NRL RapidQ: Supplementary Information and Troubleshooting Guide

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1. INTRODUCTION

NRL provides two Quality Assurance (QA) solutions for infectious disease Point of Care Testing (PoCT) under the RapidQ model: Competency Panels (CP) and External Quality Assurance (EQA).

Participation frequency in both RapidQ CP and EQA is flexible. NRL's recommended minimum and optimal testing frequencies are outlined in the RapidQ Catalogue, available on the NRL website (RapidQ - NRLQuality). Unlike traditional EQA schemes, RapidQ EQA programs do not follow fixed testing schedules, allowing flexible testing and result submission up until the panel expiry date.

2. PROGRAMS

All RapidQ samples are manufactured according to NRL procedures to ensure homogeneity. The panels are shipped ambient, requiring no UN3373 compliance. Storage and transport conditions have been validated to ensure sample stability throughout the assigned shelf life as specified on the accompanying Certificate of Analysis (CoA).

2.1 RapidQ Competency Panels

RapidQ CP consist of two samples with known reactivity (reactive and/or negative) for the target analyte(s). The accompanying Instructions for Use (IFU) provide guidance on the intended use of the RapidQ CP, panel contents, sample preparation, storage, testing procedures, relevant limitations and safety warnings, and other relevant information.

2.2 RapidQ EQA

RapidQ EQA panels consist of four samples with varying reactivity for the target analyte(s), unknown to the participants. The accompanying 'Program Handling Instructions' provide guidance on panel contents, sample preparation, storage, testing, result submission, and other relevant information.

3. EVALUATION METHODS

As RapidQ is tailored for Point of Care (PoC) testing, pre-release (reference) testing is performed internally at NRL using, where possible, the same PoC tests utilised by the RapidQ end users to confirm expected sample composition and are assigned as the reference results in EDCNet™.

- **Quantitative** analytes**:** the mean viral load value of reference testing is used to determine the preliminary evaluation criteria range of Mean +/- 0.5 $\log_{10}$.
- **Qualitative** analytes**:** the agreed assay interpretations are assigned as the reference results.

For RapidQ CP, the assigned reference results are provided to participants in the accompanying COA.

RapidQ EQA provides two levels of performance feedback:

- **Preliminary Evaluation:** immediate feedback following result submission in EDCNet™, based on assigned reference results.
- **Periodic Report:** a cumulative summary of participant quantitative and/or qualitative performance throughout the six months reporting period.

3.1 EQA Preliminary Evaluation in EDCNet™

RapidQ EQA preliminary feedback enables timely investigation of unexpected results and supports the ongoing accuracy and reliability of patient testing. Participant results are assessed against the assigned viral load evaluation criteria (assigned Mean viral load ± 0.5 $\log_{10}$) or the assigned assay interpretation for the sample. A pop-up notification displays a preliminary evaluation of either '**Concordant**' or '**Discordant**'.

- **Concordant:** Submitted result agrees with reference result.
- **Discordant:** Submitted result does not agree with reference result.

3.1.1 Examples of 'Discordant' Evaluation Outcomes

- False positive results (positive result reported for negative sample).
- False negative results (negative results reported for a positive sample).
- Submitting **Reporting Codes** in quantitative (viral load) programs.
    - '0.2' – Analytical error / unable to report a quantitative result, including invalids, instrument errors or sample not tested.
    - '0.5' – for Detected – Not Quantified (below the assay's lower limit of quantification).

Participants receiving a 'Discordant' preliminary evaluation are encouraged to promptly investigate to troubleshoot possible causes and, if further assistance is required, contact NRL RapidQ at **RapidQ@nrlquality.org.au**.

3.2 EQA Periodic Reports

RapidQ EQA Periodic Reports provide a comprehensive summary of participant quantitative and/or qualitative performance over a defined reporting period. The Report may include comparison with assigned reference results and/or within each **Peer Group** (PG), defined as participants using the same test method.

