Introducing XN and XN-L series:

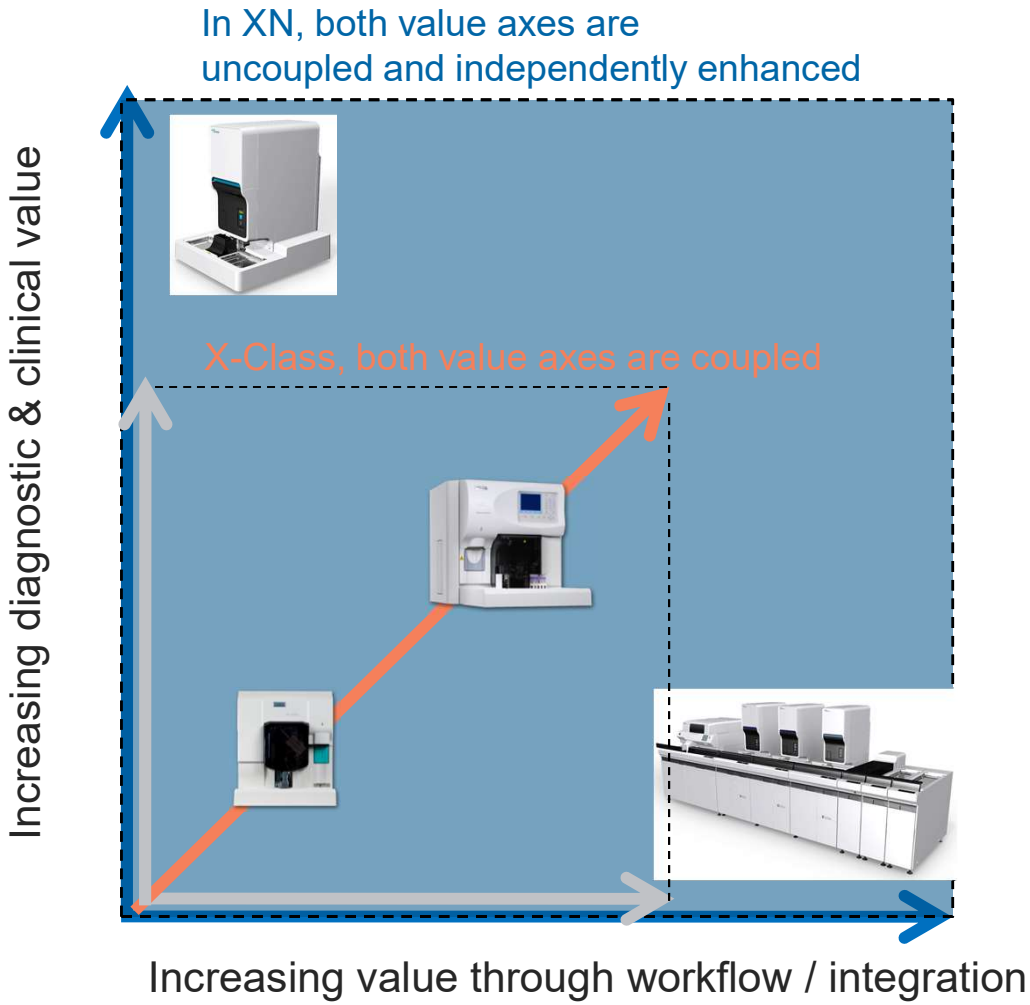
What is in it for you?

Dr Marion Münster
Manager Medical & scientific Affairs

XN Concept

CLINICAL VALUES
PROFESSIONAL SERVICES
PRODUCTIVITY VALUES
XN

Each axis with enhanced value – “Modular and Scalable”



