


| | | | | | | | |
|-------------------------------------|-----------------------------|---|---|---------------------------|--|-----------------------------|--|
| Individual Report | | QCMD 2022 BK virus DNA EQA Programme | | |  <small>Quality Control for Molecular Diagnostics</small> | | |
| Catalogue Code: QAV144166 | Ref Code: BKDNA22 | Challenge: C2 | Analysis Type: Qualitative and Quantitative | Dataset: 596626 | Report UID: 2677/596626/5109 | Laboratory: CZ023 | |

Intended Results / Panel Composition

| Sample Code | Sample Content | Matrix | Sample Relationships ^[1] | Detection Frequency ^[2] | Sample Status ^[3] | Consensus (All) ^[4] | | Range ^[5] |
|--------------|----------------|--------|-------------------------------------|------------------------------------|------------------------------|--------------------------------|-----|----------------------|
| | | | | | | (Log ₁₀) | (n) | |
| BKDNA22C2-01 | BK Type 1b-2 | Plasma | DS1_1 | Frequently Detected | CORE | N/A | N/A | N/A |
| BKDNA22C2-02 | BK Type IV | Plasma | DS2_1 | Frequently Detected | CORE | N/A | N/A | N/A |
| BKDNA22C2-03 | BK Type 1b-2 | Plasma | DS1_2 | Frequently Detected | CORE | N/A | N/A | N/A |
| BKDNA22C2-04 | Negative | Plasma | - | Negative | CORE | N/A | N/A | N/A |
| BKDNA22C2-05 | BK Type IV | Plasma | DS2_2 | Frequently Detected | CORE | N/A | N/A | N/A |

[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 (All):** Mean consensus (Log₁₀) 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 (All) reported by participants within this challenge without outliers removed.

For further details please refer to the current participant manual.

Your Summary Results

| | |
|--|-----------------------------|
| Units | N/A |
| EQA Assessment Group ^[1] | GeneProof Real Time PCR kit |
| Core Panel Detection (Qualitative) Score ^[2] | 0 |
| Core Panel Estimation (Quantitative) Score ^[3] | N/A |

| | | | | | | | |
|-------------------------------------|-----------------------------|---|---|---------------------------|--|----------------------------|--|
| Individual Report | | QCMD 2022 BK virus DNA EQA Programme | | |  <small>Quality Control for Molecular Diagnostics</small> | | |
| Catalogue Code: QAV144166 | Ref Code: BKDNA22 | Challenge: C2 | Analysis Type: Qualitative and Quantitative | Dataset: 596626 | Report UID: 2677/596626/5109 | Laboratory CZ023 | |

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] |
| BKDNA22C2-01 | N/A | - | - | - | - | 100.0 | Positive | 0 |
| BKDNA22C2-02 | N/A | - | - | - | - | 100.0 | Positive | 0 |
| BKDNA22C2-03 | N/A | - | - | - | - | 97.6 | Positive | 0 |
| BKDNA22C2-04 | N/A | - | - | - | - | 97.6 | Negative | 0 |
| BKDNA22C2-05 | N/A | - | - | - | - | 100.0 | Positive | 0 |

[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.

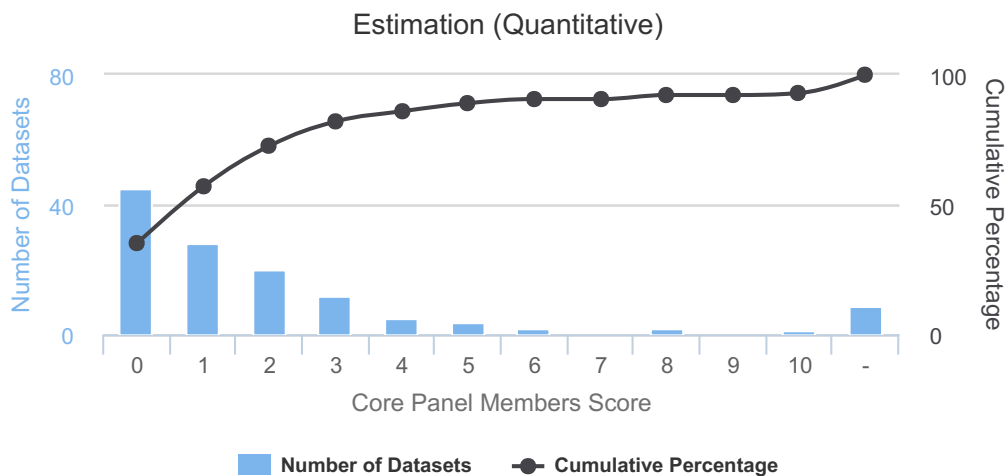
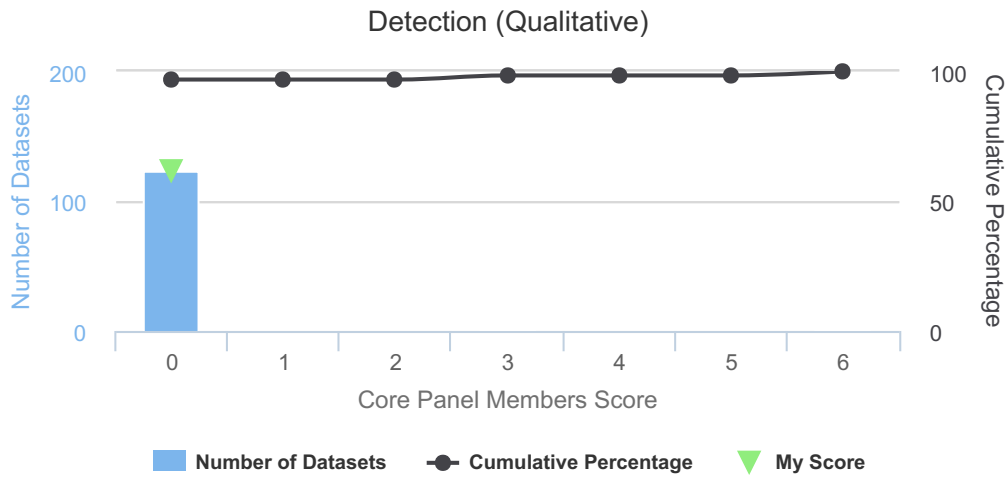
[9] **Your Qualitative Result:** The qualitative result you reported for each sample within this EQA challenge / distribution.

[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.

| | | | | | | |
|-------------------------------------|-----------------------------|---|---|---------------------------|---|-----------------------------|
| Individual Report | | QCMD 2022 BK virus DNA EQA Programme | | |  QCMD Quality Control for Molecular Diagnostics | |
| Catalogue Code: QAV144166 | Ref Code: BKDNA22 | Challenge: C2 | Analysis Type: Qualitative and Quantitative | Dataset: 596626 | Report UID: 2677/596626/5109 | Laboratory: CZ023 |


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.

| | | | | | | |
|-------------------------------------|-----------------------------|---|---|---------------------------|--|----------------------------|
| Individual Report | | QCMD 2022 BK virus DNA EQA Programme | | |  <small>Quality Control for Molecular Diagnostics</small> | |
| Catalogue Code: QAV144166 | Ref Code: BKDNA22 | Challenge: C2 | Analysis Type: Qualitative and Quantitative | Dataset: 596626 | Report UID: 2677/596626/5109 | Laboratory CZ023 |

My Workflow Details

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


| | |
|--------------------|--|
| Name | GeneProof BK Virus (BKV) PCR Kit - croBEE 2.0 (v2) |
| Description | |
| Targets |  BK virus |
| Assays | <ul style="list-style-type: none">  <i>Extraction</i> - GeneProof - croBEE 2.0 Nucleic Acid Extraction System <ul style="list-style-type: none"> ● Commercial <ul style="list-style-type: none"> ○ Kit Manufacturer: <i>GeneProof</i> ○ Kit Type: <i>myCROBE/croBEE 2.0 Universal Extraction Kit</i>  <i>Amplification</i> - GeneProof - croBEE Real-Time PCR System <ul style="list-style-type: none"> ● Commercial <ul style="list-style-type: none"> ○ Kit Manufacturer: <i>GeneProof</i> ○ Kit Type: <i>BK Virus (BKV) PCR Kit</i> ○ Kit Version: <i>GP</i> |

Further Programme Details

| | |
|---|-------------|
| Number of Participants | 122 |
| Number of Countries | 31 |
| Number of Respondents | 117 |
| Number of Datasets Submitted | 142 |
| Quantitative Results Returned (All) | 128 (90.1%) |
| - Quantitative Results Returned (Copies/ml) | 82 (64.1%) |
| - Quantitative Results Returned (IU/ml) | 45 (35.2%) |
| - Quantitative Results Returned (Other) | 1 (0.8%) |
| Qualitative Results Returned | 127 (89.4%) |

