

2021 BALL-A PARTICIPANT SUMMARY

Program Update

Beginning with 2021 BALL-B mailing, the paper challenge will be provided as online gated dot plots.

Program Note

Beginning with this mailing, MRD quantitative and immunophenotype results will no longer be displayed for negative specimens.

If your proficiency testing results are not graded, your laboratory 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**.

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 5.

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 B-ALL 01: Negative for MRD

This case contained peripheral blood only with no residual B lymphoblastic leukemia. Of the 74 participants who reported a result, 94.6% correctly reported this sample as negative, with the remaining 5.4% participants reporting this as positive.

Case B-ALL 02: Positive for MRD at approximately 0.2%

This case contained an abnormal B lymphoblast cell line diluted in peripheral blood at approximately 0.2%. Analysis of the cells by flow cytometry shows a small population of abnormal cells that were positive for CD10, dim CD13, CD19, CD22, CD34, bright CD38, and dim CD45. The population was negative for CD5 and CD20 and showed low side scatter and increased forward scatter.

Of the 74 participants who reported a result, 67 (90.5%) correctly reported this sample as positive, with the remaining 7 (9.5%) participating reporting it as negative. Of those reporting the sample as positive, the average percent of MRD detected for all methodologies was 0.154%, with a range of 0-0.51%.

Case BALL-03 List Mode Case Negative for MRD

Diagnostic plots provided for this case (as PDFs) showed a population that was positive for CD19, CD34, Tdt and cytoplasmic Cd79a and negative for CD10, CD20 and CD13/33. List mode files for MRD analysis lacked an abnormal B lymphoblast population. The B lineage population represented normal hematogones. Thus, the correct interpretation was MRD negative. A total of 85.4% of participants (41/48) reported this case as negative, with 14.6% (7/48) calling it positive.

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DIAGNOSTIC IMMUNOLOGY AND FLOW CYTOMETRY COMMITTEE

Preanalytic Information

Total Responses	76	
Lab location	LABS	%
US	50	65.8
Canada	7	9.2
Other	19	25.0

Total Responses	79	
Instrument	LABS	%
BD FACSCanto/II	45	57.0
Coulter Gallios, Navios	27	34.2
BD FACSLyric	4	5.1
Other	3	3.8

Total Responses	76	
Software	LABS	%
Beckman Coulter Kaluza	30	39.5
BD FACSDiva	25	32.9
FCS Express	11	14.5
Infinicyt	4	5.3
BD FACSuite	1	1.3
Verify Software House WinList	1	1.3
Other	4	5.3

Total Responses	74	
Gating Method	LABS	%
Abnormal population using CD45 and light scatter	36	48.6
Whole mononuclear cell population using FALS vs. RALS	8	10.8
Lymphocytes using CD45 and light scatter	7	9.5
Abnormal population using FALS vs. RALS	2	2.7
No gate	1	1.4
Other	20	27.0

MRD Reporting

BALL-01

Total Responses	74	
Results	LABS	%
MRD positive ($\geq 0.01\%$ positive)	4	5.4
MRD negative	70	94.6

Method	LABS	MEAN	SD	CV	MEDIAN	LOW	HIGH
Quantitative results are not shown for MRD negative specimens.							

Immunophenotype Results

CELL MARKER	Negative LABS	%	Positive LABS	%	Partially expressed LABS	%
Immunophenotype results are not shown for MRD negative specimens.						

MRD Reporting, cont'd

BALL-02

Total Responses	74	
Results	LABS	%
MRD positive ($\geq 0.01\%$ positive)	67	90.5
MRD negative	7	9.5

Method	LABS	MEAN	SD	CV	MEDIAN	LOW	HIGH
Mononuclear Cells	45	0.189	0.117	59.0	0.20	0.00	0.51
Total Viable Leukocytes	18	0.064	0.029	44.6	0.06	0.01	0.12
All Methods	68	0.154	0.115	75.0	0.11	0.00	0.51

