Insight™
Participant Overview Guide

Document Number: 1091-TS, Rev. 5

September 2019

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Insight

Participant Overview Guide

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Program Overview

Program Description

The ***Insight*** Interlaboratory Quality Assessment Program provides a report of approximately 33 - 40 days of analyzer performance. Each analyzer is compared to the peer group for on-average accuracy. A cumulative review of past performance over 12 months is also available.

The program is simple to use. Calendars with period end and data due dates are available on the ***Insight*** website. You can save your QC files to a removable disk drive or analyzer desktop and then upload your data to the ***Insight*** Quality Assessment Program on the Sysmex website.

Contact Information

If you have any questions concerning the information in this guide, please email the Sysmex Technical Assistance Center (TAC). Simply click on the email TAC button on the home page of the CRC, complete the form that appears and then click submit to send your question to TAC. Sending an email to TAC is recommended for non-urgent requests. For Canadian customers, please note emails to TAC are currently only processed in English.

For urgent requests, we recommend that you call the Technical Assistance Center at 1-888-879-7639 in the U.S., or at 1-888-679-7639 in Canada.

Each Analysis Mode Is A Peer Group

Sysmex *e*-CHECK™, *e*-CHECK™ (XE) and *plt*-CHECK™ controls can be analyzed in the Manual (Open) aspiration mode, the Closed aspiration mode or both (in separate files). Each mode generates a separate peer group; submitted Open Mode QC Data will be processed with the Open Mode peer group and Closed Mode QC Data will be processed with the Closed Mode peer group.

e-CHECK™ (XS), XN CHECK™, XN CHECK™ BF and XN-L CHECK™ are not separated into Open and Closed modes.

pocH-100*i*™, XP-300™ and KX-Series™ analyzers have their own model-specific peer groups.

Timelines

Timeframe

All *e*-CHECK, *e*-CHECK (XE) and *e*-CHECK (XS) ***Insight*** schedules are derived from the product's 84-day lot life.

XN CHECK and XN CHECK BF and ***Insight*** schedules are derived from the product's 82-day lot life.

XN-L CHECK ***Insight*** schedules are derived from the product's 99-day product life.

EIGHTCHECK™-3WP X-TRA ***Insight*** schedules are derived from the product's 99-day product life.

plt-CHECK™ ***Insight*** schedules are derived from the product's 84-day lot life.

Due to the various ship dates and expiration dates for each of the control products, the due dates for the submission of control data is at different weekly intervals each month.

Insight **Calendar**

Refer to the ***Insight*** calendar provided on the ***Insight*** website. This is a way to know when to expect a new lot and when control data is due to be uploaded to the ***Insight*** website.

Ship Date

e-CHECK, *e*-CHECK (XE), *e*-CHECK (XS), XN CHECK, and XN CHECK BF lots are shipped every 56 days.

EIGHTCHECK-3WP X-TRA and XN-L CHECK lots are shipped every 3 months

plt-CHECK lots are shipped every 75 days.

Data Due Dates

The QC *Data Due Dates* for each product are provided on the assay sheets and on the *Data Due Date Calendar* found on the ***Insight*** website. Data from sample dates after the Data Due Date will be included in the next reporting period.

Data Upload

QC Data needs to be uploaded to the ***Insight*** Quality Assessment Program on the Sysmex website by the *Last Date to Submit*. The *Last Date to Submit* is three to five days after the lot/period end date.

Late Data

QC data can be submitted up to one month after the lot expires. Control data arriving after the *Last Date to Submit* will not be used in the generation of the group statistics, but will still be compared to the peer group.

Types of Reports Available

First Period Report

Data uploaded by the first *Data Due Date* generates a *First Period Report* using data from approximately the first 40 days of the lot. Period Reports can be retrieved from the ***Insight*** website the day after the *Last Date to Submit*.

Second Period Report

Data uploaded by the second *Data Due Date* generates a *Second Period Report* using data from approximately the last 40 days of the lot.

> **NOTE**: The EIGHTCHECK-3WP X-TRA and XN L CHECK products have 3 reports generated using data from three 33-day time periods of each lot.

Cumulative Report

At the end of a lot of control, a *Cumulative Report* is generated using all data received for that entire lot. After sufficient lot/period data has been received, results from approximately one year of statistics will be available.

> **NOTE**: Cumulative Reports can be retrieved from the ***Insight*** website approximately one week after the final period report is closed.