EQA Programme Aims


To assess the proficiency of laboratories molecular assays in detecting various types and concentrations of BK virus (BKV). To assess the proficiency of laboratories in the reliable quantitation of BKV viral load

| | | | | | | |
|-------------------------------------|-----------------------------|---|---|---------------------------|--|-----------------------------|
| Individual Report | | QCMD 2022 BK virus DNA EQA Programme | | |  | |
| Catalogue Code: QAV144166 | Ref Code: BKDNA22 | Challenge: C2 | Analysis Type: Qualitative and Quantitative | Dataset: 596626 | Report UID: 2677/596626/5109 | Laboratory: CZ023 |

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.

| | | | | | | |
|-------------------------------------|-----------------------------|---|---|---------------------------|--|-----------------------------|
| Individual Report | | QCMD 2022 BK virus DNA EQA Programme | | |  | |
| Catalogue Code: QAV144166 | Ref Code: BKDNA22 | Challenge: C2 | Analysis Type: Qualitative and Quantitative | Dataset: 596626 | Report UID: 2677/596626/5109 | 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 ► Quantitative ► Copies/ml, IU/ml ► Qualitative

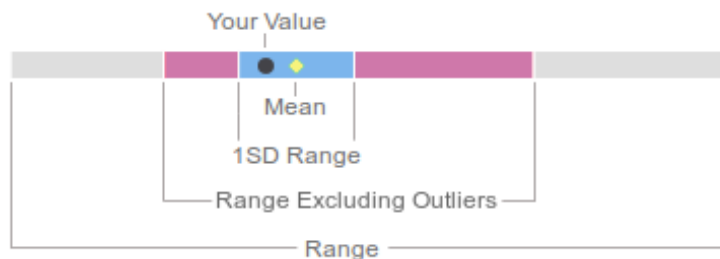
Individual Panel Member Analysis (Quantitative)


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.

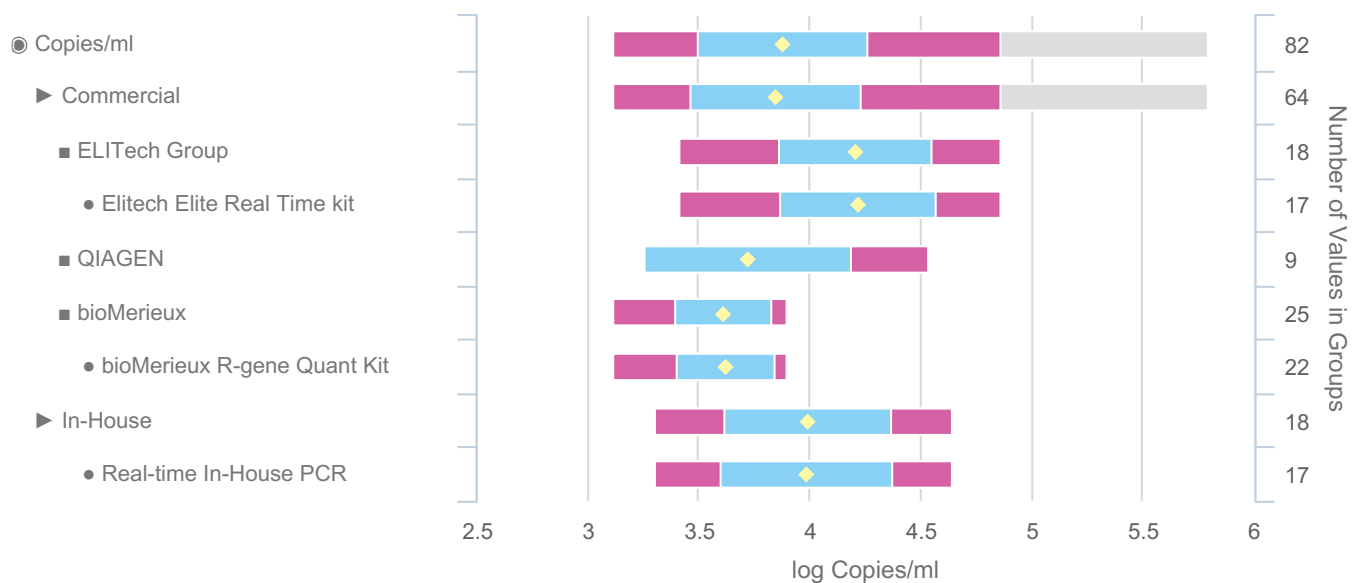
Key



| | | | | | | | |
|-------------------------------------|-----------------------------|---|---|---------------------------|---|-----------------------------|--|
| Individual Report | | QCMD 2022 BK virus DNA EQA Programme | | |  Quality Control for Molecular Diagnostics | | |
| Catalogue Code: QAV144166 | Ref Code: BKDNA22 | Challenge: C2 | Analysis Type: Qualitative and Quantitative | Dataset: 596626 | Report UID: 2677/596626/5109 | Laboratory: CZ023 | |


BKDNA22C2-01 - Quantitative Results Breakdown (Copies/ml)

| Sample Code | Sample Content | Matrix | Sample Relationships | Detection Frequency | Sample Status | Consensus (Copies/ml) | | Range |
|--------------|----------------|--------|----------------------|---------------------|---------------|-----------------------|-----|---------------|
| | | | | | | (Log ₁₀) | (n) | |
| BKDNA22C2-01 | BK Type 1b-2 | Plasma | DS1_1 | Frequently Detected | CORE | 3.874 | 82 | 3.111 - 5.790 |



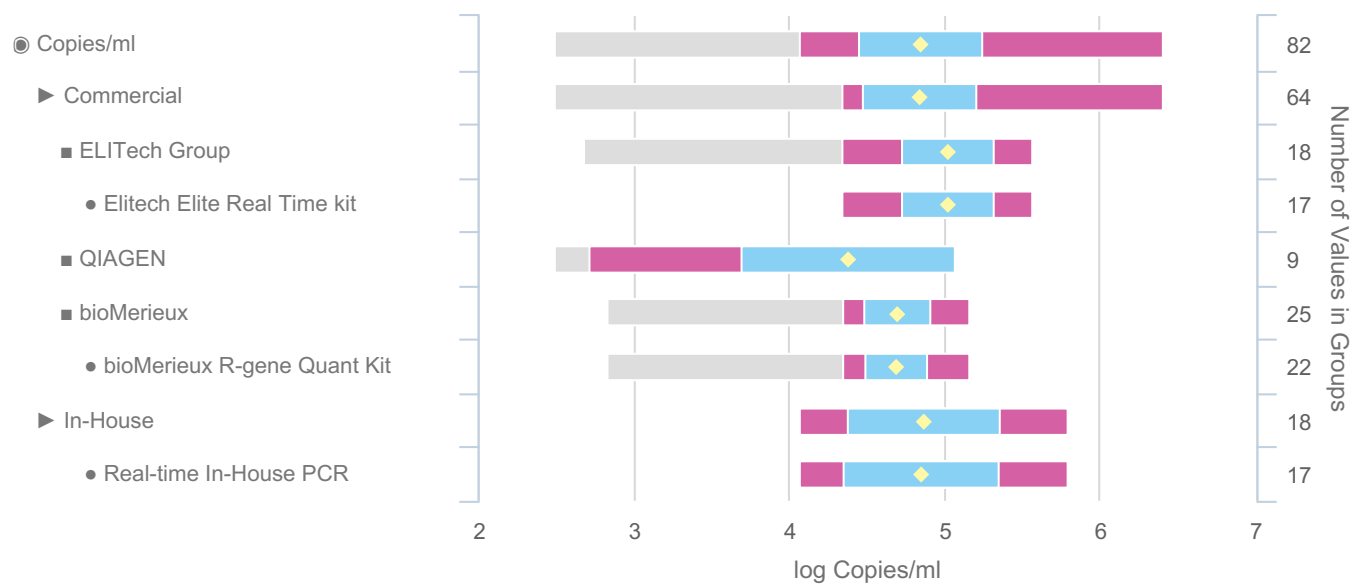
Groups below n=5: AB Analytica (n=4), AB Analytica - AB Analytica REALQUALITY RQ (n=4), Altona Diagnostics (n=2), Altona Diagnostics - Altona Diagnostics RealStar (n=2), ELITech Group - Elitech Alert Real Time Q-PCR (n=1), GeneProof (n=2), GeneProof - GeneProof Real Time PCR kit (n=2), Iontek (n=1), Iontek - Iontek Fluorion (n=1), Progenie Molecular (n=1), Progenie Molecular - Progenie Molecular RealCycler (n=1), TIB MOLBIOL (n=1), TIB MOLBIOL - TIB MOLBIOL LightMix (n=1), bioMerieux - bioMerieux Primers/Probes (n=3), fast-track DIAGNOSTICS (n=1), fast-track DIAGNOSTICS - FTD real time PCR (n=1), In-House - Conventional In-House PCR (n=1)

Groups Rolled Up: QIAGEN - QIAGEN Artus Real Time (n=9)

| | | | | | | | |
|-------------------------------------|-----------------------------|---|---|---------------------------|---|-----------------------------|--|
| Individual Report | | QCMD 2022 BK virus DNA EQA Programme | | |  Quality Control for Molecular Diagnostics | | |
| Catalogue Code: QAV144166 | Ref Code: BKDNA22 | Challenge: C2 | Analysis Type: Qualitative and Quantitative | Dataset: 596626 | Report UID: 2677/596626/5109 | Laboratory: CZ023 | |


