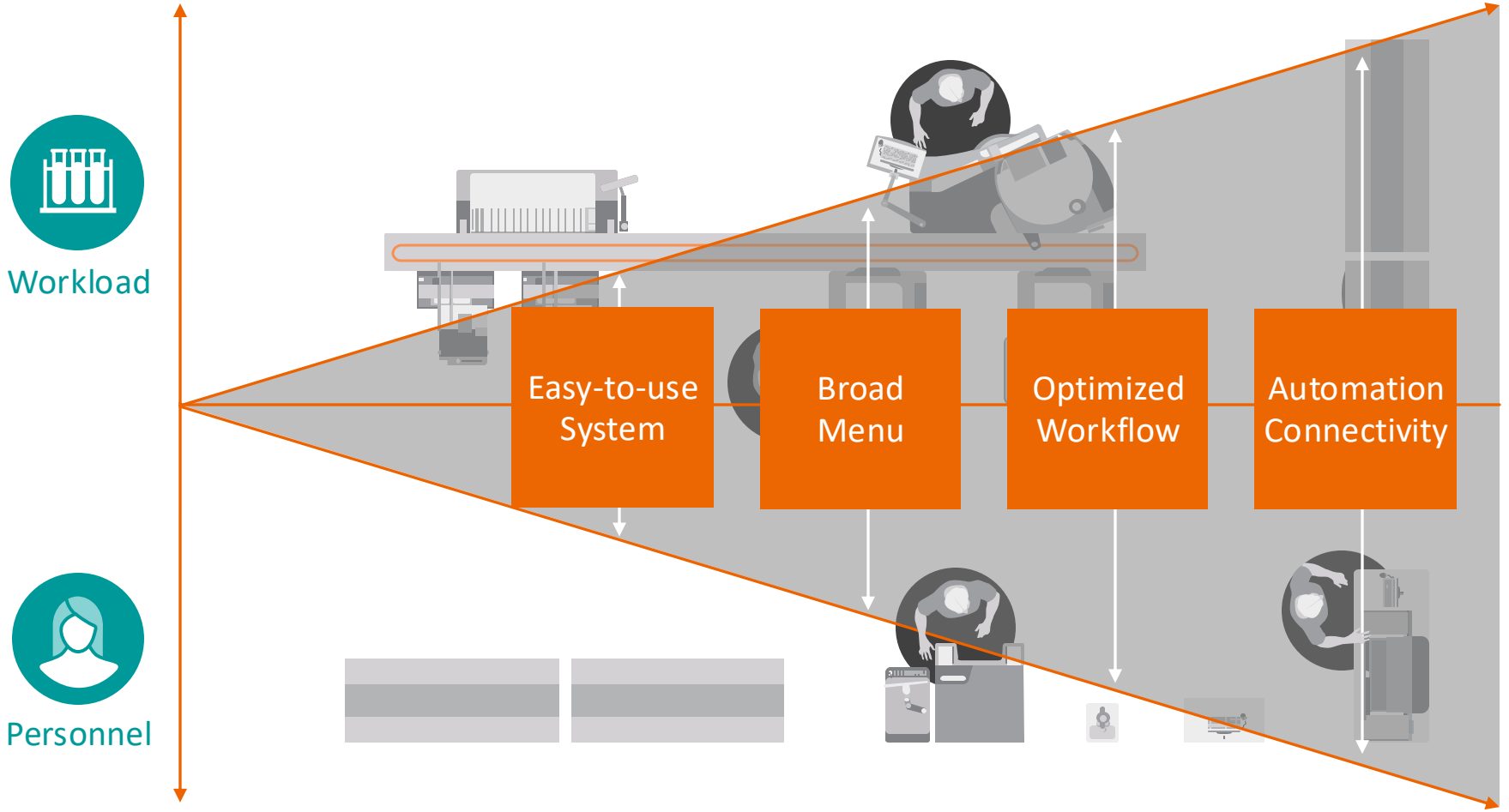
SIEMENS Healthineers

BN II System

Built on proven nephelometric experience.
Designed for the future.