Lot-To-Date Report

Lot-To-Date reports can be obtained from the ***Insight*** website immediately after the data is submitted. Data can be submitted at any time during a lot's life cycle.

Group Report

Group peer statistics for comparison of your analyzer's mean and CV are available on the ***Insight*** website to participants who do not submit QC data. The Group Report will contain only peer statistics and will not contain serial number specific results.

> **NOTE**: Participants not submitting data may retrieve Group Reports from the ***Insight*** website any time.

Email Notifications

Site Administrators will receive an email notification of the report availability within 24 hours after the *Last Date to Submit* date on the appropriate QC Data Due Date Calendar.

> **NOTE**: Site Administrators will receive email notifications of any Exceptions one week prior to a period closing.

> **NOTE**: Site Administrators can choose to opt-out of all ***Insight*** email notifications. For instructions on opting out of email notifications please refer to the Managing Your QC Data Instructions found under User Manuals on the Insight website.

Limit Range% for QC Files

Detector Control/ Service Parameters

Limit Range% values for the detector control/service parameters are provided by analyzer series. Once entered, these values should not be changed.

Use Evidence-based QC Limits

Enter *Evidence-based QC Limit Range%* values in your analyzers control files. These limits are intended to ensure reasonable error detection capability and minimal false rejection rates.

Expected Ranges

Expected Ranges on the assay sheets represent typical variance in accuracy between analyzers. They are not a measure of typical within-analyzer imprecision and are, therefore, not applicable as control file limits*.

***NOTE: Not Applicable to EIGHTCHECK-3WP X-TRA**

The mean values obtained for QC material should be within the Expected Ranges.

Do not use CLIA criteria or Medical Decision Limits

Limits that are based on *CLIA proficiency testing* criteria for acceptable performance or so called *Medical Decision Limits* reduce error detection to the point of missing medically important errors. These have no scientific justification for use as control limits.

Enter Limits for Each Mode's QC Files

If control is analyzed using both Manual (Open) and Closed modes, limits will have to be entered twice, once for each level in each mode.

Once entered on the XE-Series™ or XT-Series™ analyzers, these control limits automatically will be applied to each new lot. Refer to Operator's Manual for instructions on how to enter QC File Limits.

XN-Series and XN-L Series Detector Control/Service Parameters File Limit Range%

Enter the Limit Range% values listed below for Level 1, Level 2 and Level 3. Once entered, these values should not be changed.

DCP / Service Parameters	Limit Range%	XN-20	XN-10	XN-L
HFR	217	X	X	X
MFR	120	X	X	X
LFR	56	X	X	X
RBC-O	29	X	X	X
PDW	999	X	X	X
P-LCR	999	X	X	X
PCT	999	X	X	X
WNR-X	20.0	X	X	
WNR-Y	10.0	X	X	
WNR-Z	10.0	X	X	
WPC-X	10.0	X		
WPC-Y	50.0	X		
WPC-Z	20.0	X		
WDF-X	10.0	X	X	X
WDF-Y	50.0	X	X	X
WDF-Z	10.0	X	X	X
RET-RBC-X	60.0	X	X	X
RET-RBC-Y	8.0	X	X	X
RET-RBC-Z	30.0	X	X	X
PLT-F-RBC-X	30.0	X	X	
PLT-F-RBC-Y	8.0	X	X	
PLT-F-Z	60.0	X	X	

Evidence-based XN CHECK QC Limit Range% for XN-Series

The limits provided below are for use on the XN-Series analyzers. When analyzer specific targets are used, these evidence-based control limits will provide appropriate error detection with minimal false rejections. Limits provided here represent 4 Sigma quality.

