COLLEGE of AMERICAN PATHOLOGISTS

Surveys and Anatomic Pathology Education Programs

Comprehensive Hematology with Automated Differential
FH9-B 2021

Participant Summary

1.0 Credit of Continuing Education Available

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

TABLE OF CONTENTS

INSTRUMENT PROGRAM PLACEMENT

Being in the correct program will provide better statistics when determining instrument performance. Please use the chart below as well as the Surveys catalog page to ensure your instrument is in the correct program. Contact the CAP Customer Contact Center to make a change in program prior to the next mailing.

Instrument	**Appropriate FH program**
Abbott Alinity hq	FH9
Abbott Cell-Dyn 1200, 1400, 1600, 1700, Emerald	FH1
Abbott Cell-Dyn 3000, 3500, 3700, 4000, Ruby, Sapphire	FH3
Abbott Cell-Dyn Emerald 22/AL	FH3
Biosystems HA3/HA5	FH3
CDS/Medonic M-series	FH2
Coulter Ac·T 5diff series (AL, CP, OV)	FH10
Coulter Ac·T, MD 2,8,10, &16, ONYX, S880, S-plus V, STKR,T-series	FH2
Coulter DxH 500 series	FH16
Coulter Gen-S, HmX, LH 500, MaxM, MaxM A/L, STKS, VCS	FH6 *Note: To be discontinued in 2022*
Coulter LH 750, 755, 780, 785	FH13
Coulter UniCel DxH series (except DxH 500 series)	FH13
DIRUI BF series	FH10
Drew Scientific DC-18, DREW3, EXCELL 10, 16, 18, I-1800	FH2
Drew Scientific EXCELL 22, 2280	FH3
Horiba ABX 9000+, 9018+, 9020+	FH1
Horiba ABX Micros	FH2
Horiba ABX Pentra 60/80, 120, Pentra DF Nexus	FH10
Mindray BC-2800, 3000/3200 series, Mindray BC-6000/BC-6200/BC-6800/BC-6800Plus	FH2
Orphee Mythic 18, 22 AL, 22 OT, 60	FH3
Siemens ADVIA 120, 120 w/SP1, 2120	FH4
Siemens ADVIA 360	FH2
Siemens ADVIA 560	FH3
Sysmex K-series, KCP-1, KX21, KX21N	FH1
Sysmex pocH 100i	FH1
Sysmex XE-2100, XE-2100C, XE-2100D, XE 2100DC, XE-2100L, XE-5000, XE-Alpha, XE-HST, XE 2100D/L (Blood center)	FH9
Sysmex XN-series, XN-series (RL App), XN-L series	FH9
Sysmex XP-series	FH1
Sysmex XS-500i, 800i, 1000i, 1000i-AL, 1000iC	FH9
Sysmex XT-1800i, 2000i, 4000i	FH9

2021 FH9-B
PARTICIPANT SUMMARY

Program Update

Don't Miss Out on this Educational Opportunity!

With your participation in CAP's Surveys programs, *every member of your team* can take part in education activities that may earn Continuing Education (CE) credits or receive Self-Reported Training* at no additional charge.

This Survey mailing includes an online education activity to earn **1.0** CE credit. To access the activity, see page 37.

**CAP Self-Reported Training activities do not offer CE credit but can be used towards fulfilling requirements for maintenance of certification (MOC) by agencies such as the American Society of Clinical Pathology (ASCP). Please verify with your certifying agency to determine your education requirements.*

Evaluation Criteria

The CAP is required to submit PT results to the Centers for Medicare and Medicaid Services (CMS) for all labs that have provided a CLIA identification number. If you do not notify the CAP that your lab has discontinued testing of a regulated analyte, **a score of zero will be given**. Your reporting preferences are outlined on the CMS Analyte Reporting Selections document. If new products are ordered and/or canceled, this may affect your reporting selections, so it is recommended that you periodically check this report on e-LAB Solutions Suite, which will always reflect the most up-to-date information. This information can also be obtained by contacting the Customer Contact Center at 1-800-323-4040, Option 1, or 001-847-832-7000, Option 1 (international).

As published in the January 24, 2003 Federal Register, (42 CFR Part 493, Medicare, Medicaid, and CLIA Programs; Laboratory Requirements Relating to Quality Systems and Certain Personnel Qualifications; Final Rule) effective April 24, 2003, proficiency-testing (PT) providers are required to grade all analytes regulated for PT at 80% participant or referee consensus, with the exception of Transfusion Medicine. For information on criteria for grading analytes not regulated for PT, please review your participant summary.

The quantitative data tables provided in this participant summary include multiple statistical values which may include the median, low, and high values reported for each peer group. The low and high values are not the limits of acceptability. The acceptable limits are located on your participant evaluation report.

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

Evaluation Criteria, cont'd.

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 35. 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.**

Additional data is displayed for groups of 3-9 laboratories. This information is provided solely for internal use and may be used to perform a self-assessment.

Analytes regulated for proficiency testing appear in **bold** type.

Quantitative

Analyte	Target Value	Evaluation Criteria
Basophils*	Peer Group	± 3 SD or ±1.0 (whichever is greater)
Eosinophils*	Peer Group	± 3 SD or ±1.0 (whichever is greater)
Hematocrit	Peer Group	± 6%
Microhematocrit (waived)	Peer Group	± 6% or 2 SD (whichever is greater)
Hemoglobin	Peer Group	± 7%
IG	Not Graded	Educational
Immature Platelet Fraction	Not Graded	Educational
Lymphocytes*	Peer Group	± 3 SD or ±1.0 (whichever is greater)
MCV	Peer Group	± 3 SD
MCH	Peer Group	± 3 SD
MCHC	Peer Group	± 3 SD
Monocytes*	Peer Group	± 3 SD or ±1.0 (whichever is greater)
MPV	Peer Group	± 3 SD
Neutrophils/Granulocytes*	Peer Group	± 3 SD or ±1.0 (whichever is greater)
nRBC	Not Graded	Educational
Platelet Count	Peer Group	± 25%
RDW	Peer Group	± 3 SD
Red Blood Cell Count	Peer Group	± 6%
White Blood Cell Count	Peer Group	± 15%

Results for IG, Immature Platelet Fraction, and nRBC are **not** formally evaluated; however, statistics appear in the Participant Summary for your information.

Qualitative

Analyte	Evaluation Criteria
Blood Cell Identification*	80% referee or participant consensus

*Blood Cell Identification results are included in the CMS performance summary. In the event that Blood Cell Identification is not performed, results from the flow through differential will be reported.

White Blood Cell Count x 10E9/L or x 10E3/µL	FH9-06				FH9-07				FH9-08				FH9-09				FH9-10			
INSTRUMENT	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV
Abbott Alinity hq	30	2.87	0.10	3.3	30	16.05	0.39	2.4	29	6.37	0.20	3.2	29	7.58	0.21	2.8	29	3.01	0.13	4.5
Sysmex XE-2100,2100 D/L	33	3.01	0.10	3.3	33	16.37	0.39	2.4	33	6.65	0.24	3.6	33	7.66	0.23	3.0	33	2.90	0.11	3.7
Sysmex XE-2100 D/L (Bld Ctr)	65	3.00	0.10	3.4	65	16.26	0.46	2.8	65	6.56	0.25	3.8	63	7.57	0.19	2.5	65	2.87	0.11	3.9
Sysmex XE-5000	89	2.99	0.10	3.3	90	16.24	0.38	2.3	90	6.52	0.21	3.2	89	7.61	0.25	3.2	90	2.87	0.10	3.6
Sysmex XN-L Series	568	2.89	0.08	2.8	566	16.37	0.28	1.7	562	6.53	0.15	2.2	574	7.66	0.17	2.2	570	3.06	0.08	2.7
Sysmex XN-Series	2903	2.85	0.07	2.6	2904	15.93	0.24	1.5	2913	6.34	0.12	1.9	2905	7.52	0.15	1.9	2919	2.97	0.08	2.6
Sysmex XN-Series (RL App)	87	2.83	0.08	2.9	87	15.90	0.22	1.4	86	6.33	0.12	1.9	87	7.48	0.15	2.0	87	2.96	0.07	2.5
Sysmex XS (Except RL App)	502	2.97	0.09	2.9	499	16.66	0.33	2.0	501	6.68	0.17	2.5	499	7.82	0.19	2.4	501	3.14	0.09	2.9
Sysmex XS-1000iC (RL App)	72	2.99	0.09	3.0	71	16.84	0.32	1.9	71	6.70	0.14	2.2	72	7.84	0.18	2.3	72	3.15	0.09	3.0
Sysmex XT-1800i/2000i	93	2.99	0.09	3.1	93	16.34	0.47	2.8	93	6.81	0.23	3.4	92	7.56	0.22	2.9	92	2.89	0.10	3.4
Sysmex XT-4000i	64	2.97	0.11	3.5	63	16.21	0.45	2.8	64	6.77	0.19	2.8	64	7.57	0.23	3.0	63	2.84	0.10	3.7

Data for groups of 3-9	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH
Sysmex XE-2100C,XE2100DC	5	3.0	2.9	3.3	5	16.3	16.0	16.6	5	6.8	6.4	6.9	5	7.7	7.6	8.0	5	2.9	2.8	3.1

Red Blood Cell Count x 10E12/L or x 10E6/µL	FH9-06				FH9-07				FH9-08				FH9-09				FH9-10			
INSTRUMENT	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV
Abbott Alinity hq	29	2.190	0.030	1.4	30	5.152	0.147	2.9	28	4.265	0.074	1.7	29	2.417	0.046	1.9	28	5.116	0.116	2.3
Sysmex XE-2100,2100 D/L	33	2.303	0.032	1.4	35	5.247	0.067	1.3	35	4.402	0.059	1.3	33	2.522	0.024	0.9	35	5.239	0.062	1.2
Sysmex XE-2100 D/L (Bld Ctr)	67	2.294	0.023	1.0	66	5.216	0.063	1.2	67	4.388	0.039	0.9	67	2.513	0.029	1.2	67	5.218	0.051	1.0
Sysmex XE-5000	91	2.295	0.033	1.4	91	5.218	0.074	1.4	91	4.388	0.056	1.3	91	2.511	0.034	1.4	91	5.209	0.069	1.3
Sysmex XN-L Series	570	2.200	0.028	1.3	569	5.284	0.052	1.0	571	4.341	0.044	1.0	566	2.397	0.027	1.1	568	5.260	0.052	1.0
Sysmex XN-Series	2905	2.210	0.028	1.3	2901	5.262	0.051	1.0	2903	4.339	0.041	1.0	2894	2.409	0.029	1.2	2896	5.238	0.049	0.9
Sysmex XN-Series (RL App)	87	2.223	0.033	1.5	86	5.269	0.069	1.3	86	4.351	0.047	1.1	87	2.422	0.034	1.4	87	5.248	0.073	1.4
Sysmex XS (Except RL App)	501	2.234	0.027	1.2	504	5.278	0.057	1.1	505	4.358	0.044	1.0	503	2.444	0.030	1.2	497	5.247	0.052	1.0
Sysmex XS-1000iC (RL App)	71	2.277	0.041	1.8	71	5.264	0.041	0.8	70	4.374	0.038	0.9	71	2.488	0.039	1.6	71	5.237	0.039	0.7
Sysmex XT-1800i/2000i	90	2.295	0.026	1.2	92	5.242	0.070	1.3	89	4.422	0.052	1.2	91	2.513	0.034	1.4	91	5.218	0.054	1.0
Sysmex XT-4000i	63	2.305	0.027	1.2	63	5.250	0.050	0.9	65	4.434	0.058	1.3	64	2.528	0.036	1.4	65	5.233	0.064	1.2

Data for groups of 3-9	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH
Sysmex XE-2100C,XE2100DC	5	2.30	2.27	2.35	5	5.22	5.15	5.25	5	4.36	4.23	4.40	5	2.49	2.48	2.58	5	5.20	5.11	5.24

Hemoglobin - g/dL	FH9-06				FH9-07				FH9-08				FH9-09				FH9-10			
INSTRUMENT	**LABS**	**MEAN**	**SD**	**CV**	**LABS**	**MEAN**	**SD**	**CV**	**LABS**	**MEAN**	**SD**	**CV**	**LABS**	**MEAN**	**SD**	**CV**	**LABS**	**MEAN**	**SD**	**CV**
Abbott Alinity hq	30	6.05	0.08	1.3	30	16.56	0.16	1.0	29	12.90	0.12	0.9	28	6.35	0.06	0.9	28	16.23	0.14	0.9
Sysmex XE-2100,2100 D/L	33	6.04	0.10	1.7	33	16.52	0.19	1.2	33	12.78	0.14	1.1	33	6.33	0.08	1.3	33	16.13	0.20	1.2
Sysmex XE-2100 D/L (Bld Ctr)	76	5.96	0.07	1.2	76	16.37	0.20	1.2	75	12.69	0.13	1.0	76	6.26	0.08	1.2	76	15.99	0.16	1.0
Sysmex XE-5000	89	6.01	0.08	1.3	89	16.44	0.18	1.1	89	12.71	0.15	1.2	89	6.31	0.09	1.4	89	16.02	0.18	1.1
Sysmex XN-L Series	574	5.85	0.07	1.1	571	16.34	0.13	0.8	571	12.63	0.10	0.8	572	6.16	0.06	1.0	573	15.93	0.13	0.8
Sysmex XN-Series	2899	5.85	0.07	1.3	2905	16.30	0.14	0.8	2901	12.60	0.11	0.9	2888	6.15	0.07	1.2	2894	15.88	0.13	0.8
Sysmex XN-Series (RL App)	87	5.86	0.09	1.5	86	16.42	0.16	1.0	87	12.67	0.14	1.1	87	6.15	0.08	1.2	87	15.99	0.15	1.0
Sysmex XS (Except RL App)	503	5.79	0.08	1.3	504	16.46	0.16	1.0	500	12.65	0.13	1.0	501	6.11	0.08	1.3	501	16.02	0.16	1.0
Sysmex XS-1000iC (RL App)	70	5.80	0.07	1.2	69	16.50	0.12	0.7	70	12.66	0.12	0.9	70	6.11	0.06	1.0	70	16.03	0.12	0.8
Sysmex XT-1800i/2000i	92	5.88	0.08	1.3	93	16.27	0.19	1.2	92	12.70	0.13	1.1	91	6.19	0.07	1.2	93	15.89	0.17	1.1
Sysmex XT-4000i	64	5.88	0.07	1.2	62	16.23	0.17	1.0	64	12.70	0.14	1.1	64	6.20	0.09	1.4	64	15.85	0.17	1.1

Data for groups of 3-9	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH
Sysmex XE-2100C,XE2100DC	5	5.9	5.9	6.1	5	16.4	15.9	16.5	5	12.7	12.2	12.7	5	6.2	6.1	6.4	5	16.0	15.6	16.1

Hemoglobin - g/L	FH9-06				FH9-07				FH9-08				FH9-09				FH9-10			
INSTRUMENT	**LABS**	**MEAN**	**SD**	**CV**	**LABS**	**MEAN**	**SD**	**CV**	**LABS**	**MEAN**	**SD**	**CV**	**LABS**	**MEAN**	**SD**	**CV**	**LABS**	**MEAN**	**SD**	**CV**
Abbott Alinity hq	30	60.45	0.78	1.3	30	165.60	1.61	1.0	29	128.97	1.18	0.9	28	63.48	0.56	0.9	28	162.29	1.41	0.9
Sysmex XE-2100,2100 D/L	33	60.39	1.00	1.7	33	165.18	1.91	1.2	33	127.85	1.39	1.1	33	63.33	0.82	1.3	33	161.30	1.98	1.2
Sysmex XE-2100 D/L (Bld Ctr)	76	59.64	0.74	1.2	76	163.74	2.01	1.2	75	126.88	1.29	1.0	76	62.64	0.78	1.2	76	159.89	1.63	1.0
Sysmex XE-5000	89	60.07	0.81	1.3	89	164.37	1.84	1.1	89	127.13	1.51	1.2	89	63.11	0.86	1.4	89	160.25	1.78	1.1
Sysmex XN-L Series	574	58.51	0.65	1.1	571	163.39	1.26	0.8	571	126.31	1.01	0.8	572	61.61	0.64	1.0	573	159.34	1.25	0.8
Sysmex XN-Series	2899	58.50	0.73	1.3	2905	162.98	1.37	0.8	2901	125.97	1.09	0.9	2888	61.48	0.74	1.2	2894	158.80	1.31	0.8
Sysmex XN-Series (RL App)	87	58.62	0.87	1.5	86	164.15	1.58	1.0	87	126.67	1.39	1.1	87	61.53	0.76	1.2	87	159.85	1.52	1.0
Sysmex XS (Except RL App)	503	57.91	0.78	1.3	504	164.64	1.63	1.0	500	126.46	1.26	1.0	501	61.10	0.81	1.3	501	160.23	1.65	1.0
Sysmex XS-1000iC (RL App)	70	58.00	0.72	1.2	69	165.04	1.16	0.7	70	126.59	1.20	0.9	70	61.10	0.64	1.0	70	160.34	1.24	0.8
Sysmex XT-1800i/2000i	92	58.84	0.76	1.3	93	162.70	1.90	1.2	92	126.97	1.35	1.1	91	61.93	0.74	1.2	93	158.89	1.74	1.1
Sysmex XT-4000i	64	58.78	0.70	1.2	62	162.26	1.66	1.0	64	126.97	1.39	1.1	64	62.03	0.87	1.4	64	158.50	1.72	1.1

Data for groups of 3-9	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH
Sysmex XE-2100C,XE2100DC	5	59.0	59.0	61.0	5	164.0	159.0	165.0	5	127.0	122.0	127.0	5	62.0	61.0	64.0	5	160.0	156.0	161.0

