COLLEGE of AMERICAN PATHOLOGISTS

Surveys and Anatomic Pathology Education Programs

Flow Cytometry - B-ALL Minimal Residual Disease
BALL-B 2021

Participant Summary

This document is available online in e-LAB Solutions Suite.

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2021 BALL-B
PARTICIPANT SUMMARY

Evaluation Criteria

Results for the BALL Survey are not formally evaluated; however, statistics will appear in the participant summary for your information.

To provide a timely evaluation of your results, statistics presented in this participant summary reflect participant data received by the due date.

Cell markers with less than ten reported results were not included in this participant summary.

In the event a result is not graded, a numeric code will appear next to your result. A definition of the code will appear on the first page of your evaluation. Please see "Actions Laboratories Should Take when a PT Result is Not Graded" on page 3. Laboratories should perform a self-evaluation. For more information, go to cap.org.

1. Hover over Laboratory Improvement and click **Proficiency Testing.**
2. Under Proficiency Testing (PT) Programs, Surveys, click **PT Resources.**
3. Under Existing Customers, click **Performing a Self-Evaluation When PT is Not Graded.**

Discussion

Albeit the Survey is not formally evaluated, the committee generally utilizes 80% consensus approach and overall interpretation in determining the correct responses. In addition, the committee also considers that ≥ 20 percent of participating laboratories perform testing for any particular antigen to be included.

Case BALL-04: Positive for MRD

This case contained an abnormal B lymphoblast cell line diluted in peripheral blood at approximately 0.05%. Analysis of the cells by flow cytometry at quality control verification, showed a small population of abnormal cells that were positive for CD9, CD10, CD19, CD22, CD34, CD38, bright CD81, and dim CD45. The population was negative for CD5 and CD20 and showed low side scatter.

Of the 84 participants who reported a result, 68 (81.0%) correctly reported this sample as positive, with the remaining 16 (19.1%) participants reporting it as negative. Of those reporting the sample as positive, the average percent of MRD detected for all methodologies was 0.029%, with a range of 0.01-0.07% which is within the 0.5 log difference that could be expected with MRD testing.

Greater than 80% consensus was reached with the following positive markers: CD9, CD10, CD19, CD22, CD34, CD38, CD58, and CD81; and the following negative markers: CD5, CD20, and CD123. It should be noted that CD81 and CD123 were only run in 14 out of the 84 participants and CD5 reported in only 10 cases.

Consensus was not achieved with CD24 and CD45, and with CD13/33 where negative expression is often misinterpreted as dim positive expression.

Case BALL-05: Negative for MRD

This case contained peripheral blood only with no residual B-lymphoblastic leukemia. Of the 84 participants who reported a result, 91.7% of participants (77) correctly reported this sample as negative, with the remaining 8.3% of participants (7) reporting this as positive.

Case BALL-06 List Mode Case Positive for MRD

Diagnostic plots provided for this case (as gated dot plots) showed a population that was positive for CD9, CD10, CD19, CD45, and CD58, and positive or partially expressed for CD13/33, CD20, and CD34 and negative for CD38. The gated dot plots for MRD analysis showed an abnormal B lymphoblast population that expressed CD10 but without the normally associated CD38. Thus, the correct interpretation was MRD positive. A total of 96.6% of participants (85/88) reported this case as positive, with 3.4% (3/88) calling it negative.

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DIAGNOSTIC IMMUNOLOGY AND FLOW CYTOMETRY COMMITTEE

Preanalytic Information

Total Responses	85	
Lab location	LABS	%
US	52	61.2
Canada	6	7.1
Other	27	31.8

Total Responses	93	
Instrument	LABS	%
BD FACSCanto/II	52	55.9
Coulter Gallios, Navios	30	32.3
BD FACSLyric	8	8.6
Other	3	3.2

Total Responses	90	
Software	LABS	%
Beckman Coulter Kaluza	33	36.7
BD FACSDiva	25	27.8
FCS Express	16	17.8
Infinicyt	7	7.8
BD FACSuite	2	2.2
BD Paint-A-Gate	1	1.1
FlowJo	1	1.1
Other	5	5.6

Total Responses	84	
Gating Method	LABS	%
Abnormal population using CD45 and light scatter	30	35.7
CD19 vs RALS	18	21.4
Abnormal population using CD19 and CD10	12	14.3
Whole mononuclear cell population using FALS vs. RALS	8	9.5
Lymphocytes using CD45 and light scatter	5	6.0
Abnormal population vs CD19	2	2.4
Other	9	10.7

