Sysmex® XS-Series Automated Hematology Analyzer

Flagging Interpretation Guide

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This manual was created by Sysmex America, Inc. Questions or comments regarding the content of this manual can be directed to:

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Key Words and Phrases
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Introduction

The XS-Series Flagging Interpretation Guide is designed to serve many objectives including:

- Providing users with an explanation of criteria used for the XS-Series Interpretive Program (IP) Messages.
- Suggesting actions to be taken when samples generate IP Messages.
- Suggesting actions to resolve sample related problems.

The following sections introduce the IP Messages. Definitions and examples of each message are presented with suggested actions to be taken by qualified personnel to verify the presence of specific cell types and obtain a correct result when interference occurs. These action steps are merely suggested guidelines and not requirements. Always follow your local laboratory procedures for repeat testing or confirmation of results.

The XS-Series analyzers are designed to aid in the separation of specimens into POSITIVE and NEGATIVE categories according to preset criteria. The system bases its judgments on comprehensive surveys of numerical data, particle size distributions, and scattergrams and provides easy-to-understand flags and messages indicating the analyzer's findings. These flags and messages are referred to as IP Messages. The IP Messages may be classified as either Suspect IP Messages or Abnormal IP Messages. The IP Messages generated by the analyzer determine if the sample is judged as POSITIVE or NEGATIVE.

Suspect IP Messages are generated by analyzer software algorithms. Abnormal IP Messages are based on numerical user defined settings.

A specimen is judged NEGATIVE when there are no IP messages generated. NEGATIVE does not necessarily indicate a normal sample; however, the results are generally reported without review.

The XS-Series analyzers will generate a POSITIVE when an IP Message is present. ERROR will be generated when there is an analysis error. These judgments indicate the possibility of sample abnormality. These results should be reviewed carefully and may require further examination in accordance with your local laboratory protocol.

All analyzer flags, error messages and results must be interpreted together and in consideration of the patient's clinical condition prior to results being reported from the laboratory. Any asterisk (*) next to a parameter indicates these results may be unreliable and should be confirmed according to your laboratory protocol prior to reporting. Protocols for comparison of current results to previous results (delta checking) as well as critical value alerts are also useful for identifying potentially erroneous results prior to reporting to the clinician.

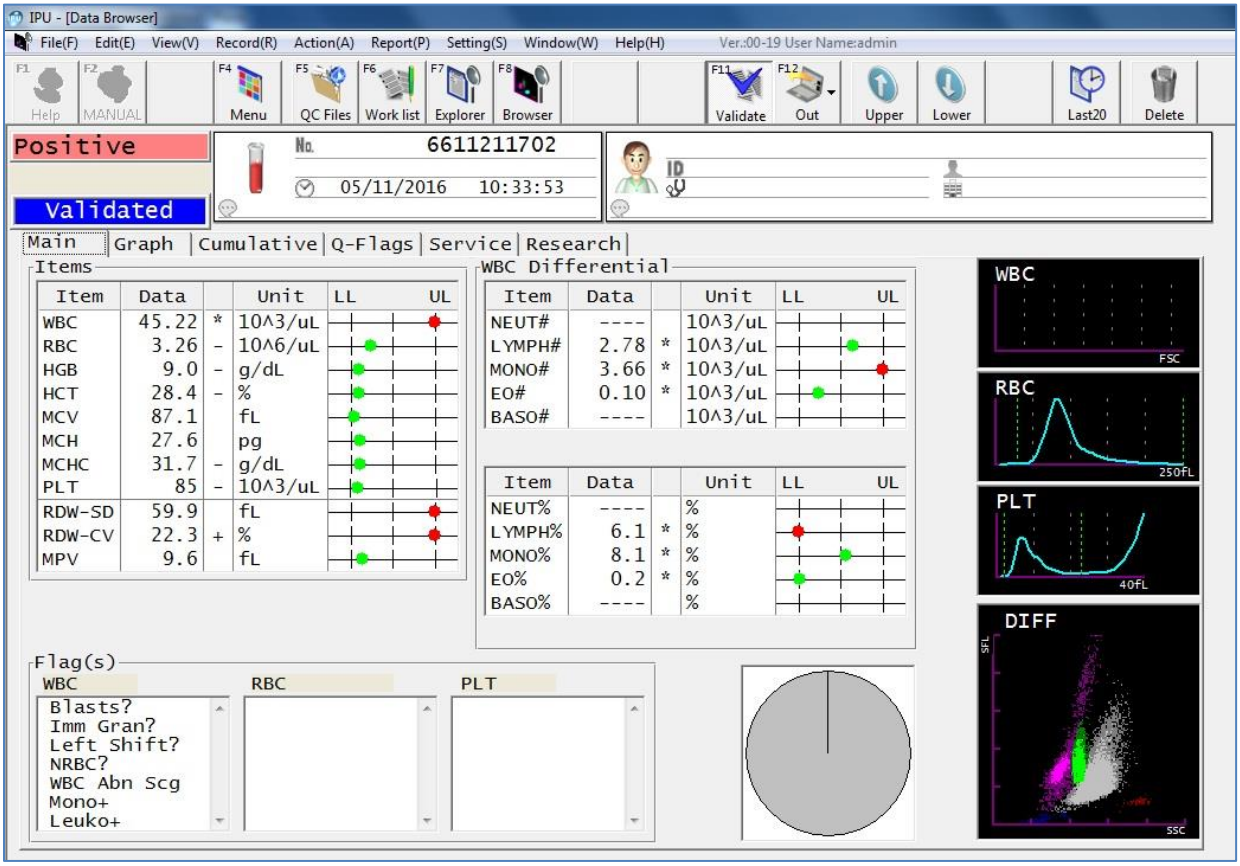
NOTE: Discrete test selection may determine availability of certain IP messages. Refer to the Instructions for Use for detailed list of IP Messages.

Abnormal, WBC Abn Scattergram

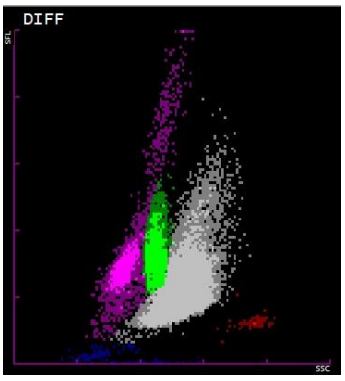
The WBC Abn Scattergram IP message is generated whenever clustering in the DIFF scattergram is abnormal. Dashes may appear in place of data that was not calculated.

In the example below, clustering failed between the Monocytes and the Neutrophils on the DIFF scattergram.

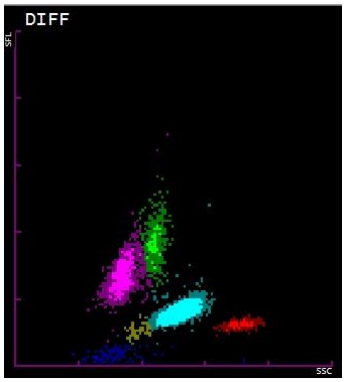
XS-Series Results



Abnormal DIFF Scatter (Close-Up)



Normal DIFF Scatter (Reference)

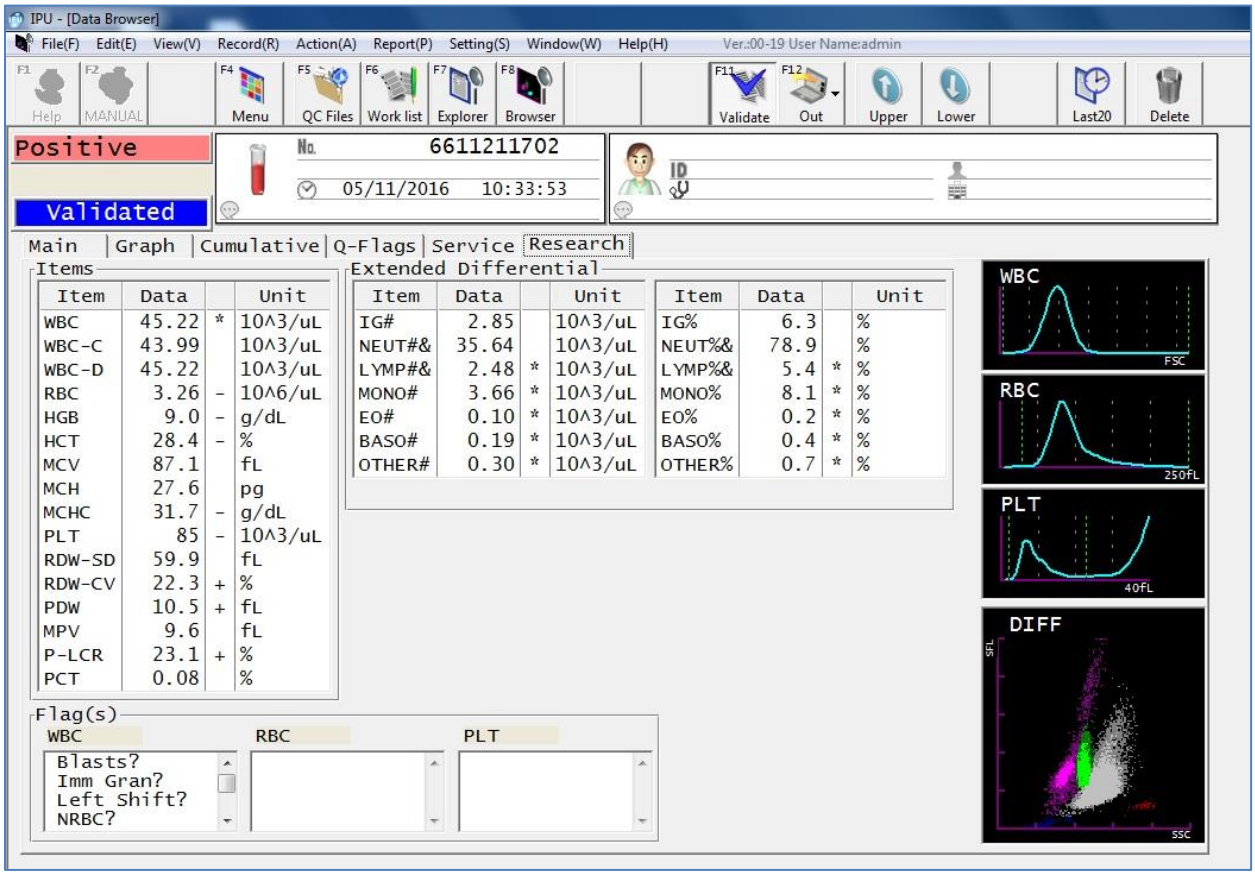


Manual Differential Results

Neutrophils	73%
Band Neutrophils	12%
Metamyelocytes	5%
Lymphocytes	5%
Monocytes	5%
NRBC	1/100 WBC

Abnormal, WBC Abn Scattergram
(continued)

The suppressed differential values can be found in the Research Tab of the Browser Screen if needed.



NOTE: Results from the Research Tab of the Browser are not directly reportable by the laboratory and must be confirmed prior to being released.