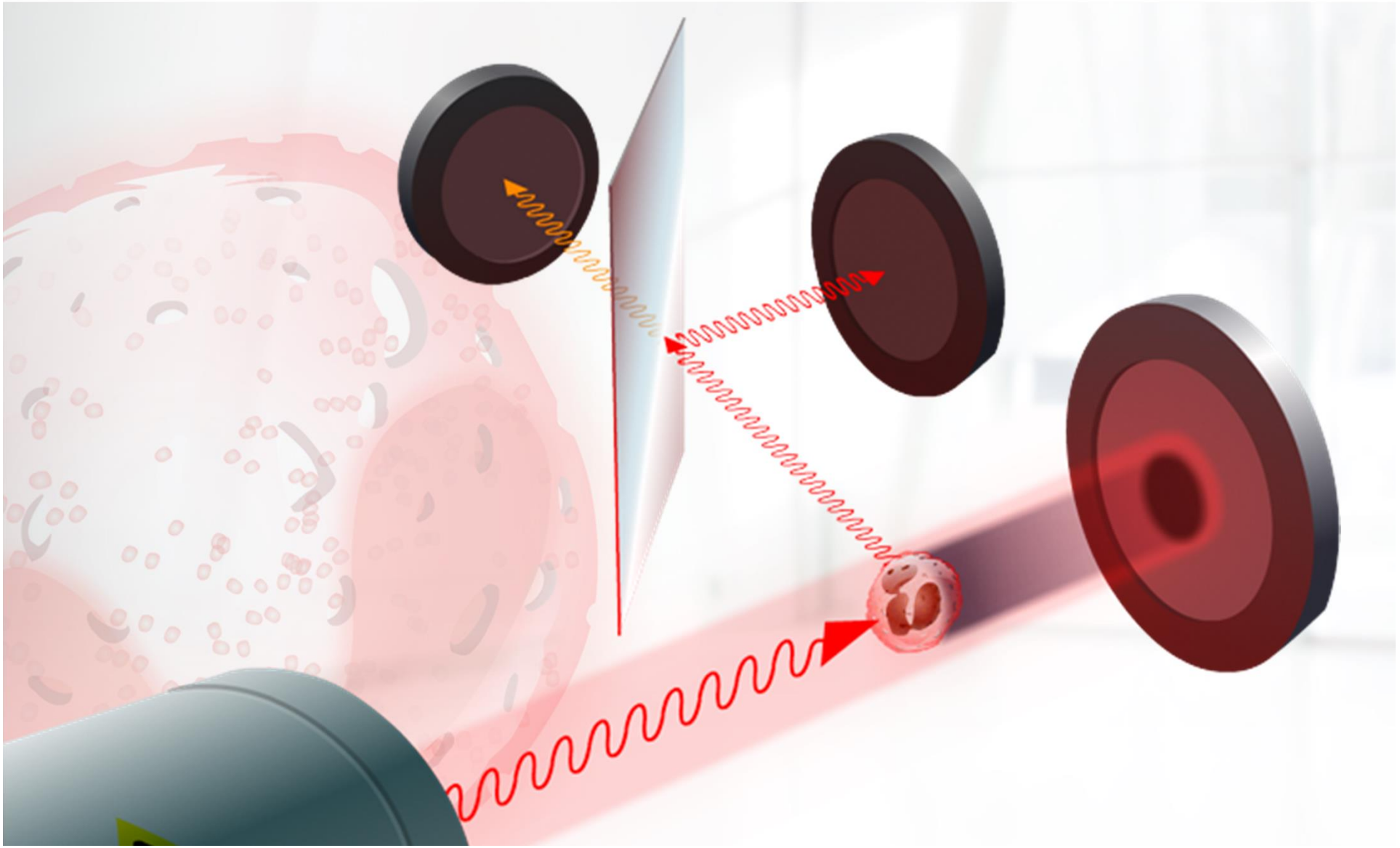
The XN-Series and XN-L Series

XN-350 XN-450 XN-550

XN-1000 XN-2000 XN-9000

XN-Series

Fluorescence Flow Cytometry

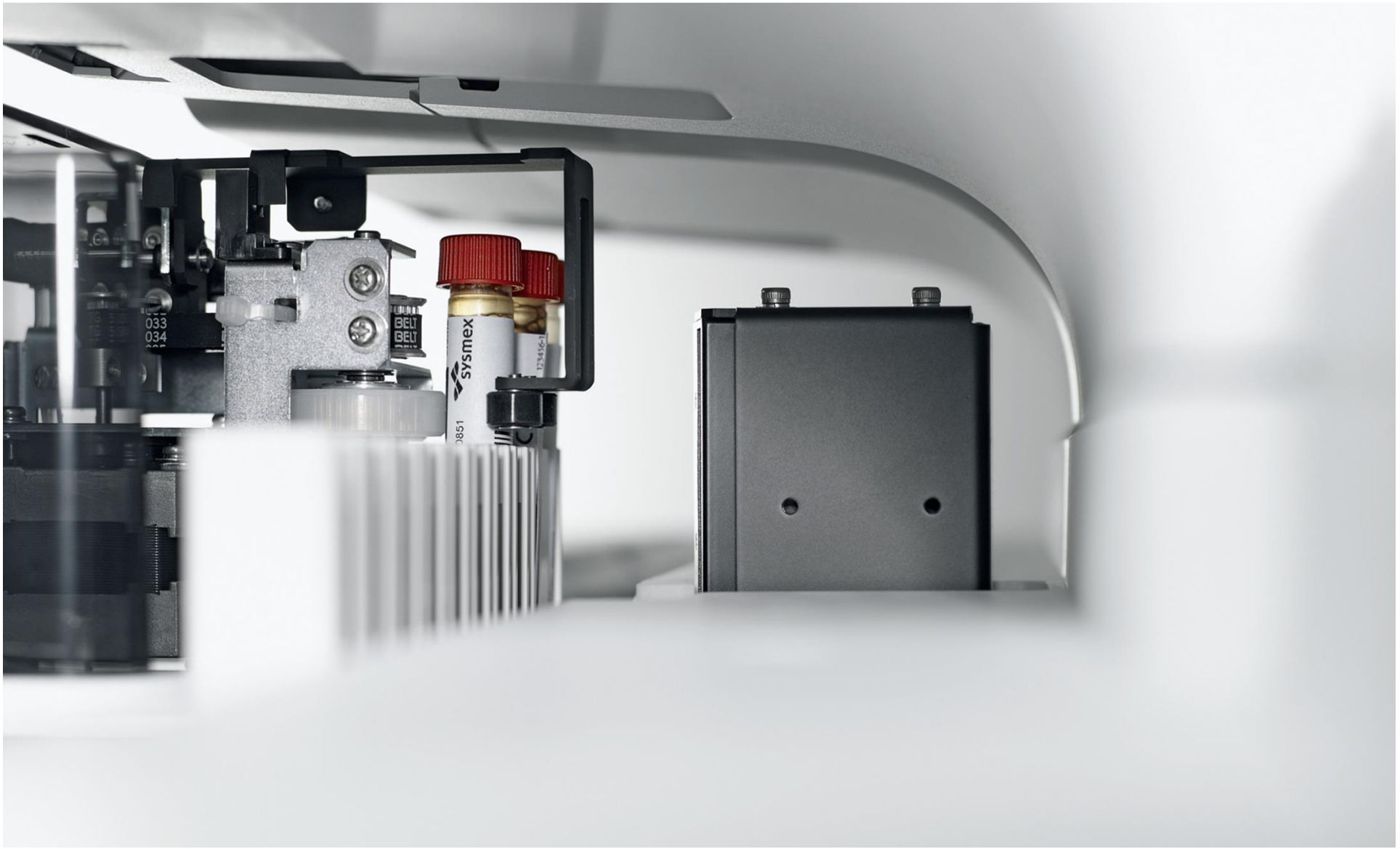


Low Aspiration Volume

Reflex Testing

Manual and Automated

Secure Sample Identification

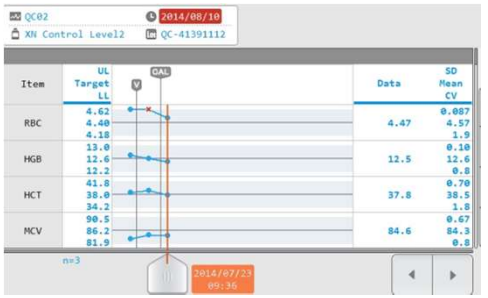


Quality Control

SNCS - Sysmex Network Communication System

- SNCS IQAS Online

Internal QC



External QC

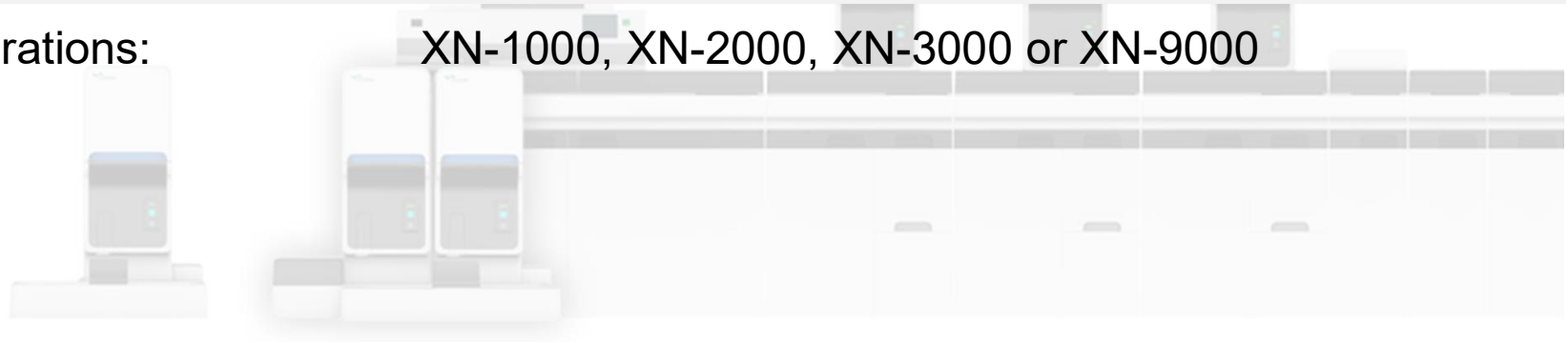
- Daily QC measurement of XN Check and XN Check BF

Reagents: Plug and Play

Reagent Management

The XN portrait

Technologies:	Fluorescence Flow Cytometry in all modes
Aspiration volume:	88 µl in all modes
Throughput:	starting from 100 samples/h
Quality control:	XN check and XN check BF
Parameters:	28 diagnostic parameters always standard *XN-CBC = always with NRBC* *XN-DIFF = efficiency of XE-5000* 16 diagnostic parameters are optional
Configurations:	XN-1000, XN-2000, XN-3000 or XN-9000



XN Concept – Productivity Values

Productivity Values

- *From bench top to automated solution*
- *Suitable for every lab organisation, lab size and workload*
- *Protects your initial investment*
- *Prepared for future growth*

