SIEMENS

ADVIA® 120
ADVIA® 2120
ADVIA® 2120i
Hematology Systems

ADVIA® 120 / 2120 / 2120i Hematology Systems

Supplemental Information
Research Use Only (RUO)

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CE

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If the system is used in a manner differently than specified by Siemens, the protection provided by the equipment may be impaired. See warning and hazard statements.

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Introduction

This Research Use Only (RUO) supplemental information manual provides information on Research Use Only (RUO) parameters. **RUO parameters are not FDA cleared and are not to be used for the reporting of patient results in any form or for any clinical or diagnostic purposes.** They are provided as an aid for laboratory personnel to alert them to suspected sample abnormalities.

For routine operation and for reporting of results the *ADVIA® 2120/2120i Operator's Manual* is to be used.

Summary

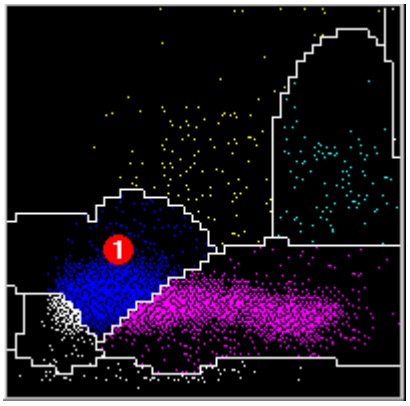
This RUO manual provides information on Research Use Only (RUO) parameters. It is used by laboratory personnel to alert them to suspected sample abnormalities through the combined use of morphology and quantitative flags (high and low). ADVIA 2120/2120i morphology flags are derived from a series of complex algorithms. These algorithms are based on the identification of conditions surrounding the presence of abnormalities.

The ADVIA 2120/2120i system does not enumerate abnormal cells. Despite a high degree of sensitivity and specificity in detecting conditions consistent with the presence of abnormal cells, test results produced by the ADVIA 2120/2120i system are intended for laboratory use only. Whenever morphology or quantitative flags are triggered, the laboratory, before reporting patient results, must validate the results and take the appropriate action in accordance with established standard operating procedures.

All general method and bibliographical information can be referenced in the *ADVIA 2120/2120i Operator's Manual*.

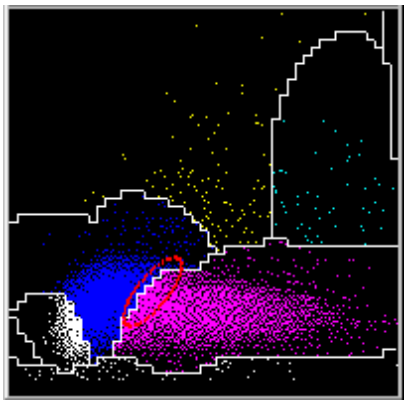
Basophil / Lobularity Method

Location of Atypical Lymphocytes on the BASO Cytogram



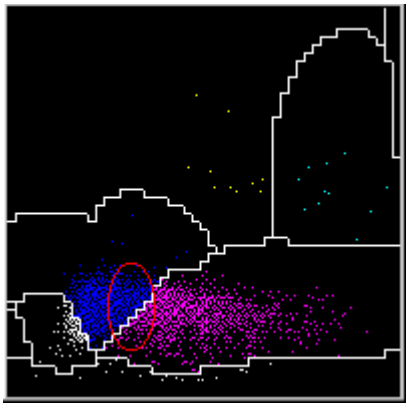
Atypical Lymphocytes appear within the mononuclear (MN) area (1) on the BASO cytogram.

Location of Immature Granulocytes on the BASO Cytogram



Immature Granulocytes appear within the MN area on the BASO cytogram.

Location of Bands on the BASO Cytogram



Bands appear between the mononuclear (MN) and polymorphonuclear (PMN) populations.

Calculating Parameters

Additional Parameters

The following parameters are for research or laboratory use only and are not for patient reporting:

Parameter	Explanation
%BASO Suspect	100 x (BASO Suspect ÷ BASO PHA Cells)
%BLAST	100 x (Blasts ÷ BASO PHA Cells)
%MN	100 x (MN ÷ BASO PHA Cells)
%PMN	100 x (PMN ÷ BASO PHA Cells)
%PMN Ratio	%PMN ÷ (%NEUTS + %EOS)
BASO % Dead Time	100 x FracDT
BASO % Noise	100 x (Noise ÷ BASO PHA Cells)
BASO % Saturation	100 x (BASO Saturation ÷ BASO PHA Cells)
BASO Flatness	$\sqrt{\frac{\text{Sum of the Squared Differences}}{9 \times \text{Mean Cell Counting Rate}}}$
LI	PMNx ÷ MNx
MNx	Peak X channel of Mononuclear cluster
MNy	Peak Y channel of Mononuclear cluster
PMNx	Peak X channel of Polymorphonuclear cluster

Parameter Key

% BASO Suspect
Percent of events from Baso Suspect area

% MN
Percent of events from Mononuclear area

% PMN
Percent of events from Polymorphonuclear area

% PMN Ratio
Ratio of the percent of the Polymorphonuclear events to the percent of NEUTS and EOS obtained from the peroxidase method

BASO % Dead Time
Percent of analysis time when the channel is busy and cannot detect flowcell events

BASO % Noise
Percent of events from Noise area

BASO % Saturation
Percent of events from Saturation area

LI
Lobularity Index

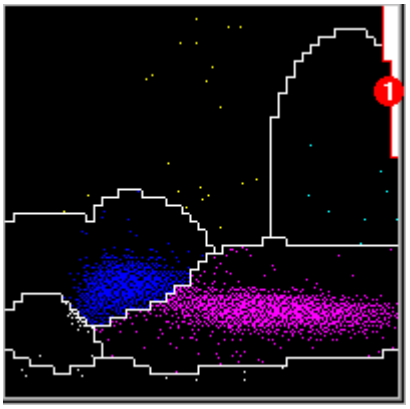
% Blast
Percent of events from Blast area

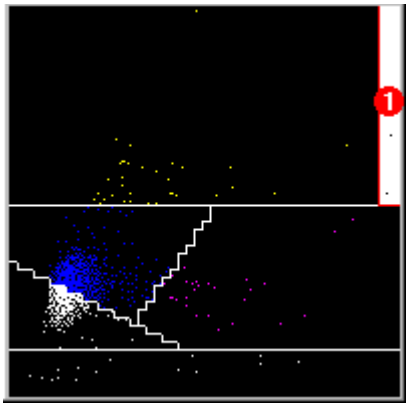
BASO PHA Cells (B-acq)
The total number of events in the BASO cytogram excluding the Noise area.

BASO PHA Total (B-tot)
The total number of events in the BASO Cytogram including the Noise area.

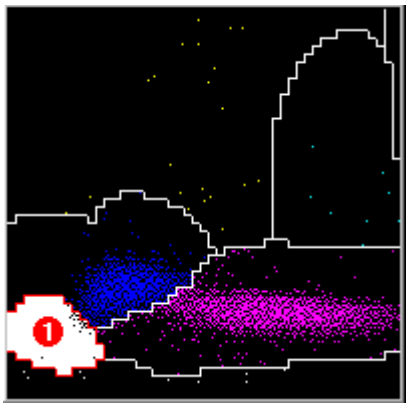
BASO Valid Cells (B-vc)
The number of valid electronic pulse signals detected from flowcell events.

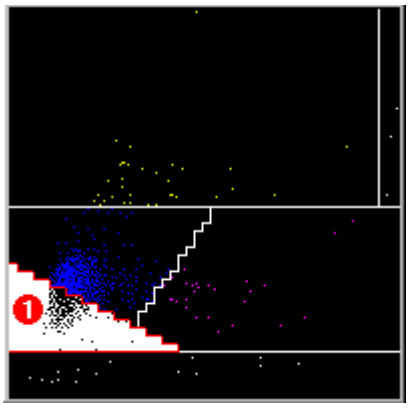
BASO Saturation
The number of events in the Saturation area (1) of the BASO cytogram.



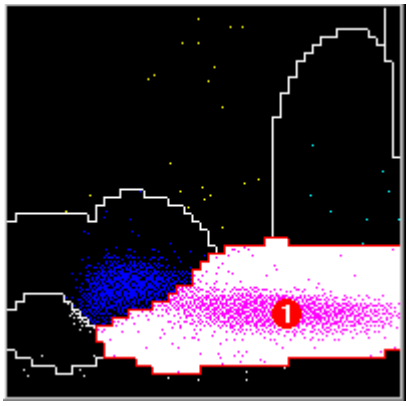
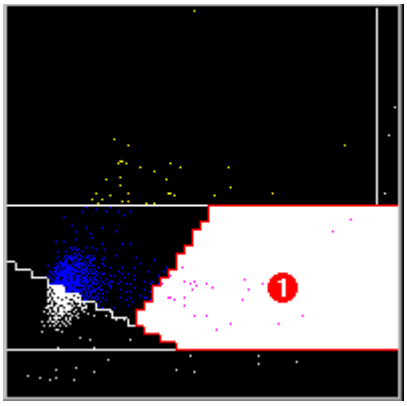


Blasts
The number of events in the Blasts area (1) of the BASO cytogram.

