (n=2), Diasorin (n=2), Diasorin - DiaSorin Simplexa (n=2), InterLabService (n=1), InterLabService - InterLabService AmpliSens (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 (n=1), Roche - Roche Cobas 4800 (n=1), Sacace (n=1), Sacace - Sacace Real TM (n=1), Seegene - Seegene Real Time PCR (n=4), Seegene - Seegene Seeplex (n=1), TIB MOLBIOL (n=1), TIB MOLBIOL - TIB-MolBiol LightMix (n=1), bioMerieux - bioMerieux R-gene Kit (n=2), In-House - Conventional In-House PCR (n=2)

Groups Rolled Up: Altona Diagnostics - Altona Diagnostics RealStar (n=7), Cepheid - Cepheid Xpert kit (n=9), ELITech Group - Elitech Elite Real Time kit (n=11), fast-track DIAGNOSTICS - FTD real time PCR (n=9)

Sample Code	Sample Content	Matrix	Sample Relationships	Expected targets	Detected / Determined		Not Detected / Not Determined		Not Tested	
					(%)	*(n)*	*(%)*	*(n)*	*(%)*	*(n)*
CNSI101S-09	Echovirus 30	Transport Medium		Enterovirus	88.9	72	7.4	6	3.7	3



Catalogue Code:	Ref Code:	Challenge:	Analysis Type:	Dataset:	Report UID:	Laboratory
QAV174195	CNSI20	S	Multiple Pathogen Qualitative	-	0/0/2913	

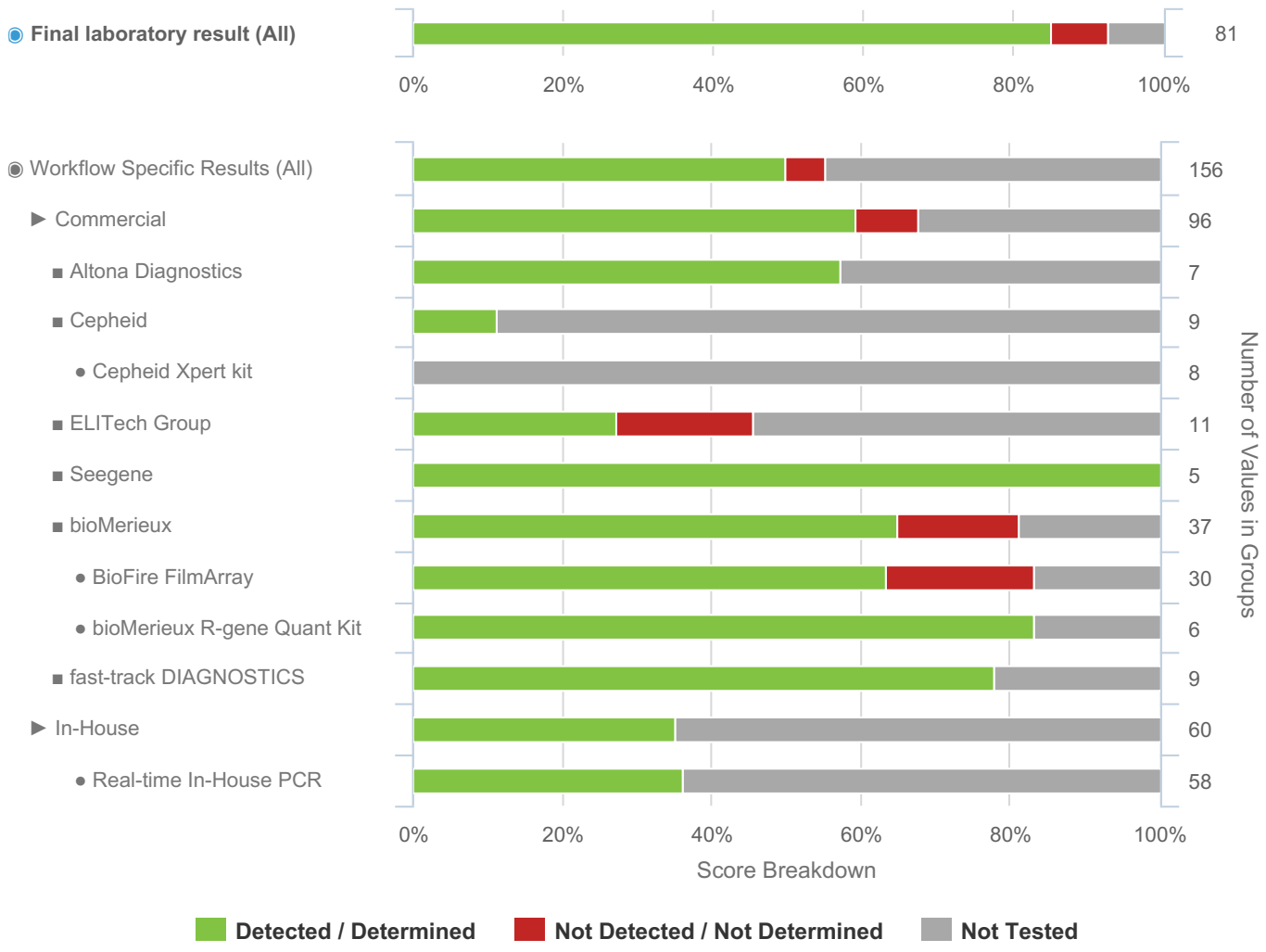
Groups below n=5: AITbiotech (n=1), AITbiotech - AITbiotech Real Time PCR (n=1), Amplex (n=1), Amplex - Amplex Easy-Plex (n=1), AusDiagnostics (n=1), AusDiagnostics - AusDiagnostics Easy-Plex (n=1), Certest (n=1), Certest - Certest Real Time PCR (n=1), Diagenode (n=2), Diagenode - Diagenode Real Time kit (n=2), Diasorin (n=2), Diasorin - DiaSorin Simplexa (n=2), InterLabService (n=1), InterLabService - InterLabService AmpliSens (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), R-Biopharm (n=1), R-Biopharm - R-Biopharm RIDA Gene (n=1), Roche (n=1), Roche - Roche Cobas 4800 (n=1), Sacace (n=1), Sacace - Sacace Real TM (n=1), Seegene - Seegene Real Time PCR (n=4), Seegene - Seegene Seeplex (n=1), bioMerieux - bioMerieux R-gene Kit (n=2), In-House - Conventional In-House PCR (n=2)

