


<b>Individual Report</b>		<b>QCMD 2021 Enterovirus RNA EQA Programme</b>			 <small>Quality Control for Molecular Diagnostics</small>	
<b>Catalogue Code:</b> QAV984104	<b>Ref Code:</b> EVRNA21	<b>Challenge:</b> C1	<b>Analysis Type:</b> Qualitative	<b>Dataset:</b> 436843	<b>Report UID:</b> 2677/436843/3395	<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)
EVRNA21C1-01	Negative	Transport Medium		Negative	CORE	99.2	127
EVRNA21C1-02	Coxsackievirus A24	Transport Medium	3.84 dPCR Log10 Copies/ml	Frequently Detected	CORE	100.0	127
EVRNA21C1-03	Enterovirus D68 B3	Transport Medium	5.10 dPCR Log10 Copies/ml	Detected	CORE	81.1	127
EVRNA21C1-04	Echovirus 25	Transport Medium	4.68 dPCR Log10 Copies/ml	Frequently Detected	CORE	100.0	127
EVRNA21C1-05	Coxsackievirus A9	Transport Medium	3.46 dPCR Log10 Copies/ml	Frequently Detected	CORE	99.2	127

[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.*

[1] **Sample Relationships:** Includes dPCR Log10 Copies/ml, the value obtained using a digital droplet PCR assay.

**Please note:** The values provided are for reference only. The values obtained by individual participating laboratories will vary from the dPCR values provided. This is because quantitation is dependent on the molecular workflow each laboratory uses (i.e. nucleic acid extraction and molecular platform / assay) as well as the standards or reference material used to calibrate the molecular workflow. In the absence of an International Standard or Certified Reference Material (CRM), QCMD uses Internal Reference Materials (IRMs) with values established using a dPCR reference assay in order to support the consistency and traceability of the EQA materials. This also helps aid the comparison of results across laboratories.


### 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
EVRNA21C1-01	99.2	Negative	0	0	Copies/ml	-
EVRNA21C1-02	100.0	Positive	0	9873	Copies/ml	27.94
EVRNA21C1-03	81.1	Positive	0	294	Copies/ml	33.05
EVRNA21C1-04	100.0	Positive	0	17454	Copies/ml	27.1
EVRNA21C1-05	99.2	Positive	0	62	Copies/ml	35.35

[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.

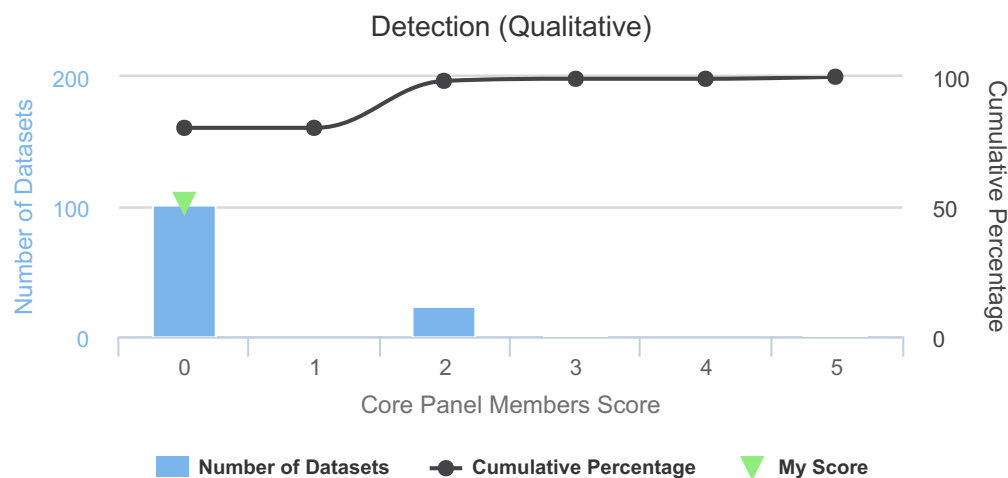
[4] **Percentage Correct (All):** Percentage of datasets (%) reporting the correct qualitative results for each panel member.