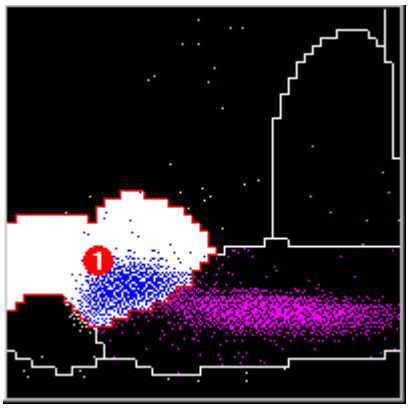
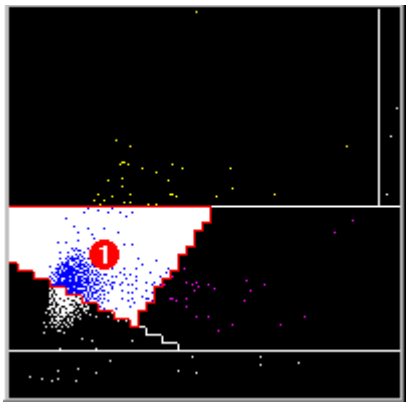




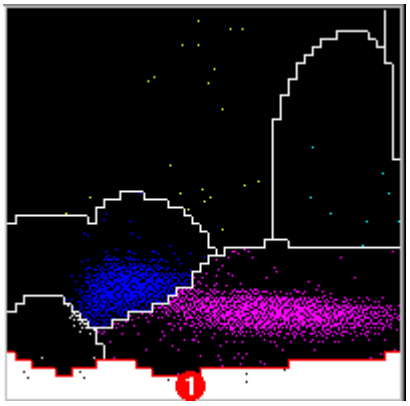
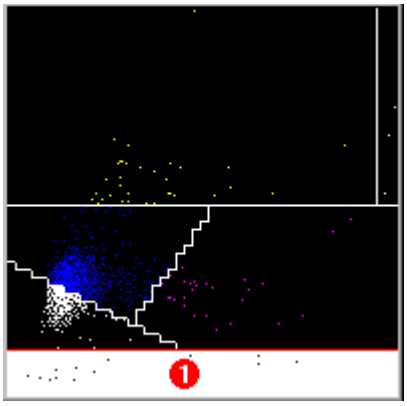
PMN
The number of events in the PMN area (1) of the BASO cytogram.

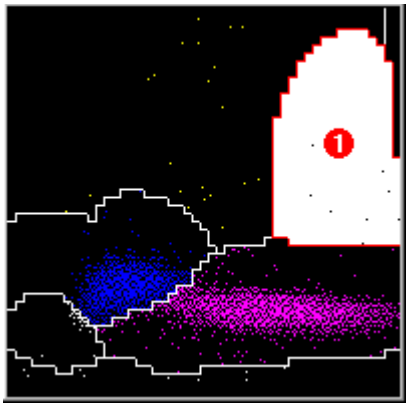
MN
The number of events in the MN area (1) of the BASO cytogram.

Noise
The number of events in the Noise area (1) of the BASO cytogram.

BASO Suspect
The number of events in the Baso Suspect area (1) of the BASO cytogram.



RawWBC
BASO Valid Cells x (BASO PHA Cells ÷ BASO PHA Total)

BasoCalFactor
The sampler-specific calibration factor:

BasoCalFactor = BASO WBC (AS) x 0.0012475

BasoCalFactor = BASO WBC (MCTS) x 0.0012475

BasoCalFactor = BASO WBC (OTS) x 0.0012475

To view the BASO WBC calibration factors, click **Cal/Gain Logs** on the System Logs menu.

FracDT
The fraction of time that the channel is busy processing flowcell events. While the Baso channel is busy identifying a particular flowcell event, it is unable to process any additional events that might occur. By measuring this "dead time," the analyzer can compensate for these events.

CSF Method

Measurement

A research-use-only eosinophil count and percent (%) is provided.

CSF Scatter/Scatter Cytogram

The CSF Scatter/Scatter Cytogram is a 100 x 100-channel, two-dimensional, pulse height distribution of the scatter high and scatter low data for WBC, RBC, and noise, where the X-axis is high-angle scatter and the Y-axis is low angle scatter. A fixed mask is used to set thresholds for Neutrophil, Lymphocyte, Monocyte and RBC regions. Eosinophils fall within the Neutrophil region in this cytogram. The number of eosinophils is determined from the Scatter/Absorption cytogram and is subtracted from the number of cells in the Neutrophil region prior to calculating WBC and Neutrophil parameters. Eosinophil data is for research purposes only and is non-reportable.

CSF Scatter/Absorption Cytogram

The CSF Scatter/Absorption Cytogram is a 100 x 100-channel, two-dimensional, pulse height distribution of the scatter high and absorption data for WBC, RBC, and noise, where the X-axis is absorption and the Y-axis is high angle scatter. A fixed mask is used to set the threshold for eosinophil analysis. Because of their higher absorption, eosinophils fall to the right of the neutrophil population in this cytogram and are thus able to be separated from the neutrophil population. The number of eosinophils is subtracted from the number of cells falling in the neutrophil region of the Scatter/Scatter cytogram before calculating WBC and Neutrophil parameters.

Calculating Parameters

Additional Parameters

The following parameters are for research or laboratory use only and are not for patient reporting:

Parameter	Explanation
%CSF Eos	%CSF Eos = 100 x CSF Eos / CSF WBC
#CSF Eos	#CSF Eos/µL = (CSF PHA Eos / CSF PHA Total x CSF PHA Cells) / (1-Fractional Dead Time) x Perox Nominal Factor
CSF PHA Total	The total number of cells displayed in the CSF Scatter/Scatter cytogram including the noise region.
CSF PHA Cells	The total number of cells displayed in the CSF Scatter/Scatter cytogram excluding the noise region.

Parameter	Explanation
CSF %Noise	The percentage of cells that are located in the noise region of the CSF Scatter/Scatter cytogram.
CSF PHA WBC	The number of cells falling into the WBC regions of the CSF Scatter/Scatter cytogram.
CSF PHA Eos	The number of cells falling in the Eosinophil Region of the CSF Scatter/Absorption cytogram.
CSF PHA Lymphs	The number of cells falling in the Lymphocyte Region of the CSF Scatter/Scatter cytogram.
CSF PHA Monos	CSF PHA Monos is the number of cells falling in the Monocyte Region of the CSF Scatter/Scatter cytogram.
CSF PHA Neuts	The number of neutrophils falling in the Neutrophil Region of the CSF Scatter/Scatter cytogram. Due to their scatter/scatter properties, both neutrophils and eosinophils fall in this region of the CSF Scatter/Scatter cytogram. The number of CSF PHA Eos is identified in the Eosinophil Region of the CSF Scatter/Absorption cytogram and subtracted from the number of cells in the Neutrophil Region of the CSF Scatter/Scatter cytogram to determine the CSF PHA Neuts. CSF PHA Neuts = # cells in Neutrophil Region (CSF Scatter/Scatter Cytogram) – CSF PHA Eos (CSF Scatter/Absorption Cytogram)
CSF R Count	The number of cells falling in the Red Cell Region of the CSF Scatter/Scatter cytogram.

Parameter Key

%CSF Eos
The research-only CSF differential percentage eosinophil cell count.

#CSF Eos
The research-only CSF absolute eosinophil cell count.

Hemoglobin Method

Calculating Parameters

Additional Parameters

The following parameters are for research or laboratory use only and are not for patient reporting:

Parameter	Explanation
Delta HGB	HGB - Calculated HGB
HGB Baseline Transmission	Baseline Mean x 3.05194E-4
HGB Sample Transmission	Sample Mean x 3.05194E-4
HGB Baseline Flatness	Maximum Baseline Value - Minimum Baseline Value
HGB Sample Flatness	Maximum Sample Value - Minimum Sample Value

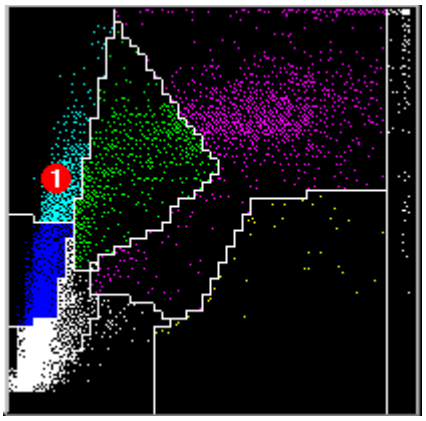
Peroxidase Method

PEROX Cytogram

Abnormal Cell Locations

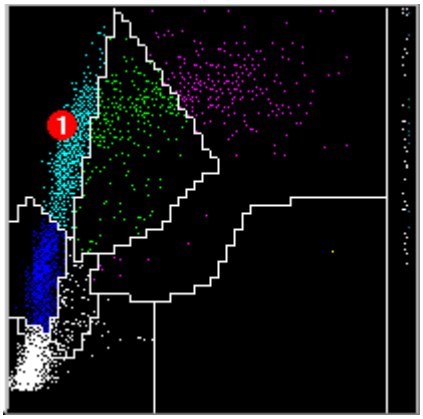
If abnormal cells are present, their size and peroxidase activity determine their location on the PEROX cytogram.

Location of Atypical Lymphocytes on PEROX Cytogram



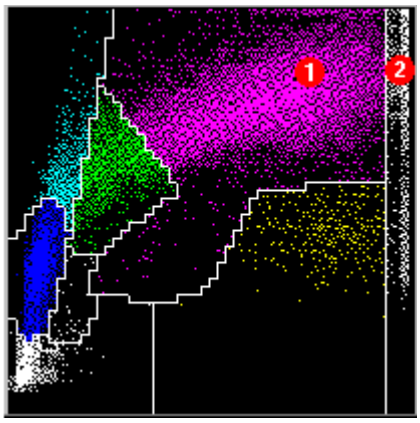
Atypical lymphocytes are large cells with no peroxidase activity that can appear in the LUC area (1).