XN Concept – Productivity Values

XN-9000
up to 900 samples/hour
discrete rack management

TUBE SORTING

XN-2000
200 samples/hour
10 rack sampler

XN-3000
200 samples/hour
10 rack sampler

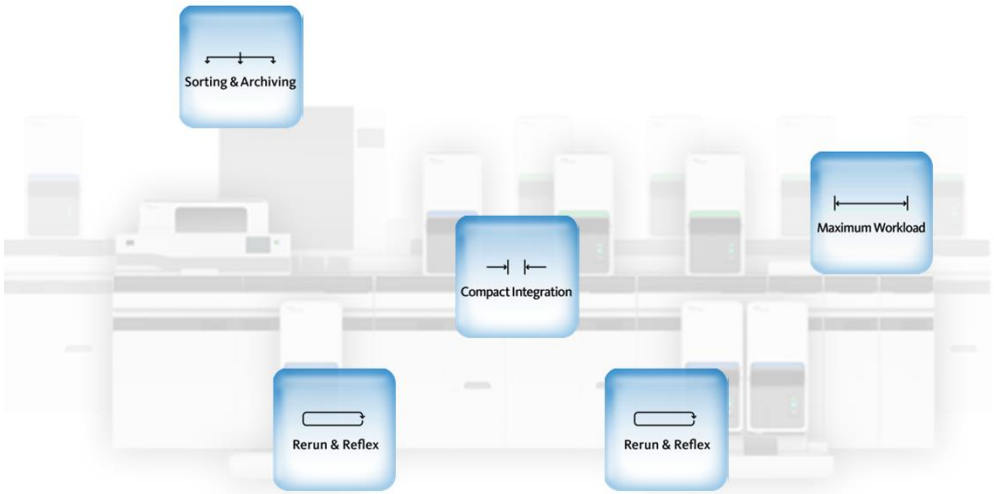
AUTOMATED SMEAR-MAKING & STAINING

XN-1000
100 samples/hour
5 rack sampler

RERUN & REFLEX

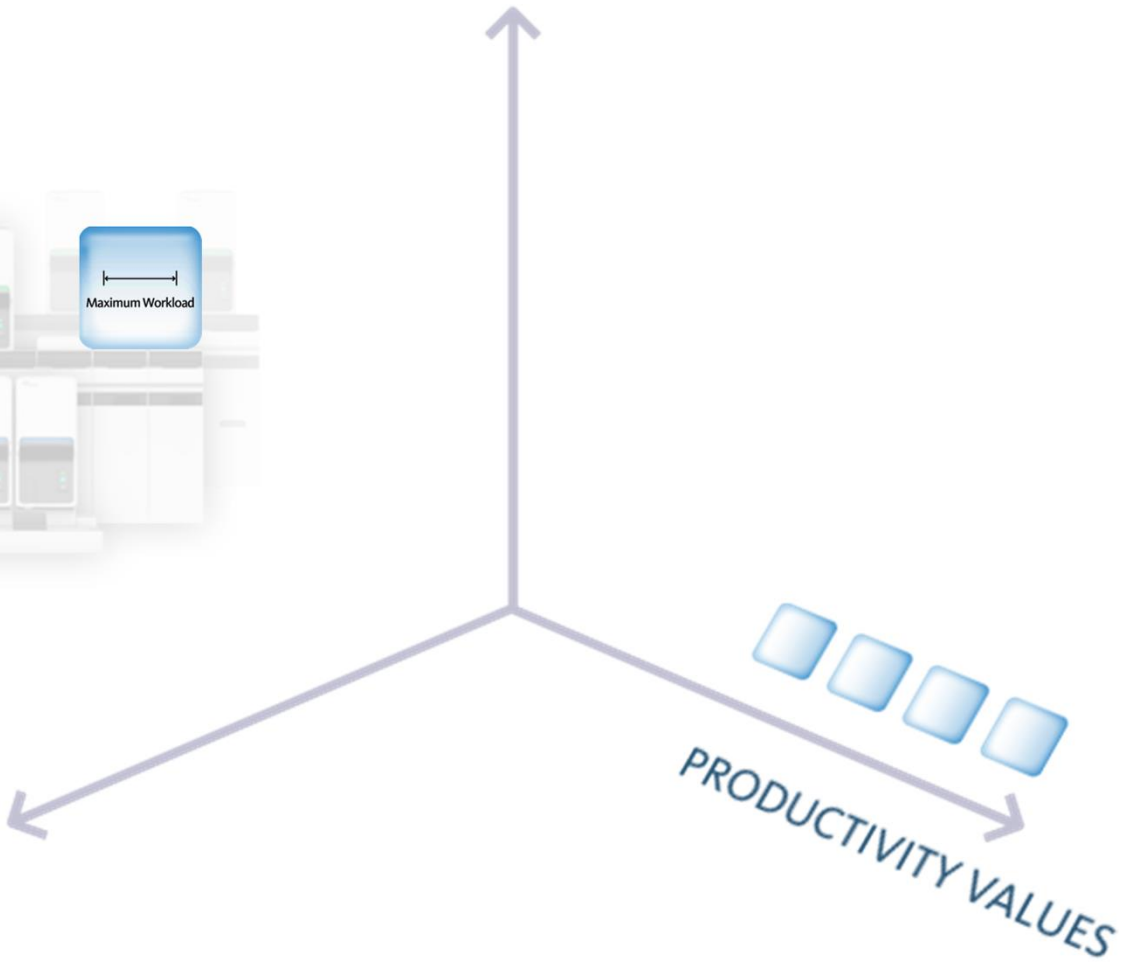
100 [SAMPLES/H] 200 300 400 500 600 700 800 900

A system for seamless integration of productivity values (= hardware)

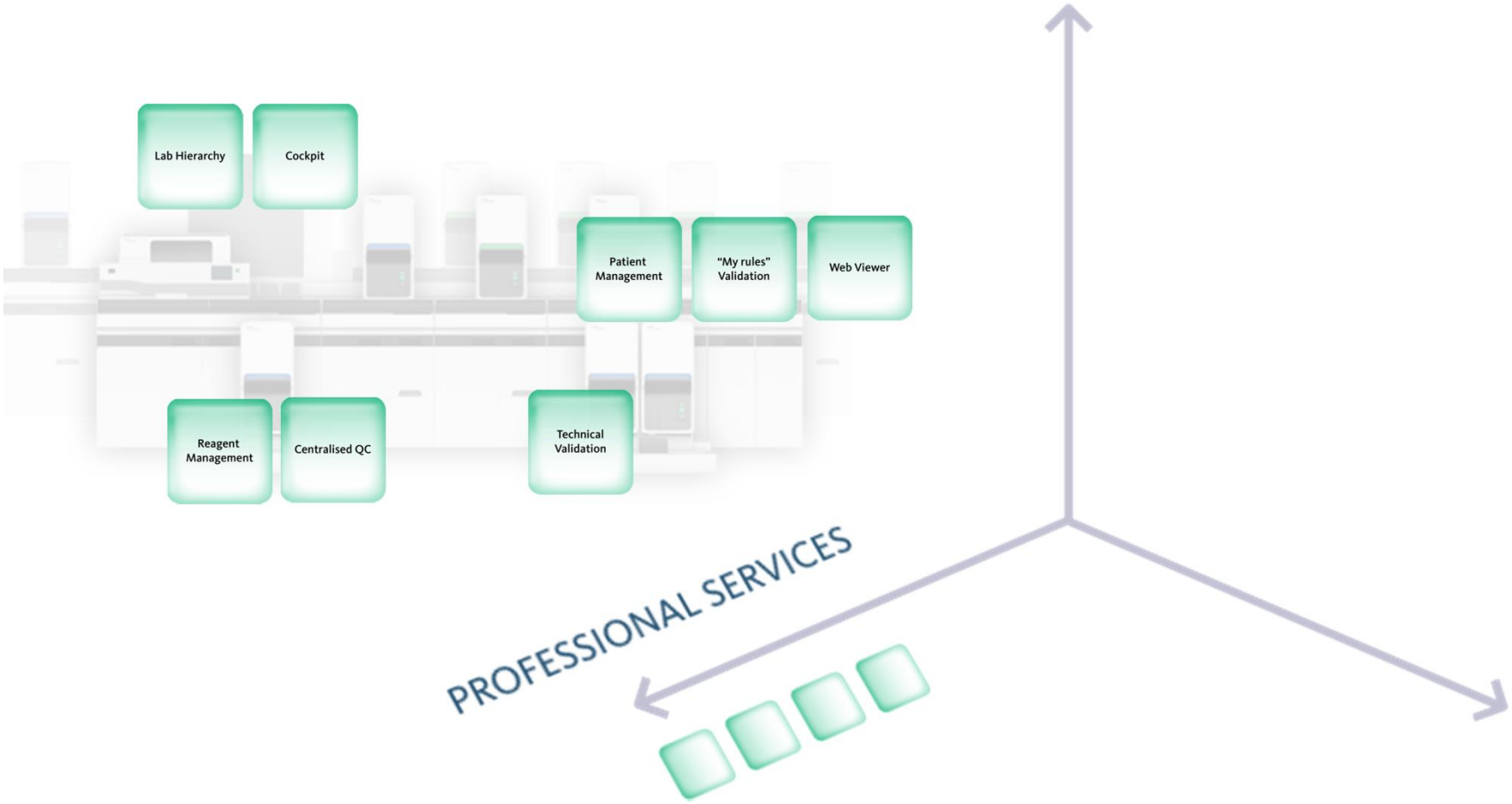


Different solutions with different names for different customer needs.