[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>	Enterovirus PCR Kit-croBEE (v4)
<b>Description</b>	
<b>Targets</b>	 enterovirus
<b>Assays</b>	<ul style="list-style-type: none"> <li> <i>Extraction - GeneProof - croBEE NA16 Nucleic Acid Extraction System</i> <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>croBEE 201A Nucleic Acid Extraction Kit</i></li> </ul> </li> </ul> </li> <li> <i>Amplification - GeneProof - croBEE Real-Time PCR System</i> <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>GeneProof Enterovirus PCR Kit</i></li> <li>○ Kit Version: <i>ISEX</i></li> </ul> </li> </ul> </li> </ul>

## Further Programme Details

Number of Participants	110
Number of Countries	25
Number of Respondents	106
Number of Datasets Submitted	127
Qualitative Results Returned	127 (100.0%)

## Comments

Core sample EVRNA21C1-03 contains enterovirus D68 (clade B3) and was reported to be positive in 81% of datasets. This strain is currently in circulation and laboratories (using commercial and/or in house assays) should re-evaluate their assays if they have failed to detect enterovirus in this sample.

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### EQA Programme Aims


To assess the ability of laboratories molecular assays to detect different types and concentrations of enterovirus (EV).

To review the performance of laboratories quantitative EV molecular assays.

### 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.

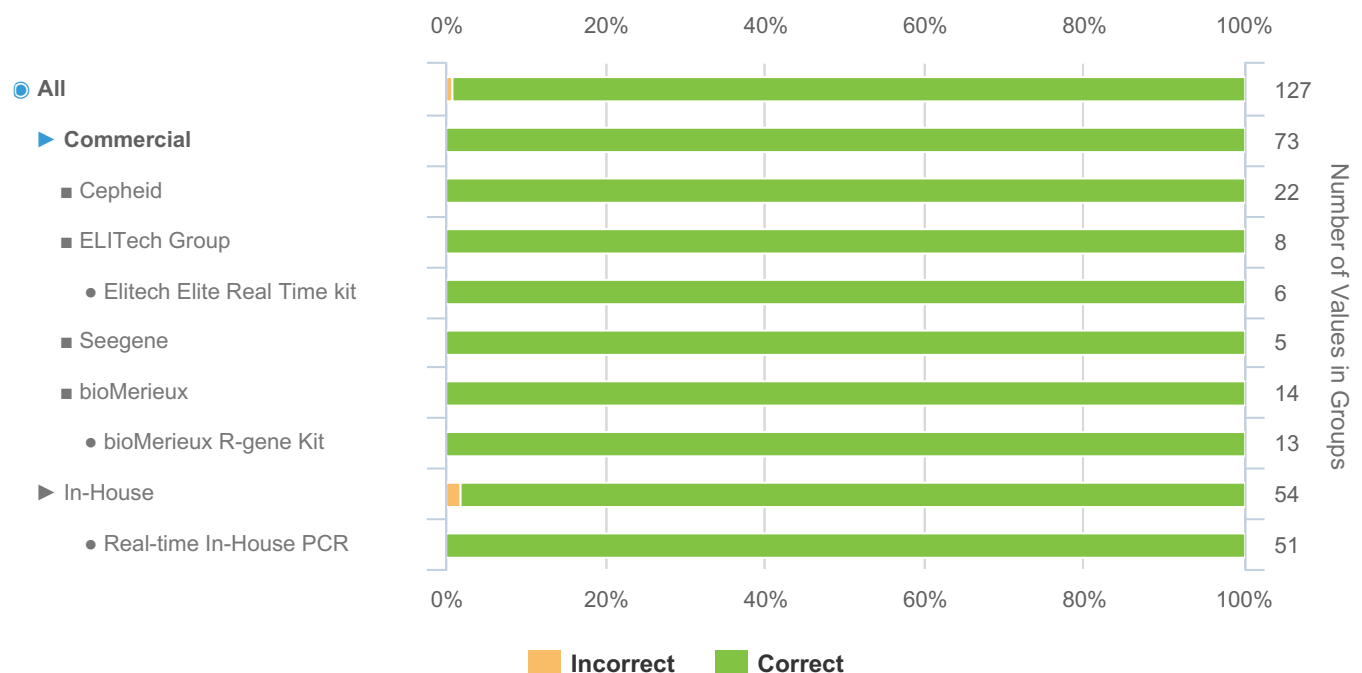
To allow meaningful assessment at the individual method level the EQA assessment group must consist of 5 or more datasets. If there are not sufficient datasets at the individual method level then your results will be included within a higher EQA assessment group based on whether it is a commercial or 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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**EVRNA21C1-01 - Qualitative Results Breakdown**