Location of Blasts on PEROX Cytogram



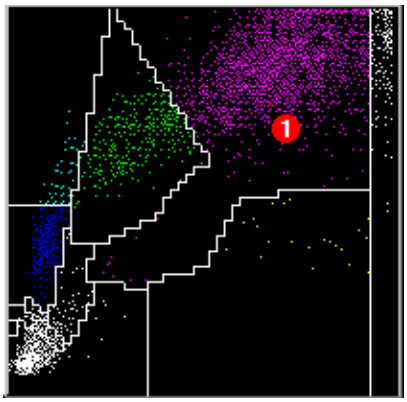
Similarly, **blasts** and other large abnormal cells with no peroxidase activity also appear in the LUC area (1).

Location of Immature Granulocytes on PEROX Cytogram



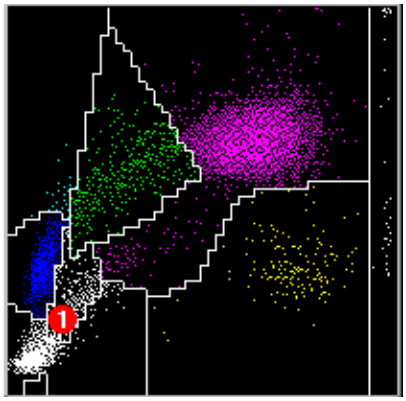
Immature Granulocytes are large cells with high peroxidase activity that can appear in the neutrophil area (1) and the saturation area (2).

Location of Bands on PEROX Cytogram



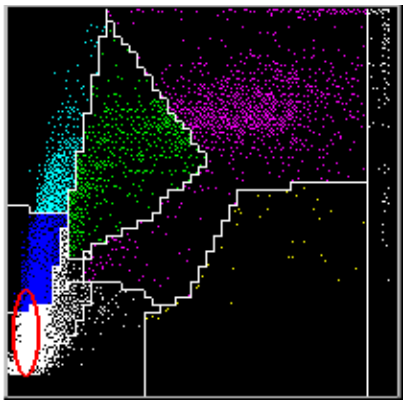
Bands appear within the the Neutrophil population (1) due to their similar size and degree of peroxidase staining.

Location of Platelet Clumps on PEROX Cytogram



Platelet Clumps form a separate cluster (1) that originates in the Noise area on the PEROX cytogram.

Location of Unlysed RBCs on PEROX Cytogram



Unlysed RBCs with no peroxidase activity appear along the left side of the PEROX cytogram.

Calculating Parameters

Additional Parameters

The following parameters are for research or laboratory use only and are not for patient reporting:

Parameter	Explanation
%HPX	100 x (HPX ÷ PHA Cells)
Clumps Count	Number of events in the Platelet Clumps area of the PEROX cytogram
Valley Count	Number of events in the NRBC area of the PEROX cytogram
Lymph Mode	Mode channel of the Lymphocyte cluster
MPXI	$\frac{(\text{X Mean of Sample Neut - Expected staining index})}{\text{Expected staining index}} * 100$
NEUT X	Mean X channel for neutrophil cluster
NEUT Y	Mean Y channel for neutrophil cluster
Noise/Lymph Valley	Valley channel between Noise and Lymph clusters
Perox d/D	$\frac{\text{Lymph Mode Count - Noise / Lymph Valley Count}}{\text{Lymph Mode Count}}$
PEROX % Dead Time	100 x FracDT
PEROX % Noise	100 x (Noise ÷ PHA Cells)
PEROX % Saturation	100 x (Perox Saturation ÷ PHA Cells)
PEROX Flatness	$\sqrt{\frac{\text{Sum of the Squared Differences}}{9 \times \text{Mean Cell Counting Rate}}}$

Parameter Key

RawWBC

Perox Valid Cells x (PHA Cells ÷ PHA Total)

PeroxCalFactor

The sampler-specific calibration factor:

PeroxCalFactor = PEROX WBC (AS) x 0.001248

PeroxCalFactor = PEROX WBC (MCTS) x 0.001248

PeroxCalFactor = PEROX WBC (OTS) x 0.001248

To view the PEROX WBC calibration factors, select **Cal/Gain Logs** at the System Logs menu.

FracDT

The fraction of time that the channel is busy processing flowcell events. While the perox channel is busy identifying a particular flowcell event, it is unable to process any additional events that might occur. By measuring this "dead time," the analyzer can compensate for these events.

MPXI

The mean peroxidase activity index or staining intensity of the neutrophil population relative to the archetype.

PEROX PHA Cells (P-acq)

The total number of events in the PEROX cytogram excluding the Noise area.

NOTE: nRBC and PLT Clump events are components of Perox Noise. Therefore, they are not included in the PEROX PHA Cells.

PEROX PHA Total (P-tot)

The total number of events in the PEROX cytogram including the Noise area.

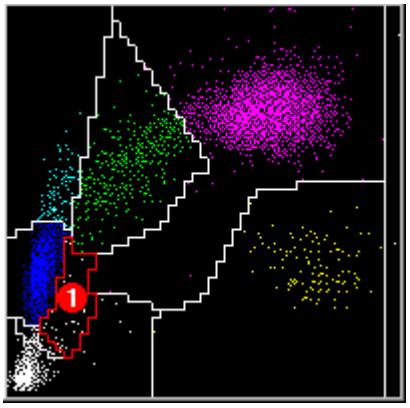
Perox Valid Cells (P-vc)

The number of valid electronic pulse signals detected from flowcell events.

HPX

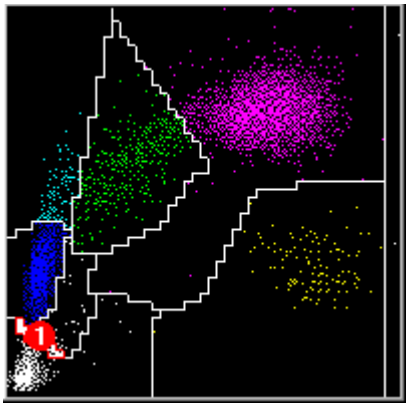
The number of events with absorption values greater than 1.4 times the X channel mean of the neutrophil cluster.

Clumps Count



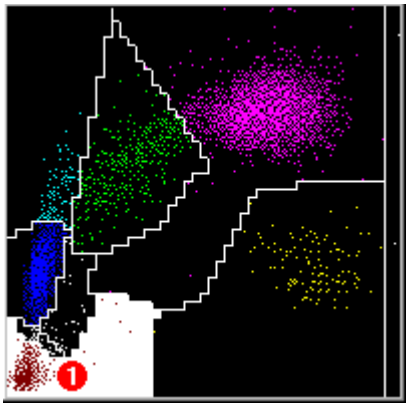
The number of events in the Platelet Clumps area (1) of the PEROX cytogram.

Valley Count



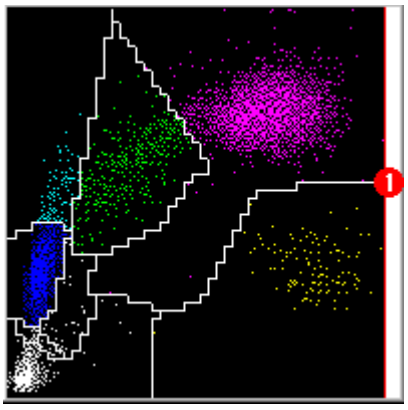
The number of events in the NRBC area (1) of the PEROX cytogram.

Perox Noise



The number of events in the Noise area (1) of the PEROX cytogram.

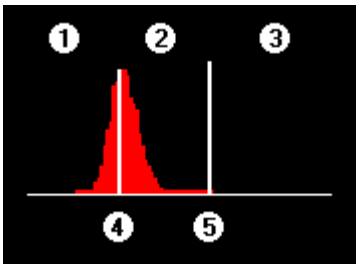
Perox Saturation



The number of events in the Saturation area (1) of the PEROX cytogram.

RBC / Platelet Method

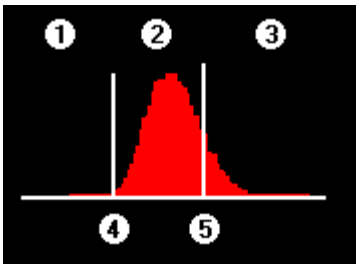
RBC Volume histogram (microcytic sample)



1 Microcytic region
2 Normocytic region
3 Macrocytic region
4 60 fL marker
5 120 fL marker

In samples with increased numbers of microcytic red blood cells, the histogram curve shifts to the left, indicating an increase in the percentage of the cells with volumes less than 60 fL.

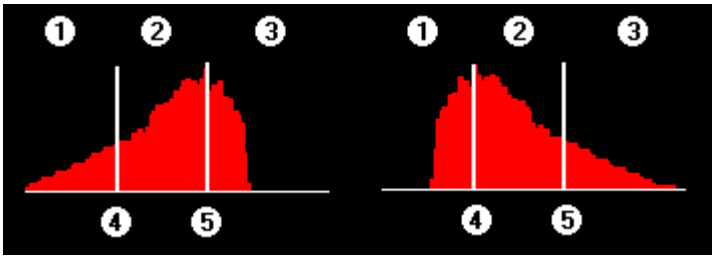
RBC Volume histogram (macrocytic sample)



1 Microcytic region
2 Normocytic region
3 Macrocytic region
4 60 fL marker
5 120 fL marker

In samples with increased numbers of macrocytic red blood cells, the histogram curve shifts to the right, indicating an increase in the percentage of the cells with volumes greater than 120 fL.

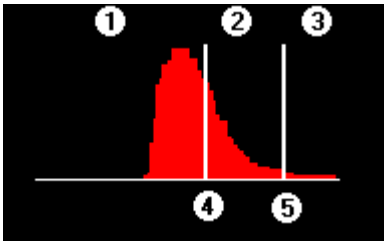
RBC Volume histogram (anisocytosis)



1 Microcytic region
2 Normocytic region
3 Macrocytic region
4 60 fL marker
5 120 fL marker

RDW is monitored as an indication of anisocytosis, and the results are flagged if the RDW exceeds 16%. Note that two specimens with the same RDW value can have different degrees of microcytosis and macrocytosis.