Immunophenotype Results, cont'd

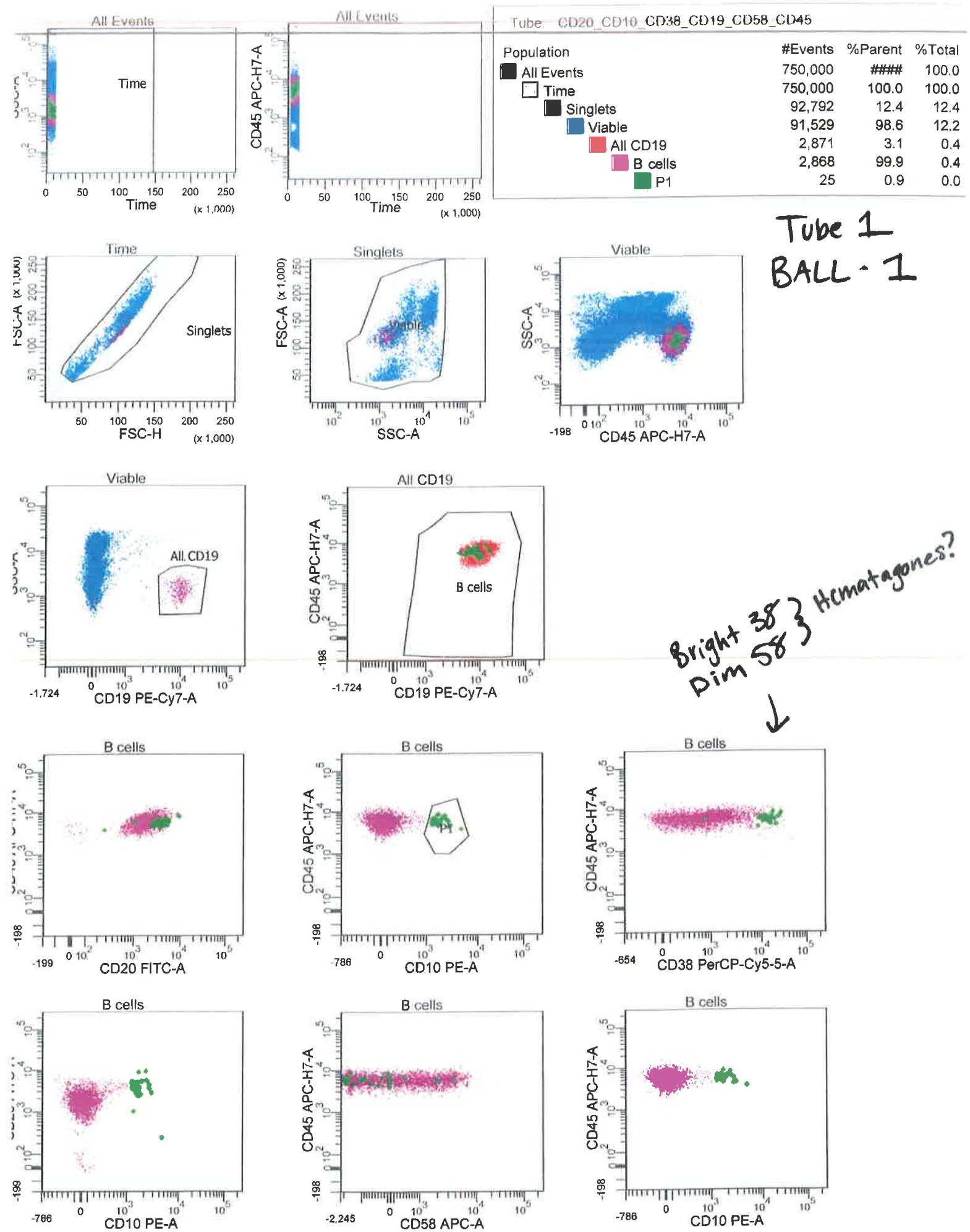
CELL MARKER	Negative		Positive		Partially expressed	
	LABS	%	LABS	%	LABS	%
Less than 10 laboratories reported distribution results for this antigen.						
CD5	-	-	43	95.5	2	4.5
CD9	-	-	69	100.0	-	-
CD10	-	-	12	23.5	29	56.8
CD13/33	-	-	-	-	10	19.7
CD19	-	-	69	100.0	-	-
CD20	10	15.1	34	51.6	22	33.3
CD22	-	-	21	91.3	2	8.7
Less than 10 laboratories reported distribution results for this antigen.						
CD24	-	-	69	100.0	-	-
CD34	-	-	-	-	-	-
CD38	2	3.0	65	95.5	1	1.5
CD45	29	42.0	24	34.8	16	23.2
CD56	-	-	-	-	-	-
CD58	-	-	56	95.0	3	5.0
CD79a	-	-	-	-	-	-
CD81	1	8.3	11	91.7	-	-
CD123	12	80.0	3	20.0	-	-
Kappa Light Chain	-	-	-	-	-	-
Lambda Light Chain	-	-	-	-	-	-
nTDT	-	-	-	-	-	-