BKDNA22C2-02 - Quantitative Results Breakdown (Copies/ml)

| Sample Code | Sample Content | Matrix | Sample Relationships | Detection Frequency | Sample Status | Consensus (Copies/ml) | | Range |
|--------------|----------------|--------|----------------------|---------------------|---------------|-----------------------|-----|---------------|
| | | | | | | (Log ₁₀) | (n) | |
| BKDNA22C2-02 | BK Type IV | Plasma | DS2_1 | Frequently Detected | CORE | 4.838 | 82 | 2.484 - 6.398 |



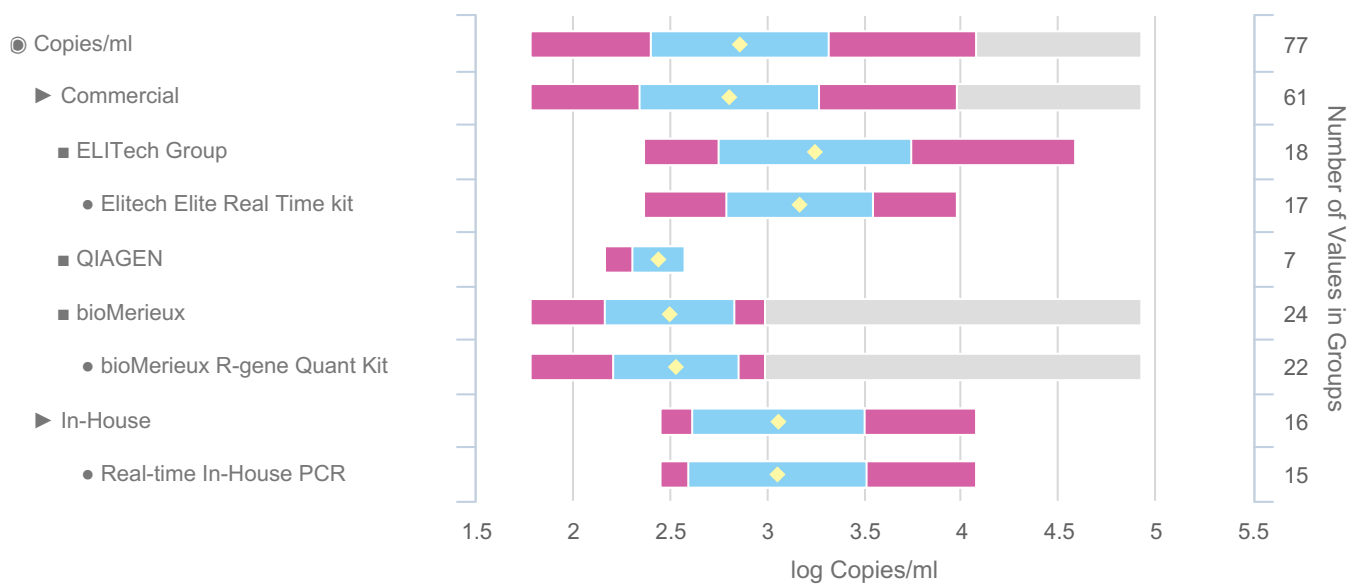
Groups below n=5: AB Analytica (n=4), AB Analytica - AB Analytica REALQUALITY RQ (n=4), Altona Diagnostics (n=2), Altona Diagnostics - Altona Diagnostics RealStar (n=2), ELITech Group - Elitech Alert Real Time Q-PCR (n=1), GeneProof (n=2), GeneProof - GeneProof Real Time PCR kit (n=2), Iontek (n=1), Iontek - Iontek Fluorion (n=1), Progenie Molecular (n=1), Progenie Molecular - Progenie Molecular RealCycler (n=1), TIB MOLBIOL (n=1), TIB MOLBIOL - TIB MOLBIOL LightMix (n=1), bioMerieux - bioMerieux Primers/Probes (n=3), fast-track DIAGNOSTICS (n=1), fast-track DIAGNOSTICS - FTD real time PCR (n=1), In-House - Conventional In-House PCR (n=1)

Groups Rolled Up: QIAGEN - QIAGEN Artus Real Time (n=9)

| | | | | | | | |
|-------------------------------------|-----------------------------|---|---|---------------------------|---|-----------------------------|--|
| Individual Report | | QCMD 2022 BK virus DNA EQA Programme | | |  Quality Control for Molecular Diagnostics | | |
| Catalogue Code: QAV144166 | Ref Code: BKDNA22 | Challenge: C2 | Analysis Type: Qualitative and Quantitative | Dataset: 596626 | Report UID: 2677/596626/5109 | Laboratory: CZ023 | |


BKDNA22C2-03 - Quantitative Results Breakdown (Copies/ml)

| Sample Code | Sample Content | Matrix | Sample Relationships | Detection Frequency | Sample Status | Consensus (Copies/ml) | | Range |
|--------------|----------------|--------|----------------------|---------------------|---------------|-----------------------|-----|---------------|
| | | | | | | (Log ₁₀) | (n) | |
| BKDNA22C2-03 | BK Type 1b-2 | Plasma | DS1_2 | Frequently Detected | CORE | 2.855 | 77 | 1.778 - 4.923 |



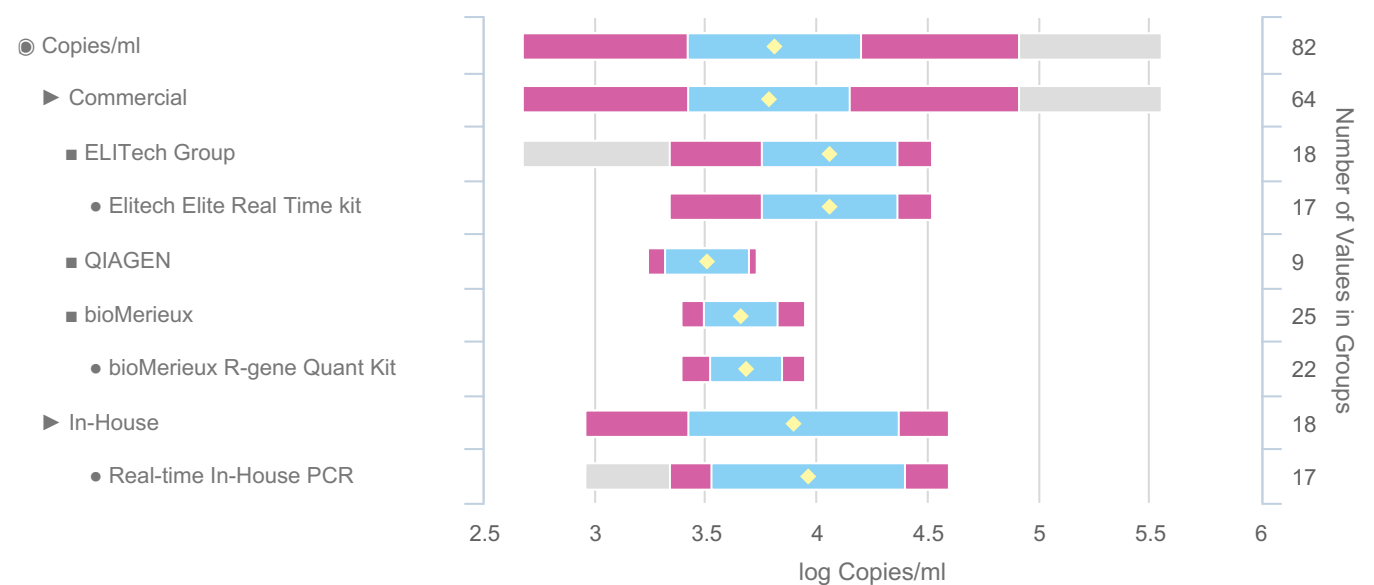
Groups below n=5: AB Analytica (n=4), AB Analytica - AB Analytica REALQUALITY RQ (n=4), Altona Diagnostics (n=2), Altona Diagnostics - Altona Diagnostics RealStar (n=2), ELITech Group - Elitech Alert Real Time Q-PCR (n=1), GeneProof (n=2), GeneProof - GeneProof Real Time PCR kit (n=2), Iontek (n=1), Iontek - Iontek Fluorion (n=1), Progenie Molecular (n=1), Progenie Molecular - Progenie Molecular RealCycler (n=1), TIB MOLBIOL (n=1), TIB MOLBIOL - TIB MOLBIOL LightMix (n=1), bioMerieux - bioMerieux Primers/Probes (n=2), fast-track DIAGNOSTICS (n=1), fast-track DIAGNOSTICS - FTD real time PCR (n=1), In-House - Conventional In-House PCR (n=1)

Groups Rolled Up: QIAGEN - QIAGEN Artus Real Time (n=7)

| | | | | | | | |
|-------------------------------------|-----------------------------|---|---|---------------------------|---|-----------------------------|--|
| Individual Report | | QCMD 2022 BK virus DNA EQA Programme | | |  Quality Control for Molecular Diagnostics | | |
| Catalogue Code: QAV144166 | Ref Code: BKDNA22 | Challenge: C2 | Analysis Type: Qualitative and Quantitative | Dataset: 596626 | Report UID: 2677/596626/5109 | Laboratory: CZ023 | |