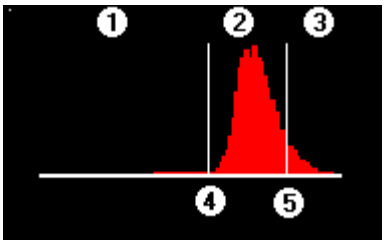
RBC HC histogram (hypochromic sample)



1 Hypochromic region
2 Normochromic region
3 Hyperchromic region
4 28 g/dL marker
5 41 g/dL marker

In samples with increased numbers of hypochromic RBCs, the histogram curve shifts to the left, indicating an increase in the percentage of the cells with hemoglobin concentrations less than 28 g/dL.

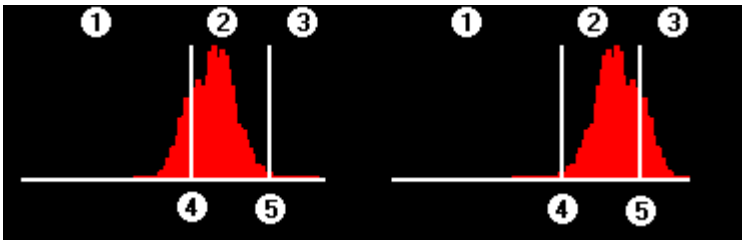
RBC HC histogram (hyperchromic sample)



1 Hypochromic region
2 Normochromic region
3 Hyperchromic region
4 28 g/dL marker
5 41 g/dL marker

In samples with increased numbers of hyperchromic RBCs, the histogram curve shifts to the right, indicating an increase in the percentage of the cells with hemoglobin concentrations greater than 41 g/dL.

RBC HC histogram (Hgb variance sample)



1 Hypochromic region
2 Normochromic region
3 Hyperchromic region
4 28 g/dL marker
5 41 g/dL marker

HDW provides an indication of Hgb concentration variance, and the results are flagged if the HDW exceeds 3.4 g/dL. Note that two specimens with the same HDW value can have different degrees of hypochromia and hyperchromia.

Since the histogram analysis uses calibration factors that are not applied to the RBC V/HC cytogram, there can be a discrepancy between the RBC matrix values and the corresponding %Micro, %Macro, %Hypo, and %Hyper values obtained from the histograms based on the value of the calibration factors. The closer the MCV and CHCM calibration factors are to 1.0, the smaller the discrepancies are.

Calculating RBC Parameters

Additional Parameters

The following parameters are for research or laboratory use only and are not for patient reporting:

Parameter	Explanation
CHDW	SD of RBC CH histogram
RBC Flatness	$\sqrt{\frac{\text{Sum of the Squared Differences}}{9 \times \text{Mean Cell Counting Rate}}}$
RBC % Dead Time	100 x (Measured Dead Time ÷ Measured Sample Time)
RBC Coin Level	Number of coincidence events to be trimmed
RBC Coin Count	Coincidence Count in RBC Scatter cytogram
RBC R Count	Number of RBCs in RBC Scatter cytogram
RBC P Count	Number of platelets in RBC Scatter cytogram
RBC Valid Cells	Number of Valid Signals Obtained from Flowcell Events
#MICRO	Cell Count (30 fL to 60 fL) in RBC Volume histogram
%MACRO	$100 \times \frac{\text{Cell Count in RBC Volume histogram} > 120\ \text{fL}}{\text{Total Cell Count in RBC Volume histogram}}$
%MICRO	$100 \times \frac{\text{Cell Count in RBC Volume histogram} < 60\ \text{fL}}{\text{Total Cell Count in RBC Volume histogram}}$
%HYPER	$100 \times \frac{\text{Cell Count in RBC HC histogram} > 41\text{g/dL}}{\text{Total Cell Count in RBC HC histogram}}$
%HYPO	$100 \times \frac{\text{Cell Count in RBC HC histogram} < 28\text{g/dL}}{\text{Total Cell Count in RBC HC histogram}}$
%MICRO/ %HYPO RATIO	%MICRO ÷ %HYPO

Parameter Key

CHDW
Cell Hemoglobin Distribution Width

RBC % Dead Time
Percent of analysis time when the channel is busy and cannot detect flowcell events

RBC Coin Level
RBC Coincidence Level

RBC Coin Count
RBC Coincidence Count

RBC R Count
Raw red blood cell count from the RBC method

RBC P Count
Raw platelet count from the RBC method

% MACRO
Percent of macrocytic red blood cells

% MICRO
Percent of microcytic red blood cells

 # MICRO
Number of microcytic red blood cells

% HYPER
Percent of hyperchromic red blood cells

% HYPO
Percent of hypochromic red blood cells

%Micro / %Hypo Ratio
This parameter is reported to be of use in differentiating two types of microcytic anemia.

Calculating Platelet Parameters

Additional Parameters

The following parameters are for research or laboratory use only and are not for patient reporting:

Parameter	Explanation
Large PLT	Platelets with volumes greater than 20 fL
MPC	Mean of Platelet PC histogram
MPM	Mean of Platelet PM histogram
PCDW	SD of Platelet PC histogram
P Count - 2D	Raw cell count for platelets and large platelets from 2D-platelet analysis
PCT	(PLT x MPV) ÷ 10,000
PDW	100 x (SD of Platelet VOL histogram ÷ MPV)
PLT N	Mean of refractive index values for platelets only
PLT X	Mean of high-angle, high-gain values for platelets only
PLT Y	Mean of low-angle, high-gain values for platelets only
PMDW	SD of Platelet PM histogram
R Count - 2D	Raw cell count for RBCs, RBC ghosts, and RBC fragments from 2D-platelet analysis
RBC - 2D Count	Number of Red Cells-2D from 2D-platelet analysis x RBC Cal Factor x Dilution Factor x Coincidence-correction Factor
RBC Fragments	Count of RBC Fragments
RBC Ghosts	Count of RBC Ghosts

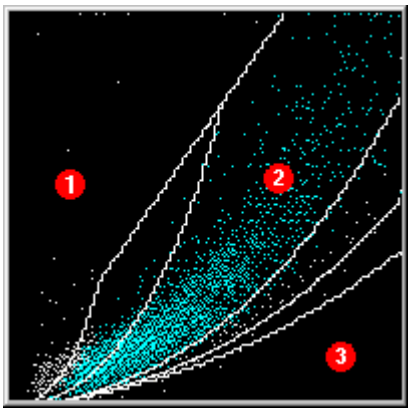
Parameter Key

Large PLT

The count of platelets with volumes greater than 20 fL is derived from the Platelet Volume histogram based on Integrated Analysis.
Large Platelet Count is in the same units selected for PLT on the Unit Set Configuration window of the System Setup tab.

RBC Fragments

This count includes events in the RBC Fragment area of the PLT Scatter cytogram that have volumes less than 30fL and refractive indexes greater than 1.400.

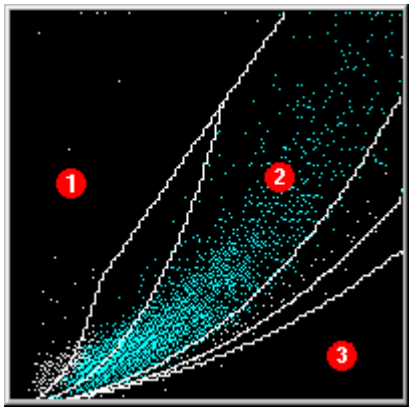


1 RBC Ghost area
2 Platelet area
3 RBC Fragment area

The RBC Fragments Count is in the same units selected for RBC on the Unit Set Configuration window of the System Setup tab.

RBC Ghosts

This count includes events in the RBC Ghost area of the PLT Scatter cytogram that have refractive indexes lower than 1.350.



1 RBC Ghost area
2 Platelet area
3 RBC Fragment area

The RBC Ghosts Count is in the same units selected for RBC on the Unit Set Configuration window of the System Setup tab.

MPC

Mean Platelet Component Concentration

MPM

Mean Platelet Dry Mass

PCDW

Platelet Component Distribution Width

PDW
Platelet Volume Distribution Width

PMDW
Platelet Dry Mass Distribution Width

PCT
Platelet Crit

RBC Fractional Dead Time
The fraction of time that the channel is busy processing flowcell events. While the RBC/Plt channel is busy identifying a particular flowcell event, it is unable to process any additional events that might occur. By measuring this "dead time," the analyzer can compensate for the missed events.

Note that the RBC / Plt channel dead time has RBC and platelet components.

Corrected Platelet Count
The corrected platelet count is calculated using the P Count-2D , R Count-2D RBC Fractional Dead Time, and RBC Valid Cells.

P Count-2D
The number of cells identified as platelets and large platelets. The platelets are obtained from the PLT Scatter cytogram, and the large platelets are obtained from the integrated analysis.

R Count-2D
The count of RBCs, RBC ghosts, and RBC fragments that is obtained from the integrated analysis.

Number of red cells-2D
(R Count-2D x RBC Valid Cells) ÷ (R Count-2D + P Count-2D)

NRBC Method

Calculating Reported NRBC Parameters

The system corrects the reported WBC count when nRBCs are detected.

Histo, Residual, or Gaussian Count

$$\frac{WBCu}{1+\frac{\%NRBC}{100}}$$

Barox Count

$$WBCB-\left(WBCP \text{ x } \frac{\%Neut+\%Eos}{100}\right)+\left(WBCB \text{ x } \frac{\%MN+\%Baso}{100}\right)$$

Reticulocyte Method

Reticulocyte Method Nomenclature

Mature (m),

The lowercase letter m, is commonly used in the reticulocyte parameters to identify a specific population.