Hematocrit -%	FH9-06				FH9-07				FH9-08				FH9-09				FH9-10			
INSTRUMENT	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV
Abbott Alinity hq	29	16.862	0.516	3.1	29	46.069	1.534	3.3	30	35.600	0.968	2.7	29	17.345	0.553	3.2	29	45.172	1.466	3.2
Sysmex XE-2100,2100 D/L	33	18.121	0.415	2.3	33	47.152	0.667	1.4	33	37.424	0.561	1.5	33	18.909	0.292	1.5	33	46.455	0.564	1.2
Sysmex XE-2100 D/L (Bld Ctr)	80	18.063	0.332	1.8	80	47.025	0.811	1.7	80	37.425	0.546	1.5	80	18.863	0.347	1.8	80	46.425	0.671	1.4
Sysmex XE-5000	89	18.056	0.315	1.7	88	46.875	0.785	1.7	88	37.341	0.641	1.7	89	18.820	0.415	2.2	88	46.216	0.633	1.4
Sysmex XN-L Series	574	17.244	0.446	2.6	572	47.051	0.753	1.6	572	36.713	0.625	1.7	574	17.908	0.350	2.0	571	46.247	0.745	1.6
Sysmex XN-Series	2921	17.240	0.434	2.5	2921	46.928	0.692	1.5	2916	36.721	0.581	1.6	2916	17.940	0.304	1.7	2901	46.197	0.661	1.4
Sysmex XN-Series (RL App)	87	17.115	0.321	1.9	86	45.605	0.708	1.6	86	35.802	0.527	1.5	87	17.747	0.437	2.5	87	44.954	0.730	1.6
Sysmex XS (Except RL App)	506	17.974	0.323	1.8	500	48.140	0.744	1.5	502	37.448	0.616	1.6	503	18.475	0.523	2.8	502	47.227	0.809	1.7
Sysmex XS-1000iC (RL App)	70	18.300	0.492	2.7	70	48.900	1.038	2.1	70	38.000	0.761	2.0	70	18.843	0.439	2.3	69	47.899	0.894	1.9
Sysmex XT-1800i/2000i	92	18.239	0.429	2.4	92	48.054	0.843	1.8	90	37.800	0.657	1.7	92	19.011	0.314	1.7	92	47.261	0.724	1.5
Sysmex XT-4000i	64	18.281	0.548	3.0	63	48.159	0.745	1.5	64	37.875	0.724	1.9	64	19.047	0.375	2.0	64	47.313	0.794	1.7

Data for groups of 3-9	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH
Sysmex XE-2100C,XE2100DC	5	18.0	17.0	18.0	5	45.0	44.0	46.0	5	36.0	12.0	37.0	5	18.0	18.0	19.0	5	45.0	43.0	46.0

Hematocrit - L/L	FH9-06				FH9-07				FH9-08				FH9-09				FH9-10			
INSTRUMENT	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV
Abbott Alinity hq	29	0.169	0.005	3.1	29	0.461	0.015	3.3	30	0.356	0.010	2.7	29	0.173	0.006	3.2	29	0.452	0.015	3.2
Sysmex XE-2100,2100 D/L	33	0.181	0.004	2.3	33	0.472	0.007	1.4	33	0.374	0.006	1.5	33	0.189	0.003	1.5	33	0.465	0.006	1.2
Sysmex XE-2100 D/L (Bld Ctr)	80	0.181	0.003	1.8	80	0.470	0.008	1.7	80	0.374	0.005	1.5	80	0.189	0.003	1.8	80	0.464	0.007	1.4
Sysmex XE-5000	89	0.181	0.003	1.7	88	0.469	0.008	1.7	88	0.373	0.006	1.7	89	0.188	0.004	2.2	88	0.462	0.006	1.4
Sysmex XN-L Series	574	0.172	0.004	2.6	572	0.471	0.008	1.6	572	0.367	0.006	1.7	574	0.179	0.003	2.0	571	0.462	0.007	1.6
Sysmex XN-Series	2921	0.172	0.004	2.5	2921	0.469	0.007	1.5	2916	0.367	0.006	1.6	2916	0.179	0.003	1.7	2901	0.462	0.007	1.4
Sysmex XN-Series (RL App)	87	0.171	0.003	1.9	86	0.456	0.007	1.6	86	0.358	0.005	1.5	87	0.177	0.004	2.5	87	0.450	0.007	1.6
Sysmex XS (Except RL App)	506	0.180	0.003	1.8	500	0.481	0.007	1.5	502	0.374	0.006	1.6	503	0.185	0.005	2.8	502	0.472	0.008	1.7
Sysmex XS-1000iC (RL App)	70	0.183	0.005	2.7	70	0.489	0.010	2.1	70	0.380	0.008	2.0	70	0.188	0.004	2.3	69	0.479	0.009	1.9
Sysmex XT-1800i/2000i	92	0.182	0.004	2.4	92	0.481	0.008	1.8	90	0.378	0.007	1.7	92	0.190	0.003	1.7	92	0.473	0.007	1.5
Sysmex XT-4000i	64	0.183	0.005	3.0	63	0.482	0.007	1.5	64	0.379	0.007	1.9	64	0.190	0.004	2.0	64	0.473	0.008	1.7

Data for groups of 3-9	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH
Sysmex XE-2100C,XE2100DC	5	0.2	0.2	0.2	5	0.5	0.4	0.5	5	0.4	0.1	0.4	5	0.2	0.2	0.2	5	0.5	0.4	0.5

MCV - Femtoliters (fL)	FH9-06				FH9-07				FH9-08				FH9-09				FH9-10			
INSTRUMENT	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV
Abbott Alinity hq	29	76.61	1.21	1.6	29	89.49	1.36	1.5	29	83.40	1.46	1.8	29	71.72	1.16	1.6	29	88.14	1.56	1.8
Sysmex XE-2100,2100 D/L	32	78.71	0.79	1.0	32	89.85	0.87	1.0	32	84.94	0.78	0.9	32	74.43	0.73	1.0	32	88.58	0.79	0.9
Sysmex XE-2100 D/L (Bld Ctr)	45	78.87	0.84	1.1	45	90.08	0.96	1.1	45	85.14	0.91	1.1	45	74.60	0.78	1.0	45	88.84	1.01	1.1
Sysmex XE-5000	88	78.75	0.94	1.2	88	89.89	1.04	1.2	88	84.98	1.02	1.2	88	74.47	0.87	1.2	88	88.68	1.03	1.2
Sysmex XN-L Series	569	78.49	0.90	1.1	570	88.97	0.99	1.1	570	84.47	0.93	1.1	569	74.38	0.85	1.1	569	87.87	0.96	1.1
Sysmex XN-Series	2902	78.08	0.83	1.1	2899	89.10	0.88	1.0	2902	84.52	0.86	1.0	2891	74.04	0.77	1.0	2897	88.08	0.88	1.0
Sysmex XN-Series (RL App)	87	76.84	0.69	0.9	84	86.48	0.60	0.7	84	82.07	0.56	0.7	86	72.80	0.58	0.8	84	85.45	0.62	0.7
Sysmex XS (Except RL App)	498	80.13	0.88	1.1	497	91.17	1.00	1.1	495	85.86	0.89	1.0	496	75.46	0.81	1.1	492	89.95	0.95	1.1
Sysmex XS-1000iC (RL App)	69	80.01	0.83	1.0	70	92.80	1.64	1.8	70	86.84	1.19	1.4	70	75.69	0.87	1.2	69	91.36	1.51	1.7
Sysmex XT-1800i/2000i	90	79.60	0.92	1.2	89	91.58	0.94	1.0	89	85.39	0.95	1.1	90	75.08	0.92	1.2	91	90.42	1.03	1.1
Sysmex XT-4000i	62	79.52	0.79	1.0	62	91.62	1.00	1.1	63	85.22	0.86	1.0	64	75.05	0.85	1.1	63	90.44	1.12	1.2

Data for groups of 3-9	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH
Sysmex XE-2100C,XE2100DC	5	77.0	74.6	77.4	5	87.0	84.7	88.5	5	83.0	80.1	83.6	5	73.0	71.0	73.3	5	85.8	83.6	86.8

MCH - Picograms (pg)	FH9-06				FH9-07				FH9-08				FH9-09				FH9-10			
INSTRUMENT	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV
Abbott Alinity hq	31	27.53	0.57	2.1	31	32.13	0.98	3.0	31	30.15	0.59	1.9	30	26.23	0.48	1.8	30	31.57	0.85	2.7
Sysmex XE-2100,2100 D/L	31	26.15	0.40	1.5	31	31.51	0.44	1.4	31	29.01	0.36	1.2	31	25.11	0.26	1.0	31	30.81	0.42	1.4
Sysmex XE-2100 D/L (Bld Ctr)	39	25.99	0.35	1.4	39	31.40	0.41	1.3	39	28.90	0.32	1.1	38	24.88	0.24	0.9	39	30.67	0.32	1.1
Sysmex XE-5000	88	26.19	0.36	1.4	88	31.51	0.39	1.3	88	28.98	0.37	1.3	88	25.13	0.35	1.4	88	30.78	0.38	1.2
Sysmex XN-L Series	556	26.61	0.37	1.4	557	30.93	0.31	1.0	558	29.10	0.30	1.0	557	25.69	0.33	1.3	558	30.30	0.34	1.1
Sysmex XN-Series	2886	26.48	0.35	1.3	2883	30.98	0.34	1.1	2880	29.03	0.32	1.1	2880	25.51	0.33	1.3	2878	30.32	0.33	1.1
Sysmex XN-Series (RL App)	86	26.36	0.32	1.2	87	31.18	0.45	1.4	87	29.12	0.37	1.3	87	25.40	0.36	1.4	87	30.47	0.40	1.3
Sysmex XS (Except RL App)	484	25.91	0.38	1.5	485	31.20	0.35	1.1	481	29.02	0.33	1.1	479	25.01	0.36	1.4	478	30.53	0.32	1.1
Sysmex XS-1000iC (RL App)	69	25.47	0.47	1.8	69	31.33	0.26	0.8	68	28.97	0.31	1.1	67	24.52	0.40	1.6	69	30.63	0.27	0.9
Sysmex XT-1800i/2000i	89	25.64	0.43	1.7	89	31.04	0.42	1.4	87	28.74	0.37	1.3	88	24.64	0.39	1.6	89	30.45	0.40	1.3
Sysmex XT-4000i	61	25.52	0.38	1.5	62	30.89	0.44	1.4	62	28.62	0.45	1.6	62	24.53	0.46	1.9	62	30.27	0.46	1.5

Data for groups of 3-9	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH
Sysmex XE-2100C,XE2100DC	5	25.9	25.4	26.0	5	31.3	30.9	31.5	5	28.9	28.6	29.2	5	24.9	24.6	25.0	5	30.7	30.5	31.0

MCHC - g/dL	FH9-06				FH9-07				FH9-08				FH9-09				FH9-10			
INSTRUMENT	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV
Abbott Alinity hq	29	36.02	0.83	2.3	29	35.98	1.12	3.1	29	36.18	0.85	2.4	29	36.63	0.87	2.4	29	35.86	1.07	3.0
Sysmex XE-2100,2100 D/L	31	33.21	0.65	2.0	31	35.05	0.54	1.5	31	34.15	0.54	1.6	31	33.73	0.49	1.4	31	34.77	0.54	1.6
Sysmex XE-2100 D/L (Bld Ctr)	39	32.93	0.67	2.0	38	34.85	0.64	1.8	39	33.92	0.50	1.5	39	33.38	0.55	1.6	39	34.49	0.52	1.5
Sysmex XE-5000	88	33.26	0.57	1.7	87	35.10	0.56	1.6	88	34.13	0.59	1.7	88	33.77	0.61	1.8	87	34.75	0.49	1.4
Sysmex XN-L Series	566	33.88	0.59	1.8	569	34.76	0.50	1.4	569	34.44	0.50	1.5	567	34.56	0.55	1.6	565	34.47	0.49	1.4
Sysmex XN-Series	2895	33.90	0.56	1.6	2895	34.77	0.49	1.4	2892	34.35	0.49	1.4	2894	34.48	0.55	1.6	2899	34.42	0.48	1.4
Sysmex XN-Series (RL App)	85	34.32	0.47	1.4	87	36.02	0.56	1.6	86	35.48	0.48	1.4	87	34.90	0.48	1.4	85	35.64	0.47	1.3
Sysmex XS (Except RL App)	495	32.33	0.59	1.8	492	34.24	0.49	1.4	494	33.79	0.51	1.5	494	33.15	0.57	1.7	491	33.94	0.49	1.4
Sysmex XS-1000iC (RL App)	68	31.82	0.63	2.0	69	33.79	0.66	2.0	69	33.35	0.66	2.0	69	32.44	0.77	2.4	69	33.54	0.64	1.9
Sysmex XT-1800i/2000i	89	32.22	0.66	2.0	89	33.90	0.60	1.8	88	33.65	0.60	1.8	88	32.87	0.58	1.8	88	33.65	0.54	1.6
Sysmex XT-4000i	60	32.10	0.54	1.7	62	33.74	0.52	1.6	62	33.56	0.58	1.7	62	32.72	0.65	2.0	60	33.49	0.52	1.6

Data for groups of 3-9	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH
Sysmex XE-2100C,XE2100DC	5	33.7	33.0	34.7	5	35.9	35.5	36.5	5	35.2	34.5	36.0	5	34.3	33.9	34.8	5	36.2	35.2	36.8

MCHC - g/L	FH9-06				FH9-07				FH9-08				FH9-09				FH9-10			
INSTRUMENT	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV
Abbott Alinity hq	29	360.21	8.32	2.3	29	359.79	11.18	3.1	29	361.83	8.53	2.4	29	366.28	8.66	2.4	29	358.55	10.69	3.0
Sysmex XE-2100,2100 D/L	31	332.06	6.53	2.0	31	350.45	5.42	1.5	31	341.45	5.45	1.6	31	337.32	4.87	1.4	31	347.74	5.39	1.6
Sysmex XE-2100 D/L (Bld Ctr)	39	329.31	6.73	2.0	38	348.50	6.38	1.8	39	339.23	4.96	1.5	39	333.77	5.49	1.6	39	344.87	5.21	1.5
Sysmex XE-5000	88	332.58	5.72	1.7	87	350.98	5.63	1.6	88	341.28	5.92	1.7	88	337.73	6.06	1.8	87	347.48	4.88	1.4
Sysmex XN-L Series	566	338.79	5.93	1.8	569	347.60	4.96	1.4	569	344.43	5.00	1.5	567	345.61	5.50	1.6	565	344.74	4.86	1.4
Sysmex XN-Series	2895	338.99	5.56	1.6	2895	347.65	4.89	1.4	2892	343.53	4.86	1.4	2894	344.82	5.51	1.6	2899	344.23	4.77	1.4
Sysmex XN-Series (RL App)	85	343.20	4.72	1.4	87	360.24	5.63	1.6	86	354.76	4.82	1.4	87	349.02	4.83	1.4	85	356.41	4.72	1.3
Sysmex XS (Except RL App)	495	323.27	5.94	1.8	492	342.39	4.91	1.4	494	337.89	5.08	1.5	494	331.52	5.67	1.7	491	339.43	4.88	1.4
Sysmex XS-1000iC (RL App)	68	318.24	6.33	2.0	69	337.88	6.60	2.0	69	333.51	6.56	2.0	69	324.39	7.66	2.4	69	335.38	6.42	1.9
Sysmex XT-1800i/2000i	89	322.20	6.59	2.0	89	339.00	5.98	1.8	88	336.52	5.97	1.8	88	328.68	5.77	1.8	88	336.53	5.39	1.6
Sysmex XT-4000i	60	321.05	5.37	1.7	62	337.44	5.25	1.6	62	335.63	5.85	1.7	62	327.16	6.47	2.0	60	334.87	5.21	1.6

Data for groups of 3-9	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH
Sysmex XE-2100C,XE2100DC	5	337.0	330.0	347.0	5	359.0	355.0	365.0	5	352.0	345.0	360.0	5	343.0	339.0	348.0	5	362.0	352.0	368.0

Platelet Count x 10E9/L or x 10E3/µL	FH9-06				FH9-07				FH9-08				FH9-09				FH9-10			
INSTRUMENT	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV
Abbott Alinity hq	27	51.3	2.1	4.2	28	460.1	15.6	3.4	28	211.9	6.9	3.2	28	326.3	11.3	3.5	28	112.2	4.7	4.2
Sysmex XE-2100,2100 D/L	33	61.9	2.8	4.6	33	512.4	18.3	3.6	33	238.2	7.0	2.9	33	369.3	9.9	2.7	33	130.1	6.4	4.9
Sysmex XE-2100 D/L (Bld Ctr)	78	63.7	2.6	4.0	79	532.5	18.5	3.5	78	246.0	7.4	3.0	79	375.4	9.6	2.6	79	137.9	6.9	5.0
Sysmex XE-5000	87	60.5	2.9	4.7	89	505.4	15.0	3.0	89	236.5	7.0	3.0	89	366.4	11.9	3.2	89	128.6	6.2	4.9
Sysmex XN-L Series	574	58.7	3.6	6.2	571	534.9	13.1	2.5	567	241.4	7.3	3.0	572	349.2	9.2	2.6	568	138.7	7.0	5.1
Sysmex XN-Series	2900	56.5	3.2	5.6	2894	527.1	11.6	2.2	2900	237.6	6.8	2.9	2894	339.9	8.1	2.4	2883	136.0	6.1	4.5
Sysmex XN-Series (RL App)	86	60.8	3.3	5.5	87	531.6	13.7	2.6	87	242.4	7.2	3.0	88	344.0	9.7	2.8	87	141.2	6.5	4.6
Sysmex XS (Except RL App)	504	59.6	3.3	5.6	505	508.4	12.9	2.5	502	232.3	6.4	2.7	492	375.1	9.4	2.5	502	129.1	6.2	4.8
Sysmex XS-1000iC (RL App)	69	61.9	3.8	6.2	69	517.2	13.4	2.6	69	236.4	7.4	3.1	70	383.5	12.7	3.3	69	131.2	6.0	4.6
Sysmex XT-1800i/2000i	93	61.6	4.1	6.7	91	479.2	18.4	3.8	91	229.3	9.2	4.0	92	362.2	11.7	3.2	92	126.5	7.3	5.8
Sysmex XT-4000i	64	61.3	3.5	5.7	61	478.2	15.5	3.2	64	231.6	8.0	3.5	63	361.5	9.4	2.6	63	126.1	6.4	5.1

Data for groups of 3-9	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH
Sysmex XE-2100C,XE2100DC	5	61	55	64	5	526	492	564	5	245	233	257	5	380	362	386	5	132	129	144