Abnormal, WBC Abn Scattergram
(continued)

Suggested Action Steps:

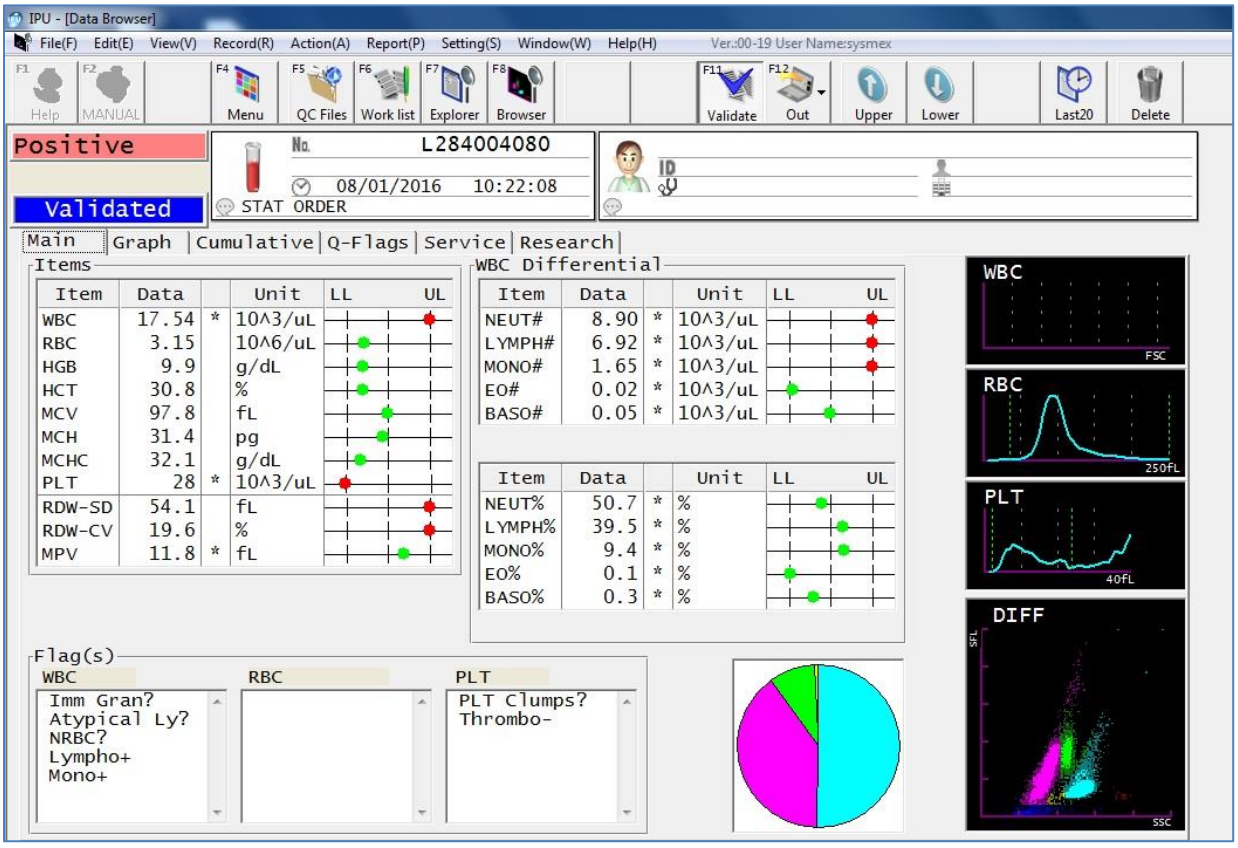
1. Dashes (— —) in place of numeric data:
    - Verify WBC and differential results according to your laboratory's policy. Possible actions may include:
        - repeating the sample
        - performing a manual differential
2. Asterisk (*) next to results:
    - Verify WBC and differential results according to your laboratory's policy. Possible actions may include:
        - scanning the slide for abnormal cells or platelet clumping and to estimate the WBC count
        - performing a manual differential if abnormal cells are observed
    - If no abnormalities are found when reviewing the smear and the WBC estimate matches the analyzer reported WBC, the results with asterisks (*) may be reported.

Suspect NRBC?

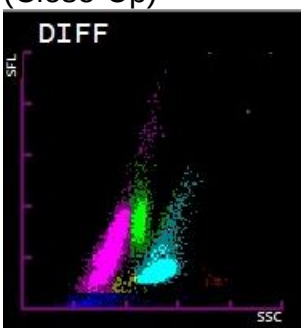
The NRBC? IP Message is generated when clustering is detected in the NRBC area between the lymphocytes and the RBC ghosts on the DIFF scattergram. An asterisk (*) appears next to the WBC and the % and # for the Neutrophils, Lymphocytes, Monocytes, Eosinophils and Basophils. The asterisk (*) indicates these results may be unreliable and should be confirmed according to your laboratory protocol prior to reporting.

NOTE: When WBC is < 0.5 x 10^3/µL, no WBC Suspect Messages will be generated

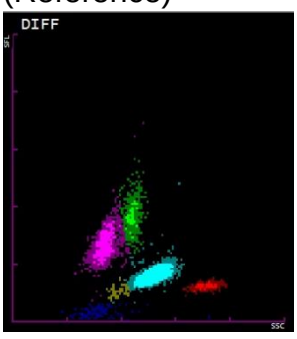
XS-Series Results



Abnormal DIFF Scatter (Close-Up)



Normal DIFF Scatter (Reference)



Suspect, NRBC?
(continued)

Suggested Action Steps:

1. Review results according to your laboratory protocol. This may include scanning the peripheral smear for the presence of NRBCs or other abnormal cells. Report any NRBCs or abnormal cells according to your laboratory protocol.
2. If a 100-cell differential is done and NRBCs are counted, the WBC result may be corrected using the following equation if indicated by your laboratory protocol.

   $$\text{Corrected WBC (x 10}^3/\mu\text{L)} = \frac{(\text{WBC} \times 100)}{(\text{NRBC} + 100)}$$

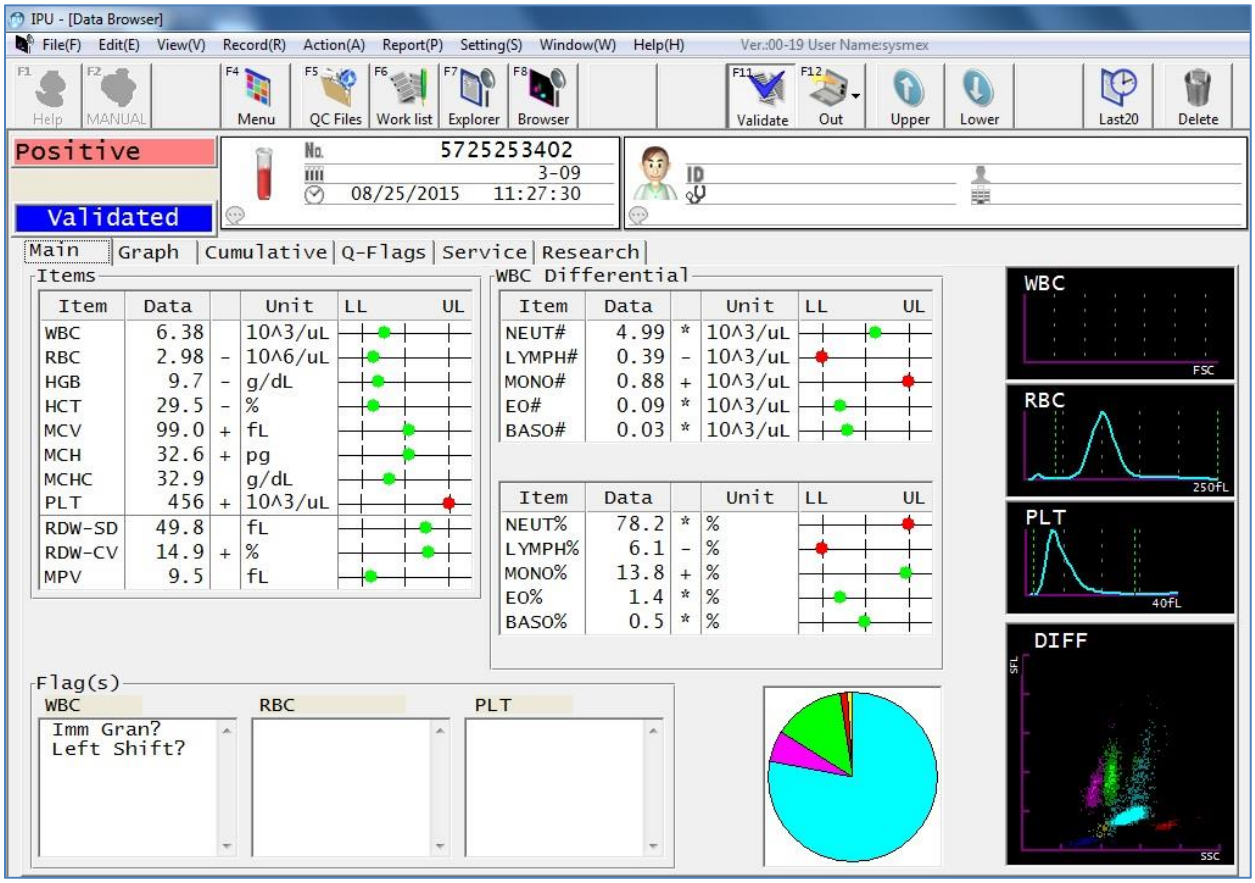
   NOTE: It is up to the laboratory to determine the NRBC count which would indicate correction of the WBC count.

3. If no abnormalities are found when reviewing the smear, the results with asterisks (*) may be reported.

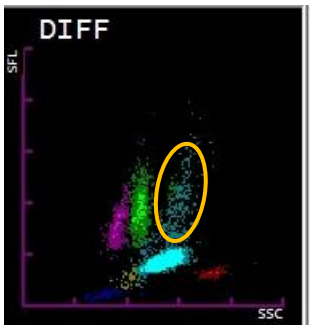
Suspect, Immature Gran?

In cases where the analyzer has detected abnormal clustering in the region for immature granulocytes in the DIFF scattergram, the Immature Gran flag is displayed. In these cases, an asterisk (*) appears next to the % and # for the Neutrophil, Eosinophil and Basophil. The asterisk (*) indicates these results may be unreliable and should be confirmed according to your laboratory protocol prior to reporting.

XS-Series Results

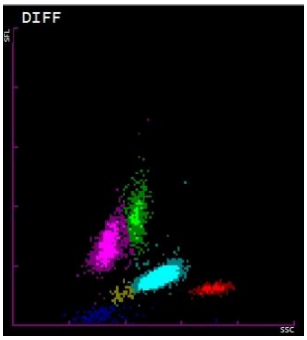


Abnormal DIFF Scatter (Close-Up)



(IG population circled)

Normal DIFF Scatter (Reference)



Suspect, Immature Gran?
(continued)

Suggested Action Steps:
When the Immature Gran flag is displayed:

1. Review results according to your laboratory protocol. This may include scanning the peripheral smear for the presence of:
    - immature granulocytes – promyelocytes, myelocytes and metamyelocytes
    - band cells in increased numbers
    - toxic granulation or vacuolation of neutrophils
    - other abnormal cells

    Report any abnormal cells according to your laboratory protocol.

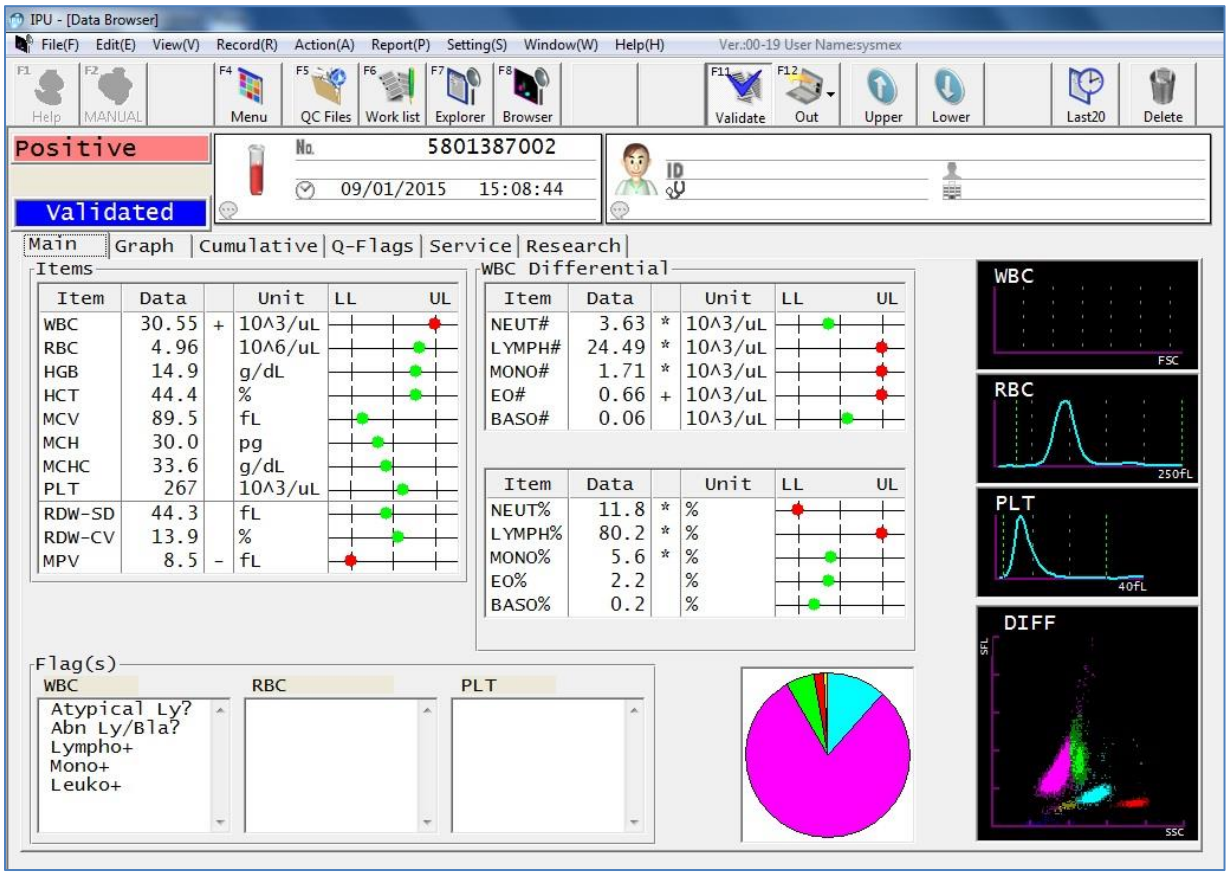
2. If no abnormalities are found when reviewing the smear, the results with asterisks (*) may be reported.