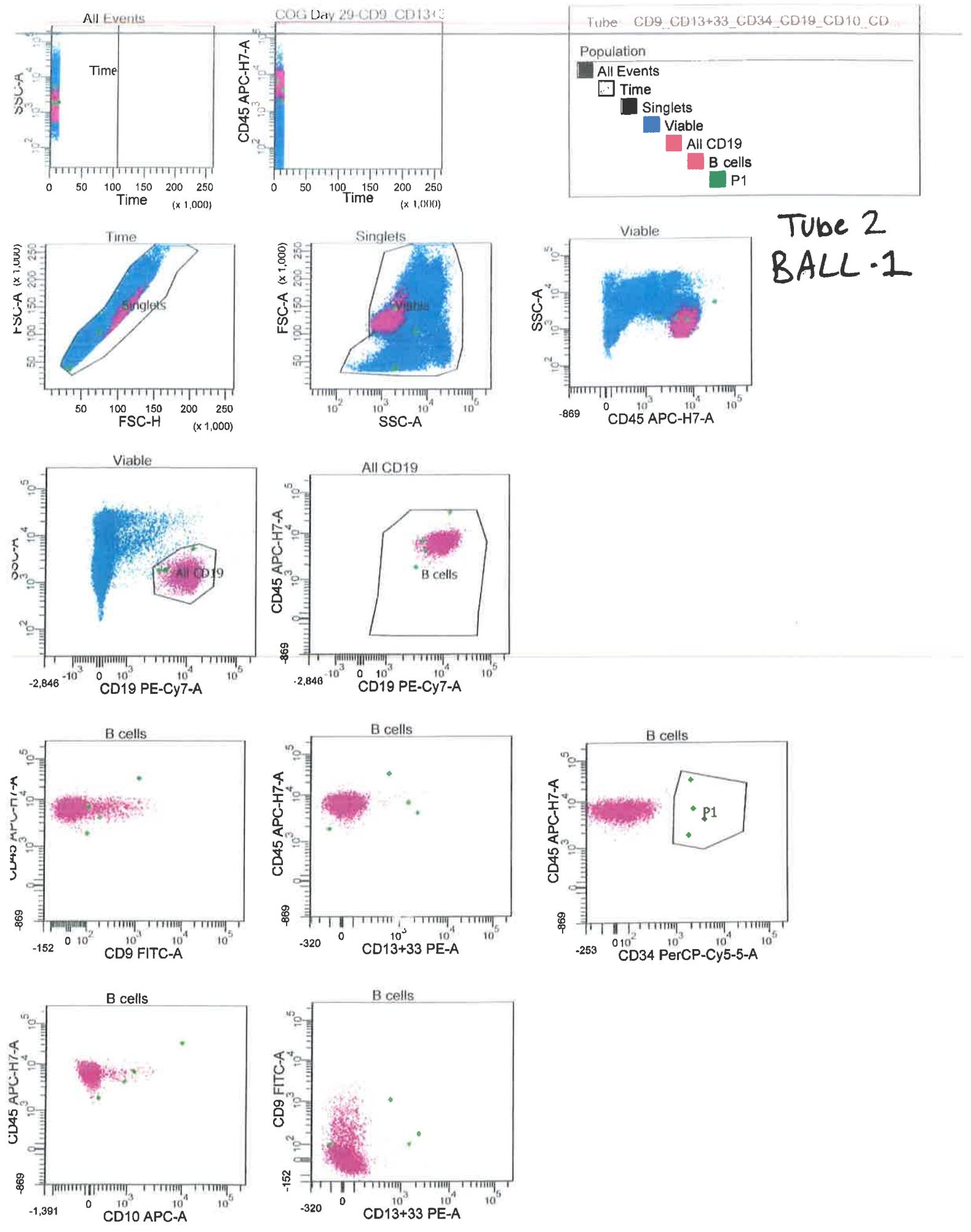
BALL-03

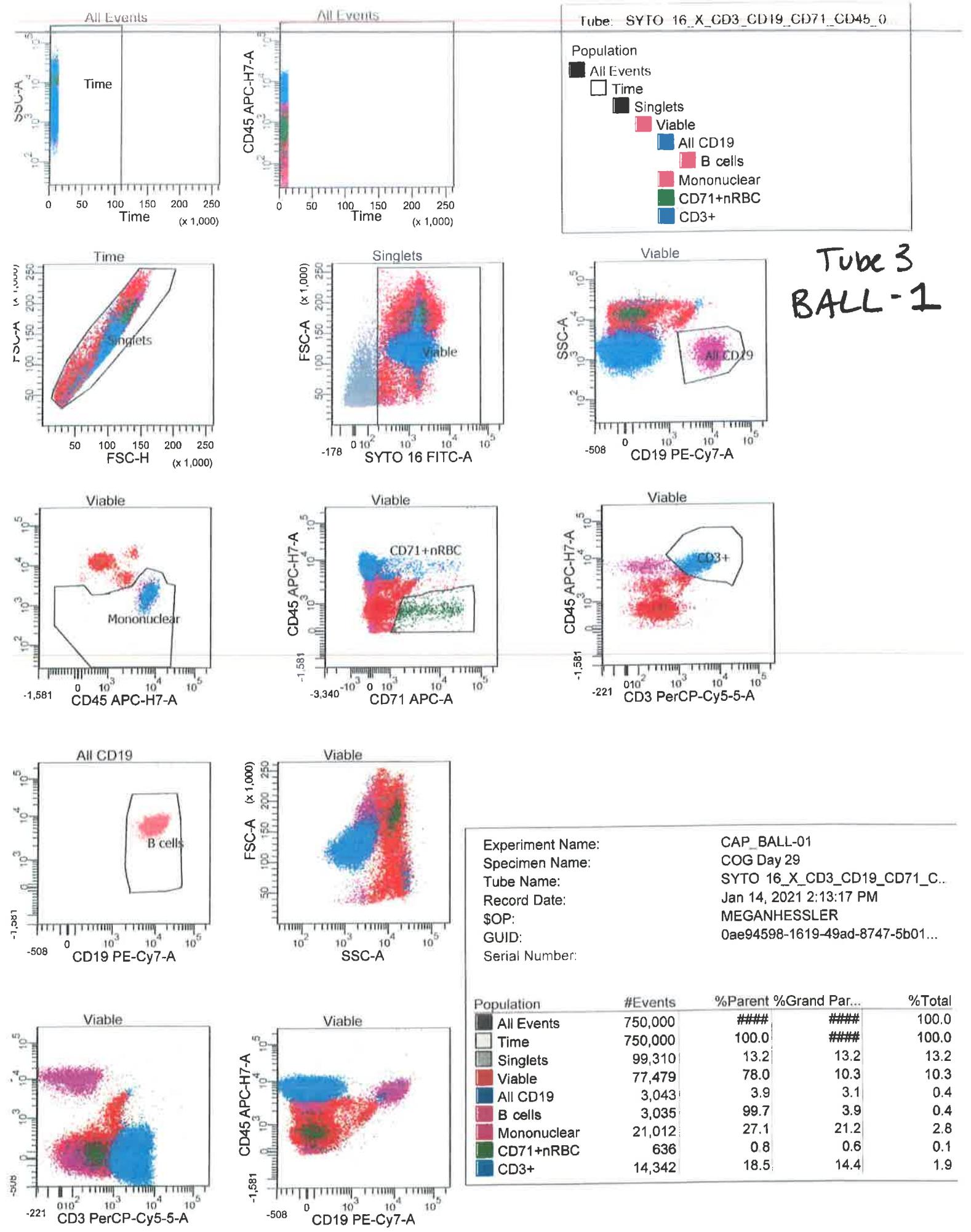
Total Responses	48	
Results	LABS	%
MRD positive ($\geq 0.01\%$ positive)	7	14.6
MRD negative	41	85.4