For example: MCVm, refers to the mean cell volume for the mature RBC.

Immature Reticulocyte Fraction

Immature Reticulocyte Fraction (IRF) is a descriptive term recommended in NCCLS Document H44-A "Methods for Reticulocyte Counting: Flow Cytometry and Supravital Dyes; Approved Guideline" to replace a previously-used term, Reticulocyte Maturation Index (RMI).

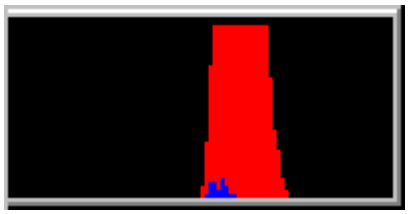
Two IRF parameters are calculated: IRF-H and IRF-H+M.

RETIC Volume Histogram Parameters

%MACROm	Percentage of mature RBC population with cell volumes greater than 120 fL
%MICROr	Percentage of reticulocyte population with cell volumes less than 60 fL
%MICROm	Percentage of mature RBC population with cell volumes less than 60 fL
%MICROg	Percentage of gated cell population with cell volumes less than 60 fL
MCVm	Mean Corpuscular Volume is the mean of the RETIC Volume histogram for the mature RBC population.
MCV Delta	MCVr - MCVm
RDWr	Red cell Distribution Width is the coefficient of variation (CV) of the RETIC Volume histogram (channels 15 to 99) for the reticulocyte population.
RDWm	Red cell Distribution Width is the coefficient of variation (CV) of the RETIC Volume histogram (channels 15 to 99) for the mature RBC population.
RDWg	Red cell Distribution Width is the coefficient of variation (CV) of the RETIC Volume histogram (channels 15 to 99) for the gated cells.
RDW Delta	RDWr - RDWm

RETIC HC Histogram

The RETIC hemoglobin concentration (RETIC HC) histogram represents the overlaid distributions of mature RBCs and reticulocytes by cellular hemoglobin concentration only. The histogram has a range from 0 g/dL to 50 g/dL. The displayed data includes the CHCMg calibration factor.



Mature RBC population (red)

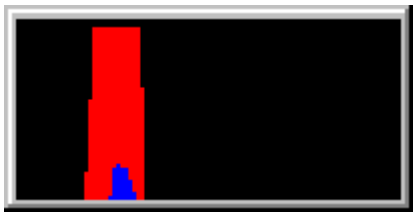
Reticulocyte population (blue)

RETIC HC Histogram Parameters

%HYPERr	Percentage of reticulocyte population with cellular hemoglobin concentration greater than 41 g/dL
%HYPERm	Percentage of mature RBC population with cellular hemoglobin concentration greater than 41 g/dL
%HYPERg	Percentage of gated cell population with cellular hemoglobin concentration greater than 41 g/dL
%HYPOr	Percentage of reticulocyte population with cellular hemoglobin concentration less than 28 g/dL
%HYPOm	Percentage of mature RBC population with cellular hemoglobin concentration less than 28 g/dL
%HYPOg	Percentage of gated cell population with cellular hemoglobin concentration less than 28 g/dL
CHCMm	Cellular Hemoglobin Concentration Mean is the mean of the RETIC HC histogram for the mature RBC population.
CHCM Delta	CHCMr - CHCMm
HDWr	Hemoglobin Distribution Width is the standard deviation (SD) of the RETIC HC histogram for the reticulocyte population.
HDWm	Hemoglobin Distribution Width is the standard deviation (SD) of the RETIC HC histogram for the mature RBC population.
HDWg	Hemoglobin Distribution Width is the standard deviation (SD) of the RETIC HC histogram for the gated cells.
HDW Delta	HDWr - HDWm

RETIC CH Histogram

The RETIC cellular hemoglobin (RETIC CH) histogram represents the overlaid distributions of mature RBCs and reticulocytes by the actual weight or mass of hemoglobin present in each cell. The histogram has a range from 0 pg to 100 pg.



Mature RBC population (red)

Reticulocyte population (blue)

RETIC CH Histogram Parameters

%HIGH CHr	Percentage of reticulocyte population with cellular hemoglobin greater than 31 pg
%HIGH CHm	Percentage of mature RBC population with cellular hemoglobin greater than 31 pg
%HIGH CHg	Percentage of gated cell population with cellular hemoglobin greater than 31 pg
%LOW CHr	Percentage of reticulocyte population with cellular hemoglobin less than 27 pg
%LOW CHm	Percentage of mature RBC population with cellular hemoglobin less than 27 pg
%LOW CHg	Percentage of gated cell population with cellular hemoglobin less than 27 pg
CHm	Cellular Hemoglobin Mean is the mean of the RETIC CH histogram for the mature RBC population.
CH Delta	CHr - CHm
CHDWr	Cellular Hemoglobin Distribution Width is the standard deviation (SD) of the RETIC CH histogram for the reticulocyte population.
CHDWm	Cellular Hemoglobin Distribution Width is the standard deviation (SD) of the RETIC CH histogram for the mature RBC population.
CHDWg	Cellular Hemoglobin Distribution Width is the standard deviation (SD) of the RETIC CH histogram for the gated cells.
CHDW Delta	CHDWr - CHDWm

Calculating Retic Parameters

System Parameters

The following parameters are for research or laboratory use only and are not for patient reporting:

Parameter	Explanation
RTC RBC	RBC Count
RTC Flatness	$\sqrt{\frac{\text{Sum of the Squared Differences}}{9 \times \text{Mean Cell Counting Rate}}}$
RTC % Dead Time	100 x (Measured Dead Time ÷ Measured Sample Time)
RTC % Noise	100 x (Outlier Cells ÷ #RTC Cells Analyzed)
Mean Absorption	Mean of the RETIC Abs histogram for the reticulocyte population
ABS Low Cell Count	Counts in x axis channels 1 to 3 of the RETIC Scatter Abs cytogram
ABS Mode	Mode channel of the Absorption population
RTC Valid Cells	Number of Valid Signals Obtained from Flowcell Events

Additional Parameters

The following parameters are for research or laboratory use only and are not for patient reporting:

Parameter	Explanation
MCVm	Mean of the RETIC Volume histogram for the mature population
#Neg RBC	Number of mature RBCs
%Neg RBC	100 x (#Neg RBC ÷ #RTC Gated Cells)
Retic Count	Number of reticulocyte events
#LRetic	Number of low absorption reticulocytes
%LRetic	100 x (#LRetic ÷ RETIC Count)
#MRetic	Number of medium absorption reticulocytes
%MRetic	100 x (#MRetic ÷ RETIC Count)

Parameter	Explanation
#HRetic	Number of high absorption reticulocytes
%HRetic	100 x (#HRetic ÷ RETIC Count)
IRF-H	100 x (#HRetic ÷ RETIC Count)
IRF-M+H	100 x ([#HRetic + #MRetic] ÷ RETIC Count)
RTC Mean X	Mean x channel of the RETIC Scatter cytogram
RTC Mean Y	Mean y channel of the RETIC Scatter cytogram
#RTC Cells Acquired	Number of Valid Signals Obtained
#RTC Cells Analyzed	Cells on RTC Scatter cytogram with nonzero volume and hemoglobin values, and are not in channel 99
#RTC Gated Cells	#Neg RBC + Retic Count within threshold limits
Slope Negative Cells	Slope of the negative (mature RBC) population relative to y axis of the RETIC Scatter ABS cytogram

Parameter Key

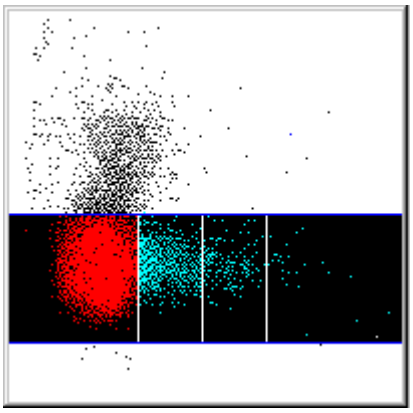
MCVm
Mean Cell Volume of mature population

RTC RBC
Red blood cell count from the Reticulocyte method. The RTC RBC count is calculated in the same manner as the RBC count from the RBC / Platelet Method.

RTC % Dead Time
Percent of analysis time when the channel is busy and cannot detect flowcell events

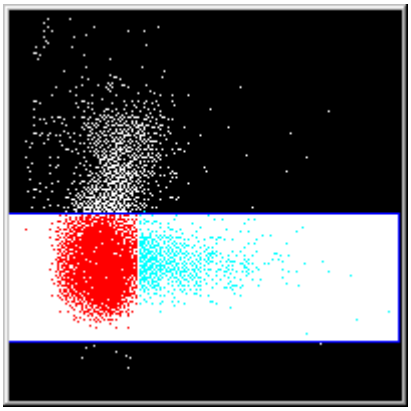
RTC % Noise
Percent of events from the outlier areas

Outlier Cells



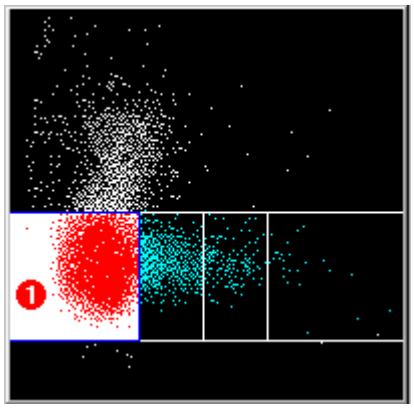
The outlier cell count includes cells with high-scatter values less than the RTC Platelet threshold, and cells with high-scatter values greater than the RTC Coincidence threshold.

RTC Gated Cells



The number of cells between the RTC platelet and RTC coincidence thresholds in the Retic Scatter Abs cytogram excluding channel 99.