Analyzer Specific Limits

Parameter	L1	L2	L3
RBC	5.1	4.4	4.4
HGB	4.9	3.5	3.5
HCT	6.0	5.7	5.3
MCV	4.3	4.2	4.0
MCH	6.1	5.3	5.1
MCHC	6.7	6.1	5.6
RDW-SD	4.7	4.9	6.3
RDW-CV	4.2	3.3	3.5
PLT	30.5	11.5	9.1
PLT-F	15.3	15.6	13.3
IPF%	10.4	15.9	16.4
IPF#	10.4	15.9	16.4
MPV	16.2	6.7	4.7
WBC	9.6	7.3	6.0
WBC-D	9.7	7.3	6.6
WBC-P	11.1	6.3	4.7
NEUT#	14.8	11.2	10.3
LYMPH#	21.6	19.1	20.6
MONO#	44.5	39.7	35.7
EO#	31.1	29.8	30.3
BASO#	18.1	12.7	10.8
IG#	17.6	14.7	14.0
NRBC#	36.1	22.4	15.7
NEUT%	11.4	8.7	8.2
LYMPH%	19.6	17.8	19.8
MONO%	43.1	38.8	35.1
EO%	29.3	28.8	29.5
BASO%	15.2	10.5	9.4
IG%	14.9	13.2	12.6
NRBC%	36.9	22.8	15.4
RET%	15.1	16.6	29.5
RET#	16.1	17.5	30.2
IRF	67.4	62.7	59.4
RET-He	11.3	10.7	11.8

Evidence-based XN CHECK BF QC Limit Range% for XN-Series

The limits provided below are for use on the XN-Series analyzers. When analyzer specific targets are used, these evidence-based control limits will provide appropriate error detection with minimal false rejections. Limits provided here represent 4 Sigma quality.

Analyzer Specific Limits

Parameter	L1	L2
WBC-BF	32.0	19.9
RBC-BF	14.4	10.6
TC-BF#	32.0	19.9
MN#	37.4	36.4
PMN#	39.7	24.3
MN%	29.7	33.9
PMN%	16.0	13.0

Evidence-based XN CHECK QC Limit Range% for XN-L Series™

The limits provided below are for use on the XN-330/XN-430/XN-530/XN-350/XN-450/XN-550 analyzers for the XN CHECK QC product. When analyzer specific targets are used, these evidence-based control limits will provide appropriate error detection with minimal false rejections. Limits provided here represent 4 Sigma quality.

Analyzer Specific Limits

Parameter	L1	L2	L3
RBC	5.1	4.4	4.4
HGB	4.9	3.5	3.5
HCT	6.0	5.7	5.3
MCV	4.3	4.2	4
MCH	6.1	5.3	5.1
MCHC	6.7	6.1	5.6
RDW-SD	4.7	4.9	6.3
RDW-CV	4.2	3.3	3.5
PLT	30.5	11.5	9.1
MPV	16.2	6.7	4.7
WBC	9.6	7.3	6
WBC-D	9.7	7.3	6.6
NEUT#	14.8	11.2	10.3
LYMPH#	21.6	19.1	20.6
MONO#	44.5	39.7	35.7
EO#	31.1	29.8	30.3
BASO#	28.1	21.4	21.1
IG#	23.3	19.2	17.2
NEUT%	11.4	8.7	8.2
LYMPH%	19.6	17.8	19.8
MONO%	43.1	38.8	35.1
EO%	29.3	28.8	29.5
BASO%	27.2	20.8	20.1
IG%	19.6	17.4	16.1
RET%	15.1	16.6	29.5
RET#	16.1	17.5	30.2
IRF	72.9	64.2	62.9
RET-HE	11.3	10.7	11.8

Evidence-based XN-L CHECK QC Limit Range% for XN-L Series

The limits provided below are for use on the XN-330/XN-430/XN-530/XN-350/XN-450/XN-550 analyzers for the XN L CHECK QC product. When analyzer specific targets are used, these evidence-based control limits will provide appropriate error detection with minimal false rejections. Limits provided here represent 4 Sigma quality.

Analyzer Specific Limits

Parameter	L1	L2	L3
RBC	5.1	4.4	4.4
HGB	4.9	3.5	3.5
HCT	6.0	5.7	5.3
MCV	4.3	4.2	4.0
MCH	4.9	4.2	4.2
MCHC	6.7	6.1	5.6
RDW-SD	6.3	6.9	8.0
RDW-CV	4.5	4.3	5.1
PLT	38.3	16.3	10.5
MPV	16.6	9.1	6.5
WBC	10.0	8.1	7.0
WBC-D	10.0	7.6	6.5
NEUT#	15.0	11.0	10.0
LYMPH#	20.0	13.0	12.0
MONO#	35.0	25.0	25.0
EO#	25.0	25.0	25.0
BASO#	27.8	21.9	19.9
IG#	25.4	23.2	23.6
NEUT%	15.0	11.0	10.0
LYMPH%	20.0	13.0	12.0
MONO%	35.0	25.0	25.0
EO%	25.0	25.0	25.0
BASO%	27.8	21.9	19.9
IG%	23.2	21.8	22.7
RET%	19.4	18.3	25.2
RET#	20.6	19.3	26.2
IRF	72.5	71.0	70.7
RET-HE	14.2	14.1	15.1