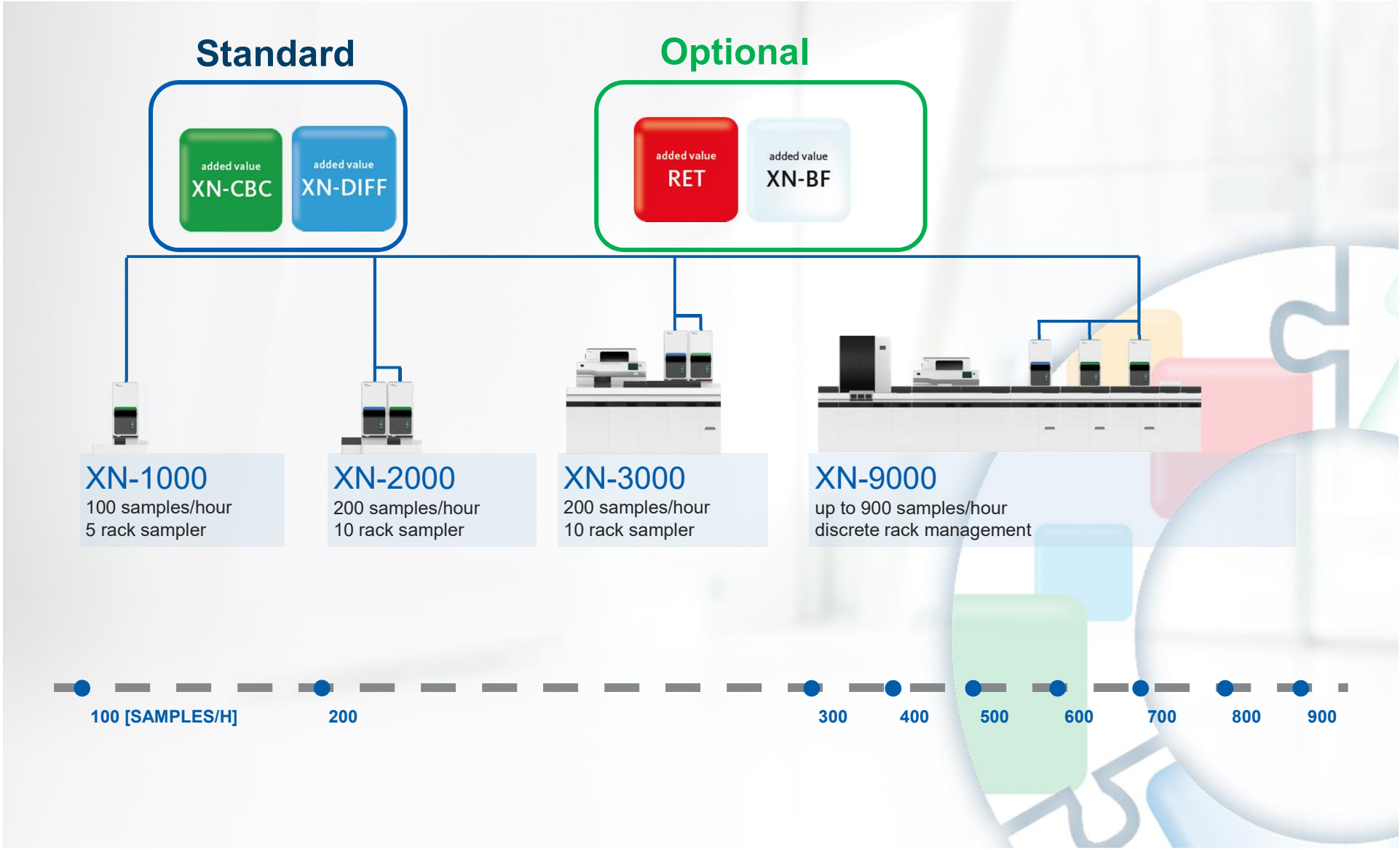
But: upgradable!



A system for seamless integration of clinical values and productivity values coupled with intelligence



XN Concept – Clinical Values



XN Concept – Clinical Values

Adding value…

…to routine haematology testing

The XN-DIFF:
World-leading diagnostic performance and flagging efficiency in all XN modules for true peace-of-mind

- Rerun/reflex “Low WBC mode” for critically low cell counts
- Multi-dimensional flagging information – highly sensitive identification of pathological cells
- Automated IG count

added value
XN-DIFF

Special „Low WBC mode“

- Extended count volume (3 x) –
  prolonged count, same aspiration volume
- For high accuracy of WBC# and differential in leucopenic samples
- WBC# triggers reflex testing in the “Low WBC mode” <1000 WBC/µL or vote out for Neut#
- Sample is automatically reflexed and rerun in low WBC mode

Accurate neutrophil count when it matters most!

“Decide whether to give or withhold chemotherapy with confidence”

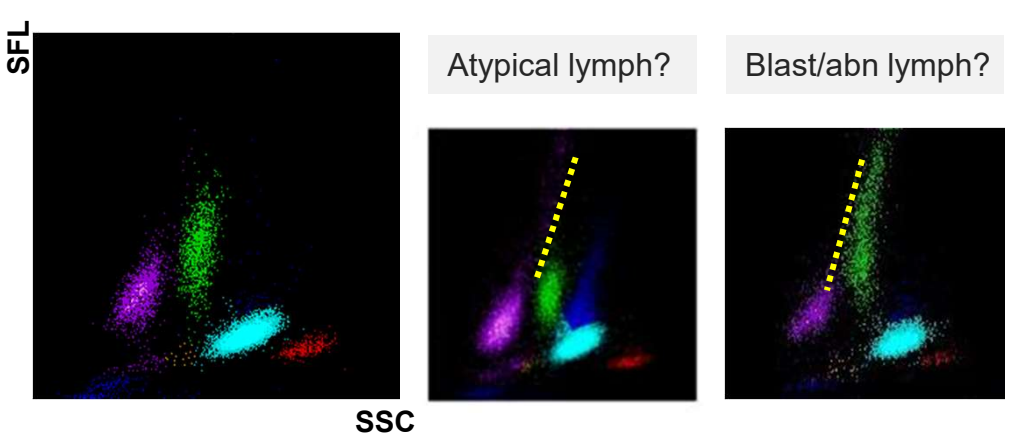
added value
XN-DIFF

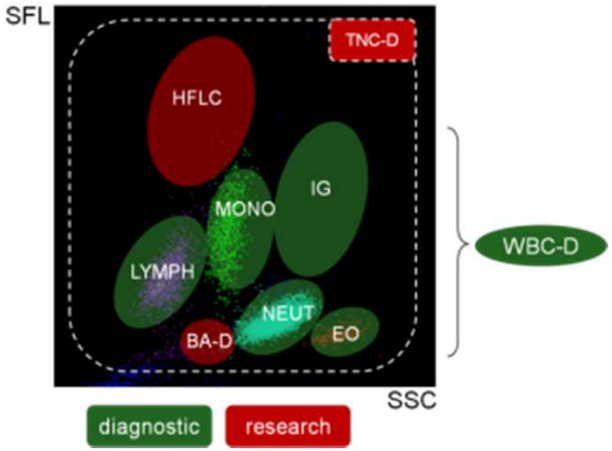
Differential count with multi-dimensional abnormal blood cell identification and flagging

sysmex

Providing more than just numeric information:

- By special shape recognition, analysis of each subpopulation
- Flexible gating for counting
- Sensitivity comparable with smear morphology





The presence of abnormal cells will not be missed!

added value
XN-DIFF

Pathological cells will not be missed!

