Individual Report	QCMD 2020 Hepatitis C Virus RNA EQA Programme	

Catalogue Code:	Ref Code:	Challenge:	Analysis Type:	Dataset:	Report UID:	Laboratory
QAV994112	HCVRNA20	C1	Qualitative and Quantitative	340043	2677/340043/2613	CZ023

Intended Results / Panel Composition

Sample Code	Sample Content	Matrix	Sample Relationships [1]	Detection Frequency [2]	Sample Status [3]	Consensus (IU/ml) [4]		Range [5]
						(Log_{10})	*(n)*	
HCVRNA20C1-01	HCV Type 3a	Plasma	DS1_1	Frequently Detected	CORE	3.297	230	2.537 - 4.220
HCVRNA20C1-02	HCV Type 3a	Plasma	DS1_2	Frequently Detected	CORE	2.332	227	1.531 - 3.179
HCVRNA20C1-03	HCV Type 1b	Plasma	D1	Frequently Detected	CORE	2.845	229	1.875 - 3.404
HCVRNA20C1-04	HCV Type 1b	Plasma	D1	Frequently Detected	CORE	2.852	228	2.373 - 3.478

[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] **Consensus (IU/ml):** Mean consensus (Log_{10}) calculated from data returned by participants with outliers removed and number of quantitative results (n) returned for each panel member.
[5] **Range:** Maximum and minimum quantitative value (IU/ml) reported by participants within this challenge without outliers removed.
For further details please refer to the current participant manual.

Your Summary Results

Units	IU/ml
EQA Assessment Group [1]	GeneProof Real Time PCR kit
Core Panel Detection (Qualitative) Score [2]	0
Core Panel Estimation (Quantitative) Score [3]	0

Core Panel Members Results

Sample Code	Unitage	EQA Assessment Group Consensus [4]	SD [5]	Quantitative Result		Qualitative Result		
				Your Result [6]	Estimation Score [7]	Percentage Correct (All) [8]	Your Result [9]	Detection Score [10]
HCVRNA20C1-01	IU/ml	4.003	0.157	4.025	0	100.0	Positive	0
HCVRNA20C1-02	IU/ml	2.860	0.226	3.039	0	97.5	Positive	0
HCVRNA20C1-03	IU/ml	3.115	0.241	3.202	0	99.4	Positive	0
HCVRNA20C1-04	IU/ml	3.127	0.286	3.106	0	98.8	Positive	0

All quantitative values above expressed in Log_{10} IU/ml.

[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] **Core Panel Estimation (Quantitative) Score:** An overall core panel estimation score provided per challenge / distribution.

[4] **EQA Assessment Group Consensus:** The mean value for all results within your EQA assessment group.

[5] **SD:** The standard deviation for results from your EQA assessment group.

[6] **Your Quantitative Result:** The quantitative result you returned for each sample within this EQA challenge. LOD/NR (limit of detection or not reported).

[7] **Estimation Score:** Your estimation (quantitative) scores are calculated based on your variation from the consensus for your EQA assessment group. With 0 (zero) scored if the quantitative value you reported is within one standard deviation (SD) from your EQA assessment group consensus, 1 (one) if your quantitative value is between one and two SDs, 2 (two) if your quantitative value is within two and three SDs and 3 (three) if your quantitative value is more than three SDs from the mean of your EQA assessment group.

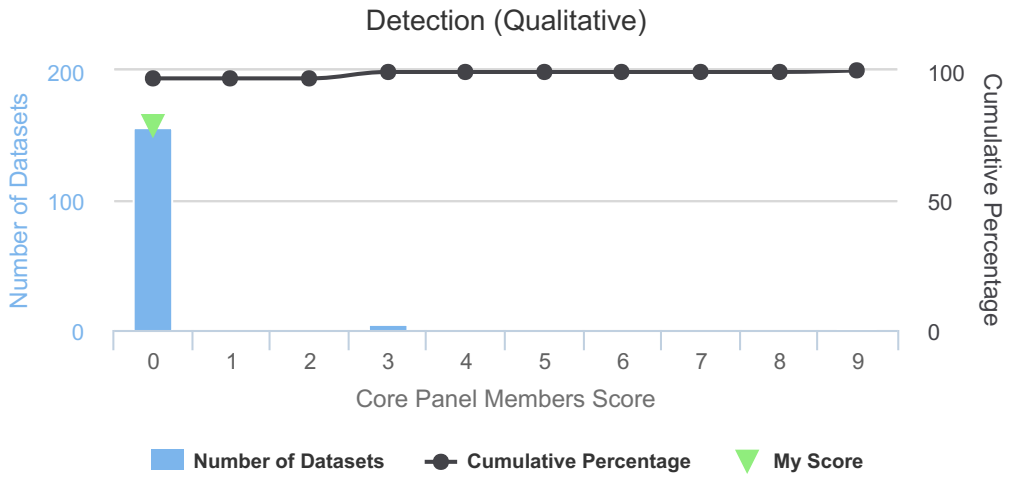
[8] **Percentage Correct (All):** Percentage of datasets (%) reporting the correct qualitative results for each panel member.

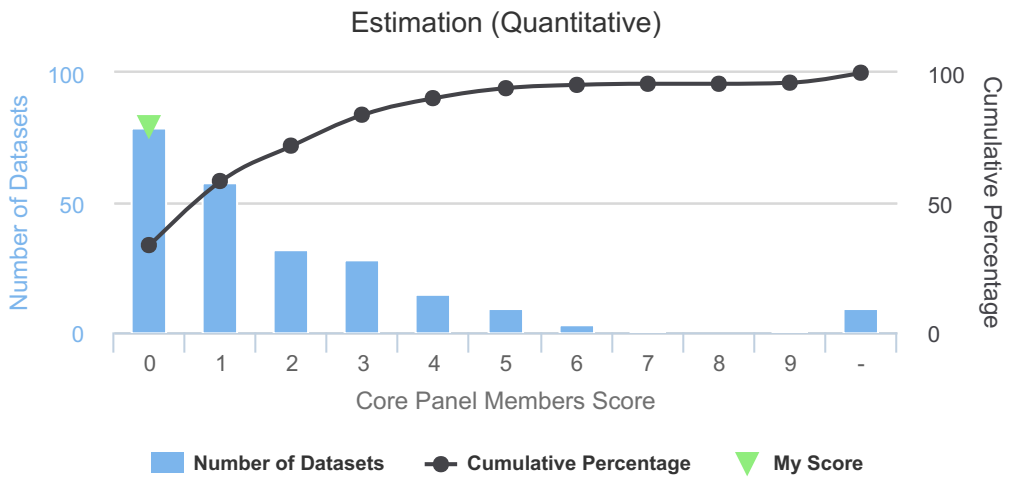
[9] **Your Qualitative Result:** The qualitative result you reported for each sample within this EQA challenge / distribution.