Growing challenges of a modern laboratory



BN II System delivers

Flexibility & reduced hands-on time

Flexible configuration and fast results with less hands-on time

Nephelometric sensitivity

For confidence in results

Intuitive software

State-of-the art software

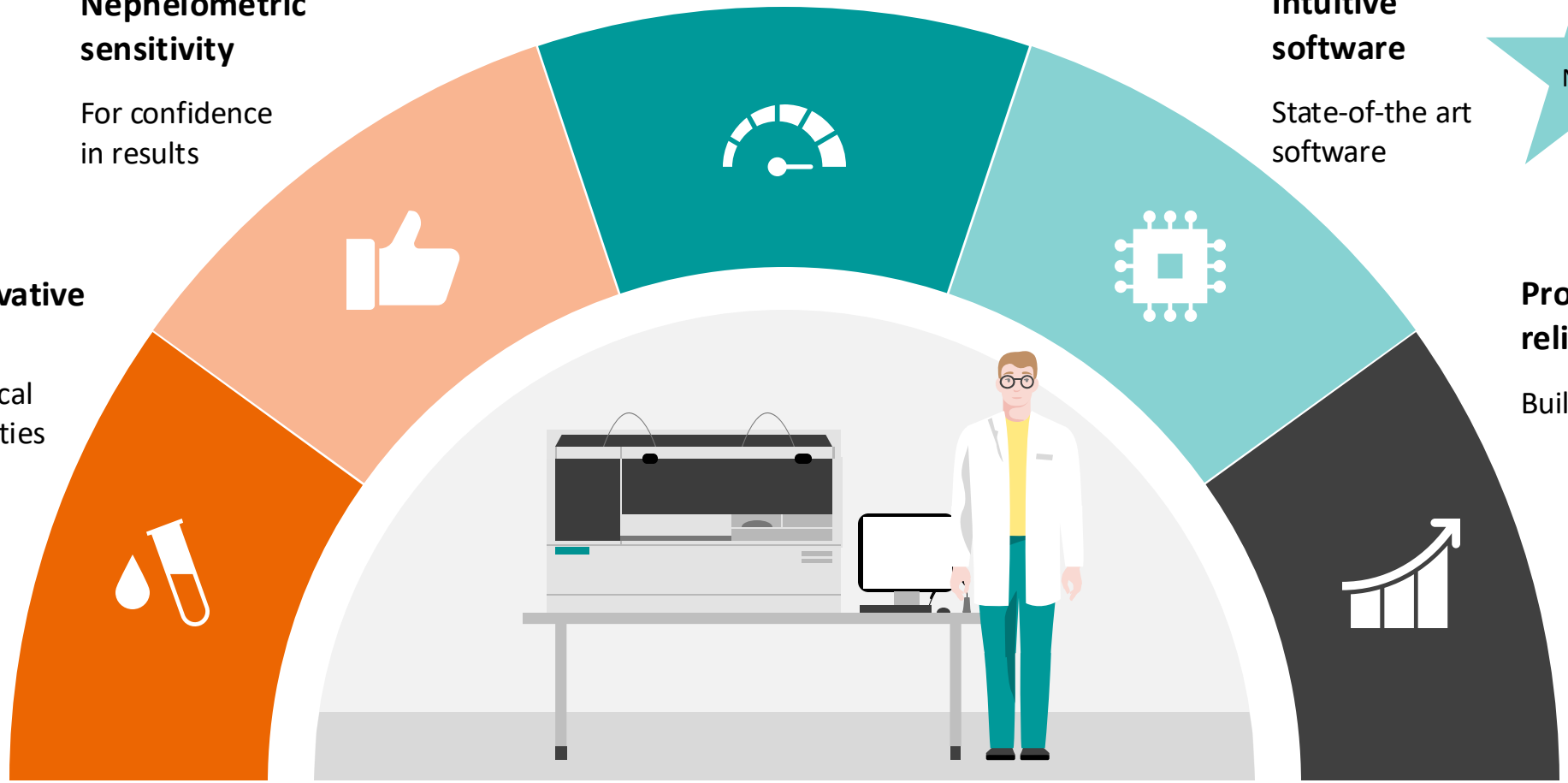
NEW

Growing innovative assay menu

To enhance clinical support capabilities

Proven reliability

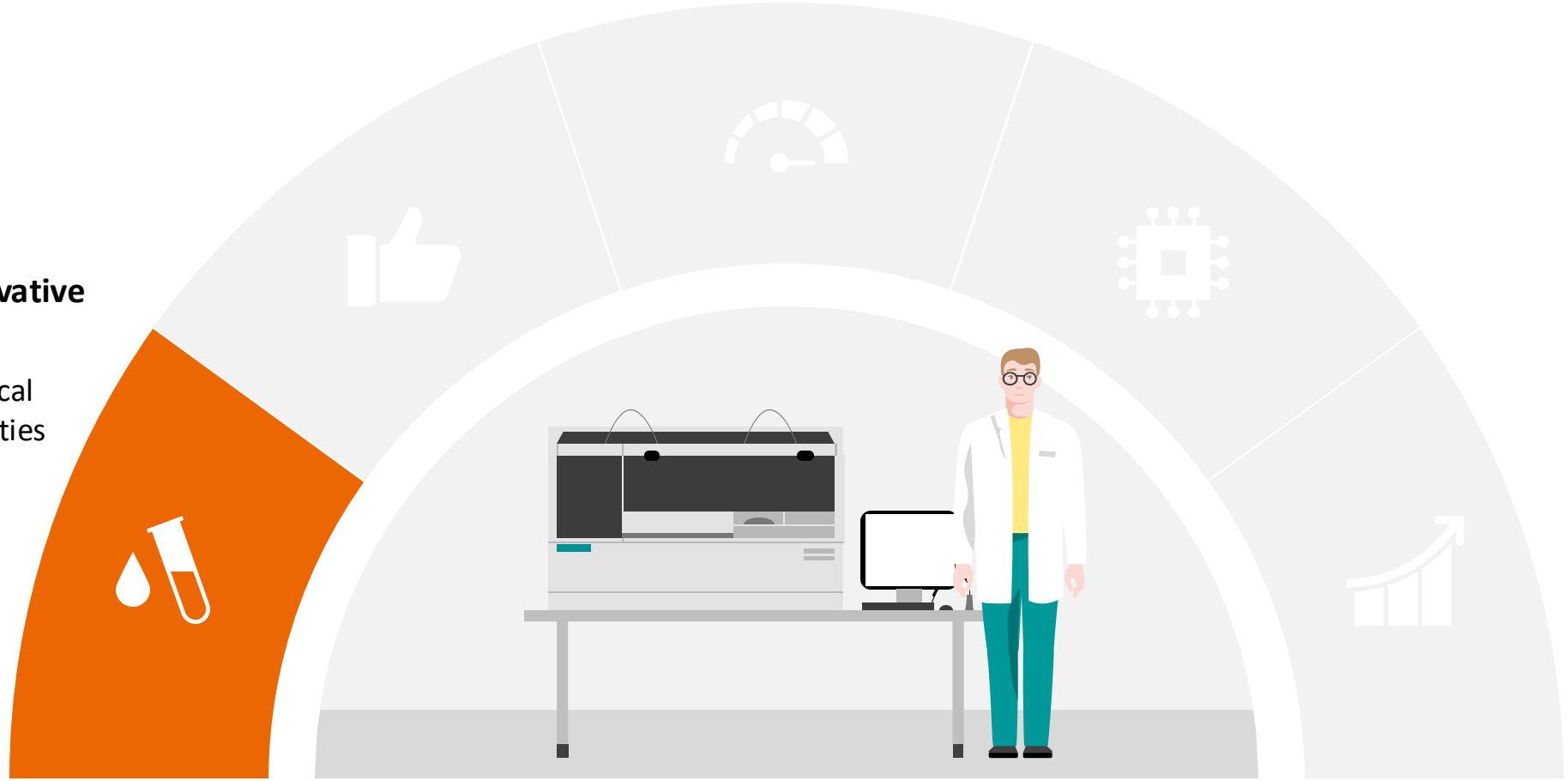
Built for the future



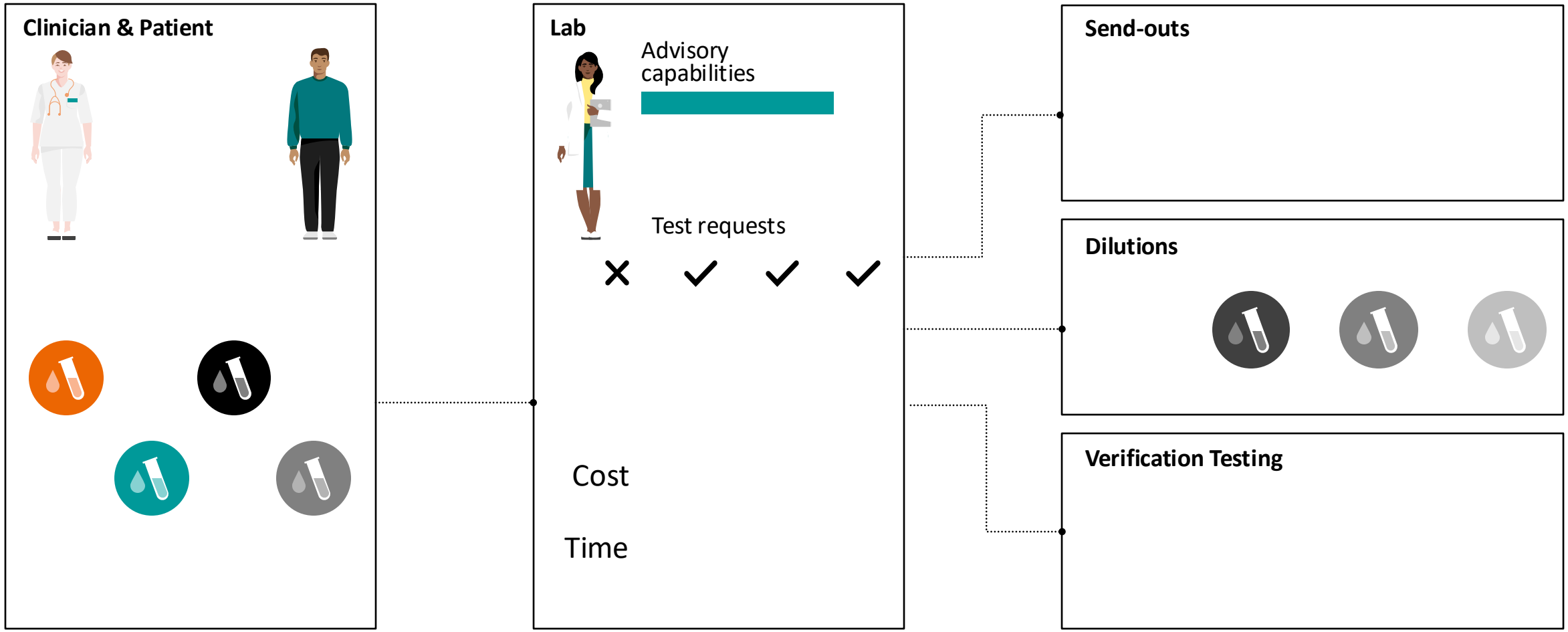
Growing innovative assay menu

Growing innovative assay menu

To enhance clinical support capabilities



Comprehensive plasma protein testing can be challenging



Increase Plasma Protein Menu and Reduce Send-out Costs

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Improves lab's value to healthcare system

