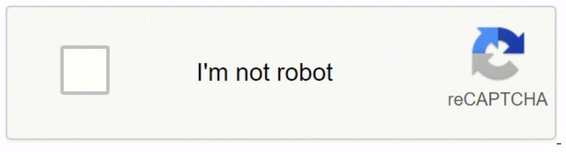
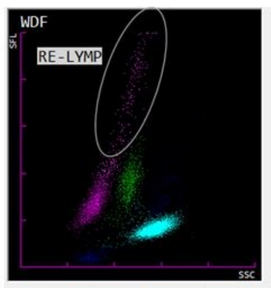


I am not robot!

Sysmex xn 1000 flagging interpretation guide

Sysmex xn 1000 dimensions.



Item	Data	Unit
WBC	9.35	10^3/uL
NEUT#	6.95	10^3/uL
NEUT%	74.3 +	%
LYMPH#	1.69	10^3/uL
LYMPH%	18.1 -	%
RE-LYMP#	0.27	10^3/uL
RE-LYMP%	2.9	%
RE-LYMP%L	16.0	%

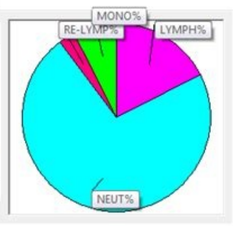


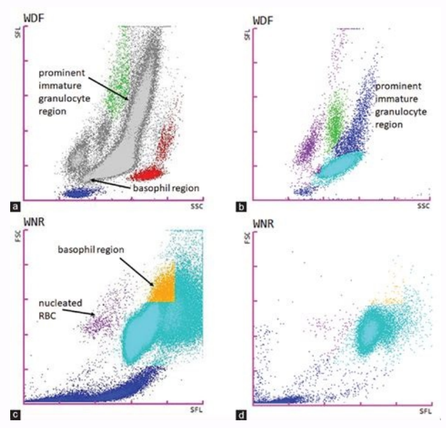
Table 3. Intrainstrumental Variability of the Sysmex XN Module* Explored From 10 Replicates

Flags and Sample No.	Presence of the Related Cells† (Absolute Cell Counts)	Q Values										Mean	Min	Max	SD	CV
		1st	2nd	3rd	4th	5th	6th	7th	8th	9th	10th					
Initial Q values 50–150																
Blasts/abnormal lymphocytes																
S1	Negative	100	90	70	80	80	90	40	30	50	50	68	30	100	21.9	35.2
S2	Negative	90	100	100	100	100	100	100	90	100	90	97	90	100	4.8	5.0
S3	Positive (130/μL)	110	110	130	120	120	100	110	100	100	110	111	100	130	9.9	9.0
Pooled												92.0			35.2	38.6
Blasts																
S4	Negative	120	0	120	100	90	0	110	0	60	40	64	0	120	50.8	79.4
S5	Positive (97/μL)	60	10	150	160	130	120	110	60	100	30	86	10	160	59.1	68.7
S6	Positive (213/μL)	100	100	110	140	120	140	130	100	130	150	122	100	150	16.7	13.4
Pooled												90.7			46.3	51.0
Atypical lymphocytes																
S7	Negative	100	130	120	110	110	90	110	100	110	110	102	70	150	21.0	22.5
S8	Negative	100	130	120	80	100	90	90	120	90	120	104	80	130	17.1	16.5
S9	Positive (106/μL)	90	100	80	70	100	150	120	100	90	120	109	90	130	11.0	10.1
Pooled												105			17.7	16.9
Initial Q values ≥150																
Blasts/abnormal lymphocytes																
S10	Positive (190/μL)	190	300	300	300	300	290	300	300	300	300	256	210	300	28.8	11.2
S11	Positive (386/μL)	290	250	260	250	300	240	300	300	300	300	260	275	240	300	25.1	9.1
S12	Positive (412/μL)	250	210	220	260	300	280	260	280	270	230	298	290	300	4.2	1.4
Pooled												276.3			22.2	8.0
Blasts																
S13	Positive (698/μL)	270	290	300	290	300	260	270	300	230	230	193	160	230	25.8	13.4
S14	Positive (321/μL)	300	300	110	300	120	300	290	290	300	290	260	110	300	76.6	29.5
S15	Positive (272/μL)	230	190	170	230	180	220	200	170	160	180	274	230	300	27.2	9.9
Pooled												242.3			49.2	20.3
Atypical lymphocytes																
S16	Positive (680/μL)	300	300	300	280	300	300	300	300	290	290	292	250	300	16.2	5.5
S17	Positive (395/μL)	300	300	300	300	300	300	300	270	300	300	297	270	300	9.5	3.2
S18	Positive (770/μL)	300	300	280	300	300	300	300	300	300	300	298	280	300	6.1	2.1
Pooled												295.7			11.4	3.9

Abbreviations: CV, coefficient of variation; Max, maximum; Min, minimum.
* Sysmex, Kobe, Japan.
† From the review of peripheral blood smear; blasts for "blast/abnormal lymphocytes" and "blast" flags, and atypical lymphocytes for "atypical lymphocytes."

White Parkway Mundelein, IL 6060 USA Document Number: MKT-40-1010No part of this publication may be reproduced in any form or by any means without prior writtenpermission.One Nelson C. White Parkway, Mundelein, IL 60060 Phone 847-996-4500 · 1-800-3SYSMEX (1-800-379-7639) www.sysmex.comThis Page Left Blank Intentionally.Table of ContentsI. Introduction .....1-1II. WBC IP Messages.....2-1 Abnormal, WBC Abn Scattergram ..... 2-1 Abnormal, NRBC Scattergram ..... 2-1 Abnormal, Blast? ..... 2-2 Suspect, Blast? ..... 2-3 Suspect, Immature Gran?

One Nelson C. White Parkway, Mundelein, IL 60060 Phone 847-996-4500 · 1-800-3SYSMEX (1-800-379-7639) www.sysmex.comThis Page Left Blank Intentionally.One Nelson C. White Parkway, Mundelein, IL 60060 Phone 847-996-4500 · 1-800-3SYSMEX (1-800-379-7639) www.sysmex.comIntroductionObjectivesThe XE-Series Abnormal Specimen Troubleshooting Guide is designed to serve manyobjectives. These include: • providing users with an explanation of criteria used for the XE-Series IP Messages that are not operator programmable. • suggesting actions to be taken when samples generate IP Messages. • suggesting actions to resolve sample related problems.The following sections introduce the IP Messages. Definitions and examples of eachmessage are presented with suggested actions to be taken by qualified personnel toverify the presence of specific cell types and obtain a correct result when interferenceoccurs.Use of the XE-Series Quick Guide (laminated card) with this document will providethe user with a better understanding of IP Message criteria. The Quick Guideincludes the information discussed in this guide in a condensed format along withscattergrams that illustrate where normal and abnormal cells are distributed.Some of these action steps may coincide with procedures previously established andimplemented in a lab. These action steps are merely suggested guidelines and shouldbe used in conjunction with your own laboratory's protocols.IP MessagesThe United States Federal Food and Drug Administration (FDA) classify modernhematology analyzers as Automated Differential Cell Counters (ADCC). The XE-Seriesformat is designed to aid in the separation of specimens into POSITIVE and NEGATIVEcategories according to preset criteria. The system bases its judgments oncomprehensive surveys of numerical data, particle size distributions, scattergrams, andprovides easy-to-understand flags/messages indicating the instruments findings. Theseflags and messages are referred to as Interpretive Program (IP) Messages.A specimen is judged NEGATIVE when there are no predefined abnormalities presentin the specimen. The results are generally reported without review.The XE-Series analyzers will generate a POSITIVE when an Interpretive Program (IP)Message is present. An established review process by lab personnel should beinitiated.POSITIVE or ERROR judgments indicate the possibility of sample abnormality.These results should be reviewed carefully and may require furtherexamination in accordance with the protocol of your laboratory.One Nelson C.
White Parkway, Mundelein, IL 60060 Phone 847-996-4500 · 1-800-3SYSMEX (1-800-379-7639) www.sysmex.comXE-Series Troubleshooting Guide Section 1: IntroductionDocument Number: MKT-40-1010 Decemeber 2008 Page 1 of 2This Page Left Blank Intentionally.One Nelson C.
White Parkway, Mundelein, IL 60060 Phone 847-996-4500 · 1-800-3SYSMEX (1-800-379-7639) www.sysmex.comXE-Series Troubleshooting Guide Section 1: IntroductionDocument Number: MKT-40-1010 Decemeber 2008 Page 2 of 2Abnormal, WBC Abn ScattergramThe WBC Abn Scattergram IP is XE-Series Resultsgenerated whenever clustering inWBC/BASO or DIFF scattergrams is WBC & 48.17 [103/µL]abnormal or when the WBC is RBC 1.77 [106/µL]< 0.5 x 103/µL. [g/dL]Dashes appear in place of data that was HGB 6.1 [%]not calculated. In the example below, HCT 19.6 [fL]clustering failed between the MCV 110.7 [pg]Lymphocytes, Monocytes and the MCH 34.5 [g/dL]Neutrophils, so there are dashes in place MCHC 31.1 [103/µL]of data for these three populations.



