



Ortho Clinical Diagnostics

Because Every Test Is A Life™

# Ortho Enabling Technology

Dec 10<sup>th</sup>, 2021

Dogy Valian



## OUR MISSION

**We improve and save lives  
with diagnostics.**

We enable our customers to  
optimize the long-term value for  
patients through our innovative  
IVD solutions and services.

Because  
**Every**  
Test  
Is A **Life**<sup>™</sup>

Ortho Clinical Diagnostics

# Importance of Result Consistency

Patient Management & Challenges

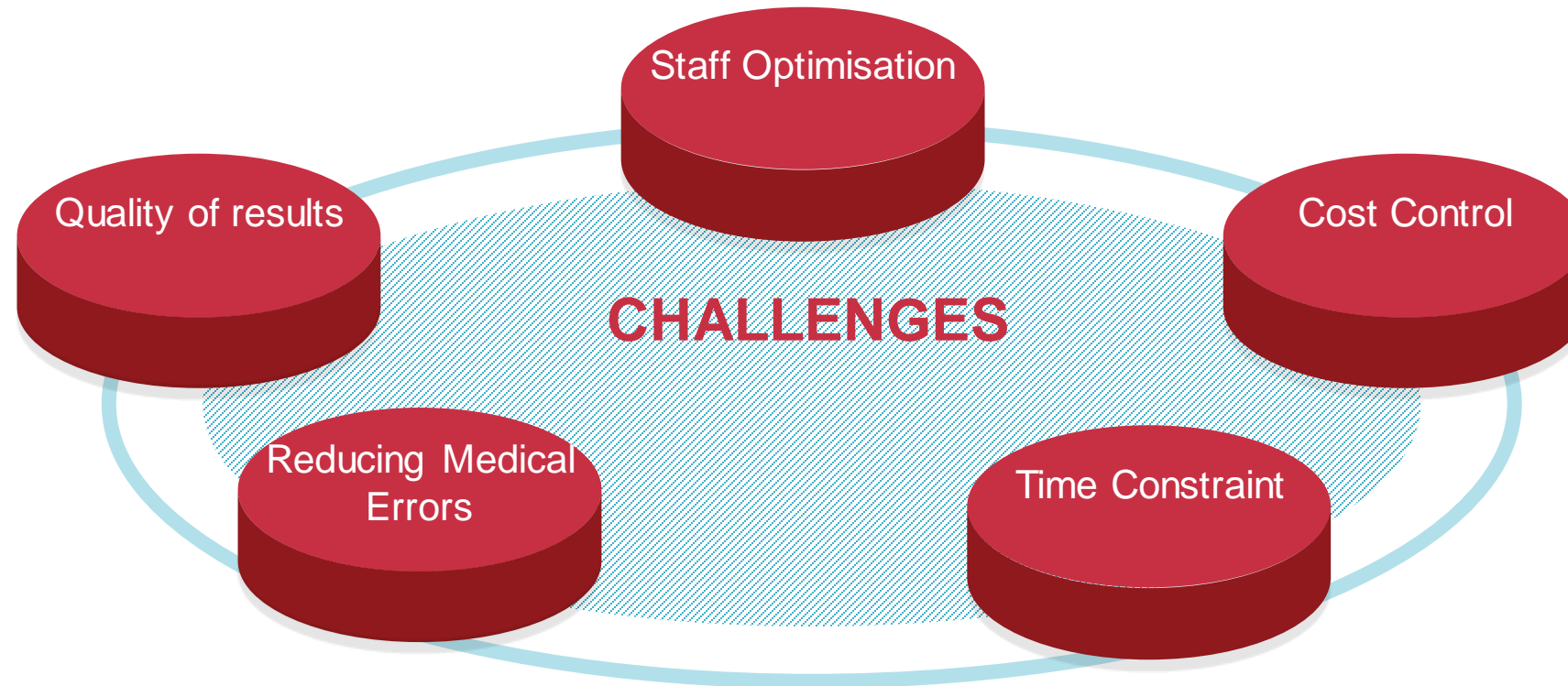
# Role of the Lab in Patient Management

The Lab provides the information required for the delivery of precise healthcare

- ✓ 70% medical decisions are based on lab reports while IVD Healthcare Expenditure is around 2%
- ✓ Tests screen for, diagnose, and prevent disease
- ✓ Provide critical data needed to select proper treatment
- ✓ Evaluate the effectiveness of treatment
- ✓ A large percentage of health care decisions, from diagnosis through therapy and prognosis, are derived from clinical laboratory tests.

# Today's Labs Face Challenges at Every Turn

## Managing Lab Operations





# Labs Also Need to Cater to STAT Requests!

## Dynamic Lab Environment

- Emergency Department
- Intensive Care (ICU)
- Neonatal ICU (NICU)
- Cardiovascular ICU (CICU)
- Coronary Care Unit (CCU)
- Surgical Department
- Trauma Wards



# Laboratory Key Challenges for STAT Tests

## Patient Results

### Quality

No time for sample quality and quantity inspection

Zero error tolerance especially those critical tests.