Suspect, Abn Lympho/Blast?

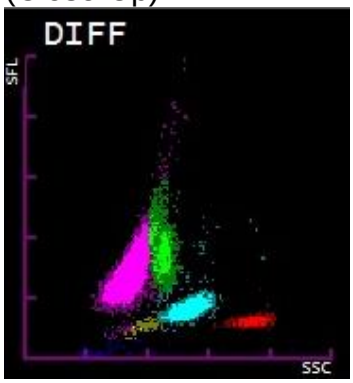
The Abn Lympho/Blast? IP message indicates that the analyzer has detected abnormal clustering in the region for blasts and abnormal lymphocytes in the DIFF scattergram.

An asterisk (*) appears next to the % and # for the Neutrophil, Lymphocyte and Monocyte. The asterisk (*) indicates these results may be unreliable and should be confirmed according to your laboratory protocol prior to reporting.

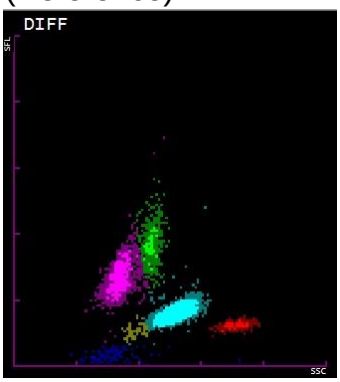
XS-Series Results



DIFF Scatter (Close-Up)



Normal DIFF Scatter (Reference)



Suspect, Abn Lympho/Blast?
(continued)

Suggested Action Steps:

1. Review results according to your laboratory protocol. This may include scanning the peripheral smear for the presence of:
    - blasts – lymphoblasts, myeloblasts, and myelomonoblasts
    - immature granulocytes – promyelocytes, myelocytes, metamyelocytes
    - atypical or immature lymphocytes
    - other abnormal cells

   Report any abnormal cells according to your laboratory protocol.

   NOTE: Reviewing the feathered edge and sides of the peripheral smear is suggested as blasts and other large cells may migrate to this area during smear preparation.

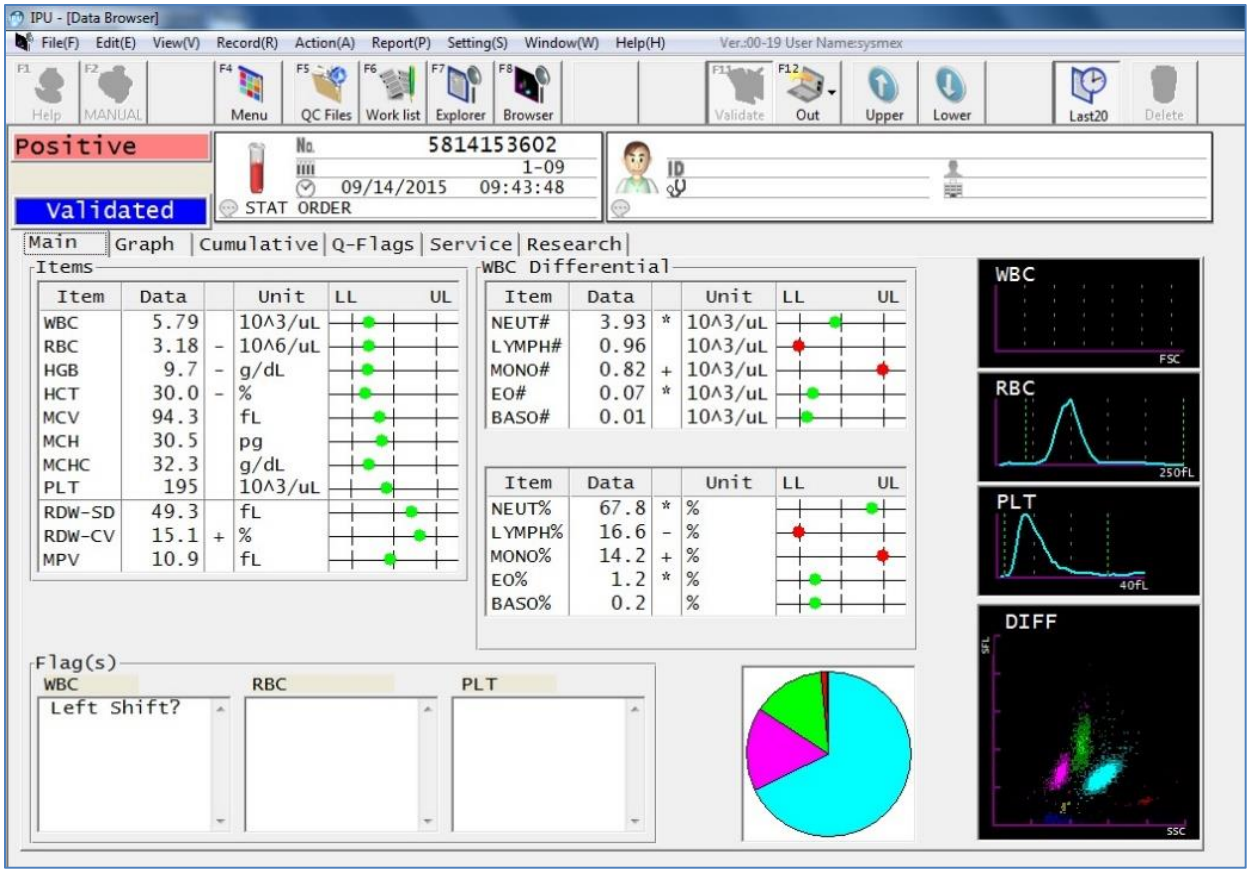
2. If no abnormalities are found, the results with the asterisk (*) may be reported.
3. If dashes (— —) are in place of numeric data, verify differential results according to your laboratory's policy. Possible actions may include:
    - repeating the sample
    - performing a manual differential

Suspect, Left Shift?

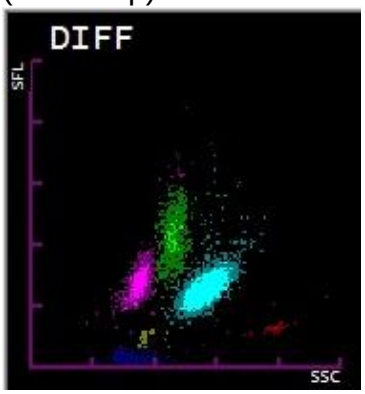
The Left Shift? IP message indicates that the analyzer has detected abnormal clustering in the region for left shift (bands) in the DIFF scattergram. When bands are present, they are included in the neutrophil population.

An asterisk (*) appears next to the % and # for the Neutrophil and Eosinophil. The asterisk (*) indicates these results may be unreliable and should be confirmed according to your laboratory protocol prior to reporting.

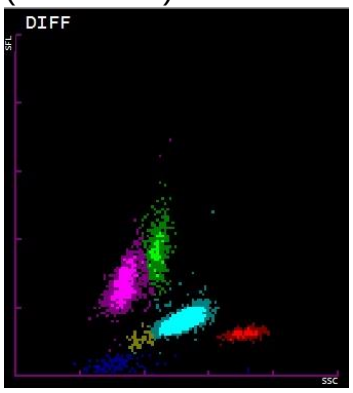
XS-Series Results



DIFF Scatter (Close-Up)



Normal DIFF Scatter (Reference)



Suspect, Left Shift?
(continued)

Suggested Action Steps:

1. Review results according to your laboratory protocol. This may include scanning the peripheral smear for the presence of:
    - band cells in increased numbers
    - toxic granulation or vacuolation of neutrophils
    - other abnormal cells

   Report any abnormal cells according to your laboratory protocol.

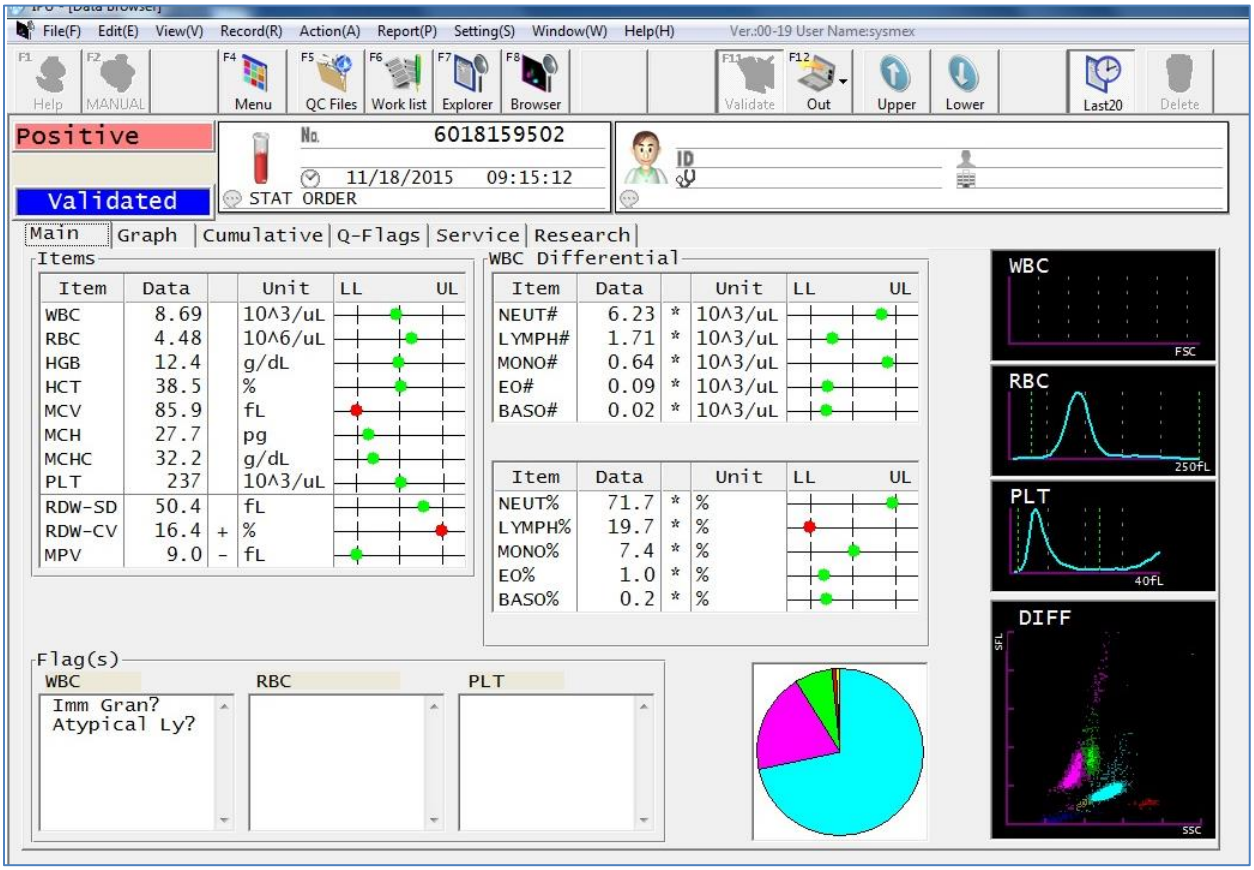
2. If no abnormalities are found, the results with the asterisk (*) may be reported.
3. If dashes (— —) are in place of numeric data, verify differential results according to your laboratory's policy. Possible actions may include:
    - repeating the sample
    - performing a manual differential

Suspect, Atypical Lymph?