One Nelson C. White Parkway, Mundelein, IL 60060 Phone 847-996-4500 · 1-800-3SYSMEX (1-800-379-7639) www.sysmex.comThis Page Left Blank Intentionally.One Nelson C. White Parkway, Mundelein, IL 60060 Phone 847-996-4500 · 1-800-3SYSMEX (1-800-379-7639) www.sysmex.comIntroductionObjectivesThe XE-Series Abnormal Specimen Troubleshooting Guide is designed to serve manyobjectives. These include: • providing users with an explanation of criteria used for the XE-Series IP Messages that are not operator programmable. • suggesting actions to be taken when samples generate IP Messages. • suggesting actions to resolve sample related problems.The following sections introduce the IP Messages. Definitions and examples of eachmessage are presented with suggested actions to be taken by qualified personnel toverify the presence of specific cell types and obtain a correct result when interferenceoccurs.Use of the XE-Series Quick Guide (laminated card) with this document will providethe user with a better understanding of IP Message criteria. The Quick Guideincludes the information discussed in this guide in a condensed format along withscattergrams that illustrate where normal and abnormal cells are distributed.Some of these action steps may coincide with procedures previously established andimplemented in a lab. These action steps are merely suggested guidelines and shouldbe used in conjunction with your own laboratory's protocols.IP MessagesThe United States Federal Food and Drug Administration (FDA) classify modernhematology analyzers as Automated Differential Cell Counters (ADCC). 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White Parkway, Mundelein, IL 60060 Phone 847-996-4500 · 1-800-3SYSMEX (1-800-379-7639) www.sysmex.comXE-Series Troubleshooting Guide Section 1: IntroductionDocument Number: MKT-40-1010 Decemeber 2008 Page 1 of 2This Page Left Blank Intentionally.One Nelson C. White Parkway, Mundelein, IL 60060 Phone 847-996-4500 · 1-800-3SYSMEX (1-800-379-7639) www.sysmex.comXE-Series Troubleshooting Guide Section 1: IntroductionDocument Number: MKT-40-1010 Decemeber 2008 Page 2 of 2Abnormal, WBC Abn ScattergramThe WBC Abn Scattergram IP is XE-Series Resultsgenerated whenever clustering inWBC/BASO or DIFF scattergrams is WBC & 48.17 [103/µL]abnormal or when the WBC is RBC 1.77 [106/µL]< 0.5 x 103/µL. [g/dL]Dashes appear in place of data that was HGB 6.1 [%]not calculated. In the example below, HCT 19.6 [fL]clustering failed between the MCV 110.7 [pg]Lymphocytes, Monocytes and the MCH 34.5 [g/dL]Neutrophils, so there are dashes in place MCHC 31.1 [103/µL]of data for these three populations. PLT 200 [fL] Figure 1: WBC/BASO Scattergram RDW-SD 81.8 [%] RDW-CV 21.0 [fL] MPV 11.2 [%] RET% 1.99 [10^6/µL] RET# 0.0352 [ratio] IRF 0.322 [103/µL] NRBC# 1.30 [/100 WBC] NRBC% 2.7 [103/µL] NEUT# —— [103/µL] —— [103/µL] LYMPH# —— [103/µL] MONO# 0.03 * [103/µL] EO# 0.54 * [%] BASO# [%] —— [%] NEUT% —— [%] LYMPH% —— [%] MONO% 0.1 * EO% 1.1 * BASO% An ampersand (&) to the left of the WBC data indicates that the WBC was corrected for the presence of NRBCs.Figure 2: DIFF Scattergram Suggested Action Steps: Figure 3: IMI Scattergram 1. Dashes (— —) in place of data: • perform a manual differential according to your laboratory's policy 2. Asterisk (*) next to data: • scan the slide for abnormal cells • perform a manual differential if abnormal cells are observed • if no abnormalities are found, the data with asterisks (*) can be reportedOne Nelson C. White Parkway, Mundelein, IL 60060 Phone 847-996-4500 · 1-800-3SYSMEX (1-800-379-7639) www.sysmex.comXE-Series Flagging Interpretation Guide Section 2: WBC IP MessagesDocument Number: MKT-40-1010 December 2008 Page 1 of 12Abnormal, NRBC Abn ScattergramThe NRBC Abn Scattergram IP Message XE-Series Results (continued)can only be generated when a NucleatedRed Blood Cell (NRBC) test is performed NEUT# 4.43 * [103/µL]on the XE-Series analyzer. This IP occurs 1.02 * [103/µL]when clustering in the NRBC scattergram is LYMPH# 0.61 * [103/µL]abnormal. MONO# 0.35 * [103/µL] EO# 0.07 * [103/µL]Dashes appear in place of data for the BASO# [%]NRBC # and NRBC%. An asterisk (*) NEUT% 68.4 * [%]displays beside the uncorrected WBC LYMPH% 15.7 * [%]and all differential parameters. The MONO% 9.4 * [%]asterisk (*) indicates these results are EO% 5.4 * [%]unreliable if abnormalities are found BASO% 1.1 *during the laboratory's review of thesample. Suggested Action Steps: Figure 4: NRBC Scattergram 1. Scan the peripheral smear for the presence of abnormal morphology: XE-Series Results 6.48 * [103/µL] • NRBCsWBC [106/µL] • WBCs (i. e. abnormal lymphocytes,RBC 3.72 immature lymphocytes, orHGB 10.4 [g/dL] lymphoblasts or very small lymphocytes)HCT 31.6 [%] • platelet clumps or other abnormalities 2. If after reviewing the smear, NRBCsMCV 84.9 [fL] are not present:MCH 28.0 [pg] • and if no abnormal WBCs are seen, report the WBC and DIFFMCHC 32.9 [g/dL]PLT 317 [103/µL] • or if abnormal WBCs are seen, perform a manual differentialRDW-SD 48.7 [fL] according to your laboratory's policy, and report the WBC according to theRDW-CV 15.6 [%] instrumentMPV 9.5 [fL] 3. If after reviewing the smear, NRBCs are present:RET% 1.05 [%]RET# 0.0391 [106/µL] • perform a manual differential according to your laboratory's policy,IRF 0.082 [ratio] enumerating the NRBCs seen.NRBC# —— [106/µL] • convert the manual NRBC count toNRBC% — — [/100 WBC] the number seen per 100 WBCs. • correct the WBC count for the presence of NRBCs counted by using the following formula: Corrected WBC =Uncorrected WBC x 100 100 + # of NRBC/100 WBC • Report the corrected WBC count, the manual differential and the manual NRBC count.One Nelson C. White Parkway, Mundelein, IL 60060 Phone 847-996-4500 · 1-800-3SYSMEX (1-800-379-7639) www.sysmex.comXE-Series Flagging Interpretation Guide Section 2: WBC IP MessagesDocument Number: MKT-40-1010 December 2008 Page 2 of 12Suspect, Blast?The Blast? IP indicates that the XE-Series Resultsinstrument has detected abnormalclustering in the region for blasts in the WBC 18.40 [103/µL]IMI and/or DIFF scattergram.
RBC 3.90 [106/µL] [g/dL]An asterisk (*) appears next to the HGB 11.2 [%]Neutrophil, Lymphocyte and HCT 33.9 [fL]Monocyte % and #. The asterisk (*) MCV 86.9 [pg]indicates these results are unreliable if MCH 28.7 [g/dL]abnormalities are found during the MCHC 33.0 [103/µL]laboratory's review of the sample. PLT 55 [fL]It is common for the Blast? IP to occur RDW-SD 44.9 [%]with WBC Abn Scattergram. For this RDW-CV 14.3 [fL]reason, the DIFF scattergram is MPV 10.1 [%]abnormal and the data is replaced with RET% 0.26 [106/µL]dashes instead of having asterisks to RET# 0.0101right. [ratio] IRF 0.166 [106/µL] NRBC# 0.00 [/100 WBC] NRBC% 0.0 [103/µL] NEUT# —— [103/µL] —— [103/µL] LYMPH# —— [103/µL] MONO# 0.0 [103/µL] EO# 0.07 [%] BASO# [%] —— [%] NEUT% —— [%] LYMPH% —— [%] MONO% 0.0 EO% 0.4 BASO%Figure 5: DIFF Scattergram Suggested Action Steps: 1. Scan the peripheral smear, especially the feathered edge and sides of the peripheral smear, for the presence of: • blasts – lymphoblasts, myeloblasts, and myelomonoblastsFigure 6: IMI Scattergram • immature granulocytes – promyelocytes, myelocytes, metamyelocytes and bands • atypical or immature lymphocytes • other abnormal cells 2. If abnormal cells are noted or there are dashes in place of data, perform a manual differential according to your laborabory's policy. Report according to individual laboratory criteria. 3. If no abnormalities are found, the data with the asterisk (*) can be reported.One Nelson C. White Parkway, Mundelein, IL 60060 Phone 847-996-4500 · 1-800-3SYSMEX (1-800-379-7639) www.sysmex.comXE-Series Flagging Interpretation Guide Section 2: WBC IP MessagesDocument Number: MKT-40-1010 December 2008 Page 3 of 12IG Present/Immature Gran?XE-2100 analyzers that have the XE-Series ResultsIG Master software can generatequantitative Immature Granulocyte WBC & 19.40 [103/µL]results. The IG Present flag is user- RBC 2.85 [106/µL]defined and is generated when the IG%or IG# exceed the user-defined value. HGB 8.6 [g/dL] HCT 25.0 [%]In cases where the instrument has MCV 87.7 [fL]detected abnormal clustering in the MCH 30.2 [pg]region for immature granulocytes in the MCHC 34.4 [g/dL]IMI and/or DIFF scattergrams, the PLT 58 [103/µL]IG Present flag is replaced withImmature Gran? IP . RDW-SD 50.5 [fL] RDW-CV 16.2 [%]In these cases an asterisk (*) appears MPV 13.3 [fL]next to the Neutrophil, Eosinophil and RET% 2.43 [%]Basophil % and #. The asterisk (*) RET# 0.0693 [106/µL]indicates these results are unreliable ifabnormalities are found during the IRF 0.449 [ratio]laboratory's review of the sample. NRBC# 1.81 [106/µL] NRBC% 9.3 [/100 WBC] NEUT# 14.38 * [103/µL] [103/µL] LYMPH# 1.41 [103/µL] MONO# 1.98 [103/µL] EO# 0.86 * [103/µL] BASO# 0.38 * [%] NEUT% 74.1* [%] LYMPH% 7.3 [%] MONO% 10.2 [%] EO% 4.4 * [%] BASO% 2.0 * [%] IG% 2.0* [103/µL] IG# 0.39*Figure 7: DIFF Scattergram Suggested Action Steps: Figure 8: IMI Scattergram When Immature Gran? Flag is present and the IG% or IG# has an asterisk (*): 1. Scan the peripheral smear for the presence of: • immature granulocytes – promyelocytes, myelocytes and metamyelocytes • band cells in increased numbers • toxic granulation or vacuolation of neutrophils • other abnormal cells 2. If abnormal cells are noted, perform a manual differential. Report according to individual laboratory criteria. 3. If no abnormalities are found, the data with the asterisk (*) can be reported.One Nelson C. White Parkway, Mundelein, IL 60060 Phone 847-996-4500 · 1-800-3SYSMEX (1-800-379-7639) www.sysmex.comXE-Series Flagging Interpretation Guide Section 2: WBC IP MessagesDocument Number: MKT-40-1010 December 2008 Page 4 of 12Suspect, Left Shift?The Left Shift?
IP indicates that the XE-Series Resultsinstrument has detected abnormalclustering in the region for left shift WBC 13.98 [103/µL](bands) in the IMI and/or DIFF RBC 2.95 [106/µL]scattergrams.