MPV - Femtoliters (fL)	FH9-06				FH9-07				FH9-08				FH9-09				FH9-10			
INSTRUMENT	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV
Abbott Alinity hq	30	11.18	0.47	4.2	29	11.29	0.34	3.0	31	11.22	0.46	4.1	31	11.27	0.53	4.7	30	11.19	0.40	3.6
Sysmex XE-2100,2100 D/L	23	9.55	0.21	2.2	24	9.76	0.18	1.8	24	9.68	0.19	2.0	23	9.17	0.14	1.6	24	10.02	0.30	3.0
Sysmex XE-2100 D/L (Bld Ctr)	29	9.26	0.31	3.3	29	9.74	0.21	2.2	29	9.64	0.19	1.9	29	9.15	0.18	1.9	28	9.81	0.28	2.8
Sysmex XE-5000	87	9.49	0.31	3.2	87	9.73	0.23	2.4	87	9.63	0.22	2.3	86	9.15	0.17	1.8	87	9.98	0.29	2.9
Sysmex XN-L Series	511	10.32	0.36	3.5	508	9.63	0.15	1.5	511	9.82	0.20	2.0	509	9.86	0.15	1.5	514	10.05	0.34	3.4
Sysmex XN-Series	2747	10.36	0.34	3.3	2767	9.67	0.13	1.4	2761	9.87	0.18	1.8	2756	9.91	0.13	1.3	2745	10.05	0.30	3.0
Sysmex XN-Series (RL App)	78	11.57	0.39	3.4	77	10.79	0.11	1.0	76	11.01	0.17	1.5	77	11.06	0.12	1.1	77	11.21	0.27	2.4
Sysmex XS (Except RL App)	432	9.39	0.30	3.2	438	9.88	0.15	1.5	436	9.67	0.19	1.9	428	9.11	0.14	1.5	438	10.21	0.30	2.9
Sysmex XS-1000iC (RL App)	63	9.60	0.35	3.6	63	10.19	0.28	2.8	63	9.93	0.28	2.8	62	9.38	0.25	2.7	63	10.47	0.32	3.1
Sysmex XT-1800i/2000i	80	9.42	0.28	2.9	80	10.04	0.13	1.3	81	9.79	0.19	2.0	81	9.26	0.16	1.7	80	10.28	0.28	2.7
Sysmex XT-4000i	58	9.48	0.33	3.5	60	10.02	0.18	1.8	60	9.81	0.18	1.8	58	9.25	0.14	1.6	59	10.26	0.24	2.4

Data for groups of 3-9	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH
Sysmex XE-2100C,XE2100DC	3	9.4	9.0	9.7	3	9.7	9.5	9.7	3	9.6	9.6	9.7	3	9.2	9.0	9.3	3	10.2	9.7	10.3

RDW % (RDW-CV)	FH9-06				FH9-07				FH9-08				FH9-09				FH9-10			
INSTRUMENT	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV
Abbott Alinity hq	28	15.91	0.41	2.6	28	15.86	0.45	2.9	29	16.07	0.39	2.4	28	14.78	0.61	4.1	28	15.53	0.48	3.1
Sysmex XE-2100,2100 D/L	17	15.92	0.14	0.9	17	14.28	0.13	0.9	17	14.88	0.13	0.9	17	16.49	0.15	0.9	17	14.06	0.10	0.7
Sysmex XE-5000	70	15.92	0.13	0.8	70	14.23	0.13	0.9	70	14.89	0.11	0.7	69	16.50	0.14	0.9	70	14.06	0.13	0.9
Sysmex XN-L Series	483	16.68	0.15	0.9	480	14.80	0.19	1.3	482	15.54	0.16	1.0	482	17.41	0.16	0.9	489	14.58	0.21	1.4
Sysmex XN-Series	2445	16.76	0.13	0.8	2436	15.05	0.17	1.1	2441	15.73	0.14	0.9	2440	17.41	0.16	0.9	2440	14.81	0.15	1.0
Sysmex XN-Series (RL App)	85	17.00	0.15	0.9	83	15.19	0.26	1.7	84	15.87	0.16	1.0	84	17.52	0.13	0.7	82	14.97	0.24	1.6
Sysmex XS (Except RL App)	428	16.03	0.24	1.5	420	15.02	0.24	1.6	425	15.40	0.19	1.2	427	16.76	0.29	1.7	424	14.73	0.25	1.7
Sysmex XS-1000iC (RL App)	66	17.78	1.13	6.3	66	16.43	0.98	6.0	66	17.05	1.04	6.1	66	18.53	1.14	6.1	66	16.13	0.92	5.7
Sysmex XT-1800i/2000i	68	16.04	0.19	1.2	68	14.80	0.18	1.2	67	15.32	0.15	1.0	68	16.80	0.18	1.1	67	14.54	0.22	1.5
Sysmex XT-4000i	48	16.05	0.17	1.1	48	14.76	0.16	1.1	49	15.29	0.14	0.9	49	16.79	0.21	1.2	49	14.51	0.21	1.4

Data for groups of 3-9	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH
Sysmex XE-2100C,XE2100DC	5	16.3	16.0	16.3	5	14.4	14.3	14.6	5	15.2	15.0	15.2	5	16.7	16.4	16.8	5	14.3	14.1	14.3
Sysmex XE-2100 D/L (Bld Ctr)	4	16.0	15.7	16.3	4	14.3	14.0	14.9	4	15.1	14.8	15.4	4	16.6	16.3	16.8	4	14.3	14.0	14.6

RDW fL (RDW-SD)	FH9-06				FH9-07				FH9-08				FH9-09				FH9-10			
INSTRUMENT	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV
Sysmex XE-2100,2100 D/L	12	45.20	0.38	0.8	11	45.56	0.34	0.7	11	45.21	0.32	0.7	12	45.08	0.82	1.8	11	44.43	0.34	0.8
Sysmex XE-2100 D/L (Bld Ctr)	28	45.42	0.68	1.5	28	45.65	0.58	1.3	28	45.46	0.77	1.7	28	45.14	0.70	1.6	28	44.56	0.66	1.5
Sysmex XE-5000	18	45.03	0.82	1.8	18	45.26	0.68	1.5	18	45.14	0.69	1.5	18	44.58	0.74	1.7	17	44.08	0.74	1.7
Sysmex XN-L Series	63	47.26	0.63	1.3	64	46.98	0.75	1.6	63	47.19	0.44	0.9	64	47.24	0.74	1.6	64	45.70	0.78	1.7
Sysmex XN-Series	409	46.08	0.57	1.2	411	46.91	0.65	1.4	408	46.79	0.59	1.3	409	46.12	0.61	1.3	410	45.50	0.75	1.6
Sysmex XS (Except RL App)	71	44.66	0.72	1.6	72	45.98	0.87	1.9	72	45.57	0.93	2.0	71	44.93	0.76	1.7	72	44.44	0.99	2.2
Sysmex XT-1800i/2000i	21	44.58	0.62	1.4	21	45.63	1.02	2.2	21	45.34	0.83	1.8	21	45.02	0.63	1.4	21	44.11	0.81	1.8
Sysmex XT-4000i	14	44.71	0.51	1.1	14	45.51	0.68	1.5	15	45.20	0.59	1.3	15	45.05	0.56	1.2	15	44.08	0.51	1.2

Data for groups of 3-9	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH
Sysmex XE-2100,2100 D/L	4	44.0	42.0	45.7	4	45.5	44.6	46.3	4	45.4	44.4	46.5	4	44.2	41.9	45.8	4	44.1	43.2	45.0

Neutrophils/Granulocytes - %	FH9-06				FH9-07				FH9-08				FH9-09				FH9-10			
INSTRUMENT	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV
Abbott Alinity hq	28	43.19	1.44	3.3	29	50.70	1.15	2.3	29	46.53	1.28	2.8	29	46.60	1.30	2.8	29	46.54	1.77	3.8
Sysmex XE-2100,2100 D/L	30	43.35	1.54	3.6	30	52.18	0.95	1.8	30	46.92	0.99	2.1	30	47.35	0.77	1.6	30	47.08	0.91	1.9
Sysmex XE-2100 D/L (Bld Ctr)	21	42.96	1.11	2.6	21	52.08	1.06	2.0	21	46.89	1.10	2.4	20	46.58	0.72	1.5	21	47.23	1.57	3.3
Sysmex XE-5000	88	43.23	1.02	2.4	88	52.15	0.94	1.8	88	46.91	0.92	2.0	88	47.06	1.10	2.3	87	47.33	1.18	2.5
Sysmex XN-L Series	527	38.06	1.10	2.9	526	45.85	0.87	1.9	524	41.46	0.90	2.2	523	41.57	0.87	2.1	525	41.49	1.08	2.6
Sysmex XN-Series	2855	39.08	1.11	2.8	2854	47.74	0.90	1.9	2852	42.77	0.98	2.3	2855	42.83	0.95	2.2	2854	42.80	1.14	2.7
Sysmex XN-Series (RL App)	85	39.31	1.08	2.7	85	47.70	0.95	2.0	85	42.68	0.88	2.1	85	42.88	0.96	2.2	84	42.87	1.29	3.0
Sysmex XS (Except RL App)	466	36.94	1.04	2.8	466	44.49	0.93	2.1	467	39.80	0.95	2.4	466	40.46	0.84	2.1	465	39.79	1.14	2.9
Sysmex XS-1000iC (RL App)	68	36.91	1.01	2.7	67	44.36	0.96	2.2	68	39.96	0.93	2.3	68	40.59	0.83	2.1	68	39.97	1.09	2.7
Sysmex XT-1800i/2000i	92	43.16	1.28	3.0	90	52.14	0.93	1.8	91	46.76	1.01	2.2	92	47.27	0.98	2.1	91	46.99	1.19	2.5
Sysmex XT-4000i	63	43.17	1.57	3.6	61	52.27	1.03	2.0	62	46.49	1.11	2.4	61	47.55	0.89	1.9	61	47.10	1.27	2.7

Data for groups of 3-9	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH
Sysmex XE-2100C,XE2100DC	5	43.0	41.2	44.2	5	53.0	50.0	53.4	5	47.7	44.6	48.1	5	47.6	47.0	49.0	5	49.0	44.0	50.4

Neutrophils/Granulocytes Absolute x 10E9/L or x 10E3/µl	FH9-06				FH9-07				FH9-08				FH9-09				FH9-10			
INSTRUMENT	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV
Abbott Alinity hq	31	1.236	0.077	6.3	30	8.074	0.287	3.6	30	2.953	0.134	4.5	31	3.505	0.161	4.6	30	1.390	0.081	5.9
Sysmex XE-2100,2100 D/L	27	1.300	0.075	5.8	27	8.491	0.189	2.2	27	3.091	0.129	4.2	27	3.619	0.139	3.8	27	1.357	0.054	4.0
Sysmex XE-2100 D/L (Bld Ctr)	20	1.283	0.045	3.5	21	8.534	0.311	3.6	21	3.094	0.139	4.5	21	3.568	0.145	4.1	21	1.363	0.067	4.9
Sysmex XE-5000	86	1.291	0.048	3.7	87	8.457	0.244	2.9	86	3.065	0.111	3.6	88	3.570	0.147	4.1	87	1.358	0.053	3.9
Sysmex XN-L Series	537	1.101	0.048	4.4	536	7.501	0.201	2.7	536	2.707	0.087	3.2	534	3.186	0.099	3.1	536	1.269	0.048	3.8
Sysmex XN-Series	2857	1.113	0.044	3.9	2851	7.605	0.188	2.5	2849	2.712	0.083	3.0	2846	3.218	0.094	2.9	2850	1.272	0.046	3.6
Sysmex XN-Series (RL App)	83	1.112	0.045	4.0	84	7.581	0.182	2.4	84	2.699	0.073	2.7	84	3.207	0.095	3.0	84	1.272	0.049	3.8
Sysmex XS (Except RL App)	487	1.097	0.045	4.1	487	7.417	0.215	2.9	483	2.659	0.088	3.3	484	3.165	0.103	3.2	482	1.249	0.053	4.2
Sysmex XS-1000iC (RL App)	66	1.104	0.042	3.8	64	7.481	0.238	3.2	66	2.684	0.093	3.5	67	3.189	0.086	2.7	67	1.263	0.055	4.3
Sysmex XT-1800i/2000i	89	1.288	0.060	4.6	89	8.518	0.308	3.6	89	3.189	0.128	4.0	88	3.575	0.137	3.8	89	1.358	0.063	4.7
Sysmex XT-4000i	61	1.289	0.056	4.4	61	8.466	0.309	3.7	61	3.160	0.108	3.4	63	3.590	0.152	4.2	63	1.335	0.065	4.9

Data for groups of 3-9	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH
Sysmex XE-2100C,XE2100DC	5	1.3	1.3	1.4	5	8.6	8.1	8.7	5	3.1	3.1	3.3	5	3.6	3.6	3.8	5	1.4	1.2	1.5

Lymphocytes - %	FH9-06				FH9-07				FH9-08				FH9-09				FH9-10			
INSTRUMENT	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV
Abbott Alinity hq	31	33.36	1.64	4.9	30	23.27	0.65	2.8	29	29.65	0.66	2.2	31	29.86	0.82	2.8	31	29.55	1.40	4.7
Sysmex XE-2100,2100 D/L	30	37.57	1.29	3.4	30	28.18	0.92	3.3	30	33.31	0.92	2.8	30	32.83	0.93	2.8	30	33.44	0.93	2.8
Sysmex XE-2100 D/L (Bld Ctr)	19	38.14	1.03	2.7	19	28.80	1.23	4.3	19	34.08	0.96	2.8	19	33.29	0.86	2.6	19	33.62	1.38	4.1
Sysmex XE-5000	90	37.79	1.34	3.5	89	28.60	1.04	3.6	90	33.65	0.92	2.7	90	33.13	0.93	2.8	89	33.52	1.14	3.4
Sysmex XN-L Series	539	36.20	1.23	3.4	525	26.25	0.64	2.4	535	32.31	0.83	2.6	536	31.97	0.71	2.2	540	32.28	1.09	3.4
Sysmex XN-Series	2870	31.78	1.30	4.1	2876	22.81	0.92	4.0	2875	28.93	0.95	3.3	2866	28.83	0.93	3.2	2874	28.92	1.12	3.9
Sysmex XN-Series (RL App)	85	31.45	1.35	4.3	85	22.55	0.82	3.6	85	28.73	0.82	2.8	85	28.42	0.81	2.9	85	28.64	1.10	3.8
Sysmex XS (Except RL App)	467	38.80	1.11	2.9	462	28.44	0.58	2.0	466	34.88	0.74	2.1	465	33.85	0.70	2.1	464	34.72	1.03	3.0
Sysmex XS-1000iC (RL App)	69	38.58	1.07	2.8	68	28.33	0.53	1.9	69	34.71	0.77	2.2	69	33.63	0.61	1.8	69	34.41	1.01	2.9
Sysmex XT-1800i/2000i	92	35.30	1.65	4.7	92	26.15	0.79	3.0	92	32.21	0.95	2.9	91	31.09	0.84	2.7	92	32.34	1.35	4.2
Sysmex XT-4000i	63	35.06	1.73	4.9	61	26.10	0.85	3.2	61	32.02	0.99	3.1	63	31.05	0.97	3.1	63	31.94	1.43	4.5

Data for groups of 3-9	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH
Sysmex XE-2100C,XE2100DC	5	38.0	37.8	39.1	5	29.0	27.2	30.8	5	33.2	33.0	36.1	5	32.0	31.3	33.4	5	32.5	31.0	35.0

Lymphocytes Absolute x 10E9/L or x 10E3/µl	FH9-06				FH9-07				FH9-08				FH9-09				FH9-10			
INSTRUMENT	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV
Abbott Alinity hq	31	0.955	0.061	6.4	30	3.742	0.134	3.6	28	1.884	0.061	3.2	31	2.245	0.105	4.7	29	0.888	0.046	5.2
Sysmex XE-2100,2100 D/L	27	1.130	0.056	5.0	27	4.591	0.196	4.3	27	2.205	0.077	3.5	27	2.513	0.086	3.4	27	0.963	0.039	4.0
Sysmex XE-2100 D/L (Bld Ctr)	19	1.136	0.044	3.9	19	4.707	0.255	5.4	19	2.243	0.114	5.1	19	2.529	0.121	4.8	19	0.966	0.046	4.8
Sysmex XE-5000	87	1.128	0.056	5.0	88	4.659	0.187	4.0	88	2.196	0.078	3.6	87	2.513	0.101	4.0	87	0.962	0.043	4.5
Sysmex XN-L Series	541	1.046	0.043	4.1	533	4.293	0.118	2.7	542	2.112	0.066	3.1	544	2.446	0.076	3.1	545	0.988	0.042	4.3
Sysmex XN-Series	2866	0.905	0.043	4.8	2869	3.635	0.157	4.3	2870	1.833	0.069	3.8	2859	2.167	0.082	3.8	2860	0.860	0.039	4.6
Sysmex XN-Series (RL App)	85	0.890	0.047	5.2	86	3.589	0.138	3.8	84	1.821	0.055	3.0	85	2.126	0.071	3.3	86	0.849	0.041	4.9
Sysmex XS (Except RL App)	485	1.152	0.044	3.8	482	4.738	0.140	2.9	484	2.331	0.074	3.2	480	2.644	0.080	3.0	482	1.090	0.046	4.2
Sysmex XS-1000iC (RL App)	66	1.155	0.052	4.5	64	4.781	0.123	2.6	66	2.342	0.070	3.0	65	2.635	0.078	3.0	67	1.083	0.045	4.2
Sysmex XT-1800i/2000i	89	1.053	0.060	5.7	89	4.266	0.182	4.3	89	2.193	0.100	4.5	88	2.339	0.076	3.2	89	0.934	0.045	4.9
Sysmex XT-4000i	62	1.042	0.059	5.7	60	4.237	0.160	3.8	60	2.176	0.079	3.6	62	2.350	0.102	4.3	62	0.907	0.042	4.6

Data for groups of 3-9	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH
Sysmex XE-2100C,XE2100DC	5	1.1	1.1	1.3	5	4.6	4.5	5.0	5	2.2	2.1	2.5	5	2.5	2.4	2.6	5	1.0	0.9	1.0

Monocytes - %	FH9-06				FH9-07				FH9-08				FH9-09				FH9-10			
INSTRUMENT	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV
Abbott Alinity hq	30	10.47	1.29	12.3	30	11.04	0.62	5.6	30	10.47	0.63	6.1	30	10.64	0.91	8.6	30	10.52	1.04	9.9
Sysmex XE-2100,2100 D/L	30	9.68	0.75	7.8	30	8.17	0.84	10.3	30	9.44	0.63	6.7	30	9.98	0.60	6.0	30	9.05	0.87	9.6
Sysmex XE-2100 D/L (Bld Ctr)	17	9.84	0.89	9.0	17	8.18	0.84	10.3	17	9.31	0.68	7.3	17	9.79	0.77	7.8	16	9.19	0.58	6.3
Sysmex XE-5000	89	9.61	0.89	9.2	88	7.96	0.94	11.8	88	9.29	0.57	6.1	89	9.81	0.68	7.0	87	9.11	0.88	9.6
Sysmex XN-L Series	533	11.06	0.82	7.4	533	10.34	0.50	4.8	534	10.43	0.60	5.7	536	10.67	0.55	5.2	537	10.38	0.76	7.3
Sysmex XN-Series	2843	14.88	1.14	7.7	2843	13.29	0.91	6.8	2837	13.31	0.83	6.2	2852	13.35	0.86	6.4	2845	13.32	0.95	7.1
Sysmex XN-Series (RL App)	86	14.98	1.00	6.7	86	13.52	0.82	6.1	85	13.52	0.71	5.3	85	13.82	0.74	5.3	86	13.52	1.02	7.6
Sysmex XS (Except RL App)	466	9.79	0.79	8.1	461	9.31	0.51	5.5	466	9.64	0.56	5.8	469	9.93	0.51	5.2	468	9.53	0.74	7.8
Sysmex XS-1000iC (RL App)	69	10.02	0.83	8.2	67	9.42	0.46	4.9	68	9.79	0.61	6.2	67	10.09	0.41	4.0	68	9.75	0.78	8.0
Sysmex XT-1800i/2000i	89	12.30	1.18	9.6	89	10.86	0.72	6.7	90	11.20	0.83	7.4	89	11.77	0.68	5.8	89	10.83	0.90	8.3
Sysmex XT-4000i	63	12.46	1.41	11.3	63	10.77	0.93	8.6	63	11.50	1.09	9.5	62	11.72	0.83	7.1	62	10.85	1.14	10.5