Sample Code	Sample Content	Matrix	Sample Relationships	Detection Frequency	Sample Status	Percentage Correct (All)	
						(%)	(n)
EVRNA21C1-01	Negative	Transport Medium		Negative	CORE	99.2	127



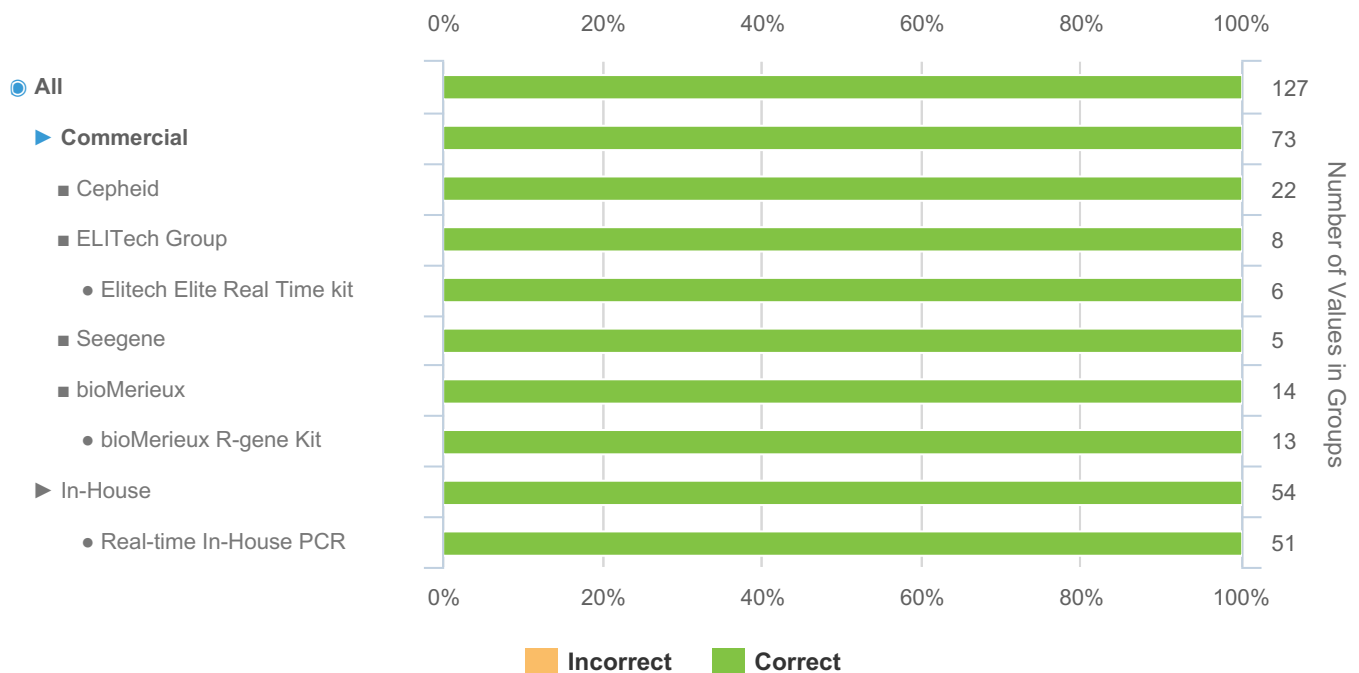
**Groups below n=5:** AB Analytica (n=3), AB Analytica - AB Analytica REALQUALITY RQ (n=3), Altona Diagnostics (n=1), Altona Diagnostics - Altona Diagnostics RealStar (n=1), AmpliSens (n=1), AmpliSens - AmpliSens Real Time PCR (n=1), AusDiagnostics (n=1), AusDiagnostics - AusDiagnostics Easy-Plex (n=1), Certest (n=1), Certest - Certest Real Time PCR (n=1), Diagenode (n=3), Diagenode - Diagenode Real Time kit (n=3), ELITech Group - Elitech Alert Real Time Q-PCR kit (n=1), ELITech Group - Elitech GeneFinder (n=1), GeneProof (n=2), GeneProof - GeneProof Real Time PCR kit (n=2), Jiangsu Bioperfectus (n=1), Jiangsu Bioperfectus - Jiangsu Bioperfectus Real Time PCR (n=1), Liferiver (n=1), Liferiver - Liferiver Real Time PCR (n=1), Progenie Molecular (n=3), Progenie Molecular - Progenie Molecular RealCycler (n=3), QIAGEN (n=1), QIAGEN - Qiagen QIastat-Dx (n=1), R-Biopharm (n=4), R-Biopharm - R-Biopharm RIDA Gene (n=4), bioMerieux - BioFire FilmArray ME (n=1), fast-track DIAGNOSTICS (n=2), fast-track DIAGNOSTICS - FTD real time PCR (n=2), In-House - Conventional In-House PCR (n=3)