IgG
IgA
IgM
FLC Iambda
FLC kappa
Total Lambda
Total kappa
B2-macroglobulin

IgG1
IgG2
IgG3
IgG4

β-trace protein (RUO)*

Ceruloplasmin
Fibronectin

C1 esterase inhibitor
C3c
C4

+

Streamlining plasma protein testing

Increase laboratory expertise

Reducing potential for errors

Financial payoff

100 samples

$4000 Savings

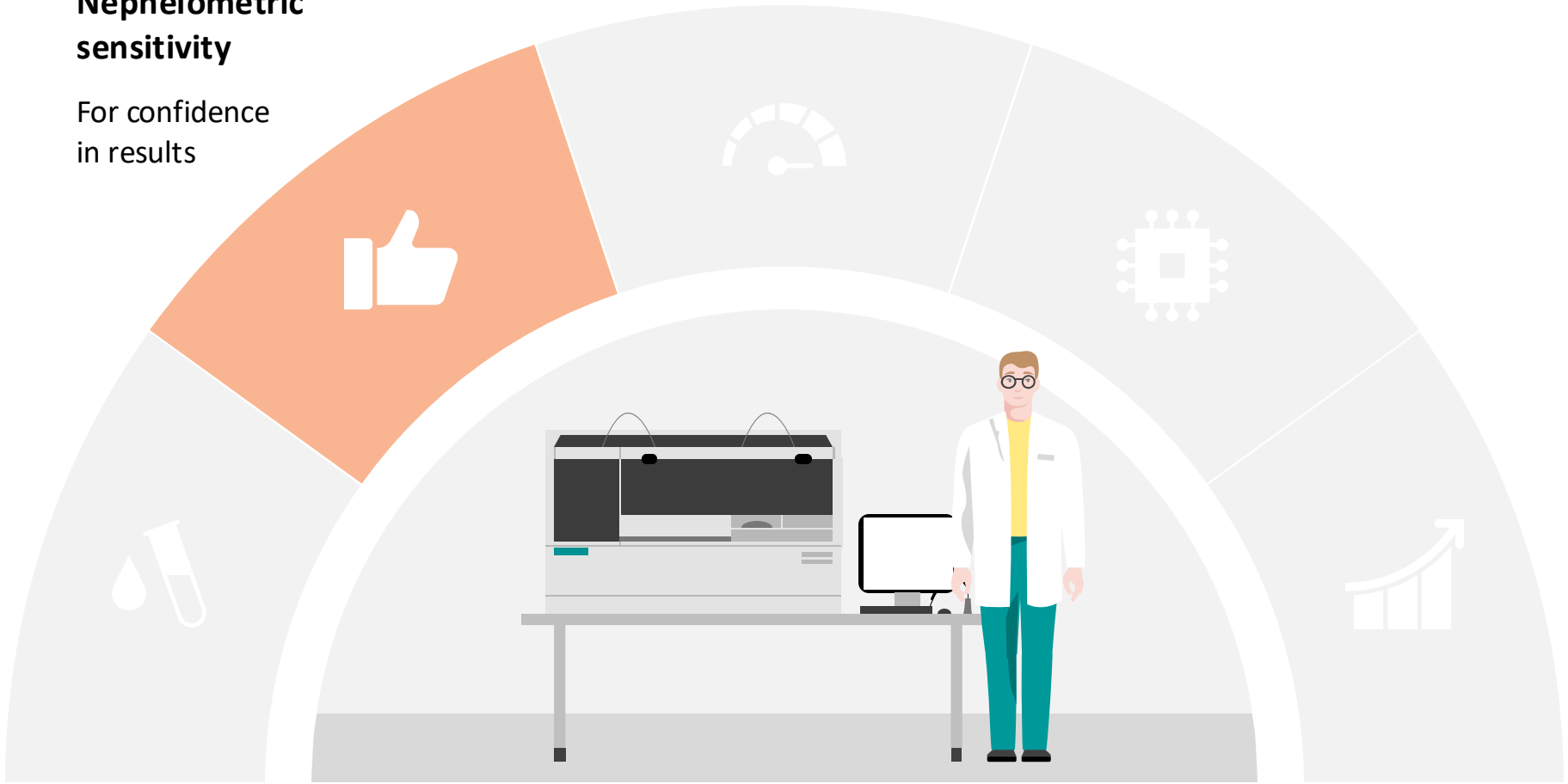
Improved patient outcomes

*Research Use only

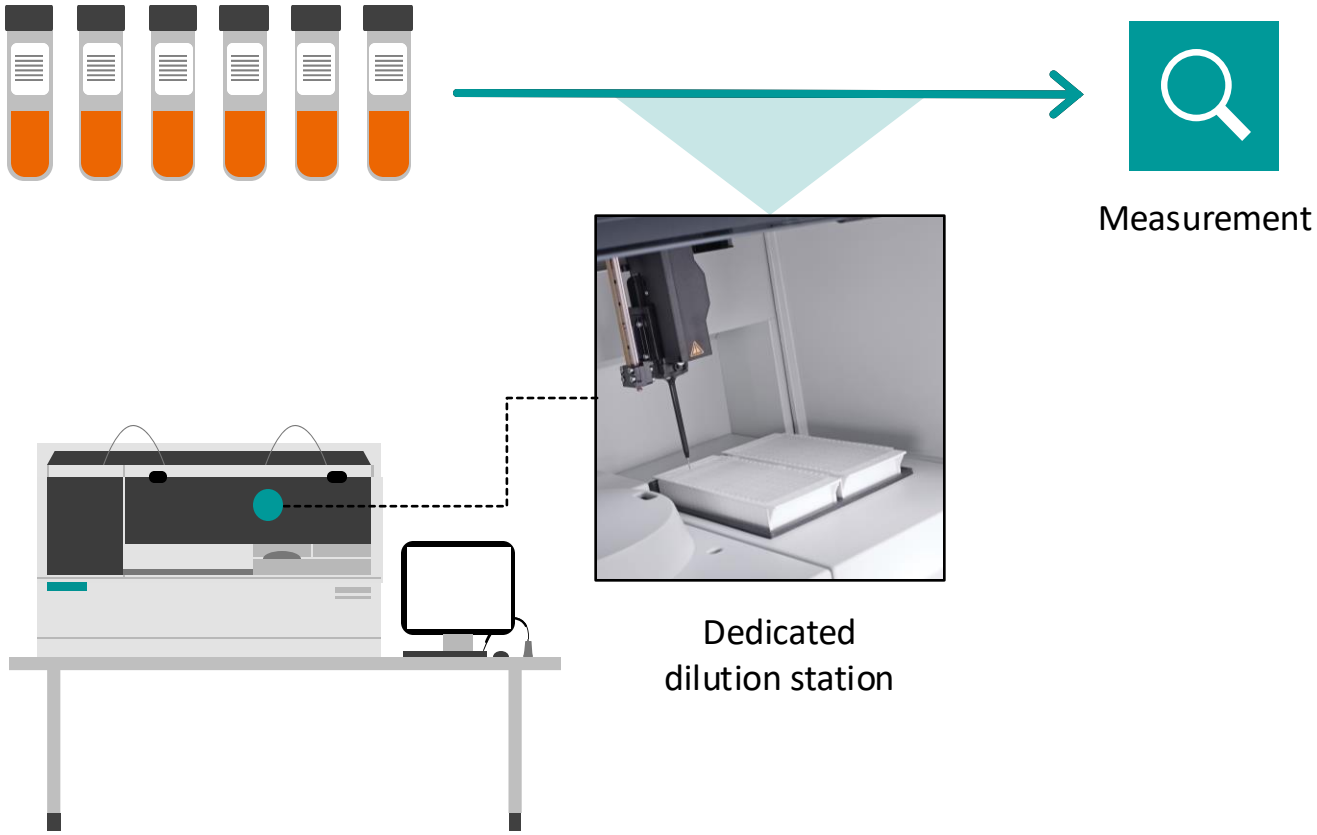
Nephelometric sensitivity

Nephelometric sensitivity

For confidence in results



Nephelometer with dedicated dilution station

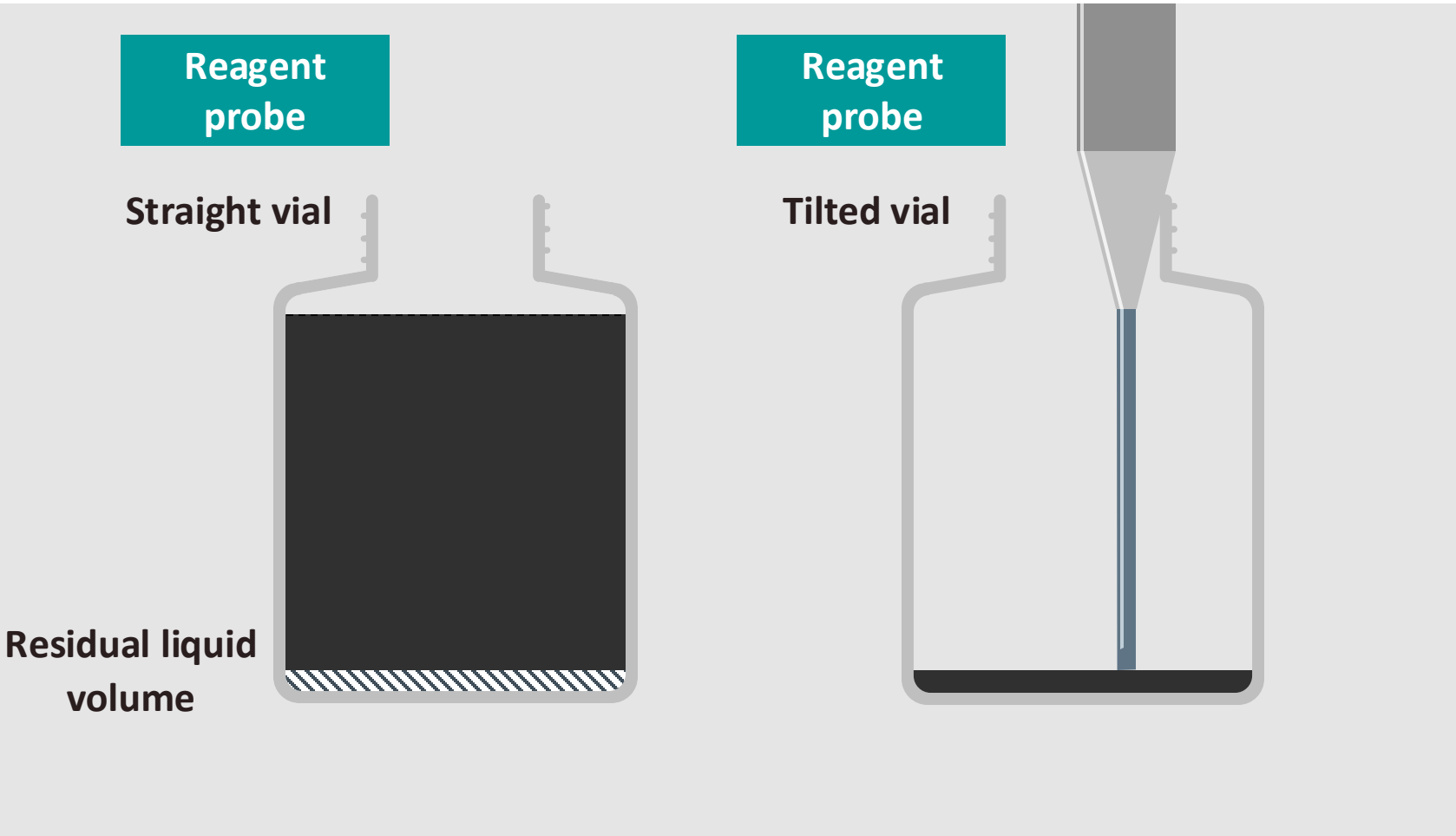


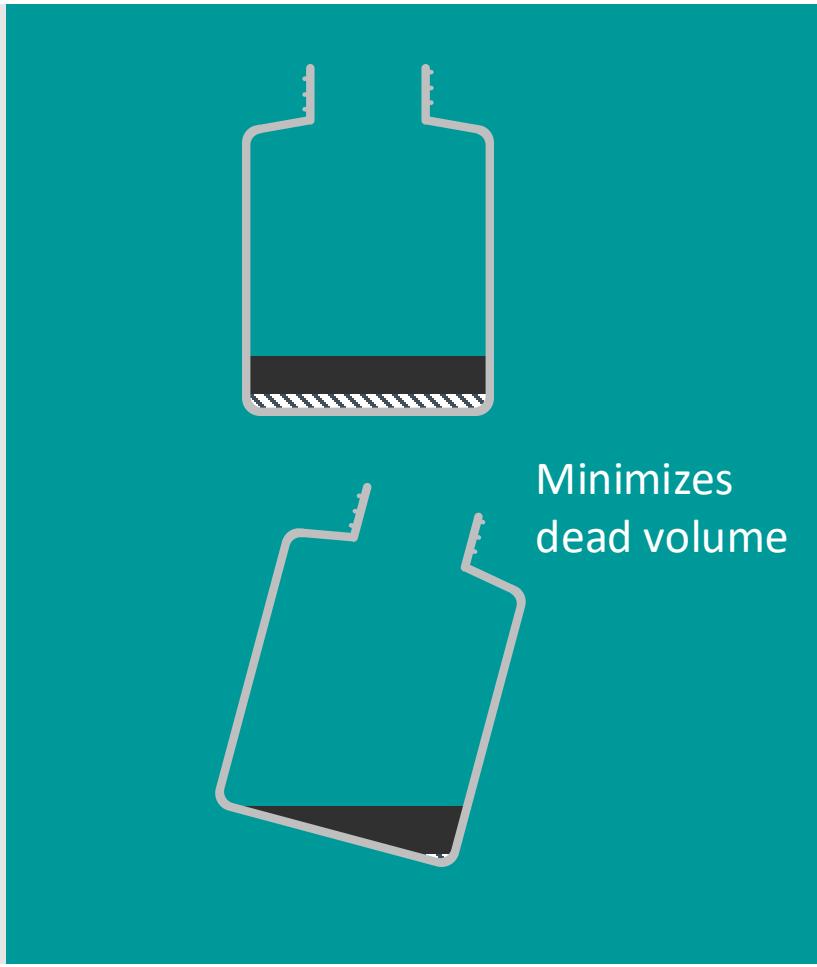
Dedicated serial dilutions provide more accuracy – **up to 1:160,000**