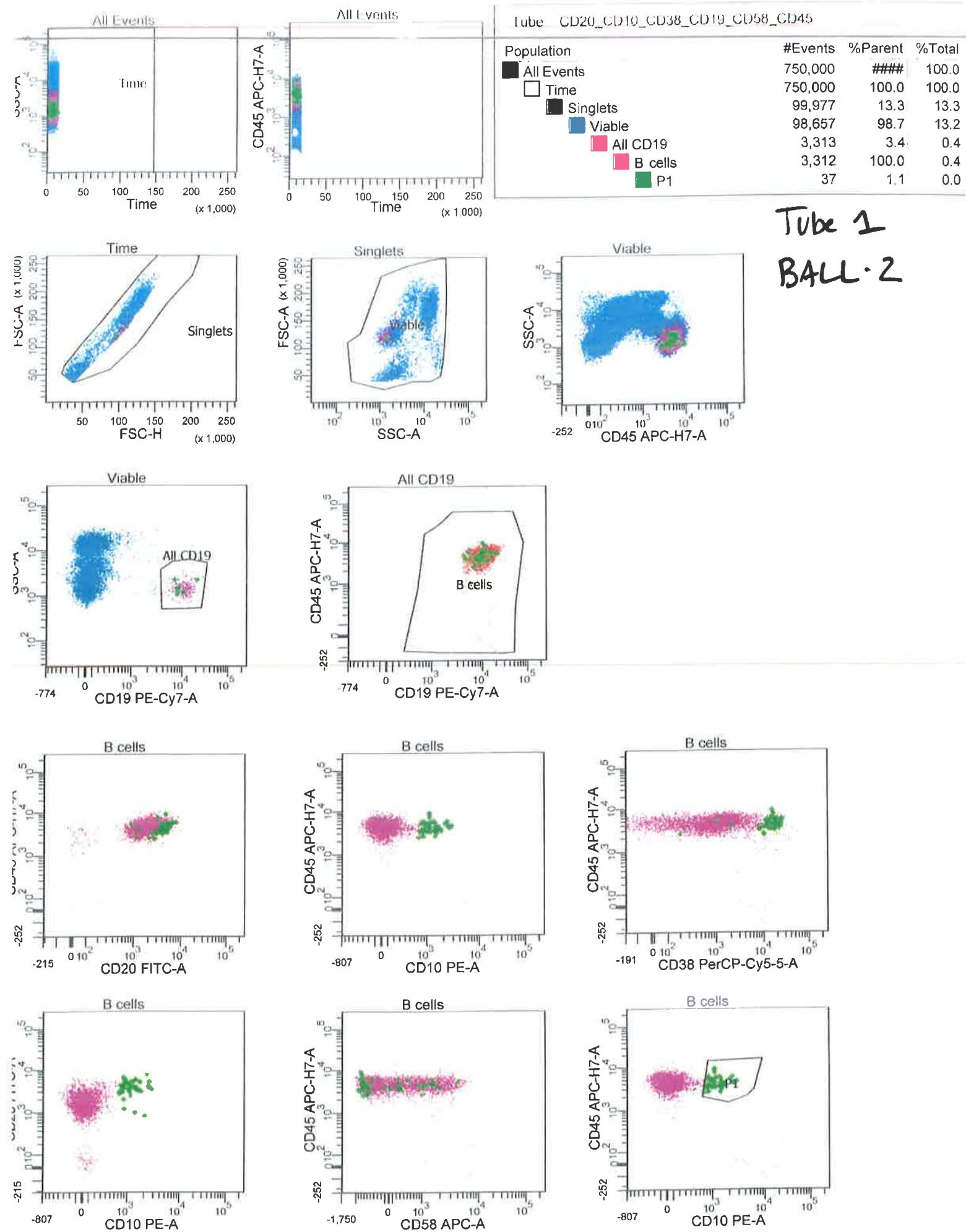
METHOD	LABS	MEAN	SD	CV	MEDIAN	LOW	HIGH
Quantitative results are not shown for MRD negative specimens.							

