Individual Report	QCMD 2020 Coronavirus Outbreak Preparedness EQA Pilot Study					
Catalogue Code: QAV204214	**Ref Code:** CVOP20	**Challenge:** S	**Analysis Type:** Qualitative	**Dataset:** 346009	**Report UID:** 2677/346009/2667	**Laboratory** CZ023

Intended Results / Panel Composition

Sample Code	Sample Content	Matrix	Sample Relationships [1]	Detection Frequency [2]	Sample Status [3]	Percentage Correct (All) [4]	
						(%)	*(n)*
CVOP20S-01	SARS-CoV-2	TM	4.30 dPCR Log10 Copies/ml (D1, DS1_2)	Frequently Detected	CORE	98.1	521
CVOP20S-02	Coronavirus NL63	TM	4.64 dPCR Log10 Copies/ml	Negative	EDUCATIONAL	96.9	521
CVOP20S-03	SARS-CoV-2	TM	3.30 dPCR Log10 Copies/ml (DS1_3)	Frequently Detected	CORE	96.9	521
CVOP20S-04	Coronavirus OC43	TM	4.03 dPCR Log10 Copies/ml	Negative	EDUCATIONAL	97.1	521
CVOP20S-05	Negative	TM		Negative	CORE	97.3	521
CVOP20S-06	SARS-CoV-2	TM	4.30 dPCR Log10 Copies/ml (D1, DS1_2)	Frequently Detected	CORE	98.5	521
CVOP20S-07	SARS-CoV-2	TM	5.30 dPCR Log10 Copies/ml (DS1_1)	Frequently Detected	CORE	99.2	521
CVOP20S-08	SARS-CoV-2	TM	2.30 dPCR Log10 Copies/ml (DS1_4)	Detected	CORE	86.0	521

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Issue Date: 27 May 2020
Report authorised by the QCMD Executive (1)

Individual Report	QCMD 2020 Coronavirus Outbreak Preparedness EQA Pilot Study	QCMD Quality Control for Molecular Diagnostics

Catalogue Code: QAV204214	Ref Code: CVOP20	Challenge: S	Analysis Type: Qualitative	Dataset: 346009	Report UID: 2677/346009/2667	Laboratory CZ023

[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 (modified from Eurosurveillance Jan 2020 Corman et al).

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.

Samples **CVOP20S-02** and **CVOP20S-04** were included in the panel as educational specificity samples. For this assessment, these samples have been assigned as SARS-CoV-2 Negative.

Your Summary Results

EQA Assessment Group [1]	Commercial
Core Panel Detection (Qualitative) Score [2]	0

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
CVOP20S-01	98.1	Positive	0		N/A	17.83
CVOP20S-03	96.9	Positive	0		N/A	21.05
CVOP20S-05	97.3	Negative	0		N/A	-
CVOP20S-06	98.5	Positive	0		N/A	17.38
CVOP20S-07	99.2	Positive	0		N/A	15.11
CVOP20S-08	86.0	Positive	0		N/A	25.45

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Catalogue Code: QAV204214	Ref Code: CVOP20	Challenge: S	Analysis Type: Qualitative	Dataset: 346009	Report UID: 2677/346009/2667	Laboratory CZ023

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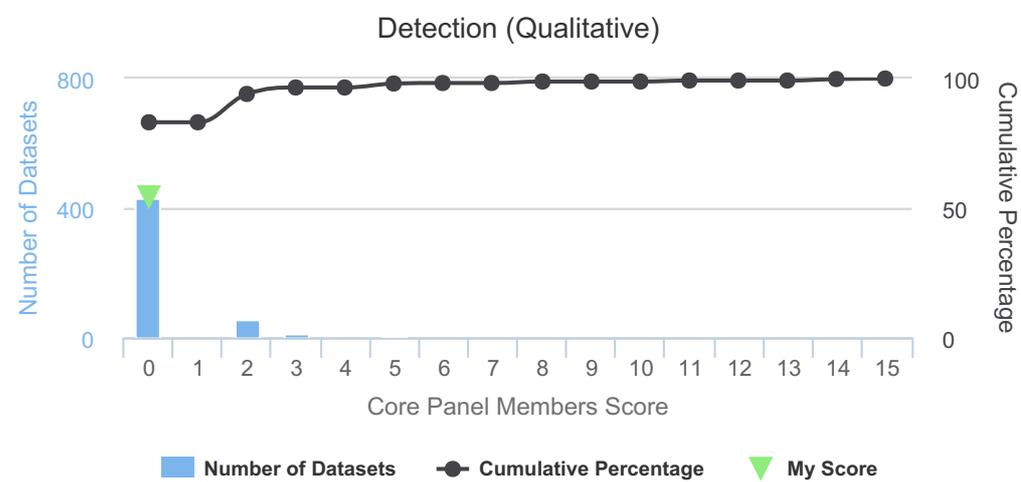
[4] **Percentage Correct (All):** Percentage of datasets (%) reporting the correct qualitative results for each panel member.

[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

Detection (Qualitative)

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.

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Issue Date: 27 May 2020
Report authorised by the QCMD Executive (1)

Individual Report	**QCMD 2020 Coronavirus Outbreak Preparedness EQA Pilot Study**	

Catalogue Code: QAV204214	Ref Code: CVOP20	Challenge: S	Analysis Type: Qualitative	Dataset: 346009	Report UID: 2677/346009/2667	Laboratory CZ023

My Workflow Details

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

Name	SARS-CoV-2 Screening PCR Kit (v3)
Description	
Targets	V coronavirus
Assays	*Extraction* - Manual Extraction Process • Commercial ○ Kit Manufacturer: *GeneProof* ○ Kit Type: *PathogenFree RNA Isolation Kit* *Amplification* - GeneProof - croBEE Real-Time PCR System • Commercial ○ Kit Manufacturer: *GeneProof* ○ Kit Type: *SARS-CoV-2 Screening PCR Kit* ○ Kit Version: *GP*

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
CVOP20S-02	96.9	Negative	0		N/A	-
CVOP20S-04	97.1	Negative	0		N/A	-

[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.

Catalogue Code: QAV204214	Ref Code: CVOP20	Challenge: S	Analysis Type: Qualitative	Dataset: 346009	Report UID: 2677/346009/2667	Laboratory CZ023

Further Programme Details

Number of Participants	406
Number of Countries	38
Number of Respondents	365
Number of Datasets Submitted	521
Qualitative Results Returned	521 (100.0%)

Comments

Thirty-six (7.1%) laboratories reported sample CVOP20S-02 as Negative for SARS-CoV-2 and correctly reported the sample as Coronavirus NL63.

Thirty-seven (7.2%) laboratories reported sample CVOP20S-04 as Negative for SARS-CoV-2 and correctly reported the sample as Coronavirus OC43.

EQA Programme Aims

To assess the proficiency of laboratories molecular technologies for the detection and determination of SARS-CoV-2 from other coronaviruses.

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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Report authorised by the QCMD Executive (1)

Individual Report	QCMD 2020 Coronavirus Outbreak Preparedness EQA Pilot Study	QCMD Quality Control for Molecular Diagnostics

Catalogue Code: QAV204214	Ref Code: CVOP20	Challenge: S	Analysis Type: Qualitative	Dataset: 346009	Report UID: 2677/346009/2667	Laboratory CZ023

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.
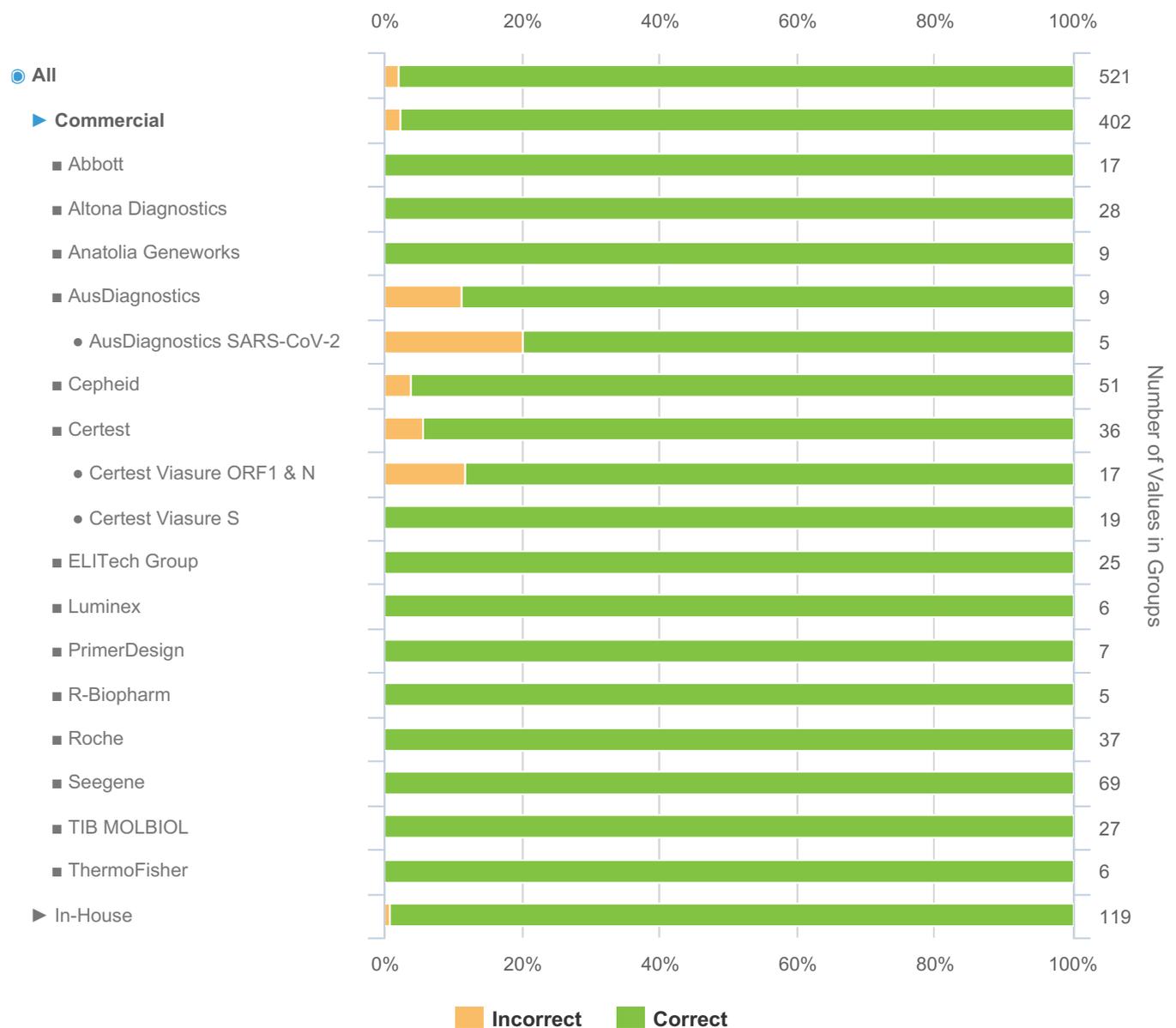
To allow meaningful assessment at the individual method level the EQA assessment group must consist of 5 or more datasets. If there are not sufficient datasets at the individual method level then your results will be included within a higher EQA assessment group based on whether it is a commercial or 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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| Catalogue Code: QAV204214 | Ref Code: CVOP20 | Challenge: S | Analysis Type: Qualitative | Dataset: 346009 | Report UID: 2677/346009/2667 | Laboratory CZ023 |