**Groups Rolled Up:** Cepheid - Cepheid Xpert kit (n=22), Seegene - Seegene Allplex (n=5)

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**EVRNA21C1-02 - Qualitative Results Breakdown**

Sample Code	Sample Content	Matrix	Sample Relationships	Detection Frequency	Sample Status	Percentage Correct (All)	
						(%)	(n)
EVRNA21C1-02	Coxsackievirus A24	Transport Medium	3.84 dPCR Log10 Copies/ml	Frequently Detected	CORE	100.0	127

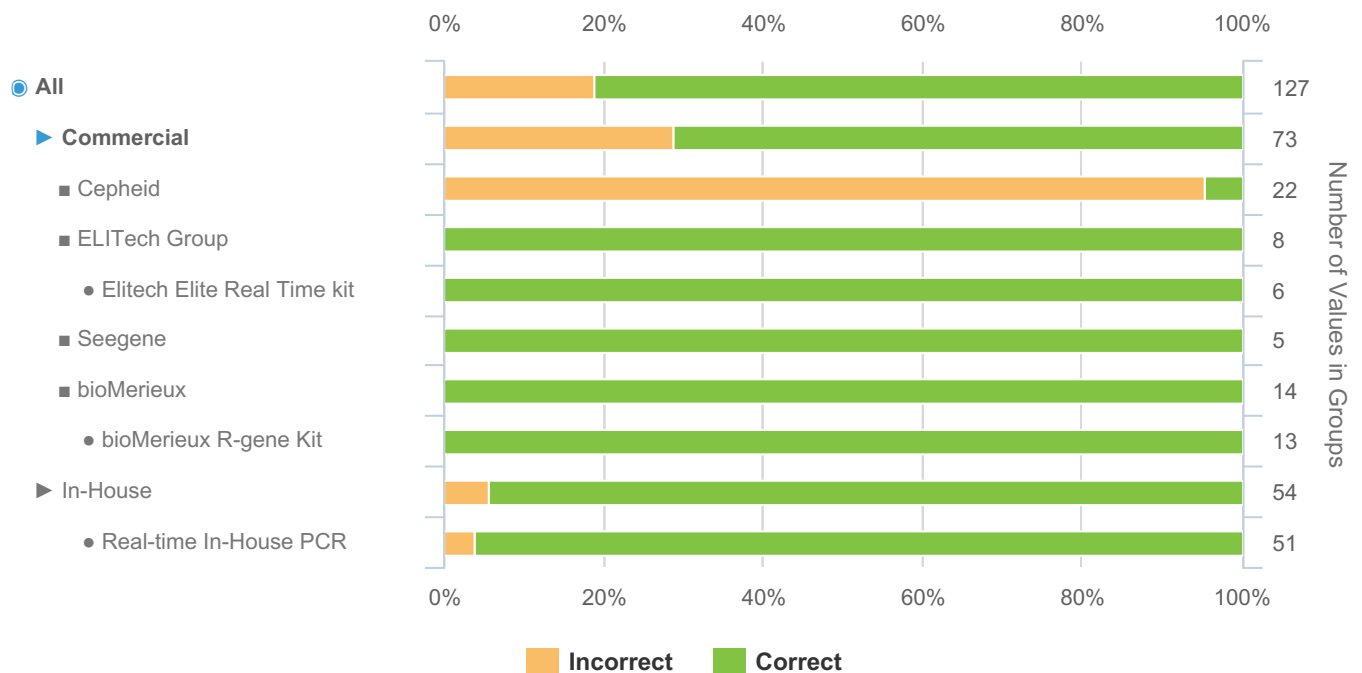


**Groups below n=5:** AB Analytica (n=3), AB Analytica - AB Analytica REALQUALITY RQ (n=3), Altona Diagnostics (n=1), Altona Diagnostics - Altona Diagnostics RealStar (n=1), AmpliSens (n=1), AmpliSens - AmpliSens Real Time PCR (n=1), AusDiagnostics (n=1), AusDiagnostics - AusDiagnostics Easy-Plex (n=1), Certest (n=1), Certest - Certest Real Time PCR (n=1), Diagenode (n=3), Diagenode - Diagenode Real Time kit (n=3), ELITech Group - Elitech Alert Real Time Q-PCR kit (n=1), ELITech Group - Elitech GeneFinder (n=1), GeneProof (n=2), GeneProof - GeneProof Real Time PCR kit (n=2), Jiangsu Bioperfectus (n=1), Jiangsu Bioperfectus - Jiangsu Bioperfectus Real Time PCR (n=1), Liferiver (n=1), Liferiver - Liferiver Real Time PCR (n=1), Progenie Molecular (n=3), Progenie Molecular - Progenie Molecular RealCycler (n=3), QIAGEN (n=1), QIAGEN - Qiagen QIAstat-Dx (n=1), R-Biopharm (n=4), R-Biopharm - R-Biopharm RIDA Gene (n=4), bioMerieux - BioFire FilmArray ME (n=1), fast-track DIAGNOSTICS (n=2), fast-track DIAGNOSTICS - FTD real time PCR (n=2), In-House - Conventional In-House PCR (n=3)

**Groups Rolled Up:** Cepheid - Cepheid Xpert kit (n=22), Seegene - Seegene Allplex (n=5)

**EVRNA21C1-03 - Qualitative Results Breakdown**


Sample Code	Sample Content	Matrix	Sample Relationships	Detection Frequency	Sample Status	Percentage Correct (All)	
						(%)	(n)
EVRNA21C1-03	Enterovirus D68 B3	Transport Medium	5.10 dPCR Log10 Copies/ml	Detected	CORE	81.1	127