HGB 9.3 [g/dL]An asterisk (*) appears next to the HCT 27.6 [%]Neutrophil and Eosinophil % and #. MCV 93.6 [fL]The IG% and IG# may also have an MCH 31.5 [pg]asterisk. The asterisk (*) indicates MCHC 33.7 [g/dL]these results are unreliable if PLT 135 [103/µL]abnormalities are found during the RDW-SD 46.4 [fL]laboratory's review of the sample. RDW-CV 13.6 [%] MPV 10.6 [fL] Figure 9: DIFF Scattergram RET% 0.75 [%] RET# 0.0221 [106/µL] IRF 0.090 [ratio] NRBC# 0.00 [106/µL] NRBC% 0.0 [/100 WBC] NEUT# 13.08 * [103/µL] [103/µL] LYMPH# 0.58 [103/µL] [103/µL] MONO# 0.26 [103/µL] EO# 0.06 * [%] BASO# 0.00 [%] NEUT% 93.6 * [%] LYMPH% 4.1 [%] [%] MONO% 1.9 EO% 0.4 * BASO% 0.0Figure 10: IMI Scattergram Suggested Action Steps: 1. Scan the peripheral smear for the presence of: • band cells in increased numbers or immature granulocytes • toxic granulation or vacuolation of neutrophils • other abnormal cells 2. If abnormal cells are noted, perform a manual differential. Report according to individual laboratory criteria. 3. If no abnormalities are found, the data with the asterisk (*) can be reported.One Nelson C. White Parkway, Mundelein, IL 60060 Phone 847-996-4500 · 1-800-3SYSMEX (1-800-379-7639) www.sysmex.comXE-Series Flagging Interpretation Guide Section 2: WBC IP MessagesDocument Number: MKT-40-1010 December 2008 Page 5 of 12Suspect, Atypical Lympho?The Atypical Lympho? IP indicates XE-Series Results (continued)that the instrument has detectedsignificant clustering in the region for MPV 11.0 [fL]atypical lymphocytes that is located in NEUT# 5.19 * [103/µL]the upper right lymphocyte region on the [103/µL]DIFF scattergram. LYMPH# 1.68 * [103/µL] MONO# 0.80 * [103/µL]An asterisk (*) appears next to the EO# 0.11 [103/µL]Neutrophil, Lymphocyte and BASO# 0.04Monocyte % and #. The asterisk (*) [%]indicates these results are unreliable if NEUT% 66.4 * [%]abnormalities are found during the LYMPH% 21.5 * [%]laboratory's review of the sample. MONO% 10.2 * [%] EO% [%] BASO% 1.4 0.5 Figure 11: DIFF Scattergram Suggested Action Steps: XE-Series Results 1. Scan the peripheral smear for the [103/µL] presence of:WBC 7.82 [106/µL] • atypical or variant lymphs • abnormal or atypical monocytesRBC 3.64 • immature lymphs, such as seen in ALL or CLLHGB 10.2 [g/dL] • other abnormal cellsHCT 32.3 [%] 2. If the estimate of atypical lymphocytes exceeds the upper limitMCV 88.7 [fL] of the laboratory's normal reference range:MCH 28.0 [pg] • report the presence of atypical lymphocytes (estimate percentMCHC 31.6 [g/dL] atypical lymphs present)PLT 215 [103/µL] • or perform a manual differential according to your laboratory's policyRDW-SD 49.6 [fL] 3. If immature monocytes orRDW-CV 15.5 [%] lymphocytes are present, perform a manual differential according to your laboratory's policy. 4. Report any abnormal morphological findings according to individual laboratory criteria. 5. If no abnormalities are found, the data with the asterisk (*) can be reported.One Nelson C. White Parkway, Mundelein, IL 60060 Phone 847-996-4500 · 1-800-3SYSMEX (1-800-379-7639) www.sysmex.comXE-Series Flagging Interpretation Guide Section 2: WBC IP MessagesDocument Number: MKT-40-1010 December 2008 Page 6 of 12Suspect, Abn Lympho/L_Blasts?The Abn Lympho/L_Blasts? IP XE-Series Resultsindicates that the instrument has detectedsignificant clustering in the region for WBC 25.56 [103/µL]abnormal lymphocytes/lymphoblasts that RBC 3.34 [106/µL]is located in the upper right area for the HGB 10.1 [g/dL]lymphocytes on the DIFF scattergram. HCT 31.6 [%]An asterisk (*) appears next to the MCV 94.6 [fL]Neutrophil, Lymphocyte and Monocyte % MCH 30.2 [pg]and #.