[10] **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





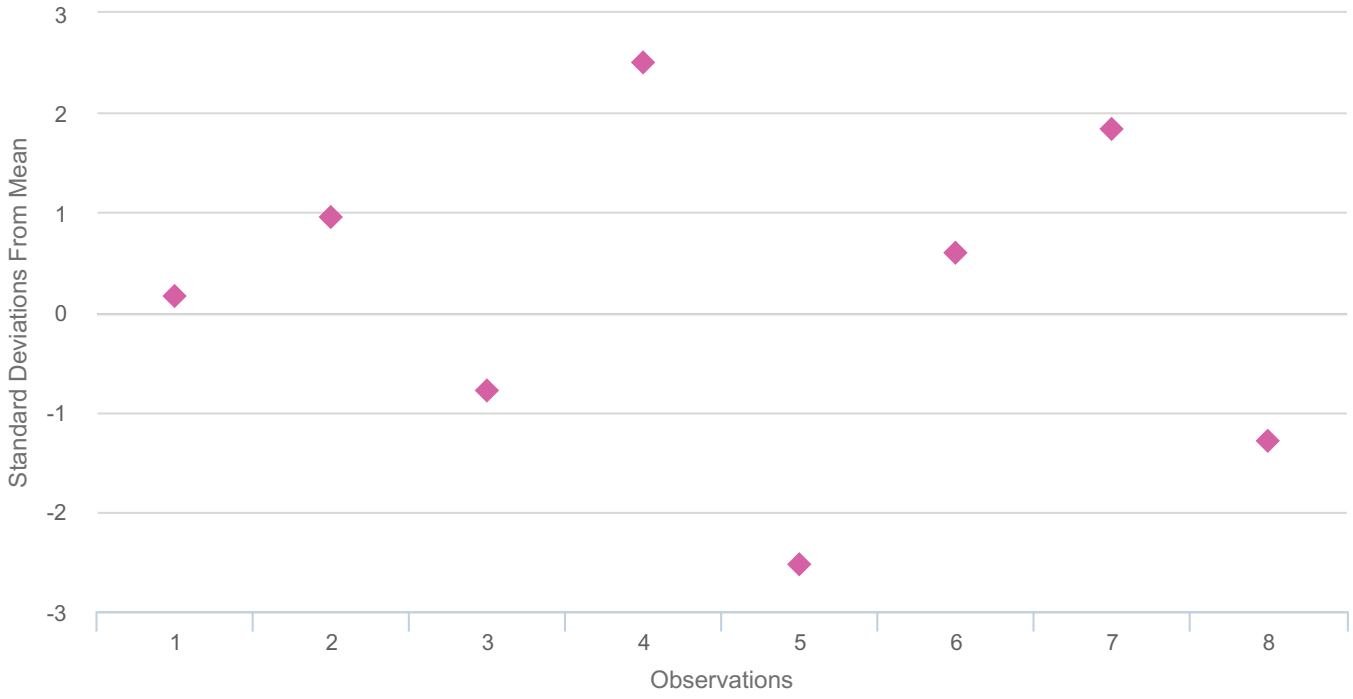
Core Panel Member Score Breakdown - Detection: This figure gives you a breakdown of the qualitative detection scores for all qualitative datasets returned within this EQA challenge / distribution independent of the EQA assessment group. Panel detection scores are generated from only those panel members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

Core Panel Member Score Breakdown - Estimation: This figure gives you a breakdown of the quantitative estimation scores for all quantitative datasets returned within this EQA challenge / distribution independent of the EQA assessment group. Panel estimation scores are based on positive core panel members only. Those datasets that did not return quantitative values for all core samples are represented by '-'.

For further details please refer to the current participant manual.

Duplicate Sample Performance Over Time

Duplicate Series 2



Observation Details

1: HCVRNA17C1-03 - HCVRNA17C1-01: Your Variation 0.015 (IU/ml): Overall Mean Variation -0.003: Overall SD 0.110.

2: HCVRNA17C3-01 - HCVRNA17C1-03: Your Variation 0.209 (IU/ml): Overall Mean Variation -0.001: Overall SD 0.220.

3: HCVRNA18C1-01 - HCVRNA17C3-01: Your Variation -0.202 (IU/ml): Overall Mean Variation -0.011: Overall SD 0.242.

4: HCVRNA18C1-02 - HCVRNA18C1-01: Your Variation 0.297 (IU/ml): Overall Mean Variation 0.006: Overall SD 0.116.

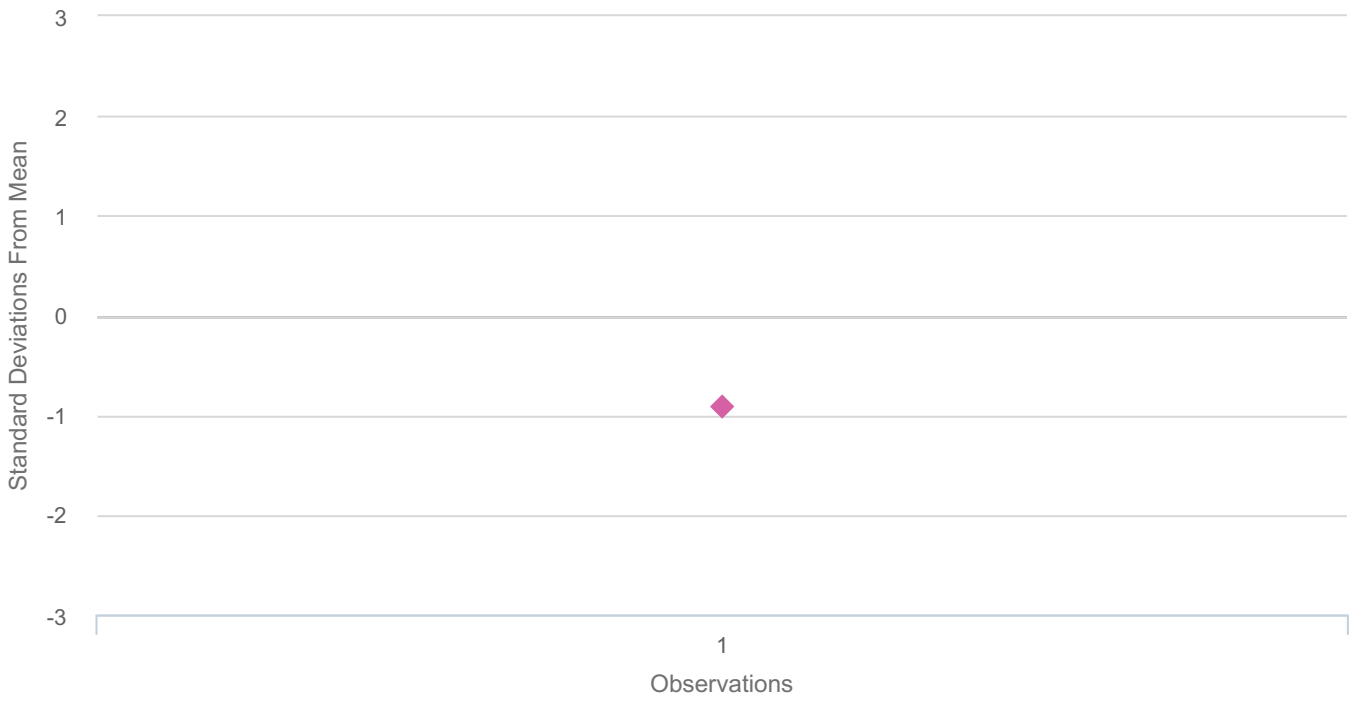
5: HCVRNA18C3-04 - HCVRNA18C1-02: Your Variation -0.533 (IU/ml): Overall Mean Variation -0.008: Overall SD 0.208.