Neg RBC

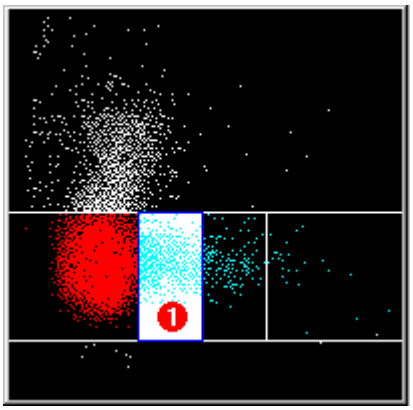


The number of cells in the mature RBC area (1) of the Retic Scatter Abs cytogram.

 # Neg RBC
Count of mature red blood cells

% Neg RBC
Percent of mature red blood cells

Number of Low Absorption Reticulocytes

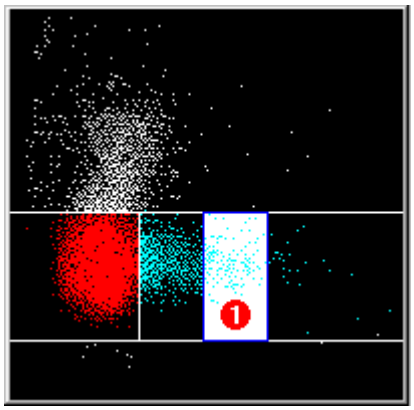


The number of gated cells (1) between the RTC and Low/Medium RTC thresholds of the Retic Scatter Abs cytogram.

#LRetic
Count of low absorption reticulocytes

%LRetic
Percent of low absorption reticulocytes

Number of Medium Absorption Reticulocytes

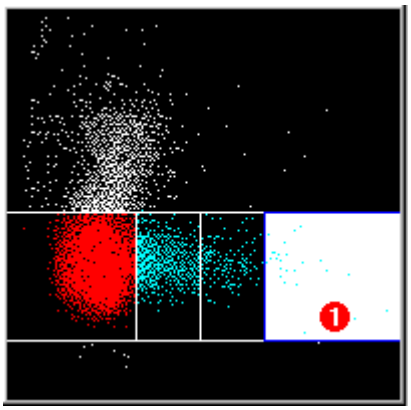


The number of gated cells (1) between the Low/Medium RTC and Medium/High RTC thresholds of the Retic Scatter Abs cytogram.

#MRetic
Count of medium absorption reticulocytes

%MRetic
Percent of medium absorption reticulocytes

Number of High Absorption Reticulocytes



The number of gated cells (1) to the right of the Medium/High RTC threshold of the Retic Scatter Abs cytogram.

#HRetic
Count of high absorption reticulocytes

%HRetic
Percent of high absorption reticulocytes

Legal Information

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SIEMENS AUTHORIZED REPRESENTATIVE 5

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This section provides the following information:

- address of the Siemens authorized representative, which is the Siemens contact within the European community
- addresses for obtaining service and technical information and for ordering supplies
- system warranty and service delivery policy information

Limited Instrument Warranty and Service Delivery Policy

Siemens and its authorized distributors may provide customers who acquire new Siemens instruments with a limited warranty either in a specific agreement or in standard language on their invoices. This limited warranty is designed to protect customers from the cost associated with repairing instruments that exhibit malfunctions due to defects in materials and/or workmanship during the warranty period.

Siemens, at its election, provides warranty service either by providing repair service of the instrument on site, or by exchanging the defective instrument or component, subject to the limitations and exclusions set forth in *Replacement of Parts* and *Warranty and Service Exclusions* below. Repairs, replacements or exchanges of instruments or components provided during the warranty or any additional service period, does not extend the warranty or service period beyond the initially agreed upon period.

When the customer calls for service, the Siemens representative or authorized distributor informs the customer of the type of service available for the customer's instrument, and instructs the customer as to how to obtain that service.

Warranty Period

The limited warranty period generally commences upon installation of the original instrument at the customer's location and extends for a period of 1 year thereafter, unless otherwise specifically agreed to by and between Siemens (or its authorized distributors) and customer in a writing signed by duly authorized representatives of both parties (sales representatives are generally not authorized representatives of Siemens for these purposes).

Additional Service Period

The customers, with some exceptions, may purchase additional service coverage beyond any initial warranty period as part of the original instrument acquisition for second or subsequent years beyond the original installation date. The customer's original Purchase Invoice or appropriate Agreement Addendum must indicate the term in months for additional service coverage.

Service During Normal Hours

The customer may obtain service for instruments during normal business hours by contacting the nearest Siemens location or authorized distributor. Refer to the list of Siemens locations in this section.

Extent of a Service Call

Warranty or service calls generally include onsite repair or exchange of instruments or components, travel to the location of the instrument, and onsite labor during normal business hours. A warranty or service call is initiated by the customer by following the instructions on how to obtain service for the customer's instrument. The service call is considered complete when any defects in material or workmanship have been corrected by repair or replacement and the instrument conforms to the applicable specifications. When service is complete, the customer receives a copy of the documentation detailing all work performed by the Siemens representative or authorized distributor.

Service Outside Normal Hours

Customers, with some exceptions, may also request service to be delivered or an exchange to be initiated outside normal business hours, including evenings, weekend days, or nationally observed holidays, by contacting the nearest Siemens location or authorized distributor. Service performed outside normal hours is subject to a surcharge unless the customer has in place a service product option that provides service at the time requested.

Replacement of Parts

In performing service, Siemens or its authorized distributors provide appropriate parts to repair the instrument, or arranges for the exchange of the instrument or affected parts, at no charge with the exception of certain parts or subassemblies that are considered Customer Maintenance Items. Customer Maintenance Items include, but are not limited to, the following items: lamps, electrodes or sensors (which are covered by a separate warranty), reagents, calibrators, controls, paper, and pens. Consult the appropriate system operator's manuals for a complete list of Customer Maintenance Items for any specific model of instrument.

Design Changes and Retrofitting of Instruments

Siemens reserves the right to change the design or construction of specific models of instruments at any time without incurring any obligation to make such changes available to individual customers or instruments. If Siemens notifies customers of a change that improves the performance or reliability of their instrument, and requests to retrofit that instrument, the customer must agree to allow Siemens or an authorized distributor, at Siemens' expense, to retrofit components or make design changes, which does not adversely affect the instrument's performance characteristics.

Key Operator Designation

Each customer designates a key operator who is available to Siemens representatives to describe instrument malfunctions by telephone and/or to perform simple adjustments and corrections as requested. If a key operator is not designated or is unavailable when the customer requests service, the delivery of service may be delayed.

OSHA Requirements (US only)

When service is required at a customer location, the customer must provide the Siemens representative with adequate facilities that comply with the regulations of the Secretary of Labor under the Occupational Safety and Health Act (OSHA) of 1970, as amended.

Warranty and Service Exclusions

The following exclusions are in addition to any exclusions provided for in any written warranty or service agreement.

IF ANY OF THE FOLLOWING EVENTS OCCUR, THE WARRANTY OR SERVICE PROVISIONS DO NOT APPLY:

1. Repairs or modifications have been made to the instrument by someone other than an authorized Siemens representative.
2. The instrument has been operated using accessories and supplies other than Siemens brand accessories, or consumable supplies and/or reagents not having the same grade, quality, and composition as defined in the system operator's manuals.
3. Siemens has notified customers of a change that improves the performance or reliability of their instrument and customer has not agreed to retrofit or make design changes to the instrument.
4. Customer did not purchase the instrument from Siemens or one of its authorized distributors.
5. The instrument has not been installed within 90 days of shipment to the customer's facility unless otherwise specified.
6. The customer has not performed appropriate customer maintenance procedures, as outlined in the system operator's manuals.
7. The instrument has been misused or used for a purpose for which it was not intended.
8. The instrument has been damaged in transit to the customer or damaged by the customer while moving or relocating it without supervision by a Siemens representative.
9. Damage was caused by floods, earthquakes, tornados, hurricanes, or other natural or man-made disasters.
10. Damage was caused by Acts of War, vandalism, sabotage, arson, or civil commotion.

11. Damage was caused by electrical surges or voltages exceeding the tolerances outlined in the system operator's manuals.
12. Damage was caused by water from any source external to the instrument.
13. The customer has purchased an alternative agreement whose terms of warranty or service supersede these provisions.

Siemens or its authorized distributors can invoice customers, at current standard labor and parts rates, for instruments repaired to correct damage or malfunctions due to any of the reasons listed above.

OTHER THAN AS STATED ABOVE, THERE ARE NO OTHER WARRANTIES, EXPRESS OR IMPLIED, WITH RESPECT TO THE INSTRUMENT, ITS SALE TO THE CUSTOMER, ITS LEASE TO THE CUSTOMER, OR THE SALE OF THE INSTRUMENT TO THE CUSTOMER AT THE EXPIRATION OR TERMINATION OF THE LEASE AGREEMENT.

SIEMENS HEALTHCARE DIAGNOSTICS SPECIFICALLY DISCLAIMS ANY AND ALL IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE.
SIEMENS HEALTHCARE DIAGNOSTICS' LIABILITY FOR BREACH OF ANY WARRANTY OR SERVICE AGREEMENT SHALL BE LIMITED ONLY TO THE REPAIR OR REPLACEMENT OF DEFECTIVE EQUIPMENT AND SHALL NOT INCLUDE ANY DAMAGES OF ANY KIND, WHETHER DIRECT, INDIRECT, INCIDENTAL, CONTINGENT, OR CONSEQUENTIAL. SIEMENS SHALL NOT BE LIABLE FOR DELAY FROM ANY CAUSE IN PROVIDING REPAIR OR EXCHANGE SERVICE.