The asterisk (*) indicates these MCHC 32.0 [g/dL]results are unreliable if abnormalities are PLT & [103/µL]found during the laboratory's review of the RDW-SD 8 [fL]sample. RDW-CV 52.7 [%] MPV 18.5 [fL] Figure 12: DIFF Scattergram RET% —— [%] RET# 3.83 [106/µL] IRF 0.1279 [ratio] NRBC# 0.120 [106/µL] NRBC% 0.0 [/100 WBC] NEUT# 0.0 [103/µL] 2.94 * [103/µL] LYMPH# [103/µL] 21.44 * [103/µL] MONO# [103/µL] 0.89 * EO# [%] 0.23 BASO# [%] 0.06 NEUT% [%] LYMPH% 11.5 * 83.9 * [%] MONO% [%] 3.5 * EO% BASO% 0.9 0.2Figure 13: IMI Scattergram Suggested Action Steps: 1. Scan the peripheral smear for the presence of: • atypical or variant lymphocytes or lymphoblasts • abnormal or atypical monocytes • immature lymphs, such as seen in ALL or CLL 2. If the estimate of atypical lymphocytes appear to exceed the upper limit of a lab's normal reference range: • report the presence of atypical lymphocytes (estimate percent atypical lymphs present) • or perform a manual differential according to your laboratory's policy (continued on next page)One Nelson C. White Parkway, Mundelein, IL 60060 Phone 847-996-4500 · 1-800-3SYSMEX (1-800-379-7639) www.sysmex.comXE-Series Flagging Interpretation Guide Section 2: WBC IP MessagesDocument Number: MKT-40-1010 December 2008 Page 7 of 12Suspect, Abn Lympho/L_Blasts?(continued)Suggested Action Steps: (continued)3. If lymphoblasts, immature lymphocytes, or immature monocytes are present, perform a manual differential according to your laboratory's policy.4. Report any abnormal morphological findings according to individual laboratory criteria.5. If no abnormalities are found, the data with the asterisk (*) can be reported.One Nelson C. White Parkway, Mundelein, IL 60060 Phone 847-996-4500 · 1-800-3SYSMEX (1-800-379-7639) www.sysmex.comXE-Series Flagging Interpretation Guide Section 2: WBC IP MessagesDocument Number: MKT-40-1010 December 2008 Page 8 of 12Suspect, NRBC?The NRBC? IP can only appear when a Figure 15: NRBC ScattergramNRBC count is not performed on the XE- (after specimen was analyzed inSeries. This is generated whenclustering is detected in the NRBC area CBC + DIFF + NRBC mode)between the lymphocytes and the RBCghosts on the DIFF scattergram. (Figure XE-Series Results14)An asterisk (*) appears next to the WBC, WBC & 15.38 [103/µL]Neutrophils, Lymphocytes, Monocytes RBC 3.86 [106/µL]and Eosinophils % and #. The asterisk HGB 11.3 [g/dL](*) indicates these results are unreliable HCT 33.4 [%]if abnormalities are found during the MCV 86.5 [fL]laboratory's review of the sample. MCH 29.3 [pg]The NRBC Present IP is operator MCHC 33.8 [g/dL]programmable. It only appears if an PLT & 273 [103/µL]NRBC is ordered and the NRBC exceeds RDW-SD 60.0 [fL]the programmed limit.

If NRBCs are > RDW-CV 19.5 [%]0.01/100 WBC, the WBC and Lymph MPV 10.5 [fL]counts are corrected. This is denoted by RET% 6.44 [%]an "&" to the left of the data. RET# 0.2486 [106/µL] IRF 0.230 [ratio] Figure 14: DIFF Scattergram NRBC# 0.52 [103/µL] NRBC% 3.4 [/100 WBC] NEUT# 9.43 [103/µL] [103/µL] LYMPH# & 4.47 [103/µL] [103/µL] MONO# 1.34 [103/µL] EO# 0.10 [%] BASO# 0.04 [%] NEUT% 61.2 [%] LYMPH% & 29.1 [%] MONO% 8.7 [%] EO% 0.7 BASO% 0.3 (continued on next page)One Nelson C. White Parkway, Mundelein, IL 60060 Phone 847-996-4500 · 1-800-3SYSMEX (1-800-379-7639) www.sysmex.comXE-Series Flagging Interpretation Guide Section 2: WBC IP MessagesDocument Number: MKT-40-1010 December 2008 Page 9 of 12Suspect, NRBC?(continued)Suggested Action Steps:1. Reanalyze the sample in CBC + DIFF + NRBC mode. If NRBCs are present, the XE will provide a quantitative NRBC % and #. The WBC and Lymph counts will be automatically corrected. In the absence of other IP s, this data can be reported.2. Individual laboratory guidelines may call for review of morphology with presence of NRBCs. • Review the smear for abnormal cell morphology (abnormal RBC and NRBCs). Comment on abnormal morphology per laboratory criteria. • An uncorrected WBC count can be found in the WBC Research screen, if it is needed. • An uncorrected WBC count can also be obtained by the following calculation: Corrected WBC + NRBC# = Uncorrected WBCOne Nelson C. White Parkway, Mundelein, IL 60060 Phone 847-996-4500 · 1-800-3SYSMEX (1-800-379-7639) www.sysmex.comXE-Series Flagging Interpretation Guide Section 2: WBC IP MessagesDocument Number: MKT-40-1010 December 2008 Page 10 of 12Suspect, RBC Lyse Resistance?The RBC Lyse Resistance? IP is XE-Series Resultsseen when WBC/BASO and DIFFscattergrams have abnormal clustering WBC 12.06 * [103/µL]near the RBC ghost populations. RBC 3.69 [106/µL] HGB 11.0 [g/dL]An asterisk (*) appears next to the WBC, HCT 34.2 [%]Neutrophils, Lymphocytes, Monocytes, MCV 92.7 [fL]Eosinophils and Basophils % and #. MCH 29.8 [pg]The asterisk (*) indicates these results MCHC 32.2 [g/dL]are unreliable if abnormalities are found PLT 248 [103/µL]during the laboratory's review of the RDW-SD 53.1 [fL]sample. RDW-CV 15.7 [%] MPV 10.2 [fL] NEUT# [103/µL] 10.32 * [103/µL] LYMPH# [103/µL] 0.63 * [103/µL] MONO# [103/µL] 0.89 * EO# [%] 0.14 * [%] BASO# 0.08 * [%] NEUT% LYMPH% 85.5 * [%] 5.2 * [%] MONO% 7.4 * EO% BASO% 1.2 * 0.7 * Figure 16: DIFF Scattergram Suggested Action Steps:Figure 17: WBC/BASO Scattergram 1. Scan the peripheral smear: • look for abnormal RBC morphology • perform a slide estimate of the WBC count • perform a manual differential according to your laboratory's policy 2. Report the results verified by the slide review and according to individual laboratory guidelines. 3. If WBC results are not verified by a slide estimate, prepare a dilution of the sample using CELLPACK™ as the diluent. • reanalyze the diluted sample to verify the WBC results • observe if there is a clinically significant change in the counts • report the results verified by the slide review and according to individual laboratory guidelinesOne Nelson C. White Parkway, Mundelein, IL 60060 Phone 847-996-4500 · 1-800-3SYSMEX (1-800-379-7639) www.sysmex.comXE-Series Flagging Interpretation Guide Section 2: WBC IP MessagesDocument Number: MKT-40-1010 December 2008 Page 11 of 12This Page Left Blank Intentionally.One Nelson C. White Parkway, Mundelein, IL 60060 Phone 847-996-4500 · 1-800-3SYSMEX (1-800-379-7639) www.sysmex.comXE-Series Flagging Interpretation Guide Section 2: WBC IP MessagesDocument Number: MKT-40-1010 December 2008 Page 12 of 12Abnormal, RBC Abn DistributionThe RBC Abn Distribution IP Message In this example, RBC parameters areis generated when the histogram pattern abnormal due to a cold-reacting RBCfrom the RBC channel is abnormal or agglutinin.when RBC < 0.5 x 106/µL. Suggested Action Steps:Dashes appear in place of data that wasnot calculated. For example, if there are 1. Scan the peripheral smear for themultiple peaks present, there would be presence of abnormal RBCdashes in place of data for the RDW-SD morphology:and RDW-CV. Sometimes this IP • increased anisocytosisMessage can cause the RDW-CV to be • multiple RBC populationsmarked with an asterisk (*). The asterisk • fragmented RBCs(*) indicates these results are unreliable if • poikilocytosisabnormalities are found during the • rouleauxlaboratory's review of the sample.

• RBC Agglutination (refer to suggested action for "RBCFigure 18: RBC Histogram Agglutination?")XE-Series Results 2. Report any clinically significant finding according to individual laboratoryWBC 6.13 [103/µL] guidelines.RBC 0.47 * [106/µL] 3.