Evidence-based XN CHECK BF QC Limit Range% for XN-L Series

The limits provided below are for use on the XN-330/XN-430/XN-530/XN-350/XN-450/XN-550 analyzers. When analyzer specific targets are used, these evidence-based control limits will provide appropriate error detection with minimal false rejections. Limits provided here represent 4 Sigma quality.

Analyzer Specific Limits

Parameter	L1	L2
WBC-BF	32.0	19.9
RBC-BF	14.4	10.6
TC-BF#	32.0	19.9
MN#	37.4	36.4
PMN#	39.7	24.3
MN%	29.7	33.9
PMN%	16.0	13.0

XE-Series™ and XT-Series™ Analyzers Detector Control/Service Parameters File Limit Range%

Enter the Limit Range% values listed below for Level 1, Level 2 and Level 3 and for both Open/Manual and Closed Mode. Once entered, these values should not be changed.

DCPs/Service Parameters	Limit Range%	XE-2100	XE-2100L	XE-2100D	XT-2000*i* XT-4000*i*	XT-1800*i*	XE-5000
DIFF-X	8	X	X	X	X	X	X
DIFF-Y	68	X	X	X	X	X	X
BASO-X	15	X	X	X	X	X	X
BASO-Y	21	X	X	X	X	X	X
IMI#	80	X	X				X
IMIDC	20	X	X				X
IMIRF	43	X	X				X
NRBC-X	14	X	X				X
NRBC-Y	14	X	X				X
RBC-O	29	X			X		X
HFF	217	X			X		X
MFR	120	X			X		X
LFR	56	X			X		X
RBC-X	64	X			X		X
RBC-Y	17	X			X		X
NRBC%	999	X	X	X			
PDW	999	X	X	X	X	X	X
PLCR	999	X	X	X	X	X	X
PCT	999	X	X	X	X	X	X

Evidence-based QC Limit Range% for *plt*-CHECK

The limits provided below are for use on the XE-2100D analyzers in Blood Centers when using the *plt*-CHECK product. When analyzer specific targets are used, these evidence-based control limits will provide appropriate error detection with minimal false rejections. Limits provided here represent 4 Sigma quality.

Analyzer Specific Limits

Level 1 Limit%	Level 2 Limit %
7.8	**7.1**

Evidence-based QC Limit Range% for XE-5000™

The limits provided below are for use on the XE-5000 analyzers. When analyzer specific targets are used, these evidence-based control limits will provide appropriate error detection with minimal false rejections. Limits provided here represent 4 Sigma quality.

Analyzer Specific Limits

Parameter	Level 1 Limit %	Level 2 Limit %	Level 3 Limit %
RBC	3.9	3.2	3.1
HGB	3.8	2.8	2.7
HCT	5.1	4.6	4.6
MCV	4.1	3.9	3.8
MCH	4.7	4.0	3.8
MCHC	5.5	4.8	4.7
PLT	18.3	9.9	7.9
RDW-SD	4.9	5.1	4.9
RDW-CV	4.4	3.6	3.5
MPV	10.7	6.7	5.7
WBC	12.0	9.0	7.7
WBC-D	12.3	9.4	9.1
NEUT%	11.3	8.3	7.6
LYMPH%	14.5	12.0	11.7
MONO%	43.1	31.5	31.0
EO%	30.7	29.5	28.8
BASO%	8.4	5.3	3.2
NEUT#	16.5	12.4	10.7
LYMPH#	18.7	14.8	13.7
MONO#	45.0	33.3	32.4
EO#	33.0	30.9	29.9
BASO#	14.7	10.5	8.3
NRBC#	43.6	26.3	17.6
NRBC%	43.9	26.5	17.1
PLT-O	27.1	17.3	15.3
RET#	22.9	21.6	28.0
RET%	22.5	21.5	28.0
IRF	58.2	64.5	66.3
IG#	24.1	20.8	20.4
IG%	20.9	18.8	20.4
HPC	21.6	16.3	16.0
RET-H*e*	11.2	11.1	12.4
IPF%	18.9	18.9	19.3

Evidence-based QC Limit Range% for XE-2100™ Series

The limits provided below are for use on the XE-2100 Series analyzers. When analyzer specific targets are used, these evidence-based control limits will provide appropriate error detection with minimal false rejections. Limits provided here represent 4 Sigma quality.