Preserving precious samples volumes by avoiding additional sample uptakes for each separate dilution

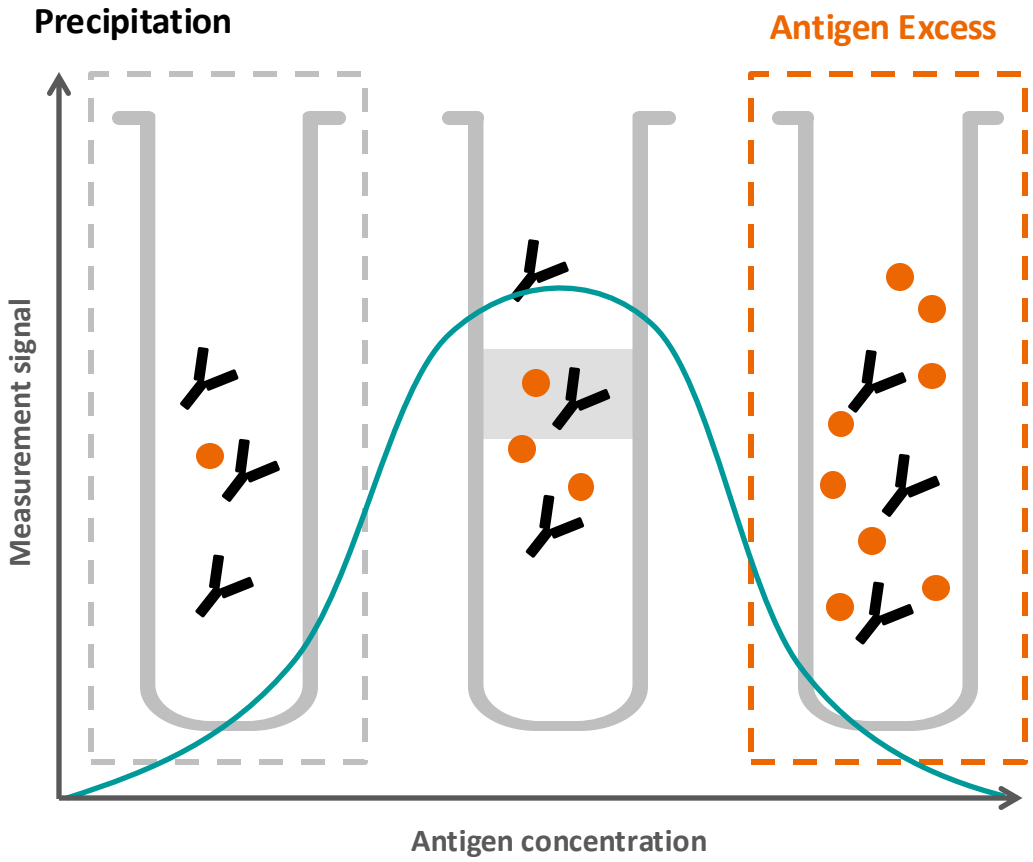
Quick sample release – sample volume is stored in the dilutions