ANY LIMITATIONS OR OTHER PROVISIONS NOT CONSISTENT WITH APPLICABLE LAW IN PARTICULAR JURISDICTIONS OR A SPECIFIC WRITTEN AGREEMENT DO NOT APPLY TO CUSTOMERS IN THOSE JURISDICTIONS OR SUBJECT TO THOSE AGREEMENTS.

Information for Technical Assistance

Refer to the procedures in this appendix to provide system information that you may need when you call for technical assistance.

Contact Information

This section provides the following information:

- the address of the Siemens authorized representative, which is the Siemens contact within the European community
- the Siemens addresses for obtaining service and technical information and for ordering supplies

Siemens Authorized Representative

Siemens Healthcare Diagnostics Ltd.
Sir William Siemens Sq., Frimley, Camberley, UK GU16 8QD.

Addresses

For technical assistance contact your local technical support provider. For customer service or additional information contact your local technical support distributor.

Siemens Healthcare Diagnostics Inc.
Tarrytown, NY 10591-5097 USA

EC REP Siemens Healthcare Diagnostics Ltd.
Sir William Siemens Sq.
Frimley, Camberley, UK GU16 8QD

www.siemens.com/diagnostics

Siemens Healthcare
Diagnostics Pty Ltd
885 Mountain Highway
Bayswater Victoria 3153
Australia

シーメンスヘルスケア・
ダイアグノスティクス株式会社
東京都品川区東五反田 3－20－14
Siemens Healthcare Diagnostics
輸入

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Warnings

 **ELECTRICAL WARNING**

To avoid exposure to shock hazards and/or damage to the instrument while performing this procedure, power off the analyzer before proceeding.

 **BIOHAZARD**

All products or objects that come in contact with human or animal body fluids should be handled, before and after cleaning, as if capable of transmitting infectious diseases. Wear facial protection, gloves, and protective clothing.

The operator should follow the recommendations to prevent the transmission of infectious agents in health-care settings as recommended by the Clinical and Laboratory Standards Institute (formerly NCCLS) in *Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline - Third Edition.* 2005. CLSI Document M29-A3. This document contains complete information on user protection and it can be used as reference material for instructions on laboratory safety.

 **LASER WARNING**

To avoid damage to the eyes, never look directly at the laser beam or at its reflection from a shiny surface. All field service procedures must be followed precisely. Only Siemens-trained field service personnel should perform procedures related to laser assemblies.

For more safety information and laser specifications, refer to **Safety Information, Protecting yourself from lasers**.

 **WARNING**

Regular strength household bleach is 5% sodium hypochlorite. Extra-strength household bleach is 6% sodium hypochlorite. Either strength may be used with the ADVIA 2120/2120i Hematology System. When using or handling ADVIA EZ KLEEN / EZ WASH, bleach, any cleaning or antiviral agent, or any other potentially hazardous liquids, wear protective clothing, gloves, and safety glasses. **Siemens further recommends the use of face shields with safety glasses whenever using or handling these materials to provide optimal safety.** These materials are harmful if swallowed and may cause eye or skin irritation.

Use household bleach that is free of heavy metals, such as Clorox.

To prepare a 25% solution of household bleach, dilute one part of bleach with three parts of clean distilled water, or clean deionized water. The prepared solution is stable for one week when stored at room temperature.

Safety Information

Safety features have been incorporated into the ADVIA 2120/2120i system to protect the operator from injury, the analyzer from damage, and the test results from inaccuracies.

Regulatory Compliance

Standards or Regulations

The ADVIA 2120/2120i conforms to the following safety standards or regulations:

EN61010-1: 1993	Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use; Part 1
EN60825-1	Safety of Laser Products; Part 1
UL 3101-1	Electrical Equipment for Laboratory Use; Part 1: General Requirements.
CAN/CSA C22.2 No. 1010.1 - 92	Safety requirements for Electrical Equipment for Measurement, Control, and Laboratory Use; Part 1: General Requirements
CFR 47: Chapt. 1 FCC Subpart B Part 15.103 Exempted Devices (C) Part 15.105 (A)	This equipment has been tested and found to comply with the limits of a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference, in which case the user will be required to correct the interference at his own expense.

CE Mark Requirements

The ADVIA 2120/2120i conforms to the following standard. It therefore meets the EMC conformity requirements for “CE” marking according to the European IVDD Directive 98/79 EC.

EN 61326-1 1997+ A1:1998 + A2:2001 (Class "A")	Electrical Equipment for measurement, control, and laboratory use - EMC requirements

Noise-limit Requirement

The ADVIA 2120/2120i conforms to the following noise-limit requirement:

EN27779: 1989 Measurement of Airborne Noise Emitted By Computer and Business Equipment (61 dBA)

Documentation

In the printed and online documentation, all hazards (except those associated with reagents) are categorized as follows:

WARNING Indicates the risk of personal injury or loss of life if operating procedures and practices are not correctly followed.

CAUTION Indicates the possibility of damage to or destruction of equipment if operating procedures and practices are not strictly observed.

IMPORTANT Indicates that system functions, including test results, may be adversely affected if operating procedures and practices are not correctly followed.

Hazards associated with the presence, handling, or use of required reagents are categorized as follows:

CAUTION ! Indicates a hazard that could cause illness, burns, skin reactions, and so on. Substances such as diluted acids, mild caustics, minor skin irritants, and combustible materials are assigned to this category.

ATTENTION Indicates that a specific risk exists to the user or performance.

Refer to the labels on the reagent containers and to the Material Safety Data Sheets for information about the hazards and precautions associated with the reagents.

System Symbols

This section describes the symbols that can appear on the exterior of the ADVIA 2120/2120i system or on the system packaging. The symbols on the system provide you with the location of certain components and with warnings for proper operation. The symbols on the system packaging provide you with other important information.

Warnings and Cautions

- A Warning indicates the risk of personal injury or loss of life if operating procedures and practices are not correctly followed.
- A Caution indicates the possibility of loss of data or damage to or destruction of equipment if operating procedures and practices are not strictly observed.

When this symbol appears on the system without additional information, you must consult the instructions for use.

Biohazard

The biohazard warning label mounted on the front of the analyzer alerts you to the possibility of exposure to a biohazard during the sampling process or through contamination of the analyzer.

This symbol identifies a product that may contain an infectious agent.

This symbol alerts you to a potentially harmful substance.

These symbols together alert you to a waste biohazard.

Laser hazard

Electrical hazard

This symbol indicates an *in vitro* diagnostic device or an *in vitro* diagnostic medical device.

This symbol indicates that you should consult the operating instructions for necessary information.

REF	This symbol indicates the number used for ordering a part or product.
SN	This symbol indicates the serial number of a part or product.
LOT	This symbol indicates the batch code for a product.
	This symbol indicates the name and location of the product manufacturer.
	This symbol indicates the date of manufacture of the product.
EC REP	This symbol indicates the manufacturer's authorized representative within the European community.
CE	This symbol indicates that the product complies with the applicable directives of the European Union.
TÜV C NRTL US	This symbol indicates that the product was IEC 61010-1 safety tested by TUV for conformity to global markets including Canada, US, and EU.
TIC	This symbol indicates that the colorimeter conforms with DIN standard 58 960 developed by the Working Committee on Photometers of the Standards Committee on Medicine (NAMed) in the DIN Deutsches Institute für Normung e.V.
Class 1 Laser Product	This symbol indicates that the product is a Class 1 laser product, with no laser exposure during normal operation.
	This symbol indicates that the product is a Class 2 laser product, with potential exposure to a laser beam.
	This is the On symbol.

This is the Off symbol.

This is the Start symbol.

This is the Standby symbol.

This symbol indicates the switch position for normal system operation of the waste container.

This symbol indicates the switch position for emptying the waste container.

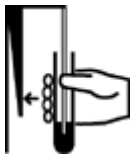
This symbol indicates the need to empty the waste container.

This symbol indicates the open and closed positions for a spigot.

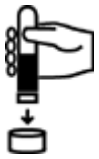
This symbol indicates liquid waste.

This symbol indicates pressure. In this example, the symbol indicates 20 PSI.

This symbol indicates vacuum. In this example, the symbol indicates a vacuum of 20" Hg.



This symbol indicates the manual open-tube sampler.



This symbol indicates the manual closed-tube sampler.

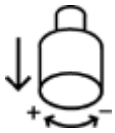
This symbol indicates that there is a rack in the sampler.

This is the eject rack symbol.

This is the network symbol.

This is the monitor symbol.

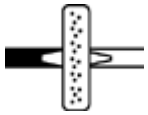
This symbol indicates the maximum level.



This is the knob symbol.

This is the fuse symbol.

This is the filter symbol.



This is the vacushield symbol.

This is the CPU symbol.

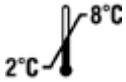
This symbol indicates a protective terminal.

This is the barcode scanner symbol.

This symbol indicates that moving the component can cause injury.

This symbol identifies a product that contains recyclable material.

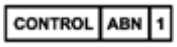
This symbol indicates the top of the package.



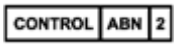
This symbol indicates the acceptable temperature range for storage of the product.

This symbol identifies the date by which the product should be used.

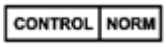
This is the Setpoint Calibrator symbol.



This is the TESTpoint 3-in-1 Hematology Control Abnormal 1 symbol.



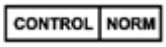
This is the TESTpoint 3-in-1 Hematology Control Abnormal 2 symbol.



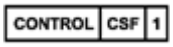
This is the TESTpoint 3-in-1 Hematology Control Normal symbol.

This is the TESTpoint High Control symbol.

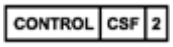
This is the TESTpoint Low Control symbol.



This is the TESTpoint Normal Control symbol.



This is the CSF Control 1 symbol.