CELL MARKER	Negative		Positive		Partially expressed	
	LABS	%	LABS	%	LABS	%
Immunophenotype results are not shown for MRD negative specimens.						

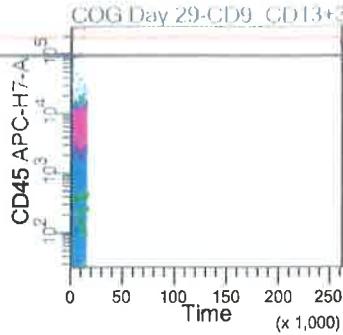
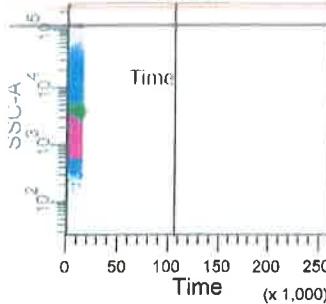








All Events

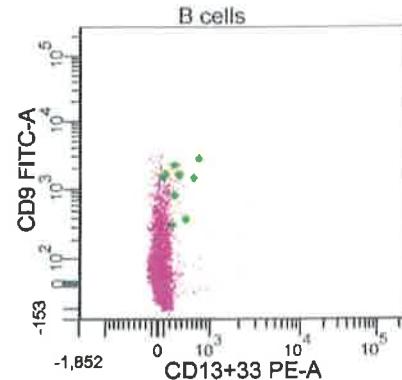
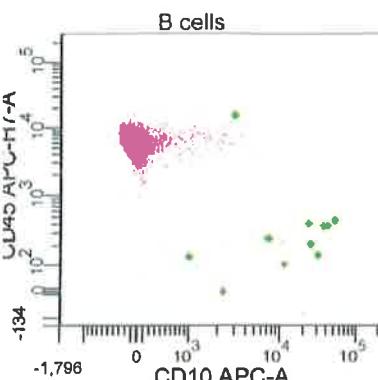
