Disclaimer

The uses or clinical applications described are based on published scientific and clinical evidences.

It is the clinician's responsibility to validate any off-label applications for use in routine clinical practice.

Notice of Intended Use

The XN-Series modules are quantitative multi-parameter automated hematology analysers intended to be used in clinical laboratories for in vitro diagnostic use in screening patient populations.

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STANDARDISATION

EFFICIENCY

INFORMATIVE

UPGRADABILITY

Haematology laboratories care about the system they use because what they do is important to the welfare of the patient. Laboratory results provide insight into the clinical well-being of patients, which leads to accurate diagnosis and delivery of appropriate treatment.

Laboratories depend on Sysmex for the technology, capabilities and reliability to give them confidence.

Choosing a haematology solution is not an easy task but the Sysmex XN-Series simplifies the process and gives laboratories the freedom to define their own unique solution.

Experience Sysmex. Experience XN-9000 Solutions.

STANDARDISATION
Through automation

Laboratories seeking to improve processes through automation can achieve their goals in scalable phases.

Various modules can be integrated with the XN-9000 allowing automation to be introduced gradually to the laboratory. These components include:

- XN-Series automated haematology analysers with a comprehensive test menu to accommodate a variety of laboratory settings and test volumes.
- Fully automated slide maker and stainer, SP-10, that optimises the smearing conditions for every sample based on haematocrit.
- Digital morphology analyser, DI-60, captures cells and performs pre-classification automatically.
- Tube sorter, TS-10, sorts and archives samples into pre-defined sorting areas.

1

TS-10 - integrated tube sorter and archiver

Benefits:

- Allows sorting of abnormal samples for quick identification and timely action leading to a reduction in turnaround time (TAT).
- With an upgrade kit, sorting speed and capacity can be expanded. This allows laboratories to keep the initial investment and have a scalable solution to meet an increase in workload or sorting capacity.

2

DI-60 - integrated digital morphology

Benefits:

- Standardisation of differential results, operational and validation processes, delivering consistency.
- Facilitates collaboration, review and consultation between morphology experts, creating flexible and cost-effective utilisation of staff and resources through the Sysmex remote review software.
- Monitors and promotes cell morphology competence with a web-based proficiency application.
- Reduces the neck, wrist and eye fatigue associated with traditional microscopy.

3

SP-10- fully automated slide maker and stainer

Benefits:

- Standardisation and efficiency in smear preparation for timely cellular morphology assessment and interpretation.
- Slides are only prepared when samples fulfill user pre-defined conditions, promoting workflow efficiency based on clinical needs.

4

XN-Series analysers are comprised of

XN-10 (green panel)

- CBC+DIFF+NRBC is standard.

XN-20 (blue panel)

- CBC+DIFF+NRBC+RET+WPC is standard.

Benefits:

- Workflow standardisation and improvement through automation.
- Faster test results to support the clinicians' diagnosis for better patient management.