- With highly sensitive flagging
- Samples needing manual review are automatically identified
- Technologist is guided in what to look for **BUT……..**

To ensure that microscopic review will provide a report that can be trusted for clinical judgement……..

Quality of smear and stain MUST be optimal

Best way to achieve this is by means of automation of slide-making and staining

Sysmex Staining Solutions

Semi-Automated Solution

- 5 slides at a time
- Various staining protocols
- Methanol free stain
- 300 slides/kit or 28 days
- Timing, rinsing, drying – controlled.

Fully Automated Solution

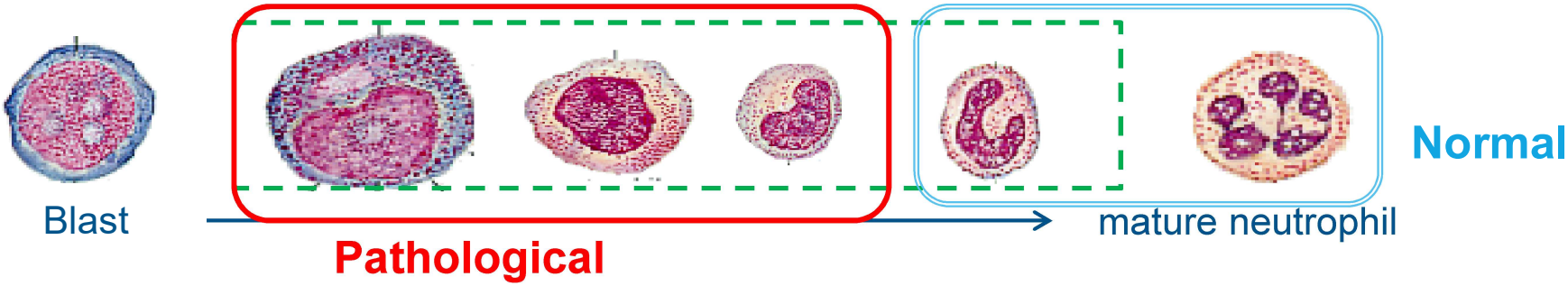
- 10 slides at a time
- Various staining protocols

Kit RAL StainBox MCDh

Immature Granulocytes – what's the clinical relevance?

- Manual peripheral blood smear review – includes reporting on presence or absence of *"Left Shift"*

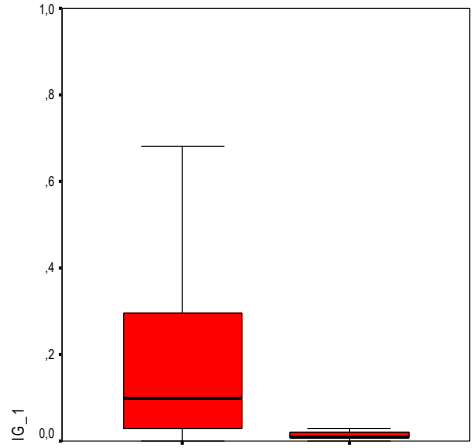
But what does this actually mean to clinicians?
"Left Shift" = granulocytic cells in various stages of development.



- The standard Sysmex XN DIFF count includes automated IG count
- The IG count is comprised of metamyelocytes, myelocytes and promyelocytes
- It excludes band cells.
- The presence of IG is **ALWAYS pathological** - with the exception of neonates and in post-partum females (≤5days)

Clinical utility of the Automated IG count?

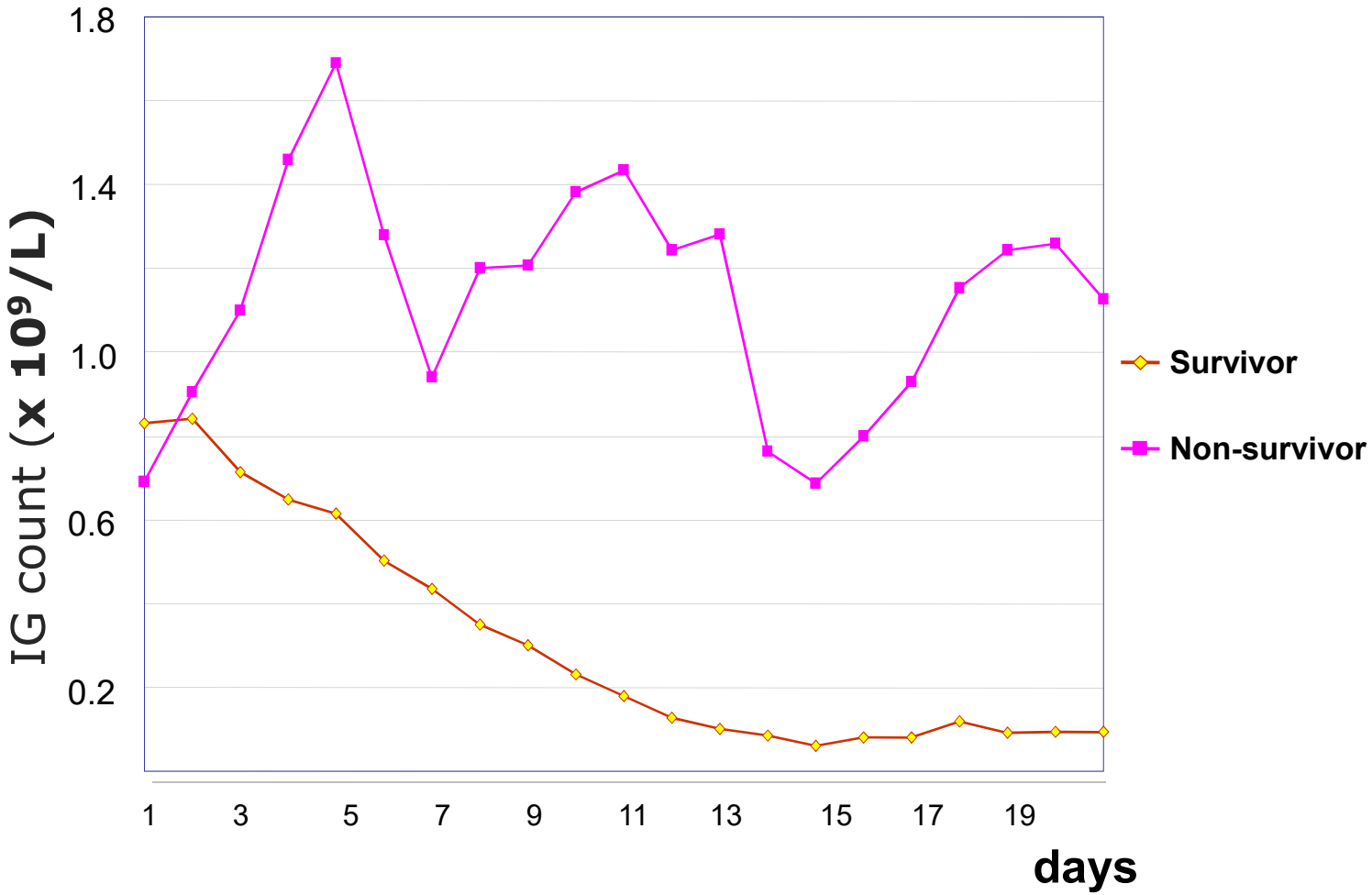
- Precursor granulocytes in peripheral blood are pathological
  - Sepsis
  - Haematological disease
  - Bone marrow infiltration
- New cases – suggest use as alert for microscopic review
- Follow-up cases – use automated count for follow-up
  - Sepsis – successful treatment – reduction in IG
  - Bone Marrow recovery post chemotherapy – increase in IG



IG values	Septic Patients	Healthy Donors
Median	0.1	0.01
Minimum	0.0	0.0
Maximum	1.36	0.06
N	40	38

Automated IG count = enhanced precision and accuracy
Useful for detection and monitoring of infections and marrow recovery

Time course of IG in sepsis patients



The added value of XN-DIFF

Features and specifications

added value
XN-DIFF

Productivity values:

- Smear reduction and decreased TAT
- Improved flagging efficiency

Clinical values:

- High sensitivity detection of WBC abnormalities and efficient flagging
- Support detection of inflammation and/or infection and monitoring response to treatment.