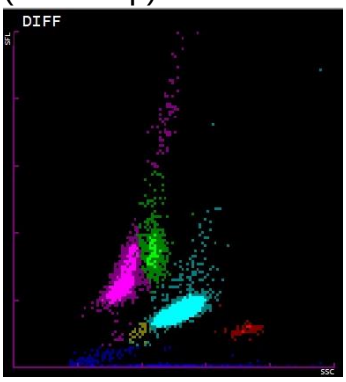
The Atypical Lymph? IP message indicates that the analyzer has detected significant clustering in the region for atypical lymphocytes that is located in the upper left lymphocyte region on the DIFF scattergram.

An asterisk (*) appears next to the % and # for the Neutrophil, Lymphocyte and Monocyte. The asterisk (*) indicates these results may be unreliable and should be confirmed according to your laboratory protocol prior to reporting.

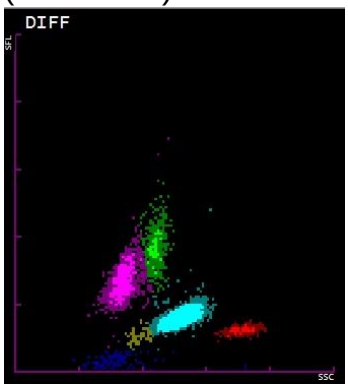
XS-Series Results



DIFF Scatter (Close-Up)



Normal DIFF Scatter (Reference)



Suspect, Atypical Lymph?
(continued)

Suggested Action Steps:

1. Review results according to your laboratory protocol. This may include scanning the peripheral smear for the presence of:
    - atypical or variant lymphocytes
    - abnormal or atypical monocytes
    - immature lymphocytes, such as seen in ALL or CLL
    - immature monocytes
    - smudge cells
    - other abnormal cells

   Report any abnormal cells according to your laboratory protocol.

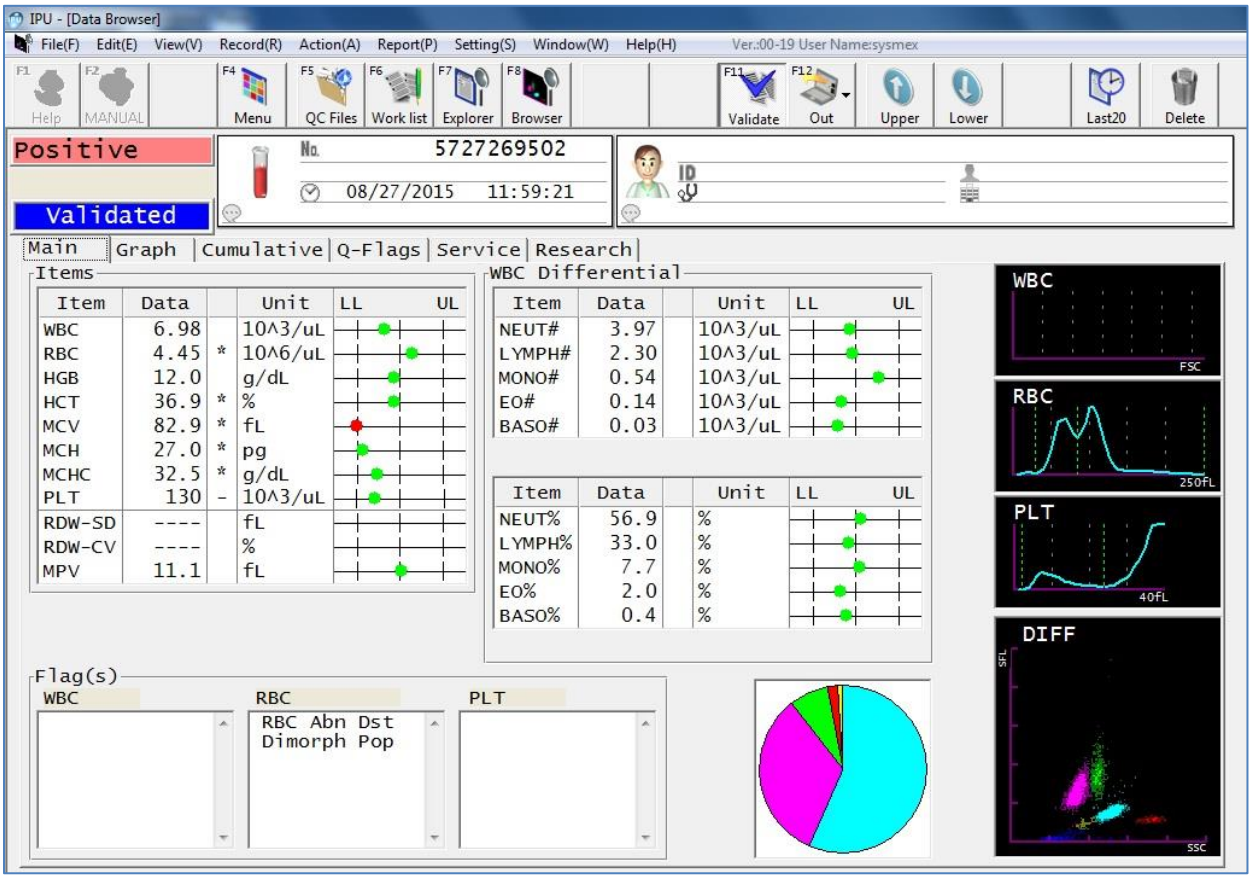
2. If no abnormalities are found, the results with the asterisk (*) may be reported.
3. If dashes (— —) are in place of numeric data, verify differential results according to your laboratory's policy. Possible actions may include:
    - repeating the sample
    - performing a manual differential

Abnormal, RBC Abn Distribution

The RBC Abn Distribution IP Message is generated when the histogram pattern from the RBC channel is abnormal or when RBC < 0.50 x 10^6/µL.

Dashes appear in place of affected results. For example, if there are multiple peaks present on the RBC histogram, there would be dashes in place of results for the RDW-SD and RDW-CV. Sometimes this IP Message can cause the RDW-SD and RDW-CV to be marked with an asterisk (*). The asterisk (*) indicates these results may be unreliable and should be confirmed according to your laboratory protocol prior to reporting.

XS-Series Results



Abnormal, RBC Abn Distribution (continued)

Suggested Action Steps:

1. Review results according to your laboratory protocol. This may include scanning the peripheral smear for the presence of abnormal RBC morphology such as:
    1. increased anisocytosis
    2. multiple RBC populations
    3. fragmented RBCs
    4. poikilocytosis
    5. rouleaux or RBC agglutination (refer to suggested action for “RBC Agglutination?” if present)

    Report any abnormal RBC morphology according to your laboratory protocol.

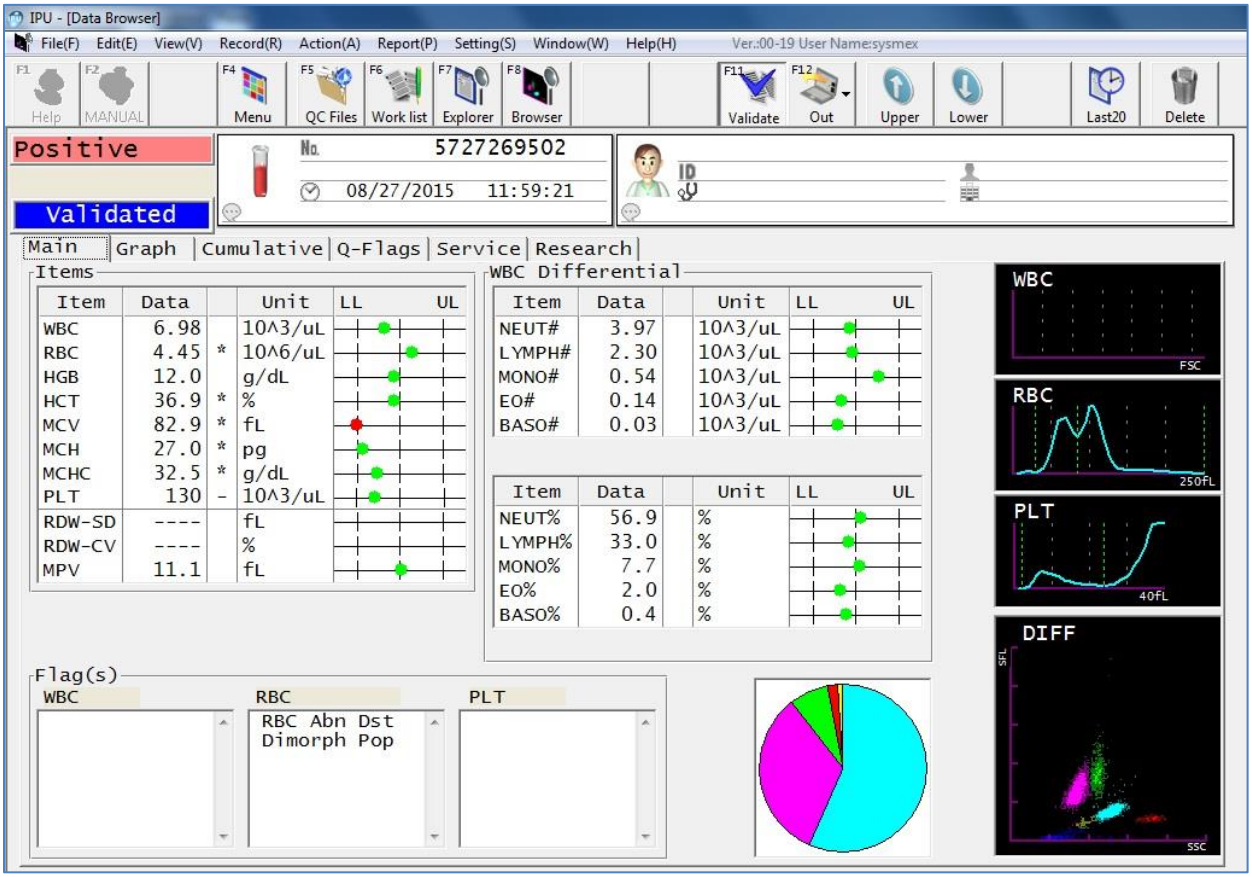
2. If no abnormalities are found, the results with the asterisk (*) may be reported.
3. If dashes (— —) are in place of numeric data, verify results according to your laboratory’s policy. Possible actions may include repeating the sample or reporting RBC morphology from smear review.
4. If the RBC morphology is normal and the MCHC is abnormal (<30 or >37.5 g/dL) an interfering substance or condition may be present. Refer to the suggested guidelines for the HGB/Turbidity Interference? IP Message.

Abnormal, Dimorphic Population

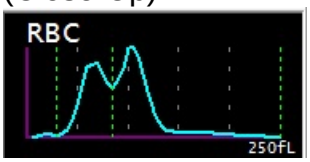
The Dimorphic Population IP Message is generated when there are multiple peaks in the RBC histogram pattern. This message may occur with the RBC Abn Distribution IP Message.

Dashes appear in place of results for the RDW-SD and RDW-CV. This message may cause certain RBC parameters to be marked with an asterisk (*). The asterisk (*) indicates these results may be unreliable and should be confirmed according to your laboratory protocol prior to reporting.