If the RBC morphology is normal andHGB 11.2 [g/dL] the HGB and HCT are not compatibleHCT 5.0 * [%] or do not match the "rules of 3", RBCMCV 106.4 * [fL] agglutination or rouleaux should beMCH 238.3 * [pg] suspected. If present, follow theMCHC 224.0 * [g/dL] suggested guidelines for thePLT 225 [103/µL] HGB/Turbidity Interference? IP Message.RDW-SD —— [fL]RDW-CV —— [%] Note: If the RBC morphology isMPV 11.5 [fL] abnormal, the 'rules of 3' do notRET% 3.69 [%] always hold true.RET# 0.0173 * [106/µL]One Nelson C. White Parkway, Mundelein, IL 60060 Phone 847-996-4500 · 1-800-3SYSMEX (1-800-379-7639) www.sysmex.comXE-Series Troubleshooting Guide Section 3: RBC IP MessagesDocument Number: MKT-40-1010 December 2008 Page 1 of 16Abnormal, Dimorphic PopulationThe Dimorphic Population IP Message Suggested Action Steps:is generated when there are multiplepeaks in the RBC histogram pattern. 1. Scan the peripheral smear for the presence of abnormal RBCDashes appear in place of data for the morphology:RDW-SD and RDW-CV. This occurs with • increased anisocytosisRBC Abn Distribution IP Message, • multiple RBC populationscausing certain RBC parameters to be • fragmented RBCsmarked with an asterisk (*). The asterisk • poikilocytosis(*) indicates these results are unreliable if • rouleauxabnormalities are found during the • RBC Agglutination (refer tolaboratory's review of the sample. suggested action for "RBC Agglutination?")Figure 19: RBC Histogram 2.

Report any clinically significant findingWBC XE-Series Results according to individual laboratoryRBC 14.13 [103/µL] guidelines.

2.40 * [106/µL]HGB 3. If the RBC morphology is normal andHCT 10.8 [g/dL] the HGB and HCT are not compatibleMCV 30.6 * [%] or do not match the "rules of 3", RBCMCH 127.5 * [fL] agglutination or rouleaux should beMCHC 45.0 * [pg] suspected. If present, follow thePLT 35.3 * [g/dL] suggested guidelines for the HGB/Turbidity Interference?RDW-SD 80 [103/µL] IP Message.RDW-CVMPV — — [fL] Note: If the RBC morphology isRET% — — [%] abnormal, the 'rules of 3' do notRET# 11.5 [fL] always hold true. 6.22 [%]IRF 0.1493 [106/µL] 0.196 [ratio]One Nelson C. White Parkway, Mundelein, IL 60060 Phone 847-996-4500 · 1-800-3SYSMEX (1-800-379-7639) www.sysmex.comXE-Series Troubleshooting Guide Section 3: RBC IP MessagesDocument Number: MKT-40-1010 December 2008 Page 2 of 16Abnormal, RET Abn ScattergramThe RET Abn Scattergram IP Message XE-Series Resultscan only be generated on the XE-2100 ifthe Reticulocyte parameter is ordered. WBC & 15.38 [103/µL]This IP Message indicates that the RBC 3.86 [106/µL]instrument has detected increased activityin the RET-THR (threshold) area, the RET HGB 11.3 [g/dL]scattergram or increased activity in the HCT 33.4 [%]RET-UPP (Upper Particle Plateau) area MCV 86.5 [fL]on the RET-EXT scattergram.

MCH 29.3 [pg] MCHC 33.8 [g/dL]Asterisks (*) appear next to the RET%, PLT 273 [103/µL]RET# and IRF parameters. The asterisk(*) indicates these results are unreliable if RDW-SD 60.0 [fL]abnormalities are found during the RDW-CV 19.5 [%]laboratory's review of the sample. MPV 10.5 [fL] RET% 6.44 * [%] RET# 0.2486* [106/µL] IRF 0.230 * [ratio] [106/µL] NRBC# 0.52 [1.00 WBC] NRBC% 3.4Figure 20: RET Scattergram Suggested Action Steps: 1. The RET Abnormal Scattergram? is from increased activity in the following areas of the reticulocyte scattergram: • RET-UPP area on the RET-EXT screen • RET-THR area on the RET scattergram 2. Prepare a 1:5 dilution with CELLPACKTM diluent to minimize interference.

Run the 1:5 dilution in the manual mode (NOT the capillary mode). Dilutions greater than 1:5 should not be used. Figure 21: RET-EXT (Retic Extended) 3. If the RET Abn Scattergram? flag is eliminated, multiply the absolute countRET-EXT Scattergram: The RET-UPP area by 5 and report. The Retic% and IRF%(green area past retics) is abnormal due to do not need to be multiplied by theNRBCs, Howell-Jolly Bodies and stress retics. dilution factor since these percentagesThese are not included in RET count. should remain the same upon dilution. (continued on next page)One Nelson C. White Parkway, Mundelein, IL 60060 Phone 847-996-4500 · 1-800-3SYSMEX (1-800-379-7639) www.sysmex.comXE-Series Troubleshooting Guide Section 3: RBC IP MessagesDocument Number: MKT-40-1010 December 2008 Page 3 of 16Abnormal, RET Abn Scattergram 6. Decisions to report with a comment or perform an alternative method should be (continued) based on your laboratories practices.

Suggested Action Steps: 7. If the flag is persistent, rule out analyzer for functional errors. (continued) • reanalyze the patient sample to ensure there is not a functional error4. Check that the RBC (x5) on the • begin troubleshooting activity by dilution sample matches the original running a known normal patient RBC count to ensure that dilutional sample to see if the RET Abn errors have not occurred. Also, Scattergram?

occurs on all patients check that the diluted RBC count is or only the one in question not less than 0.35. In flow cytometry adequate particles must be present for accurate gating to occur. If the diluted sample's RBC count is <0.35 make a lower dilution (i.e. 1:2 or 1:3) in order to increase the RBC count.5. If the flag is not eliminated, or the RBC count is <0.35, there are 2 options to consider: • review the peripheral smear for the presence of polychromasia, NRBC's, Howell-Jolly Bodies or basophilic stippling.

If present, report the results with a comment saying that the results may be affected by the presence of interfering substances. • or perform the reticulocyte by an alternative method.One Nelson C. White Parkway, Mundelein, IL 60060 Phone 847-996-4500 · 1-800-3SYSMEX (1-800-379-7639) www.sysmex.comXE-Series Troubleshooting Guide Section 3: RBC IP MessagesDocument Number: MKT-40-1010 December 2008 Page 4 of 16Suspect, RBC Agglutination?The RBC Agglutination? IP Message is Figure 23: RBC Histogramdetermined by calculation and size (after specimen pre-warmed)comparison of certain RBC items (MCHC,MCH, RBC, RU%*). XE-Series ResultsAsterisks (*) appear next to the RBC, HCT,MCV, MCH and MCHC parameters. Theasterisk (*) indicates these results areunreliable if abnormalities are foundduring the laboratory's review of thesample.* The RU% is the upper RBC histogramdiscriminator.

This is not a reportable parameter,but it is used in the RBC Agglutination algorithm. Pre-warmed at 37 degrees Celsius for 15-30 minutes Figure 22: RBC Histogram WBC 5.23 [103/µL] RBC 2.82 [106/µL] XE-Series Results[103/µL] HGB 8.4 [g/dL]WBC 6.12 HCT 27.0 [%] 0.24 * [106/µL] MCV 95.7 [fL]RBC MCH 29.8 [pg] MCHC 31.1 g/dL]HGB 11.2 [g/dL] PLT 205 [103/µL]HCT 2.9 * [%] RDW-SD 53.6 [fL] RDW-CV 18.3 [%]MCV 120.8 * [fL] MPV —— [fL] RET 3.16 [%]MCH 466.7 * [pg] RET 0.0891 [106/µL] [103/µL]MCHC 386.2 * g/dL] NEUT# 2.97 [103/µL]PLT 272 [103/µL] [103/µL] LYMPH# 1.70 [103/µL]RDW-SD — — [fL] 103/µL] MONO# 0.37RDW-CV — — [%] [%] EO# 0.15 [%]MPV 11.7 [fL] [%] BASO# 0.04RET 3.40 [%] [%]RET 0.0082 [106/µL] NEUT% 56.7 LYMPH% 32.5 [%]NEUT# 3.53 [103/µL] MONO% 7.1LYMPH# 1.94 [103/µL] EO% 2.9 BASO% 0.8MONO# 0.47 [103/µL]EO# 0.14 [103/µL] (continued on next page)BASO# 0.04 [103/µL]NEUT% 57.6 [%]LYMPH% 31.7 [%]MONO% 7.7 [%]EO% 2.3 [%]BASO% 0.7 [%]One Nelson C. White Parkway, Mundelein, IL 60060 Phone 847-996-4500 · 1-800-3SYSMEX (1-800-379-7639) www.sysmex.comXE-Series Troubleshooting Guide Section 3: RBC IP MessagesDocument Number: MKT-40-1010 December 2008 Page 5 of 16Suspect, RBC Agglutination? (continued)Suggested Action Steps:1. Scan the peripheral smear for the presence of agglutinated RBCs. Visually check the sample tube for agglutination.2. If agglutinated RBCs are present, warm the sample at 37 degrees Celsius for 15-30 minutes according to laboratory policy. Reanalyze the warmed sample in the manual mode after mixing by manual inversion 10 times.