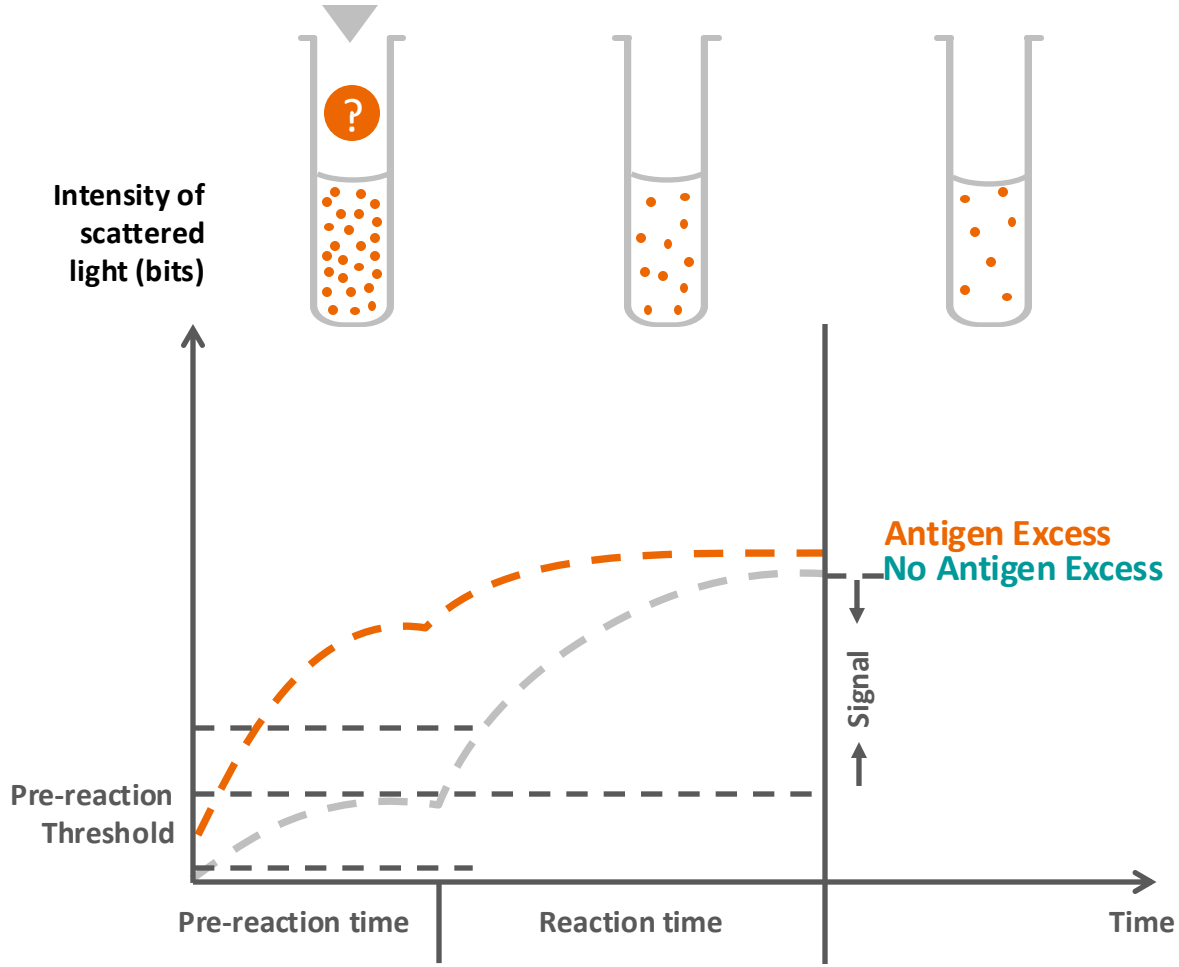
Convenient reagent handling





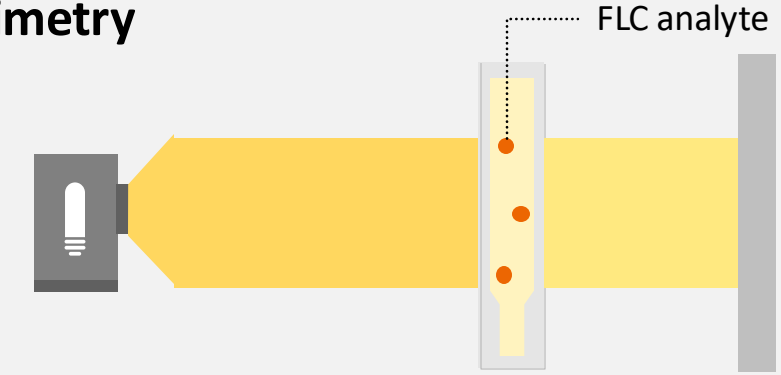
Antigen excess checks



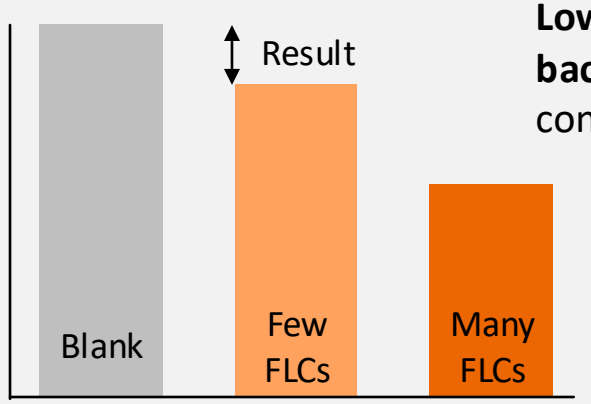


Nephelometry offers excellent sensitivity

Turbidimetry

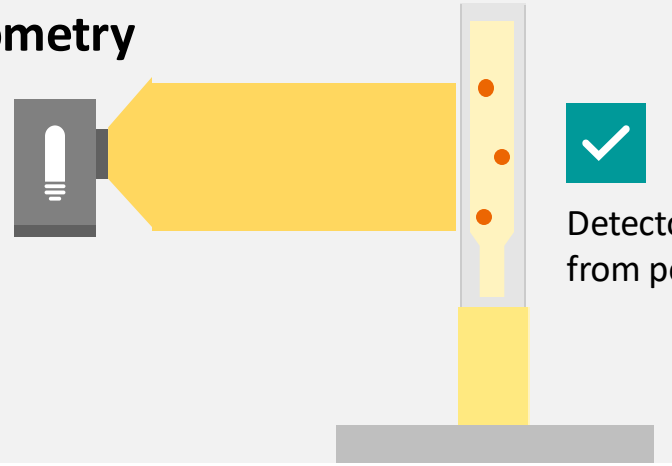


Detector receives **strong light signal**

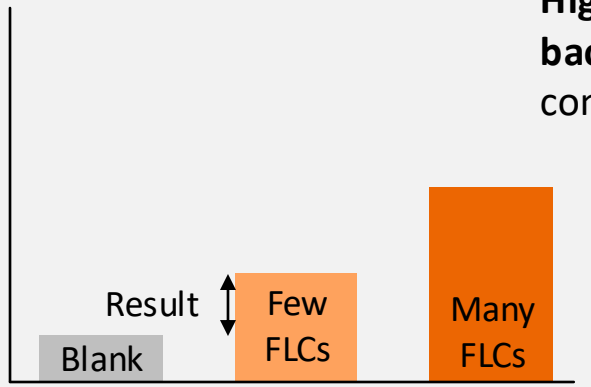


Low signal-to-background ratio at low concentration levels

Nephelometry



Detector **avoids interference** from possibly transmitted light



High signal-to-background ratio at low concentration levels

Nephelometric sensitivity of Latex-based assays on

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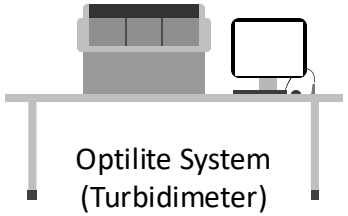


Optilite System
(Turbidimeter)

Free Light Chains[i]

Low end concentration

Lambda – 1.3 mg/l

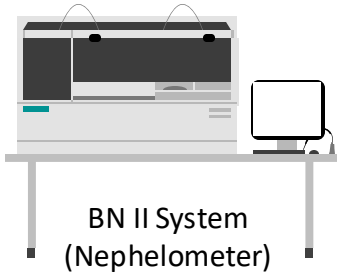
Kappa – 0.6 mg/l

IgG3 & IgG 4[ii]

Low end concentration

IgG3 – 5.5 mg/l

IgG4 – 4.3 mg/l



BN II System
(Nephelometer)

Increased Sensitivity +68%

Lambda – 0.48 mg/l ✓

Kappa – 0.17 mg/l ✓

Increased Sensitivity +55%

IgG3 - 1.7 mg/l ✓

IgG4 - 2.6 mg/l ✓

Why sensitivity matters

- Immunosuppressive therapies lowers Immunoglobulin concentration, and the FLC ratio is a fraction which jumps drastically at low concentrations [1]

Nephelometry in the guidelines

IMWG Guidelines

"The free light chain (FLC) assay is an automated **nephelometric** assay that identifies and measures **κ and λ light immunoglobulin chains** that circulate unbound to heavy chains in the serum."[2]

ESMO Guidelines

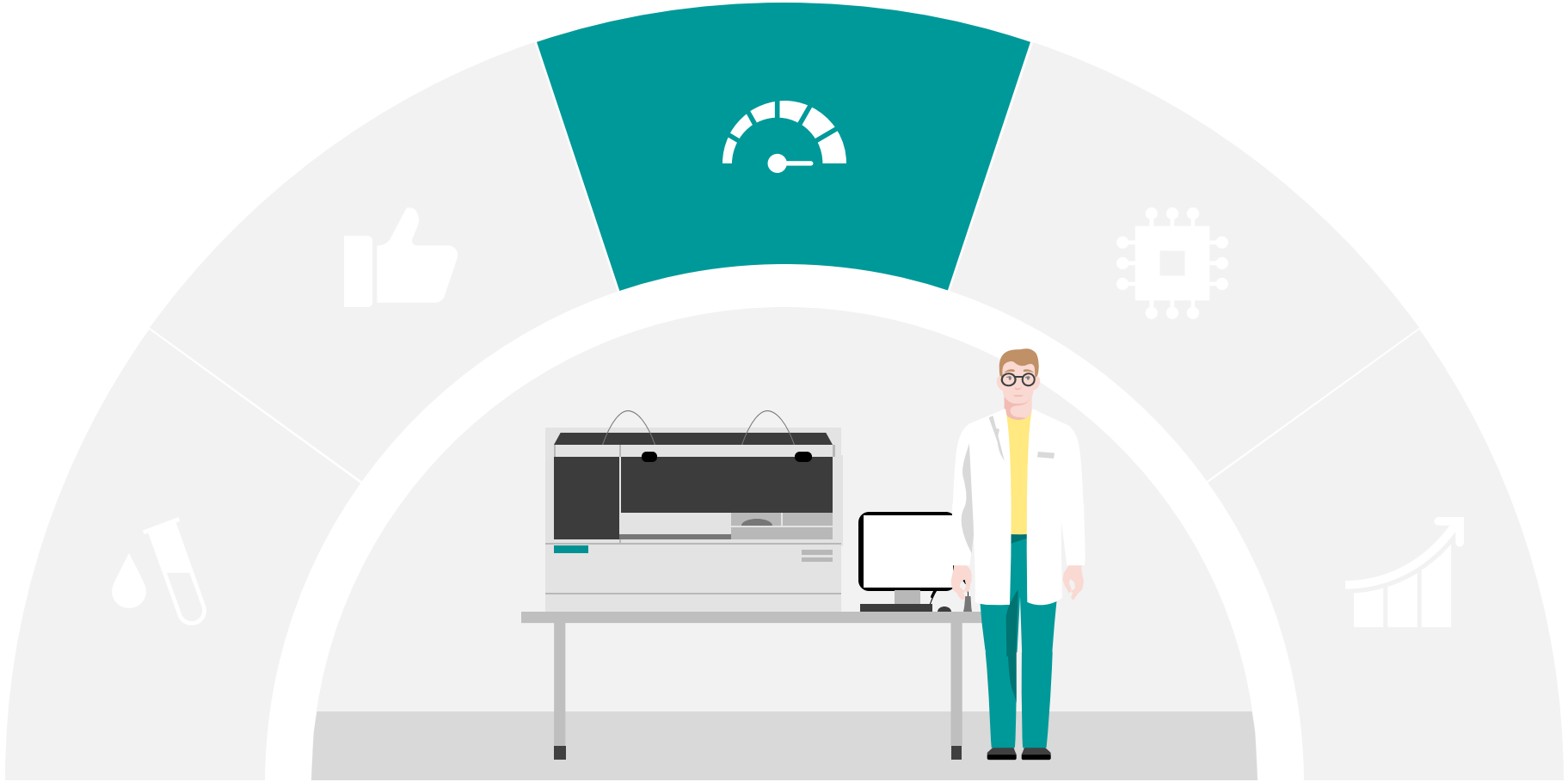
"Diagnosis of MM should be based on the following tests: Detection and evaluation of the monoclonal (M) component by serum and/or urine protein electrophoresis (concentrate of 24h urine collection); **nephelometric quantification of IgG, IgA and IgM immunoglobulins**; characterisation of the heavy and light chains by immunofixation; and **serum-free light-chain (FLC) measurement**." [3]

[1]Pratt et al. Br J Haematol. 2007;138(5):563-79
[2]Rajkumar et al. Lancet Oncol 2014; 15: e538-48.
[3]Moreau et al., Annals of Oncology 28 (Supplement 4): iv52–iv61, 2022.
[i-ii]Instructions for use from manufacturers

Flexibility & reduced hands-on time

Flexibility & reduced hands-on time

Flexible configuration and fast results with less hands-on time



Flexible sample handling

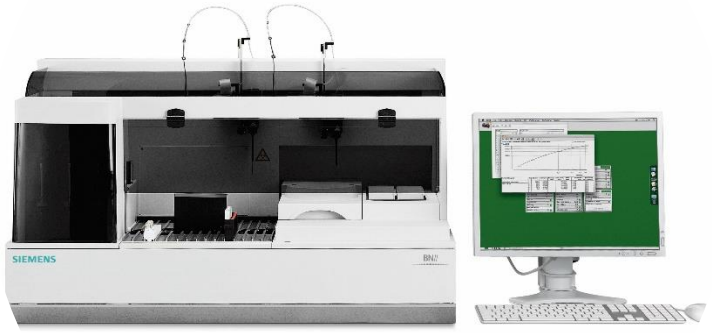
CSF

Plasma

Serum

Urine

Securely process different types of samples on one platform



Less hands-on time

Fast results

Improve your lab's productivity & efficiency

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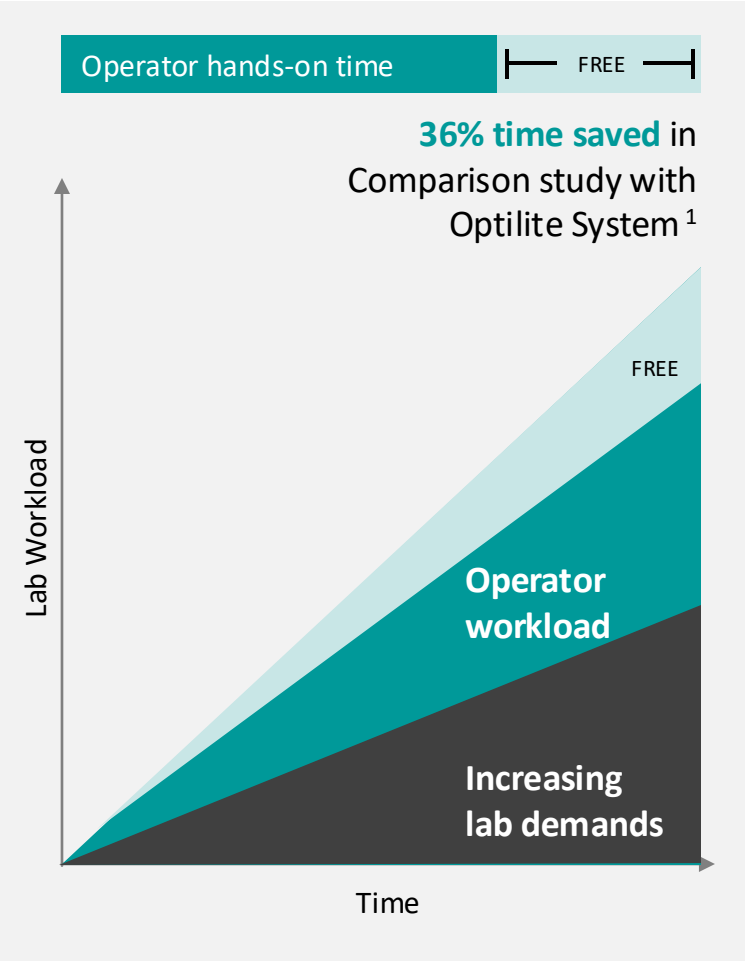
130