BKDNA22C2-05 - Quantitative Results Breakdown (Copies/ml)

| Sample Code | Sample Content | Matrix | Sample Relationships | Detection Frequency | Sample Status | Consensus (Copies/ml) | | Range |
|--------------|----------------|--------|----------------------|---------------------|---------------|-----------------------|-----|---------------|
| | | | | | | (Log ₁₀) | (n) | |
| BKDNA22C2-05 | BK Type IV | Plasma | DS2_2 | Frequently Detected | CORE | 3.806 | 82 | 2.672 - 5.551 |



Groups below n=5: AB Analytica (n=4), AB Analytica - AB Analytica REALQUALITY RQ (n=4), Altona Diagnostics (n=2), Altona Diagnostics - Altona Diagnostics RealStar (n=2), ELITech Group - Elitech Alert Real Time Q-PCR (n=1), GeneProof (n=2), GeneProof - GeneProof Real Time PCR kit (n=2), Iontek (n=1), Iontek - Iontek Fluorion (n=1), Progenie Molecular (n=1), Progenie Molecular - Progenie Molecular RealCycler (n=1), TIB MOLBIOL (n=1), TIB MOLBIOL - TIB MOLBIOL LightMix (n=1), bioMerieux - bioMerieux Primers/Probes (n=3), fast-track DIAGNOSTICS (n=1), fast-track DIAGNOSTICS - FTD real time PCR (n=1), In-House - Conventional In-House PCR (n=1)

Groups Rolled Up: QIAGEN - QIAGEN Artus Real Time (n=9)

Individual Report

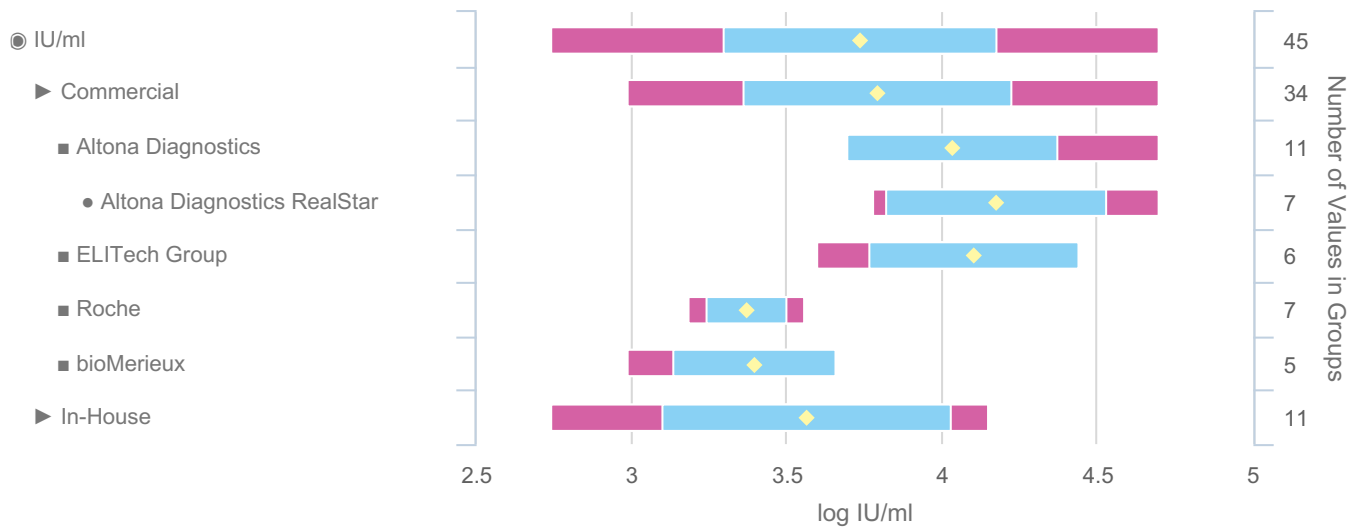
QCMD 2022 BK virus DNA EQA Programme



| | | | | | | |
|-------------------------------------|-----------------------------|-------------------------|---|---------------------------|--|-----------------------------|
| Catalogue Code: QAV144166 | Ref Code: BKDNA22 | Challenge: C2 | Analysis Type: Qualitative and Quantitative | Dataset: 596626 | Report UID: 2677/596626/5109 | Laboratory: CZ023 |
|-------------------------------------|-----------------------------|-------------------------|---|---------------------------|--|-----------------------------|

BKDNA22C2-01 - Quantitative Results Breakdown (IU/ml)

| Sample Code | Sample Content | Matrix | Sample Relationships | Detection Frequency | Sample Status | Consensus (IU/ml) | | Range |
|--------------|----------------|--------|----------------------|---------------------|---------------|----------------------|-----|---------------|
| | | | | | | (Log ₁₀) | (n) | |
| BKDNA22C2-01 | BK Type 1b-2 | Plasma | DS1_1 | Frequently Detected | CORE | 3.734 | 45 | 2.740 - 4.695 |

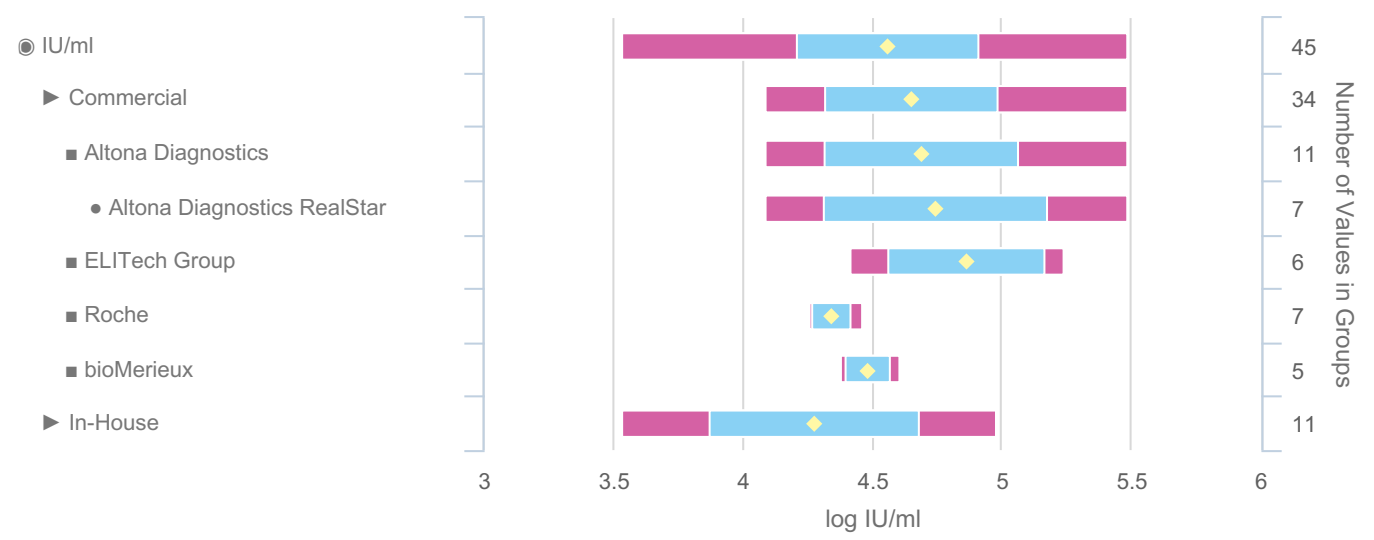


Groups below n=5: Altona Diagnostics - Altona Diagnostics AltoStar (n=4), GeneProof (n=3), GeneProof - GeneProof Real Time PCR kit (n=3), QIAGEN (n=2), QIAGEN - QIAGEN Artus Real Time (n=2)

Groups Rolled Up: ELITech Group - Elitech Elite Real Time kit (n=6), Roche - Roche Cobas 6800/8800 (n=7), bioMerieux - bioMerieux R-gene Quant Kit (n=5), In-House - Real-time In-House PCR (n=11)


BKDNA22C2-02 - Quantitative Results Breakdown (IU/ml)

| Sample Code | Sample Content | Matrix | Sample Relationships | Detection Frequency | Sample Status | Consensus (IU/ml) | | Range |
|--------------|----------------|--------|----------------------|---------------------|---------------|----------------------|-----|---------------|
| | | | | | | (Log ₁₀) | (n) | |
| BKDNA22C2-02 | BK Type IV | Plasma | DS2_1 | Frequently Detected | CORE | 4.556 | 45 | 3.531 - 5.482 |