**Groups below n=5:** AB Analytica (n=3), AB Analytica - AB Analytica REALQUALITY RQ (n=3), Altona Diagnostics (n=1), Altona Diagnostics - Altona Diagnostics RealStar (n=1), AmpliSens (n=1), AmpliSens - AmpliSens Real Time PCR (n=1), AusDiagnostics (n=1), AusDiagnostics - AusDiagnostics Easy-Plex (n=1), Certest (n=1), Certest - Certest Real Time PCR (n=1), Diagenode (n=3), Diagenode - Diagenode Real Time kit (n=3), ELITech Group - Elitech Alert Real Time Q-PCR kit (n=1), ELITech Group - Elitech GeneFinder (n=1), GeneProof (n=2), GeneProof - GeneProof Real Time PCR kit (n=2), Jiangsu Bioperfectus (n=1), Jiangsu Bioperfectus - Jiangsu Bioperfectus Real Time PCR (n=1), Liferiver (n=1), Liferiver - Liferiver Real Time PCR (n=1), Progenie Molecular (n=3), Progenie Molecular - Progenie Molecular RealCycler (n=3), QIAGEN (n=1), QIAGEN - Qiagen QIastat-Dx (n=1), R-Biopharm (n=4), R-Biopharm - R-Biopharm RIDA Gene (n=4), bioMerieux - BioFire FilmArray ME (n=1), fast-track DIAGNOSTICS (n=2), fast-track DIAGNOSTICS - FTD real time PCR (n=2), In-House - Conventional In-House PCR (n=3)

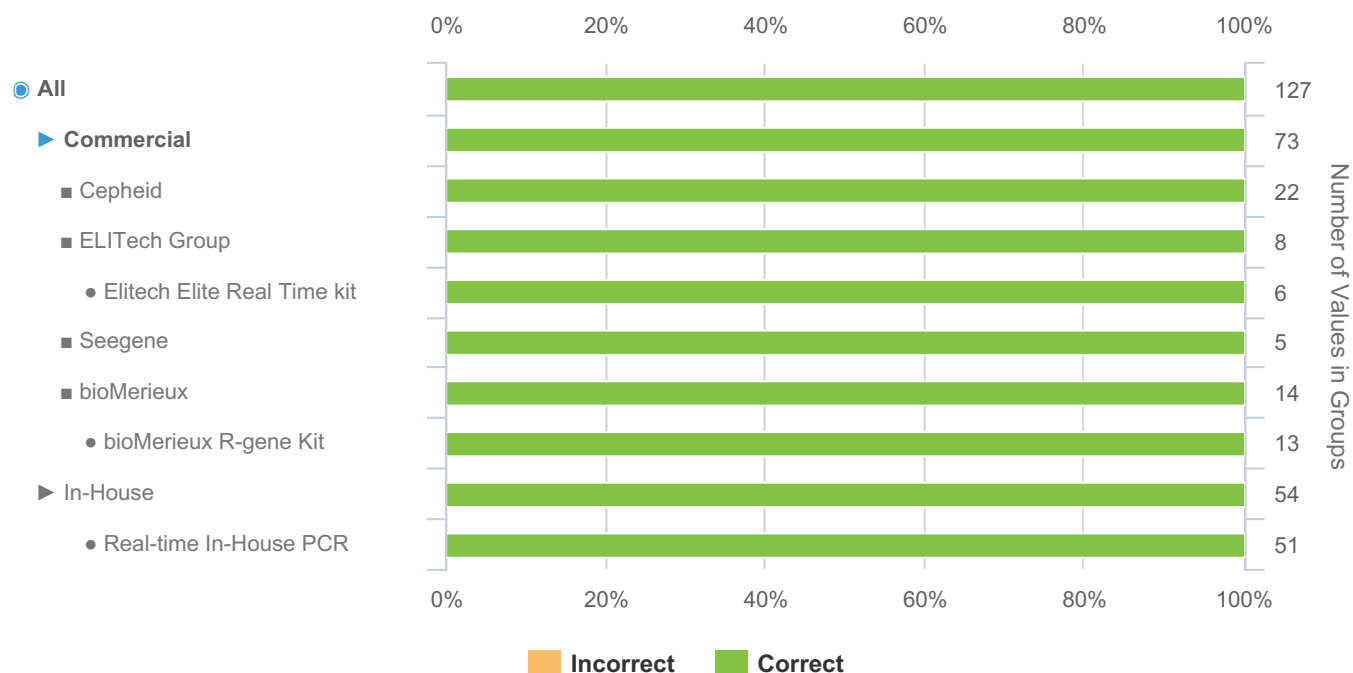
**Groups Rolled Up:** Cepheid - Cepheid Xpert kit (n=22), Seegene - Seegene Allplex (n=5)