Analyzer Specific Limits

Parameter	Level 1 Limit %	Level 2 Limit %	Level 3 Limit %
RBC	3.9	3.2	3.1
HGB	3.8	2.8	2.7
HCT	5.1	4.6	4.6
MCV	4.1	3.9	3.8
MCH	4.7	4.0	3.8
MCHC	5.5	4.8	4.7
PLT	18.3	9.9	7.9
RDW-SD	4.9	5.1	4.9
RDW-CV	4.4	3.6	3.5
MPV	10.7	6.7	5.7
WBC	12.0	9.0	7.7
NEUT%	11.3	8.3	7.6
LYMPH%	14.5	12.0	11.7
MONO%	43.1	31.5	31.0
EO%	30.7	29.5	28.8
BASO%	8.4	5.3	3.2
NEUT#	16.5	12.4	10.7
LYMPH#	18.7	14.8	13.7
MONO#	45.0	33.3	32.4
EO#	33.0	30.9	29.9
BASO#	14.7	10.5	8.3
NRBC#	13.3	10.7	9.5
NRBC%	999	999	999
NRBC# [*e*-CHECK(XE)]	43.6	26.3	17.6
NRBC% [*e*-CHECK(XE)]	43.9	26.5	17.1
PLT-O	27.1	17.3	15.3
RET#	22.9	21.6	28.0
RET%	22.5	21.5	28.0
IRF	58.2	64.5	66.3
IG#	24.1	20.8	20.4
IG%	20.9	18.8	20.4
HPC	21.6	16.3	16.0
RET-H*e*	11.2	11.1	12.4
IPF%	18.9	18.9	19.3

Evidence-based QC Limit Range% for XT-Series™

The limits provided below are for use on the XT-Series analyzers. When analyzer specific targets are used, these evidence-based control limits will provide appropriate error detection with minimal false rejections. Limits provided here represent 4 Sigma quality.

Analyzer Specific Limits

Parameter	Level 1 Limit %	Level 2 Limit %	Level 3 Limit %
RBC	4.3	3.8	3.6
HGB	4.5	3.2	2.8
HCT	5.2	4.6	4.5
MCV	3.9	3.6	3.5
MCH	5.6	4.5	4.3
MCHC	6.0	5.1	4.8
PLT	20.9	10.6	8.1
RDW-SD	5.7	5.9	6.9
RDW-CV	5.4	4.6	4.8
MPV	10.3	5.6	4.1
WBC	11.7	8.4	7.3
WBC-D (XT-4000*i*)	12.7	10.7	10.4
NEUT%	11.2	8.3	7.4
LYMPH%	18.1	13.6	10.5
MONO%	51.3	35.0	31.0
EO%	30.0	28.7	28.1
BASO%	7.8	4.8	3.0
NEUT#	16.3	11.7	10.3
LYMPH#	21.3	15.7	12.7
MONO#	53.2	36.2	31.9
EO#	31.9	29.8	29.1
BASO#	14.2	9.6	8.0
PLT-O	27.7	19.0	16.4
RET#	21.7	23.7	33.0
RET%	21.1	23.3	32.9
IRF	51.9	56.9	61.3
IG#	22.9	19.6	42.5
IG%	19.6	18.0	41.9
RET-H*e*	8.1	8.3	11.3

Evidence-based QC Limit Range% for XS-Series™

The limits provided below are for use on the XS-Series analyzers. When analyzer specific targets are used, these evidence-based control limits will provide appropriate error detection with minimal false rejections. Limits provided here represent 4 Sigma quality.