Make a new peripheral smear from the warmed sample if agglutination is severe and WBCs and PLTs cannot be accurately assessed.3. Sometimes agglutination can be so severe that warming the sample does not enable accurate analysis. • In cases with high cold agglutinin titers, a plasma replacement using warm CELLPACK™ may be necessary. • In cases where a warm-reacting antibody has caused agglutination, a plasma replacement may also be necessary to get rid of the antibody. Room temperature CELLPACK can be used to replace the plasma.4. Additional laboratory procedures may be necessary to confirm the presence of a cold agglutinin or a warm-reacting antibody. Further testing procedures should be suggested based on laboratory policy.One Nelson C. White Parkway, Mundelein, IL 60060 Phone 847-996-4500 · 1-800-3SYSMEX (1-800-379-7639) www.sysmex.comXE-Series Troubleshooting Guide Section 3: RBC IP MessagesDocument Number: MKT-40-1010 December 2008 Page 6 of 16Suspect, Turbidity/HGB Interference?The Turbidity/HGB Interference? XE-Series ResultsIP Message occurs when the MCHC is> 36.5 g/dL and indicates that turbidity (continued)may be present in the diluted and lysedsample. This turbidity could interfere Spun HCT = 20%with the HGB detection light path and Plasma – lipemicfalsely increase the HGB value. Action:Asterisks (*) appear next to the HGB, Dilute specimen and reanalyzeMCH and MCHC parameters.

The HGB = 6.5 g/dLasterisk (*) indicates these results are MCH = 30.0 pg, MCHC = 34.4 d/dLunreliable if abnormalities are foundduring the laboratory's review of the Suggested Action Steps:sample. Figure 24: RBC Histogram Note: An MCHC up to 37.5 g/dL may indicate a normal specimen on XE-Series Results[103/µL] the high end of normal range, in which case no action would beWBC 4.64 [106/µL] taken. If action is indicated, determine if the HGB is falselyRBC 2.17 elevated or the HCT is falsely decreased.HGB 10.0 * [g/dL] 1. Spin hematocrit (or spin an aliquotHCT 18.9 [%] of sample if HCT centrifuge not available) to:MCV 87.1 [fL] • compare the instrument HCTMCH 46.5 * [pg] to the spun HCT if performed.MCHC 53.4 * g/dL] • examine the plasma for lipemia,PLT & 184 [103/µL] hemolysis or icterus. If sample is lipemic or icteric perform aRDW-SD 47.1 [fL] plasma replacement or a dilution to obtain accurate HGB.RDW-CV 15.7 [%] Recalculate MCH and MCHC using the corrected HGBMPV 14.4 [fL] results and the original RBC and HCT results.RET 1.07 [%]RET 0.0232 [106/µL] • If the sample is hemolyzed, the RBC and HCT may beIRF 0.058 [ratio] inaccurate if severe in vitroNRBC# 0.00 [106/µL] hemolysis has occurred. The HGB will be accurate.NRBC% 0.0 [/100 WBC] Recollect the sample if possible. (continued on next page)One Nelson C. White Parkway, Mundelein, IL 60060 Phone 847-996-4500 · 1-800-3SYSMEX (1-800-379-7639) www.sysmex.comXE-Series Troubleshooting Guide Section 3: RBC IP MessagesDocument Number: MKT-40-1010 December 2008 Page 7 of 16Suspect, Turbidity/HGB Interference? 4. Other possible causes of increased MCHC up to 38 fl. (continued) • spherocytes as seen in hereditary spherocytosis Suggested Action Steps (continued): • other severe poikilocytosis • If in vivo hemolysis has Note: If the RBC morphology is occurred, the HGB reflects both abnormal, the "rules of 3" do not plasma and cellular HGB. The always hold true. MCHC and MCH will be falsely increased. The plasma HGB and cellular HGB may be measured separately. The plasma HGB can be determined by analyzing the plasma on the XE-Series instrument. The cellular HGB can be calculated by using the following formula:Cellular HGB = Total HGB – [(1- HCT/ 100) x Plasma HGB] Recalculate the indices using the cellular HGB value. 2. If WBC > 100.00 x 103/µl and the "Turbidity/ HGB Interference?" suspect flag is present: • make a dilution of the sample using CELLPACKTM as the diluent. If the HGB results change, report the HGB from the dilution and recalculate the MCH and MCHC. If the WBC is greater than your laboratory's established linearity, report the WBC from the dilution as well. 3. Other possible causes of falsely increased HGB or falsely decreased HCT include: • abnormal plasma proteins – perform plasma replacement procedure • severe hyponatremia – dilute sample, allow to stand 10 minutes and analyze • cold agglutinins – pre-warm specimen 15-30 minutes per lab protocolOne Nelson C. White Parkway, Mundelein, IL 60060 Phone 847-996-4500 · 1-800-3SYSMEX (1-800-379-7639) www.sysmex.comXE-Series Troubleshooting Guide Section 3: RBC IP MessagesDocument Number: MKT-40-1010 December 2008 Page 8 of 16Suspect, Iron Deficiency?The Iron Deficiency? IP Message is Due to the presence of fragmented RBCs, the PLT-Odetermined by calculation and size comparison was reported by the XE-2100. This is denoted by theof certain RBC items (MCHC, MCV, RDW). ampersand next to the platlet count (PLT &). Figure 25: RBC Histogram Suggested Action Steps: 1. Scan the peripheral smear for the Figure 26: PLT Histogram presence of microcytic and hypochromic XE-Series Results RBCs. [106/µL]RBC 5.86 2. Report the presence of any clinically significant RBC morphologicHGB 8.3 [g/dL] abnormalities according to individual laboratory policy. 3. If extremely microcytic RBCs are present: • estimate the PLT count • if the RET was not ordered, the XE-2100 may generate an Action Message stating, "Count RET Channel". The operator can reanalyze the specimen in CBC + RET mode. The XE judges whether or not to switch to report the PLT-O. 4. Suggest confirmatory testing for iron deficiency anemia in keeping with laboratory policy. Note: If the RBC morphology is abnormal, the "rules of 3" do not always hold true.HCT 29.1 [%]MCV 49.7 [fL]MCH 14.2 [pg]MCHC 28.5 g/dL]PLT & 351 [103/µL]RDW-SD 39.5 [fL]RDW-CV 22.5 [%]MPV — — [fL]RET % 1.81 [%] 0.1061 [106/µL]RET #IRF 0.215 [ratio] Research (R) Screen [103/µL]PLT-I 372 * 351 [103/µL]PLT-OOne Nelson C.