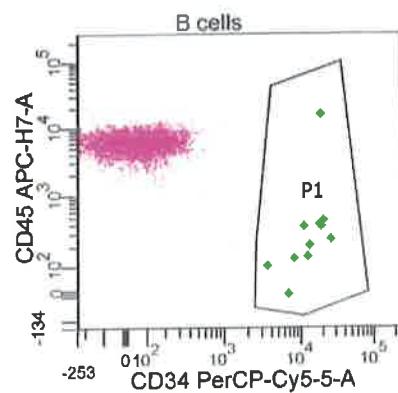
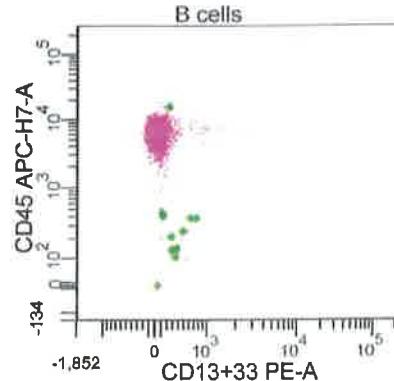
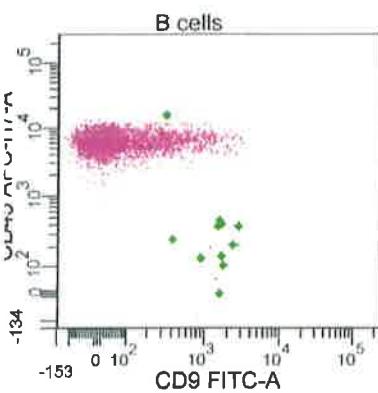
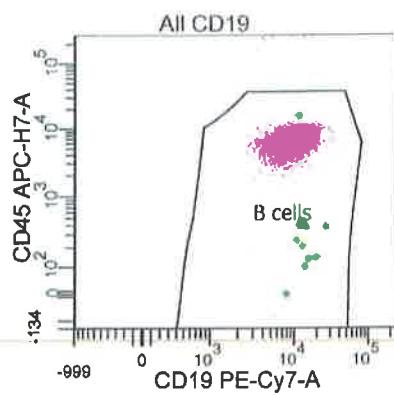
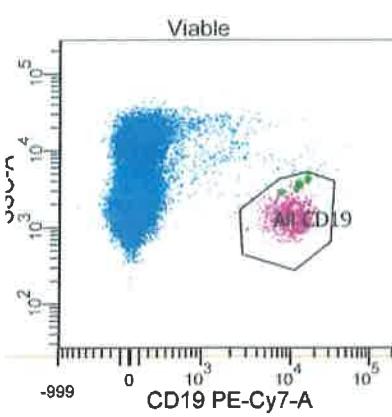
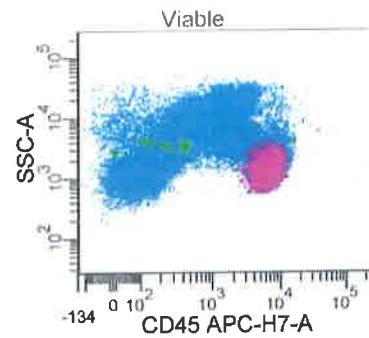
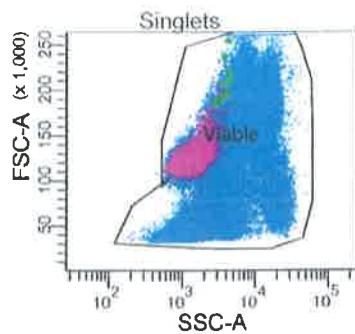
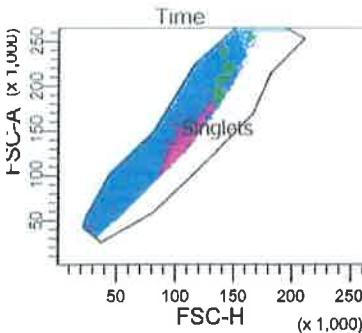