This is the CSF Control 2 symbol.

This is the ADVIA RETIC High Control symbol.

This is the ADVIA RETIC Low Control symbol.

This is the DEFOAMER symbol.

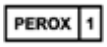
This is the EZ KLEEN symbol.

This is the BASO Reagent symbol.

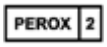
This is the CSF Reagent symbol.

This is the HGB Reagent symbol.

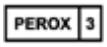
This is the CN-FREE HGB Reagent symbol.



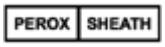
This is the PEROX 1 Reagent symbol.



This is the PEROX 2 Reagent symbol.



This is the PEROX 3 Reagent symbol.



This is the PEROX SHEATH symbol.

This is the RBC/PLT Reagent symbol.

This is the SHEATH/RINSE symbol.

Interpretation of Results

System operators and laboratory supervisors are responsible for operating and maintaining Siemens products in accordance with the procedures described in the applicable Product Labeling (online documentation, package inserts, bulletins), and for determining that product performance conforms to the applicable claims.

If, under these prescribed conditions of operation and maintenance, an aberrant or abnormal result, as defined by the laboratory protocol, occurs, laboratory personnel should first make certain that the system is performing and is being operated in accordance with the Product Labeling; then follow the laboratory protocol for advising the clinician of a result that appears to have deviated from the norms established by the laboratory.

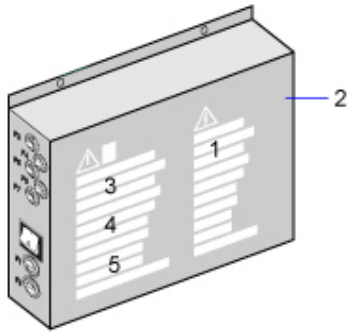
Siemens products do not make diagnoses on patients. Siemens intends its diagnostic products (systems, reagents, software, hardware) to be used to collect data reflecting the patient's chemical, hematological, or immunological status at a certain point in time. Such data must be used in conjunction with other diagnostic information and with the attending physician's evaluation of the patient's condition to arrive at a diagnosis and a clinical course of treatment.

Any malfunction of a Siemens diagnostic product (for example, failure to meet a performance specification or to perform as intended) should be appropriately addressed by laboratory personnel. Various sections of the Product Labeling address malfunctions and their possible effect on results.

Explanation of the Warning Labels on the AC Power Box

1. The AC power box must be opened by qualified personnel only. The only operator serviceable parts in the AC power box are fuses F1 through F7, which are replaced without opening the module.

2. The two electrical outlets on the side of the AC power box are intended only for the computer and monitor supplied with the system. These outlets are designed to ensure proper operation of the system devices and to maintain the system safety certifications. Do not connect other devices to them.



AC power box location

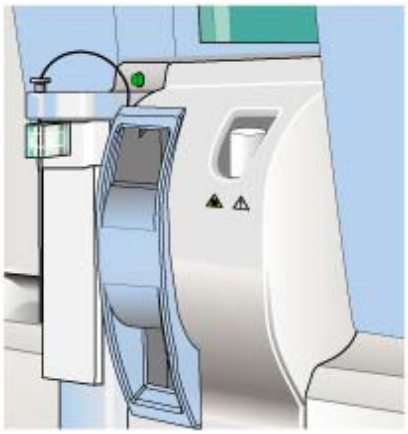
3. Since electrical power is still applied to some system components even after the power switch is turned off, you must unplug the main power before servicing the system (for example, when replacing fuses).

4. Always replace fuses F1 and F2 at the same time. Any high-current event that causes one of these fuses to fail can damage the other one and shorten its service life.

5. Always replace a fuse with one of the same type and rating. If the fuse label is missing or illegible, refer to the fuse information table. Be sure to select the fuse requirements appropriate for your system's input voltage.

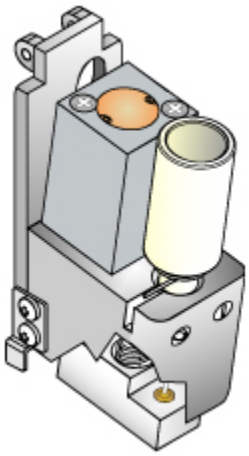
Explanation of the Warning Labels on the Manual Closed-Tube Sampler

Sampler Door



Never put your finger into the manual closed-tube sampler centering collar.

Manual Closed-Tube Sampler



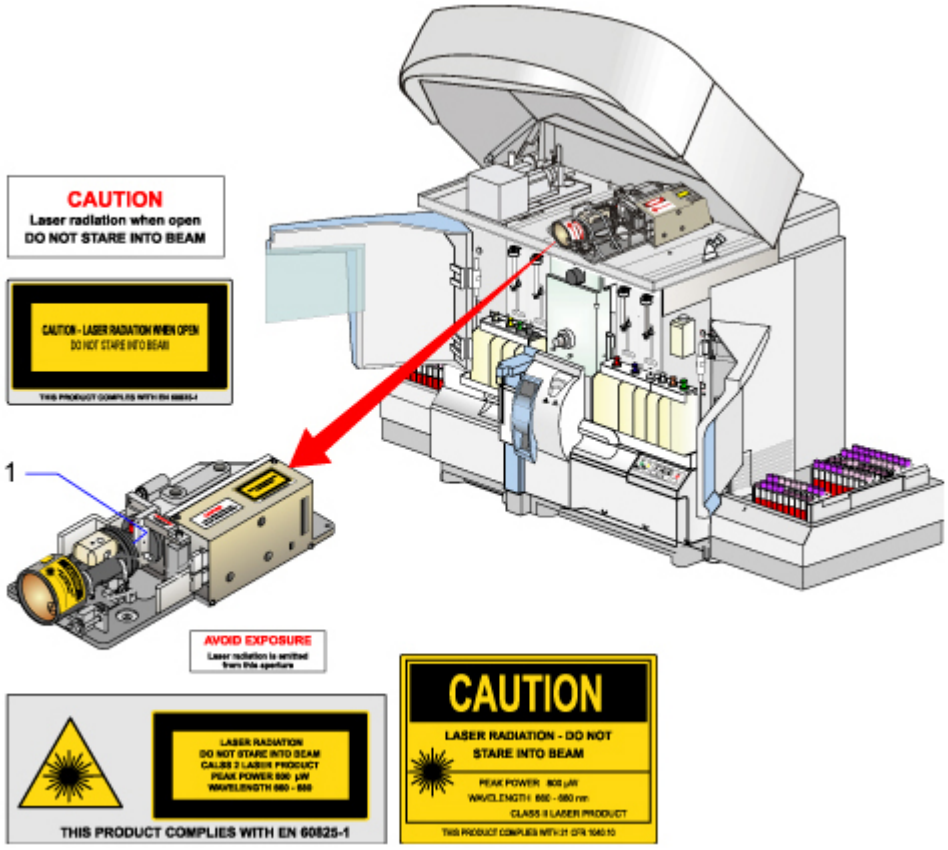
To avoid injury when removing or replacing the manual closed-tube sampler needle or centering collar, the system must be off. You must place a protective cover over the needle immediately after removing the centering collar.

Protecting Yourself from Lasers

The ADVIA 2120/2120i Hematology System is classified as a Class I laser product as defined by the National Center for Devices and Radiological Health (CDRH) regulations 21 CFR 1040 and by EN-60825.

RBC Laser Optical Assembly

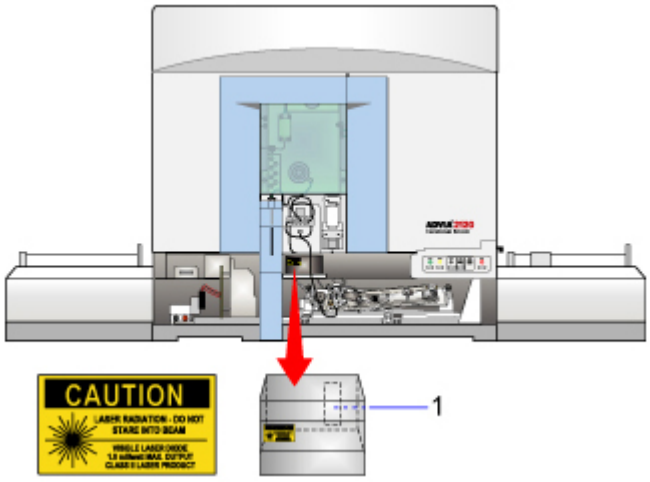
The RBC laser optical assembly is classified as a Class II laser device which has a maximum power output of 800 µW at 670 nm (nominally) and a continuous wave output. The RBC laser assembly is set internally to have a maximum output of 290 ±58 µW. The laser beam path is enclosed in a series of non-interlocked protective housings that prevent human access to laser radiation during operation and maintenance of the laser product.



1 Laser Aperture

Autosampler Barcode Reader

The autosampler barcode reader is classified as a Class II laser device. It has a maximum power output of 1 mW at a wavelength of 670 nm, a pulse duration of 90 ns, and 3.6 mr units of beam divergence.



1 **Laser aperture in back of barcode reader**

LASER WARNING

Some field service procedures require the removal of the protective housings that prevent human access to the laser radiation. All field service procedures must be followed precisely to prevent possible eye injury from the laser radiation. Only Siemens-trained field service personnel should perform procedures related to the ADVIA 2120/2120i laser optics bench.

Laser Hazard Precautions

The following list of precautions must be observed when servicing the ADVIA 2120/2120i laser optics:

- Remove all jewelry from hands and wrists.
- Do not look directly at the laser beam.
- Do not look at specular reflections from the laser beam.
- Do not place reflective objects, such as screwdrivers or jewelry, into the beam path.
- Always ensure that the laser beam is terminated with a beam stop.