CVOP20S-01 - Qualitative Results Breakdown

Sample Code	Sample Content	Matrix	Sample Relationships	Detection Frequency	Sample Status	Percentage Correct (All)	
						(%)	*(n)*
CVOP20S-01	SARS-CoV-2	TM	4.30 dPCR Log10 Copies/ml (D1, DS1_2)	Frequently Detected	CORE	98.1	521

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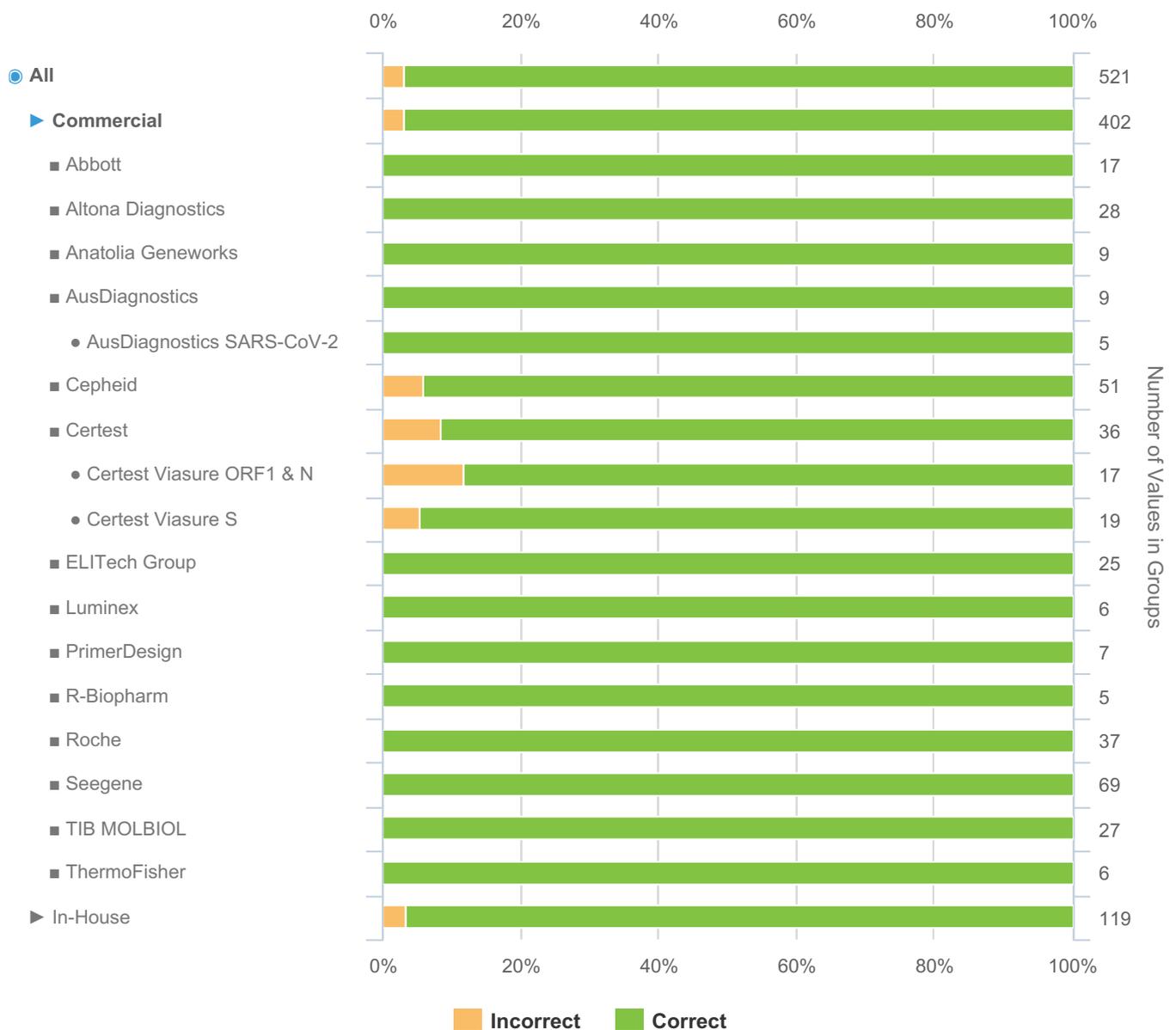| Catalogue Code: QAV204214	Ref Code: CVOP20	Challenge: S	Analysis Type: Qualitative	Dataset: 346009	Report UID: 2677/346009/2667	Laboratory CZ023

Groups below n=5: AB Analitica (n=3), AB Analitica - AB Analitica REALQUALITY RQ (n=3), ABL (n=1), ABL - ABL UltraGene (n=1), Anchor Diagnostics (n=3), Anchor Diagnostics - Anchor Diagnostics SARS CoV-2 (n=3), Applied Biosystems (n=2), Applied Biosystems - Applied Biosystems Real Time PCR Kit (n=2), Appolon biotek (n=1), Appolon biotek - Appolon biotek SARS-CoV-2 (n=1), AusDiagnostics - AusDiagnostics Easy-Plex (n=4), BGI (n=2), BGI - BGI Real Time PCR (n=2), BioGX (n=1), BioGX - BioGX SARS-CoV-2 (n=1), Bioeksen (n=2), Bioeksen - Bioeksen Biospeedy SARS-CoV-2 (n=2), CDC (n=3), CDC - CDC SARS-CoV-2 (n=3), Co-Diagnostics Inc (n=3), Co-Diagnostics Inc - Co-Diagnostics Inc Logix Smart (n=3), DiaCarta (n=1), DiaCarta - DiaCarta QuantiVirus PCR kit (n=1), DiaSorin (n=2), DiaSorin - DiaSorin Simplexa (n=2), Diagenode (n=1), Diagenode - Diagenode Real-Time PCR (n=1), EUROIMMUN (n=3), EUROIMMUN - EUROIMMUN SARS-CoV-2 (n=3), GenMark (n=1), GenMark - GenMark SARS-CoV-2 (n=1), GeneProof (n=4), GeneProof - GeneProof SARS-CoV-2 (n=4), Genematrix (n=1), Genematrix - Genematrix NeoPlex (n=1), Hologic (n=2), Hologic - Hologic Panther Fusion (n=2), Hybribio Limited (n=1), Hybribio Limited - Hybribio Real-Time PCR Kit (n=1), Immundiagnostik (n=1), Immundiagnostik - Immundignostik MutaPLEX (n=1), Kogene Biotech (n=1), Kogene Biotech - Kogene Powerchek (n=1), Liferiver (n=1), Liferiver - Liferiver 2019-nCoV (n=1), Luminex - Luminex ARIES (n=2), Luminex - Luminex xTAG (n=4), Mediven (n=1), Mediven - Mediven GenoAmp PCR (n=1), Mikrogen (n=4), Mikrogen - Mikrogen ampliCube (n=4), Mobidiag (n=4), Mobidiag - Mobidiag Amplidiag (n=4), QIAGEN (n=4), QIAGEN - Qiagen QIAstat-Dx (n=4), Randox (n=2), Randox - Randox COVID-19 Array (n=1), Randox - Randox Extended Array (n=1), Sansure Biotech (n=1), Sansure Biotech - Sansure Biotech nCoV PCR Kit (n=1), Serosep (n=1), Serosep - Serosep Real Time PCR (n=1), Shanghai BioGerm (n=1), Shanghai BioGerm - Shanghai BioGerm Real Time PCR (n=1), Shanghai Fosun Pharmaceutical (n=1), Shanghai Fosun Pharmaceutical - Shanghai Fosun Real Time PCR (n=1), Vazyme (n=1), Vazyme - Vazyme SARS-CoV-2 (n=1), Vitassay (n=4), Vitassay - Vitassay SARS-CoV-2 (n=4), bioMerieux (n=4), bioMerieux - BioFire FilmArray (n=1), bioMerieux - bioMerieux R-gene SARS-CoV-2 (n=3), fast-track DIAGNOSTICS (n=2), fast-track DIAGNOSTICS - FTD real time PCR (n=2)