Analyzer Specific Limits

Parameter	Level 1 Limit %	Level 2 Limit %	Level 3 Limit %
RBC	5.0	4.0	4.0
HGB	6.0	4.3	4.2
HCT	6.0	5.1	5.0
MCV	4.9	4.3	4.0
MCH	5.6	4.5	4.3
MCHC	6.8	5.7	5.4
PLT	23.0	12.0	9.7
RDW-SD	7.1	7.3	8.1
RDW-CV	7.5	5.9	6.3
MPV	10.9	6.9	5.5
WBC-C	11.4	7.8	7.8
WBC-D	10.5	8.5	7.6
NEUT%	11.1	8.9	8.1
LYMPH%	12.1	9.1	7.7
MONO%	35.0	24.0	19.7
EO%	29.3	28.3	28.4
BASO%	34.9	31.1	31.1
NEUT#	15.1	12.4	11.1
LYMPH#	16.1	12.5	10.9
MONO#	36.5	25.5	21.0
EO#	31.2	29.6	29.6
BASO#	36.3	32.9	32.0
INPUT THE VALUES BELOW AND DON'T CHANGE			
DIFF-X	8.0	8.0	8.0
DIFF-Y	68.0	68.0	68.0
FSC-X	30.0	30.0	30.0

Suggested QC Limit Range% for XP-300™

The limits provided below are for use on the XP-300 analyzers. These limits are only for use in the interim while collecting data to establish your analyzer-specific control limits. Limits provided here represent three times the average analyzer's cumulative Standard Deviation or cumulative CV%.

Use for Reportable Parameters Prior To Establishing Analyzer Specific Limits

Parameter	Level 1 Absolute Limits	Level 2 Absolute Limits	Level 3 Absolute Limits
WBC	0.3	0.5	1.2
RBC	0.12	0.17	0.26
HGB	0.3	0.5	0.5
HCT	1.0	1.7	2.2
MCV	3.0	3.2	3.4
MCH	1.7	1.5	1.6
MCHC	2.6	2.3	2.3
PLT	13	24	43
LYMPH%	2.7	2.4	2.4
MIXED%	6.3	4.6	3.2
NEUT%	3.2	2.3	2.0
LYMPH#	0.2	0.5	1.5
MIXED#	0.3	0.6	0.9
NEUT#	0.4	0.4	0.9
W-SMV	2.5	3.5	3.5
W-LMV	5.9	5.9	5.9
RDW-CV	0.9	0.8	0.8
RDW-SD	2.7	2.0	1.8
MPV	1.1	0.8	0.4

Parameter	Level 1 % Limits	Level 2 % Limits	Level 3 % Limits
WBC	11.0	7.0	7.0
RBC	5.0	4.0	5.0
HGB	5.0	3.5	3.0
HCT	6.0	5.0	5.0
MCV	4.0	4.0	4.0
MCH	6.0	5.0	5.0
MCHC	7.0	6.0	6.0
PLT	25.0	12.0	9.0
LYMPH%	11.0	8.0	7.0
MIXED%	60.0	40.0	20.0
NEUT%	5.0	4.0	4.0
LYMPH#	25.0	25.0	25.0
MIXED#	100.0	75.0	31.0
NEUT#	19.0	11.0	10.0
W-SMV	4.0	5.5	5.5
W-LMV	3.0	3.0	3.0
RDW-CV	8.0	8.0	8.0
RDW-SD	8.0	6.0	5.0
MPV	12.0	8.5	4.0

Suggested QC Limit Range% for KX-Series™

The limits provided below are for use on the KX-Series analyzers. These limits are only for use in the interim while collecting data to establish your analyzer-specific control limits. Limits provided here represent three times the average analyzer's cumulative Standard Deviation or cumulative CV%.

Use for Reportable Parameters Prior To Establishing Analyzer Specific Limits

Parameter	Level 1 Absolute Limits	Level 2 Absolute Limits	Level 3 Absolute Limits
WBC	0.3	0.5	1.2
RBC	0.12	0.17	0.26
HGB	0.3	0.5	0.5
HCT	1.0	1.7	2.2
MCV	3.0	3.2	3.4
MCH	1.7	1.5	1.6
MCHC	2.6	2.3	2.3
PLT	13	24	43
LYMPH%	2.7	2.4	2.4
MIXED%	6.3	4.6	3.2
NEUT%	3.2	2.3	2.0
LYMPH#	0.2	0.5	1.5
MIXED#	0.3	0.6	0.9
NEUT#	0.4	0.4	0.9
W-SMV	2.5	3.5	3.5
W-LMV	5.9	5.9	5.9
RDW-CV	0.9	0.8	0.8
RDW-SD	2.7	2.0	1.8
MPV	1.1	0.8	0.4