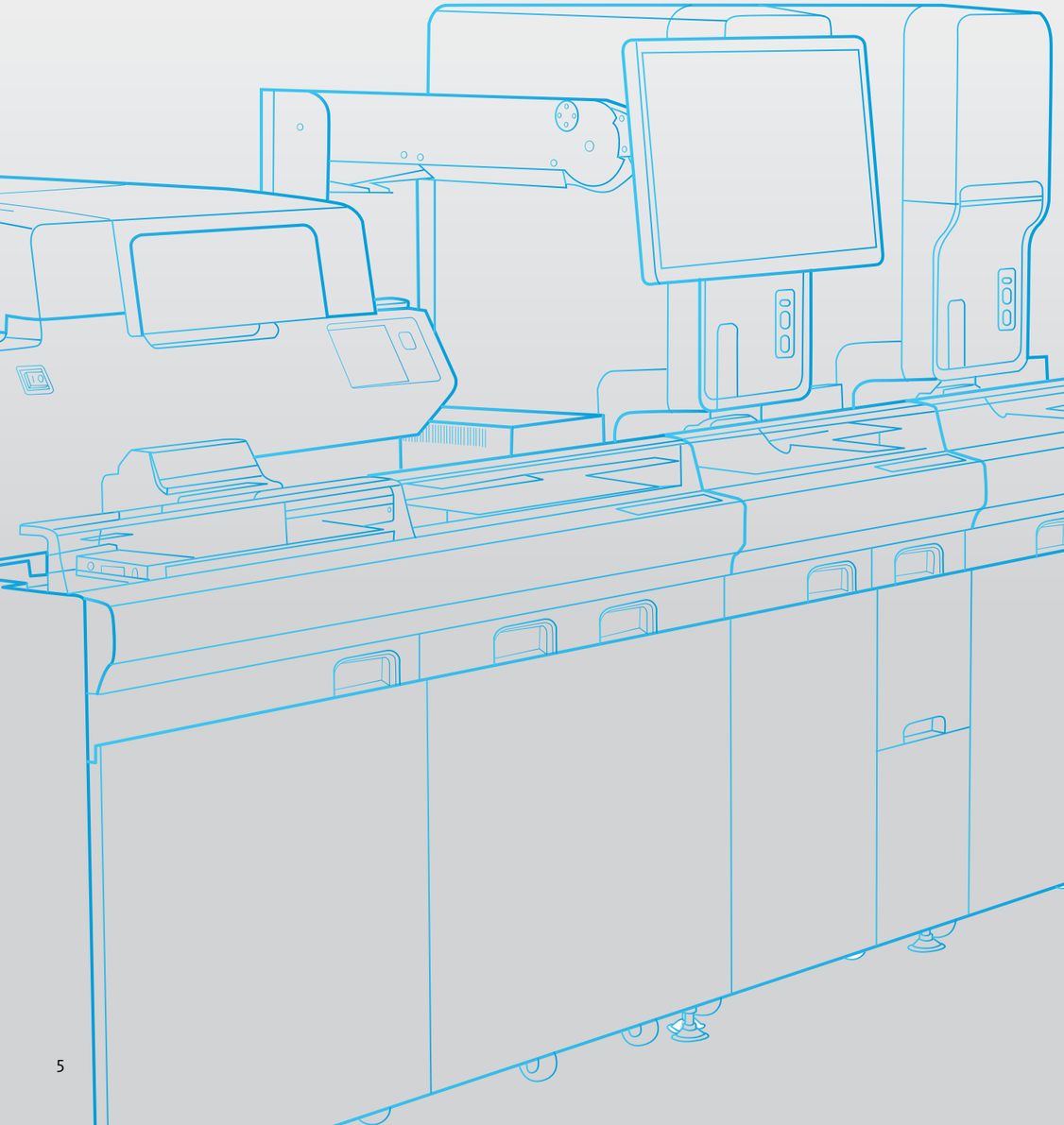
EFFICIENCY

Truly walkaway system

Laboratory technologists today face growing demands to multi-task. Expansion of duties such as sample processing, analysis of results, sample archiving and documentation can impact KPI achievements.

The XN-9000 Series is a scalable, easy to operate solution, that can help address these growing demands and challenges.

Using Sysmex technology to maximise efficiency, operators only need to load and unload samples on the XN-9000, facilitating more productive use of staff for complex tasks.



Single master switch for easy startup of the XN-9000

Uninterrupted during sample loading, analysis and reflex testing, smear preparation, cell pre-classification, sample sorting and archiving.

Automatic sample analysis is performed on XN-analysers according to the LIS test orders, including reflex testing

Smear preparation and cell pre-classification based on user-defined rules and sample condition

Auto rerun/reflex capability

On board rerun and reflex capability promotes workflow standardisation

With onboard rerun and reflex capability, the XN-Series is able to automatically reanalyse samples with abnormal or unreliable results defined by the laboratory. The benefits include:

- Delivery of highly reproducible results in the shortest time possible improving turnaround time.
- Minimal manual interventions for a more efficient use of time and manpower resources.
- Standardised sample processing workflow, promoting peace of mind in the laboratory

INFORMATIVE

Trustworthy technology providing insight on patient well-being

The XN-Series analysers utilise laser flow cytometry to enumerate blood cells. The complex algorithms are applied to the measured cellular characteristics for classification of WBCs, RBCs, PLTs as well as for flagging of abnormal cellular populations.