Data for groups of 3-9	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH
Sysmex XE-2100C,XE2100DC	5	9.0	8.1	10.3	5	8.3	6.1	9.3	5	9.9	8.5	10.0	5	10.0	9.0	11.0	5	9.0	7.2	10.0

Monocytes Absolute x 10E9/L or x 10E3/µl	FH9-06				FH9-07				FH9-08				FH9-09				FH9-10			
INSTRUMENT	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV
Abbott Alinity hq	29	0.299	0.036	12.0	29	1.759	0.135	7.7	28	0.663	0.046	7.0	29	0.801	0.076	9.5	28	0.313	0.033	10.7
Sysmex XE-2100,2100 D/L	27	0.285	0.023	7.9	27	1.314	0.134	10.2	27	0.616	0.048	7.8	27	0.752	0.048	6.3	27	0.260	0.028	10.8
Sysmex XE-2100 D/L (Bld Ctr)	17	0.295	0.030	10.0	17	1.335	0.136	10.2	17	0.612	0.049	7.9	17	0.745	0.049	6.6	16	0.263	0.021	8.1
Sysmex XE-5000	88	0.287	0.032	11.3	87	1.291	0.160	12.4	87	0.608	0.046	7.5	88	0.745	0.061	8.2	88	0.261	0.034	13.0
Sysmex XN-L Series	531	0.320	0.027	8.4	532	1.691	0.096	5.7	532	0.682	0.045	6.6	532	0.816	0.049	6.0	532	0.318	0.026	8.2
Sysmex XN-Series	2844	0.423	0.036	8.4	2841	2.115	0.152	7.2	2836	0.843	0.057	6.7	2837	1.002	0.069	6.9	2830	0.395	0.030	7.6
Sysmex XN-Series (RL App)	86	0.424	0.029	6.8	85	2.155	0.130	6.0	85	0.855	0.050	5.9	86	1.032	0.064	6.2	86	0.402	0.030	7.5
Sysmex XS (Except RL App)	490	0.291	0.026	8.9	482	1.550	0.093	6.0	488	0.645	0.042	6.5	488	0.779	0.045	5.8	484	0.299	0.024	7.9
Sysmex XS-1000iC (RL App)	68	0.299	0.026	8.6	66	1.585	0.085	5.4	66	0.660	0.040	6.0	67	0.788	0.041	5.2	66	0.306	0.026	8.5
Sysmex XT-1800i/2000i	88	0.368	0.040	11.0	87	1.780	0.117	6.6	86	0.764	0.053	6.9	87	0.887	0.059	6.6	85	0.311	0.025	8.0
Sysmex XT-4000i	62	0.370	0.045	12.0	61	1.752	0.147	8.4	62	0.778	0.078	10.0	62	0.883	0.071	8.0	60	0.307	0.038	12.3

Data for groups of 3-9	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH
Sysmex XE-2100C,XE2100DC	5	0.3	0.3	0.3	5	1.3	1.0	1.5	5	0.7	0.6	0.7	5	0.8	0.7	0.9	5	0.3	0.2	0.3

Eosinophils - %	FH9-06				FH9-07				FH9-08				FH9-09				FH9-10			
INSTRUMENT	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV
Abbott Alinity hq♦	29	2.29	0.38	16.5	30	2.87	0.27	9.3	30	2.29	0.39	17.2	30	2.23	0.29	13.1	30	2.13	0.39	18.3
Sysmex XE-2100,2100 D/L	30	9.33	0.85	9.1	30	11.47	0.74	6.4	30	10.30	0.77	7.5	30	9.84	0.74	7.6	30	10.42	0.88	8.4
Sysmex XE-2100 D/L (Bld Ctr)	18	9.12	0.70	7.7	18	11.25	0.85	7.6	18	9.91	0.79	8.0	18	10.28	0.78	7.6	18	9.91	0.79	7.9
Sysmex XE-5000	89	9.35	0.83	8.9	89	11.29	0.84	7.4	89	10.18	0.80	7.8	89	10.03	0.80	8.0	88	10.06	0.86	8.5
Sysmex XN-L Series	527	9.36	0.74	7.9	526	11.25	0.82	7.2	526	10.09	0.79	7.8	527	10.09	0.77	7.7	523	10.10	0.79	7.9
Sysmex XN-Series	2863	9.47	0.72	7.6	2853	11.33	0.81	7.2	2853	10.18	0.79	7.8	2858	10.19	0.79	7.8	2863	10.17	0.83	8.2
Sysmex XN-Series (RL App)	86	9.51	0.76	8.0	86	11.38	0.89	7.8	86	10.24	0.78	7.6	86	10.12	0.73	7.3	85	10.12	0.82	8.1
Sysmex XS (Except RL App)	468	8.87	0.67	7.5	468	10.82	0.76	7.0	468	9.68	0.70	7.3	468	9.67	0.72	7.5	465	9.70	0.75	7.7
Sysmex XS-1000iC (RL App)	68	8.83	0.73	8.2	67	10.90	0.81	7.4	68	9.65	0.73	7.6	68	9.62	0.69	7.2	68	9.61	0.75	7.8
Sysmex XT-1800i/2000i	91	9.17	0.73	7.9	91	10.90	0.76	7.0	90	9.83	0.71	7.2	91	9.97	0.74	7.4	91	9.90	0.74	7.5
Sysmex XT-4000i	63	9.14	0.72	7.9	62	10.90	0.74	6.8	63	10.03	0.77	7.6	63	9.72	0.72	7.4	63	10.08	0.76	7.6

Data for groups of 3-9	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH
Sysmex XE-2100C,XE2100DC	5	10.0	9.5	10.0	5	10.4	9.7	12.1	5	10.0	8.8	11.0	5	10.4	10.0	11.0	5	10.1	9.6	11.0

♦ Per the Urgent Field Safety Notice from Abbott dated July 2020, there is a known issue with the Alinity hq analyzer misclassifying eosinophils as neutrophils, resulting in underestimation of eosinophils. The results of this PT event are consistent with this known issue. For further information or questions, please contact Abbott's customer support.

Eosinophils Absolute x 10E9/L or x 10E3/µl	FH9-06				FH9-07				FH9-08				FH9-09				FH9-10			
INSTRUMENT	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV
Abbott Alinity hq♦	29	0.065	0.012	18.2	29	0.459	0.045	9.7	30	0.140	0.027	19.5	30	0.169	0.023	13.8	29	0.063	0.014	22.0
Sysmex XE-2100,2100 D/L	28	0.280	0.029	10.3	28	1.865	0.138	7.4	28	0.676	0.059	8.7	28	0.751	0.062	8.2	28	0.299	0.028	9.5
Sysmex XE-2100 D/L (Bld Ctr)	18	0.273	0.025	9.1	18	1.838	0.146	8.0	18	0.650	0.062	9.6	18	0.782	0.061	7.8	18	0.284	0.025	8.9
Sysmex XE-5000	90	0.279	0.026	9.5	90	1.837	0.146	7.9	90	0.663	0.058	8.7	90	0.762	0.069	9.0	88	0.290	0.026	8.9
Sysmex XN-L Series	518	0.271	0.024	8.7	516	1.839	0.137	7.4	518	0.659	0.058	8.8	517	0.771	0.064	8.3	518	0.309	0.027	8.8
Sysmex XN-Series	2835	0.270	0.022	8.1	2839	1.806	0.132	7.3	2836	0.645	0.052	8.0	2837	0.766	0.062	8.1	2842	0.302	0.026	8.5
Sysmex XN-Series (RL App)	86	0.270	0.023	8.5	86	1.811	0.147	8.1	86	0.647	0.052	8.0	86	0.759	0.056	7.4	86	0.300	0.024	8.2
Sysmex XS (Except RL App)	485	0.264	0.022	8.5	488	1.803	0.134	7.4	487	0.648	0.051	7.9	486	0.755	0.060	7.9	481	0.304	0.025	8.1
Sysmex XS-1000iC (RL App)	67	0.266	0.025	9.5	66	1.834	0.129	7.0	66	0.647	0.049	7.6	66	0.755	0.060	7.9	67	0.304	0.026	8.5
Sysmex XT-1800i/2000i	90	0.273	0.024	8.9	90	1.777	0.127	7.1	90	0.673	0.058	8.6	90	0.750	0.056	7.5	90	0.286	0.023	8.2
Sysmex XT-4000i	62	0.272	0.025	9.1	61	1.770	0.134	7.6	62	0.682	0.056	8.3	62	0.738	0.055	7.5	61	0.289	0.022	7.6

Data for groups of 3-9	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH
Sysmex XE-2100C,XE2100DC	5	0.3	0.3	0.3	5	1.7	1.6	2.0	5	0.6	0.6	0.8	5	0.8	0.7	0.9	5	0.3	0.3	0.3

Basophils - %	FH9-06				FH9-07				FH9-08				FH9-09				FH9-10			
INSTRUMENT	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV
Abbott Alinity hq	30	2.39	0.99	41.3	28	1.44	0.31	21.2	28	1.77	0.50	28.4	29	1.40	0.35	25.0	29	1.80	0.50	27.5
Sysmex XE-2100,2100 D/L	30	62.48	1.70	2.7	30	73.07	0.90	1.2	30	66.41	1.06	1.6	30	68.51	0.85	1.2	30	68.31	1.07	1.6
Sysmex XE-2100 D/L (Bld Ctr)	18	62.93	1.52	2.4	18	72.90	0.85	1.2	18	66.53	1.09	1.6	18	68.42	0.81	1.2	17	67.51	1.18	1.7
Sysmex XE-5000	87	62.75	1.34	2.1	85	73.04	0.65	0.9	87	66.62	1.05	1.6	87	68.52	0.79	1.2	86	68.06	1.27	1.9
Sysmex XN-L Series	527	5.26	0.39	7.5	524	6.33	0.37	5.9	525	5.67	0.34	6.0	525	5.68	0.35	6.1	526	5.70	0.41	7.1
Sysmex XN-Series	2854	4.80	0.17	3.5	2851	4.81	0.12	2.5	2849	4.80	0.13	2.8	2849	4.81	0.13	2.6	2860	4.79	0.18	3.7
Sysmex XN-Series (RL App)	86	4.76	0.20	4.2	86	4.80	0.11	2.3	85	4.81	0.13	2.6	86	4.80	0.14	2.9	85	4.81	0.15	3.2
Sysmex XS (Except RL App)	467	5.61	0.50	8.9	467	6.97	0.56	8.1	467	6.01	0.47	7.9	468	6.07	0.50	8.2	465	6.28	0.53	8.5
Sysmex XS-1000iC (RL App)	68	5.59	0.47	8.4	67	6.99	0.51	7.3	67	5.86	0.45	7.8	68	6.08	0.50	8.3	68	6.28	0.61	9.7
Sysmex XT-1800i/2000i	90	61.95	1.10	1.8	91	74.64	0.64	0.9	91	65.00	1.05	1.6	90	67.83	0.74	1.1	91	69.88	1.37	2.0
Sysmex XT-4000i	61	62.18	1.37	2.2	60	74.67	0.71	0.9	61	65.03	1.06	1.6	61	67.93	0.98	1.4	60	69.54	1.21	1.7

Data for groups of 3-9	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH
Sysmex XE-2100C,XE2100DC	5	62.0	59.9	64.2	5	73.0	71.4	73.5	5	67.0	66.0	68.3	5	68.5	67.0	69.0	5	68.0	66.7	69.8

♦ Per the Urgent Field Safety Notice from Abbott dated July 2020, there is a known issue with the Alinity hq analyzer misclassifying eosinophils as neutrophils, resulting in underestimation of eosinophils. The results of this PT event are consistent with this known issue. For further information or questions, please contact Abbott's customer support.

Basophils Absolute x 10E9/L or x 10E3/µl	FH9-06				FH9-07				FH9-08				FH9-09				FH9-10			
INSTRUMENT	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV
Abbott Alinity hq	31	0.070	0.031	43.5	29	0.239	0.064	26.7	29	0.108	0.037	34.5	29	0.101	0.030	30.1	30	0.052	0.020	38.4
Sysmex XE-2100,2100 D/L	27	1.870	0.097	5.2	27	11.882	0.251	2.1	27	4.370	0.148	3.4	27	5.224	0.170	3.3	27	1.962	0.071	3.6
Sysmex XE-2100 D/L (Bld Ctr)	18	1.884	0.071	3.8	18	11.914	0.378	3.2	18	4.357	0.202	4.6	18	5.206	0.167	3.2	18	1.943	0.079	4.1
Sysmex XE-5000	85	1.872	0.071	3.8	86	11.840	0.300	2.5	86	4.342	0.147	3.4	85	5.205	0.175	3.4	85	1.951	0.076	3.9
Sysmex XN-L Series	517	0.153	0.014	9.4	517	1.033	0.066	6.4	516	0.371	0.024	6.4	517	0.435	0.029	6.6	517	0.175	0.014	8.1
Sysmex XN-Series	2842	0.136	0.009	6.4	2830	0.767	0.022	2.9	2823	0.304	0.010	3.2	2823	0.362	0.013	3.6	2838	0.142	0.010	7.0
Sysmex XN-Series (RL App)	83	0.134	0.007	5.1	86	0.763	0.022	2.8	86	0.304	0.010	3.2	86	0.361	0.015	4.2	82	0.142	0.005	3.8
Sysmex XS (Except RL App)	485	0.168	0.017	10.1	488	1.160	0.096	8.3	486	0.403	0.034	8.4	484	0.474	0.040	8.5	482	0.197	0.017	8.8
Sysmex XS-1000iC (RL App)	67	0.169	0.015	9.1	66	1.180	0.087	7.4	67	0.397	0.034	8.7	67	0.478	0.045	9.5	67	0.198	0.018	9.3
Sysmex XT-1800i/2000i	89	1.846	0.073	3.9	89	12.185	0.368	3.0	88	4.421	0.177	4.0	87	5.118	0.145	2.8	89	2.019	0.077	3.8
Sysmex XT-4000i	59	1.843	0.071	3.9	58	12.141	0.324	2.7	59	4.410	0.128	2.9	60	5.149	0.167	3.2	60	1.977	0.071	3.6

Data for groups of 3-9	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH
Sysmex XE-2100C,XE2100DC	5	1.9	1.8	2.1	5	11.9	11.6	12.0	5	4.5	4.3	4.7	5	5.2	5.2	5.5	5	2.0	1.9	2.0

Immature Granulocytes (IG) - % (Ungraded)	FH9-06				FH9-07				FH9-08				FH9-09				FH9-10			
INSTRUMENT	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV
Abbott Alinity hq	21	8.44	1.04	12.4	21	10.78	1.12	10.4	21	9.39	0.95	10.1	21	9.23	1.00	10.8	21	9.56	1.14	11.9
Sysmex XE-2100,2100 D/L	20	10.01	0.40	4.0	20	12.03	0.57	4.8	20	10.92	0.47	4.3	20	11.02	0.56	5.1	20	10.80	0.51	4.7
Sysmex XE-5000	88	10.08	0.53	5.3	88	12.21	0.64	5.2	88	10.85	0.49	4.5	88	11.03	0.50	4.5	87	11.00	0.59	5.3
Sysmex XN-L Series	459	9.97	0.41	4.1	458	12.02	0.39	3.2	459	10.82	0.39	3.6	460	10.85	0.37	3.4	459	10.90	0.44	4.0
Sysmex XN-Series	2681	10.04	0.37	3.7	2680	12.06	0.37	3.1	2677	10.90	0.34	3.2	2680	10.90	0.33	3.0	2681	10.92	0.40	3.7
Sysmex XN-Series (RL App)	83	10.09	0.34	3.4	83	12.06	0.37	3.0	83	10.89	0.34	3.1	84	10.83	0.35	3.3	83	10.97	0.41	3.8
Sysmex XT-1800i/2000i	47	11.75	0.60	5.1	47	14.16	0.72	5.1	47	12.74	0.62	4.9	47	12.73	0.59	4.7	47	12.94	0.46	3.6
Sysmex XT-4000i	51	11.76	0.54	4.6	51	14.12	0.64	4.5	53	12.59	0.68	5.4	51	12.78	0.49	3.8	51	12.82	0.53	4.2

Data for groups of 3-9	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH
Sysmex XE-2100C,XE2100DC	3	10.0	9.5	10.1	3	11.7	10.8	13.1	3	10.3	10.3	11.2	3	11.2	11.0	11.8	3	11.3	10.9	11.3

Immature Granulocytes (IG) Absolute x 10E9/L or x 10E3/µL (Ungraded)	FH9-06				FH9-07				FH9-08				FH9-09				FH9-10			
INSTRUMENT	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV	LABS	MEAN	SD	CV
Abbott Alinity hq	21	0.239	0.032	13.4	21	1.720	0.200	11.7	21	0.599	0.069	11.6	21	0.699	0.079	11.3	21	0.285	0.041	14.3
Sysmex XE-2100,2100 D/L	22	0.298	0.015	5.1	22	1.953	0.098	5.0	22	0.714	0.046	6.5	22	0.839	0.046	5.5	22	0.310	0.018	5.8
Sysmex XE-5000	85	0.300	0.019	6.2	85	1.986	0.111	5.6	86	0.709	0.040	5.6	85	0.840	0.045	5.3	85	0.315	0.020	6.4
Sysmex XN-L Series	461	0.288	0.016	5.6	460	1.965	0.075	3.8	461	0.705	0.040	5.7	461	0.831	0.034	4.1	460	0.333	0.018	5.3
Sysmex XN-Series	2669	0.286	0.013	4.5	2660	1.920	0.065	3.4	2657	0.691	0.025	3.6	2662	0.818	0.029	3.6	2667	0.324	0.014	4.4
Sysmex XN-Series (RL App)	59	0.285	0.013	4.5	59	1.918	0.071	3.7	59	0.689	0.025	3.6	58	0.807	0.025	3.1	59	0.324	0.016	4.8
Sysmex XT-1800i/2000i	48	0.352	0.022	6.2	48	2.408	0.132	5.5	48	0.861	0.051	6.0	48	0.955	0.059	6.2	48	0.388	0.020	5.2
Sysmex XT-4000i	51	0.349	0.023	6.7	50	2.383	0.135	5.7	52	0.849	0.053	6.3	50	0.970	0.050	5.2	51	0.378	0.021	5.5