6: HCVRNA19C1-01 - HCVRNA18C3-04: Your Variation 0.135 (IU/ml): Overall Mean Variation 0.025: Overall SD 0.185.

7: HCVRNA19C1-02 - HCVRNA19C1-01: Your Variation 0.225 (IU/ml): Overall Mean Variation 0.016: Overall SD 0.114.

8: HCVRNA19C3-02 - HCVRNA19C1-02: Your Variation -0.421 (IU/ml): Overall Mean Variation -0.055: Overall SD 0.284.

Duplicate series 4



Observation Details

1: HCVRNA20C1-04 - HCVRNA20C1-03: Your Variation -0.096 (IU/ml): Overall Mean Variation 0.002: Overall SD 0.107.

QCMD monitors your laboratory's performance over time based on the reported quantitative variation between duplicate panel members within the EQA challenge and, where appropriate, across EQA challenges.

The mean variation and standard deviation are calculated from the quantitative variation reported by each participant between duplicate panel members in the same unit of measurement once outliers have been removed. (See 'Observation Details')

Previous and current observations are plotted on the chart as the number of standard deviations your variation was from the mean variation for all participants who submitted corresponding results in the same unitage.

Any reported variation greater than ±3 SD will not be shown on the graph, but your variation value will be provided **in red** in the *Observation Details*.

When "N/A" is displayed for an observation, either no valid quantitative results were provided or there was a change in reported unitage.

My Workflow Details

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

Name	GeneProof Hepatitis C Virus (HCV) PCR Kit-croBEE (v3)
Description	
Targets	V hepatitis C virus

Assays	*Extraction* - GeneProof - croBEE NA16 Nucleic Acid Extraction System
	• Commercial
	  ○ Kit Manufacturer: *GeneProof*
	  ○ Kit Type: *201A Nucleic Acid Extraction Kit*
	
	Amplification - GeneProof - croBEE Real-Time PCR System
	• Commercial
	  ○ Kit Manufacturer: *GeneProof*
	  ○ Kit Type: *GeneProof Hepatitis C Virus (HCV) PCR Kit*
	  ○ Kit Version: *ISEX*

Further Programme Details

Number of Participants	276
Number of Countries	37
Number of Respondents	254
Number of Datasets Submitted	273
Quantitative Results Returned (All)	235 (86.1%)
- Quantitative Results Returned (IU/ml)	230 (97.9%)
- Quantitative Results Returned (Copies/ml)	4 (1.7%)
- Quantitative Results Returned (RLU)	1 (0.4%)
Qualitative Results Returned	162 (59.3%)

EQA Programme Aims

To assess the proficiency of laboratories in the detection and quantitation of hepatitis C virus (HCV) RNA.

To assess the proficiency of laboratories in the detection and quantitation of different HCV genotypes.

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.

Additional Core Samples Information

The following section has been categorised as shown below:

Core ► Quantitative ► IU/ml ► Qualitative

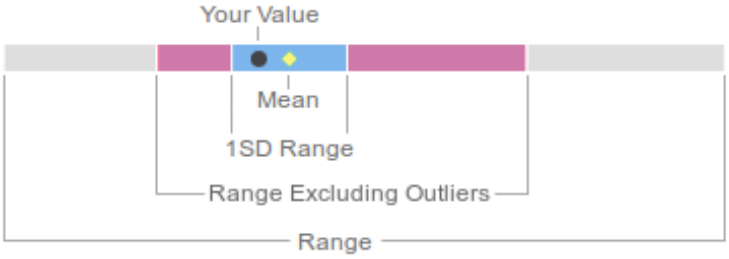
Individual Panel Member Analysis (Quantitative)

Quantitative 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 reported results using the same unit of measurement (i.e. Copies/ml or IU/ml).

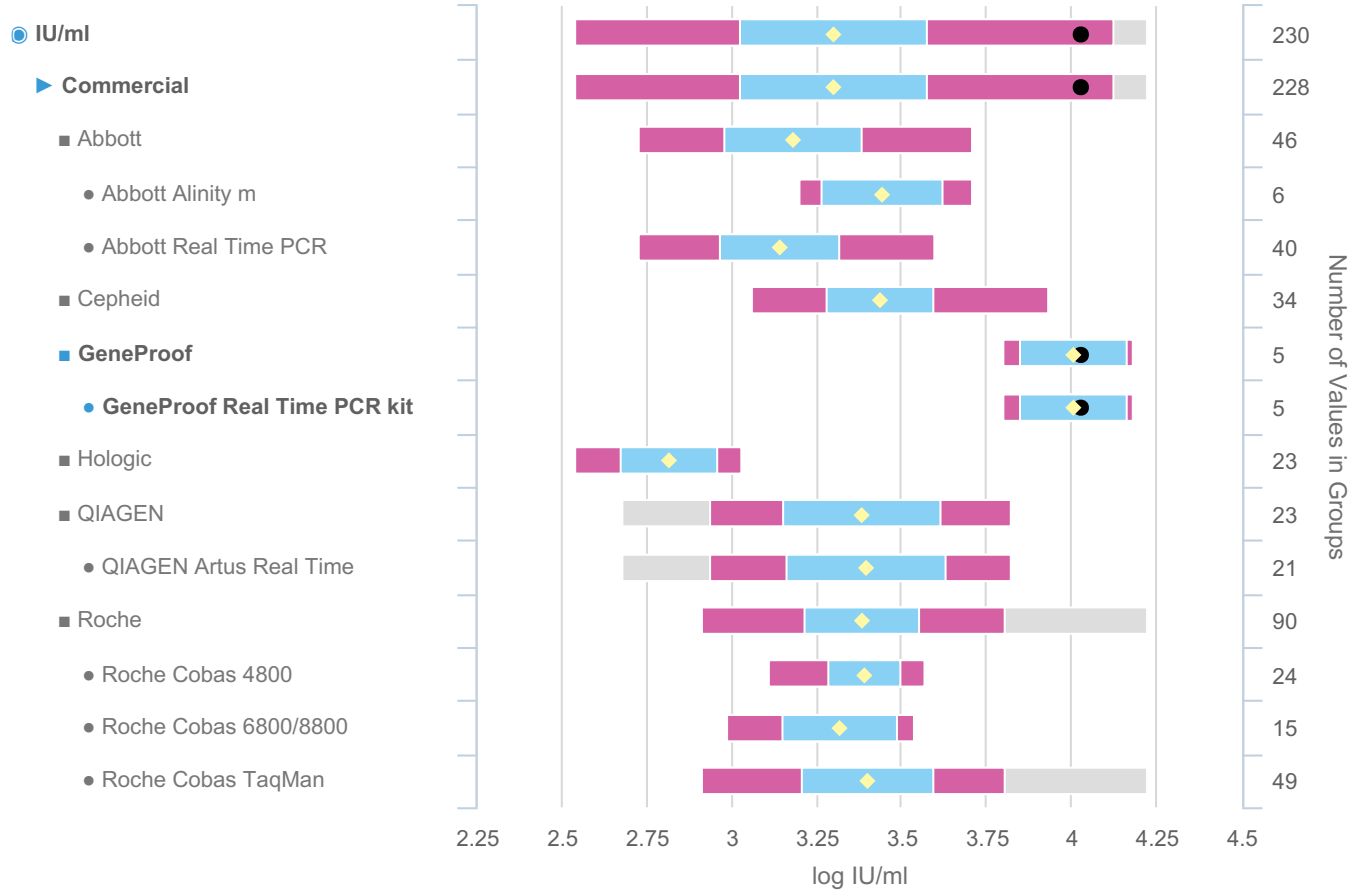
The results below provide a breakdown of participant reported values on each of the panel members within this EQA challenge / distribution. Your result for each panel member is indicated by "your value". You can compare your value to the “mean” within your EQA assessment group and the overall consensus for each sample within this EQA challenge / distribution.