Numerous parameters are also available providing information about different disease states:

1 Response to erythropoietic stress

NRBCs are a useful indicator of erythropoietic stress or red cell related disorders such as thalassemia, myeloproliferative disorders etc. The duration and presence of NRBCs is also associated with poor prognosis in critically ill patients[1].

On XN-Series

- NRBC is a standard parameter with every CBC analysis.
- Stained directly with a linearity up to 600 NRBC/100 WBCs.
- Automatic correction of WBC when NRBCs are present.

Benefits:

- Increase productivity and improve sample TAT.
- Cost reduction as additional testing for NRBCs is no longer necessary.
- Therapeutic support with reliable NRBC counts.

2 Supports infection/inflammation diagnosis and therapy monitoring

Immature Granulocytes (IG) allows for differentiation between SIRS and sepsis and a useful marker in monitoring infection/ inflammation in patients undergoing therapy[2].

On XN-Series

- IG is a standard parameter with every DIFF analysis, providing a 6-part differential.
- IG includes metamyelocytes, myelocytes and promyelocytes.

Benefits:

- Enhance workload efficiency through reduction in blood smear and manual microscopy.
- Support diagnostic and prognostic use in infection/ inflammation and therapeutic monitoring in combination with other parameters such as cytokines.

3 Differentiates hypo-production from peripheral destruction as a cause of thrombocytopenia

Immature Platelet Fraction (IPF) are young, reticulated platelets containing residual RNA. IPF reflects thrombopoiesis with a low count pointing to impaired platelet production, while a high IPF count suggests peripheral destruction. It is an early indicator of bone marrow recovery and a potential marker for a more optimised platelet transfusion approach[3,4].

On XN-Series

- Fluorescent platelets and IPF are both reported from the PLT-F channel where platelet-specific stain is used and cells are counted 5x more.
- Accurately reflects the rate of thrombopoiesis.

Benefits:

- Aids in appropriate treatment decision.
- Supports optimised platelet transfusion approach.

4 Accurate timing of peripheral blood stem cell transplant (PBSCT) harvest

High comparability between **Human Progenitor Cells (HPC)** measurement and CD34 analysis supports the use of XN-HPC in determining optimal PB stem cell collection[5] .

On XN-Series

- Human progenitor cells (HPC) are counted in a dedicated mode of measurement in the WPC channel.
- Automated analysis with good comparability with CD34+cells.

Benefits:

- Rapid analysis allows for a prompt determination of optimal stem cell harvest time.
- Realise savings in workflow and resources.

5 Body fluid (BF) analysis in infection or inflammatory conditions

The Body Fluid (BF) analysis in the XN system provides rapid and accurate measurement of body fluids such as the CSF, synovial fluid, pleural fluid and CAPD. The 2-part differential results of mononuclear (MN) and polymorphonuclear (PMN) cell population aid in the quick distinction between viral and bacterial infection.[6]

On XN-Series

- Automated body fluids analysis is done in a dedicated mode of measurement.
- No sample pretreatment and additional reagents are required.

Benefits:

- Improve sample turnaround time (TAT)
- Better standardisation and reproducibility of results reducing errors commonly associated with manual procedures.
- Quick distinction between viral and bacterial infection guides clinical decisions for patient treatment.

6 Diagnosis and assessment of iron status and therapy.

RET-He The haemoglobin content of reticulocyte, reflects real-time iron bioavailability and quality of erythropoeisis. A low Ret-He value means iron is lacking or is not bioavailable for erythropoiesis. The Ret-He parameter differentiates the classical cause of iron deficiency from a functional cause. It can also be used to monitor response to EPO or iron therapy where positive responses are indicated by an increase in value[7].