Data for groups of 3-9	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH
Sysmex XE-2100C,XE2100DC	3	0.3	0.3	0.3	3	1.9	1.8	2.1	3	0.7	0.7	0.7	3	0.9	0.8	0.9	3	0.3	0.3	0.3

nRBC – % (Ungraded)	FH9-06				FH9-07				FH9-08				FH9-09				FH9-10			
INSTRUMENT	**LABS**	**MEAN**	**SD**	**CV**	**LABS**	**MEAN**	**SD**	**CV**	**LABS**	**MEAN**	**SD**	**CV**	**LABS**	**MEAN**	**SD**	**CV***	**LABS**	**MEAN**	**SD**	**CV***
Sysmex XE-2100,2100 D/L																				
eCheck XE Control	13	4.78	0.74	15.4	13	6.86	0.41	6.0	13	6.65	0.27	4.0	13	0.00	0.00	0.0	13	0.00	0.00	0.0
Sysmex XE-5000																				
eCheck XE Control	85	4.75	0.60	12.5	85	6.84	0.34	4.9	85	6.59	0.53	8.1	86	0.00	0.00	0.0	86	0.00	0.00	0.0
Sysmex XN-Series																				
XN Check Control	2659	4.47	0.46	10.3	2652	6.43	0.23	3.5	2645	6.07	0.35	5.7	2685	0.06	0.07	*	2667	0.06	0.12	*
Sysmex XN-Series (RL App)																				
XN Check Control	46	4.35	0.47	10.8	46	6.42	0.25	3.9	46	5.99	0.30	5.0	45	0.06	0.05	78.8	47	0.06	0.12	*

Data for groups of 3-9	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH
Sysmex XE-2100,2100 D/L																				
eCheck Control	8	100.0	100.0	100.0	8	100.0	100.0	100.0	8	100.0	100.0	100.0	8	100.0	100.0	100.0	8	100.0	100.0	100.0
Sysmex XN-L Series																				
XN Check Control	3	4.6	4.3	5.6	3	6.4	0.8	6.5	3	6.2	2.1	6.4	3	0.0	0.0	0.2	3	0.3	0.0	0.3
Sysmex XN-Series																				
eCheck Control	3	4.1	3.1	4.4	3	6.5	6.2	6.6	3	5.8	5.1	6.1	3	0.0	0.0	0.1	3	0.0	0.0	0.0

nRBC Absolute x 10E9/L or x 10E3/µL (Ungraded)	FH9-06				FH9-07				FH9-08				FH9-09				FH9-10			
INSTRUMENT	**LABS**	**MEAN**	**SD**	**CV**	**LABS**	**MEAN**	**SD**	**CV**	**LABS**	**MEAN**	**SD**	**CV**	**LABS**	**MEAN**	**SD**	**CV**	**LABS**	**MEAN**	**SD**	**CV***
Sysmex XE-2100,2100 D/L																				
eCheck Control	10	2.775	0.104	3.7	10	15.897	0.372	2.3	-	-	-	-	10	7.438	0.175	2.4	10	2.963	0.108	3.6
eCheck XE Control	13	0.137	0.019	13.8	13	1.051	0.056	5.4	13	0.412	0.019	4.7	13	0.000	0.000	0.0	13	0.000	0.000	0.0
Sysmex XE-5000																				
eCheck XE Control	80	0.134	0.016	11.9	82	1.039	0.051	4.9	82	0.403	0.031	7.8	82	0.000	0.000	0.0	82	0.000	0.000	0.0
Sysmex XN-Series																				
XN Check Control	2532	0.127	0.013	10.1	2528	1.023	0.035	3.4	2525	0.385	0.022	5.7	2546	0.006	0.006	99.9	2532	0.002	0.004	*
Sysmex XN-Series (RL App)																				
XN Check Control	41	0.122	0.013	10.8	41	1.020	0.031	3.1	41	0.379	0.017	4.6	42	0.007	0.006	77.5	42	0.002	0.004	*

Data for groups of 3-9	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH
Sysmex XE-2100,2100 D/L																				
eCheck Control	-	-	-	-	-	-	-	-	9	6.2	5.8	6.6	-	-	-	-	-	-	-	-
Sysmex XN-L Series																				
XN Check Control	3	0.1	0.1	0.1	3	1.1	0.0	1.1	3	0.4	0.1	0.4	3	0.0	0.0	0.0	3	0.0	0.0	0.0
Sysmex XN-Series																				
eCheck Control	4	0.1	0.1	0.1	4	1.0	1.0	1.1	4	0.4	0.3	0.4	4	0.0	0.0	0.0	4	0.0	0.0	0.0
eCheck XE Control	4	0.1	0.1	0.1	4	1.0	1.0	1.0	4	0.4	0.4	0.4	4	0.0	0.0	0.0	4	0.0	0.0	0.0

* When low results are reported on an analyte, a high coefficient of variation (CV) may result. When the mean value is very low, the CV may be exaggerated

Immature Platelet Fraction (IPF) or Reticulated Platelet (RP) – % (Ungraded)	FH9-06				FH9-07				FH9-08				FH9-09				FH9-10			
INSTRUMENT	**LABS**	**MEAN**	**SD**	**CV**	**LABS**	**MEAN**	**SD**	**CV**	**LABS**	**MEAN**	**SD**	**CV**	**LABS**	**MEAN**	**SD**	**CV**	**LABS**	**MEAN**	**SD**	**CV**
Abbott Alinity hq	11	16.24	4.22	26.0	11	15.49	5.28	34.1	11	15.83	4.93	31.2	11	15.63	5.24	33.5	11	15.98	4.20	26.3
Sysmex XE-5000	74	21.44	0.97	4.5	74	21.50	0.82	3.8	74	21.63	0.93	4.3	73	21.72	1.00	4.6	73	21.38	0.77	3.6
Sysmex XN-Series	2013	20.01	0.53	2.6	2012	20.02	0.69	3.4	2006	19.99	0.63	3.2	2013	20.00	0.74	3.7	2014	20.01	0.51	2.5
Sysmex XN-Series (RL App)	36	20.01	0.54	2.7	36	20.07	0.71	3.5	36	19.95	0.67	3.4	36	20.18	0.64	3.2	36	20.01	0.53	2.6

Data for groups of 3-9	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH	LABS	MEDIAN	LOW	HIGH
Sysmex XE-2100,2100 D/L	3	21.4	21.3	22.1	3	21.5	21.3	22.3	3	22.7	21.8	22.8	3	21.5	20.2	22.6	3	21.2	20.7	22.2
Sysmex XN-L Series	3	20.1	19.5	20.7	3	20.3	19.7	20.5	3	20.4	20.0	26.7	3	19.9	0.0	21.0	3	19.5	3.3	20.1

Red cell distribution width (RDW-SD vs. RDW-CV) discussion:
The red cell distribution width (RDW) is a calculated value which quantitatively reflects the degree of anisocytosis, or variation in red blood cell size, in a given blood sample. The RDW, in conjunction with the mean cell volume (MCV) and other red cell indices, may be a useful parameter in the laboratory evaluation of anemia and other hematologic conditions. An elevated RDW generally conveys increased variation in red blood cell size, and is seen in a variety of clinical settings including iron deficiency, autoimmune hemolysis, and in some patients with myelodysplastic syndrome.

Many modern automated hematology analyzers produce two distinct RDW measurements. The most commonly used and reported in clinical practice is the coefficient of variation RDW (RDW-CV), which is based on the coefficient of variation of the red blood cell distribution volume. The RDW-CV is calculated using the formula below, and the reference range in adults is typically 11.0 - 15.0%.

$$\text{RDW-CV} = \frac{1\text{SD}}{\text{MCV}} \times 100$$

Another way of expressing the RDW is the red cell distribution width-standard deviation, or RDW-SD. The RDW-SD is an actual measurement of the width of the red cell distribution curve and provides an absolute value in femtoliters (fL). The RDW-SD more accurately reflects red cell anisocytosis because it is directly measured and is not influenced by the MCV. The reference range for RDW-SD in adults is typically 36 - 47 fL.

The RDW-CV and RDW-SD are different expressions of the RDW, and laboratories should exercise caution so as not to confuse them for purposes of clinical reporting as well as proficiency testing.

Hematology and Clinical Microscopy Committee

References:

1. Constantino, BT. The red cell histogram and the dimorphic red cell population. *LabMedicine*. 2011; 42(5):300-308.
2. Kjeldsberg CR, Perkins SL, eds. *Practical Diagnosis of Hematologic Disorders*. 5th ed. American Society for Clinical Pathology; 2010.
3. MediaLab, Inc. Website. http://www.medialabinc.net/spg579122/red_blood_cell_distribution_width_rdw_definition_a.aspx. Accessed June 3, 2013.

Blood Cell Identification – Graded

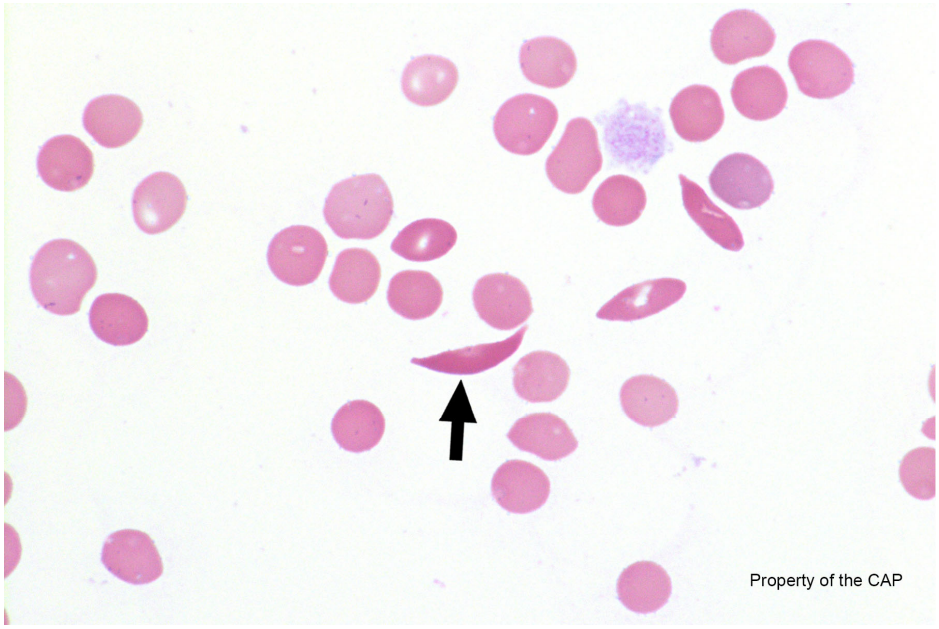
Case History

This peripheral blood smear is from a 29-year-old woman with history of sickle cell disease, who presents with acute pain crisis. Laboratory data include: **Corrected** WBC = 18.6 × 10E9/L; RBC = 1.61 × 10E12/L; HGB = 5.6 g/dL; HCT = 16.3 %; MCV = 101 fL; MCHC = 34.1 g/dL; PLT = 184 × 10E9/L; and RDW = 20 %. Identify the arrowed object(s) on each image.

(PERIPHERAL BLOOD, WRIGHT-GIEMSA)

To access the online Hematology Glossary, please click the hyperlink below:
https://documents.cap.org/documents/2021-hematology-and-clinical-microscopy-glossary.pdf

BCP-11

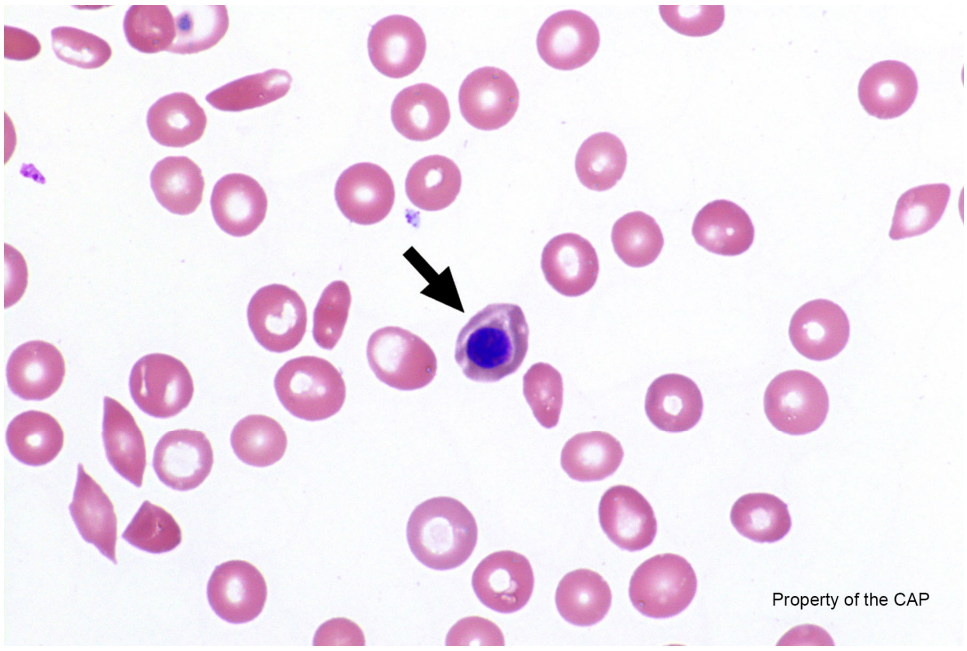


Identification	Referees		Participants		Evaluation
	No.	%	No.	%	
Sickle cell (drepanocyte)	185	100.0	5526	99.5	Good

The arrowed cell is a sickle cell (drepanocyte), as correctly identified by 100.0% of referees and 99.5% of participants. Red blood cells appearing in the shape of a thin crescent with two pointed ends are called sickle cells. The polymerization of deoxygenated hemoglobin S may cause red blood cells to appear in one or more of the following forms: crescent-shaped, boat-shaped, filament-shaped, holly-leaf form, or envelope cells. These cells usually lack central pallor. Sickle cells may be seen particularly in the absence of splenic function or after splenectomy in patients with the various forms of sickle cell disease including hemoglobin SS disease, SC disease, SD disease, and S-beta-thalassemia.

Blood Cell Identification – Graded

BCP-12

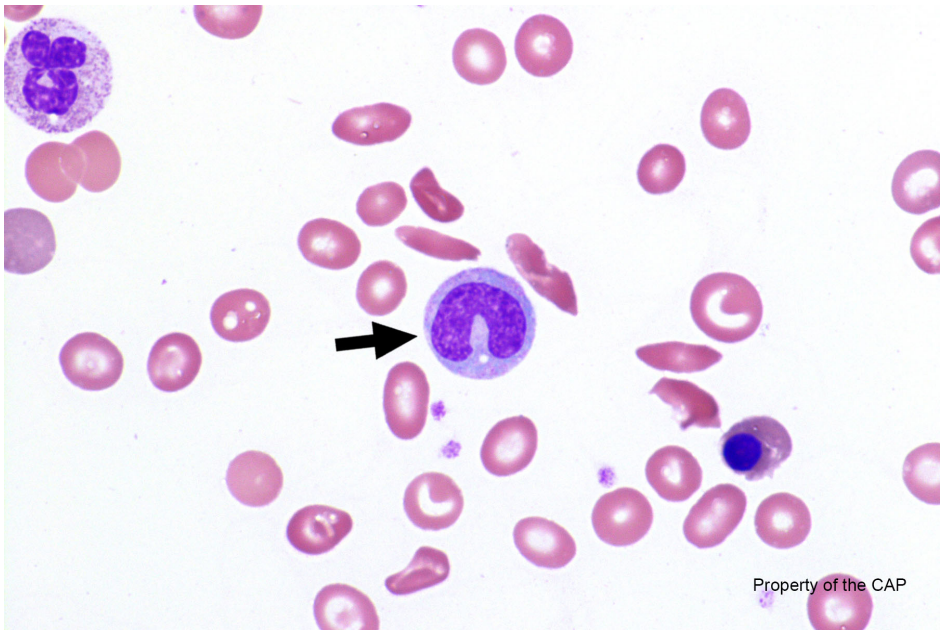


Identification	Referees		Participants		Evaluation
	No.	%	No.	%	
Nucleated red blood cell, normal or abnormal morphology	183	98.9	5519	99.4	Good
Immature or abnormal cell, would refer for identification	2	1.1	23	0.4	Unacceptable

The arrowed cell is a nucleated red blood cell, as correctly identified by 98.9% of referees and 99.4% of participants. The term nucleated red blood cell (nRBC) is used to state the presence of normoblasts in the peripheral blood and includes all normoblasts regardless of the stage of maturation. Typically, the circulating nucleated red blood cell is at the orthochromic stage of differentiation. Both megaloblastic and dysplastic changes can be seen in these circulating red blood cells, reflecting simultaneous erythroid maturation abnormalities present in the bone marrow. Caution should be used in classifying a circulating nucleated red blood cell as dysplastic on the basis of abnormal nuclear shape (lobated or fragmented), as these changes may occur during their egress from the marrow space and may not be present in the maturing erythroid precursors present in the marrow. For the purposes of proficiency testing, it is adequate to identify a cell as a nucleated red blood cell when it is present in the peripheral blood, be it normal or abnormal (ie, exhibits megaloblastic or dysplastic changes).

Blood Cell Identification – Graded

BCP-13



Identification	Referees		Participants		Evaluation
	No.	%	No.	%	
Monocyte	137	74.0	4161	75.0	Non-consensus
Neutrophil, segmented or band	42	22.7	1180	21.3	Non-consensus
Neutrophil, giant band or giant metamyelocyte	5	2.7	118	2.1	Non-consensus
Polychromatophilic (non-nucleated) red blood cell	1	0.5	1	0.0	Non-consensus

The arrowed cell is a monocyte, as correctly identified by 74% of referees and 75% of participants. Monocytes are slightly larger than neutrophils, ranging from 12 to 20 µm in diameter. Most monocytes are round with smooth edges, but some may have pseudopod-like cytoplasmic extensions. The cytoplasm is abundant, with a gray or gray-blue ground-glass appearance, and may contain vacuoles or fine, evenly distributed azurophilic granules. The N:C ratio ranges from 4:1 to 2:1. The nucleus is usually indented, often resembling a three-pointed hat, but it can also be folded or band-like. The chromatin is condensed but is usually less dense than that of a neutrophil or lymphocyte. Nucleoli are generally absent, but occasional monocytes may contain a small, inconspicuous nucleolus.