Key



HCVRNA20C1-01 - Quantitative Results Breakdown (IU/ml)

Sample Code	Sample Content	Matrix	Sample Relationships	Detection Frequency	Sample Status	Consensus (IU/ml)		Range
						(Log$_{10}$)	*(n)*	
HCVRNA20C1-01	HCV Type 3a	Plasma	DS1_1	Frequently Detected	CORE	3.297	230	2.537 - 4.220

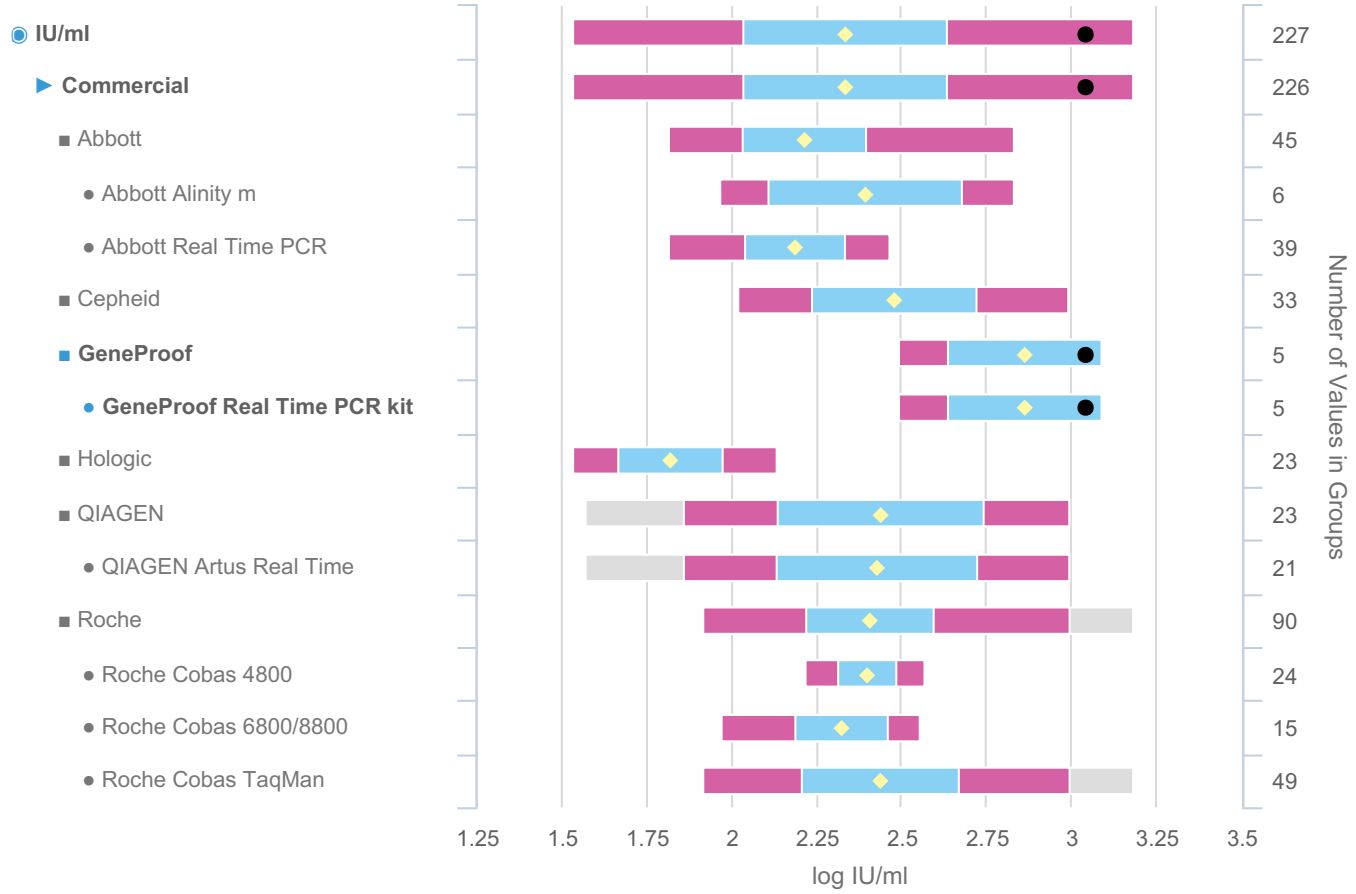


Groups below n=5: Anatolia Geneworks (n=3), Anatolia Geneworks - Anatolia Geneworks Bosphore (n=3), QIAGEN - Qiagen NeuMoDx (n=2), Roche - Roche Cobas Amplicor (n=2), Sacace (n=1), Sacace - Sacace Real TM (n=1), Siemens (n=3), Siemens - Siemens Versant (n=3), In-House (n=2), In-House - Real-time In-House PCR (n=2)

Groups Rolled Up: Cepheid - Cepheid Xpert kit (n=34), Hologic - Hologic Aptima (n=23)

HCVRNA20C1-02 - Quantitative Results Breakdown (IU/ml)

Sample Code	Sample Content	Matrix	Sample Relationships	Detection Frequency	Sample Status	Consensus (IU/ml)		Range
						(Log$_{10}$)	*(n)*	
HCVRNA20C1-02	HCV Type 3a	Plasma	DS1_2	Frequently Detected	CORE	2.332	227	1.531 - 3.179

