

UNDERSTANDING YOUR PERFORMANCE REPORT

Performance Report - Qualitative Analytes

Acceptable Results

Results submitted by laboratories for a qualitative analyte will be found under the column titled 'Result'. An analyte will be graded as acceptable (ACC) if the submitted result is one of the Acceptable Results or Reference Results. If it is not, the analyte will be graded as unacceptable (UNACC). If there is a lack of consensus, the grade not evaluated (NE) is used.

If no result is submitted by laboratories before the deadline for a given analyte, laboratories will receive the grade UNACC (failure to participate). Finally, if laboratories submit a Problem Code instead of a result, they will be graded NE by default¹.

The title Answer % refers to the percentage of laboratories graded as acceptable for a given Acceptable Result or Reference Result.

Example

For Sample D of Pathogen Identification, the result was graded as ACC since the laboratory submitted the result 'Staphylococcus saprophyticus', which was one of the Acceptable Results. Any of the results under Acceptable Result such as 'Staphylococcus coagulase negative' or 'aerobic gram-positive bacterium, Staphylococcus saprophyticus' would have been considered acceptable as long as it agrees with the extent of the laboratory. Additional information regarding programs with extents is included in a later section of this guide.

For the particular extent and method employed by this participant, 65% of participants as shown under Answer % chose the same answer. By adding all the Acceptable Results, we find that 75% answered correctly for this analyte, and 25% submitted unacceptable results (100% minus 75%).

¹ Certain Collaboration Members might elect to request a different outcome based on the Problem Code selected.

Analyte / Sample	Result	Grade	Peer Group Count	Acceptable Result	Answer % PG: Method/Submethod
Bacterial identification					
Pathogen Identification					
D	Staphylococcus saprophyticus	ACC	20	Staphylococcus coagulase negative Staphylococcus saprophyticus aerobic gram positive bacterium Staphylococcus saprophyticus aerobic gram positive bacterium anaerobic cultures not performed Staphylococcus saprophyticus	5% SM: /Manual 85% 0% 5%

Antimicrobial Susceptibility

Antimicrobial susceptibility is available in the programs BACT (Bacteriology), Blood Culture (BLCU) and URIC (Urine Culture). When reporting this analyte, laboratories need to ensure that the antimicrobials they test follow CLSI or EUCAST guidelines as appropriate for the organism detected in the sample. Antimicrobials which are inappropriate for a given organism will automatically be graded UNACC.

This is why Nitrofurantoin in the example below is not showing any acceptable result and was graded UNACC. More information on the acceptable antimicrobials can be found on the performance report following the evaluation.

Analyte / Sample	Result	Grade	Peer Group Count	Acceptable Result	Answer % PG: Method/Submethod
Antibiogram					
Antimicrobial Susceptibility – CLSI Guidelines					
Cefoxitin (CLSI)					
A	Susceptible	ACC	12	Susceptible	100% SM: /Manual
Ciprofloxacin (CLSI)					
A	Susceptible	ACC	11	Susceptible	100% SM: /Manual
Clindamycin (CLSI)					
A	Susceptible	ACC	16	Susceptible	100% SM: /Manual
Erythromycin (CLSI)					
A	Susceptible	ACC	20	Susceptible	95% SM: /Manual
Nitrofurantoin (CLSI)					
A	Susceptible	UNACC	1		SM: /Manual

Clinical Interpretation

Certain programs with images, such as Hematology programs that include Cell Morphology images, include a clinical interpretation in addition to the Acceptable Result(s). The clinical interpretation accompanied by a picture on the performance report can be used for training purposes or for troubleshooting an unacceptable grade.

Programs with Extent


For any bacteriology, mycobacteriology, mycology and parasitology program, laboratories register their complexity of testing by selecting the corresponding 'extent'. Extent 1 is for basic testing (i.e. gram stains). Increasingly complex testing correlates to higher extent values. Please refer to the catalogue for more detail regarding the extents of each discipline and program. Here is an example of extent 1 for BACT435:

Interpret Gram stains or perform primary inoculation, or both; and refer cultures to another laboratory appropriately certified for the subspecialty of bacteriology for identification.