Average throughput:
130 tests/hour

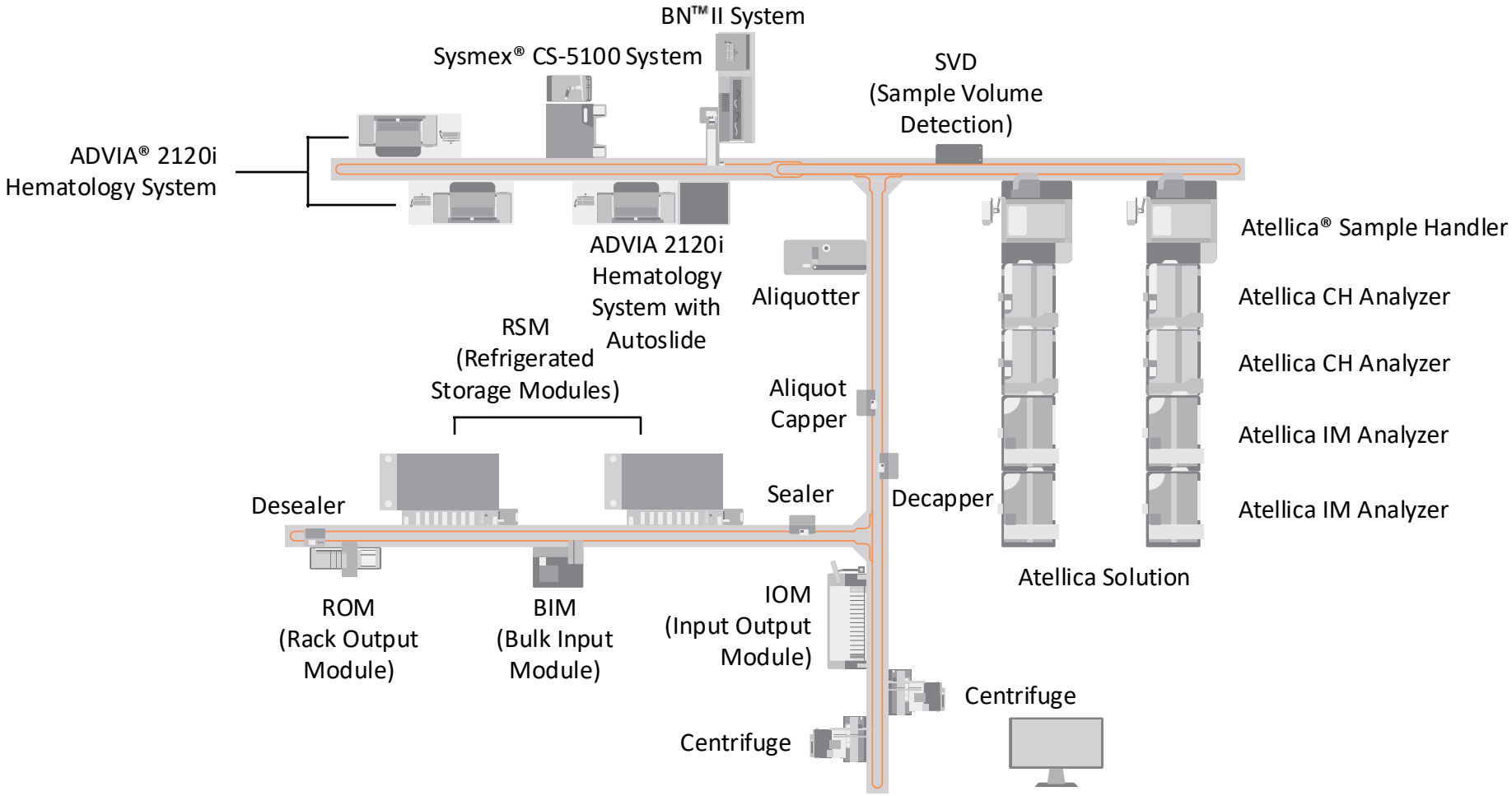
Quick
sample release

Connection to laboratory
automation



[1] LD Workflow Study BNII vs Optilite System 10 2020

BN II System connectivity to Aptio automation



Advantages of BN II System Automation Connection

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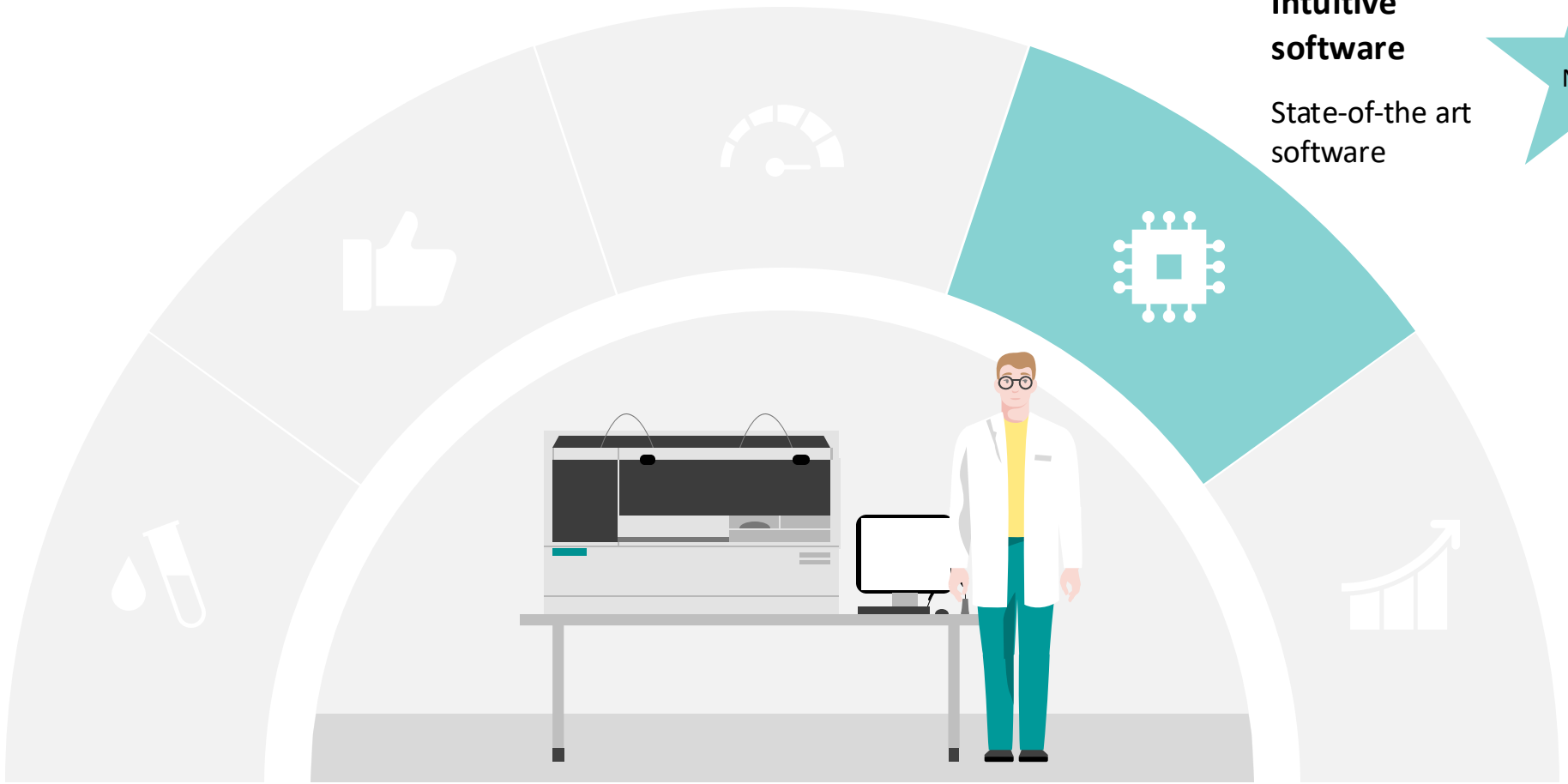
Less user intervention