Parameter	Level 1 % Limits	Level 2 % Limits	Level 3 % Limits
WBC	11.0	7.0	7.0
RBC	5.0	4.0	5.0
HGB	5.0	3.5	3.0
HCT	6.0	5.0	5.0
MCV	4.0	4.0	4.0
MCH	6.0	5.0	5.0
MCHC	7.0	6.0	6.0
PLT	25.0	12.0	9.0
LYMPH%	11.0	8.0	7.0
MIXED%	60.0	40.0	20.0
NEUT%	5.0	4.0	4.0
LYMPH#	25.0	25.0	25.0
MIXED#	100.0	75.0	31.0
NEUT#	19.0	11.0	10.0
W-SMV	4.0	5.5	5.5
W-LMV	3.0	3.0	3.0
RDW-CV	8.0	8.0	8.0
RDW-SD	8.0	6.0	5.0
MPV	12.0	8.5	4.0

Suggested QC Limit Range% for pocH-100*i*™

The limits provided below are for use on the pocH-100*i* analyzers. These limits are only for use in the interim while collecting data to establish your analyzer-specific control limits. Limits provided here represent three times the average analyzer's cumulative Standard Deviation or cumulative CV%.

Use for Reportable Parameters Prior To Establishing Analyzer Specific Limits

Parameter	Level 1 Absolute Limits	Level 2 Absolute Limits	Level 3 Absolute Limits
WBC	0.3	0.6	1.3
RBC	0.2	0.2	0.3
HGB	0.4	0.6	0.8
HCT	1.5	2.7	3.2
MCV	5.4	4.7	4.9
MCH	1.8	1.8	1.9
MCHC	2.8	2.6	2.6
PLT	13.5	27.5	52.0
LYMPH%	3.8	2.9	2.4
MIXED%	4.5	3.2	2.8
NEUT%	4.9	3.7	2.9
LYMPH#	0.2	0.3	0.7
MIXED#	0.3	0.4	0.6
NEUT#	0.3	0.5	0.8
W-SMV	4.8	4.3	4.3
W-LMV	12.4	11.7	11.4
RDW-CV	1.1	1.0	1.2
RDW-SD	2.6	2.7	3.2
MPV	1.3	0.9	0.7

Parameter	Level 1 % Limits	Level 2 % Limits	Level 3 % Limits
WBC	12.0	9.0	7.5
RBC	6.5	5.5	5.5
HGB	6.0	5.0	5.0
HCT	8.0	7.0	7.0
MCV	7.0	5.5	5.5
MCH	7.0	6.5	6.0
MCHC	8.5	8.0	7.5
PLT	25.0	14.0	11.0
LYMPH%	15.5	9.5	7.0
MIXED%	44.0	28.0	17.0
NEUT%	7.5	6.5	6.0
LYMPH#	24.5	16.0	10.5
MIXED#	110.0	35.0	20.0
NEUT#	16.5	12.0	10.0
W-SMV	7.0	6.5	6.5
W-LMV	6.0	6.0	5.5
RDW-CV	7.0	7.5	8.0
RDW-SD	6.0	6.5	7.0
MPV	13.0	9.0	7.0

Control Data Handling

Please Review and Edit Control Data Prior to Period Closures

The ***Insight*** Report is a quality assessment tool that is intended to reflect on-average analyzer operation. Each ***Insight*** report should allow the laboratory to detect significant systematic increases in inaccuracy and to monitor performance trends across reports.

Review Requirement
After QC files have been submitted to ***Insight*** and before the period closes, the QC data should be reviewed to manage out-of-control data that was due to a known cause.

When to Include Data
When no known cause can be assigned, an out-of-control result must be documented as random error. These errors should be included in data submitted to ***Insight*** as they reflect normal process variation. Inclusion ensures the statistically acceptable ranges for inaccuracy do not become too narrow.

When to Exclude Data
Where a known cause can be assigned to an out-of-range result, (control run in wrong file, short sample, suspect reagents or control vials, etc.) that result should be excluded.

Summary
Management of control results before the ***Insight*** period closes can ensure a more accurate analyzer report and provide a better assessment of analyzer performance.

Document Control Data

Requirement
Documentation of any out-of-range result is required for regulatory inspection and accreditation.

Comments can be added to ***Insight*** for any QC sample. These comments are stored on your ***Insight*** reports.

Report Retrieval
Insight reports are stored on the ***Insight*** website for a minimum of 2½ years and can be viewed when needed.