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**EVRNA21C1-04 - Qualitative Results Breakdown**

Sample Code	Sample Content	Matrix	Sample Relationships	Detection Frequency	Sample Status	Percentage Correct (All)	
						(%)	(n)
EVRNA21C1-04	Echovirus 25	Transport Medium	4.68 dPCR Log10 Copies/ml	Frequently Detected	CORE	100.0	127



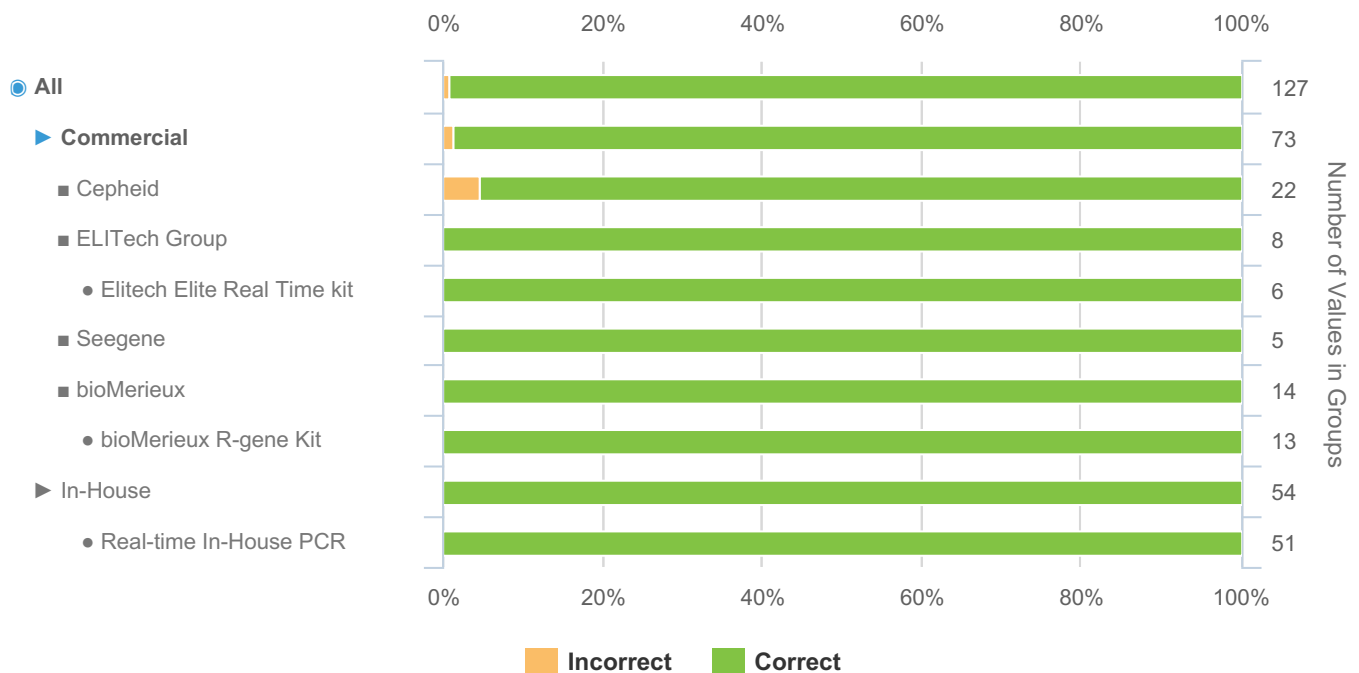
**Groups below n=5:** AB Analytica (n=3), AB Analytica - AB Analytica REALQUALITY RQ (n=3), Altona Diagnostics (n=1), Altona Diagnostics - Altona Diagnostics RealStar (n=1), AmpliSens (n=1), AmpliSens - AmpliSens Real Time PCR (n=1), AusDiagnostics (n=1), AusDiagnostics - AusDiagnostics Easy-Plex (n=1), Certest (n=1), Certest - Certest Real Time PCR (n=1), Diagenode (n=3), Diagenode - Diagenode Real Time kit (n=3), ELITech Group - Elitech Alert Real Time Q-PCR kit (n=1), ELITech Group - Elitech GeneFinder (n=1), GeneProof (n=2), GeneProof - GeneProof Real Time PCR kit (n=2), Jiangsu Bioperfectus (n=1), Jiangsu Bioperfectus - Jiangsu Bioperfectus Real Time PCR (n=1), Liferiver (n=1), Liferiver - Liferiver Real Time PCR (n=1), Progenie Molecular (n=3), Progenie Molecular - Progenie Molecular RealCycler (n=3), QIAGEN (n=1), QIAGEN - Qiagen QIastat-Dx (n=1), R-Biopharm (n=4), R-Biopharm - R-Biopharm RIDA Gene (n=4), bioMerieux - BioFire FilmArray ME (n=1), fast-track DIAGNOSTICS (n=2), fast-track DIAGNOSTICS - FTD real time PCR (n=2), In-House - Conventional In-House PCR (n=3)