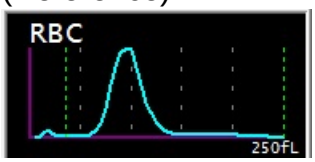
XS-Series Results



RBC Histogram (Close-Up)

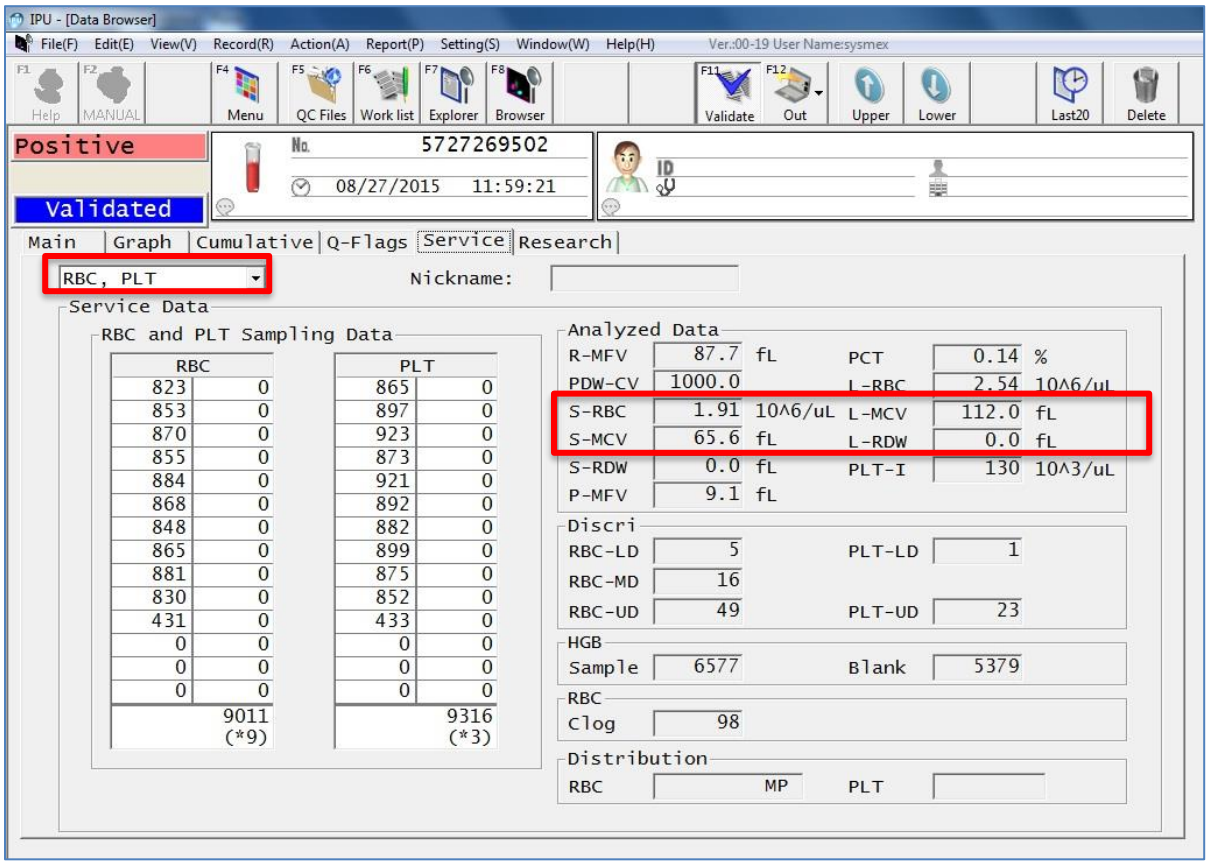


Normal RBC Histogram (Reference)



Abnormal, Dimorphic Population (continued)

The RBC count and MCV for the two populations shown on the RBC histogram can be found in the Service/RBC/PLT tab of the Browser Screen if needed.



NOTE: Results from the Service Tab are not directly reportable by the laboratory and must be confirmed prior to reporting.

Abnormal, Dimorphic Population (continued)

Suggested Action Steps:

1. Review results according to your laboratory protocol. This may include scanning the peripheral smear for the presence of abnormal RBC morphology such as:
    - increased anisocytosis
    - multiple RBC populations
    - fragmented RBCs
    - poikilocytosis
    - rouleaux or RBC agglutination (refer to suggested action for “RBC Agglutination?” if present)

    Report any abnormal RBC morphology according to your laboratory protocol.

2. If no abnormalities are found, the results with the asterisk (*) may be reported.
3. If dashes (— —) are in place of numeric data, verify results according to your laboratory’s policy. Possible actions may include repeating the sample or reporting RBC morphology from smear review.
4. If the RBC morphology is normal and the MCHC is abnormal (<30 or >37.5 g/dL) an interfering substance or condition may be present. Refer to the suggested guidelines for the HGB/Turbidity Interference? IP Message.

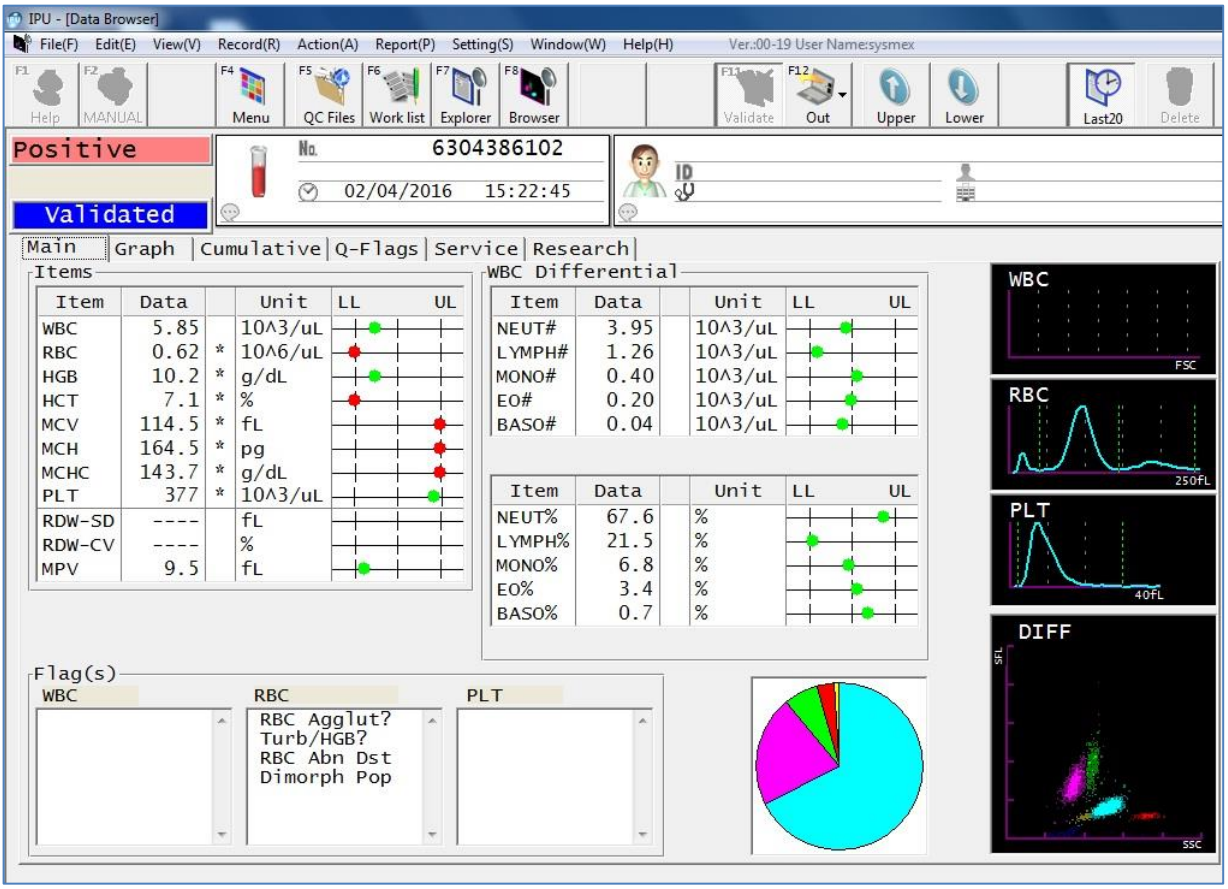
Suspect, RBC Agglutination?

The RBC Agglutination? IP Message is determined by calculation and size comparison of certain RBC items (MCHC, MCH, RBC, Upper RBC histogram discriminator [RU%] *).

*The RU% is not a reportable parameter, but it is used in the RBC Agglutination algorithm.

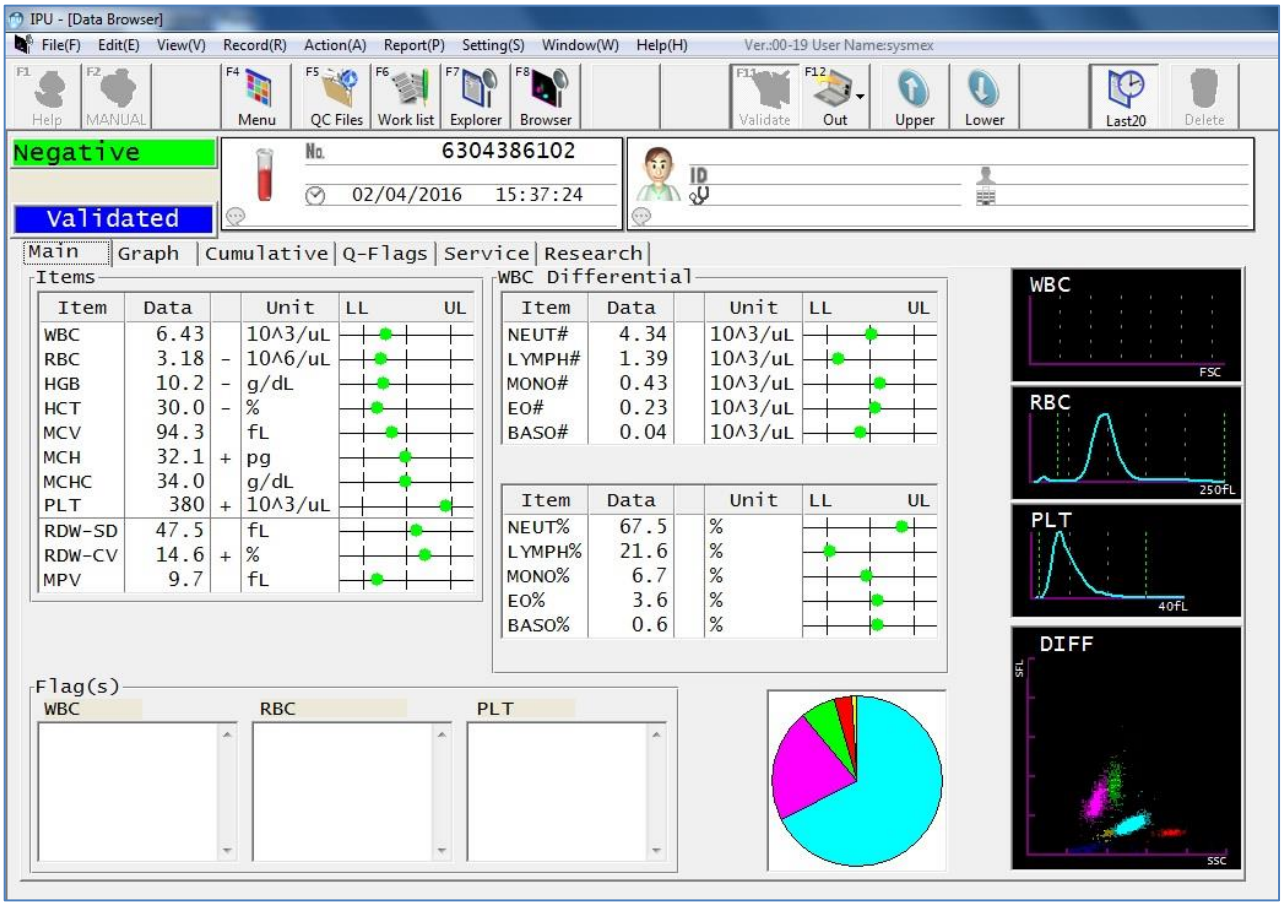
Asterisks (*) appear next to the RBC, HCT, MCV, MCH and MCHC parameters. The asterisk (*) indicates these results may be unreliable and should be confirmed according to your laboratory protocol prior to reporting.

XS-Series Results (initial run)



Suspect, RBC Agglutination?
(continued)

XS-Series Results (after warming at 37ºC)



Suggested Action Steps:

1. Follow your laboratory protocol and scan the peripheral smear for the presence of agglutinated RBCs or visually check the sample tube for agglutination.

2. If agglutinated RBCs are present, warm the sample at 37ºC for 15-30 minutes according to your laboratory policy. Reanalyze the warmed sample in the manual mode after mixing by manual inversion 10 times. Make a new peripheral smear from the warmed sample if agglutination is severe and WBCs and PLTs cannot be accurately assessed.

NOTE: Sometimes agglutination can be so severe that warming the sample does not enable accurate analysis.

