

XT-4000*i*[™] Automated Hematology Analyzer

Differentiate with the XT-4000i



Advanced Technology Solutions to Meet Your Lab's Needs



Even with these challenges, the need for hematology testing has remained steady or continued to grow. Laboratories are searching for hematology analyzers that can improve productivity and efficiency while providing enhanced clinical information. Designed to be reliable and efficient, the Sysmex XT-4000*i* offers medium to high volume labs an automated hematology system that can truly meet and exceed their expectations. The XT-4000*i* streamlines your workflow by providing testing for up to 100 samples per hour, enabling rapid turnaround time.

Today's Laboratory Challenges

Laboratories continue to face a number of challenges. These include clinical, operational and financial issues such as:

- Demand for clinically relevant information
- Medical technologist labor shortage
- Increased workload
- Need for faster turnaround time
- · Requirement for high reliability
- Limited laboratory budgets

Fluorescent Flow Cytometry Yields Optimized Productivity

The Sysmex XT-4000*i* Automated Hematology System utilizes the power of fluorescent flow cytometry and hydrodynamic focusing technologies. Using a unique, state-of-the-art, diode laser bench, Sysmex fluorescent flow cytometry provides the sensitivity needed for measuring and differentiating cell types in whole blood and body fluid samples. Fluorescent technology and hydrodynamic focusing enable the XT-4000*i* to consistently classify normal WBC, RBC and PLT populations from abnormal populations, thereby decreasing the number of manual interventions

Clinically Relevant Information

Effective Red Cell Disorder Screening and Therapy Monitoring

The XT-4000*i* System provides the panel of standard parameters for basic and reliable anemia screening and monitoring.

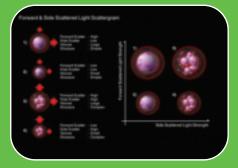
RBCs and PLTs

RBCs and PLTs are counted in a dedicated channel using Impedance or Direct Current (DC) detection method combined with hydrodynamic focusing technology. Challenges to cell counting such as coincidence or recirculation are circumvented and automatic discriminators separate the two cell populations.

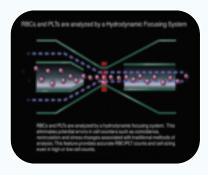
Even with samples at extremely low or unusually high concentrations, the Sysmex XT-4000*i* analyzes RBCs and PLTs with uncompromised precision and accuracy.



Laser Technology



Adaptive Cluster Analysis System (ACAS) WBC Differential Counting



RBC and **PLT** Counting



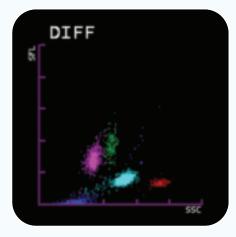
Non-cyanide Hemoglobin

High Quality Hemoglobin (HGB) Analysis

The XT-4000*i* utilizes the non-cyanide reagent, Sodium Laurel Sulfate Hemoglobin (SLS). The end product is a colored compound that is measured spectrophotometrically. Since hemoglobin determinations are performed from a dilution and in its own separate chamber, there is no interference from high WBC counts, lipemia or abnormal proteins.

Direct Hematocrit (HCT) Measurement

The cumulative pulse heights of all the RBC counts yield the HCT. This is based on the principle that the pulse height (voltage change) produced by cells passing through the aperture is proportional to cell volume.



WBC Differential Scattergram

WBC, A Clear Differentiation

The combination of side scatter (cell complexity), forward scatter (size) and fluorescence (DNA & RNA concentration) of nucleated cells provides a concise and precise image of each detected peripheral blood cell.

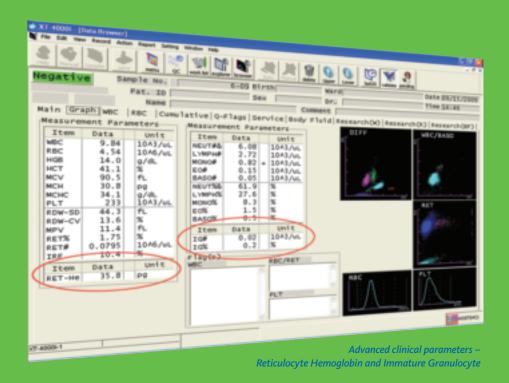
Fluorescent technology enables the XT-4000*i* to reliably differentiate normal WBC populations from abnormal WBC populations. The sensitivity of the unique application of fluorescent flow cytometry gives the lab a high level of confidence in reporting accurate WBC differentials, even on critical patient samples when the WBC count is low.