Groups Rolled Up: Abbott - Abbott SARS-CoV-2 (n=17), Altona Diagnostics - Altona Diagnostics RealStar (n=28), Anatolia Geneworks - Anatolia Geneworks Bosphore nCoV (n=9), Cepheid - Cepheid Xpert SARS-CoV-2 (n=51), ELITech Group - Elitech GeneFinder (n=25), PrimerDesign - PrimerDesign Genesig (n=7), R-Biopharm - R-Biopharm RIDA Gene (n=5), Roche - Roche Cobas SARS-CoV 2 (n=37), Seegene - Seegene Allplex SARS-CoV-2 (n=69), TIB MOLBIOL - TIB MOLBIOL LightMix (n=27), ThermoFisher - Thermofisher TaqPath COVID-19 (n=6), In-House - Real-time In-House PCR (n=119)

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Catalogue Code: QAV204214	Ref Code: CVOP20	Challenge: S	Analysis Type: Qualitative	Dataset: 346009	Report UID: 2677/346009/2667	Laboratory CZ023

CVOP20S-03 - Qualitative Results Breakdown

Sample Code	Sample Content	Matrix	Sample Relationships	Detection Frequency	Sample Status	Percentage Correct (All)	
						(%)	*(n)*
CVOP20S-03	SARS-CoV-2	TM	3.30 dPCR Log10 Copies/ml (DS1_3)	Frequently Detected	CORE	96.9	521

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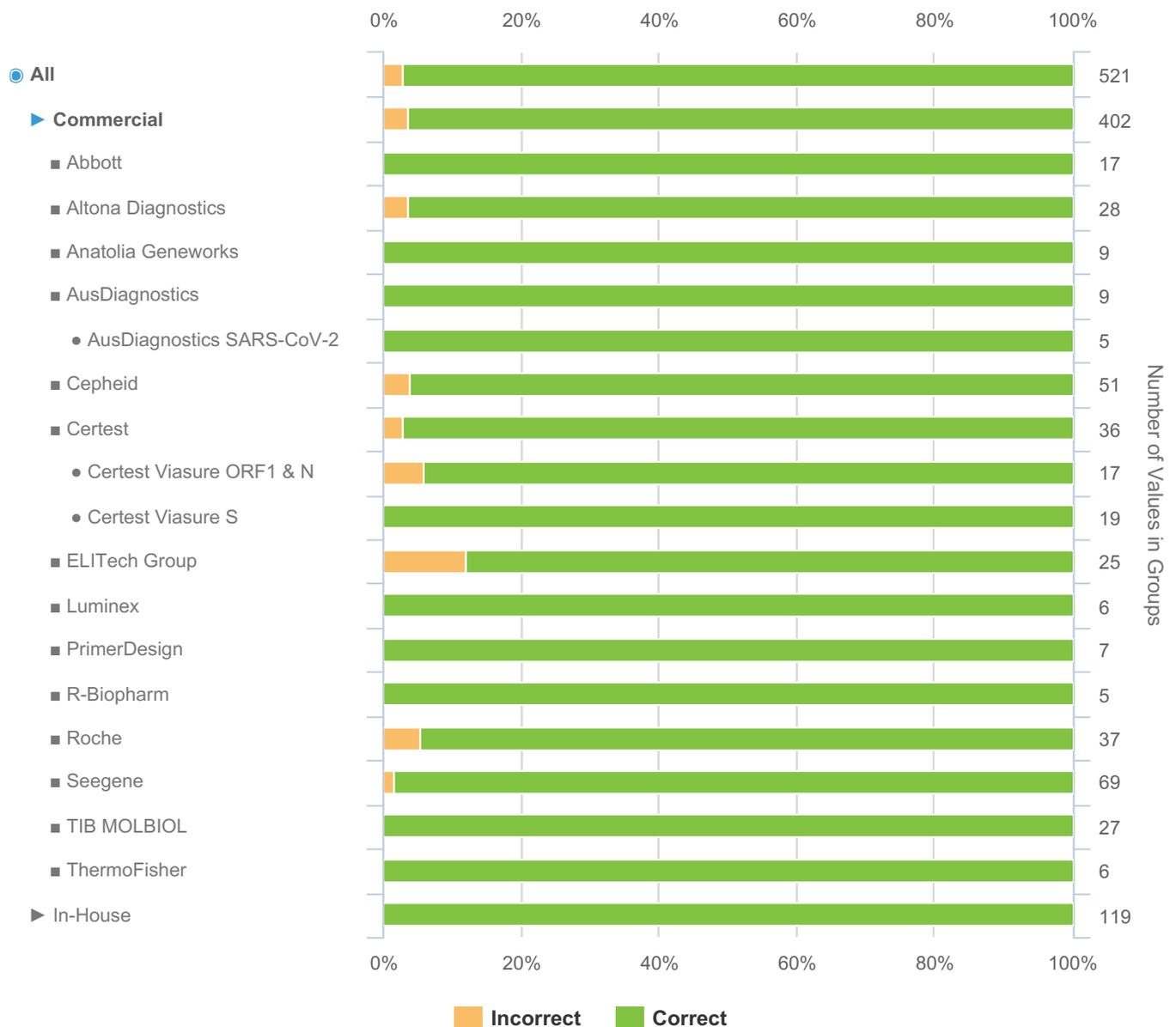| Catalogue Code: QAV204214 | Ref Code: CVOP20 | Challenge: S | Analysis Type: Qualitative | Dataset: 346009 | Report UID: 2677/346009/2667 | Laboratory CZ023 |

Groups below n=5: AB Analitica (n=3), AB Analitica - AB Analitica REALQUALITY RQ (n=3), ABL (n=1), ABL - ABL UltraGene (n=1), Anchor Diagnostics (n=3), Anchor Diagnostics - Anchor Diagnostics SARS CoV-2 (n=3), Applied Biosystems (n=2), Applied Biosystems - Applied Biosystems Real Time PCR Kit (n=2), Appolon biotek (n=1), Appolon biotek - Appolon biotek SARS-CoV-2 (n=1), AusDiagnostics - AusDiagnostics Easy-Plex (n=4), BGI (n=2), BGI - BGI Real Time PCR (n=2), BioGX (n=1), BioGX - BioGX SARS-CoV-2 (n=1), Bioeksen (n=2), Bioeksen - Bioeksen Biospeedy SARS-CoV-2 (n=2), CDC (n=3), CDC - CDC SARS-CoV-2 (n=3), Co-Diagnostics Inc (n=3), Co-Diagnostics Inc - Co-Diagnostics Inc Logix Smart (n=3), DiaCarta (n=1), DiaCarta - DiaCarta QuantiVirus PCR kit (n=1), DiaSorin (n=2), DiaSorin - DiaSorin Simplexa (n=2), Diagenode (n=1), Diagenode - Diagenode Real-Time PCR (n=1), EUROIMMUN (n=3), EUROIMMUN - EUROIMMUN SARS-CoV-2 (n=3), GenMark (n=1), GenMark - GenMark SARS-CoV-2 (n=1), GeneProof (n=4), GeneProof - GeneProof SARS-CoV-2 (n=4), Genematrix (n=1), Genematrix - Genematrix NeoPlex (n=1), Hologic (n=2), Hologic - Hologic Panther Fusion (n=2), Hybribio Limited (n=1), Hybribio Limited - Hybribio Real-Time PCR Kit (n=1), Immundiagnostik (n=1), Immundiagnostik - Immundignostik MutaPLEX (n=1), Kogene Biotech (n=1), Kogene Biotech - Kogene Powerchek (n=1), Liferiver (n=1), Liferiver - Liferiver 2019-nCoV (n=1), Luminex - Luminex ARIES (n=2), Luminex - Luminex xTAG (n=4), Mediven (n=1), Mediven - Mediven GenoAmp PCR (n=1), Mikrogen (n=4), Mikrogen - Mikrogen ampliCube (n=4), Mobidiag (n=4), Mobidiag - Mobidiag Amplidiag (n=4), QIAGEN (n=4), QIAGEN - Qiagen QIAstat-Dx (n=4), Randox (n=2), Randox - Randox COVID-19 Array (n=1), Randox - Randox Extended Array (n=1), Sansure Biotech (n=1), Sansure Biotech - Sansure Biotech nCoV PCR Kit (n=1), Serosep (n=1), Serosep - Serosep Real Time PCR (n=1), Shanghai BioGerm (n=1), Shanghai BioGerm - Shanghai BioGerm Real Time PCR (n=1), Shanghai Fosun Pharmaceutical (n=1), Shanghai Fosun Pharmaceutical - Shanghai Fosun Real Time PCR (n=1), Vazyme (n=1), Vazyme - Vazyme SARS-CoV-2 (n=1), Vitassay (n=4), Vitassay - Vitassay SARS-CoV-2 (n=4), bioMerieux (n=4), bioMerieux - BioFire FilmArray (n=1), bioMerieux - bioMerieux R-gene SARS-CoV-2 (n=3), fast-track DIAGNOSTICS (n=2), fast-track DIAGNOSTICS - FTD real time PCR (n=2)