Laboratories must report at least the minimum amount of required information as outlined in the extent or the grade will automatically be set as UNACC.

Performance Report - Quantitative Analytes



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		Print Date 2019/Sep/05
		Status Final
Participant:	BCHE433 Chemistry/Immunoassay	
Subscription ID:	2019/Jul/17	
Results Deadline:	2019/Jul/17	
Accreditation:	 This program is accredited by A2LA as compliant with ISO/IEC 17043:2010 under Oneworld Accuracy's scope of accreditation, number 4839.01.	

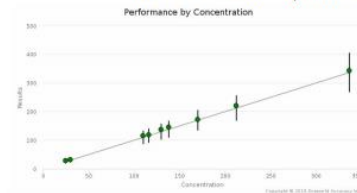
Sample Conditions	
Date samples were received (YYYY/MMM/DD)	2019/Jun/27
Were the samples received in good condition?	Yes

Instrument Model: Ortho Vitros 250 (VITROS 350)

Analyte / Sample	PARTICIPANT DATA				COMPARATIVE GROUP DATA				Acceptable Range	Evaluation Criteria
	Result	PAD Score (%)	Grade	Statistical Count	Mean	SD	CV(%)	Peer Group Code:Description		

Alanine Aminotransferase U/L

A	116	29.22	ACC	40	109.6	7.8	7.2	IG:Ortho Vitros Systems	87 - 132	Peer Group Mean \pm 20.0%
B	343	10.12	ACC	36	336.2	10.8	3.2	IG:Ortho Vitros Systems	269 - 404	Peer Group Mean \pm 20.0%
C	137	29.73	ACC	39	129.3	8.3	6.4	IG:Ortho Vitros Systems	103 - 156	Peer Group Mean \pm 20.0%



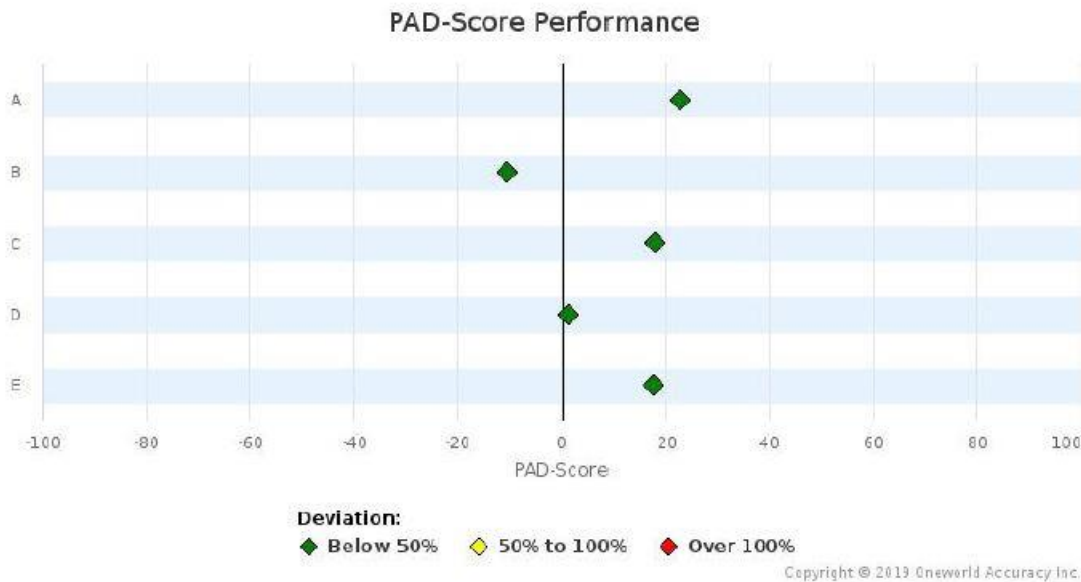
Grade: ACC - Acceptable; UNACC - Unacceptable; NE - Not Evaluated