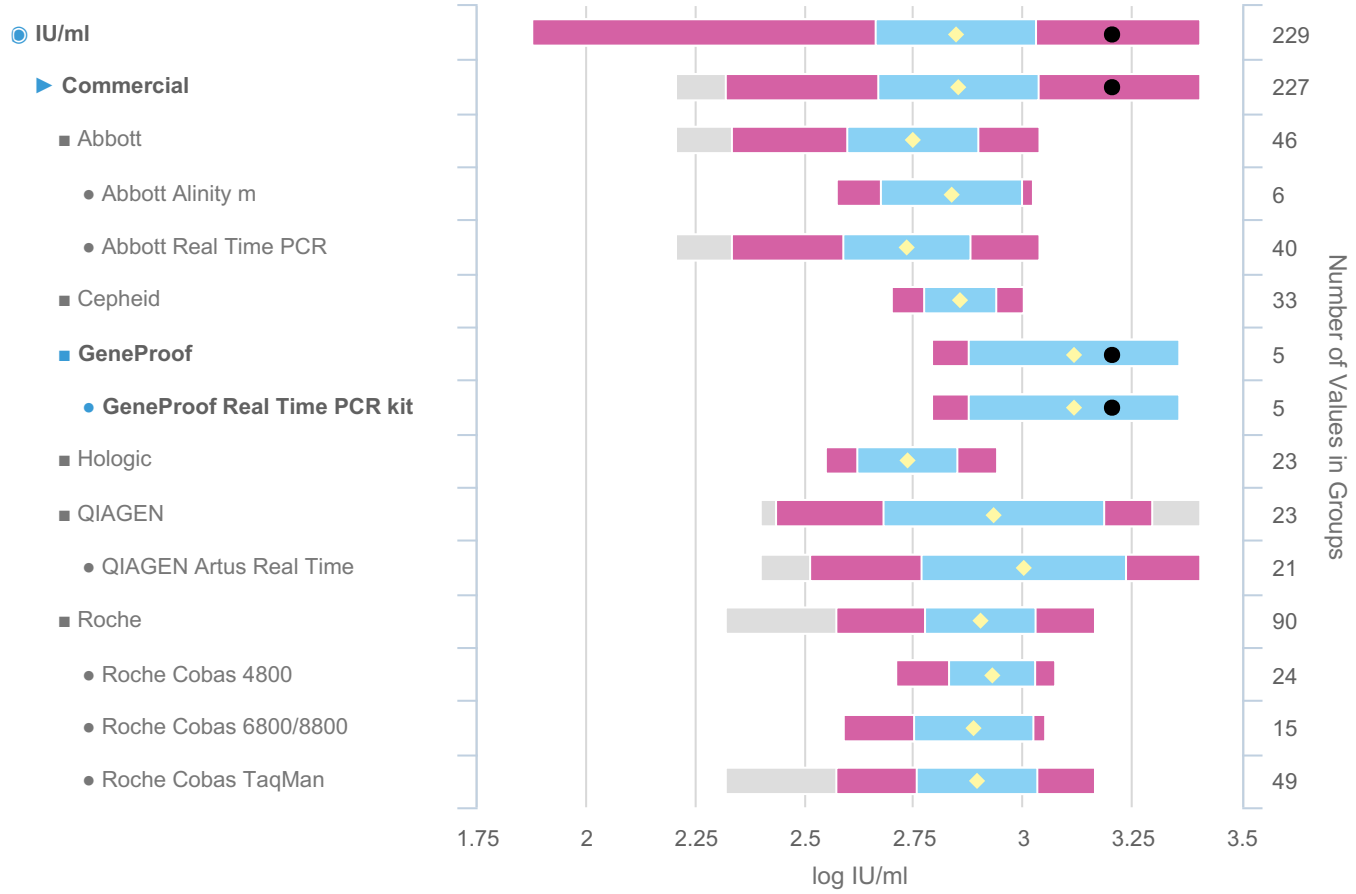


Groups below n=5: Anatolia Geneworks (n=3), Anatolia Geneworks - Anatolia Geneworks Bosphore (n=3), QIAGEN - Qiagen NeuMoDx (n=2), Roche - Roche Cobas Amplicor (n=2), Sacace (n=1), Sacace - Sacace Real TM (n=1), Siemens (n=3), Siemens - Siemens Versant (n=3), In-House (n=1), In-House - Real-time In-House PCR (n=1)

Groups Rolled Up: Cepheid - Cepheid Xpert kit (n=33), Hologic - Hologic Aptima (n=23)

HCVRNA20C1-03 - Quantitative Results Breakdown (IU/ml)

Sample Code	Sample Content	Matrix	Sample Relationships	Detection Frequency	Sample Status	Consensus (IU/ml)		Range
						(Log_{10})	*(n)*	
HCVRNA20C1-03	HCV Type 1b	Plasma	D1	Frequently Detected	CORE	2.845	229	1.875 - 3.404

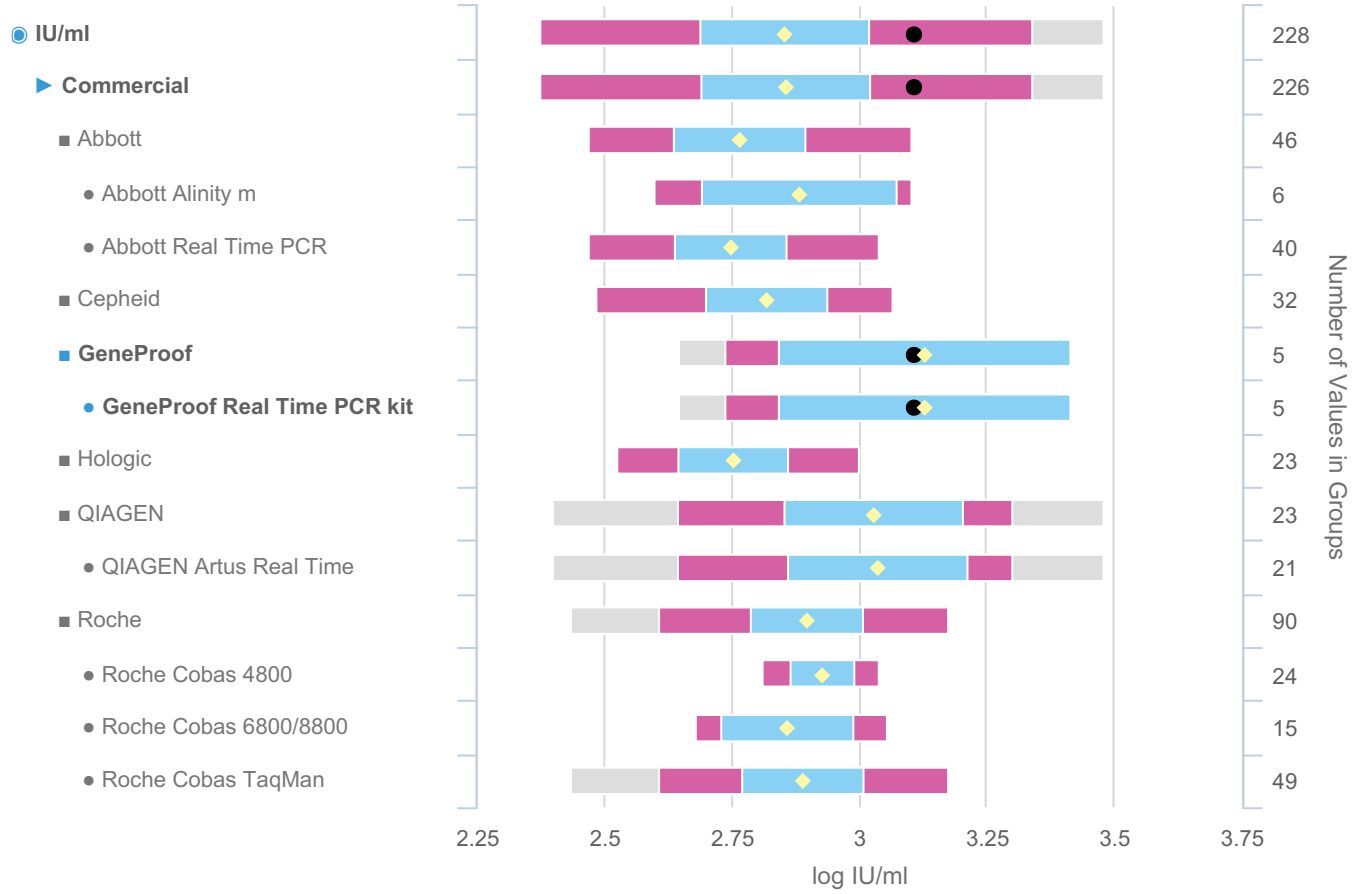


Groups below n=5: Anatolia Geneworks (n=3), Anatolia Geneworks - Anatolia Geneworks Bosphore (n=3), QIAGEN - Qiagen NeuMoDx (n=2), Roche - Roche Cobas Amplicor (n=2), Sacace (n=1), Sacace - Sacace Real TM (n=1), Siemens (n=3), Siemens - Siemens Versant (n=3), In-House (n=2), In-House - Real-time In-House PCR (n=2)