Groups Rolled Up: Altona Diagnostics - Altona Diagnostics RealStar (n=7), Cepheid - Cepheid Xpert kit (n=9), ELITech Group - Elitech Elite Real Time kit (n=11), fast-track DIAGNOSTICS - FTD real time PCR (n=9)

Individual Report	QCMD 2020 Central Nervous System I (Viral Meningitis and Encephalitis) EQA Pilot Study	

Catalogue Code:	Ref Code:	Challenge:	Analysis Type:	Dataset:	Report UID:	Laboratory
QAV174195	CNSI20	S	Multiple Pathogen Qualitative	-	0/0/2913	

Sample Code	Sample Content	Matrix	Sample Relationships	Expected targets	Detected / Determined		Not Detected / Not Determined		Not Tested	
					(%)	*(n)*	*(%)*	*(n)*	*(%)*	*(n)*
CNSI101S-10	Herpes Simplex Virus Type 1	Transport Medium		Herpes simplex virus	85.2	69	7.4	6	7.4	6



Catalogue Code:	Ref Code:	Challenge:	Analysis Type:	Dataset:	Report UID:	Laboratory
QAV174195	CNSI20	S	Multiple Pathogen Qualitative	-	0/0/2913	

Groups below n=5: AITbiotech (n=1), AITbiotech - AITbiotech Real Time PCR (n=1), Amplex (n=1), Amplex - Amplex Easy-Plex (n=1), AusDiagnostics (n=1), AusDiagnostics - AusDiagnostics Easy-Plex (n=1), Cepheid - Cepheid SmartCycler (n=1), Certest (n=1), Certest - Certest Real Time PCR (n=1), Diagenode (n=2), Diagenode - Diagenode Real Time kit (n=2), Diasorin (n=2), Diasorin - DiaSorin Simplexa (n=2), InterLabService (n=1), InterLabService - InterLabService AmpliSens (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 (n=1), Roche - Roche Cobas 4800 (n=1), Sacace (n=1), Sacace - Sacace Real TM (n=1), Seegene - Seegene Real Time PCR (n=4), Seegene - Seegene Seeplex (n=1), TIB MOLBIOL (n=1), TIB MOLBIOL - TIB-MolBiol LightMix (n=1), bioMerieux - bioMerieux R-gene Kit (n=1), In-House - Conventional In-House PCR (n=2)
Groups Rolled Up: Altona Diagnostics - Altona Diagnostics RealStar (n=7), ELITech Group - Elitech Elite Real Time kit (n=11), fast-track DIAGNOSTICS - FTD real time PCR (n=9)