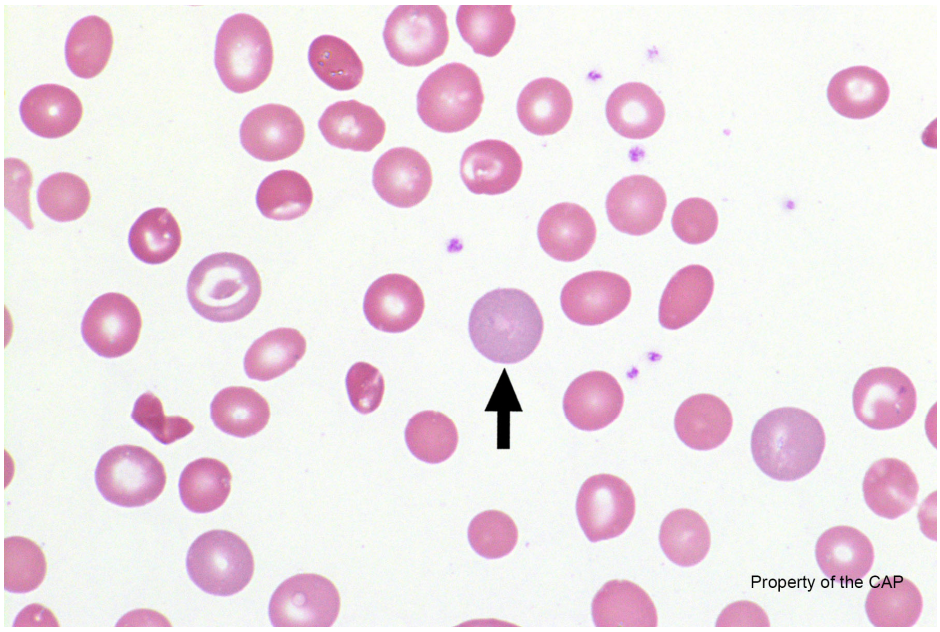
Approximately 22.7% of referees and 21.3% of participants identified the arrowed cell as a neutrophil, segmented/band. Segmented neutrophils and their immediate precursors, bands, constitute 12% to 25% of the nucleated cells in the bone marrow. Band neutrophils, also known as stabs, constitute 5% to 10% of the nucleated cells in the blood under normal conditions. The band is round-to-oval and 10 to 18 µm in diameter. The N:C ratio is 1:1.5 to 1:2 and the nuclear chromatin is condensed. The nucleus is indented to more than half the distance to the farthest nuclear margin, but the chromatin is not condensed to a single filament (as is the defining feature of the fully mature neutrophil). The nucleus can assume many shapes: it can be band- or sausage-like; S-, C-, or U-shaped; and twisted or folded on itself. The cytoplasm is similar to that of other post-mitotic

neutrophils, with specific granules predominating in an otherwise pale cytoplasm. The segmented neutrophil is the predominant blood leukocyte. It has a similar size to a band neutrophil (ie, 10 to 15 µm in diameter), as well as comparable shape (round to oval), and cytoplasmic appearance (pale pink cytoplasm with specific granules). The N:C ratio is 1:3 and the nuclear chromatin is highly condensed. The nucleus is segmented or lobated (with a normal range of three to five lobes). The lobes are connected by a thin filament that contains no internal chromatin, giving it the appearance of a solid, dark, thread-like line. The presence of these thread-like filaments is the basis for distinguishing the segmented neutrophil from the band neutrophil. The arrowed cell lacks the typical cytoplasmic appearance of neutrophils as its cytoplasm is not pale pink and specific granules are absent. Moreover, the chromatin pattern is finer than a typical neutrophil. Compare the arrowed cell in BCP-13 to the white blood cells in image BCP-15. In BCP-15, the white blood cells (ie, neutrophils) have coarser chromatin, pink cytoplasm, and specific granules. These features distinguish the arrowed monocyte in BCP-13 from neutrophils. Therefore, the choice of neutrophil, segmented/band is incorrect.

2.7% of referees and 2.1% of participants identified the arrowed cell as a neutrophil, giant band. Giant bands resulting from megaloblastic hematopoiesis show an increase in size, and they have nuclei that show aberrant maturation, whereby the nucleus appears less mature than the cytoplasm. These cells have diameters 1.5 times those of normal metamyelocytes or bands. The arrowed cell lacks the typical cytoplasmic appearance of neutrophils as its cytoplasm is not pale pink and specific granules are absent. Instead, the cytoplasm of the arrowed cell is gray-blue, and thereby consistent with a monocyte. Therefore, the choice of neutrophil, giant band is incorrect.

Blood Cell Identification – Graded

BCP-14



Identification	Referees		Participants		Evaluation
	No.	%	No.	%	
Polychromatophilic (non-nucleated) red blood cell	181	97.8	5431	97.9	Good
Spherocyte	2	1.1	43	0.8	Unacceptable
Macrocyte, oval or round (excluding polychromatophilic red blood cell)	1	0.5	62	1.1	Unacceptable

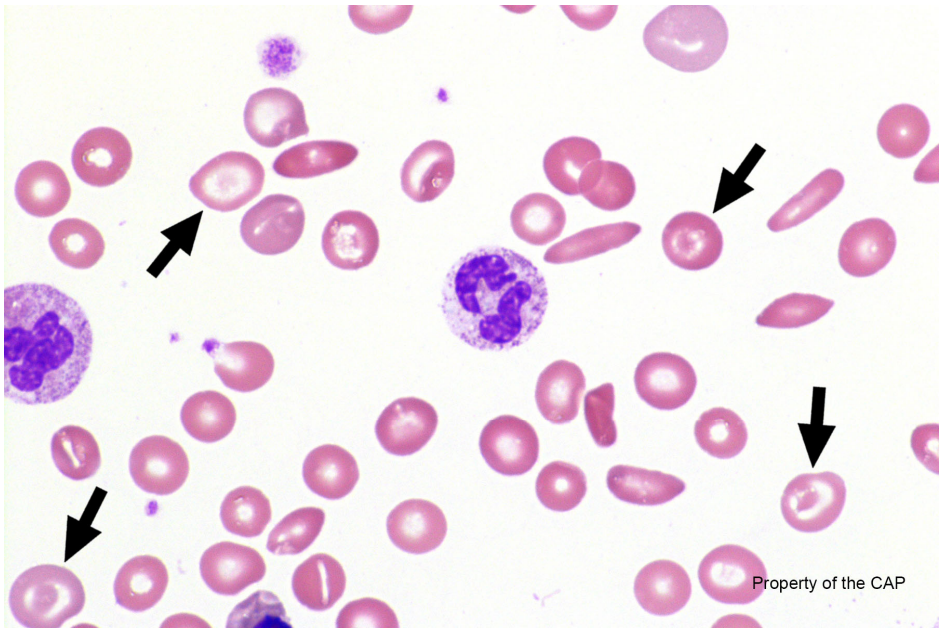
The arrowed cell is a polychromatophilic (non-nucleated) red blood cell, as correctly identified by 97.8% of referees and 97.9% of participants. A polychromatophilic red blood cell is a non-nucleated, round or ovoid red blood cell that represents the final stage of red blood cell maturation after exiting the bone marrow. It is larger than a mature erythrocyte and usually lacks central pallor. It primarily contains hemoglobin with a small amount of RNA, and thereby stains pale purple to pink-gray with Romanowsky or Wright-Giemsa stain. These cells can be stained as reticulocytes and enumerated by using supravital stains, such as new methylene blue. With supravital staining, reticulocytes reveal deep blue granular and/or filamentous structures. This reticulin network is called the “substantia reticulofilamentosa.” The intensity of the polychromasia will vary with the amount of RNA and the age of the cell, with younger cells (ie, earlier polychromatophilic red cells) appearing more purple or blue and relatively more mature cells (i.e. later polychromatophilic red cells) appearing more pink-gray. Automated technologies for assessing reticulocytes improve the accuracy and precision of determining reticulocyte numbers.

1.1% of participants identified the arrowed cell as macrocyte, oval/round. Macrocytes are abnormally large red blood cells (diameter > 8.5 µm). They are best detected by comparing to other red blood cells in a smear in the context of the MCV. They may be oval or round. The hemoglobin concentration is normal; these cells lack significant polychromasia. If polychromasia is readily identified, the term polychromatophilic red blood cell is

preferred for proficiency testing purposes. Therefore, given the overt presence of polychromasia in the arrowed cell (compare this arrowed cell to the mature spherocyte below it which lacks polychromasia), the choice of macrocyte, oval/round is incorrect.

Blood Cell Identification – Graded

BCP-15



Identification	Referees		Participants		Evaluation
	No.	%	No.	%	
Target cell (codocyte)	185	100.0	5527	99.6	Good

The arrowed cells are target cells (codocytes), as correctly identified by 100.0% of referees and 99.6% of participants. Target cells are thin red blood cells with an increased surface membrane-to-volume ratio. They are often flattened out on the smears and may appear macrocytic. Target cells are believed to arise from disturbances in red blood cell membrane cholesterol and lecithin content or decreased cytoplasmic hemoglobin content. Target cells are characterized by a central hemoglobinized area within the surrounding area of pallor, which in turn is surrounded by a peripheral hemoglobinized zone giving target cells the appearance of a bull's-eye. Target cells associated with hemoglobin C may have a slightly reduced or normal MCV, whereas those associated with hemoglobin E disorders or hemoglobin H disease exhibit microcytosis of varying degree. Target cells are usually seen in thalassemias, iron deficiency anemia, following splenectomy or in patients who are jaundiced or who have chronic liver disease; in the latter two conditions, the MCV may be normal or increased. Target cells may also appear as artifacts from slow drying the slides in a humid environment or from specimens anticoagulated with excessive EDTA. The drying artifact results in the presence of numerous target cells in some fields, but none or few in other fields.

Clinical Presentation:

This peripheral blood smear is from a 29-year-old woman with history of sickle cell disease, who presents with acute pain crisis. Laboratory data include: Corrected WBC = 18.6 × 10E9/L; RBC = 1.61 × 10E12/L; HGB = 5.6 g/dL; HCT = 16.3 %; MCV = 101 fL; MCHC = 34.1 g/dL; PLT = 184 × 10E9/L; and RDW = 20 %.

(PERIPHERAL BLOOD, WRIGHT-GIEMSA)

CASE DISCUSSION: SICKLE CELL DISEASE WITH ACUTE PAIN CRISIS

Sickle cell disease is a term that describes an inherited group of disorders that share the presence of abnormal, sickle-shaped RBCs. Sickle cell anemia is characterized by two copies of mutant hemoglobin S, whereas sickle cell disease is a broader term that includes sickle cell anemia and conditions characterized by one copy of mutant hemoglobin S and a second mutated hemoglobin (other than hemoglobin S). On the contrary, sickle cell trait is characterized by one copy of hemoglobin S and one normal copy of the beta globin gene. Sickle cell trait is a mostly benign carrier condition with normal CBC indices and peripheral blood appearance. This case focuses on sickle cell anemia, which is the most common monogenic disorder in the world, with approximately 300,000 people born each year with this disease.

Hemoglobin S results from a single point mutation in beta globin gene that changes the 6th amino acid in the protein, glutamine, to a valine. When both copies of the beta-globin gene carry this mutation (sickle cell anemia), this mutant beta globin protein combines with normal alpha globin to produce hemoglobin S. Hemoglobin S has reduced oxygen carrying capacity and polymerizes when deoxygenated, resulting in physical deformation of the red blood cell to a characteristic ‘sickle’ shape. ‘Sickled’ red blood cells have decreased deformability and are therefore predisposed to occlude small blood vessels, resulting in many of the clinical findings of sickle cell anemia including acute pain crisis.

The clinical manifestations of sickle cell disease are variable and affect many different organ systems; common and serious manifestations include acute painful episodes, acute chest syndrome, stroke, anemia, splenic infarcts predisposing to functional asplenia and sepsis from encapsulated organisms, and many others. Clinical symptoms predominantly arise as either acute or chronic sequelae of vaso-occlusion. Acute pain crisis, also known as acute pain episodes, are one of the most common complications of vaso-occlusion in sickle cell disease. The patient’s assessment of their pain is the only measurement of this event; there is no correlation between pain and laboratory findings such as hemoglobin level or level of hemolysis. Treatment is individualized for each patient and variable. Importantly, acute pain episodes can co-occur with other life-threatening complications of sickle cell disease, and thorough evaluation for these complications is warranted in addition to treatment of pain.

The diagnosis of sickle cell anemia is typically made in adults by high performance liquid chromatography (HPLC). HPLC separates hemoglobin variants based on protein charge and is very effective at differentiating the majority of common hemoglobin variants. Newborn screening programs also exist in some jurisdictions and often employ HPLC-based methodology, potentially with confirmatory isoelectric focusing or DNA-based testing. High-voltage capillary electrophoresis and thin-layer isoelectric focusing are two additional methods that can be employed to identify hemoglobin S based on differences in protein charge. Metabisulfite or dithionite testing (reagents used to precipitate hemoglobin S *in vitro*) has largely been supplanted by HPLC and related methods and is generally not in routine clinical use in the hematology laboratory. However, these assays are routinely used in blood banks and transfusion services to determine which donors carry sickle cell trait so hemoglobin S-containing positive blood donations can be transfused to the appropriate patient population.

Review of the peripheral blood smear show characteristic findings in sickle cell anemia, including the presence of sickled red cells, anemia, and polychromasia due to a reticulocytosis in response to chronic hemolytic anemia. Other findings such as Howell-Jolly bodies and RBC anisocytosis are frequently present and are due to hyposplenism that has resulted from splenic auto-infarction secondary to repeated vaso-occlusion by sickle cells.

Philipp W. Raess, MD, PhD
Hematology and Clinical Microscopy Committee

References:

1. Azar S, Wong TE. Sickle cell disease: a brief update. *Med Clin North Am*. 2017;101(2):375-393.
2. McPherson RA, Pincus MR. *Henry's Clinical Diagnosis and Management by laboratory Methods*. 22nd ed. Saunders; 2011.
3. Piel FB, Steinberg MH, Rees DC. Sickle cell disease. *N Engl J Med*. 2017;376(16):1561-1573.

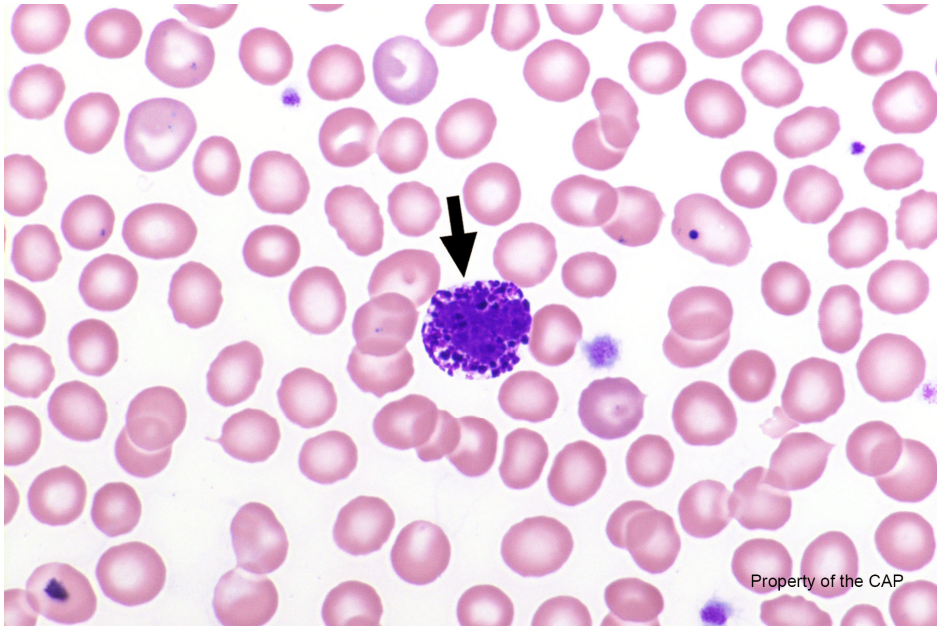
Blood Cell Identification – Ungraded

Case History
This peripheral blood smear is from a 76-year-old Japanese woman diagnosed with bladder cancer and history of mature T-cell leukemia/lymphoma. Laboratory data include: WBC = 51.2 × 10E9/L; RBC = 3.69 × 10E12/L; HGB = 12.2 g/dL; HCT = 35.9 %; MCV = 97 fL; MCHC = 34.2 g/dL; PLT = 108 × 10E9/L; and RDW = 16 %. Identify the arrowed object(s) on each image.

(PERIPHERAL BLOOD, WRIGHT-GIEMSA)

To access the online Hematology Glossary, please click the hyperlink below:
https://documents.cap.org/documents/2021-hematology-and-clinical-microscopy-glossary.pdf

BCP-16

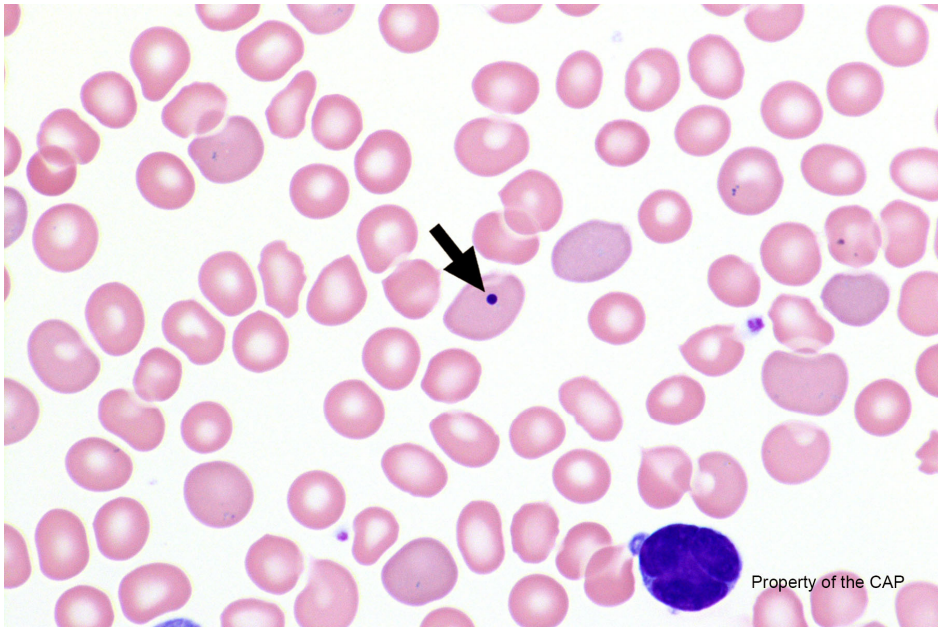


Identification	Referees		Participants		Evaluation
	No.	%	No.	%	
Basophil, any stage	183	98.9	5470	99.6	Educational
Basophilic stippling (coarse)	2	1.1	16	0.3	Educational

The arrowed cell is a basophil, as correctly identified by 98.9% of referees and 99.6% of participants. Basophils are characterized by the presence of numerous coarse and densely stained granules of varying sizes and shapes. The granules are larger than the granules of neutrophils, and most are roughly spherical. The granules are typically blue-black, but some may be purple-red when stained using Wright-Giemsa preparations. The granules are unevenly distributed and frequently overlay and obscure the nucleus. Basophils are comparable in size to neutrophils, ie, 10 to 15 µm in diameter, and the nuclear-to-cytoplasmic (N:C) ratio ranges from 1:2 to 1:3. Basophilia may be seen in several contexts, including in association with (but not limited to) myeloproliferative neoplasms, in hypersensitivity reactions, with hypothyroidism, iron deficiency, and renal disease.