3.2.1 Sample Classifications

For each analyte, reference results may be used to consolidate sample manufacturing lots under sample classifications such as Negative, Low, Medium or High Positivity/Reactivity to assist with meaningful comparison of participant performance.

3.2.2 Qualitative Performance

For qualitative analytes and programs, participant results for **assay interpretations** are compared with the applicable reference results presented in the relevant table(s) of the Periodic Report.

3.2.3 Quantitative (Viral Load) Performance

For molecular viral load programs, **$\log_{10}$ transformed** viral load results submitted by participants within each peer group are analysed. Viral load results that are not $\log_{10}$ transformed are identified as 'Discordant' in EDCNet™ preliminary evaluation and are excluded from statistical analyses in Periodic Reports.

3.2.4 Peer Group Statistics

For each sample lot, quantitative peer group statistics are generated subject to sufficient valid quantitative results (n) being available:

- Statistical n≥3: Where a minimum of three valid results is available for a sample lot, the PG Median and associated range (PG Median ± 0.5 $\log_{10}$) can be determined.
- Statistical n<3: Where fewer than three valid results are available for a sample lot, insufficient data is available to generate meaningful statistics.

3.2.5 Graphing

Periodic Reports include bar graphs displaying the qualitative analysis of overall peer group concordance. Each bar represents the entire peer group's results (presented as 100%).

- Pink section: percentage of Detected/Positive/Reactive results.
- Blue section: percentage of Not Detected/Negative/Non-reactive results.
- Green tick: denotes the Reference Result. Located within the corresponding colour-coded section for that sample lot (e.g., a green tick in the pink section denotes a reactive reference result for that sample).

3.2.6 Educational Samples

Some EQA samples are intentionally prepared with target analyte concentrations close to an assay's analytical limit. For molecular assays, this may be near the limit of detection or quantification, while for serology assays, it may be close to the cut-off.

Greater variability in results is expected for these samples, even when testing is performed correctly. They are included primarily for educational purposes to demonstrate assay performance at low analyte concentrations and to facilitate comparison of assay performance where sufficient peer group data are available.

While preliminary feedback provided at the time of result submission is based on the assigned viral load or assay interpretation, results that reflect expected variability at these analytical limits may be classified as **Not Evaluated** in the Periodic Report. However, assay performance may still be improved by evaluating operator competency, instrument performance and maintenance, and any assay-specific limitations described by the manufacturer before repeat testing.

4. COMPLAINTS AND APPEALS PROCESS

Participants may submit appeals, complaints or any other feedback regarding any aspect of their participation in RapidQ EQA, including but not limited to, samples, shipping, communication, assessment (grading and data analysis) and reports.

All appeals and complaints will be reviewed in accordance with NRL's quality management system to ensure fair and timely resolution. Participants may submit their appeal or complaint in writing to NRL at **RapidQ@nrlquality.org.au**.

5. TROUBLESHOOTING

Not Evaluated: Results which are classified as 'Not Evaluated' in the Periodic Report may include educational samples or where a problem may have occurred such as invalid results or error codes on instrumentation.

To assist with investigations into **Discordant** results, some common causes of errors that may occur are:

- Data entry error.
- Sample mix-up.
- Cross-contamination or carryover.
- Presence of inhibitors or non-specific binding.
- Reagents contaminated, expired or subject to batch variation.
- Insufficient sample mixing or reconstitution.
- Incorrect storage of samples or test kits.
- Incorrect sample volume.
- Subjective interpretation of rapid diagnostic tests.
- Instrument error.

Recommended troubleshooting actions:

- Double check sample ID prior to testing and reporting of results.
- Ensure correct sample handling and preparation by referring to the associated EQA program instructions or Competency Panel IFU.
- Ensure instrument functioning properly by conducting any required periodic maintenance and calibration as required by manufacturer.
- Confirm correct kit and panel sample storage conditions and are within expiry dates.
- Ensure operator competency and adherence to the manufacturer's instructions for use.
- Repeat testing where appropriate and investigate any recurring trends.