White Parkway, Mundelein, IL 60060 Phone 847-996-4500 · 1-800-3SYSMEX (1-800-379-7639) www.sysmex.comXE-Series Troubleshooting Guide Section 3: RBC IP MessagesDocument Number: MKT-40-1010 December 2008 Page 9 of 16Suspect, HGB Defect?The HGB Defect? IP Message is Suggested Action Steps:determined by calculation and sizecomparison of certain RBC items 1. Scan the peripheral smear for the(MCV and RDW-CV). presence of abnormal RBC morphology, such as: • microcytosis • hypochromia • target cells • sickle cells • HGB C crystals 2. Report the presence of any clinically significant RBC morphologic abnormalities according to individual laboratory policy.Figure 27: RBC Histogram 3. If extremely microcytic RBCs are present:XE-Series Results • estimate the PLT count. • If the RET was not ordered, theWBC 10.55 [103/µL] XE-2100 may generate an ActionRBC 4.73 [106/µL] Message stating, "Count RETHGB 9.9 [g/dL] Channel". The operator canHCT 30.7 [%] reanalyze the specimen in CBC +MCV 64.9 [fL] RET mode. The XE judges whetherMCH 20.9 [pg] or not to switch to report the PLT-O.MCHC 32.2 [g/dL]PLT & 149 [103/µL] 4. Suggest confirmatory testing forRDW-SD 33.6 [fL] hemoglobinopathies as indicated byRDW-CV 14.4 [%] laboratory policy.MPV —— [fL]RET% 1.02 [%] Note: If the RBC morphology is abnormal, theRET# 0.0482 [106/µL] "rules of 3" do not always hold true.IRF 0.107 [ratio]NRBC# 0.00

[106/µL]NRBC% 0.0 [/100 WBC]Due to PLT Abnormal Distribution, the PLT-Owas reported by the XE-2100. This is denotedby the ampersand next to the platelet count(PLT &).One Nelson C. White Parkway, Mundelein, IL 60060 Phone 847-996-4500 · 1-800-3SYSMEX (1-800-379-7639) www.sysmex.comXE-Series Troubleshooting Guide Section 3: RBC IP MessagesDocument Number: MKT-40-1010 December 2008 Page 10 of 16Suspect, Fragments?The Fragments? IP Message isdetermined from RET Scattergramand/or by calculation and sizecomparison of certain RBC and PLTitems (MCV, RDW-SD, MCHC, RL*,PU*, PU%*).* RBC lower discriminator, PLT upperdiscriminator, % of the PLT upper discriminator Figure 31: PLT-O Scattergram XE-Series ResultsFigure 28: RBC Histogram RBC 2.95 [106/µL] HGB 8.0 [g/dL] HCT 28.2 [%] MCV 95.6 [fL] MCH 27.1 [pg] MCHC 28.4 [g/dL] PLT & 191 [103/µL] RDW-SD 98.4 [fL] RDW-CV 29.6 [%] MPV —— [fL] RET% 3.62 [%] [106/µL] RET# 0.1068 [ratio] IRF 0.353 Research (R) ScreenFigure 29: PLT Histogram PLT-I 233 * [103/µL] PLT-O 191 [103/µL] Due to presence of fragmented RBCs, the PLT-O was reported by the XE-2100.

This is denoted by the ampersand next to the PLT count (PLT &). (continued on next page)Figure 30: RET ScattergramOne Nelson C. White Parkway, Mundelein, IL 60060 Phone 847-996-4500 · 1-800-3SYSMEX (1-800-379-7639) www.sysmex.comXE-Series Troubleshooting Guide Section 3: RBC IP MessagesDocument Number: MKT-40-1010 December 2008 Page 11 of 16Suspect, Fragments?(continued)Suggested Action Steps:1. Scan the peripheral smear for the presence of fragmented RBCs and other poikilocytosis.2. Report the presence of any clinically significant RBC morphology according to individual laboratory policy.3. If extremely microcytic RBCs are present: • Estimate the PLT count • If the RET was not ordered, the XE-2100 may generate an Action Message stating, “Count RET Channel”. The operator can reanalyze the specimen in CBC + RET mode. The XE judges whether or not to switch to report the PLT-O.Note: If the RBC morphology is abnormal, the “rules of 3” do not always hold true.One Nelson C. White Parkway, Mundelein, IL 60060 Phone 847-996-4500 · 1-800-3SYSMEX (1-800-379-7639) www.sysmex.comXE-Series Troubleshooting Guide Section 3: RBC IP MessagesDocument Number: MKT-40-1010 December 2008 Page 12 of 16Abnormal, PLT Abn DistributionThe PLT Abn Distribution IP Message XE-Series Resultsis generated by calculation and sizecomparison of certain PLT items (PDW, RBC 2.95 [106/µL]PL%* [% of PLT lower discriminator],PU%* [% of upper discriminator], PMFV, HGB 8.0 [g/dL]PLT, PLCR* [platelet large cell rates], HCT 28.2 [%]MPV, PU* [platelet upper discriminator]). MCV 95.6 [fL] MCH 27.1 [pg]* These are all non-reportable parameters that MCHC 28.4 g/dL] PLT & 191 * [103/µL] are used as part of this flagging algorithm. RDW-SD 98.4 [fL] RDW-CV 29.6 [%]Dashes may appear in place of data for MPV —— [fL]the MPV or the MPV is marked with an RET % 3.62 [%]asterisk (*). The asterisk (*) indicates [106/µL]these results are unreliable if RET # 0.1068 [ratio]abnormalities are found during the IRF 0.353laboratory’s review of the sample. Research (R) Screen 255 [103/µL] PLT-I 191 [103/µL] PLT-OFigure 32: RBC Histogram Due to PLT Abnormal Distribution, theFigure 33: PLT Histogram PLT-O was reported by the XE-2100. Since the PLT& has an * (asterisk), it has been deemed unreliable and needs to be confirmed. Suggested Action Steps: Note: For laboratories with the XE-2100L or XE-2100D, proceed to Step 2. 1. For laboratories with the XE-2100, re-analyze the sample ordering a CBC and RET. By ordering the CBC and RET, an optical platelet (PLT-O) is performed using fluorescent flow cytometry. If the instrument switches to the PLT-O, the PLT has an “&” to the left of the result. In the absence of other IP Messages, the PLT-O may be reported. If other IP Messages or an * (asterisk) is present, proceed to Step 2. (continued on next page)One Nelson C. White Parkway, Mundelein, IL 60060 Phone 847-996-4500 · 1-800-3SYSMEX (1-800-379-7639) www.sysmex.comXE-Series Troubleshooting Guide Section 4: PLT IP MessagesDocument Number: MKT-40-1010 December 2008 Page 1 of 8Abnormal, PLT Abn Distribution(continued)Suggested Action Steps (continued):2. Scan the peripheral smear for the presence of abnormal PLT morphology: • large or giant platelets • small platelets • platelet clumps • fragmented RBCs • microcytic RBCs3. Perform a manual platelet estimate to ensure the count is accurate. If platelet estimate confirms accuracy of count, it may be reported. If platelet clumps have interfered, perform one of the alternate procedures recommended by the Suggested Actions for PLT Clumps?

IP Message.4. Report any clinically significant RBC and/or PLT morphology according to individual laboratory guidelines.One Nelson C. White Parkway, Mundelein, IL 60060 Phone 847-996-4500 · 1-800-3SYSMEX (1-800-379-7639) www.sysmex.comXE-Series Troubleshooting Guide Section 4: PLT IP MessagesDocument Number: MKT-40-1010 December 2008 Page 2 of 8Abnormal, PLT Abn ScattergramThe PLT Abn Scattergram IP Messagecan only be generated when a Reticulocytecount is performed on the XE-2100analyzer. This IP Message occurs whenclustering in the PLT-O area on the RETICand RET-EXT Scattergrams is abnormal.The PLT-O is not reported.

Asterisks (*) Figure 36: PLT Histogramappear next to the PLT-I and MPV. Theasterisk (*) indicates these results are XE-Series Resultsunreliable if abnormalities are found during 480.00 @ [103/µL]the laboratory’s review of the sample. WBC [106/µL] Figure 34: PLT-O Scattergram RBC 3.80 Figure 35: RET EXT Scattergram HGB 11.5 [g/dL] (Retic Extended) HCT 32.1 [%] MCV 84.5 [fL] MCH 30.3 [pg] MCHC 35.8 g/dL] [103/µL] PLT 222* RDW-SD 42.0 [fL] RDW-CV 15.2 [%] MPV 10.6* [fL] RET 2.73 [%] 0.1037 [106/µL] RET IRF 0.672 [ratio] [103/µL] NEUT —— [103/µL] LYMPH —— [103/µL] MONO —— EO 0.62* [103/µL] 103/µL] BASO —— NEUT — — [%] LYMPH — — [%] MONO — — [%] EO% 0.3* [%] BASO% — — [%] “@” to the right of the WBC indicates this data is outside of linearity (continued on next page)One Nelson C. White Parkway, Mundelein, IL 60060 Phone 847-996-4500 · 1-800-3SYSMEX (1-800-379-7639) www.sysmex.comXE-Series Troubleshooting Guide Section 4: PLT IP MessagesDocument Number: MKT-40-1010 December 2008 Page 3 of 8Abnormal, PLT Abn Scattergram(continued)Suggested Action Steps:1. Scan the peripheral smear for the presence of abnormal PLT or RBC morphology: • large or giant platelets • platelet clumps • fragmented RBCs2. Perform a manual platelet estimate to ensure the count is accurate. • If platelet clumps have interfered, perform one of the alternate procedures recommended by the Suggested Actions for PLT Clumps? IP Message.