Groups Rolled Up: Abbott - Abbott SARS-CoV-2 (n=17), Altona Diagnostics - Altona Diagnostics RealStar (n=28), Anatolia Geneworks - Anatolia Geneworks Bosphore nCoV (n=9), Cepheid - Cepheid Xpert SARS-CoV-2 (n=51), ELITech Group - Elitech GeneFinder (n=25), PrimerDesign - PrimerDesign Genesig (n=7), R-Biopharm - R-Biopharm RIDA Gene (n=5), Roche - Roche Cobas SARS-CoV 2 (n=37), Seegene - Seegene Allplex SARS-CoV-2 (n=69), TIB MOLBIOL - TIB MOLBIOL LightMix (n=27), ThermoFisher - Thermofisher TaqPath COVID-19 (n=6), In-House - Real-time In-House PCR (n=119)

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CVOP20S-05 - Qualitative Results Breakdown

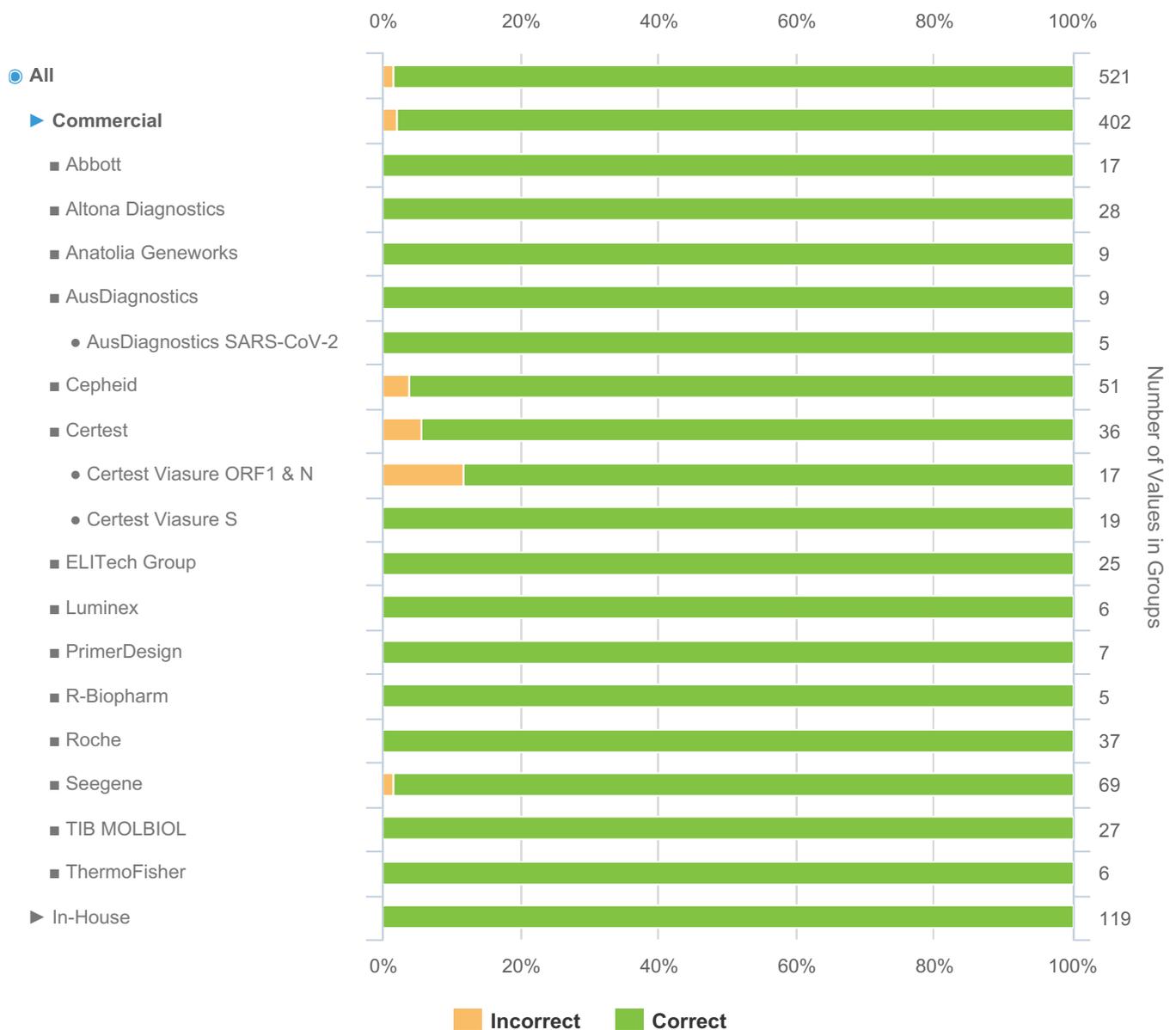| Sample Code	Sample Content	Matrix	Sample Relationships	Detection Frequency	Sample Status	Percentage Correct (All)	
						(%)	*(n)*
CVOP20S-05	Negative	TM		Negative	CORE	97.3	521

Groups below n=5: AB Analitica (n=3), AB Analitica - AB Analitica REALQUALITY RQ (n=3), ABL (n=1), ABL - ABL UltraGene (n=1), Anchor Diagnostics (n=3), Anchor Diagnostics - Anchor Diagnostics SARS CoV-2 (n=3), Applied Biosystems (n=2), Applied Biosystems - Applied Biosystems Real Time PCR Kit (n=2), Appolon biotek (n=1), Appolon biotek - Appolon biotek SARS-CoV-2 (n=1), AusDiagnostics - AusDiagnostics Easy-Plex (n=4), BGI (n=2), BGI - BGI Real Time PCR (n=2), BioGX (n=1), BioGX - BioGX SARS-CoV-2 (n=1), Bioeksen (n=2), Bioeksen - Bioeksen Biospeedy SARS-CoV-2 (n=2), CDC (n=3), CDC - CDC SARS-CoV-2 (n=3), Co-Diagnostics Inc (n=3), Co-Diagnostics Inc - Co-Diagnostics Inc Logix Smart (n=3), DiaCarta (n=1), DiaCarta - DiaCarta QuantiVirus PCR kit (n=1), DiaSorin (n=2), DiaSorin - DiaSorin Simplexa (n=2), Diagenode (n=1), Diagenode - Diagenode Real-Time PCR (n=1), EUROIMMUN (n=3), EUROIMMUN - EUROIMMUN SARS-CoV-2 (n=3), GenMark (n=1), GenMark - GenMark SARS-CoV-2 (n=1), GeneProof (n=4), GeneProof - GeneProof SARS-CoV-2 (n=4), Genematrix (n=1), Genematrix - Genematrix NeoPlex (n=1), Hologic (n=2), Hologic - Hologic Panther Fusion (n=2), Hybribio Limited (n=1), Hybribio Limited - Hybribio Real-Time PCR Kit (n=1), Immundiagnostik (n=1), Immundiagnostik - Immundignostik MutaPLEX (n=1), Kogene Biotech (n=1), Kogene Biotech - Kogene Powerchek (n=1), Liferiver (n=1), Liferiver - Liferiver 2019-nCoV (n=1), Luminex - Luminex ARIES (n=2), Luminex - Luminex xTAG (n=4), Mediven (n=1), Mediven - Mediven GenoAmp PCR (n=1), Mikrogen (n=4), Mikrogen - Mikrogen ampliCube (n=4), Mobidiag (n=4), Mobidiag - Mobidiag Amplidiag (n=4), QIAGEN (n=4), QIAGEN - Qiagen QIAstat-Dx (n=4), Randox (n=2), Randox - Randox COVID-19 Array (n=1), Randox - Randox Extended Array (n=1), Sansure Biotech (n=1), Sansure Biotech - Sansure Biotech nCoV PCR Kit (n=1), Serosep (n=1), Serosep - Serosep Real Time PCR (n=1), Shanghai BioGerm (n=1), Shanghai BioGerm - Shanghai BioGerm Real Time PCR (n=1), Shanghai Fosun Pharmaceutical (n=1), Shanghai Fosun Pharmaceutical - Shanghai Fosun Real Time PCR (n=1), Vazyme (n=1), Vazyme - Vazyme SARS-CoV-2 (n=1), Vitassay (n=4), Vitassay - Vitassay SARS-CoV-2 (n=4), bioMerieux (n=4), bioMerieux - BioFire FilmArray (n=1), bioMerieux - bioMerieux R-gene SARS-CoV-2 (n=3), fast-track DIAGNOSTICS (n=2), fast-track DIAGNOSTICS - FTD real time PCR (n=2)

Groups Rolled Up: Abbott - Abbott SARS-CoV-2 (n=17), Altona Diagnostics - Altona Diagnostics RealStar (n=28), Anatolia Geneworks - Anatolia Geneworks Bosphore nCoV (n=9), Cepheid - Cepheid Xpert SARS-CoV-2 (n=51), ELITech Group - Elitech GeneFinder (n=25), PrimerDesign - PrimerDesign Genesig (n=7), R-Biopharm - R-Biopharm RIDA Gene (n=5), Roche - Roche Cobas SARS-CoV 2 (n=37), Seegene - Seegene Allplex SARS-CoV-2 (n=69), TIB MOLBIOL - TIB MOLBIOL LightMix (n=27), ThermoFisher - Thermofisher TaqPath COVID-19 (n=6), In-House - Real-time In-House PCR (n=119)

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Report authorised by the QCMD Executive (1)

Catalogue Code: QAV204214	Ref Code: CVOP20	Challenge: S	Analysis Type: Qualitative	Dataset: 346009	Report UID: 2677/346009/2667	Laboratory CZ023