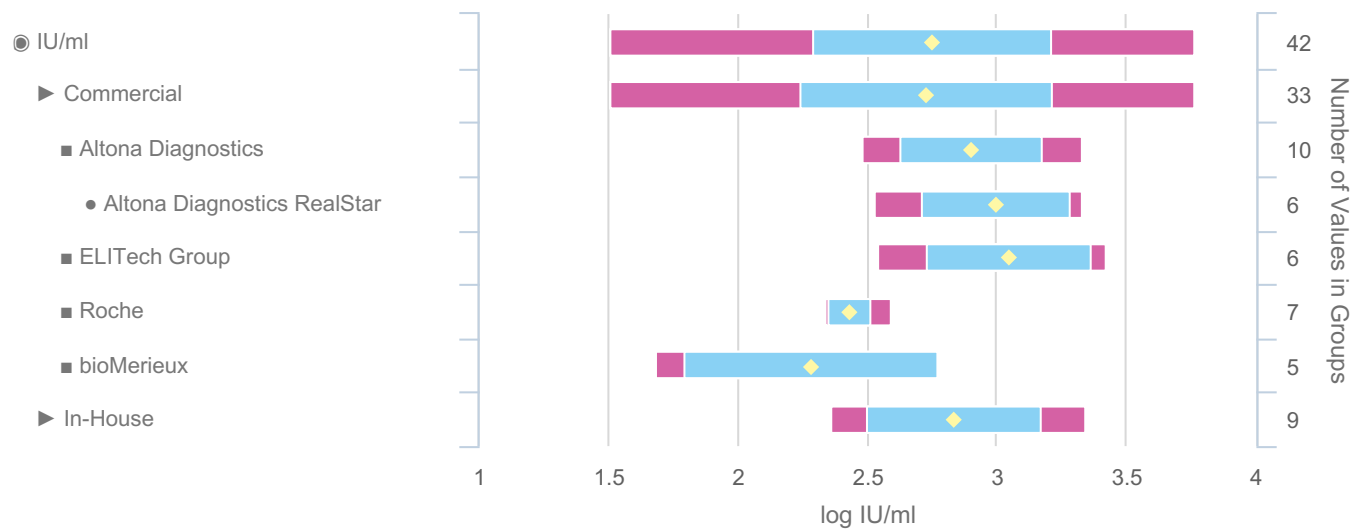
Groups below n=5: Altona Diagnostics - Altona Diagnostics AltoStar (n=4), GeneProof (n=3), GeneProof - GeneProof Real Time PCR kit (n=3), QIAGEN (n=2), QIAGEN - QIAGEN Artus Real Time (n=2)

Groups Rolled Up: ELITech Group - Elitech Elite Real Time kit (n=6), Roche - Roche Cobas 6800/8800 (n=7), bioMerieux - bioMerieux R-gene Quant Kit (n=5), In-House - Real-time In-House PCR (n=11)

| | | | | | | | |
|-------------------------------------|-----------------------------|---|---|---------------------------|---|-----------------------------|--|
| Individual Report | | QCMD 2022 BK virus DNA EQA Programme | | |  Quality Control for Molecular Diagnostics | | |
| Catalogue Code: QAV144166 | Ref Code: BKDNA22 | Challenge: C2 | Analysis Type: Qualitative and Quantitative | Dataset: 596626 | Report UID: 2677/596626/5109 | Laboratory: CZ023 | |

BKDNA22C2-03 - Quantitative Results Breakdown (IU/ml)

| Sample Code | Sample Content | Matrix | Sample Relationships | Detection Frequency | Sample Status | Consensus (IU/ml) | | Range |
|--------------|----------------|--------|----------------------|---------------------|---------------|----------------------|-----|---------------|
| | | | | | | (Log ₁₀) | (n) | |
| BKDNA22C2-03 | BK Type 1b-2 | Plasma | DS1_2 | Frequently Detected | CORE | 2.747 | 42 | 1.505 - 3.760 |

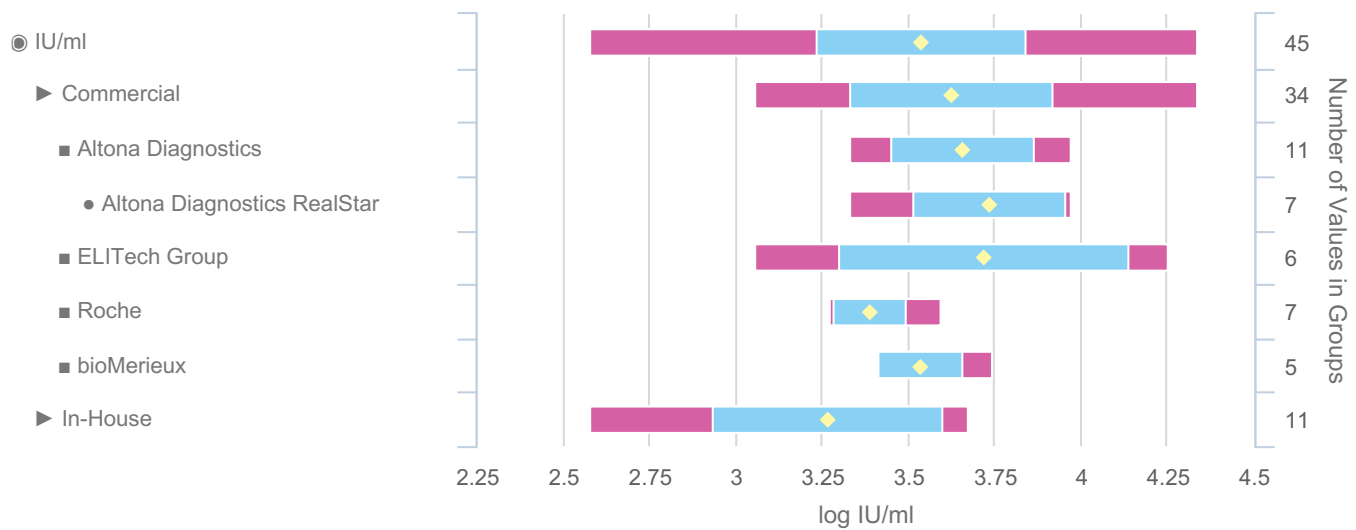


Groups below n=5: Altona Diagnostics - Altona Diagnostics AltoStar (n=4), GeneProof (n=3), GeneProof - GeneProof Real Time PCR kit (n=3), QIAGEN (n=2), QIAGEN - QIAGEN Artus Real Time (n=2)

Groups Rolled Up: ELITech Group - Elitech Elite Real Time kit (n=6), Roche - Roche Cobas 6800/8800 (n=7), bioMerieux - bioMerieux R-gene Quant Kit (n=5), In-House - Real-time In-House PCR (n=9)

BKDNA22C2-05 - Quantitative Results Breakdown (IU/ml)

| Sample Code | Sample Content | Matrix | Sample Relationships | Detection Frequency | Sample Status | Consensus (IU/ml) | | Range |
|--------------|----------------|--------|----------------------|---------------------|---------------|----------------------|-----|---------------|
| | | | | | | (Log ₁₀) | (n) | |
| BKDNA22C2-05 | BK Type IV | Plasma | DS2_2 | Frequently Detected | CORE | 3.534 | 45 | 2.576 - 4.334 |



Groups below n=5: Altona Diagnostics - Altona Diagnostics AltoStar (n=4), GeneProof (n=3), GeneProof - GeneProof Real Time PCR kit (n=3), QIAGEN (n=2), QIAGEN - QIAGEN Artus Real Time (n=2)


Groups Rolled Up: ELITech Group - Elitech Elite Real Time kit (n=6), Roche - Roche Cobas 6800/8800 (n=7), bioMerieux - bioMerieux R-gene Quant Kit (n=5), In-House - Real-time In-House PCR (n=11)

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.