MRD Reporting

BALL-04

Total Responses	84	
Results	LABS	%
MRD positive (≥0.01% positive)	68	81.0
MRD negative	16	19.1

Method	LABS	MEAN	SD	CV	MEDIAN	LOW	HIGH
Mononuclear Cells	41	0.035	0.017	48.1	0.03	0.01	0.07
Total Viable Leukocytes	21	0.022	0.007	34.2	0.02	0.01	0.03
All Methods	67	0.029	0.016	56.1	0.03	0.00	0.07

Immunophenotype Results

	Negative		Positive		Partially expressed	
CELL MARKER	LABS	%	LABS	%	LABS	%
CD5	10	100.0	-	-	-	-
CD9	-	-	42	95.5	2	4.5
CD10	2	2.9	65	94.2	2	2.9
CD13/33	24	47.1	18	35.3	9	17.6
CD19	-	-	69	100.0	-	-
CD20	55	80.9	8	11.8	5	7.3
CD22	-	-	27	90.0	3	10.0
CD24	7	58.3	4	33.3	1	8.3
CD34	1	1.5	67	98.5	-	-
CD38	3	4.4	63	92.7	2	2.9
CD45	26	38.2	34	50.0	8	11.8
CD56	Less than 10 laboratories reported distribution results for this antigen.					
CD58	6	10.2	51	86.4	2	3.4
CD79a	Less than 10 laboratories reported distribution results for this antigen.					
CD81	-	-	14	100.0	-	-
CD123	12	85.7	2	14.3	-	-
Kappa Light Chain	Less than 10 laboratories reported distribution results for this antigen.					
Lambda Light Chain	Less than 10 laboratories reported distribution results for this antigen.					
nTDT	Less than 10 laboratories reported distribution results for this antigen.					

MRD Reporting, cont'd

BALL-05

Total Responses	84	
Results	LABS	%
MRD positive (≥0.01% positive)	7	8.3
MRD negative	77	91.7

METHOD	LABS	MEAN	SD	CV	MEDIAN	LOW	HIGH

Quantitative results are not shown for MRD negative specimens.

BALL-06

Total Responses	88	
Results	LABS	%
MRD positive (≥0.01% positive)	85	96.6
MRD negative	3	3.4

Immunophenotype Results, cont'd

	Negative		Positive		Partially expressed	
CELL MARKER	LABS	%	LABS	%	LABS	%

Immunophenotype results are not shown for MRD negative specimens.

	Negative		Positive		Partially expressed	
CELL MARKER	LABS	%	LABS	%	LABS	%
CD9	-	-	76	91.6	7	8.4
CD10	-	-	85	100.0	-	-
CD13/33	15	18.1	48	57.8	20	24.1
CD19	-	-	84	100.0	-	-
CD20	1	1.2	60	70.6	24	28.2
CD34	8	9.5	64	76.2	12	14.3
CD38	80	95.2	1	1.2	3	3.6
CD45	1	1.2	68	81.9	14	16.9
CD58	-	-	83	98.8	1	1.2

Actions Laboratories Should Take when a PT Result is Not Graded

The CAP uses exception reason codes that signify the proficiency testing (PT) for an analyte has not been graded. The exception reason code is located on the evaluation report in brackets to the right of the result. Your laboratory must identify all analytes with an exception reason code, review, and document the acceptability of performance as outlined below and retain documentation of review for at least 2 years. The actions laboratories should take include, but are not limited to:

Code	***Exception Reason Code Description***	***Action Required***
11	Unable to analyze	Document why the specimens were not analyzed (eg, instrument not functioning or reagents not available). Perform and document alternative assessment (ie, split samples) for the period that commercial PT was not tested to the same level and extent that would have been tested.
20	Response was not formally graded due to insufficient peer group data. Please see the participant summary for additional information.	Applies to a response that is not formally evaluated when a peer group is not established due to fewer than 10 laboratories reporting. Document that the laboratory performed a self-evaluation using the data presented in the participant summary and compared its results to a similar method, all method, all participant statistics, or data tables for groups of 3-9 laboratories, if provided. Perform and document the corrective action of any unacceptable results. If self-evaluation is not possible, it is up to the laboratory director/designee to determine an alternative performance assessment.
21	Specimen problem	Document that the laboratory has reviewed the proper statistics supplied in the participant summary. Perform and document alternative assessment for the period that commercial PT was not tested to the same level and extent that would have been tested. Credit is not awarded in these cases.
22	Result is outside the method/ instrument reportable range	Document the comparison of results to the proper statistics supplied in the participant summary. Verify detection limits. Perform and document the corrective action of any unacceptable results.
24	Incorrect response due to failure to provide a valid response code	Document the laboratory's self-evaluation against the proper statistics and evaluation criteria supplied in the participant summary. Perform and document the corrective action of any unacceptable results. Document corrective action to prevent future failures.
25	Inappropriate use of antimicrobial	Document the investigation of the results as if they were unacceptable and review the proper reference documents to gain knowledge of the reason your response is not appropriate.
26	Educational challenge	Review participant summary for comparative results and document performance accordingly. Evaluation criteria are not established for educational challenges. Laboratories should determine their own evaluation criteria approved by their laboratory director for self-evaluation.
27,31	Lack of participant or referee consensus	Document that the laboratory performed a self-evaluation and compared its results to the intended response when provided in the participant summary. If comparison is not available, perform and document alternative assessment (ie, split samples) for the period that commercial PT reached non-consensus to the same level and extent that would have been tested.
28	Response qualified with a greater than or less than sign; unable to quantitate	Applies to a response that is not formally evaluated when a less than or greater than sign is reported. Document that the laboratory performed a self-evaluation and compared its results to the proper statistics supplied in the participant summary. Verify detection limits. Perform and document the corrective action of any unacceptable results.
30	Scientific committee decision	Applies to a response that is not penalized based on scientific committee decision. Document that the laboratory has reviewed the proper statistics supplied in the participant summary.

Actions Laboratories Should Take when a PT Result is Not Graded

The CAP uses exception reason codes that signify the proficiency testing (PT) for an analyte has not been graded. The exception reason code is located on the evaluation report in brackets to the right of the result. Your laboratory must identify all analytes with an exception reason code, review and document the acceptability of performance as outlined below and retain documentation of review for at least 2 years. The actions laboratories should take include but are not limited to:

Code	***Exception Reason Code Description***	***Action Required***
33	Specimen determined to be unsatisfactory after contacting the CAP	Document that the laboratory has contacted the CAP and no replacements specimens were available. Perform and document alternative assessment (ie, split samples) for the period that commercial PT was not tested to the same level and extent that would have been tested.
40 41	Results for this kit were not received. Results for this kit were received past the evaluation cut-off date.	Document why results were not received, corrective action to prevent recurrence and the laboratory's self-evaluation of the results by comparing results to the proper statistics and evaluation criteria supplied in the participant summary. If PT specimens were not analyzed, perform and document alternative assessment (ie, split samples) for the period that commercial PT was not tested to the same level and extent that would have been tested.
42	No credit assigned due to absence of response	The participant summary indicates which tests are graded (see evaluation criteria) and which tests are not evaluated/educational. Updates to grading will also be noted. If a test is educational, the laboratory is not penalized for leaving a result(s) blank. If a test is graded (regulated and non-regulated analytes) and your laboratory performs that test, results cannot be left blank. The laboratory is required to submit results for **all** challenges within that test or use an appropriate exception code or indicate test not performed/not applicable/not indicated. Exceptions may be noted in the kit instructions and/or the result form. Document corrective actions to prevent future failures.
44	This drug is not included in our test menu. Use of this code counts as a correct response.	Verify that the drug is not tested on patient samples and document to ensure proper future reporting.
45	Antimicrobial agent is likely ineffective for this organism or site of infection	Document that the laboratory performed a self-evaluation of written protocols and practices for routine reporting of antimicrobial susceptibility reports to patient medical records. Document that routine reporting of this result to clinicians for patient care is compliant with specific recommendations of relevant medical staff and committees (eg, infectious diseases, pharmacy and therapeutics, infection control).
77	Improper use of the exception code for this mailing	Document the identification of the correct code to use for future mailings.
91	There was an insufficient number of contributing challenges to establish a composite grade.	Document the investigation of the result as if it were an unacceptable result. Perform and document the corrective action if required.
35, 43, 46, 88, 92	Various codes	No action required.

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This concludes the report.

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