Adding value…

…to the reticulocyte count

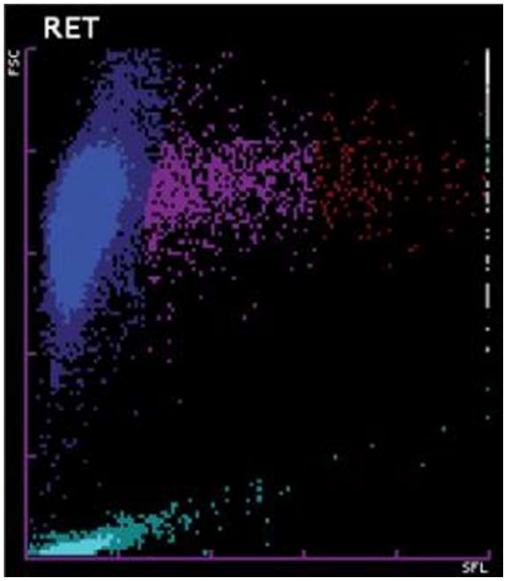
The XN-RET:
Providing the complete picture of erythropoiesis using qualitative and quantitative information

- Highly accurate reticulocyte count
- Identification and quantification fragments
- Real-time information on functional iron availability – RET-He

added value
RET

The Reticulocyte Count – a neglected parameter?

- Most underutilised test in haematology laboratory
- RET# essential for causative diagnosis of anaemia - peripheral destruction or bone marrow production failure?
- Supports early prognosis and optimised treatment serial by monitoring

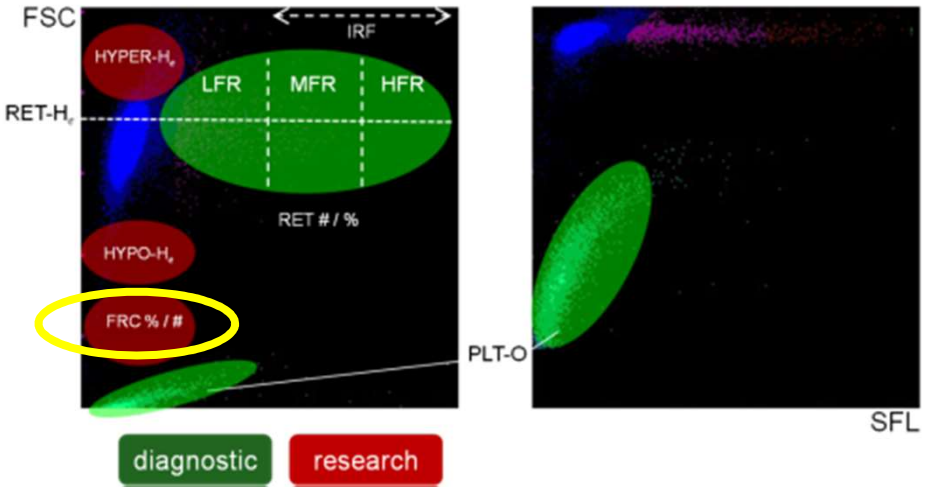


added value
RET

RBC sub-population analysis

- Traditional RBC indices provide “average” information of red cell mass produced over past 120 days
- Sub-population analysis provides more dynamic information and aids evaluation of anaemia
- RBC fragments – medical emergency until proven otherwise
  - Automated identification – early warning system

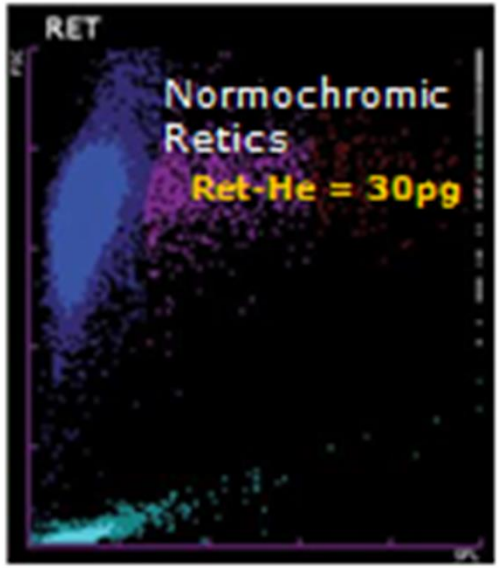
Automated identification of fragments – early warning system for possible for development of microangiopathic haemolysis



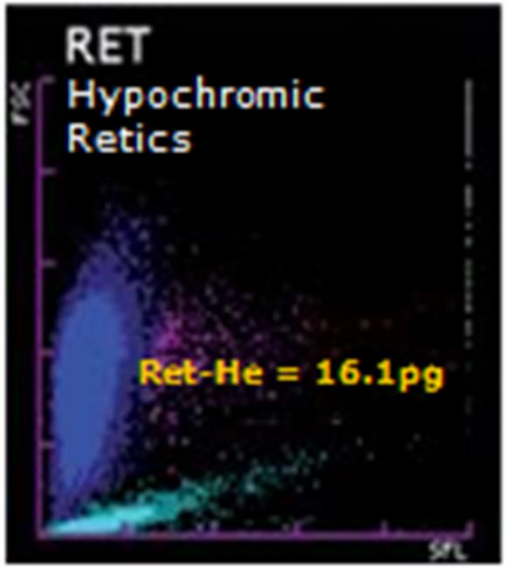
added value
RET

Reticulocyte Haemoglobin Content

- Real-time snapshot of haemoglobin concentration in developing RBCs
- Measure of iron availability for erythropoiesis in clinically relevant timeframe



Normal Ret-He



Greatly Reduced Ret-He

The clinical value of RET-He

A common diagnostic dilemma

Does the patient have true iron deficiency or functional iron deficiency?

Will the patient respond to oral iron supplementation?

Clinical usefulness of RET-He - cancer patients

American Journal of Clinical Pathology

Using the Hemoglobin Content of Reticulocytes (RET-He) to Evaluate Anemia in Patients With Cancer

American Society for Clinical Pathology

Ellinor I. B. Peerschke, PhD; Melissa S. Pessin, MD, PhD; Peter Maslak, MD

Disclosures

Am J Clin Pathol. 2014;142(4):506-512.

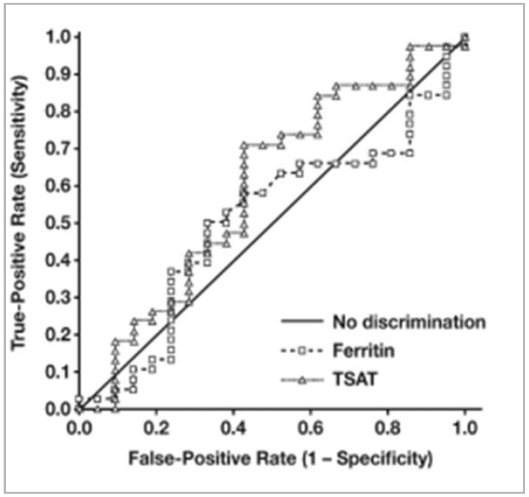
- Cancer patients regularly monitored for cytopenias → FBC standard test
- Biochemical iron studies are often included in standard test orders for follow-up visits to speed up management of anaemias

→ RET-he rapidly rules out iron deficiency anaemia
→ Iron studies could be reduced by 80% (209 to 43 in this study)