Groups Rolled Up: Cepheid - Cepheid Xpert kit (n=33), Hologic - Hologic Aptima (n=23)

HCVRNA20C1-04 - Quantitative Results Breakdown (IU/ml)

Sample Code	Sample Content	Matrix	Sample Relationships	Detection Frequency	Sample Status	Consensus (IU/ml)		Range
						(Log$_{10}$)	*(n)*	
HCVRNA20C1-04	HCV Type 1b	Plasma	D1	Frequently Detected	CORE	2.852	228	2.373 - 3.478



Groups below n=5: Anatolia Geneworks (n=3), Anatolia Geneworks - Anatolia Geneworks Bosphore (n=3), QIAGEN - Qiagen NeuMoDx (n=2), Roche - Roche Cobas Amplicor (n=2), Sacace (n=1), Sacace - Sacace Real TM (n=1), Siemens (n=3), Siemens - Siemens Versant (n=3), In-House (n=2), In-House - Real-time In-House PCR (n=2)

Groups Rolled Up: Cepheid - Cepheid Xpert kit (n=32), Hologic - Hologic Aptima (n=23)

Individual Panel Member Analysis (Qualitative)

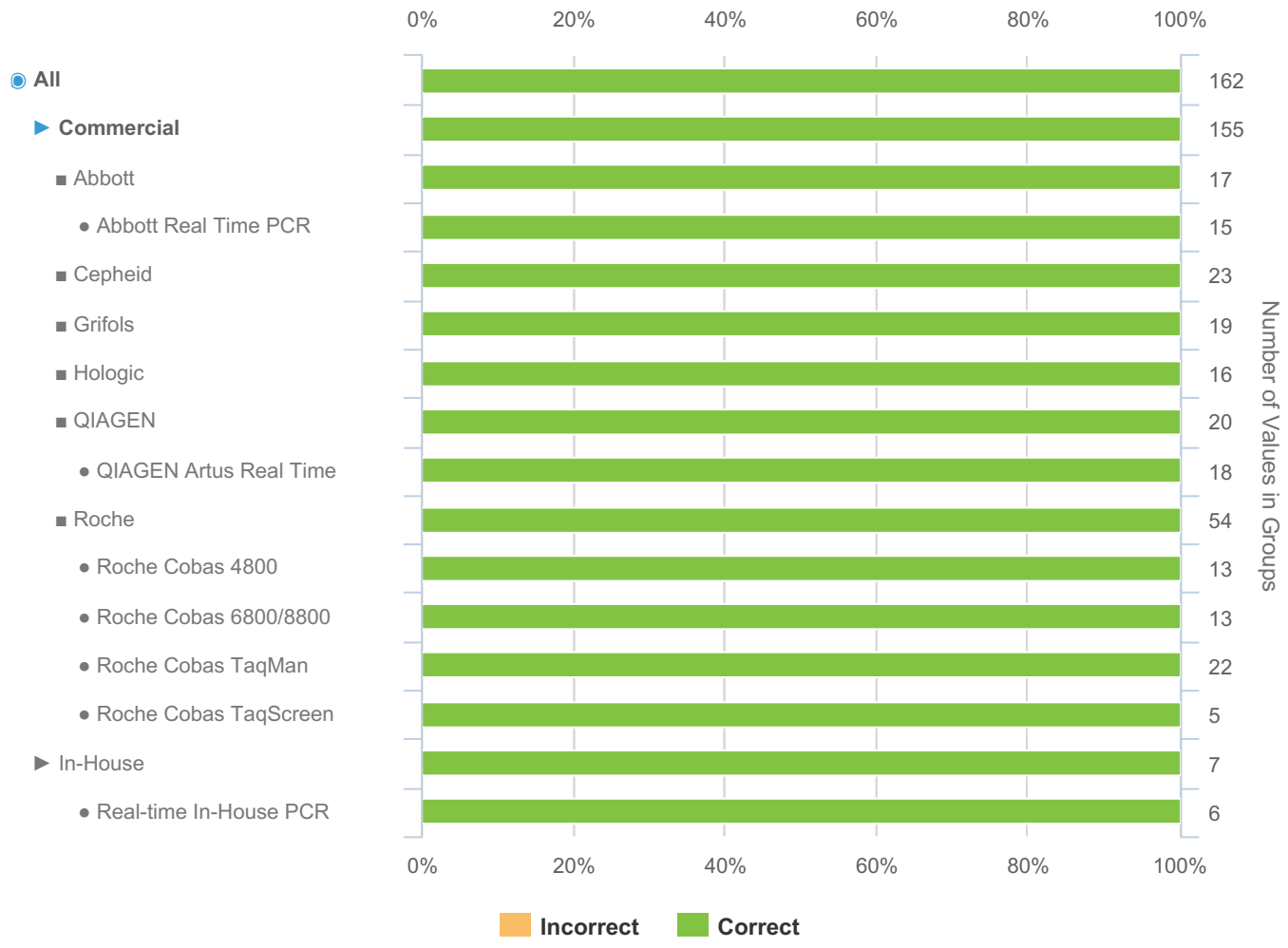
Qualitative analysis for each panel member is provided in relation to your EQA assessment group. EQA assessment groups are established using the molecular workflow information reported by all participants within this EQA challenge / distribution. The principal level of assessment is at the individual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

HCVRNA20C1-01 - Qualitative Results Breakdown

Sample Code	Sample Content	Matrix	Sample Relationships	Detection Frequency	Sample Status	Percentage Correct (All)	
						(%)	*(n)*
HCVRNA20C1-01	HCV Type 3a	Plasma	DS1_1	Frequently Detected	CORE	100.0	162