CVOP20S-06 - Qualitative Results Breakdown

Sample Code	Sample Content	Matrix	Sample Relationships	Detection Frequency	Sample Status	Percentage Correct (All)	
						(%)	*(n)*
CVOP20S-06	SARS-CoV-2	TM	4.30 dPCR Log10 Copies/ml (D1, DS1_2)	Frequently Detected	CORE	98.5	521

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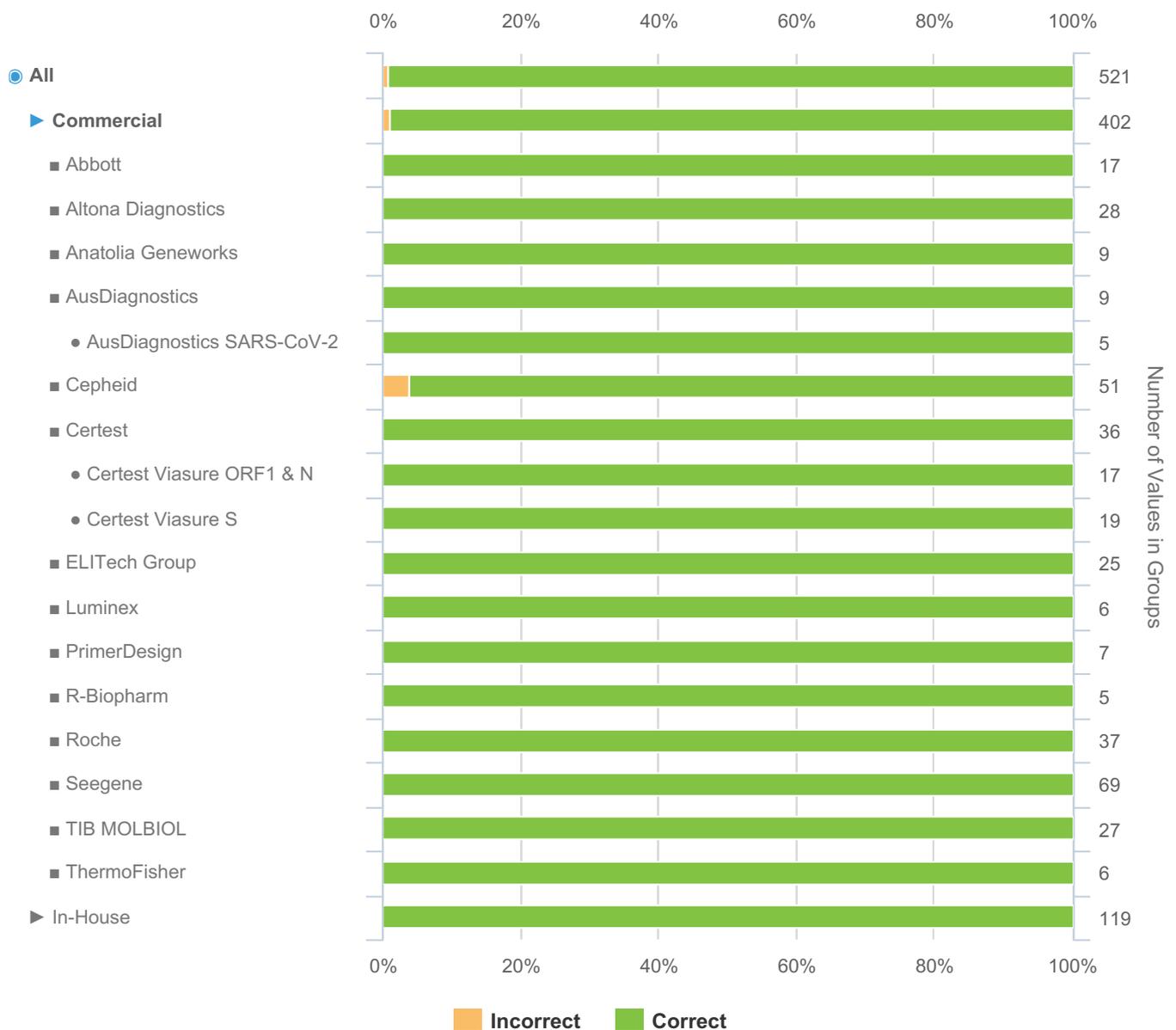Report authorised by the QCMD Executive (1)

Groups below n=5: AB Analitica (n=3), AB Analitica - AB Analitica REALQUALITY RQ (n=3), ABL (n=1), ABL - ABL UltraGene (n=1), Anchor Diagnostics (n=3), Anchor Diagnostics - Anchor Diagnostics SARS CoV-2 (n=3), Applied Biosystems (n=2), Applied Biosystems - Applied Biosystems Real Time PCR Kit (n=2), Appolon biotek (n=1), Appolon biotek - Appolon biotek SARS-CoV-2 (n=1), AusDiagnostics - AusDiagnostics Easy-Plex (n=4), BGI (n=2), BGI - BGI Real Time PCR (n=2), BioGX (n=1), BioGX - BioGX SARS-CoV-2 (n=1), Bioeksen (n=2), Bioeksen - Bioeksen Biospeedy SARS-CoV-2 (n=2), CDC (n=3), CDC - CDC SARS-CoV-2 (n=3), Co-Diagnostics Inc (n=3), Co-Diagnostics Inc - Co-Diagnostics Inc Logix Smart (n=3), DiaCarta (n=1), DiaCarta - DiaCarta QuantiVirus PCR kit (n=1), DiaSorin (n=2), DiaSorin - DiaSorin Simplexa (n=2), Diagenode (n=1), Diagenode - Diagenode Real-Time PCR (n=1), EUROIMMUN (n=3), EUROIMMUN - EUROIMMUN SARS-CoV-2 (n=3), GenMark (n=1), GenMark - GenMark SARS-CoV-2 (n=1), GeneProof (n=4), GeneProof - GeneProof SARS-CoV-2 (n=4), Genematrix (n=1), Genematrix - Genematrix NeoPlex (n=1), Hologic (n=2), Hologic - Hologic Panther Fusion (n=2), Hybribio Limited (n=1), Hybribio Limited - Hybribio Real-Time PCR Kit (n=1), Immundiagnostik (n=1), Immundiagnostik - Immundignostik MutaPLEX (n=1), Kogene Biotech (n=1), Kogene Biotech - Kogene Powerchek (n=1), Liferiver (n=1), Liferiver - Liferiver 2019-nCoV (n=1), Luminex - Luminex ARIES (n=2), Luminex - Luminex xTAG (n=4), Mediven (n=1), Mediven - Mediven GenoAmp PCR (n=1), Mikrogen (n=4), Mikrogen - Mikrogen ampliCube (n=4), Mobidiag (n=4), Mobidiag - Mobidiag Amplidiag (n=4), QIAGEN (n=4), QIAGEN - Qiagen QIAstat-Dx (n=4), Randox (n=2), Randox - Randox COVID-19 Array (n=1), Randox - Randox Extended Array (n=1), Sansure Biotech (n=1), Sansure Biotech - Sansure Biotech nCoV PCR Kit (n=1), Serosep (n=1), Serosep - Serosep Real Time PCR (n=1), Shanghai BioGerm (n=1), Shanghai BioGerm - Shanghai BioGerm Real Time PCR (n=1), Shanghai Fosun Pharmaceutical (n=1), Shanghai Fosun Pharmaceutical - Shanghai Fosun Real Time PCR (n=1), Vazyme (n=1), Vazyme - Vazyme SARS-CoV-2 (n=1), Vitassay (n=4), Vitassay - Vitassay SARS-CoV-2 (n=4), bioMerieux (n=4), bioMerieux - BioFire FilmArray (n=1), bioMerieux - bioMerieux R-gene SARS-CoV-2 (n=3), fast-track DIAGNOSTICS (n=2), fast-track DIAGNOSTICS - FTD real time PCR (n=2)

Groups Rolled Up: Abbott - Abbott SARS-CoV-2 (n=17), Altona Diagnostics - Altona Diagnostics RealStar (n=28), Anatolia Geneworks - Anatolia Geneworks Bosphore nCoV (n=9), Cepheid - Cepheid Xpert SARS-CoV-2 (n=51), ELITech Group - Elitech GeneFinder (n=25), PrimerDesign - PrimerDesign Genesig (n=7), R-Biopharm - R-Biopharm RIDA Gene (n=5), Roche - Roche Cobas SARS-CoV 2 (n=37), Seegene - Seegene Allplex SARS-CoV-2 (n=69), TIB MOLBIOL - TIB MOLBIOL LightMix (n=27), ThermoFisher - Thermofisher TaqPath COVID-19 (n=6), In-House - Real-time In-House PCR (n=119)

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Catalogue Code: QAV204214	Ref Code: CVOP20	Challenge: S	Analysis Type: Qualitative	Dataset: 346009	Report UID: 2677/346009/2667	Laboratory CZ023

CVOP20S-07 - Qualitative Results Breakdown

Sample Code	Sample Content	Matrix	Sample Relationships	Detection Frequency	Sample Status	Percentage Correct (All)	
						(%)	*(n)*
CVOP20S-07	SARS-CoV-2	TM	5.30 dPCR Log10 Copies/ml (DS1_1)	Frequently Detected	CORE	99.2	521