The Sysmex XT-4000*i* offers a 6-part differential, which includes an **Immature Granulocyte Count** (IG%, #). The IG count offers reportable, quantitative results for immature granulocytes (metamyelocytes, myelocytes and promyelocytes).

Advanced Parameters In One Comprehensive System

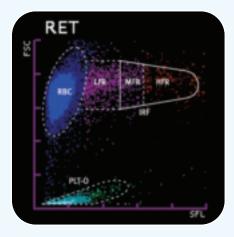
XT-4000*i* Technology Provides Clinically Relevant, Reportable Parameters:

- Retic: Fluorescent reticulocyte count to reduce manual confirmation methods and their inherent errors
- RET-He: Reticulocyte Hemoglobin Content measures the incorporation of iron into the red cell to assist in anemia evaluation and management (e.g., functional iron deficiency anemia)
- PLT-O: Fluorescent optical platelet count and traditional impedance
 PLT counting to improve accuracy of very low and very high PLT counts
- NRBC: Fluorescent NRBC flagging



Reticulocyte Hemoglobin (RET-He) Benefits

- Rapid, direct analysis of an earlier stage of RBC development for prompt clinical follow-up
- Assessment of anemia and is an established parameter used in KDOQI (Kidney Disease Outcomes Quality Initiative) guidelines for assessing the initial iron status of patients
- Accuracy and sensitivity in measurement of red cell production that supports effective monitoring of costly drug protocols for cell stimulation by clinicians



Fluorescent Reticulocyte Count

Fluorescent Reticulocyte Count

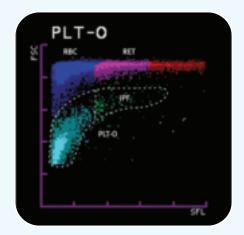
Known as the "Gold Standard" reticulocyte testing parameter, the fluorescent reticulocyte count is available on the XT-4000i. Sysmex provides on-board retic testing in a dedicated channel, improving your efficiency in reporting reticulocytes 24 hours per day.

Reticulocyte Channel Benefits

- Accurate reticulocyte % and #
- Improved immature reticulocyte information (IRF) for earlier diagnosis and treatment by clinicians
- Elimination of common interferences from Howell-Jolly bodies, Pappenheimer bodies and immature reticulocytes to avoid manual counts

In addition, the Reticulocyte Hemoglobin (RET- He) is a parameter measured in the RET Channel and is used to measure the incorporation of iron into erythrocyte hemoglobin.

Improved Productivity & Efficiency



Fluorescent Optical Platelet

Fluorescent Optical Platelet

The XT-4000*i* offers a Fluorescent Optical Platelet (PLT-O) in addition to the traditional impedance PLT (PLT-I) count. These dual technologies support maximizing instrument information from abnormal patient samples. Flagging associated with atypical or abnormal platelets due to increased size or fragmentation is minimized by use of the optical platelet count. Accuracy in reporting is supported by the availability of both technologies.

Fluorescent Optical Platelet (PLT-O) Benefits

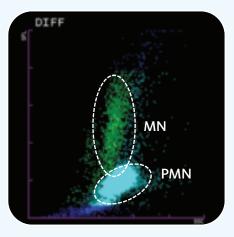
- Improved accuracy on low platelet counts
- Accurate counts when interferences are present, thus reducing manual intervention
- Automated judgment for reporting PLT-O or PLT-I through instrument settings, eliminating tech-to-tech decision variability

XT-4000*i* Body Fluid Mode

The XT-4000*i* analyzer includes a body fluid specific mode. This mode provides a reportable RBC, WBC, WBC differential (polymorphonuclear and mononuclear) and a total count (TC-BF) for all common body fluid samples (CSF, synovial and serous). The analyzer applies proven impedance and fluorescent flow cytometry ensuring an accurate body fluid count.