Peer Group(PG) Codes: AR-all results; AU-all results in specific unit; ME-method; SM-submethod; RM-reagent manufacturer; RG-reagent group; RE-reagent; IM-instrument manufacturer; IG-instrument group; ID-instrument model

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PAD Score Graph

When the evaluation criterion is **not** 'Peer Group \pm SD' for all samples, then the system will display the PAD Score % (Percentage of Allowed Deviation Score %). The PAD score is calculated by this formula: (Difference between participant's result and target value/evaluation limit) x 100. PAD scores of the current test event as well as previous test events (if available) will be graphed, for every sample and analyte:



There will be a horizontal bar usually with a scale of -100 to 100 with a marker showing the PAD score of the participant and a color change relating to the following:

PAD Score value	Color
0-50% or 0%- (-50%)	Green
50-100% or -50% -(-100%)	Yellow
>100% or < -100%	Red

Z-Score Graph

When the evaluation criterion is 'Peer Group \pm SD' for all samples, then the system will display the z score (previously SDI, or standard deviation index). Z-score is calculated according to this formula: (Difference between participant's result and target value/1

standard deviation). Z scores of the current test event as well as previous test events (if available) will be graphed, for every sample and analyte:



There will be a horizontal bar, usually with a scale of -3 to 3 or -2 to 2, depending on the evaluation limit, with a marker showing the z score of the participant and color change relating to the following:

Z-Score value	Color
0 to 1 or -1 to 0	Green
-3 to -1 or 1 to 3	Yellow
>3 or < -3	Red

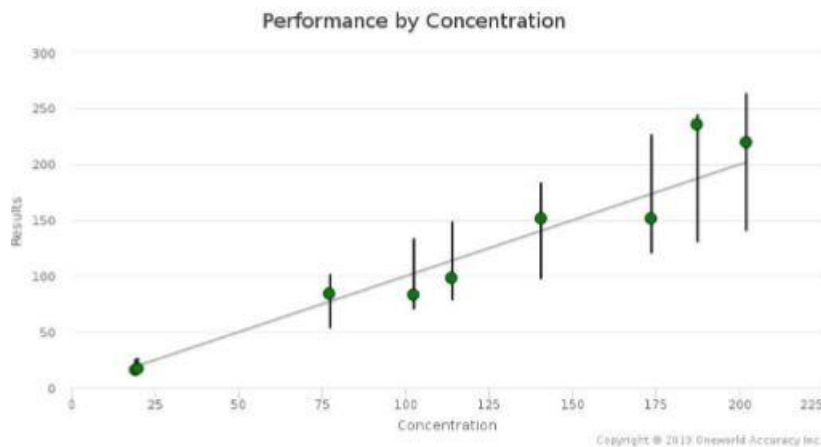
Historical Performance

The graph will show up to one year's worth of data. If the participant is new and participated in just one test event, it will show the information for just that test event.



Performance by Concentration

The graph will show up to one year's worth of data. If the participant is new and participated in just one test event, it will show the information for just that test event. If the participant participated for a year, it will show the results in relation to concentration (target value) for the whole year.



The vertical lines extending from the linear regression line indicate the acceptable ranges, while the markers indicate the participant's results in relation to their positions within the ranges.

Note - For any of the graphs, if a blank space is shown, that means a result has not been submitted, or a result is not evaluated (NE status). Occasionally, a [] bracket might be shown with the sample ID, which indicates a result has exceeded the following limits: z score of 4, or PAD score of 133.33%.