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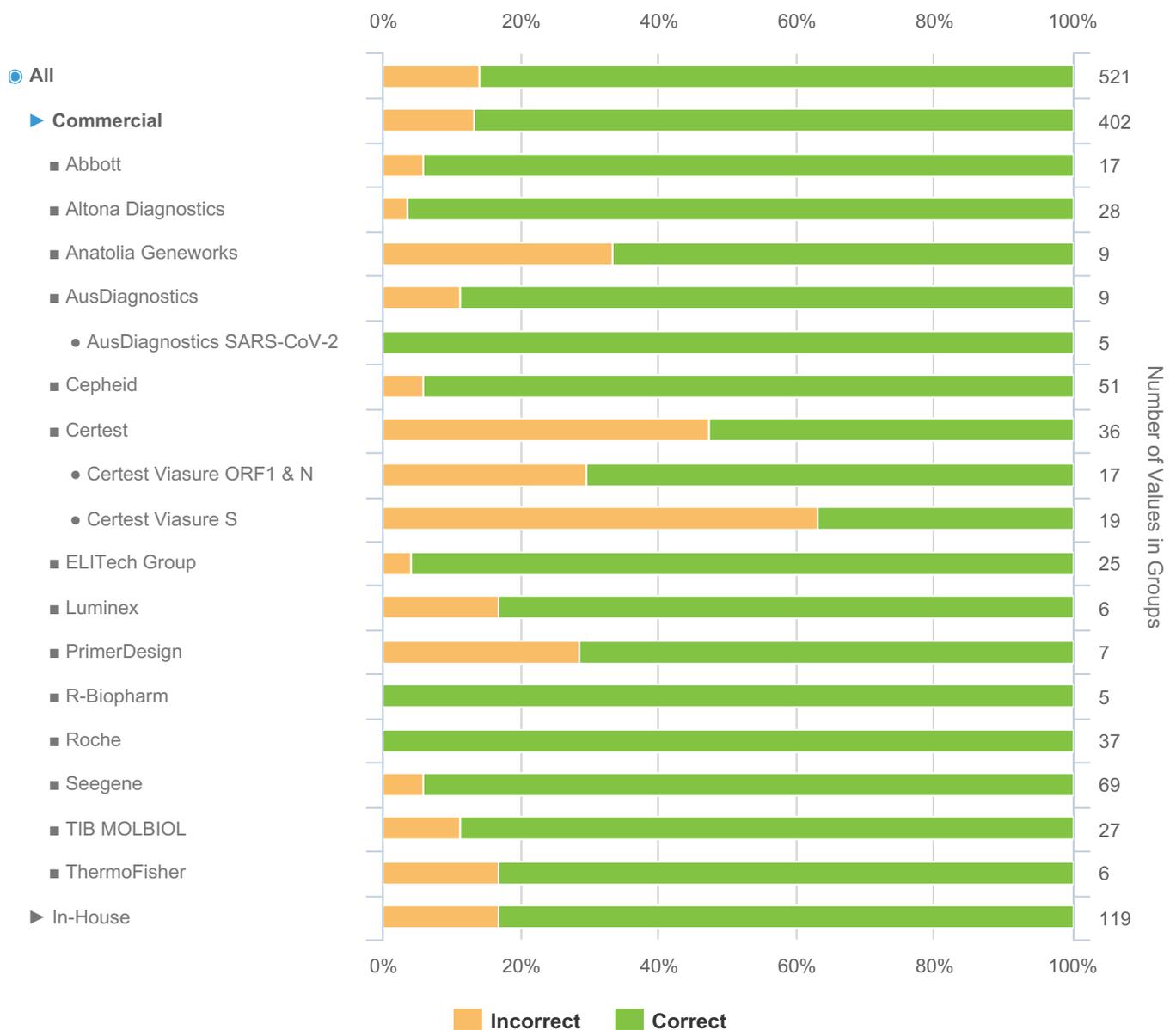Report authorised by the QCMD Executive (1)

Groups below n=5: AB Analitica (n=3), AB Analitica - AB Analitica REALQUALITY RQ (n=3), ABL (n=1), ABL - ABL UltraGene (n=1), Anchor Diagnostics (n=3), Anchor Diagnostics - Anchor Diagnostics SARS CoV-2 (n=3), Applied Biosystems (n=2), Applied Biosystems - Applied Biosystems Real Time PCR Kit (n=2), Appolon biotek (n=1), Appolon biotek - Appolon biotek SARS-CoV-2 (n=1), AusDiagnostics - AusDiagnostics Easy-Plex (n=4), BGI (n=2), BGI - BGI Real Time PCR (n=2), BioGX (n=1), BioGX - BioGX SARS-CoV-2 (n=1), Bioeksen (n=2), Bioeksen - Bioeksen Biospeedy SARS-CoV-2 (n=2), CDC (n=3), CDC - CDC SARS-CoV-2 (n=3), Co-Diagnostics Inc (n=3), Co-Diagnostics Inc - Co-Diagnostics Inc Logix Smart (n=3), DiaCarta (n=1), DiaCarta - DiaCarta QuantiVirus PCR kit (n=1), DiaSorin (n=2), DiaSorin - DiaSorin Simplexa (n=2), Diagenode (n=1), Diagenode - Diagenode Real-Time PCR (n=1), EUROIMMUN (n=3), EUROIMMUN - EUROIMMUN SARS-CoV-2 (n=3), GenMark (n=1), GenMark - GenMark SARS-CoV-2 (n=1), GeneProof (n=4), GeneProof - GeneProof SARS-CoV-2 (n=4), Genematrix (n=1), Genematrix - Genematrix NeoPlex (n=1), Hologic (n=2), Hologic - Hologic Panther Fusion (n=2), Hybribio Limited (n=1), Hybribio Limited - Hybribio Real-Time PCR Kit (n=1), Immundiagnostik (n=1), Immundiagnostik - Immundignostik MutaPLEX (n=1), Kogene Biotech (n=1), Kogene Biotech - Kogene Powerchek (n=1), Liferiver (n=1), Liferiver - Liferiver 2019-nCoV (n=1), Luminex - Luminex ARIES (n=2), Luminex - Luminex xTAG (n=4), Mediven (n=1), Mediven - Mediven GenoAmp PCR (n=1), Mikrogen (n=4), Mikrogen - Mikrogen ampliCube (n=4), Mobidiag (n=4), Mobidiag - Mobidiag Amplidiag (n=4), QIAGEN (n=4), QIAGEN - Qiagen QIAstat-Dx (n=4), Randox (n=2), Randox - Randox COVID-19 Array (n=1), Randox - Randox Extended Array (n=1), Sansure Biotech (n=1), Sansure Biotech - Sansure Biotech nCoV PCR Kit (n=1), Serosep (n=1), Serosep - Serosep Real Time PCR (n=1), Shanghai BioGerm (n=1), Shanghai BioGerm - Shanghai BioGerm Real Time PCR (n=1), Shanghai Fosun Pharmaceutical (n=1), Shanghai Fosun Pharmaceutical - Shanghai Fosun Real Time PCR (n=1), Vazyme (n=1), Vazyme - Vazyme SARS-CoV-2 (n=1), Vitassay (n=4), Vitassay - Vitassay SARS-CoV-2 (n=4), bioMerieux (n=4), bioMerieux - BioFire FilmArray (n=1), bioMerieux - bioMerieux R-gene SARS-CoV-2 (n=3), fast-track DIAGNOSTICS (n=2), fast-track DIAGNOSTICS - FTD real time PCR (n=2)

Groups Rolled Up: Abbott - Abbott SARS-CoV-2 (n=17), Altona Diagnostics - Altona Diagnostics RealStar (n=28), Anatolia Geneworks - Anatolia Geneworks Bosphore nCoV (n=9), Cepheid - Cepheid Xpert SARS-CoV-2 (n=51), ELITech Group - Elitech GeneFinder (n=25), PrimerDesign - PrimerDesign Genesig (n=7), R-Biopharm - R-Biopharm RIDA Gene (n=5), Roche - Roche Cobas SARS-CoV 2 (n=37), Seegene - Seegene Allplex SARS-CoV-2 (n=69), TIB MOLBIOL - TIB MOLBIOL LightMix (n=27), ThermoFisher - Thermofisher TaqPath COVID-19 (n=6), In-House - Real-time In-House PCR (n=119)

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Report authorised by the QCMD Executive (1)

Catalogue Code: QAV204214	Ref Code: CVOP20	Challenge: S	Analysis Type: Qualitative	Dataset: 346009	Report UID: 2677/346009/2667	Laboratory CZ023

CVOP20S-08 - Qualitative Results Breakdown

Sample Code	Sample Content	Matrix	Sample Relationships	Detection Frequency	Sample Status	Percentage Correct (All)	
						(%)	*(n)*
CVOP20S-08	SARS-CoV-2	TM	2.30 dPCR Log10 Copies/ml (DS1_4)	Detected	CORE	86.0	521

Chart: Percentage Correct/Incorrect by group

Group	Number of Values in Groups
All	521
Commercial	402
Abbott	17
Altona Diagnostics	28
Anatolia Geneworks	9
AusDiagnostics	9
AusDiagnostics SARS-CoV-2	5
Cepheid	51
Certest	36
Certest Viasure ORF1 & N	17
Certest Viasure S	19
ELITech Group	25
Luminex	6
PrimerDesign	7
R-Biopharm	5
Roche	37
Seegene	69
TIB MOLBIOL	27
ThermoFisher	6
In-House	119

Legend: Incorrect (orange), Correct (green)

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Issue Date: 27 May 2020
Report authorised by the QCMD Executive (1)

Individual Report	QCMD 2020 Coronavirus Outbreak Preparedness EQA Pilot Study	**QCMD** Quality Control for Molecular Diagnostics

Catalogue Code: QAV204214	Ref Code: CVOP20	Challenge: S	Analysis Type: Qualitative	Dataset: 346009	Report UID: 2677/346009/2667	Laboratory CZ023