The XT-4000*i* Body Fluid Count Provides

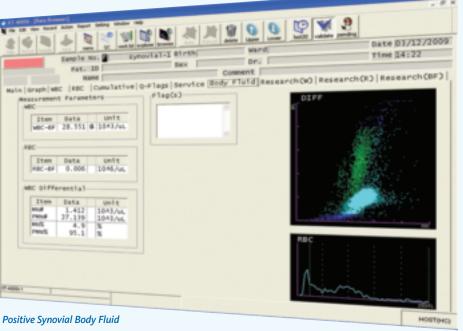
- Expanded sensitivity and linearity;
 WBC and RBC counts
 reportable to 3 decimal places
- 2-Part Differential
- No sample pretreatment
- No additional reagents
- No additional quality control material required
- An automatic background check prior to analyzing a sample



WBC Body Fluid Count

The XT-4000*i* Body Fluid Count Benefits

- Improved productivity
- Decreased turnaround time (TAT)
- Decreased manual technical intervention



Maximizing Uptime

e-Tools: Assuring Quality and Optimizing Performance

SNCS™, Sysmex Network Communications System, is proprietary software which enables fast, secure communication from your analyzer to Sysmex servers using a high-speed, outbound internet connection. This powerful tool is the instrument data link feeding a variety of innovative tools and services.

InsightTM

Insight is a web-based Inter-laboratory Quality
Assessment Program (QAP) which allows on-demand
quality control reporting with access anytime, anywhere.
Meet requirements to document peer comparison data
for your analyzer while eliminating manual steps.

Remote Monitoring

Continuous collection and monitoring of instrument performance data is linked to our tracking and dispatch system. We monitor your instrument performance, instrument configuration settings and back-up settings continuously.

Make your lab more efficient with:

- Unobtrusive, remote and real-time monitoring
- Proactive identification and follow-up of potential issues
- Enhanced first-time field fixes, if needed

Productivity

The system provides a throughput of up to 100 samples per hour, producing high-quality results rapidly for clinicians to use in diagnosis and treatment decisions. The XT-4000*i* can be used in conjunction with Sysmex WAM™ Decision Support Software for the Clinical Laboratory, which enhances sample and data workflow and improves turnaround time (TAT).

Improved Patient Care

The XT-4000*i* offers a CBC, 6-part differential and one of the highest throughputs in the market for a mid-range analyzer. The small whole blood sample size – closed mode: 150µL, open mode: 85µL – can be utilized for your pediatric and oncology patient samples. The capillary mode, pre-dilute analysis mode, requiring only 40µL of whole blood, provides quality clinical data, rapidly and consistently. Results from the capillary mode include CBC and Retic counts and user-defined flagging from very low volume samples.



Differentiate with the XT-4000i

The XT-4000*i* offers a comprehensive clinical testing menu for both whole blood and body fluids, providing accurate, precise and sensitive results. With its rapid throughput, your clinicians receive quality results to assist in management and diagnosis of all patients. Clinically relevant information from one comprehensive system!

Sysmex XT-4000*i* Specifications

Excellent Performance

- Reliable platform
- Low sample volume requirements
- Sysmex Network Communications System (SNCS™) remote diagnostic monitoring system supporting maximum uptime
- Ranked by independent third party as highest vendor for reliability for 9 consecutive years*

*IMV ServiceTrak 2009

Reportable, Diagnostic Information from a Single Sample Analysis

- 6-part whole blood WBC differential (NE + Lymph + Mono + Eo + Baso + IG)with NRBC flagging
- · Body fluid cell count and 2-part differential
- Anemia evaluation parameters; Reticulocyte, IRF, and RET-He
- · Optical and Impedance Platelet measurement capabilities

Easy-to-use

- · Intuitive software menus
- On-board help key for rapid troubleshooting
- Comprehensive quality control information
- · Barcoded reagent management

Principles & Technologies

Fluorescent Flow Cytometry: WBC-Diff, IG, RET, IRF, PLT-O

Hydrodynamic Focusing, Direct Current:

RBC, HCT, PLT

Non-cyanide, Sodium Lauryl Sulfate (SLS):

27 Whole Blood Reportable Parameters

WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT (Impedance and Fluorescent Optical), NEUT%, LYMPH%, MONO%, EO%, BASO%, IG%, NEUT#, LYMPH#, MONO#, EO#, BASO#, IG#, RDW-SD, RDW-CV, MPV, RET%,

RET#, IRF, RET-He

7 Body Fluid Reportable Parameters

WBC-BF, RBC-BF, TC-BF, MN%, MN#,

PMN%, PMN#

Linearity

WBC: $0 - 440.00 \times 10^3/\mu L$ RBC: $0 - 8.00 \times 10^6/\mu L$ PLT: $0 - 5{,}000 \times 10^{3}/\mu L$

Body Fluid Linearity

WBC-BF: $0.004 - 10.000 \times 10^3/\mu L$ RBC-BF: 0.001 - 5.000 X 10⁶/µL

 $0.004 - 10.000 \times 10^{3}/\mu L$ TC-BF:

Throughput

Whole Blood Mode: 100 samples/hour Body Fluid Mode: 30 samples/hour

Sample Volumes

Closed mode: 150µL Open mode: 85µL Capillary mode: 40µL

Data Storage

(IPU: Information Processing Unit)

10,000 samples including graphics

Quality Control

(Total QC Management)

Levey-Jennings Control Charts

X-bar M file

Comprehensive QC files including "current" and "new" lot feature Online Quality Assurance Program

Interfaces

ASTM

Sysmex WAM™ (HL7 & ASTM)

Dimensions/Weight

w x h x d [in] / [lbs]

Main Unit including sampler: 20.9" x 24.8" x 28.3" / 130 lbs.

Pneumatic Unit:

11.0" x 15.7" x 14.0" / 37.5 lbs.

Sysmex Corporation 1-5-1 Wakinohama-Kaigandori, Chuo-ku, Kobe 651-0073, Japan Tel. +81 (78) 265-0521 Fax +81 (78) 265-0530 www.sysmex.co.jp

Sysmex America, Inc. One Nelson C. White Pkwy, Mundelein, IL 60060, U.S.A. Tel. +1 (847) 996-4500 Fax +1 (847) 996-4397

www.sysmex.com/usa

www.sysmex.ca

Sysmex Canada, Inc. 5045 Oribitor Drive, Building 9, Suite 401 Mississauga, ON, L4W 4Y4, Canada Tel. +1 (905) 366-7900 Fax +1 (905) 366-7899

Sysmex do Brasil Indústria e Comércio Ltda Rua Joaquim Nabuco, 615 - Bairro Cidade Jardim, São José dos Pinhais Paraná – Brasil – CEP 83040-210 Tel. +55 (41) 2104-1314 Fax +55 (41) 2104-1300 www.sysmex.com.br

Sysmex Europe GmbH Bornbarch 1, 22848, Norderstedt, Germany Tel. +49 (40) 52726-0 Fax +49 (40) 52726-100 www.sysmex-europe.com

Sysmex Deutschland GmbH

Bornbarch 1, 22848, Norderstedt, Germany Tel. +49 (40) 5341020 Fax +49 (40) 5232302 www.sysmex.de

Sysmex UK, Ltd.
Sysmex House, Garamond Drive, Wymbush
Milton Keynes, Buckinghamshire, Mk8 8DF, U.K. Tel. +44 (870) 9029270 Fax +44 (870) 9029211 www.sysmex.co.uk

Sysmex Asia Pacific PTE, Ltd.

2 Woodlands Sector 1, #01-06 Woodlands Spectrum, Singapore 738068, Singapore Tel. +65 (6221) 3629 Fax +65 (6221) 3687 www.sysmex-ap.com

Sysmex Shanghai, Ltd. 9th Floor, Azia Center, 1233 Lujiazui Road, Shanghai, 200120, China Tel. +21 (6886) 3300 Fax +21 (6886) 3355 www.sysmex.com.cn