Acceptable Results

Results submitted by laboratories for a quantitative analyte will be found under the column titled 'Result'. An analyte will be graded as ACC if the submitted result is within the Acceptable Range. If it is not, the analyte will be graded as UNACC. If there is a lack of consensus or if there is an insufficient number of participants for a statistically relevant evaluation (normally 10 participants), the grade NE is issued.

If no result is submitted by laboratories before the deadline for a given analyte, laboratories will receive the grade UNACC (failure to participate). Finally, if laboratories submit a Problem Code instead of a result, they will be graded NE by default².

Example

Below is an example of a performance report for the analyte Sodium. Please refer to the User Guide (appendix 1A) for help with the terminology as needed.

Analyte / Sample	PARTICIPANT DATA			COMPARATIVE GROUP DATA					Acceptable Range	Evaluation Criteria
	Result	PAD Score (%)	Grade	Statistical Count	Mean	SD	CV(%)	Peer Group Code:Description		
Sodium mmol/L										
A	126.58	27.00	ACC	66	125.5	3.4	2.7	SM:Direct (No Sample Dilution)	121 - 130	Peer Group Mean ± 4
B	136.87	-3.25	ACC	64	137.0	3.6	2.6	SM:Direct (No Sample Dilution)	133 - 141	Peer Group Mean ± 4
C	144.43	-24.25	ACC	68	145.4	3.7	2.6	SM:Direct (No Sample Dilution)	141 - 150	Peer Group Mean ± 4
D	151.66	-51.00	ACC	68	153.7	4.8	3.1	SM:Direct (No Sample Dilution)	149 - 158	Peer Group Mean ± 4
E	161.32	-127.00	UNACC	68	166.4	6.1	3.7	SM:Direct (No Sample Dilution)	162 - 171	Peer Group Mean ± 4

± For vial A to D, the results entered by the laboratory are within the Acceptable Ranges, thus all vials are graded as ACC. The Acceptable Range is based on the Evaluation Criteria, which is Peer Group Mean ± 4 mmol/L. The PAD or Z-score indicates the distance of the result from the Peer Group Mean.

The statistical count, mean, standard deviation (SD) and coefficient of variation (CV(%)) are Comparative Group Data that provides descriptive statistical information about the peer group in which the result is evaluated in.

Please refer to the footer of the performance report for a description of each peer group. Here, the laboratory was evaluated with other participants using the submethod (SM) "Direct (No Sample Dilution)".

² Certain Collaboration Members might elect to request a different outcome based on the Problem Code selected.

Analytes that are never evaluated

Certain analytes are always graded as NE since they are only submitted as background information. These results are collected for troubleshooting purposes in case of a failure.

Peer Group Formation

When evaluation criteria are based on a peer group, each participant is associated with the most specific peer group that matches the registration for the analyte. The minimum number of participants must be met in order for a peer group to be formed. This minimum number varies between analytes but is usually equal to 10.

Performance Report – Program with assays

Performance Reports for programs with assays (certain Clinical Serology programs and all Clinical Nucleic Acid Testing programs) are usually prepared by the science architect NRL - National Serology Reference Laboratory - Australia and information is presented in a comprehensive way: In these reports, you will find information on assays, assay interpretation and final interpretation. At the end of each Performance Report, NRL includes a Final Report.

Blank reports

If no assay information is submitted by laboratories for a given test event, the report will simply show “No Resulted Assay” on the first page. There will be no evaluation or statistics provided, but the Final Report will be included.

Performance Report		Page 1 / 1
Participant:	TREP435 Syphilis Serology	
Subscription ID:		
Results Deadline:	2013/Oct/30	
Assay	No Resulted Assay	

Assay Results

Laboratories results will be displayed based on the particular methodology of laboratories and will reflect the number of runs (under Run) and replicates (under Replicate 1, 2 or 3) used.

Since assay data is used to determine an interpretation and considered as background information, it is not evaluated and always flagged as NE (under Flag). For the same reason, there will be no data below Reference Results (RR) and Concordant with RR n(%).