Suspect, RBC Agglutination?
(continued)

3. In cases with high cold agglutinin titers, a plasma replacement using warm CELLPACK® may be necessary to reduce the interference from the antibody. Further warming post-plasma replacement may also be necessary.

    a. To perform a plasma replacement
        i. Centrifuge an aliquot of blood from the primary tube to separate the cells from the plasma.
        ii. Using a pipette, remove a measured amount of plasma removing as much plasma as possible without disturbing the buffy coat.
        iii. Add back the same amount of CELLPACK as the volume of plasma removed in step ii. (Example: If 0.5 mL of plasma is removed then add back 0.5 mL of CELLPACK.)
        iv. Cap the tube and mix the sample by manual inversion until the cells are fully re-suspended in the CELLPACK.
        v. Reanalyze the sample in the manual mode.

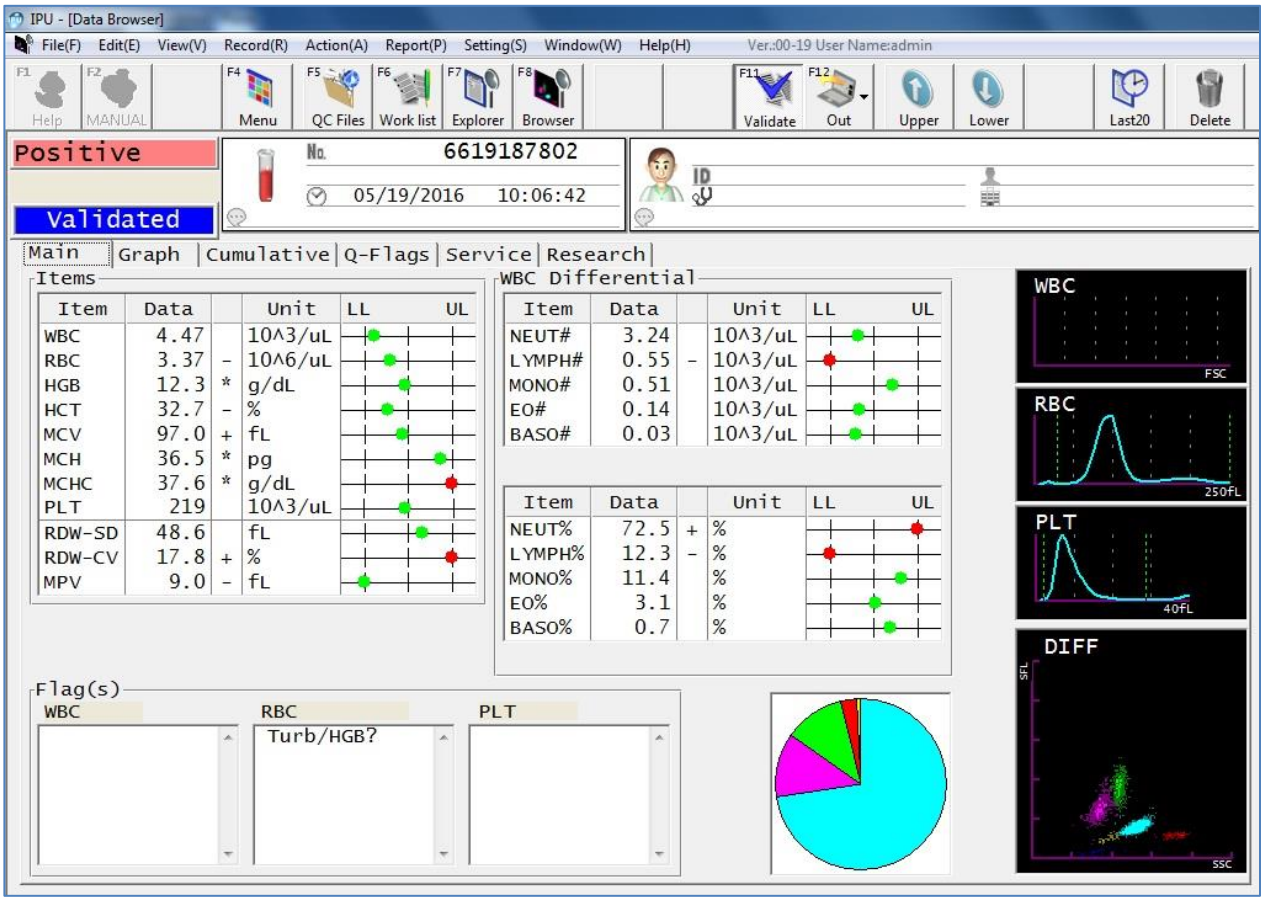
4. In cases where a warm-reacting antibody has caused agglutination, a plasma replacement may reduce the interference from the antibody. Room temperature CELLPACK may be used to replace the plasma.

Suspect, Turbidity/HGB Interference?

The Turbidity/HGB Interference? IP Message occurs when the MCHC is >36.5 g/dL and indicates that turbidity may be present in the diluted and lysed sample. This turbidity could interfere with the HGB detection light path and falsely increase the HGB value. Other interfering substances or conditions may impact the hematocrit and also cause an increased MCHC.

Asterisks (*) appear next to the HGB, MCH and MCHC parameters. The asterisk (*) indicates these results may be unreliable and should be confirmed according to your laboratory protocol prior to reporting.

XS-Series Results



NOTE: An MCHC up to 37.5 g/dL may indicate a normal specimen on the high end of normal range in which case no action is needed. This may occur more often in samples with higher hemoglobin and hematocrit results.

Consider the MCHC and the MCV together when evaluating results and the reasons for the interference. Refer to the following table for possible interferences and corrective actions.

Suspect, Turbidity/HGB Interference? (continued)

<table>
<tr><th>Pattern of Results</th><th>Encountered in</th></tr>
<tr><td>Low or Normal MCV
High MCHC (>37.5 g/dL)</td><td>• Hemolysis
• Plasma electrolyte abnormalities (i.e., low sodium) affecting hematocrit results
• Severe lipemia
• Icterus
• Severe leukocytosis affecting hemoglobin measurement
• Abnormal plasma protein precipitation affecting hemoglobin measurement
Refer to Troubleshooting Chart</td></tr>
<tr><td>High MCV
High MCHC (>37.5 g/dL)</td><td>• RBC Agglutination
• Rouleaux
Refer to Troubleshooting Chart</td></tr>
<tr><td colspan="2">Troubleshooting Chart
Always follow your local laboratory procedure for repeat testing or rejection of samples</td></tr>
<tr><td>Low Sodium Affecting Hematocrit?</td><td>RBC Agglutination?</td><td>Severe Lipemia, Icterus, Abnormal Protein or Leukocytosis Affecting Hemoglobin Measurement or Hemolysis?</td></tr>
<tr><td>1. Perform a 1:5 dilution of sample with CELLPACK
2. Allow the dilution to equilibrate for ten to fifteen minutes
3. Rerun after equilibration
4. Correct results for dilution factor prior to reporting.
NOTE: MCV, MCH, MCHC, RDW-SD, RDW-CV, MPV and differential percent results are unaffected by dilution and do not require correction.</td><td>1. Prewarm at 37°C for fifteen to thirty minutes then rerun
2. Severe cold agglutinins or rouleaux may require dilution or plasma replacement with CELLPACK.
3. For severe cold agglutinins, additional incubation at 37°C may be necessary following dilution or plasma replacement.</td><td>1. Perform a 1:5 dilution of sample with CELLPACK
2. Repeat diluted sample
3. Correct results for dilution factor prior to reporting.

Lipemia or Icterus Only
Perform a plasma replacement procedure

Hemolysis:
Recollect a new sample.</td></tr>
</table>

Suspect, Iron Deficiency?

The Iron Deficiency? IP Message is determined by calculation and size comparison of certain RBC items (MCV, RDW-CV).

NOTE: It is suggested to use this flag as an alert to evaluate the MCV and RDW-CV results. If your laboratory protocol does not require further action based on the MCV and RDW-CV results, results may be reported without further investigation.

Suspect, HGB Defect?

The HGB Defect? IP Message is determined by calculation and size comparison of certain RBC items (MCV and RDW-CV).

NOTE: It is suggested to use this flag as an alert to evaluate the MCV and RDW-CV results. If your laboratory protocol does not require further action based on the MCV and RDW-CV results, results may be reported without further investigation.

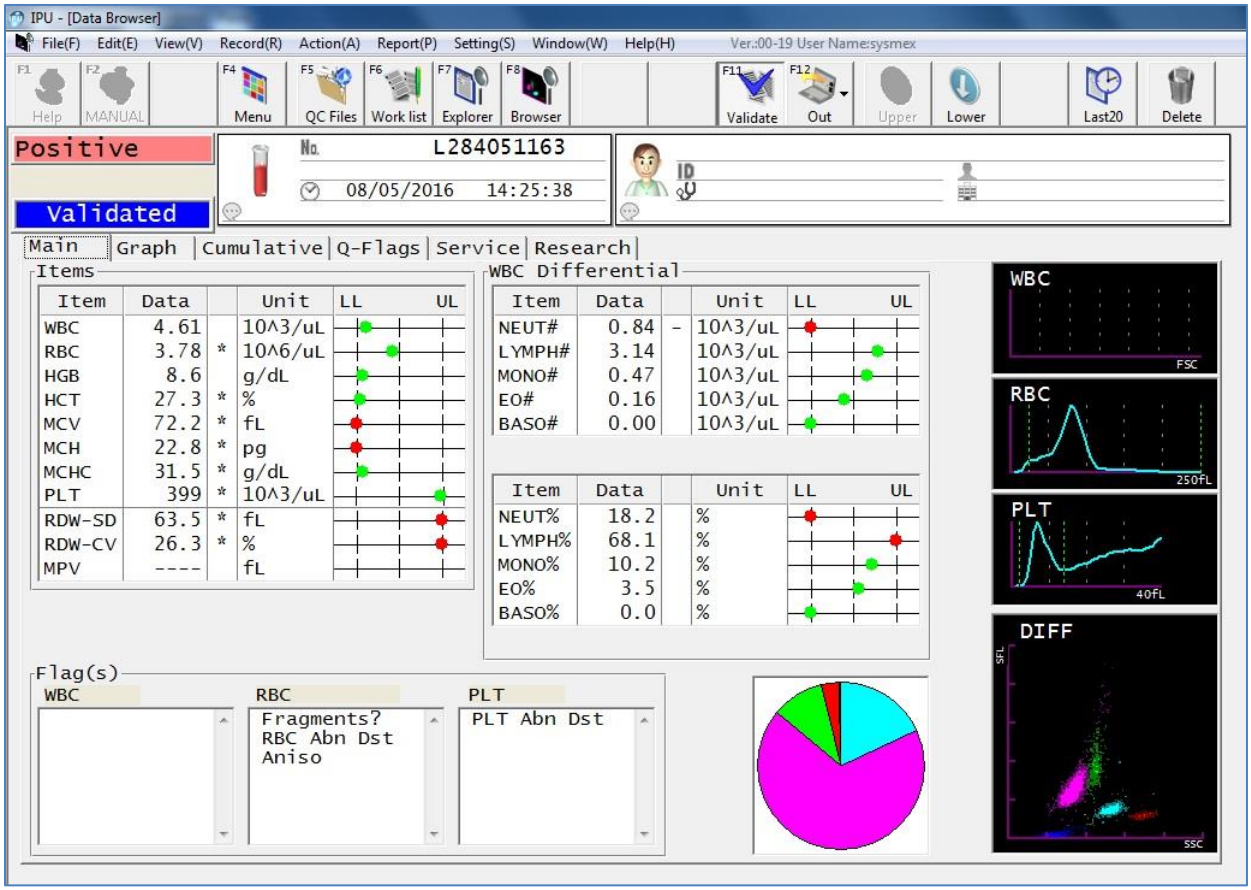
Suspect, Fragments?

The Fragments? IP Message is determined from calculation and size comparison of certain RBC and PLT items (MCV, RDW-SD, MCHC, RBC Lower Discriminator [RL]*, PLT Upper Discriminator [PU]*, PLT Upper Discriminator % [PU%]*).

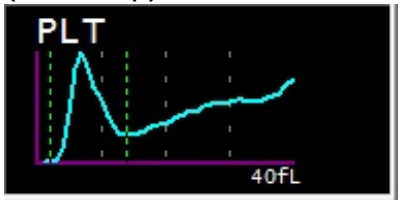
*RBC lower discriminator, PLT upper discriminator, % of the PLT upper discriminator. These parameters are not reportable, and are used only in the algorithm for the Suspect, Fragments flag.