On XN-Series

- Ret-He is available with every retic analysis along with immature retic fraction (IRF), Hypo-He and Hyper-He.
- Hypo-He and Hyper-He together with %Micro,%Macro, are also useful in classification of various types of anaemia.

Benefits:

- RET-He helps differentiate between functional and classical iron deficiency,
- Ret-He, in combination with other retics-related parameters, allows clinicians to draw conclusions on the quality and quantity of the young RBC fraction supporting effective treatment decisions.
- Ret-He aids in monitoring responses to EPO and IV iron therapy.

UPGRADABILITY
Modularity concept that caters to changing needs

Over time, laboratories can have changing clinical needs and increasing workloads. This means laboratories require a flexible solution that can cater to their changing needs. The Sysmex XN-9000 Series are available in various flexible configurations that meet the needs of different laboratories. The modularity concept of the XN-9000 Series allows new modules to be easily added to an existing configuration to meet the increasing workload of the laboratory.

The XN-9000 Series can be either a linear, L-shaped or U-shaped configuration to accommodate existing building fixtures such as pillars or water supply points without the laboratory undergoing any major renovations.

Flexible activation of applications

The clinical demand of laboratories changes according to patient population and the needs of clinicians. Advanced clinical parameters can be introduced and reported routinely one at a time.

Without replacing the XN-Series analysers, optional applications such as RETICS, PLT-F, Body Fluids and HPC can be added. They need not be activated when the XN-9000 Series is installed. Instead, the activation can take place in incremental steps. Application of specific reagents need only be connected upon activation of respective channels. Laboratories can secure their initial investment, maintain an economical running cost, and have a flexible solution for now and tomorrow.

Initial XN-9000 configuration:
Hourly throughput
XN-Series x 3 : up to 300 test
SP-10 x 1: up to 120 slides*

Addition of DI-60
Additional hourly throughput
DI-60: up to 30 slides

Addition of TS-10
Additional hourly throughput
TS-10: up to 500 tubes
TS-10 upgrade: up to 1,000 tubes

Addition of RU-20 (reagent unit)
The benefits of RU-20 include:

- Less inventory space is needed maximising the use of limited storage space.
- Fewer reagent changes provide greater instrument availability and efficient workflow.
- Promotes workplace safety and reduces back injuries by minimising heavy lifting of reagent boxes from the loading dock to the storage area.

Applications

CBC+DIFF

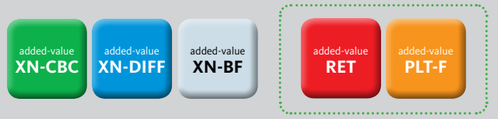
NRBC increases in response to erythropoeitic stress

IG aids in the diagnosis, prognosis and therapy monitoring of infection/ inflammation.

+ Body Fluids application

Automated 2 part differential body fluids results allowing quick distinction between viral and bacterial infection

+ RETICS & PLT-F applications



RET-He, IPF provides insight about the causes of anaemia and thrombocytopenia.

+ HPC application

HPC helps to assess optimal timing of peripheral blood stem cell transplant (PBSCT) harvest

*A standalone SP-10 allows up to 120 samples/ hour. When combined into an XN-9000 configuration, the SP-10 x 1 allows up to 100 slides/hour

The XN-Series at a glance

The Standard Diagnostic Components for each XN Module

Analytic Components: XN-CBC and XN-DIFF are standard.

All other applications are optional

added-value **XN-CBC** | added-value **XN-DIFF** | added-value **RET** | added-value **WPC** | added-value **PLT-F** | added-value **XN-BF**

XN-1000
First step into full automation

- Excellent productivity
- Improved workflow efficiency with integrated reflex function

XN-2000
Workload optimisation

- Catering to testing of routine and specialty analysis
- Workload balance solution

XN-3000
Compact automation

- Integrated slide making and staining solution
- Standardisation of workflow

XN-9000
Scalable automation solutions

- Broad capabilities catering to different clinical demands
- Workflow optimising configurations

NOTES