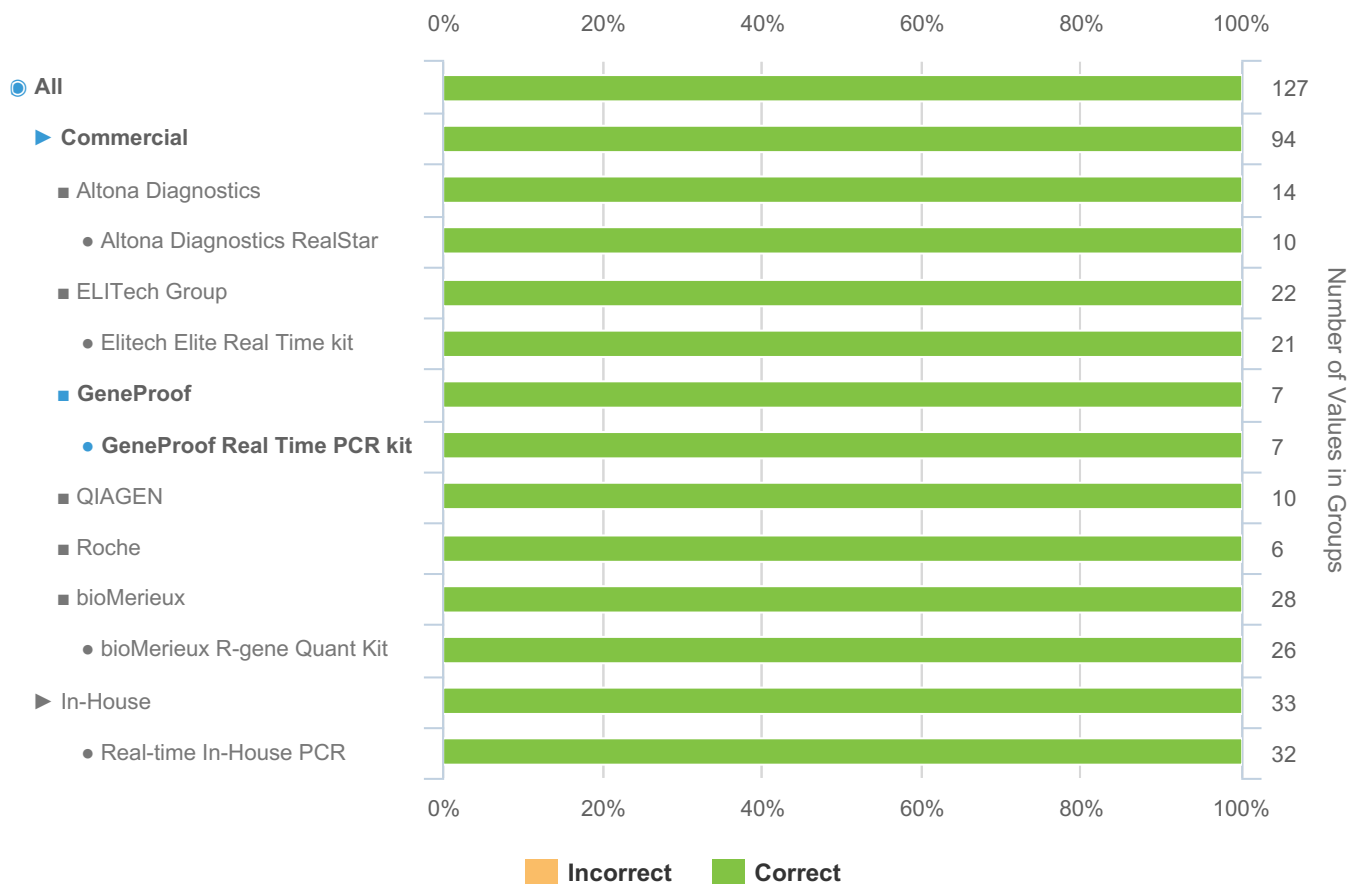
To allow meaningful assessment at the individual method level the EQA assessment group must consist of 5 or more datasets. If there are not sufficient datasets at the individual method level then your results will be included within a higher EQA assessment group based on whether it is a commercial or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

| | | | | | | | |
|-------------------------------------|-----------------------------|---|---|---------------------------|---|-----------------------------|--|
| Individual Report | | QCMD 2022 BK virus DNA EQA Programme | | |  Quality Control for Molecular Diagnostics | | |
| Catalogue Code: QAV144166 | Ref Code: BKDNA22 | Challenge: C2 | Analysis Type: Qualitative and Quantitative | Dataset: 596626 | Report UID: 2677/596626/5109 | Laboratory: CZ023 | |


BKDNA22C2-01 - Qualitative Results Breakdown

| Sample Code | Sample Content | Matrix | Sample Relationships | Detection Frequency | Sample Status | Percentage Correct (All) | |
|--------------|----------------|--------|----------------------|---------------------|---------------|--------------------------|-----|
| | | | | | | (%) | (n) |
| BKDNA22C2-01 | BK Type 1b-2 | Plasma | DS1_1 | Frequently Detected | CORE | 100.0 | 127 |



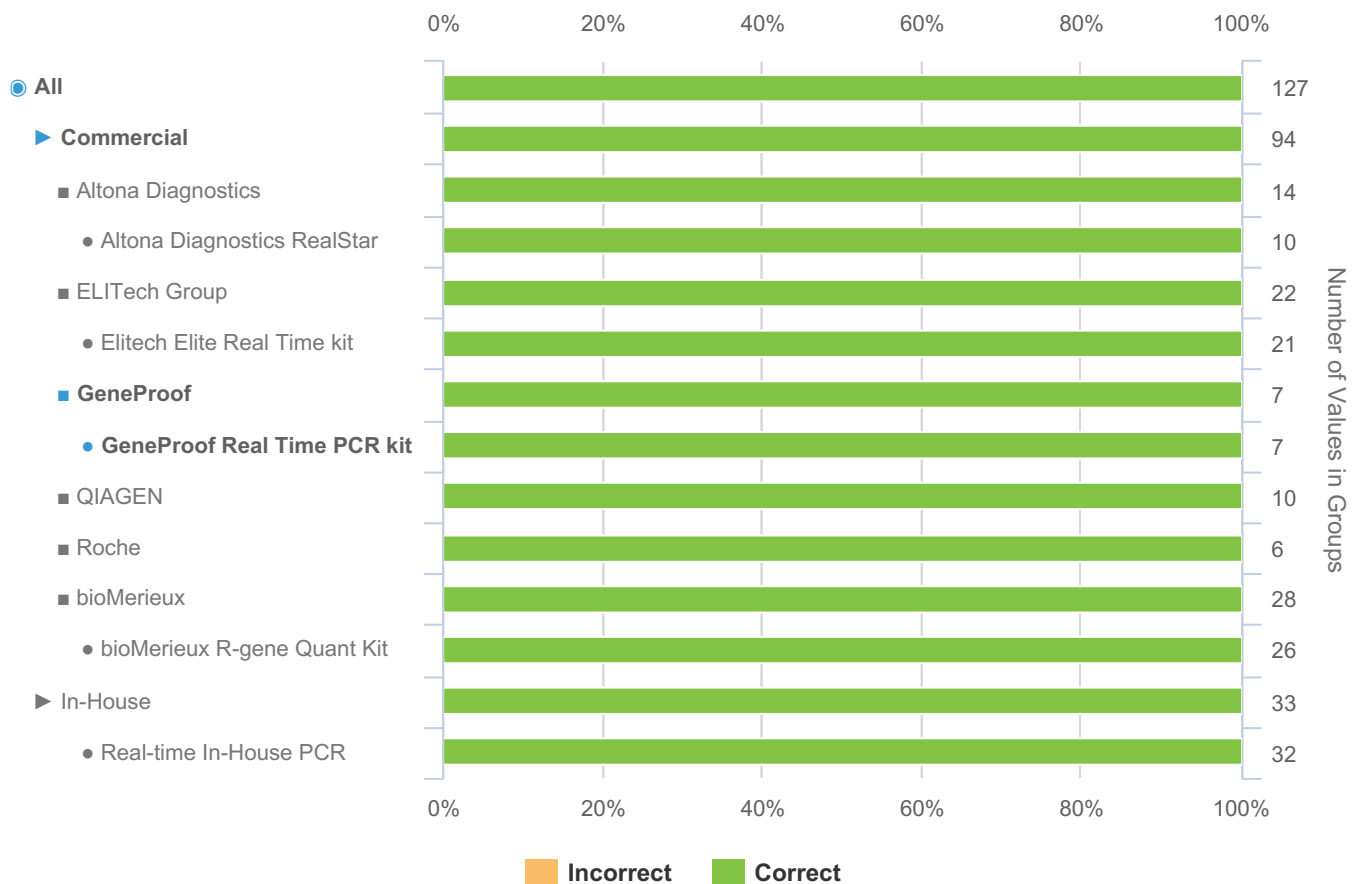
Groups below n=5: AB Analytica (n=2), AB Analytica - AB Analytica REALQUALITY RQ (n=2), Altona Diagnostics - Altona Diagnostics AltoStar (n=4), Certest (n=1), Certest - Certest Real Time PCR (n=1), ELITech Group - Elitech Alert Real Time Q-PCR (n=1), Iontek (n=1), Iontek - Iontek Fluorion (n=1), Master Diagnostica (n=1), Master Diagnostica - Master Diagnostica Flow Chip (n=1), Progenie Molecular (n=1), Progenie Molecular - Progenie Molecular RealCycler (n=1), bioMerieux - bioMerieux Primers/Probes (n=2), fast-track DIAGNOSTICS (n=1), fast-track DIAGNOSTICS - FTD real time PCR (n=1), In-House - Conventional In-House PCR (n=1)

Groups Rolled Up: QIAGEN - QIAGEN Artus Real Time (n=10), Roche - Roche Cobas 6800/8800 (n=6)

| | | | | | | | |
|-------------------------------------|-----------------------------|---|---|---------------------------|---|-----------------------------|--|
| Individual Report | | QCMD 2022 BK virus DNA EQA Programme | | |  Quality Control for Molecular Diagnostics | | |
| Catalogue Code: QAV144166 | Ref Code: BKDNA22 | Challenge: C2 | Analysis Type: Qualitative and Quantitative | Dataset: 596626 | Report UID: 2677/596626/5109 | Laboratory: CZ023 | |

BKDNA22C2-02 - Qualitative Results Breakdown

| Sample Code | Sample Content | Matrix | Sample Relationships | Detection Frequency | Sample Status | Percentage Correct (All) | |
|--------------|----------------|--------|----------------------|---------------------|---------------|--------------------------|-----|
| | | | | | | (%) | (n) |
| BKDNA22C2-02 | BK Type IV | Plasma | DS2_1 | Frequently Detected | CORE | 100.0 | 127 |