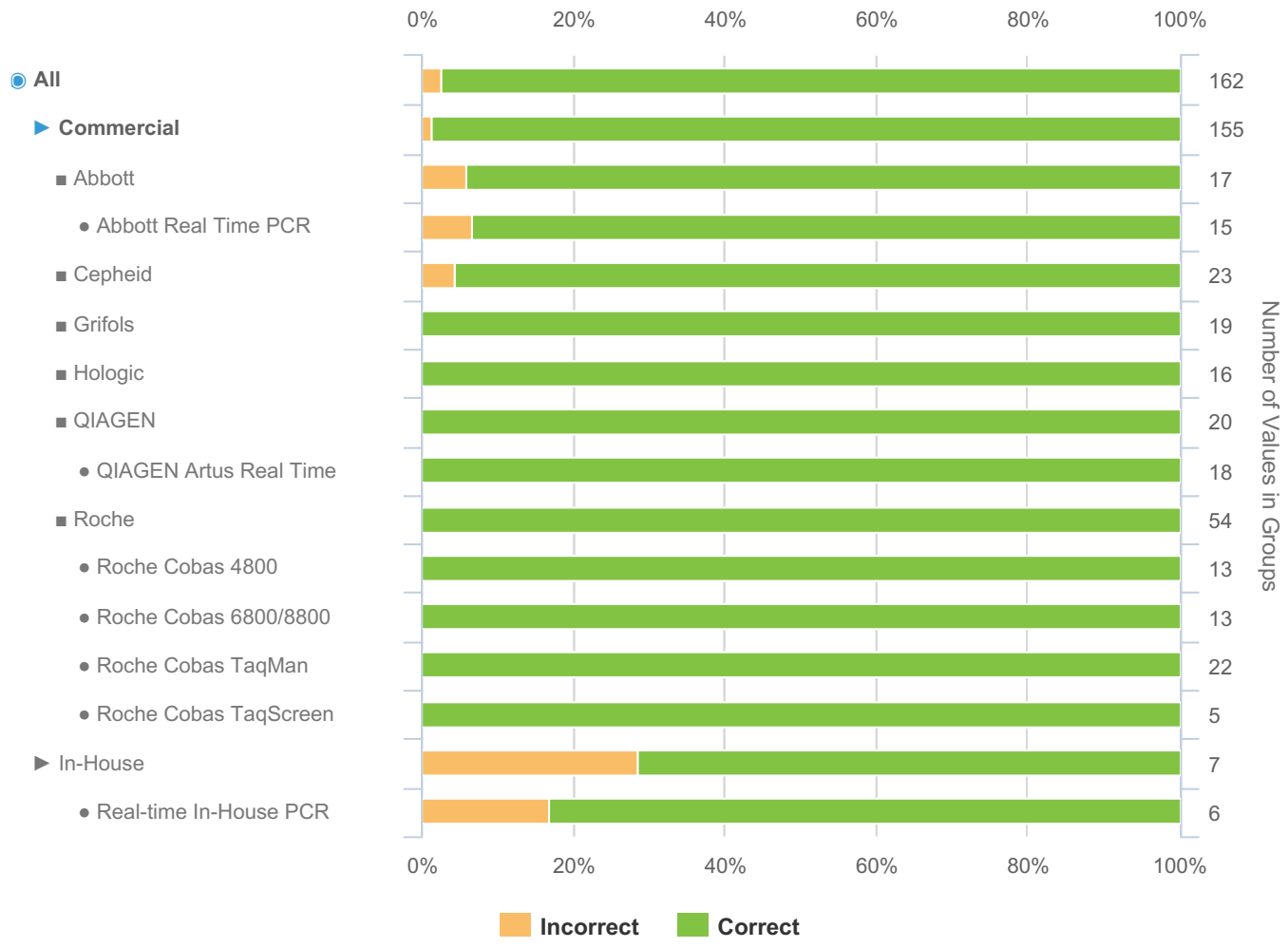


Groups below n=5: Abbott - Abbott Alinity m (n=2), GFE Blut (n=1), GFE Blut - GFE Blut PoET (n=1), GeneProof (n=4), GeneProof - GeneProof Real Time PCR kit (n=4), QIAGEN - Qiagen NeuMoDx (n=2), Roche - Roche Cobas Amplicor (n=1), Sacace (n=1), Sacace - Sacace Real TM (n=1), In-House - Conventional In-House PCR (n=1)

Groups Rolled Up: Cepheid - Cepheid Xpert kit (n=23), Grifols - Grifols Procleix Ultrio (n=19), Hologic - Hologic Aptima (n=16)

HCVRNA20C1-02 - Qualitative Results Breakdown

Sample Code	Sample Content	Matrix	Sample Relationships	Detection Frequency	Sample Status	Percentage Correct (All)	
						(%)	*(n)*
HCVRNA20C1-02	HCV Type 3a	Plasma	DS1_2	Frequently Detected	CORE	97.5	162