Groups below n=5: AB Analitica (n=3), AB Analitica - AB Analitica REALQUALITY RQ (n=3), ABL (n=1), ABL - ABL UltraGene (n=1), Anchor Diagnostics (n=3), Anchor Diagnostics - Anchor Diagnostics SARS CoV-2 (n=3), Applied Biosystems (n=2), Applied Biosystems - Applied Biosystems Real Time PCR Kit (n=2), Appolon biotek (n=1), Appolon biotek - Appolon biotek SARS-CoV-2 (n=1), AusDiagnostics - AusDiagnostics Easy-Plex (n=4), BGI (n=2), BGI - BGI Real Time PCR (n=2), BioGX (n=1), BioGX - BioGX SARS-CoV-2 (n=1), Bioeksen (n=2), Bioeksen - Bioeksen Biospeedy SARS-CoV-2 (n=2), CDC (n=3), CDC - CDC SARS-CoV-2 (n=3), Co-Diagnostics Inc (n=3), Co-Diagnostics Inc - Co-Diagnostics Inc Logix Smart (n=3), DiaCarta (n=1), DiaCarta - DiaCarta QuantiVirus PCR kit (n=1), DiaSorin (n=2), DiaSorin - DiaSorin Simplexa (n=2), Diagenode (n=1), Diagenode - Diagenode Real-Time PCR (n=1), EUROIMMUN (n=3), EUROIMMUN - EUROIMMUN SARS-CoV-2 (n=3), GenMark (n=1), GenMark - GenMark SARS-CoV-2 (n=1), GeneProof (n=4), GeneProof - GeneProof SARS-CoV-2 (n=4), Genematrix (n=1), Genematrix - Genematrix NeoPlex (n=1), Hologic (n=2), Hologic - Hologic Panther Fusion (n=2), Hybribio Limited (n=1), Hybribio Limited - Hybribio Real-Time PCR Kit (n=1), Immundiagnostik (n=1), Immundiagnostik - Immundignostik MutaPLEX (n=1), Kogene Biotech (n=1), Kogene Biotech - Kogene Powerchek (n=1), Liferiver (n=1), Liferiver - Liferiver 2019-nCoV (n=1), Luminex - Luminex ARIES (n=2), Luminex - Luminex xTAG (n=4), Mediven (n=1), Mediven - Mediven GenoAmp PCR (n=1), Mikrogen (n=4), Mikrogen - Mikrogen ampliCube (n=4), Mobidiag (n=4), Mobidiag - Mobidiag Amplidiag (n=4), QIAGEN (n=4), QIAGEN - Qiagen QIAstat-Dx (n=4), Randox (n=2), Randox - Randox COVID-19 Array (n=1), Randox - Randox Extended Array (n=1), Sansure Biotech (n=1), Sansure Biotech - Sansure Biotech nCoV PCR Kit (n=1), Serosep (n=1), Serosep - Serosep Real Time PCR (n=1), Shanghai BioGerm (n=1), Shanghai BioGerm - Shanghai BioGerm Real Time PCR (n=1), Shanghai Fosun Pharmaceutical (n=1), Shanghai Fosun Pharmaceutical - Shanghai Fosun Real Time PCR (n=1), Vazyme (n=1), Vazyme - Vazyme SARS-CoV-2 (n=1), Vitassay (n=4), Vitassay - Vitassay SARS-CoV-2 (n=4), bioMerieux (n=4), bioMerieux - BioFire FilmArray (n=1), bioMerieux - bioMerieux R-gene SARS-CoV-2 (n=3), fast-track DIAGNOSTICS (n=2), fast-track DIAGNOSTICS - FTD real time PCR (n=2)

Groups Rolled Up: Abbott - Abbott SARS-CoV-2 (n=17), Altona Diagnostics - Altona Diagnostics RealStar (n=28), Anatolia Geneworks - Anatolia Geneworks Bosphore nCoV (n=9), Cepheid - Cepheid Xpert SARS-CoV-2 (n=51), ELITech Group - Elitech GeneFinder (n=25), PrimerDesign - PrimerDesign Genesig (n=7), R-Biopharm - R-Biopharm RIDA Gene (n=5), Roche - Roche Cobas SARS-CoV 2 (n=37), Seegene - Seegene Allplex SARS-CoV-2 (n=69), TIB MOLBIOL - TIB MOLBIOL LightMix (n=27), ThermoFisher - Thermofisher TaqPath COVID-19 (n=6), In-House - Real-time In-House PCR (n=119)

Additional Educational Samples Information

The following section has been categorised as shown below:

Educational ► Qualitative

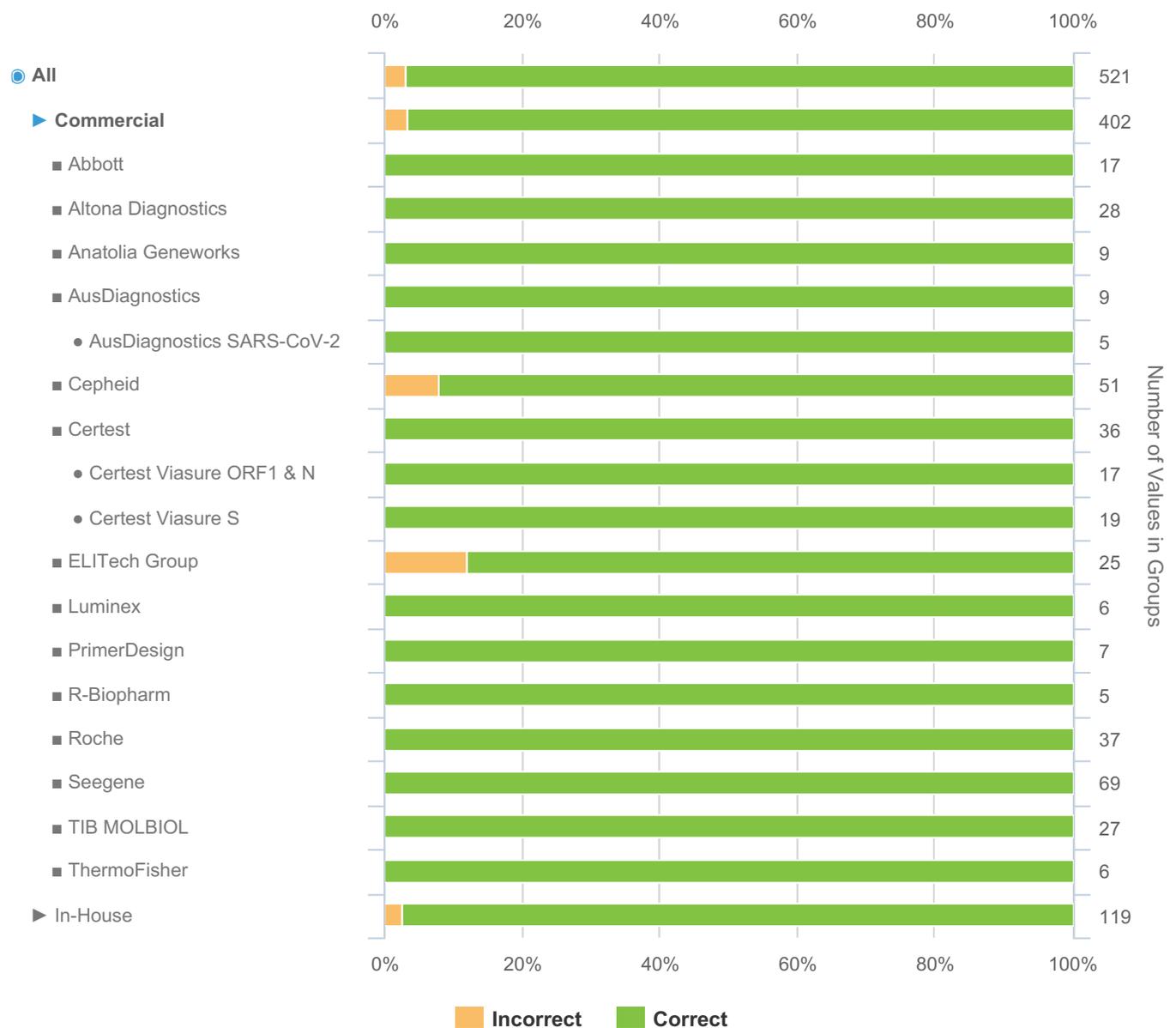## Individual Panel Member Analysis (Qualitative)

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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Individual Report	QCMD 2020 Coronavirus Outbreak Preparedness EQA Pilot Study	QCMD Quality Control for Molecular Diagnostics

Catalogue Code: QAV204214	Ref Code: CVOP20	Challenge: S	Analysis Type: Qualitative	Dataset: 346009	Report UID: 2677/346009/2667	Laboratory CZ023

CVOP20S-02 - Qualitative Results Breakdown

Sample Code	Sample Content	Matrix	Sample Relationships	Detection Frequency	Sample Status	Percentage Correct (All)	
						(%)	*(n)*
CVOP20S-02	Coronavirus NL63	TM	4.64 dPCR Log10 Copies/ml	Negative	EDUCATIONAL	96.9	521

Group	Number of Values in Groups
◉ **All**	521
▶ **Commercial**	402
■ Abbott	17
■ Altona Diagnostics	28
■ Anatolia Geneworks	9
■ AusDiagnostics	9
● AusDiagnostics SARS-CoV-2	5
■ Cepheid	51
■ Certest	36
● Certest Viasure ORF1 & N	17
● Certest Viasure S	19
■ ELITech Group	25
■ Luminex	6
■ PrimerDesign	7
■ R-Biopharm	5
■ Roche	37
■ Seegene	69
■ TIB MOLBIOL	27
■ ThermoFisher	6
▶ In-House	119