To the right of the report, peer group information can be found: number of participants in the peer group (Participants (n)), number of results submitted by participants in this peer group (Results (n)) and number of results reported excluding Problem Code, Reason Code, statistical outliers and results removed prior to analysis (Statistical (n)).

Finally, the Peer Group Description can be found below the vial results.

Example

The results below are for HBsAg Reactivity for the program HEPM435 – Hepatitis Serology. You will notice that none of the results have been evaluated (NE below Flags) since this is considered as background information.

HBsAg Reactivity				Replicate 1			Replicate 2			Replicate 3			Peer Group Statistics			
Sample	Run	Result	Flags	Result	Flags	Result	Flags	Participants (n)	Results (n)	Statistical (n)	Concordant Reference Results with RR n(%)	RR				
A	1	Negative	⚡NE					10	10	10						
B	1	Negative	⚡NE					10	10	10						
C	1	Reactive	⚡NE					10	10	10						
D	1	Reactive	⚡NE					10	10	10						
E	1	Negative	⚡NE					10	10	10						
Peer Group Description																
PG ID	PG Code	Test Process	Kit	Technique	Instrument Model											
13105	AS1	Detection	Human Hexagon HBsAg 1-Step													

Assay Interpretation

The assay interpretation report is similar to the previous section except that there are no runs and replicates and Reference Results (RR) are provided.

When laboratories result for the interpretation is the same as the RR, there will be no flag. Notice that this is different than the other reports provided by Oneworld Accuracy where acceptable results receive the Grade ACC.

As explained in the User Guide, various flags are used to highlight specific issues:

- Aberrant (diamond icon): Submitted results that do not meet the evaluation criteria or do not agree with the reference result. This is the equivalent of the grade unacceptable (UNACC) found in most other reports.

- Statistical outlier (circle icon): A numerical result that is outside the upper or lower statistical limits as defined by ISO Robust Statistics. Results that have been flagged as outlier are removed from statistical calculations.
- Removed prior to analysis (square icon): NRL may remove specific results from the dataset prior to analysis. For example, a laboratory may have tested the wrong sample rendering the submitted results inappropriate for analysis.

Please note that aberrant and statistical outlier flags are not mutually exclusive and one or both could appear on the report for the same sample.

Example

In the example below, there are no flag for the results of sample B, C and D since they are concordant with the Reference Results (RR). Sample A and E are flagged as aberrant (diamond icon) since the RR was Reactive and the laboratory submitted Negative.

Assay Amertik HCV

Anti-HCV Interpretation

Sample	Result	Flags	Peer Group Counts					Reference Results (RR)
			Participants (n)	Results (n)	Statistical (n)	Concordant with RR (n)	Concordant with RR (%)	
A	Negative	◆	4	4	4	3	75	Reactive
B	Negative		4	4	4	4	100	Negative
C	Negative		4	4	4	4	100	Negative
D	Negative		4	4	4	4	100	Negative
E	Negative	◆	4	4	4	3	75	Reactive

Peer Group Description						
PG ID	PG Code	Test Process	Kit	Technique	Instrument Model	
47337	AS1	Detection	Ameritek dBest HCV Rapid Test (Strip)			

Final Interpretation

The programs C. trachomatis I N. gonorrhoeae DNA (CTNG435), Qualitative Hepatitis Serology (HEPM435/4310), HIV Serology (HIVC435/HIVC4310), HTLV Serology (HTLV435/HTLV4310), Leptospirosis DNA Qualitative (LEPN435) and Toxoplasma, Rubella and CMV Serology (TORC435) include a final interpretation. This final interpretation establishes a Serology Status/DNA test result based on all pertinent assay interpretations.

Final Report

The Final Report provides further information to understand the evaluation. It is a valuable educational tool that laboratories should use to improve their testing quality. It includes the program objective, information on the material and statistical analysis, details concerning laboratories results and a troubleshooting guide for aberrant results.