Blood Cell Identification – Ungraded

BCP-17

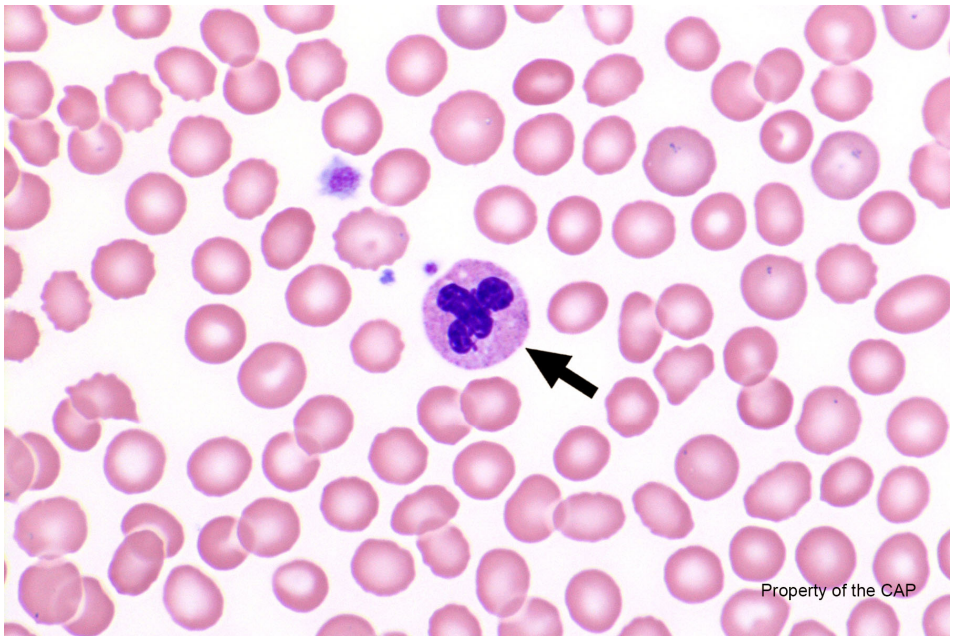


Identification	Referees		Participants		Evaluation
	No.	%	No.	%	
Howell-Jolly body	183	98.9	5350	98.6	Educational
Pappenheimer bodies (iron or Wright stain)	1	0.5	25	0.5	Educational
Platelet, normal	1	0.5	10	0.2	Educational

The arrowed object is a Howell-Jolly body, as correctly identified by 98.9% of referees and 98.6% of participants. Howell-Jolly bodies are small, round, dark purple homogeneous masses that measure about 1 µm in diameter. They are larger, more rounded and darker staining than Pappenheimer bodies and are composed of DNA. They are formed in the process of red blood cell nuclear karyorrhexis or when an aberrant chromosome becomes separated from the mitotic spindle and remains behind after the rest of the nucleus is extruded. Normally, the spleen is very efficient in removing Howell-Jolly bodies from red blood cells, but if the spleen is missing or hypofunctional, they may be readily found in the peripheral blood. Howell-Jolly bodies are usually present singly in a given red blood cell. Multiple Howell-Jolly bodies within a single red blood cell are less common and are typically seen in megaloblastic anemia.

Blood Cell Identification – Ungraded

BCP-18



Identification	Referees		Participants		Evaluation
	No.	%	No.	%	
Neutrophil, segmented or band	175	94.6	5010	92.4	Educational
Neutrophil, Toxic (to include toxic granulation and/or Döhle bodies, and/or toxic vacuolization)	8	4.3	236	4.3	Educational
Neutrophil with hypersegmented nucleus	1	0.5	56	1.0	Educational
Neutrophil necrobiosis (degenerated neutrophil)	1	0.5	21	0.4	Educational

The arrowed cell is a neutrophil, as correctly identified by 94.6% of referees and 92.4% of participants. Segmented neutrophils are the predominant blood leukocyte. They are about 10 to 15 µm in diameter, round to oval, and display pale pink cytoplasm with specific granules. The N:C ratio is 1:3, and the nuclear chromatin is highly condensed. The nucleus is segmented or lobated, with a normal range of three to five lobes. The lobes are connected by a thin filament that contains no internal chromatin, giving it the appearance of a solid, dark, thread-like line. For the purposes of proficiency testing, it is not required that segmented or band neutrophils be differentiated.

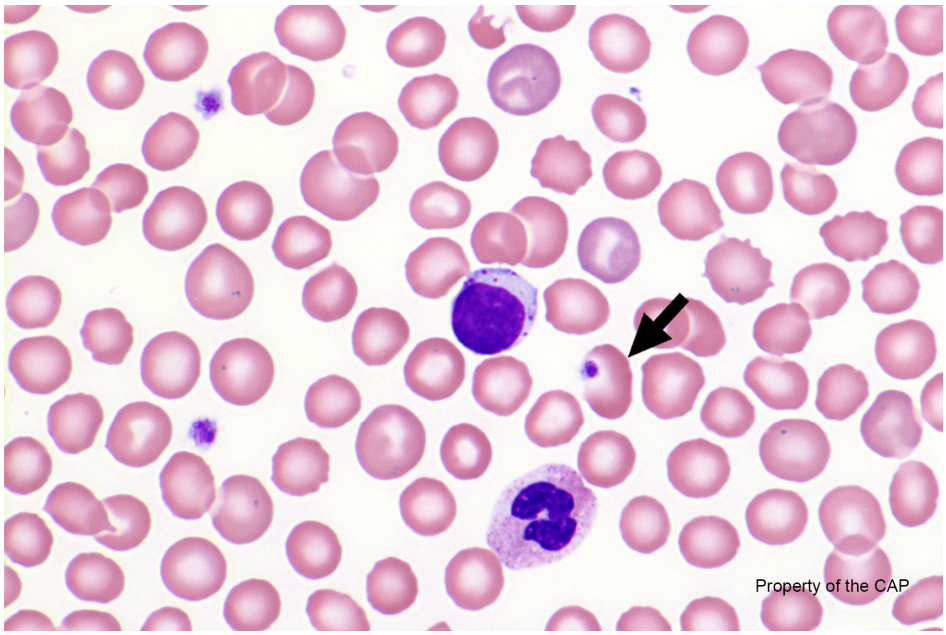
A minority of laboratories (4.3% of referees and 4.3% of participants) identified this cell as a toxic neutrophil. Toxic changes in neutrophils include toxic granulation, toxic vacuolization, and Döhle bodies. Toxic granulation and Döhle bodies each may be present in an individual cell without the other finding. Either change alone is sufficient to designate a neutrophil as toxic. Toxic granulation is defined by the presence of large, purple or dark blue cytoplasmic granules in neutrophils, bands, and metamyelocytes. In this cell ID, the vacuoles are not prominent and Döhle bodies are not seen. The granules here are not large, prominent, nor deeply stained enough to be considered toxic by the committee members. Admittedly, it can be challenging to make that determination on a single photomicrograph, and it is best to review the entire slide and assess the overall granulation of neutrophils.

BCP-18, cont'd.

Around 1.0% of participants responded with "neutrophil with hypersegmented nucleus." This is not the intended response and is not acceptable. Neutrophils qualify as hypersegmented when they contain six or more lobes. Hypersegmented neutrophils are uncommon unless there is megaloblastic hematopoiesis. In the clinical vignette, the MCV would not qualify as indicative of megaloblastic hematopoiesis, though it is at the upper limit of the normal reference range at 97 fL.

Blood Cell Identification – Ungraded

BCP-19



Identification	Referees		Participants		Evaluation
	No.	%	No.	%	
Erythrocyte with overlying platelet	175	94.6	5114	94.3	Educational
Ovalocyte (elliptocyte)	5	2.7	129	2.4	Educational
Erythrocyte, normal	2	1.1	30	0.6	Educational
Howell-Jolly body	2	1.1	53	1.0	Educational
Platelet, normal	1	0.5	39	0.7	Educational

The arrowed cell is an erythrocyte with an overlying platelet, as correctly identified by 94.6% of referees and 94.3% of participants. Platelets may adhere to or overlap red blood cells; this appearance may mimic a red blood cell inclusion (such as a Howell-Jolly body) or parasite. A correct interpretation depends on carefully examining the morphology of the platelet and comparing the size, staining characteristics, and granularity with known platelets in the same field, as well as determining whether the platelet is in the same plane of focus as the red blood cell. Many times, the platelet is surrounded by a thin clear zone or halo (as in this case), which is not a feature of most genuine red blood cell inclusions.

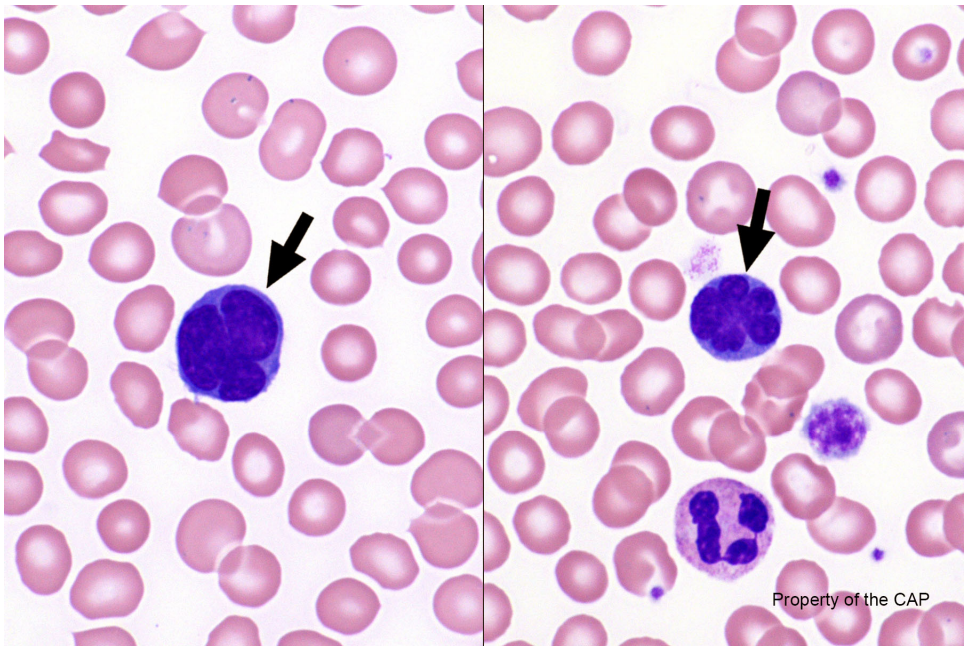
Several referees (2.7%) and participants (2.4%) incorrectly identified this cell as an ovalocyte or elliptocyte. These red cells appear in the shape of a pencil or a thin cigar, with blunt ends and parallel sides. Though the arrowed cell appears somewhat elongated, the hemoglobin is not concentrated at the ends, as it would be in the case of an elliptocyte/ovalocyte. Furthermore, elliptocytes/ovalocytes are commonly increased in cases of iron deficiency or hereditary elliptocytosis. The normal MCV and hemoglobin presented in the clinical vignette for this patient would not support iron deficiency anemia. Hereditary elliptocytosis would have normal red cell indices, but elliptocytes would represent a significant percentage of all red cells (>25% of red cells would be elliptocytes). In this photomicrograph, the red blood cells are predominantly normocytic and normochromic, with only a few poikilocytes.

BCP-19, cont'd.

Around 1.1 % of referees and 1.0% of participants erroneously identified this as a Howell-Jolly body. Howell-Jolly bodies are small (1 μm in diameter), round, dark purple homogeneous masses. They are composed of DNA, formed in the process of red blood cell nuclear karyorrhexis or when an aberrant chromosome becomes separated from the mitotic spindle and remains behind after the rest of the nucleus is extruded. As previously mentioned, red cell inclusions (like a Howell-Jolly body) can superficially resemble the intended response (ie, erythrocyte with an overlying platelet). This particular platelet overlying a red blood cell appears round and mostly homogeneous, mimicking a Howell-Jolly body. Upon closer inspection, however, the contours of the platelet are round, but ill-defined, and there is a hint of a pale blue clear peripheral region (ie, hyalomere) next to the darker central region (ie, granulomere) of the platelet. Lastly, the overlying platelet is surrounded by a clear zone or a halo (as in this case), which is not a feature of genuine red blood cell inclusions.

Blood Cell Identification – Ungraded

BCP-20



Identification	Referees		Participants		Evaluation
	No.	%	No.	%	
Malignant lymphoid cell (other than blast)	149	80.5	4212	77.7	Educational
Immature or abnormal cell, would refer for identification	14	7.6	307	5.7	Educational
Lymphocyte, reactive (includes plasmacytoid and immunoblastic forms)	11	6.0	366	6.8	Educational
Monocyte	3	1.6	54	1.0	Educational
Blast	2	1.1	159	2.9	Educational
Lymphocyte	2	1.1	131	2.4	Educational
Metastatic tumor cell	2	1.1	21	0.4	Educational
Megakaryocyte (normal, abnormal, or nuclear fragment)	1	0.5	31	0.6	Educational
Monocyte, immature (promonocyte, monoblast)	1	0.5	47	0.9	Educational

The arrowed cells are malignant lymphoid cells, as correctly identified by 80.5% of referees and 77.7% of participants. Lymphoma cells exhibit a variety of appearances depending on the lymphoma subtype, and definitive diagnosis can be difficult. Regarding the present case, however, these cells have such a characteristic morphology as to raise high suspicion for adult T-cell leukemia/lymphoma (ATLL). These so-called “flower cells” feature deeply convoluted nuclear contours which mimic flower petals or a clover-leaf pattern. The chromatin in these cells is coarsely clumped, with variably visible nucleoli. Some cells may display finely textured, blast-like chromatin. The cytoplasm is typically scant and basophilic. Supplemental studies, such as immunophenotyping, are necessary to arrive at a diagnosis.

BCP-20, cont'd.

Although these "flower-like cells" are technically lymphocytes (as classified by 1.1% of referees and 2.4% of participants), the best response is "malignant lymphoid cells." In reviewing the clinical vignette that was provided, this patient of Japanese ancestry has a history of mature T-cell leukemia/lymphoma. In the context of these abnormal cells, this clinical history provided should raise one's suspicion for a particular lymphoma (see the Continuing Education material for further discussion). The designation of "lymphocyte" or "lymphocyte, reactive (includes plasmacytoid and immunoblastic forms)" [erroneously identified by 6.0% of referees and 6.8% of participants presumes that such cells are non-neoplastic. The key distinguishing feature of reactive lymphocytes is their wide range of cellular sizes and shapes, as well as nuclear sizes, shapes, and chromatin patterns. This feature is a reflection of lymphocytes reacting to an immune stimulus and are frequently increased in viral illnesses. In contrast, while lymphoma cells can exhibit a wide range of morphologic appearances, any individual case tends to show a more monotonous population of abnormal cells. In this photomicrograph, although the 2 lymphoma cells vary in size (the one on the left is larger than the one on the right), the Committee contends that the two cells are actually strikingly similar in their flower-like nuclear contours, coarsely clumped chromatin, and scant basophilic cytoplasm. Another important distinction between a reactive lymphocyte versus lymphoma cell is the difference in their N:C ratios. The N:C ratio tends to be low in reactive lymphocytes, while it is high in lymphoma cells.

Around 7.6% of referees and 5.7% of participants responded with "immature or abnormal cell, would refer", indicating that this necessitates a pathology consultation. This is an acceptable response, given the challenging identification.

Approximately 1.1% of referees and 2.9% incorrectly identified these cells as blasts. Lymphoblasts, in particular, can exhibit a spectrum of chromatin quality, from finely dispersed to dense chromatin. On the other hand, a case of acute lymphoblastic leukemia with occasionally dense chromatin, will almost always feature blasts with finely textured chromatin. In this particular mature T-cell leukemia/lymphoma (information provided in the clinical vignette), blast-like cells can sometimes be observed, however, the arrowed cells shown here uniformly display mature, coarsely clumped chromatin. In addition, the deep flower-petal nuclear convolutions observed here are quite unusual for lymphoblasts.

Lastly, 1.6% of referees and 1.0% of participants mistakenly identified these lymphoma cells as monocytes. Although monocyte nuclear contours can be variable (from looking like a three-pointed hat to being folded or band-like), they are never as deeply convoluted as these lymphoma cells. Monocytic chromatin is condensed and cytoplasm is gray or gray-blue, and abundant; in contrast, these lymphoma cells have coarsely clumped chromatin and only sparse cytoplasm.

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.

COLLEGE of AMERICAN PATHOLOGISTS

Don’t Miss Out on This Opportunity to Earn Continuing Education Credit

***** Enter the information below and distribute to your laboratory staff. *****

Program Mailing and Year:	FH (1-4, 6, 9-10, 13,16)-B 2021
Activity Start Date:	June 14, 2021
Activity Expiration Date:	June 13, 2022

How to Access Your Online Education Activities

1. **Access Your Account**
   a. Go to cap.org and click **Login**.
   b. **If you are associated with one laboratory** that purchased kits for this activity, the system will register you into the activity. A kit will be associated to your registration.
   c. **If you are associated with more than one laboratory** that purchased kits for this activity, you will need to select the laboratory by clicking the **Select or Change Laboratory** button. The system will register you into the activity. A kit will be associated to your registration.
   d. **If you are not associated with a laboratory**, you need to add a laboratory affiliation by following these steps:
      - Under the **Login** menu, click **Update My Profile**.
      - Click the **Business/Professional** tab.
      - Click **+ Add Affiliation.**

2. **Access Your Online Education Activities**
   a. Go to cap.org and click **Login**.
   b. Enter your User ID and Password.
   c. Click on the **Learning** from the menu bar.
   d. Enter the Program code in the Search box (eg, BMD, CGL), then click the magnifying glass.
   e. Click **Register.**
   f. Review the **Activity Overview** page.
   g. Click the confirmation checkbox at the bottom of the **Activity Overview** page.
   h. If you choose to return to the activity later, it can be found on the **In-Progress Learning** tab. Click the activity title to return to the activity.