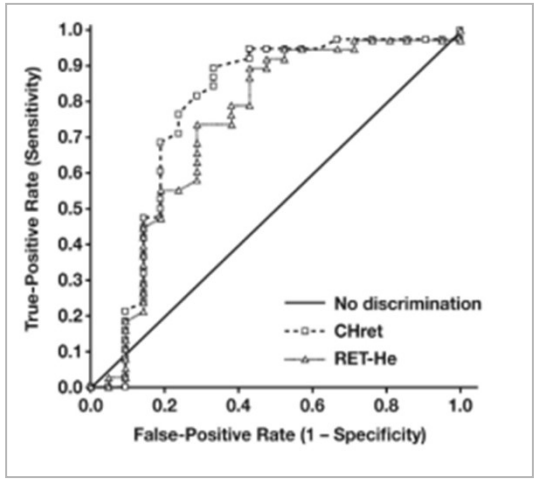
added value
RET

Clinical usefulness of RET-He – Renal Patients

- Included in international renal anaemia guidelines to determine when iron supplementation is needed
- Predictor of iron deficiency in haemodialysis patients
- Superior to traditional iron studies



Ferritin: 0.53
TSAT: 0.56



Ret-He : 0.72

Buttarello et al, Am J Clin pathol, 2010; 133:949-954

Clinical usefulness of RET-He

- Reduction in blood transfusion requirements in major orthopaedic surgery – guides when to give EPO to boost pre-operative haemoglobin
- Superior to Ferritin & TSAT in diagnosing iron deficiency – using BM stainable iron as gold standard
- Identification of iron deficiency in children – superior to ferritin and TSAT

PEDIATRICS®

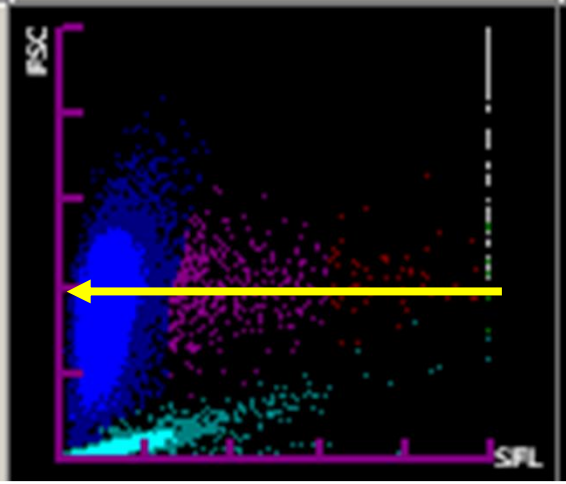
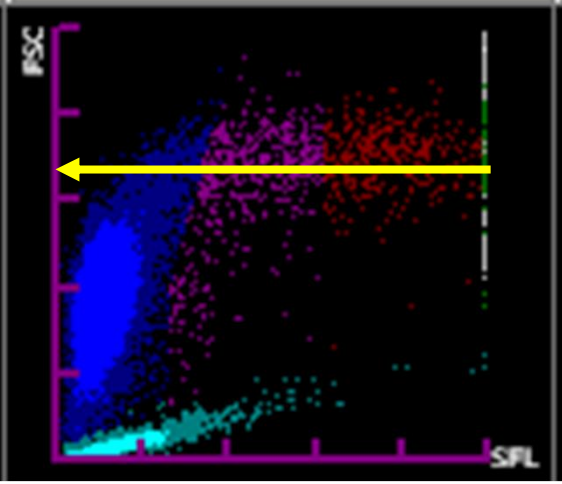
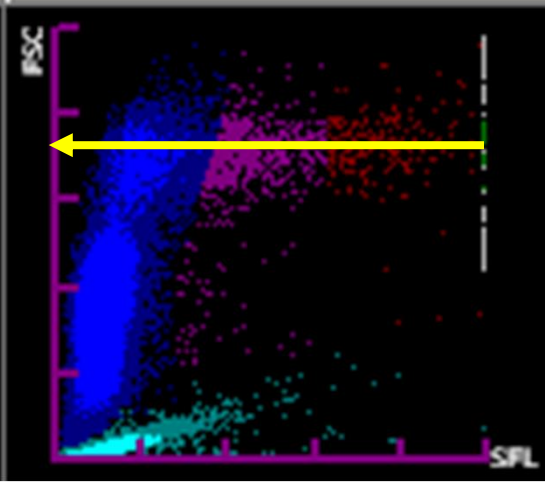
OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

Diagnosis and Prevention of Iron Deficiency and Iron-Deficiency Anemia in Infants and Young Children (0 3 Years of Age)

Robert D. Baker, Frank R. Greer and The Committee on Nutrition
Pediatrics 2010;126;1040-1050; originally published online Oct 5, 2010;
DOI: 10.1542/peds.2010-2576

added value
RET

Successful treatment of iron deficiency

Date	03/16	03/19	03/22
Time	12:32	15:52	11:54
RET			
	RET-He 21.9 pg	**RET-He 29.6 pg**	**RET-He 31.3 pg**

RET-He allows for rapid assessment of response to iron supplementation

The added value of RET:
A closer look at erythropoiesis

Features and specifications

added value
RET

Productivity values:

- Quick screening of erythropoietic status

Clinical values:

- Quantitative and qualitative data on erythropoietic status of patient to guide anaemia management

Adding value…

…by automating body fluid analysis for rapid diagnosis

XN-BF: A dedicated channel for automated cell counting of body fluids with the same precision and accuracy demanded for blood

- Accurate and rapid analysis of body fluids facilitates diagnosis and treatment of several diseases.
- Ability to distinguish between bacterial and non-bacterial infections
- Enhanced accuracy and precision for improved serial monitoring

added value
XN-BF

CSF analysis – when every second counts

- Question 1: Does the patient have meningitis??

Answer : ↑ WCC
Adults > 5-10 cells/µL;
Children > 10–30 cells/µL

- Accurate cell counting at very low levels is vital!
- Question 2: Is it bacterial meningitis??
  - Medical emergency
  - Delayed onset treatment – permanent brain damage or death

Answer : predominance of polymorphonuclear cells
(all other causes of ↑ WCC in CSF are due to mononuclear cells

- Accurate differential count on body fluid is essential for diagnosis

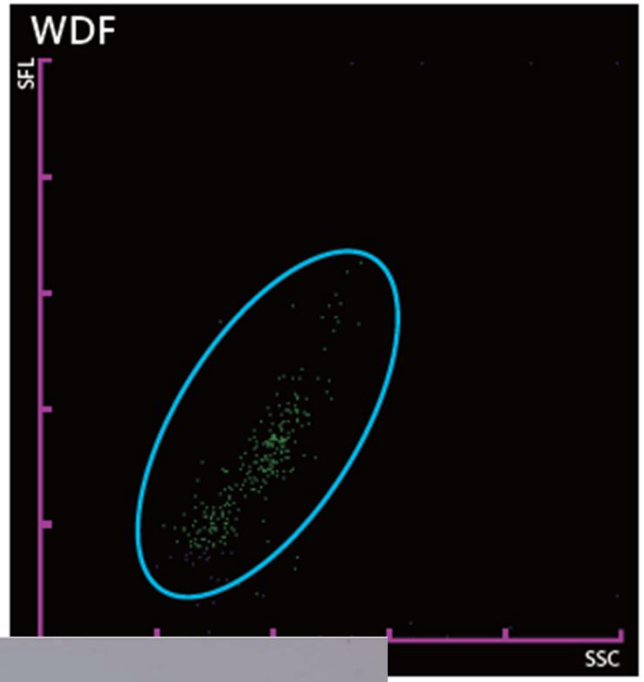
Acute Lymphoblastic Leukaemia with meningeal infiltration