Standardized sample flow

Unaffected system operation

Versatility

Intuitive software



Intuitive software

State-of-the art software

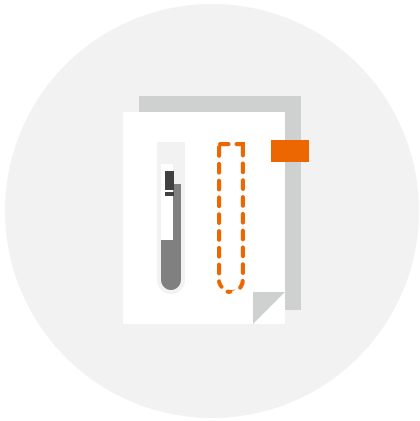
NEW

Overview of new software features

Data privacy

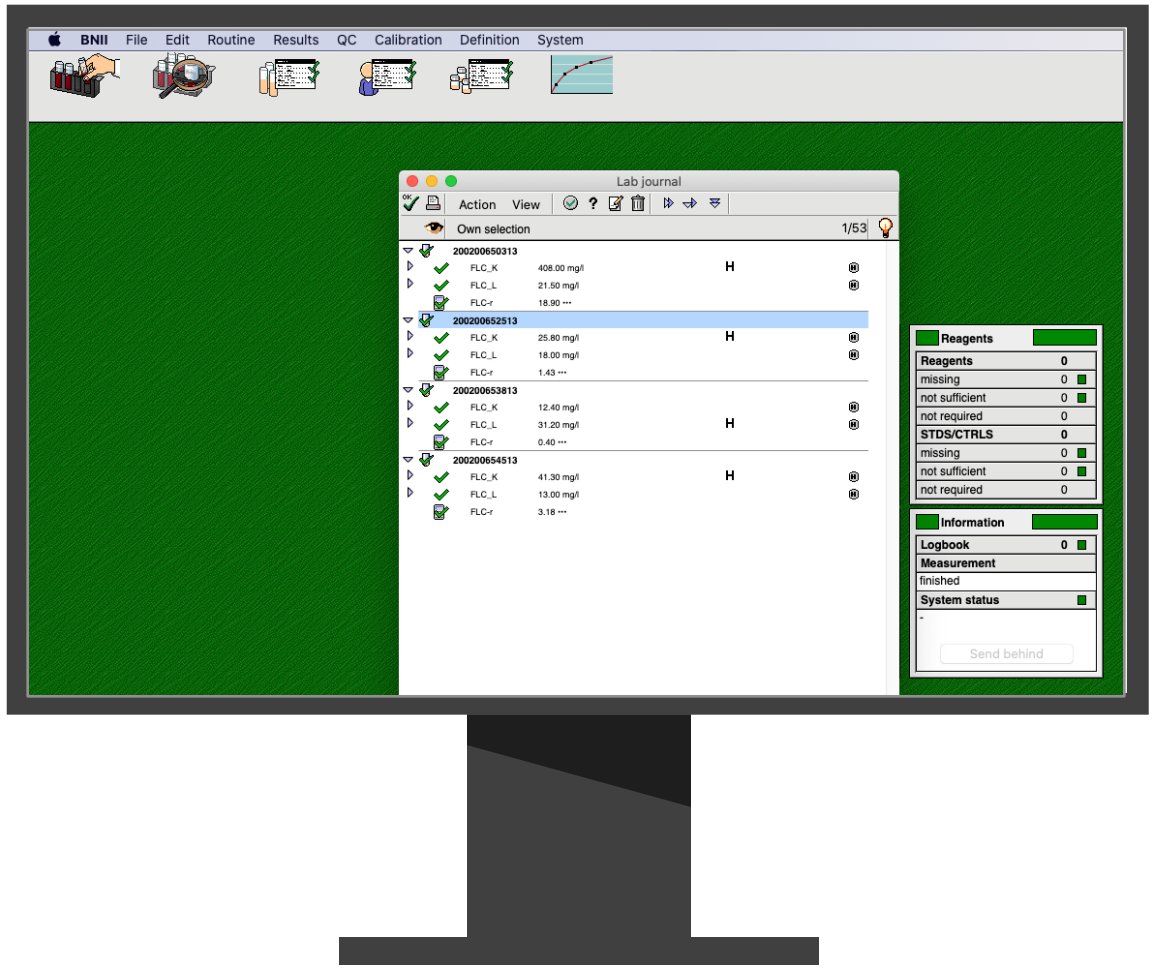
User management

Audit trail



Traceability

New features: Data Privacy

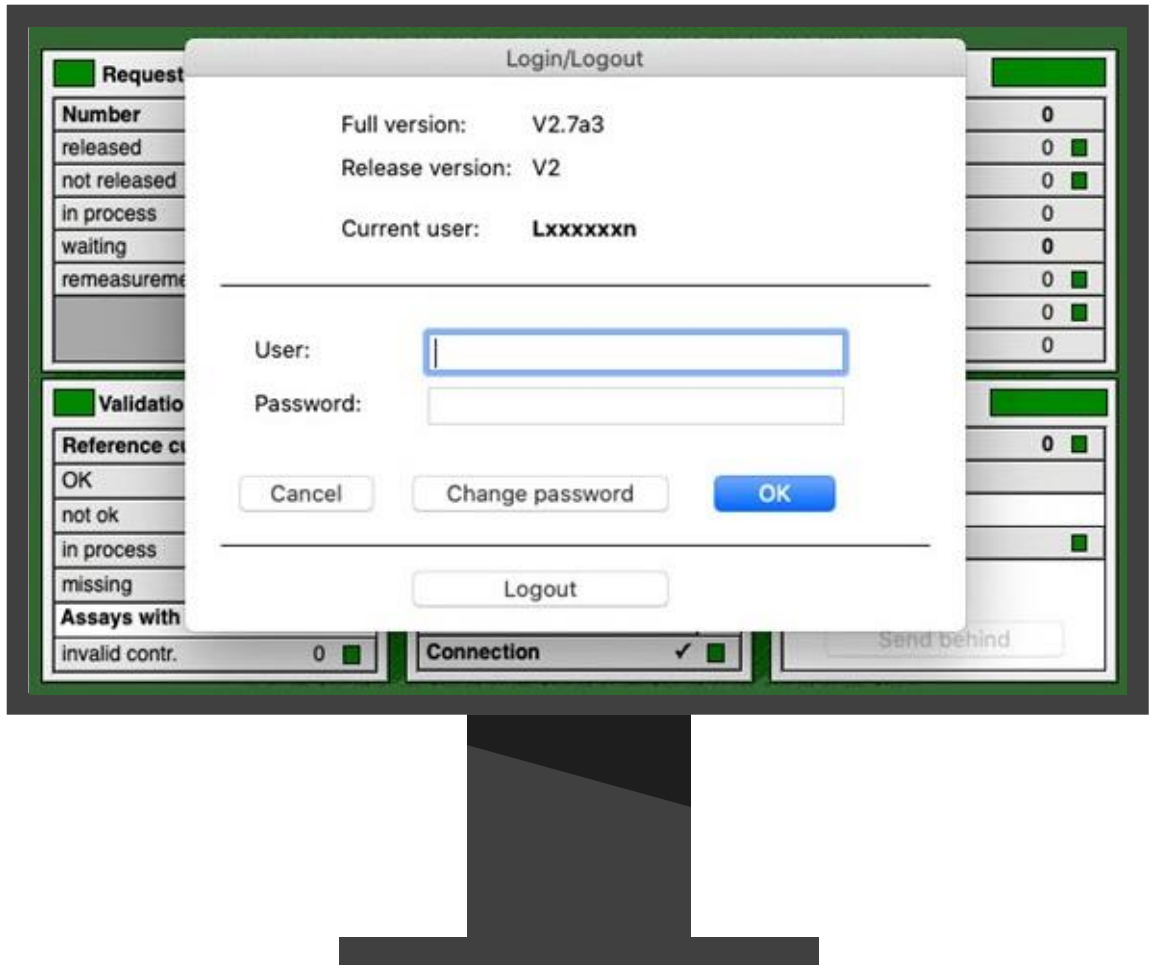


User management privileges ensure private user and patient data is **protected**

Privileges can be **configured** to suit your institution's access policies

Systems enables compliance with **data privacy regulations**, e.g., GDPR

New features: User management

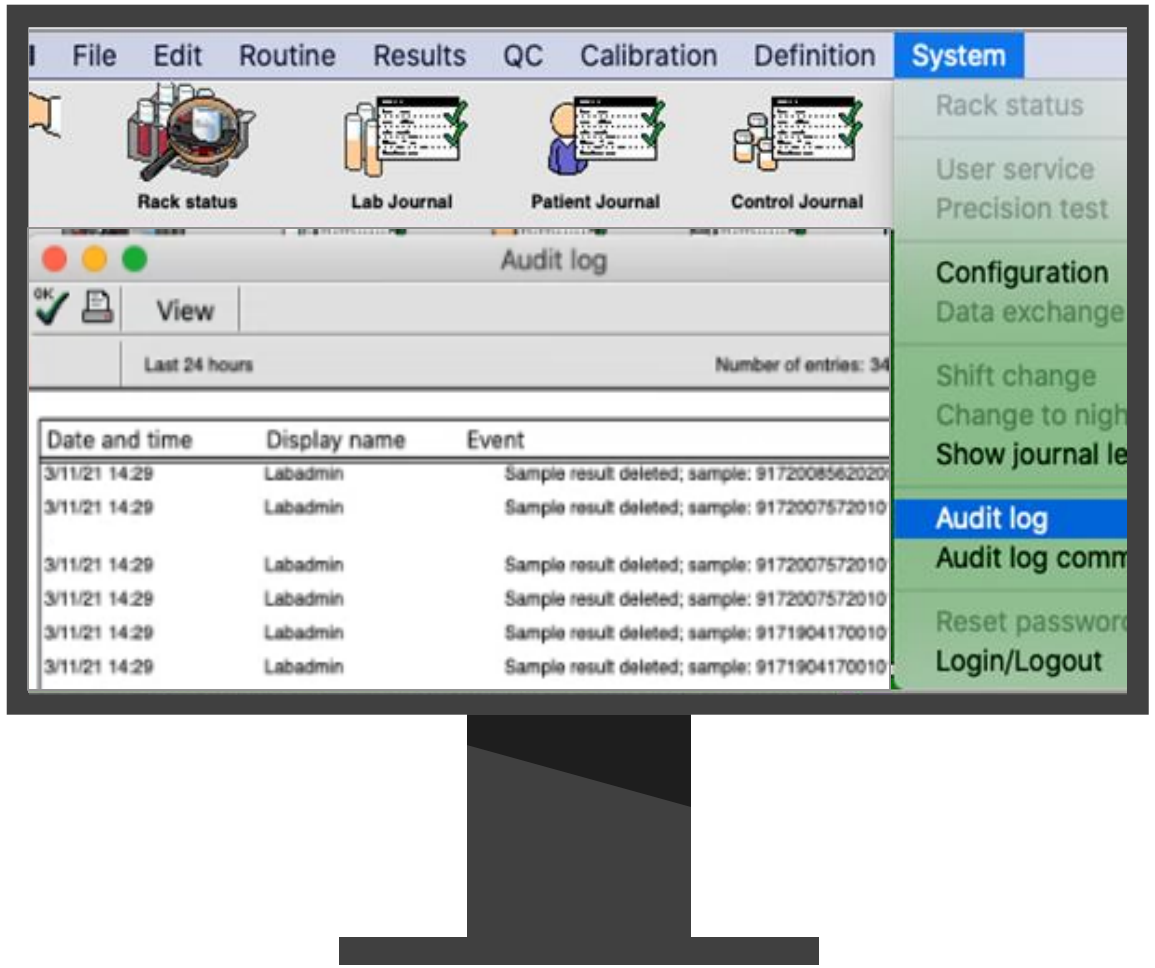


Individual user accounts
rather than role-based system

User activity **traceable**
using electronic signature

Only users with **authorized logins**
can view patient data

New features: Audit trail – FDA 21 CFR part 11

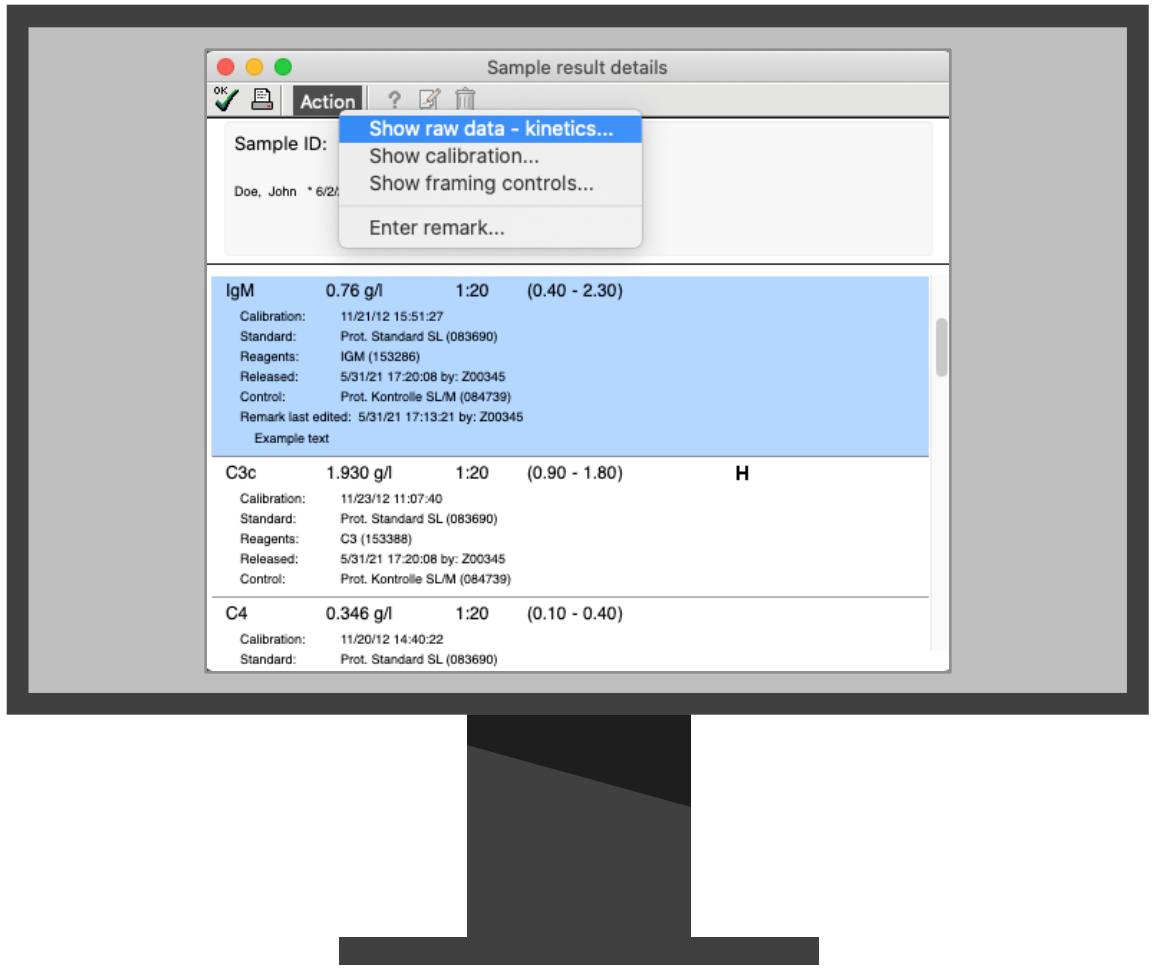


Track and comment
on user activity

Audit trail logs storage, commenting & printing