• If the RBC fragments have interfered, the lab may not be able to give a numerical value.3. Report any clinically significant WBC, RBC and/or PLT morphology according to individual laboratory guidelines.One Nelson C. White Parkway, Mundelein, IL 60060 Phone 847-996-4500 · 1-800-3SYSMEX (1-800-379-7639) www.sysmex.comXE-Series Troubleshooting Guide Section 4: PLT IP MessagesDocument Number: MKT-40-1010 December 2008 Page 4 of 8Suspect, PLT Clumps?The PLT Clumps? IP Message is XE-Series Resultsdetermined by a continuation of 5.28 * [103/µL]clustering in upper right ghost regions WBC [106/µL]in the DIFF, IMI, and/or NRBC RBC 2.84scattergrams. HGB 8.8 [g/dL]Asterisks (*) will appear next to the HCTWBC, Neutrophil, Lymphocyte, MCV 27.2 [%]Monocyte, Eosinophil, NRBC, PLT, and MCHMPV. The asterisk (*) indicates these MCHC 95.8 [fL]results are unreliable if abnormalities PLT &are found during the laboratory’s review RDW-SD 31.0 [pg]of the sample. RDW-CV MPV 32.4 [g/dL] RET% 30 * [103/µL] RET# 56.9 [fL] IRF 16.5 [%] 10.2 * [fL] 0.81 [%] 0.023 [106/µL] 0.212 [ratio]Figure 37: IMI Scattergram Suggested Action Steps: 1. Scan the peripheral smear for the presence of abnormal morphology: • fibrin strands – look at feathered edge • platelet clumps 2. If any of the above is present, verify the WBC and PLT by a manual slide estimate. If the estimate does not match the instrument count, refer to the next step to obtain an accurate count. (continued on next page)Figure 38: PLT HistogramOne Nelson C. White Parkway, Mundelein, IL 60060 Phone 847-996-4500 · 1-800-3SYSMEX (1-800-379-7639) www.sysmex.comXE-Series Troubleshooting Guide Section 4: PLT IP MessagesDocument Number: MKT-40-1010 December 2008 Page 5 of 8Suspect, PLT Clumps?(continued)Suggested Action Steps (continued):3. If platelet clumps or fibrin strands have interfered, perform one of the following alternate procedures to obtain an accurate count: • Re-draw specimen in EDTA and Na Citrate tubes if possible. Analyze re-drawn EDTA tube. If the platelet and/or white counts are correct and have no PLT Clumps? IP Message, report these results. • If there are still clumped platelets, it could be an in vitro reaction with EDTA. Analyze the Na Citrate tube. Observe only the WBC and PLT counts from these results (Na Citrate alters RBC morphology). Multiply the WBC and PLT counts by 1.1 to account for the dilution of the Na Citrate. • Recollection is not possible, estimate the platelet count and report as low, normal, or high and comment “platelet clumps present, unable to report count”.4. If no abnormalities are found, the data with asterisks (*) can be reported.One Nelson C. White Parkway, Mundelein, IL 60060 Phone 847-996-4500 · 1-800-3SYSMEX (1-800-379-7639) www.sysmex.comXE-Series Troubleshooting Guide Section 4: PLT IP MessagesDocument Number: MKT-40-1010 December 2008 Page 6 of 8Suspect, PLT Clumps(S)?The PLT Clumps(S)? IP Message is Suggested Action Steps:determined by a calculation of and sizecomparison of certain PLT items (PDW, 1. Scan the peripheral smear for thePL%, PU%, PMFV, PLT, PLCR, MPV, presence of abnormal morphology:PU). This flag is generated if platelet • fibrin strands – look at feathered edgeclumps are suspected when the CBC • platelet clumpsdiscrete mode is used and no Diff • giant plateletsparameters are ordered. 2. If any of the above is present, verify Figure 39: PLT Histogram the WBC and PLT by a manual slide estimate. If the estimate does not XE-Series Results match the instrument count, refer to the next step to obtain an accurateWBC 8.40 * [103/µL] count.RBC 4.48 [106/µL] 3. If platelet clumps or fibrin strands haveHGB 11.8 [g/dL] interfered, perform one of the followingHCT 37.7 [%] alternate procedures to obtain anMCV 84.2 [fL] accurate count.MCH 26.3 [pg] • Re-draw specimen in EDTA andMCHC 31.3 [g/dL] Na Citrate tubes if possible.PLT 191 * [103/µL] Analyze re-drawn EDTA tube.RDW-SD 69.5 [fL] If the platelet and/or white countsRDW-CV 22.5 [%] correct and have no PLTMPV —— Clumps(S)? IP message, report these results.In this example, the MPV is dashed out • If there are still clumped platelets,due to PLT Abnormal Distribution. it could be an in vitro reaction with EDTA. Analyze the Na Citrate tube. Observe only the WBC and PLT counts from these results (Na Citrate alters RBC morphology).

Multiply the WBC and PLT counts by 1.1 to account of the dilution for the Na Citrate.

• If recollection is not possible, estimate the platelet count and report as low, normal, or high and comment “platelet clumps present, unable to report count”. 4. If no abnormalities are found, the data with asterisks (*) can be reported.One Nelson C. White Parkway, Mundelein, IL 60060 Phone 847-996-4500 · 1-800-3SYSMEX (1-800-379-7639) www.sysmex.comXE-Series Troubleshooting Guide Section 4: PLT IP MessagesDocument Number: MKT-40-1010 December 2008 Page 7 of 8This Page Left Blank Intentionally.One Nelson C. White Parkway, Mundelein, IL 60060 Phone 847-996-4500 · 1-800-3SYSMEX (1-800-379-7639) www.sysmex.comXE-Series Troubleshooting Guide Section 4: PLT IP MessagesDocument Number: MKT-40-1010 December 2008 Page 8 of 8InterferencesSome abnormal samples may interfere with automated cell counting methods. Thefollowing is a list from the Sysmex XE-Series Operator’s Manual (Main Unit,Introduction) of possible substances that may interfere with these parameters.WBC: Cold agglutinins, platelet aggregation, nucleated RBCs, cryoglobulins, lyse- resistant RBCs in patients with hemoglobinopathies, severe liver disease or neonatesRBC: Cold agglutinins, severe microcytosis, fragmented RBCs, large numbers of giant platelets, in vitro hemolysisHGB: Lipemia, abnormal proteins in blood plasma, severe leukocytosis (above 100,000 /µL). The effect of abnormal proteins and lipemia may be removed by plasma replacement or plasma blank procedures.HCT: Cold agglutinins, leukocytosis (above 100,000/µL), abnormal red cell fragility, spherocytosisPLT: Pseudothrombocytopenia, platelet aggregation, increased microcytosis, megalocytic plateletsRET#: Cold agglutinin, diagnostic intravenous fluorescent dyes, e.g. fluorescein, giant or clumped platelets, MalariaRET%: Diagnostic intravenous fluorescent dyes e.g. fluorescein, giant or clumped platelets, Malaria.Note: The Sysmex XE-Series Analyzer is designed to flag abnormal samples that may contain interfering substances. These results should be reviewed carefully and may require further examination in accordance with the protocol of your laboratory.One Nelson C. White Parkway, Mundelein, IL 60060 Phone 847-996-4500 · 1-800-3SYSMEX (1-800-379-7639) www.sysmex.comXE-Series Troubleshooting Guide Section 5: InterferencesDocument Number: MKT-40-1010 December 2008 Page 1 of 2This Page Left Blank Intentionally.One Nelson C. White Parkway, Mundelein, IL 60060 Phone 847-996-4500 · 1-800-3SYSMEX (1-800-379-7639) www.sysmex.comXE-Series Troubleshooting Guide Section 5: InterferencesDocument Number: MKT-40-1010 December 2008 Page 2 of 2ReferencesBrown, Barbara A. Hematology: Principles and Procedures, Sixth Edition, LippincottWilliams & Wilkins, Media, PA, 1993, pp. 102 – 107, 111 - 116.Cornbleet Joanne, M.D., “Spurious Results from Automated Hematology Cell Counters.”Laboratory Medicine, Vol. 14, No. 8, August 1983.Harmening, Denise M.

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Hoffman R, et al). Churchill LivingstonInc. 1995; 710-729.Sysmex XE-2100 Main Unit Operator’s Manual, Sysmex Corporation, April 2004.Sysmex XE-2100 IPU Operator’s Manual, Sysmex Corporation, April 2004.One Nelson C.

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