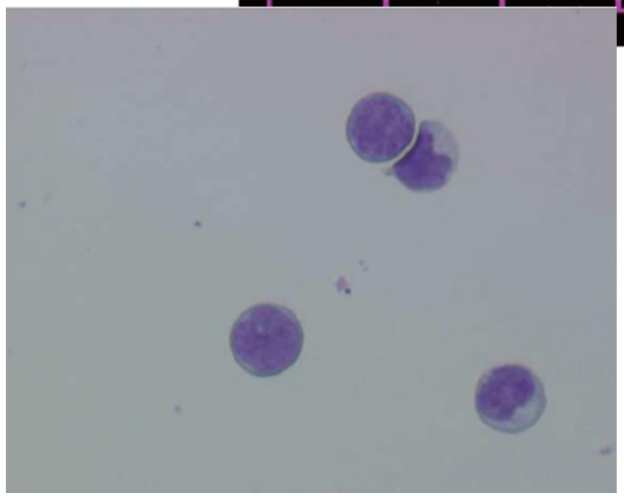
Information from XN-Series

WBC-BF	0.024	10^9/L		
RBC-BF	0.000	10^{12}/L		
MN	0.024	10^9/L	100.0	%
PMN	0.000	10^9/L	0.0	%
TC-BF	0.025	10^9/L		

Research parameters

LY-BF	0.020	10^9/L	83.3	%
MO-BF	0.004	10^9/L	16.7	%
NE-BF	0.000	10^9/L	0.0	%
EO-BF	0.000	10^9/L	0.0	%
HF-BF	0.001	10^9/L	4.2	/100WBC
RBC-BF2	0.0002	10^{12}/L		





The added value of XN-BF: the Body Fluids

Features and specifications

added value
XN-BF

Productivity values:

- Standardization and reproducibility
- Convenient automatic measurement of a variety of body fluids without need for manual sample preparation
- Rapid TAT

Clinical values:

- Trustworthy results with better precision at clinically relevant cut-off values

Larger laboratories are hooked on XN ...

Smallest building block –
100 samples/hour

Smaller laboratories …

The XN-L-Series

It truly is XN

- Identical technology
- Flexible model line-up to cater for the needs of any small laboratory

XN-350	XN-450	XN-550
Open analysis model	Closed analysis model	Sampler analysis model

It truly is XN

- Identical “axis concept”
- Identical concept of “modularity” and “scalability”

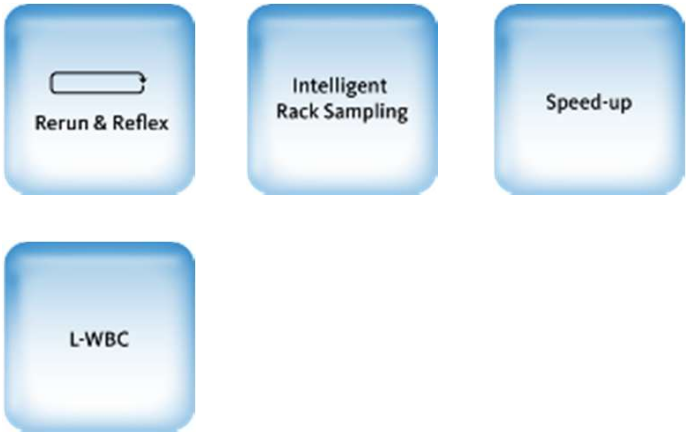
Specifications Portrait

Modes:	WB, PD, L-WBC*, BF*
Aspiration volumes:	25 µL in WB and L-WBC mode, 70 µL in BF and PD mode Auto dispense function, one aspiration line
Throughput:	60 samples/h, 70 samples/h with Speed-up license*
Parameters:	26 standard diagnostic parameters 15 optional diagnostic parameters
Interface	RS-232C, 2x Ethernet (RJ45), 4x USB
IPU	**Integrated**, embedded WIN 7 with McAfee Security

* optional

It truly is XN

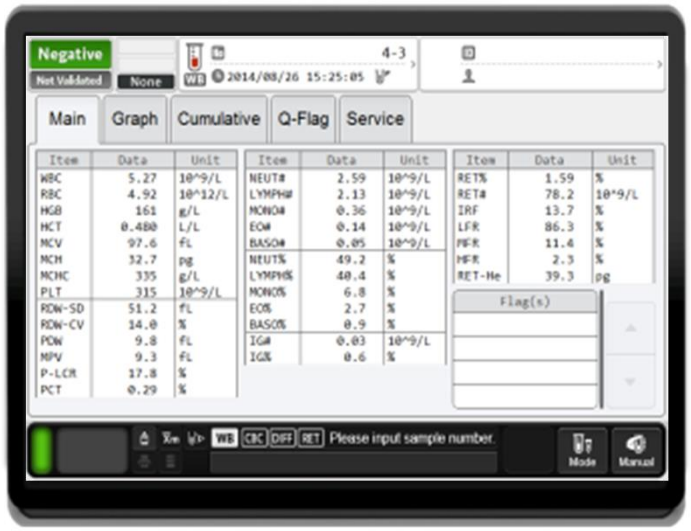
- Identical Productivity Value APPs
- Optional flexible speed of the sampler (60 or 70 samples/h)

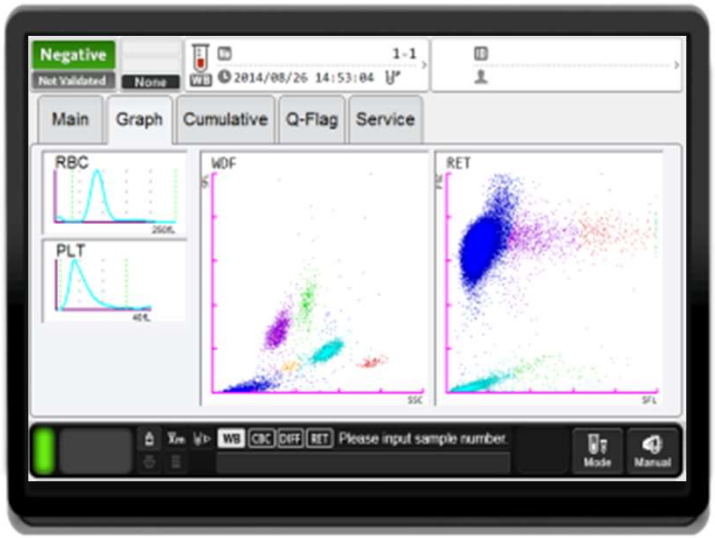


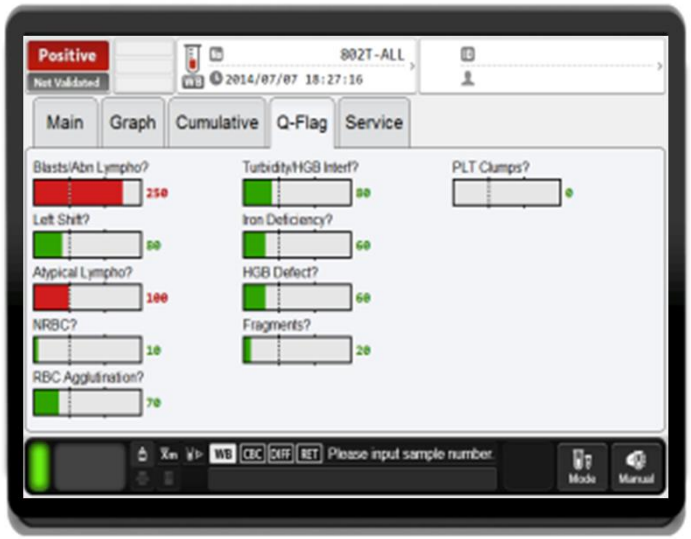
It truly is XN

- The same Clinical Value APPs
- Standard: CBC, XN-DIFF
- Optional: RET, XN-BF

XN-L Series Integrated IPU







XN-L Series Reagent Concept

- The reagents and the concept for the XN-L Series are the same as for the XN-Series
- The lower throughput of the XN-L has however been taken into consideration
- As a result, smaller reagent pack sizes will be available

Support for XN and XN-L

- Robust systems – in keeping with the long standing Sysmex reputation
- Installation, end-user training and after sales service support
- Easy transition from XN to XN-L and vice versa
  - Software look and feel the same
  - Reagents can be interchangeable (except RET fluorocell)
  - QC management identical
- Quality management
  - SNCS
  - Sysmex Quality Guidance Manual

XN Concept

User

Clinician

CLINICAL VALUES

PROFESSIONAL SERVICES

WHAT ARE

YOUR NEEDS?

Supervisor

PRODUCTIVITY VALUES

Purchaser