Provide information efficiently
when lab is being audited

New features: Traceability

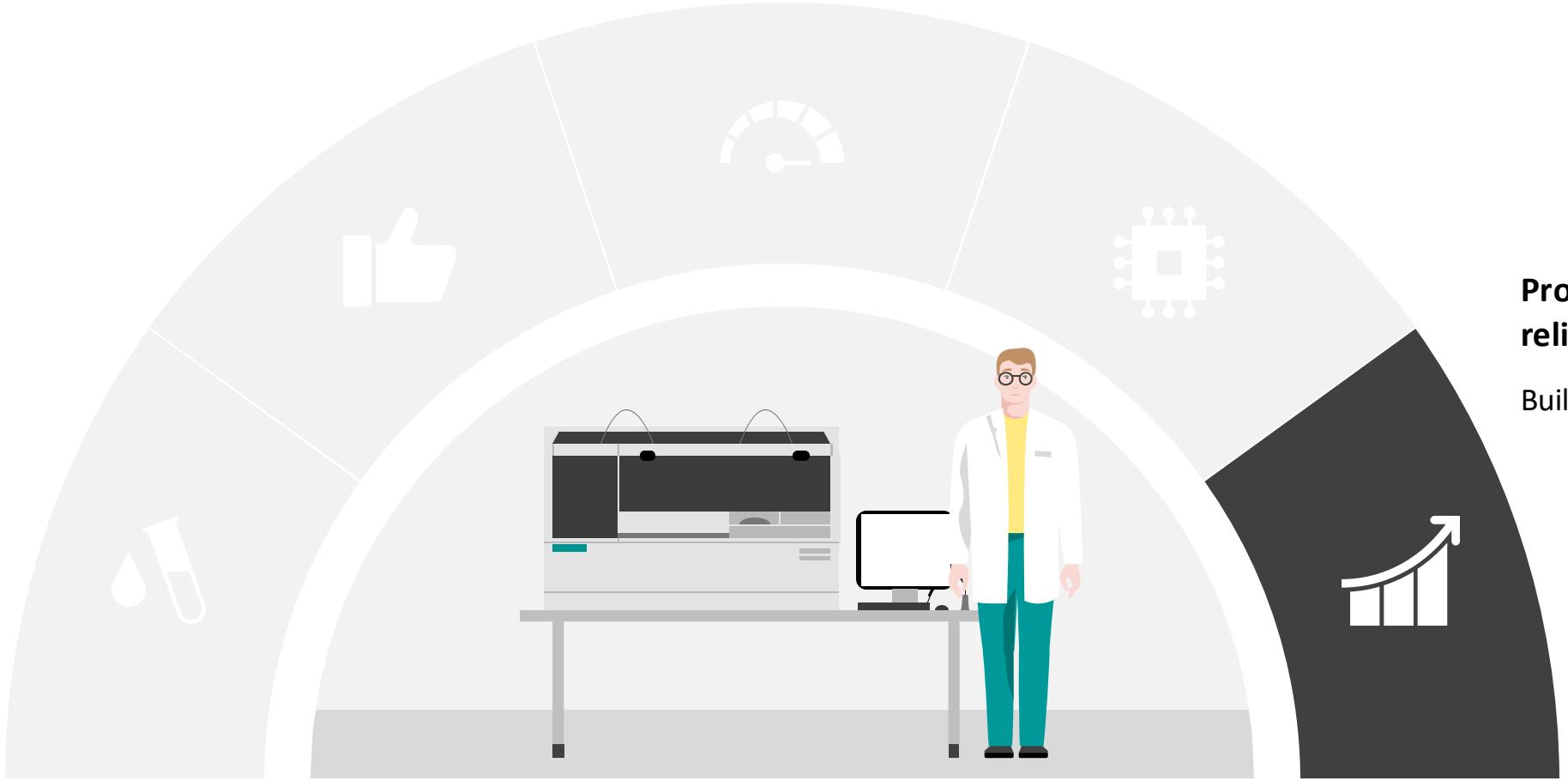


Improved traceability of results, having e.g. calibrations, controls, lot numbers and release details in one spot

For each released result have quick access to **calibrations curves, framing controls and archived results**

Improved overall sample search **efficiency and walk-away time**

Proven reliability



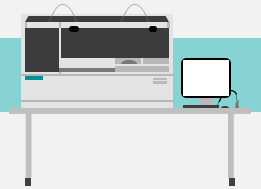
Proven reliability

Built for the future

Proven instrument reliability – Built for the future

Built for the future

Instrument timeline | BN II System launch | ROHS compliance | LAS | Special sample rack | **BN II System next generation**



Excellent **service track record** with average 2-3 service visits per year.

Long term experience as an **instrument service provider**, delivers expertise and routine confidence in times of need.

Future Focus

- **Innovative assays**
- **Instrument Performance & workflow excellence**
- **Digitalization**