Important: Before viewing review the System Requirements page on cap.org. Pop-up blockers must be turned off to complete the activity.

For assistance, call the Customer Contact Center at 800-323-4040 or 847-832-7000 option 1.

Continuing Education Information

CE (Continuing Education for non-physicians)
The CAP designates this educational activity for a maximum of 1 credit of continuing education. Participants should only claim credit commensurate with the extent of their participation in the activity.

The American Society for Clinical Pathology (ASCP) Board of Certification (BOC) Certification Maintenance Program (CMP) accepts this activity to meet the continuing education requirements.

This activity is approved for continuing education credit in the states of California and Florida.

Disclosure Statement

The following authors/planners have no financial relationships to disclose:
None

The following authors/planners have financial relationships to disclose:

Author	Commercial Interest	Your Role	What was received
Maria (Ria) Vergara-Lluri, MD, FCAP	*Chronos Health, Inc.*	*Advisory Board Member*	*Grant*

The following In-Kind Support has been received for this activity:
None

The following Commercial Support has been received for this activity:
None

All speakers/authors of a CAP educational activity must disclose to the program audience any proprietary entity producing, marketing, reselling or distributing health care goods or services consumed by, or used on patients that may be discussed in the educational activity or with any proprietary entity producing, marketing, reselling, or distributing health care goods or services consumed by, or used on patients that is directly competitive with a product discussed in the presentation. Relevant financial relationships are considered to be any financial relationships in any amount occurring within the past 12 months that create a conflict of interest.

The College of American Pathologists does not view the existence of these interests or uses as implying bias or decreasing the value to participants. The CAP feels that this disclosure is important for the participants to form their own judgment about each presentation.

All College educational activities hold to the highest standards of educational quality and are dedicated to promoting improvement in healthcare quality and not a specific proprietary business interest of a commercial interest. All recommendations and/or planning criteria involving clinical medicine are based on evidence that is accepted within the profession of medicine as adequate justification for this indication and contraindication in the care of patients.

Learning Objectives

1. Describe the diagnostic criteria of adult T-cell leukemia/lymphoma (ATLL), including the classification of clinical subtypes.
2. Identify the clinical, morphologic, and common laboratory features of ATLL.
3. Recognize the essential role of HTLV-1 infection in the pathogenesis of ATLL.
4. Describe the utility of common laboratory tests used to confirm and further investigate cases of ATLL, including flow cytometry, cytogenetics, and molecular sequencing.

FH (1-4, 6, 9-10, 13, 16)-B 2021: Adult T-Cell Leukemia/Lymphoma

Case Presentation

This peripheral blood smear is from a 76-year-old Japanese woman diagnosed with bladder cancer and history of mature T-cell leukemia/lymphoma. Laboratory data include: WBC = 51.2 x 10E9/L; RBC = 3.69 x 10E12/L; HGB = 12.2 g/dL; HCT = 35.9%; MCV = 97 fL; MCHC = 34.2 g/dL; PLT = 108 x 10E9/L; and RDW = 16%.

(PERIPHERAL BLOOD, WRIGHT-GIEMSA)

INTRODUCTION

Adult T-cell leukemia/lymphoma (ATLL) is a rare, mature T-cell lymphoma that is associated with infection by human T-cell lymphotropic virus type 1 (HTLV-1). It displays protean clinical presentations, and its severity and prognosis depend on these clinical variants. Unfortunately, most cases (around 80%) demonstrate poor clinical behavior with few therapeutic interventions. Patients suffer from opportunistic infections, suggesting a component of immunodeficiency in this lymphoma.

Epidemiology

HTLV-1 infection plays an essential role in the development of ATLL. As many as 10 million people worldwide are affected by the retrovirus in Japan, the Caribbean Basin, Africa, Central and South America, Romania, and northern Iran. The incidence of HTLV-1 infection is highest in Japan, with 27 persons infected per 100,000 individuals. Notably, only 1% to 5% of those with HTLV-1 infection will eventually develop ATLL. In contrast, in the United States, ATLL is observed mostly in individuals who have immigrated from endemic regions, with an approximate incidence of five persons with ATLL per 10 million individuals. A slight male predominance is observed in ATLL (male-to-female ratio of 1.5:1.0).

Pathogenesis

Transmission of the HTLV-1 retrovirus is thought to occur through breastmilk (from mother to child), sexual intercourse, and blood transfusion. Carriers of the HTLV-1 infection do not uniformly progress to malignancy; as previously mentioned, only 1% to 5% of carriers go on to develop ATLL. Thus, the virus itself is insufficient to produce malignant transformation. However, the long duration of HTLV-1 infection promotes other molecular events to induce tumor growth.

Interestingly, HTLV-1 infection can also lead to other non-neoplastic disorders, including HTLV-1 associated myelopathy (tropical spastic paraparesis), HTLV-1 associated infective dermatitis, and other HTLV-1 inflammatory disorders (eg, uveitis, thyroiditis, pneumonitis, myositis).

Clinical Features

Four clinical variants or subtypes are recognized. The aggressive variants are the acute and lymphomatous subtypes, while the more favorable variants are chronic and smoldering. Most cases of ATLL (60%) present as the acute variant, followed by lymphomatous (20%), chronic (15%), and smoldering (5%). Opportunistic infections are common in all types of ATLL, and include infections with *Pneumocystis carinii, Strongyloides stercoralis*, *Cryptococcus neoformans*, and other bacterial and fungal organisms. Cutaneous lesions are frequent and can range from a diffuse, red rash to papules or larger nodules. Some nodules may ulcerate.

The **acute subtype** is characterized by overt peripheral blood leukemic involvement with marked lymphocytosis and the presence of abnormal circulating lymphoma cells. Patients experience constitutional symptoms and display many cutaneous lesions, including nodules and papules. Disseminated lymphoma in multiple organ sites can lead to infiltration of bone marrow, liver, spleen, lung, and other sites; thus, manifestations such as hepatosplenomegaly and cytopenias are common with this variant. Central nervous system (CNS) involvement can be observed. Significant laboratory abnormalities include high levels of serum calcium and lactate dehydrogenase (LDH). The hypercalcemia can be severe. Increased bone osteoclastic activity, evidenced by lytic bone lesions on imaging, can be seen in this subtype.

The **lymphomatous subtype** is typified by extensive lymphadenopathy without significant blood involvement by abnormal lymphocytes. Constitutional symptoms due to widespread lymphomatous involvement in both nodal and extranodal sites (including CNS) can be observed. As with the acute variant, this subtype is clinically aggressive.

The **chronic subtype** is considered one of the less aggressive variants, with mild disease manifestations. While lymphocytosis and circulating lymphoma cells can be seen, and while serum LDH is elevated, the increase is slight in comparison with the acute subtype. Hepatosplenomegaly and lymphadenopathy may be observed, yet these occur only to a mild degree when compared to the lymphomatous subtype. A widespread redness, scaling, and even peeling of the skin over large areas of the body (ie, exfoliative rash) is common in this subtype.

Finally, the **smoldering subtype**, which is the least frequent ATLL clinical subtype, is also categorized as less aggressive. It can be recognized by the presence of circulating lymphoma cells that are greater than 5% of the WBC count, yet is not accompanied by an absolute lymphocytosis. Cutaneous lesions (erythema and papules) and lung involvement are frequent. However, there is no associated hypercalcemia, bone marrow infiltration, lymphadenopathy, or hepatosplenomegaly. Table 1 provides a summary of the findings that are associated with the clinical variants of ATLL.

Table 1. Comparison of the presentation and findings in the clinical variants of ATLL.

		CLINICAL VARIANTS			
Presentation and Findings		**Acute**	**Lymphomatous**	**Chronic**	**Smoldering**
History, Physical Examination, and Imaging Findings	**Systemic symptoms**	+++	+++	+	-
	Skin manifestations (cutaneous lesions)	++	+++	++ exfoliative skin rash	Erythema, papules
	Lymphadenopathy	++	+++	+	-
	Hepatosplenomegaly	++	++	+	-
	Extranodal involvement (eg, lungs, liver, GI tract, CNS)	++	++	+	+/-

		CLINICAL VARIANTS			
Presentation and Findings		**Acute**	**Lymphomatous**	**Chronic**	**Smoldering**
Pertinent Laboratory and Pathology Studies	**Increased absolute lymphocyte count**	+++	-	++	-
	Circulating lymphoma cells	+++ (marked atypia)	< 1% circulating lymphoma cells	+++ (mild atypia)	> 5% circulating lymphoma cells (mild atypia)
	Hypercalcemia	+++	++	-	-
	Increased lactate dehydrogenase	+++	+++	+	-
	Bone marrow findings	+/- involvement Bone remodeling	+/-	No BM infiltration	No BM infiltration
Clinical Behavior	**Prognosis**	Aggressive	Aggressive	Protracted; better survival compared to acute and lymphomatous phases	Protracted; better survival compared to acute and lymphomatous phases

Symbols: -, condition or feature is absent; +/-, condition or feature is observed to a variable degree; +, present to a mild degree or in a minor subset (< 10%) of cases; ++, present to a moderate degree or in a moderately high percentage (10% - 50%) of cases; +++, seen to marked degree or in a high percentage (≥ 50%) of cases.

DIAGNOSIS

Complete blood count and peripheral blood smear evaluation.

The degree of absolute lymphocytosis and/or the presence of the characteristic “flower cells” depend on the clinical subtype. In the acute variant, an absolute lymphocytosis exceeding 4,000/µL is seen in 88% of cases, with half displaying overt lymphocytosis beyond 15,000/µL. Cytologic atypia in the so-called ATLL “flower cells” is striking. Their deeply convoluted nuclear contours are reminiscent of flower petals or a clover-leaf pattern. Chromatin is coarsely clumped with variably visible nucleoli. A subset of cells can display finely textured, blast-like chromatin. The cytoplasm is typically scant and intensely basophilic.

The lymphomatous variant, on the other hand, is defined by extensive lymphadenopathy coupled with the absence of lymphocytosis and scarcity of circulating lymphoma cells (< 1%). Of the more favorable variants, the chronic subtype is the one that displays lymphocytosis as well as greater numbers of circulating lymphoma cells. Lymphocytosis is not observed in the smoldering subtype, though circulating lymphoma cells can account for > 5% of WBCs. The degree of cytologic atypia in both the chronic and smoldering variants is mild, mimicking the appearance of normal lymphocytes.

ANCILLARY STUDIES IN THE DIAGNOSTIC WORK-UP

Flow cytometry is essential in uncovering the distinctive lymphoma immunophenotype. The lymphoma cells are T cells whose closest normal counterpart are T-regulatory cells, which are CD4+, CD25+ T cells. The typical ATLL lymphoma immunophenotype includes expression of T-cell markers CD3, CD2, CD4, and CD5; CD7 expression is typically lost. Though the typical phenotype is that of a CD4+ T cell, other cases may display a double negative (ie, CD4-/CD8-) or double positive (ie, CD4+/CD8+) phenotype. Most exhibit high expression of CD25 (a characteristic but not specific marker for Treg cells), and a significant subset are positive for CD30. On tissue sections, **immunohistochemistry** can be employed to demonstrate T-cell lineage and FOXP3 expression (a transcription factor characteristic of Treg cells).

Regarding other ancillary studies, such as **cytogenetic analysis**, there is no specific karyotypic abnormality ascribed to ATLL. Clonal peaks in PCR studies for T-cell receptor gene rearrangements are invariably present, as they are in most other T-cell lymphomas.

To summarize the diagnostic work-up, the combination of overt lymphocytosis with circulating “flower cells” with a T-regulatory immunophenotype as above, severe systemic manifestations (ie, constitutional symptoms, adenopathy, organomegaly, etc), and positive HTLV-1 serology in an individual from an endemic region are diagnostic of ATLL (particularly the acute subtype).

Table 2 shows some of the salient diagnostic features during the laboratory and pathology work-up for the acute subtype of ATLL.

Table 2. Selected features in the diagnostic laboratory and pathology work-up of acute subtype of ATLL.

Test	Typical Features
CBC with differential	Absolute lymphocytosis; leukemic presentation of lymphoma
Peripheral blood smear	Lymphoma cells with flower-like cytology
HTLV-1 serology	Positive in all cases
Flow cytometry	T-cell marker expression: positive for CD2, CD3, CD4 (typically CD4+/CD8-), CD5, and CD25. Usually negative for CD7. Other cases may have double negative (ie, CD4-/CD8-) or double positive (ie, CD4+/CD8+) T cells.
Skin pathology	Epidermal infiltration with Pautrier-like microabscesses common, mimicking mycosis fungoides
Lymph node pathology	Variable morphology can mimic other lymphoma types. Some cases show paracortical expansion with highly pleomorphic lymphoma cells with Hodgkin-like cytology. Some resemble angioimmunoblastic T-cell lymphoma with EBV+ B-cells.
Bone marrow pathology	Variable lymphomatous infiltration, from sparse to moderate patchy involvement Osteoclastic bone activity
Immunohistochemistry	T-cell marker expression (as in flow cytometry). Also, markers of T-regulatory cells are evident, such as CD25 and FOXP3.
Cytogenetics	No associated pathognomonic karyotypic abnormalities
Molecular	Demonstration of abnormalities is not essential for diagnosis (see text for further discussion)

MOLECULAR SEQUENCING

The demonstration of **molecular abnormalities** is not necessary for the diagnosis of ATLL. However, research studies have shown that the gene, *HBZ* (HTLV-1 basic leucine zipper), is consistently expressed in high levels on all ATLL cases, while *CCR4* mutations are detected in 25%. A large number of other recurrently mutated genes have been discovered, some of them involved in T-cell receptor signaling and regulation of the NF-kappa-B pathway. Other significant abnormalities point to inactivation of the tumor suppressor gene *TP73* (a *TP53* homologue) and aberrations in mechanisms that control genes for important immune system activities; these abnormalities ultimately lead to tumor cells successfully evading the immune system.

Differential Diagnosis

Despite the seemingly characteristic features, not all cases of ATLL "read the textbook." Some ATLL cases can display cytologic, histomorphologic, and immunophenotypic features that are practically indistinguishable from other T-cell lymphomas, such as Sézary syndrome, angioimmunoblastic T-cell lymphoma and other lymphomas of T-follicular helper cell origin, and peripheral T-cell lymphoma. As an example, a widespread erythrodermic skin rash and numerous circulating lymphoma cells with cerebriform morphology in ATLL could clinically and pathologically mimic a case of Sézary syndrome. The key is in recognizing that the patient is from an endemic region and to evaluate for the presence of HTLV-1 infection through serology.

Therapy and prognosis

As discussed previously, the acute and lymphomatous variants behave aggressively, while the chronic and smoldering variants have a more protracted disease course.

For the aggressive variants, several combination chemotherapy regimens have been employed; these can vary geographically and with hematologists' preferences. For example, a specific protocol called VCAP-AMP-VECP is widely adopted in Japan, while other providers prefer CHOP, DA-EPOCH, or other etoposide-based regimens. Other more intensive regimens are being tested in clinical trials. Despite these interventions, ultimately 90% of patients will experience disease recurrence within months of concluding treatment. Patients may die within weeks to months of diagnosis, with only a very few surviving beyond one year. Because of these dismal outcomes, allogeneic stem cell transplantation at first complete remission is an essential consideration for the hematologist/oncologist.

In Japan, a relatively new antibody drug targeted against *CCR4* (an antigen that can be found in T-regulatory cells), mogamulizumab, has been approved for use in the setting of relapsed or persistent ATLL with some promising results. Additional studies using this drug in combination with conventional chemotherapy are underway. Other novel drugs are also being investigated in clinical trials, such as the anti-CD30 monoclonal antibody brentuximab vedotin and checkpoint inhibitors (eg, nivolumab).

Antiviral therapies have been employed with some success in the chronic and smoldering subtypes. Another approach by some practitioners is to monitor these patients and employ watchful waiting. Unfortunately, though typically less aggressive, the chronic and smoldering subtypes do carry a 25% risk for progression to the acute variant.

REFERENCES

1. Cook LB, Phillips AA. How I treat adult T-cell leukemia/lymphoma. *Blood* 2021; 137(4):459-470. doi:10.1182/blood.2019004045.
2. Glassy EF, ed. *Color Atlas of Hematology: An Illustrated Field Guide Based on Proficiency Testing*. 2nd ed. College of American Pathologists; 2018.
3. Khanlari M, Ramos JC, Sanchez SP, et al. Adult T-cell leukemia/lymphoma can be indistinguishable from other more common T-cell lymphomas. The University of Miami experience with a large cohort of cases. *Mod Pathol.* 2018;31(7):1046-1063.
4. Mehta-Shah N, Ratner L, Horwitz SM. Adult T-cell leukemia/lymphoma. *J Oncol Pract.* 2017;13(8):487-492.
5. Shimoyama M, Lymphoma Study Group members. Diagnostic criteria and classification of clinical subtypes of adult T-cell leukaemia-lymphoma: a report from the Lymphoma Study Group (1984-87). *Br J Haematol.* 1991;79(3):428-437.
6. Swerdlow SH, Campo E, Harris NL, et al. *WHO Classification of Tumours of Haematopoietic and Lymphoid Tissues*. Revised 4th ed. IARC Press; 2017.

AUTHOR'S BIOGRAPHY

Maria (Ria) Vergara-Lluri, MD, FCAP, is an assistant professor of clinical pathology at the Keck School of Medicine of USC (University of Southern California) in Los Angeles, California. She serves as the medical director of LAC+USC Medical Center's Core Laboratory Flow Cytometry and Hematology sections and as a staff hematopathologist at USC. Dr. Vergara-Lluri has authored several articles, book chapters, and educational activities, and she serves as a member of the Hematology and Clinical Microscopy Committee for the College of American Pathologists.

NOTES

NOTES

NOTES

This concludes the report.

COLLEGE of AMERICAN PATHOLOGISTS

325 Waukegan Road
Northfield, IL 60093-2750
800-323-4040
847-832-7000 (Country code: 001)