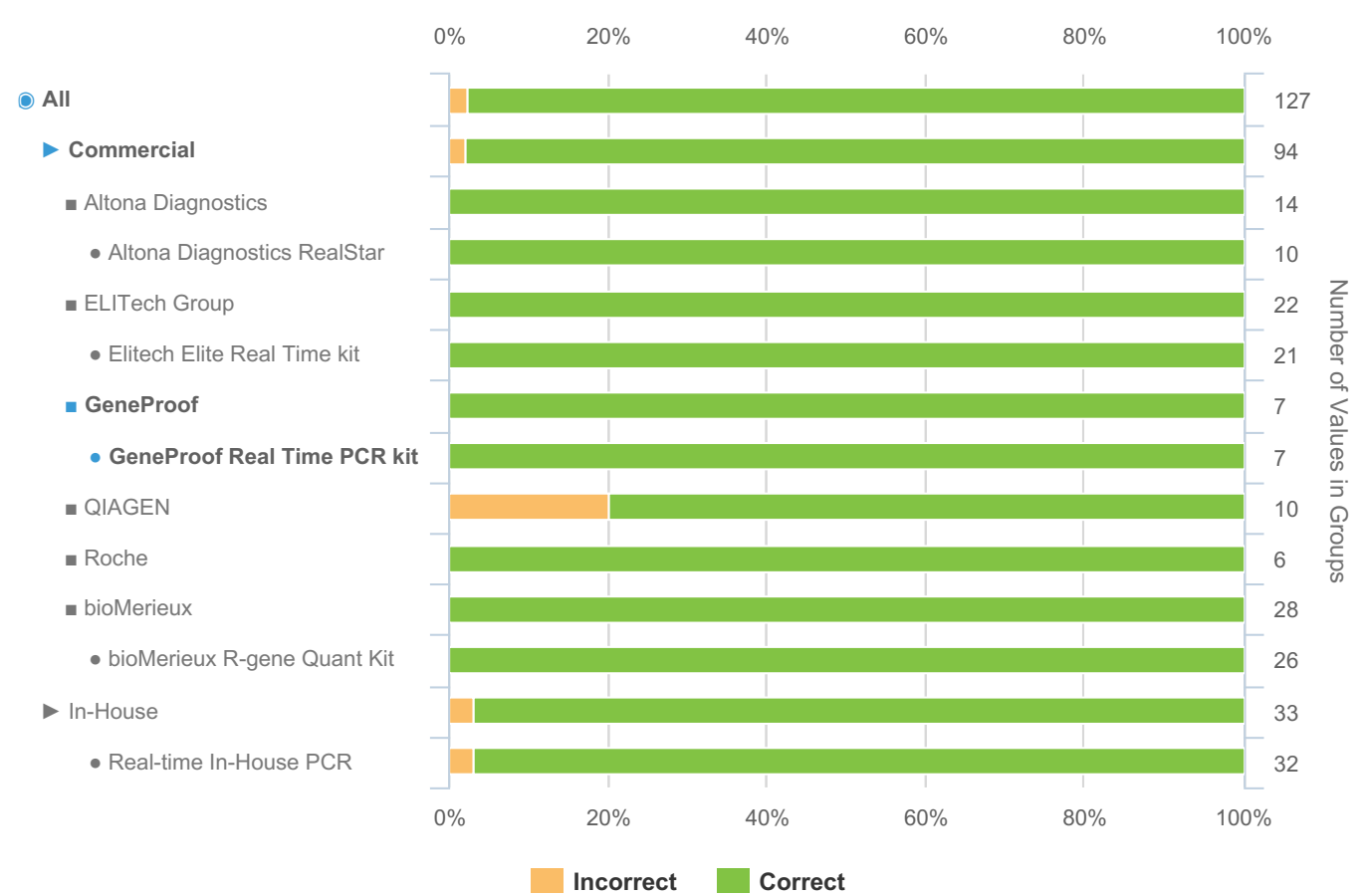


Groups below n=5: AB Analytica (n=2), AB Analytica - AB Analytica REALQUALITY RQ (n=2), Altona Diagnostics - Altona Diagnostics AltoStar (n=4), Certest (n=1), Certest - Certest Real Time PCR (n=1), ELITech Group - Elitech Alert Real Time Q-PCR (n=1), Iontek (n=1), Iontek - Iontek Fluorion (n=1), Master Diagnostica (n=1), Master Diagnostica - Master Diagnostica Flow Chip (n=1), Progenie Molecular (n=1), Progenie Molecular - Progenie Molecular RealCycler (n=1), bioMerieux - bioMerieux Primers/Probes (n=2), fast-track DIAGNOSTICS (n=1), fast-track DIAGNOSTICS - FTD real time PCR (n=1), In-House - Conventional In-House PCR (n=1)

Groups Rolled Up: QIAGEN - QIAGEN Artus Real Time (n=10), Roche - Roche Cobas 6800/8800 (n=6)

BKDNA22C2-03 - Qualitative Results Breakdown

| Sample Code | Sample Content | Matrix | Sample Relationships | Detection Frequency | Sample Status | Percentage Correct (All) | |
|--------------|----------------|--------|----------------------|---------------------|---------------|--------------------------|-----|
| | | | | | | (%) | (n) |
| BKDNA22C2-03 | BK Type 1b-2 | Plasma | DS1_2 | Frequently Detected | CORE | 97.6 | 127 |

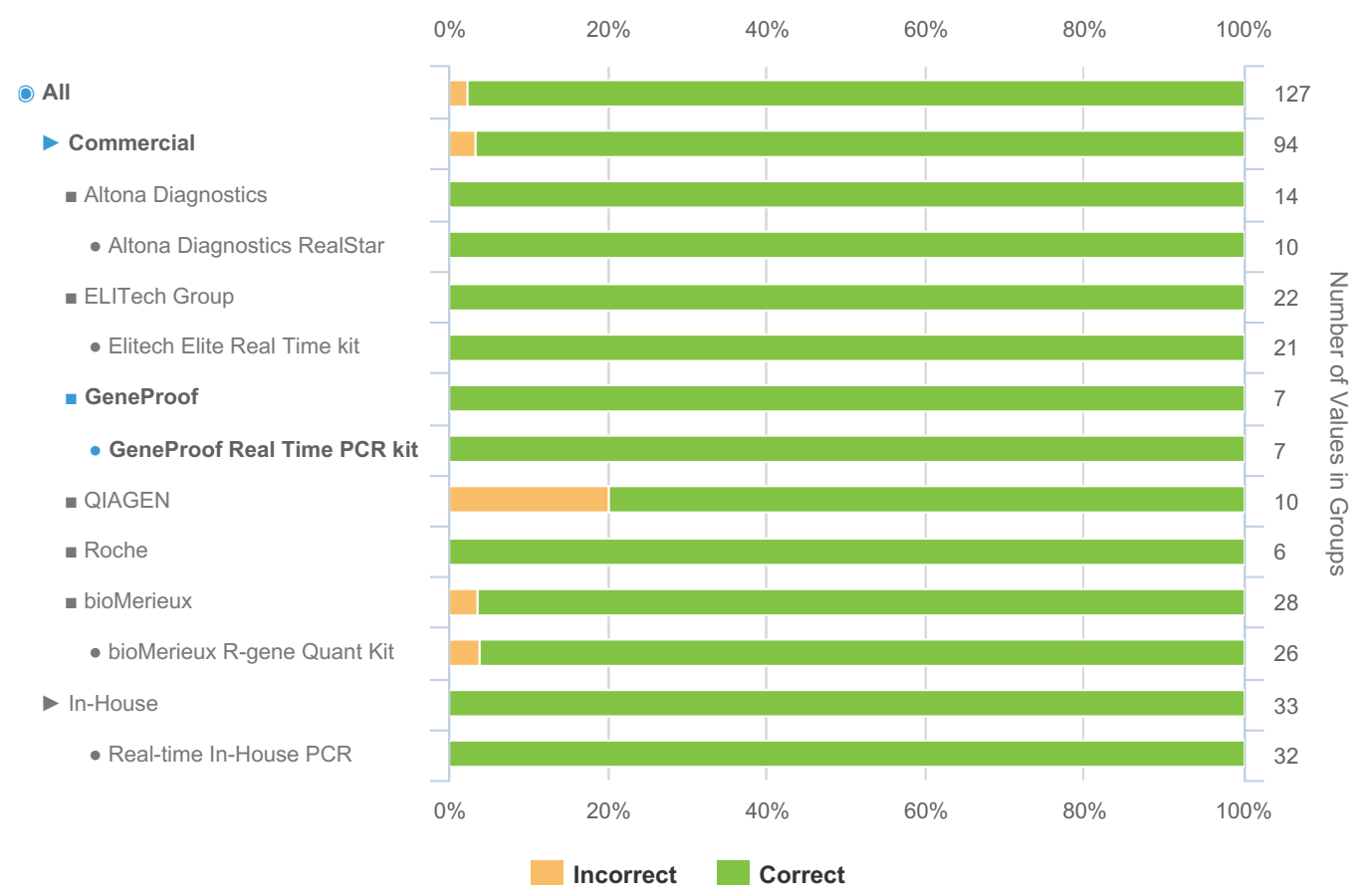


Groups below n=5: AB Analytica (n=2), AB Analytica - AB Analytica REALQUALITY RQ (n=2), Altona Diagnostics - Altona Diagnostics AltoStar (n=4), Certest (n=1), Certest - Certest Real Time PCR (n=1), ELITech Group - Elitech Alert Real Time Q-PCR (n=1), Iontek (n=1), Iontek - Iontek Fluorion (n=1), Master Diagnostica (n=1), Master Diagnostica - Master Diagnostica Flow Chip (n=1), Progenie Molecular (n=1), Progenie Molecular - Progenie Molecular RealCycler (n=1), bioMerieux - bioMerieux Primers/Probes (n=2), fast-track DIAGNOSTICS (n=1), fast-track DIAGNOSTICS - FTD real time PCR (n=1), In-House - Conventional In-House PCR (n=1)

