POCT SURVEY REPORT

Data Analysis

Return rate

3/3 (100%) results were returned for 1 devices by the closing date.

Results

0 devices reported incorrect results for 3 cases. 0 devices reported test failed results.

Discussion

Testing of EQA samples should, as far as possible, replicate testing for patients. Only one EQA sample should be taken out and tested at a time, and the same level of good clinical practice should apply as with clinical samples.

If a patient who is MT-RNR1 **detected** is genotyped as MT-RNR1 **not detected**, they will be administered an aminoglycoside. Administration of aminoglycosides to an MT-RNR1 detected patient can lead to deafness.

If a patient who is MT-RNR1 **not detected** is genotyped as MT-RNR1 **detected**, they will be administered an alternative antibiotic. Although alternative therapies can treat the condition, gentamicin is preferred as a defence against antibiotic resistance.

If a patient receives a **test fail**, they will be administered an alternative antibiotic. Although alternative therapies can treat the condition, gentamicin is preferred as a defence against antibiotic resistance. Additionally, repeated test failures should be investigated to identify issues with staff training and equipment.

Sample Concordance and Scoring:

EMQN aim to provide swabs with a range of cell loads. Scoring for test failures has been graded, so that the penalty is lower for swabs at lower cell loads.

Concordance of results between centres participating in the survey is monitored by EMQN. Scoring will be adjusted based on concordance. Samples that have had scoring adjusted due to concordance will be marked with an asterisk (*).

A summary of the scoring and performance calculation can be found in the appendix of this document.

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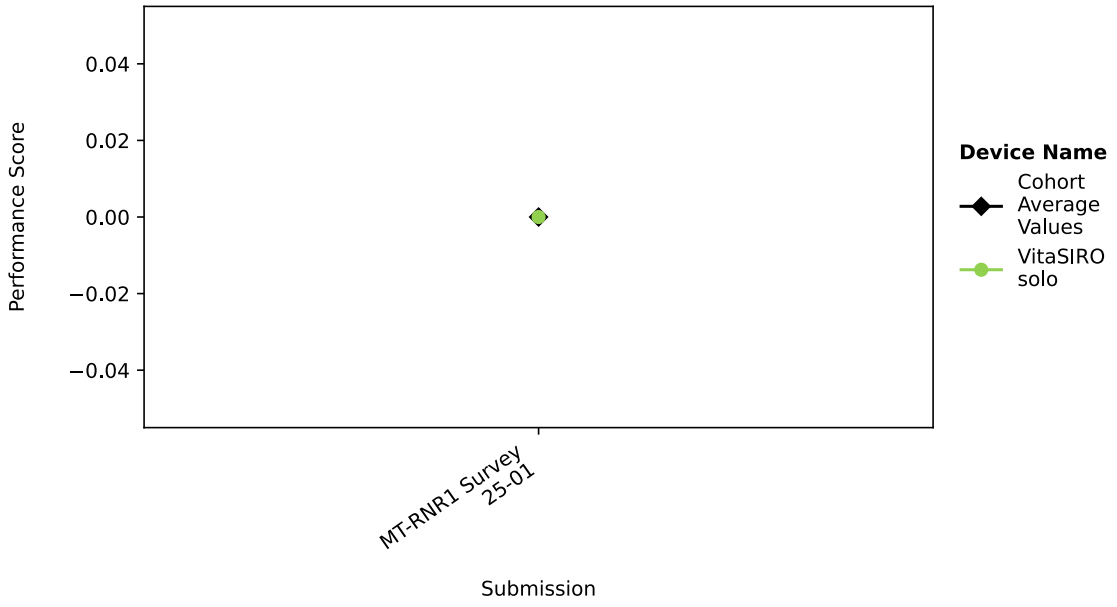
Submission MT-RNR1 Survey 25-01 Results Summary:

Device Name	Serial Number	Average Score	Performance
VitaSIRO solo	ACA23L25007	0.00	Good

Device performance (12-month rolling window):

Device Name	Serial Number	MT-RNR1 Survey 25-01	Average	Failure Rate
VitaSIRO solo	ACA23L25007	0.00	0.00	0.00 %

Device Performance against Cohort:



Case Specific Performance:

Device Name: VitaSIRO solo

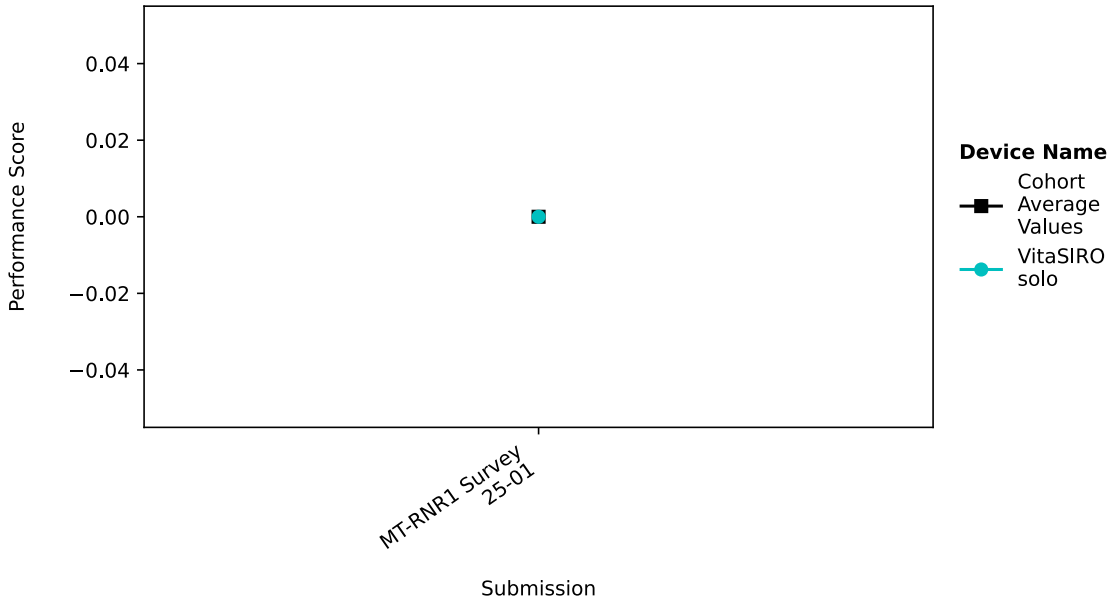
Device Type: Credo Diagnostics VitaSIRO Solo

Device Number: 3872-1

Serial Number: ACA23L25007

Case	Expected Result	Your Result	Cell Load	Concordance	Score	Performance	Comments
Case 1	Detected	Detected	Low	100.00 % (1/1)	0	Good	m.1555G
Case 2	Detected	Detected	High	100.00 % (1/1)	0	Good	m.1555G
Case 3	Not Detected	Not Detected	Medium	100.00 % (1/1)	0	Good	m.1555A
Average score					0.00	Good	

Device Performance against Cohort:



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Statistical Analysis (POCT MT-RNR1)

Scoring

The report shows the individual device scores for each sample, along with an average score across the 3 samples per survey, and an overall average score across different surveys. The scoring system used broadly reflects the clinical significance of the results obtained:

- A correct result is given a score of 0.
- A sliding scale score between 1 and 6 is assigned for incorrectly identified results, where 6 represents a gross misclassification of the result.
- A test failure is given a score of 1, 2 or 4, depending on the sample's cell load.
- A negative result for a positive sample is given a score of 6.
- A positive result for a negative sample is given a score of 5.

In general, a missed positive sample receives a larger penalty than a misclassified negative sample, as it could lead to an inappropriate treatment decision.

Table: Scoring matrix

Expected results	Your results	Assigned Score	Adjusted score*
Detected	Detected	0	0
Not Detected	Not Detected	0	0
Not Detected	Detected	5	2.5
Detected	Not Detected	6	3
Detected or Not Detected	Test failed	1, 2 or 4	0.5, 1 or 2
Detected or Not Detected	Not submitted	3	3

*Adjusted scores are assigned when <80% (50+ total submissions) or < 90% (30+ total submissions) of participants record the correct result. Adjusted scores are not applied for a total submission less than 30.

Survey performance calculation

The overall individual device performer status is determined by the average score across the 3 samples per survey, based on the following conditions:

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Table: Performance status

Average score condition (AvgS)	Performer status
0 ≤ AvgS < 1	**Good**
1 ≤ AvgS < 2	**Acceptable**
AvgS ≥ 2	**Poor**

For more information about report statistics please download EMQN Participant's Manual.

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