Incorrect ■ Correct ■

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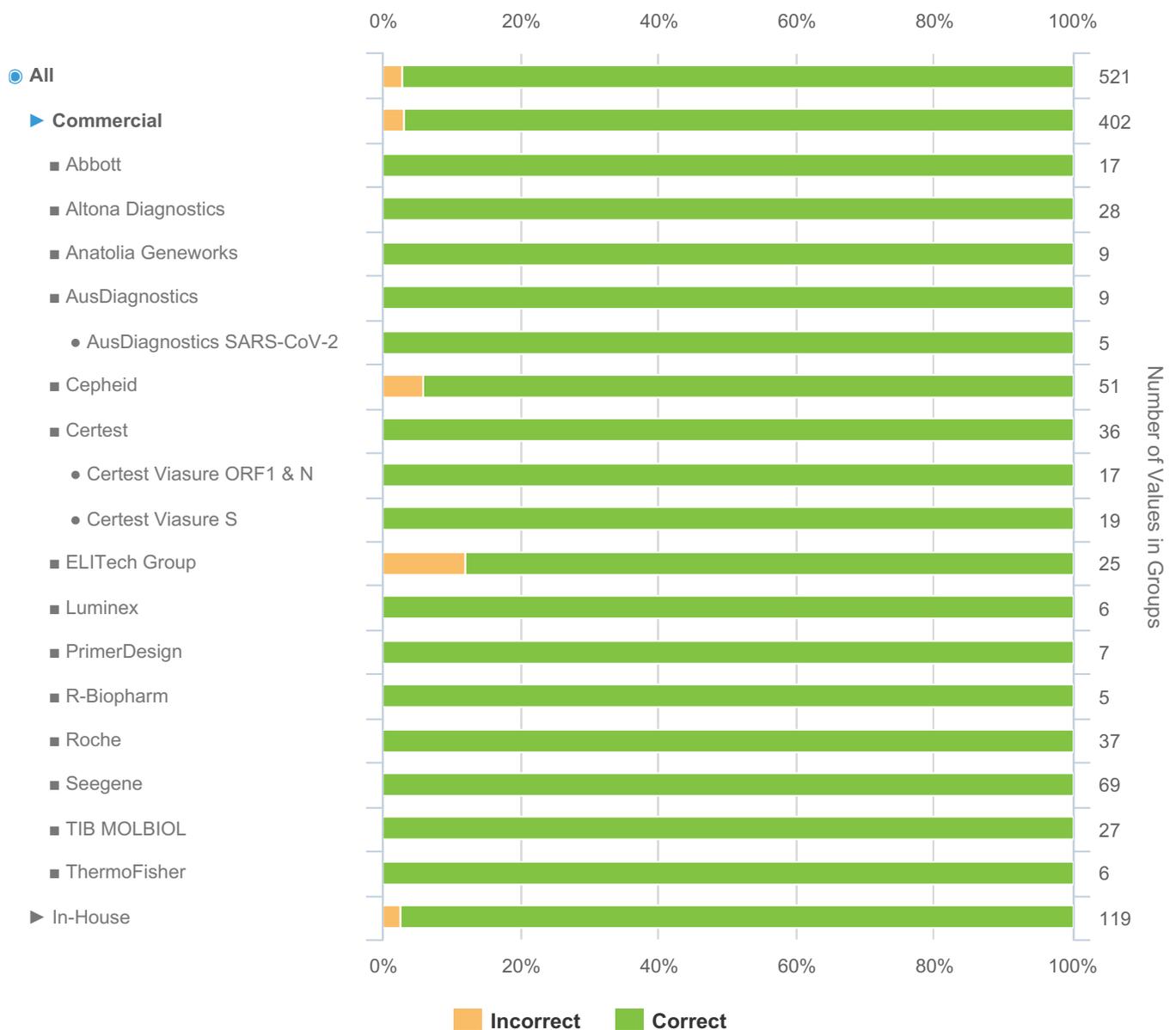| Catalogue Code: QAV204214	Ref Code: CVOP20	Challenge: S	Analysis Type: Qualitative	Dataset: 346009	Report UID: 2677/346009/2667	Laboratory CZ023

Groups below n=5: AB Analitica (n=3), AB Analitica - AB Analitica REALQUALITY RQ (n=3), ABL (n=1), ABL - ABL UltraGene (n=1), Anchor Diagnostics (n=3), Anchor Diagnostics - Anchor Diagnostics SARS CoV-2 (n=3), Applied Biosystems (n=2), Applied Biosystems - Applied Biosystems Real Time PCR Kit (n=2), Appolon biotek (n=1), Appolon biotek - Appolon biotek SARS-CoV-2 (n=1), AusDiagnostics - AusDiagnostics Easy-Plex (n=4), BGI (n=2), BGI - BGI Real Time PCR (n=2), BioGX (n=1), BioGX - BioGX SARS-CoV-2 (n=1), Bioeksen (n=2), Bioeksen - Bioeksen Biospeedy SARS-CoV-2 (n=2), CDC (n=3), CDC - CDC SARS-CoV-2 (n=3), Co-Diagnostics Inc (n=3), Co-Diagnostics Inc - Co-Diagnostics Inc Logix Smart (n=3), DiaCarta (n=1), DiaCarta - DiaCarta QuantiVirus PCR kit (n=1), DiaSorin (n=2), DiaSorin - DiaSorin Simplexa (n=2), Diagenode (n=1), Diagenode - Diagenode Real-Time PCR (n=1), EUROIMMUN (n=3), EUROIMMUN - EUROIMMUN SARS-CoV-2 (n=3), GenMark (n=1), GenMark - GenMark SARS-CoV-2 (n=1), GeneProof (n=4), GeneProof - GeneProof SARS-CoV-2 (n=4), Genematrix (n=1), Genematrix - Genematrix NeoPlex (n=1), Hologic (n=2), Hologic - Hologic Panther Fusion (n=2), Hybribio Limited (n=1), Hybribio Limited - Hybribio Real-Time PCR Kit (n=1), Immundiagnostik (n=1), Immundiagnostik - Immundignostik MutaPLEX (n=1), Kogene Biotech (n=1), Kogene Biotech - Kogene Powerchek (n=1), Liferiver (n=1), Liferiver - Liferiver 2019-nCoV (n=1), Luminex - Luminex ARIES (n=2), Luminex - Luminex xTAG (n=4), Mediven (n=1), Mediven - Mediven GenoAmp PCR (n=1), Mikrogen (n=4), Mikrogen - Mikrogen ampliCube (n=4), Mobidiag (n=4), Mobidiag - Mobidiag Amplidiag (n=4), QIAGEN (n=4), QIAGEN - Qiagen QIAstat-Dx (n=4), Randox (n=2), Randox - Randox COVID-19 Array (n=1), Randox - Randox Extended Array (n=1), Sansure Biotech (n=1), Sansure Biotech - Sansure Biotech nCoV PCR Kit (n=1), Serosep (n=1), Serosep - Serosep Real Time PCR (n=1), Shanghai BioGerm (n=1), Shanghai BioGerm - Shanghai BioGerm Real Time PCR (n=1), Shanghai Fosun Pharmaceutical (n=1), Shanghai Fosun Pharmaceutical - Shanghai Fosun Real Time PCR (n=1), Vazyme (n=1), Vazyme - Vazyme SARS-CoV-2 (n=1), Vitassay (n=4), Vitassay - Vitassay SARS-CoV-2 (n=4), bioMerieux (n=4), bioMerieux - BioFire FilmArray (n=1), bioMerieux - bioMerieux R-gene SARS-CoV-2 (n=3), fast-track DIAGNOSTICS (n=2), fast-track DIAGNOSTICS - FTD real time PCR (n=2)

Groups Rolled Up: Abbott - Abbott SARS-CoV-2 (n=17), Altona Diagnostics - Altona Diagnostics RealStar (n=28), Anatolia Geneworks - Anatolia Geneworks Bosphore nCoV (n=9), Cepheid - Cepheid Xpert SARS-CoV-2 (n=51), ELITech Group - Elitech GeneFinder (n=25), PrimerDesign - PrimerDesign Genesig (n=7), R-Biopharm - R-Biopharm RIDA Gene (n=5), Roche - Roche Cobas SARS-CoV 2 (n=37), Seegene - Seegene Allplex SARS-CoV-2 (n=69), TIB MOLBIOL - TIB MOLBIOL LightMix (n=27), ThermoFisher - Thermofisher TaqPath COVID-19 (n=6), In-House - Real-time In-House PCR (n=119)

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CVOP20S-04 - Qualitative Results Breakdown

Sample Code	Sample Content	Matrix	Sample Relationships	Detection Frequency	Sample Status	Percentage Correct (All)	
						(%)	*(n)*
CVOP20S-04	Coronavirus OC43	TM	4.03 dPCR Log10 Copies/ml	Negative	EDUCATIONAL	97.1	521

Group	Number of Values in Groups
◉ All	521
▶ Commercial	402
■ Abbott	17
■ Altona Diagnostics	28
■ Anatolia Geneworks	9
■ AusDiagnostics	9
● AusDiagnostics SARS-CoV-2	5
■ Cepheid	51
■ Certest	36
● Certest Viasure ORF1 & N	17
● Certest Viasure S	19
■ ELITech Group	25
■ Luminex	6
■ PrimerDesign	7
■ R-Biopharm	5
■ Roche	37
■ Seegene	69
■ TIB MOLBIOL	27
■ ThermoFisher	6
▶ In-House	119

Incorrect ▮ Correct ▮

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