Groups Rolled Up: QIAGEN - QIAGEN Artus Real Time (n=10), Roche - Roche Cobas 6800/8800 (n=6)

BKDNA22C2-04 - Qualitative Results Breakdown

| Sample Code | Sample Content | Matrix | Sample Relationships | Detection Frequency | Sample Status | Percentage Correct (All) | |
|--------------|----------------|--------|----------------------|---------------------|---------------|--------------------------|-----|
| | | | | | | (%) | (n) |
| BKDNA22C2-04 | Negative | Plasma | - | Negative | CORE | 97.6 | 127 |

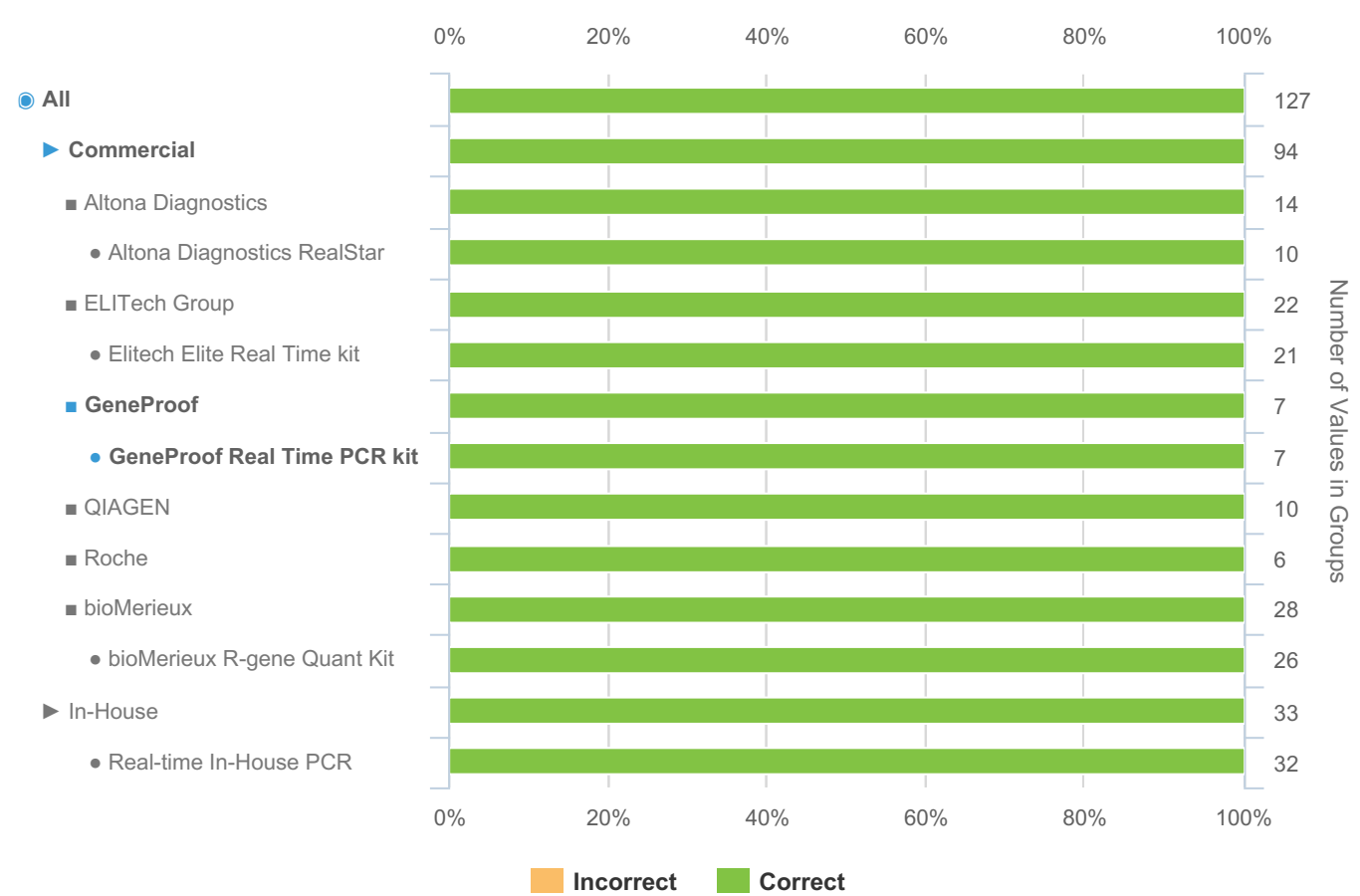


Groups below n=5: AB Analytica (n=2), AB Analytica - AB Analytica REALQUALITY RQ (n=2), Altona Diagnostics - Altona Diagnostics AltoStar (n=4), Certest (n=1), Certest - Certest Real Time PCR (n=1), ELITech Group - Elitech Alert Real Time Q-PCR (n=1), Iontek (n=1), Iontek - Iontek Fluorion (n=1), Master Diagnostica (n=1), Master Diagnostica - Master Diagnostica Flow Chip (n=1), Progenie Molecular (n=1), Progenie Molecular - Progenie Molecular RealCycler (n=1), bioMerieux - bioMerieux Primers/Probes (n=2), fast-track DIAGNOSTICS (n=1), fast-track DIAGNOSTICS - FTD real time PCR (n=1), In-House - Conventional In-House PCR (n=1)

Groups Rolled Up: QIAGEN - QIAGEN Artus Real Time (n=10), Roche - Roche Cobas 6800/8800 (n=6)


BKDNA22C2-05 - Qualitative Results Breakdown

| Sample Code | Sample Content | Matrix | Sample Relationships | Detection Frequency | Sample Status | Percentage Correct (All) | |
|--------------|----------------|--------|----------------------|---------------------|---------------|--------------------------|-----|
| | | | | | | (%) | (n) |
| BKDNA22C2-05 | BK Type IV | Plasma | DS2_2 | Frequently Detected | CORE | 100.0 | 127 |



Groups below n=5: AB Analytica (n=2), AB Analytica - AB Analytica REALQUALITY RQ (n=2), Altona Diagnostics - Altona Diagnostics AltoStar (n=4), Certest (n=1), Certest - Certest Real Time PCR (n=1), ELITech Group - Elitech Alert Real Time Q-PCR (n=1), Iontek (n=1), Iontek - Iontek Fluorion (n=1), Master Diagnostica (n=1), Master Diagnostica - Master Diagnostica Flow Chip (n=1), Progenie Molecular (n=1), Progenie Molecular - Progenie Molecular RealCycler (n=1), bioMerieux - bioMerieux Primers/Probes (n=2), fast-track DIAGNOSTICS (n=1), fast-track DIAGNOSTICS - FTD real time PCR (n=1), In-House - Conventional In-House PCR (n=1)

Groups Rolled Up: QIAGEN - QIAGEN Artus Real Time (n=10), Roche - Roche Cobas 6800/8800 (n=6)

| | | | | | | |
|-------------------------------------|-----------------------------|---|---|---------------------------|--|-----------------------------|
| Individual Report | | QCMD 2022 BK virus DNA EQA Programme | | |  | |
| Catalogue Code: QAV144166 | Ref Code: BKDNA22 | Challenge: C2 | Analysis Type: Qualitative and Quantitative | Dataset: 596626 | Report UID: 2677/596626/5109 | Laboratory: CZ023 |

QCMD © 2022. The QCMD EQA programme samples, associated reports and data generated during this programme are intended for External Quality Assessment (EQA) and Proficiency Testing (PT) purposes only. QCMD operates according to a strict Code of Practice which is in line with ISO/IEC 17043 and associated standards. Data reported in QCMD programmes is representative of a laboratory's standard diagnostic testing protocols irrespective of the technology they use. The data provided in the reports are based on technical information provided by the individual laboratories as part of the assessment process, as such it does not constitute a formal technology method comparison. All text and images produced by QCMD are the property of QCMD unless otherwise stated.

The reproduction and use of these materials is not permitted without the express written consent of QCMD. The use of the information provided in QCMD reports for commercial purposes is strictly prohibited.