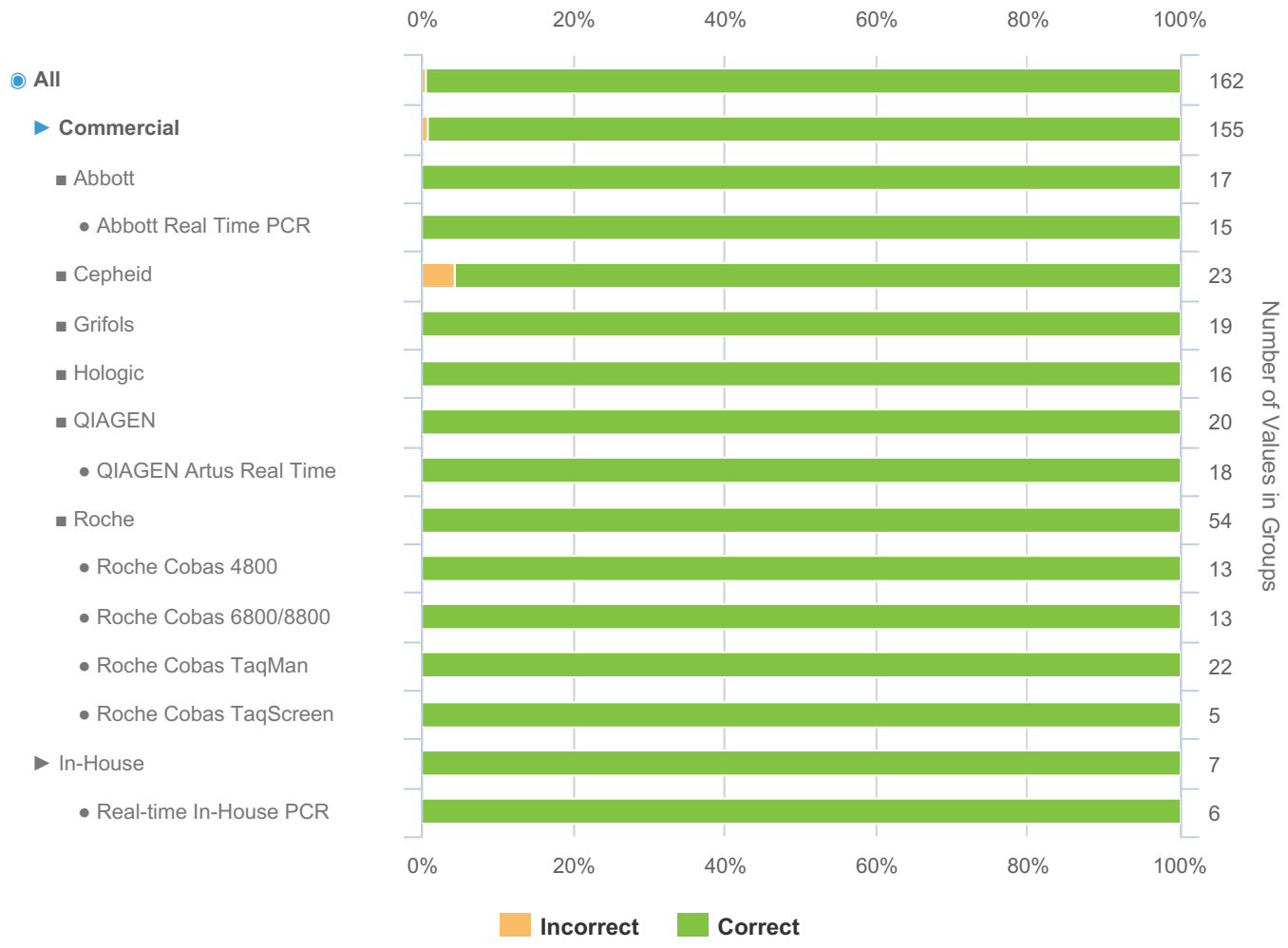


Groups below n=5: Abbott - Abbott Alinity m (n=2), GFE Blut (n=1), GFE Blut - GFE Blut PoET (n=1), GeneProof (n=4), GeneProof - GeneProof Real Time PCR kit (n=4), QIAGEN - Qiagen NeuMoDx (n=2), Roche - Roche Cobas Amplicor (n=1), Sacace (n=1), Sacace - Sacace Real TM (n=1), In-House - Conventional In-House PCR (n=1)

Groups Rolled Up: Cepheid - Cepheid Xpert kit (n=23), Grifols - Grifols Procleix Ultrio (n=19), Hologic - Hologic Aptima (n=16)

HCVRNA20C1-03 - Qualitative Results Breakdown

Sample Code	Sample Content	Matrix	Sample Relationships	Detection Frequency	Sample Status	Percentage Correct (All)	
						(%)	*(n)*
HCVRNA20C1-03	HCV Type 1b	Plasma	D1	Frequently Detected	CORE	99.4	162

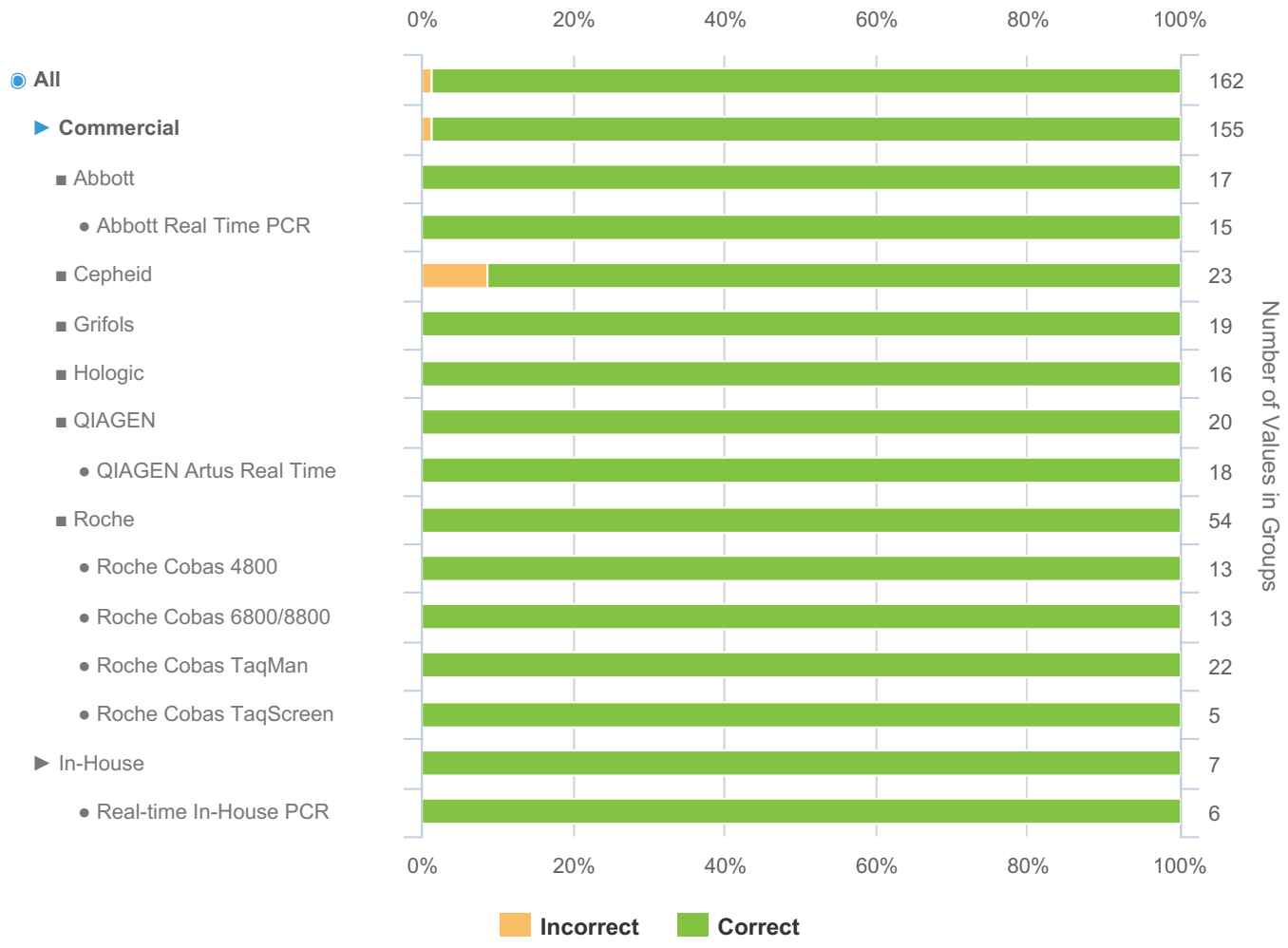


Groups below n=5: Abbott - Abbott Alinity m (n=2), GFE Blut (n=1), GFE Blut - GFE Blut PoET (n=1), GeneProof (n=4), GeneProof - GeneProof Real Time PCR kit (n=4), QIAGEN - Qiagen NeuMoDx (n=2), Roche - Roche Cobas Amplicor (n=1), Sacace (n=1), Sacace - Sacace Real TM (n=1), In-House - Conventional In-House PCR (n=1)

Groups Rolled Up: Cepheid - Cepheid Xpert kit (n=23), Grifols - Grifols Procleix Ultrio (n=19), Hologic - Hologic Aptima (n=16)

HCVRNA20C1-04 - Qualitative Results Breakdown

Sample Code	Sample Content	Matrix	Sample Relationships	Detection Frequency	Sample Status	Percentage Correct (All)	
						(%)	*(n)*
HCVRNA20C1-04	HCV Type 1b	Plasma	D1	Frequently Detected	CORE	98.8	162



Groups below n=5: Abbott - Abbott Alinity m (n=2), GFE Blut (n=1), GFE Blut - GFE Blut PoET (n=1), GeneProof (n=4), GeneProof - GeneProof Real Time PCR kit (n=4), QIAGEN - Qiagen NeuMoDx (n=2), Roche - Roche Cobas Amplicor (n=1), Sacace (n=1), Sacace - Sacace Real TM (n=1), In-House - Conventional In-House PCR (n=1)

Groups Rolled Up: Cepheid - Cepheid Xpert kit (n=23), Grifols - Grifols Procleix Ultrio (n=19), Hologic - Hologic Aptima (n=16)

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