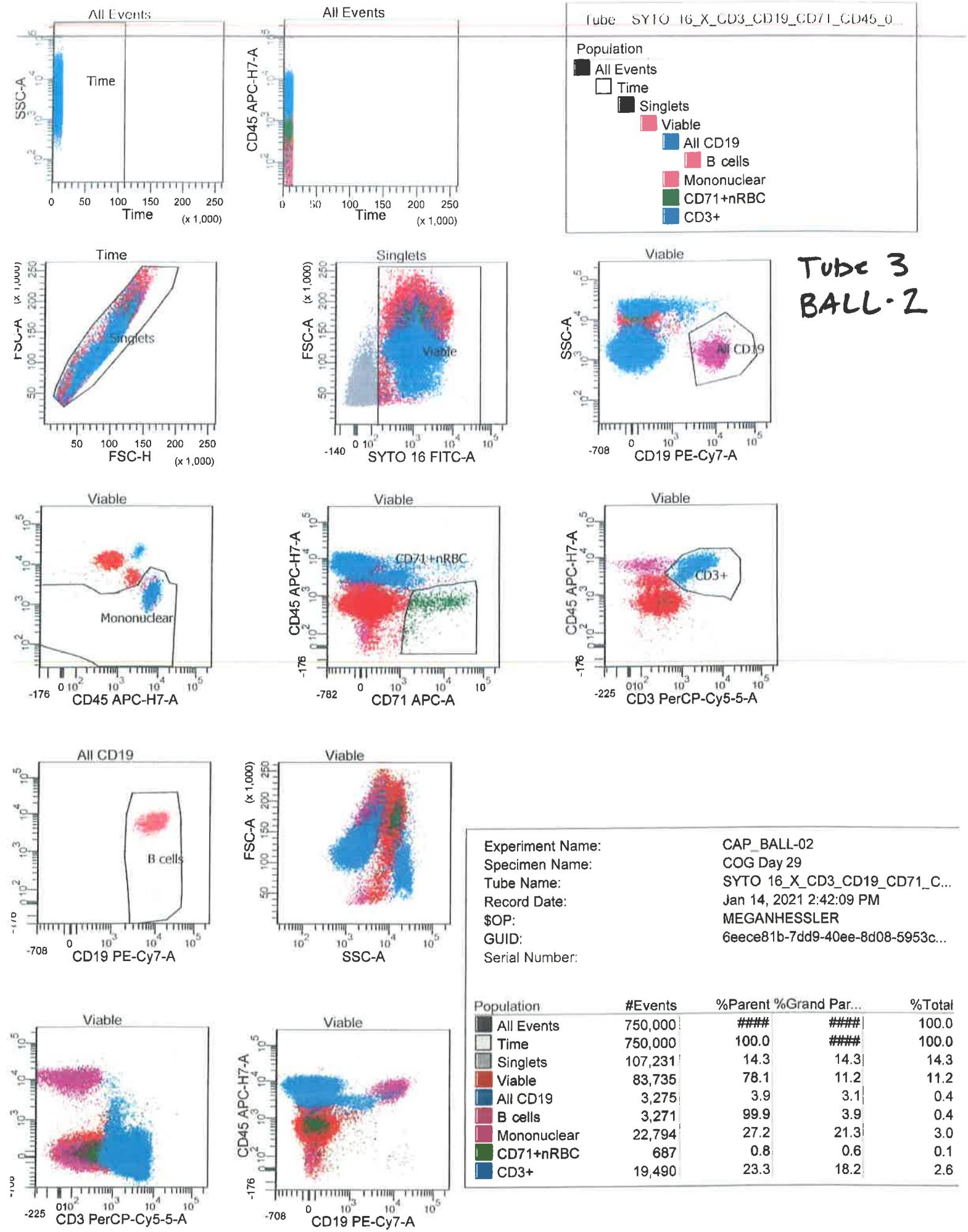
Tube_ CD9_CD13+33_CD34_CD19_CD10_CD

Population

- All Events
- Time
- Singlets
- Viable
- All CD19
- B cells
- P1

TUBE 2
BALL 2





Allen Quigley - Fwd: [EXTERNAL] CAP PT Alert: BALL-A 2021 Important Program Information – Error Message

From: Jennifer Heimkes
To: Allen Quigley
Date: 1/21/2021 10:26 AM
Subject: Fwd: [EXTERNAL] CAP PT Alert: BALL-A 2021 Important Program Information -- Error Message
Attachments: Jennifer Heimkes.vcf

>>> College of American Pathologists <contactcenter@cap.org> 1/21/2021 8:17 AM >>>



CAP PT Alert: BALL-A 2021 Important Program Information – Error Message

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

It has come to our attention that the 2021 BALL-A program, shipped to your laboratory on Wednesday, January 13, 2021, may include files that result in an error message on the BD FACS DIVA analysis software. If you receive an error message after importing the BALL-03 challenge files, contact your manufacturer for further instructions. If unable to resolve, select exception code 33 on the result form.

If you have any questions, please call a Customer Contact Center representative at 800-323-4040, +001-847-832-7000 option 1, or email contactcenter@cap.org.

Thank you for your continued support of the CAP.

College of American Pathologists

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