**Groups Rolled Up:** Cepheid - Cepheid Xpert kit (n=22), Seegene - Seegene Allplex (n=5)

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**EVRNA21C1-05 - Qualitative Results Breakdown**

Sample Code	Sample Content	Matrix	Sample Relationships	Detection Frequency	Sample Status	Percentage Correct (All)	
						(%)	(n)
EVRNA21C1-05	Coxsackievirus A9	Transport Medium	3.46 dPCR Log10 Copies/ml	Frequently Detected	CORE	99.2	127



**Groups below n=5:** AB Analytica (n=3), AB Analytica - AB Analytica REALQUALITY RQ (n=3), Altona Diagnostics (n=1), Altona Diagnostics - Altona Diagnostics RealStar (n=1), AmpliSens (n=1), AmpliSens - AmpliSens Real Time PCR (n=1), AusDiagnostics (n=1), AusDiagnostics - AusDiagnostics Easy-Plex (n=1), Certest (n=1), Certest - Certest Real Time PCR (n=1), Diagenode (n=3), Diagenode - Diagenode Real Time kit (n=3), ELITech Group - Elitech Alert Real Time Q-PCR kit (n=1), ELITech Group - Elitech GeneFinder (n=1), GeneProof (n=2), GeneProof - GeneProof Real Time PCR kit (n=2), Jiangsu Bioperfectus (n=1), Jiangsu Bioperfectus - Jiangsu Bioperfectus Real Time PCR (n=1), Liferiver (n=1), Liferiver - Liferiver Real Time PCR (n=1), Progenie Molecular (n=3), Progenie Molecular - Progenie Molecular RealCycler (n=3), QIAGEN (n=1), QIAGEN - Qiagen QIastat-Dx (n=1), R-Biopharm (n=4), R-Biopharm - R-Biopharm RIDA Gene (n=4), bioMerieux - BioFire FilmArray ME (n=1), fast-track DIAGNOSTICS (n=2), fast-track DIAGNOSTICS - FTD real time PCR (n=2), In-House - Conventional In-House PCR (n=3)

**Groups Rolled Up:** Cepheid - Cepheid Xpert kit (n=22), Seegene - Seegene Allplex (n=5)

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