Asterisks (*) appear next to the RBC, HCT, MCV, MCH, MCHC, RDW-SD and RDW-CV parameters. The PLT parameter may also have an asterisk. The asterisk (*) indicates these results may be unreliable and should be confirmed according to your laboratory protocol prior to reporting.

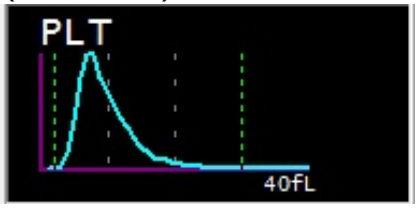
XS-Series Results



Platelet Histogram (Close-Up)



Normal Platelet Histogram (Reference)



Suspect, Fragments?
(continued)

Suggested Action Steps:

1. Scan the peripheral smear for the presence of fragmented RBCs and other poikilocytosis according to your local laboratory protocol.

2. Report the presence of any clinically significant RBC morphology according to your local laboratory protocol.

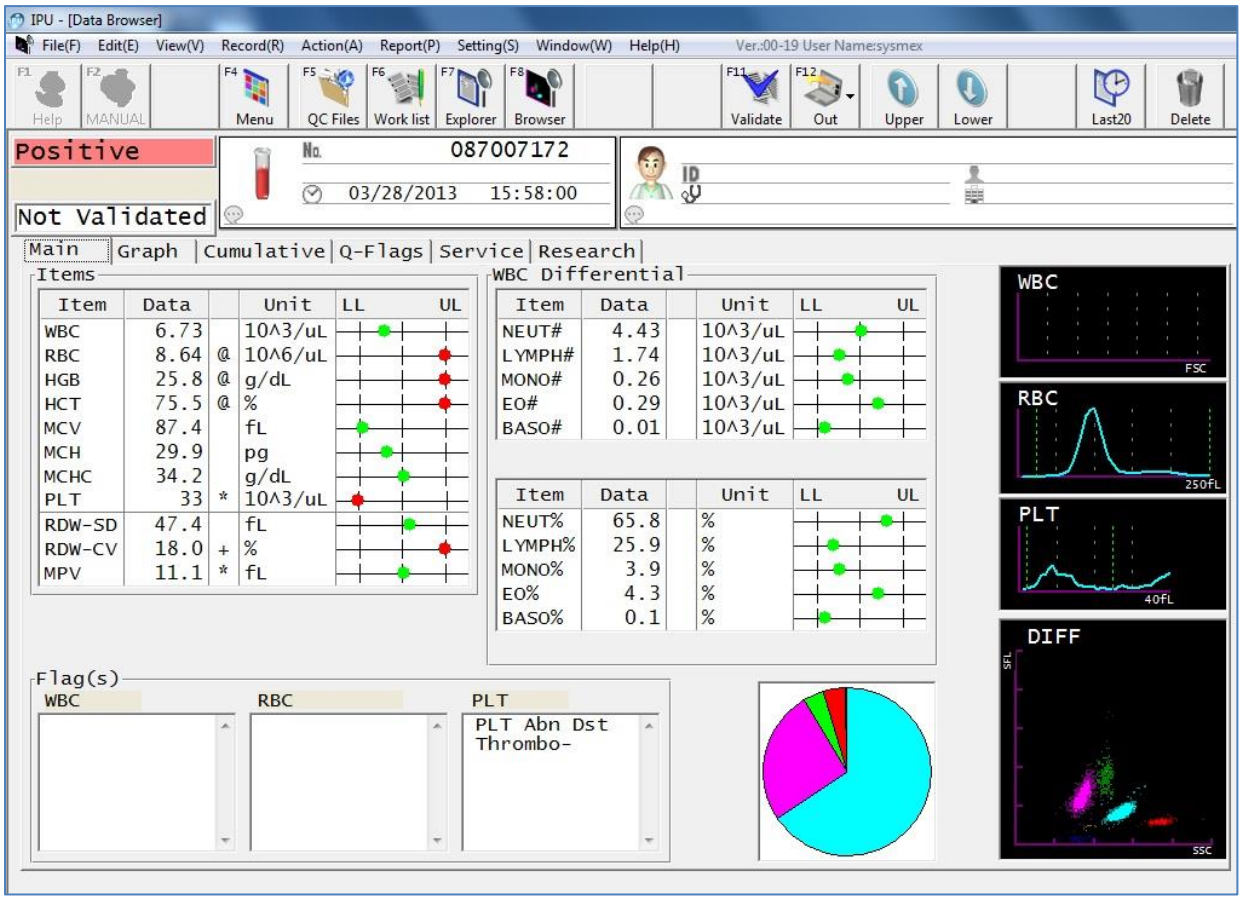
Abnormal, PLT Abn Distribution

The PLT Abn Distribution IP Message is generated by calculation and size comparison of certain PLT items (PDW*, % of PLT lower discriminator [PL%] *, % of upper discriminator [PU%] *, platelet mean-frequent volume [PMFV]*, platelet large cell ratio*, MPV, platelet upper discriminator [PU]*).

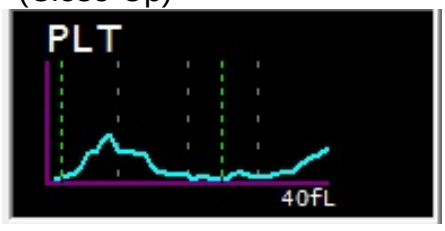
*These are all non-reportable parameters that are used as part of the flagging algorithm.

Dashes may appear in place of data for the MPV or the MPV may be marked with an asterisk (*). The asterisk (*) indicates these results may be unreliable and should be confirmed according to your local laboratory protocol prior to reporting.

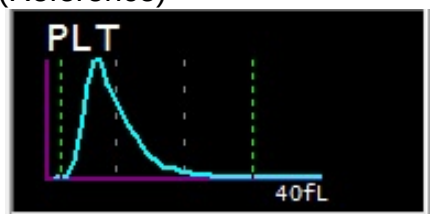
XS-Series Results



Platelet Histogram (Close-Up)



Normal Platelet Histogram (Reference)



Abnormal, PLT Abn Distribution
(continued)

Suggested Action Steps:

1. Review results according to your local laboratory protocol. Possible actions include:

   a. Scan the peripheral smear to estimate the platelet count and review for the presence of abnormal RBC or PLT morphology such as:
      - large or giant platelets
      - small platelets
      - platelet clumps
      - fragmented RBCs
      - microcytic RBCs
      - parasites

      If abnormal RBC, PLT or other morphology is noted, report according to your local laboratory protocol.

   NOTE: Reviewing the feathered edge and sides of the peripheral smear is suggested as platelet clumps and fibrin strands may migrate to this area during smear preparation.

2. If platelet estimate confirms accuracy of analyzer count, it may be reported.

3. If platelet estimate does not confirm accuracy of analyzer count, confirm with an alternate method such as a manual platelet count according to your local laboratory protocol. Depending on the source of the interference, the analyzer PLT count may be falsely increased or decreased. Report any clinically significant RBC and/or PLT morphology according to your local laboratory protocol.

4. If platelet clumps have interfered, perform one of the alternate procedures recommended in the section Suggested Actions for PLT Clumps? IP Message.

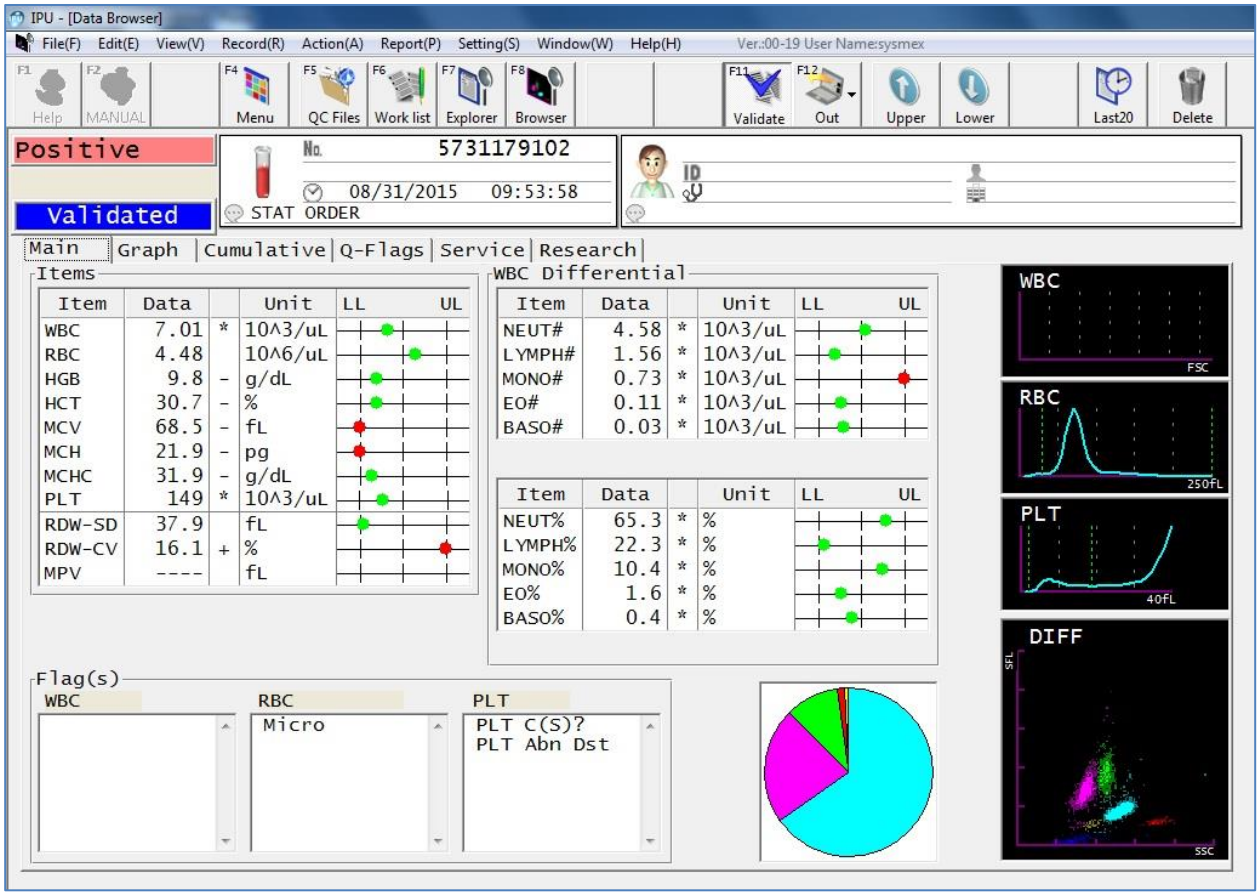
Suspect, PLT C(S)?

The PLT C(S)? IP Message is generated by calculation and size comparison of certain PLT items (PDW*, % of PLT lower discriminator [PL%] *, % of upper discriminator [PU%] *, platelet mean-frequent volume [PMFV]*, platelet large cell ratio*, MPV, platelet upper discriminator [PU]*).

*These are all non-reportable parameters that are used as part of the flagging algorithm.

Asterisks (*) will appear next to the PLT results. Dashes may appear in place of data for the MPV or the MPV may be marked with an asterisk (*). The asterisk (*) indicates these results may be unreliable and should be confirmed according to your laboratory protocol prior to reporting.

XS-Series Results



Suggested Action Steps:

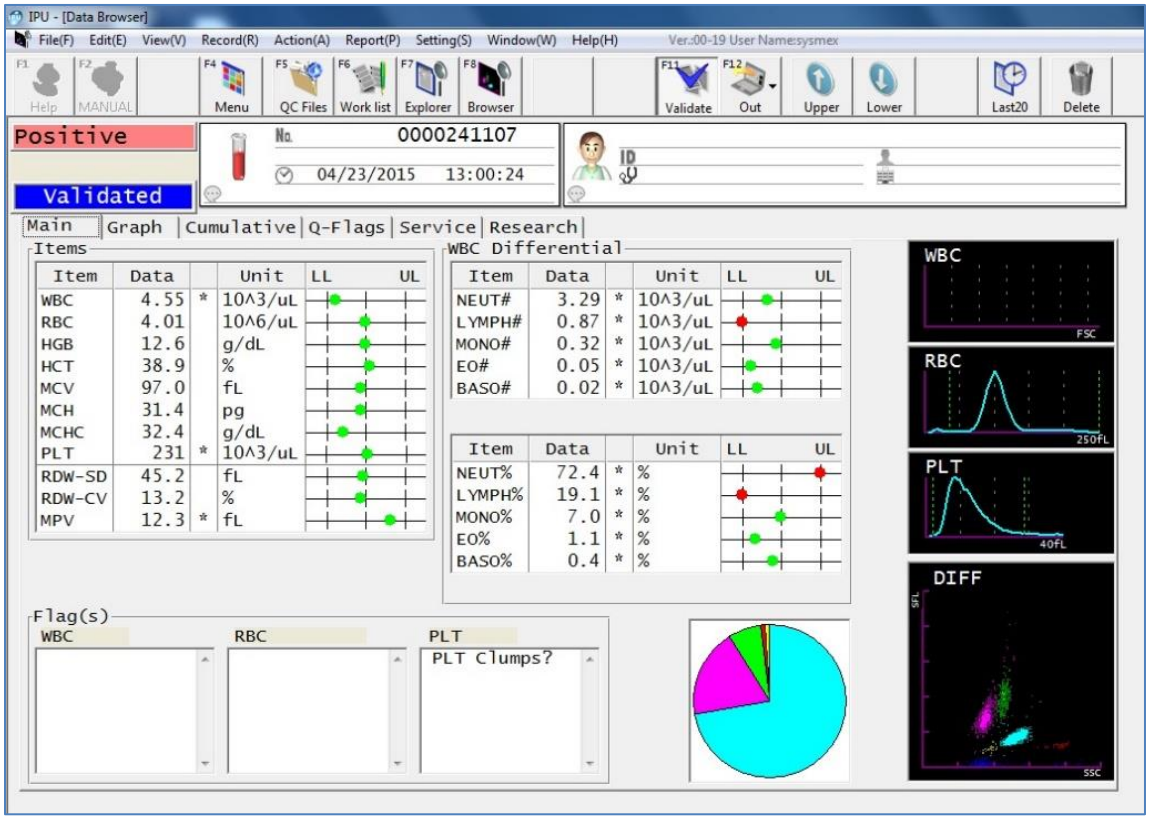
1. Follow your local laboratory protocol.
2. Refer to the suggested action steps for the PLT Clumps? IP Message for further information.

Suspect, PLT Clumps?

The PLT Clumps? IP Message is determined by abnormal clustering in the DIFF scattergrams.

Asterisks (*) will appear next to the PLT result. Dashes may appear in place of data for the MPV or the MPV may be marked with an asterisk (*). The asterisk (*) indicates these results may be unreliable and should be confirmed according to your laboratory protocol prior to reporting.

XS-Series Results



Suspect, PLT Clumps?
(continued)

Suggested Action Steps:

1. Follow your local laboratory protocol. Possible actions may include:
    a. Checking the sample for the presence of clots

    b. Scanning the peripheral smear, especially the feathered edge, for the presence of abnormal morphology including:
        - fibrin strands
        - platelet clumps
            i. If any of the above are present, verify the WBC and PLT by a manual slide estimate.
            ii. If the WBC and PLT estimates match the analyzer counts, report the results according to your local laboratory protocol.
            iii. If the estimates do not match the analyzer counts, refer to the next step to obtain an accurate count.

    NOTE: Reviewing the feathered edge and sides of the peripheral smear is suggested as platelet clumps and fibrin strands may migrate to this area during smear preparation.

2. If platelet clumps or fibrin strands have interfered, perform one of the following alternate procedures to obtain an accurate count:
    a. Re-draw specimen in EDTA and sodium citrate tubes if possible. Analyze re-drawn EDTA tube. If the repeat run has no PLT Clumps? IP Message, report these results.
    b. If there is still a PLT Clumps? IP Message and platelet clumps are present on smear review it could be an in vitro reaction with EDTA. Analyze the sodium citrate tube. Obtain only the WBC and PLT counts from the sodium citrate tube as sodium citrate alters RBC morphology and indices.
    c. Multiply the WBC and PLT results from the sodium citrate tube by the factor used by your laboratory.
    d. If recollection is not possible or if platelet clumps persist when using sodium citrate, estimate the platelet count and report as decreased, adequate or increased and comment on the platelet clumps according to your local laboratory protocol.

Suspect, PLT Clumps?
(continued)

NOTES:

1. There are different methods for handling samples with platelet clumps. These methods include vortexing of the original sample, recollection and analysis of a new sample in sodium citrate or adding amikacin to the original sample and reanalyzing. Individual facilities should define and validate the method, anticoagulant type, and any dilution factors used.

2. Some samples with severe platelet clumping may not be resolved (or only be partially resolved) using any method. In such samples, the only option is to not report the numeric platelet result and instead report a platelet estimate from a review of a stained smear.

3. The incidence of completely unflagged instances of pseudothrombocyopenia is very low. However, to identify samples with pseudothrombocytopenia due to platelet clumping, multiple approaches must be employed together. Approaches for detecting platelet clumping may include:
    a. Smear review based on analyzer generated or user defined flags such as “Thrombocytopenia” or “Platelet Abnormal Distribution”, etc.
    b. Use of delta checks comparing the current result against previous results
    c. Review of smears based on both PLT and Mean Platelet Volume (MPV) results. (Low PLT with high MPV may indicate the presence of platelet clumps.)
    d. Use of review criteria for results that fall between the “thrombocytopenia” threshold and a critical low value that might warrant transfusion support.

Action Messages

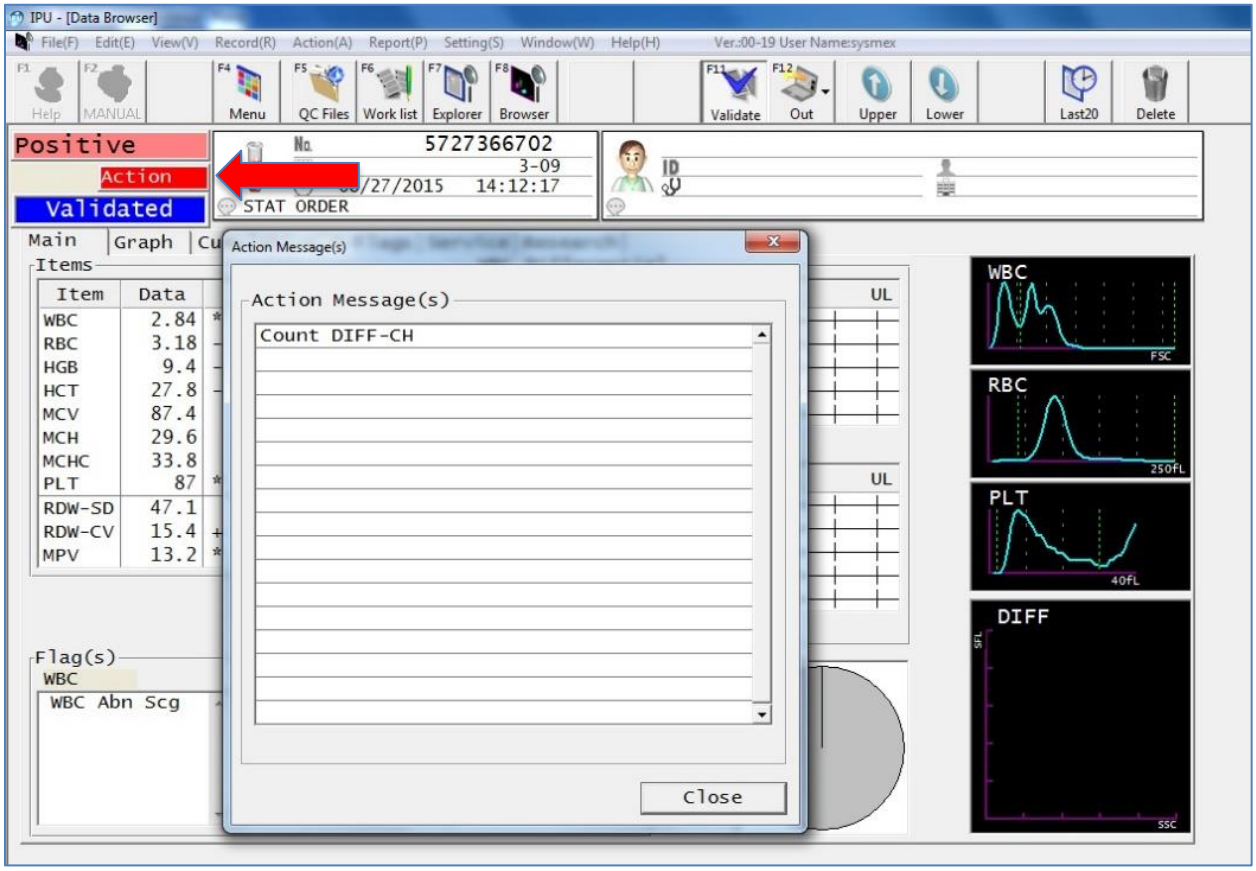
Count DIFF-CH

In the CBC discrete test selection, WBC measurement is performed using blood lysed with STROMATOLYSER® 4-DL and FSC (Forward Light Scatter) measurement. This message is generated in the CBC discrete test selection when interference is suspected in the WBC histogram based on the FSC measurement.

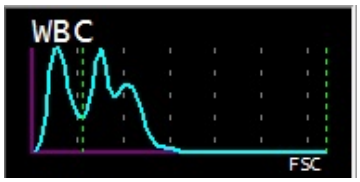
Asterisks (*) will appear next to the WBC result. The asterisk (*) indicates these results may be unreliable and should be confirmed according to your laboratory protocol prior to reporting. This action message may appear with the WBC Abnormal Scattergram flag.

The message is printed on the report and can be displayed on the Browser screen by selecting the red Action box as shown below.

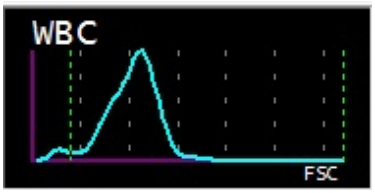
XS-Series Results



WBC Histogram (Close-Up)



Normal WBC Histogram (Reference)



Action Message
COUNT DIFF-CH
(continued)

Suggested Action Steps:

1. Rerun the sample using the CBC+DIFF discrete test selection.
2. Verify WBC and differential results according to your laboratory's protocol and flagging which occurs on the CBC+DIFF run. Possible actions may include:
    a. Scanning the slide for abnormal cells and to estimate the WBC count.
    b. Performing a manual differential if abnormal cells are observed.
    If no abnormalities are found when reviewing the smear and the WBC estimate matches the analyzer reported WBC, the results may be reported according to your laboratory's protocol.

Interfering Substances

Some abnormal samples may interfere with automated cell counting methods. The following is a list from the Sysmex XS-Series Instructions for Use of possible substances that may interfere with these parameters.

NOTE: Compromised samples, such as those not properly collected, stored, transported, or containing clots may cause misleading results. Always use good laboratory practices for inspecting specimens for acceptability and verifying results.

WBC: Leukocyte aggregation, platelet aggregation, lyse resistant erythrocytes, erythrocyte aggregation (cold agglutinin), erythroblasts (nucleated red blood cells), cryoprotein, cryoglobulin, fibrin, giant platelets (Platelets > 1,000,000/µL)

RBC: Erythrocyte aggregation (cold agglutinin), microcytosis, fragmented RBCs, leukocytosis (lymphocytes > 100,000/µL), giant platelets (Platelets > 1,000,000/µL)

HGB: Leukocytosis (lymphocytes > 100,000/µL), lipemia, abnormal protein. The effect of abnormal proteins and lipemia may be removed by plasma replacement or plasma blank procedures.

HCT: Erythrocyte aggregation (cold agglutinin), microcytosis, fragmented RBCs, leukocytosis (lymphocytes > 100,000/µL), severe diabetes (hyperglycemia), uremia, spherocytosis

PLT: PLT aggregation, pseudothrombocytopenia, giant platelets, microcytosis, fragmented RBCs, fragmented leukocytes, cryoprotein, cryoglobulin

NOTE: The Sysmex XS-Series Analyzer is designed to flag abnormal samples that may contain interfering substances. These results should be reviewed carefully and may require further examination in accordance with your local laboratory protocol.

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