For example: Electrolytes, BMP, CMP

### Efficiency

TAT pressure from physicians – Emergency, Adult & Neonatal ICU, High

Dependent Unit, Cardiac Care Unit and Surgical Department

No time waiting for repeat testing and redraw samples

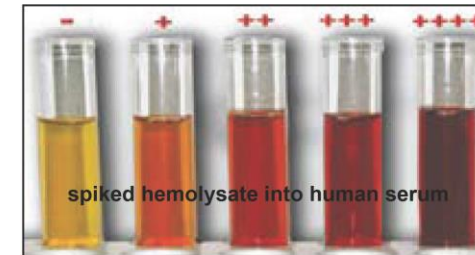
### Ease of Use

Labor shortage especially skilled manpower

Less maintenance and downtime

Less calibration and QC needs

True random access



# Quality Indicators & Challenges for Lab

Patient Management & Challenges



# Quality Indicators

## Lab Performance

- QIs are tools that support objective monitoring of errors and form an integral component of a laboratory's quality management program.
- Good approach to prioritizing QIs specific to a laboratory's unique setting is to conduct a risk assessment that identifies sources of error within testing processes.
- In the United States, laboratories are required to assess quality performance throughout the total testing process (pre-analytic, analytic, post-analytic).



<https://www.aacc.org/publications/cln/articles/2016/february/choosing-and-retiring-quality-indicators>

# Sources of Lab Errors

## Quality improvement

- It is well published that most errors occur in the pre- and post-analytical phases
- Not processing a specimen properly prior to analysis or substances interfering with assay performance can affect test results in the analytical phase.
- Implementation of a Total Quality Management (TQM) system is the most effective strategy to minimize uncertainty in laboratory diagnostics.
  - preventing adverse events (error prevention),
  - making them visible (error detection),
  - mitigating their adverse consequences when they occur (error management)

**Table 1\_ Types and Rates of Error in the 3 Stages of the Laboratory Testing Process<sup>9,20</sup>**

Phase of Total Testing Process	Type of Error	Rates
Pre-analytical	Inappropriate test request	46%-68.2%
	Order entry errors	
	Misidentification of patient	
	Container inappropriate	
	Sample collection and transport inadequate	
	Inadequate sample/anticoagulant volume ratio	
	Insufficient sample volume	
	Sorting and routing errors	
	Labeling errors	
Analytical	Equipment malfunction	7%-13%
	Sample mix-ups/interference	
	Undetected failure in quality control	
	Procedure not followed	
Post-analytical	Failure in reporting	18.5%-47%
	Erroneous validation of analytical data	
	Improper data entry	

Ref - A Review of Medical Errors in Laboratory Diagnostics and Where We Are Today; February/March 2012 ■ Volume 43 Number 2 ■  
LABMEDICINE

# Analytical Errors

## What Impacts Quality

- Instrument malfunctioning
- Lack of specificity of the testing methodology
- WATER QUALITY
- Interfering substances – Paraproteins, drugs etc.
- Sample quality/ Serum Indices (HIL)
  - ✓ Hemolysis
  - ✓ Icterus
  - ✓ Lipemia

# Sample quality- Assays Affected by HIL

## Larger Impact on Critical Care

### Common biochemical tests affected by hemolysed sample

Increased	Decreased
Potassium (K <sup>+</sup> )	Haptoglobin
Lactate Dehydrogenase (LDH)	Bilirubin
SGOT/AST	Amylase
SGPT/ALT	Bicarbonate (HCO <sub>3</sub> <sup>-</sup> )
Creatine Kinase (CK)	
Iron	
Phosphate (PO <sub>4</sub> <sup>-</sup> )	
Total Protein	
Albumin	
Magnesium (Mg <sup>++</sup> )	
Calcium (Ca <sup>++</sup> )	
Alkaline Phosphatase (ALP)	

### Common biochemical tests affected by lipemic sample

Increased	Decreased
Total Bilirubin	Sodium (Na <sup>+</sup> )
Direct Bilirubin (BuBc)	Potassium (K <sup>+</sup> )
TIBC	Chloride (Cl <sup>-</sup> )
Magnesium (Mg <sup>++</sup> )	Bicarbonate (HCO <sub>3</sub> <sup>-</sup> )
	Lactate Dehydrogenase (LDH)



### Common biochemical tests affected by icteric sample

Increased	Decreased
Magnesium (Mg <sup>++</sup> )	Cholesterol
	Triglyceride
	Creatinine
	Total Protein
	Uric Acid
	GGT

Ref - <https://laboratoryinfo.com/tests-affected-hemolyzed-lipemic-icteric-samples-mechanism/>

# Challenges with electrolyte measurements

## Direct ISE Vs Indirect ISE

- Electrolyte disorders are common in hospital populations across a broad spectrum of patients (from asymptomatic to critically ill) and associated with increased morbidity and mortality
- The incidence of electrolyte disorders is nearly 25% in ICU patients where serum sodium and potassium levels are significant predictors of mortality.
- Prompt and complete correction of electrolyte disorders in ICU patients is vitally important which requires rapid TAT and accuracy.
- Hemolysis which is common in hospitalized/ ED patients impacts electrolyte results.
- Inaccuracies in electrolyte values are common in patients with abnormal levels of lipids and proteins. Abnormal levels of lipids and proteins are commonly seen in –
  - Patients with Diabetes Mellitus
  - Critically ill and ICU patients
  - Oncology patients
  - Obesity with hypertriglyceridemia and/ hypercholesterolemia

*Direct ISE is highly recommended over indirect ISE in such cases. However, most of the high throughput auto-analyzers offer indirect ISE for electrolyte measurement.<sup>1,2</sup>*

1 - R.A. Sulaiman, P.J. Twomey, R. Gama. Mitigation and detection of spurious potassium and sodium results Clinica Chimica Acta 412 (2011) 1–6. 2 - Fundamentals of Clinical Chemistry 3rd Edition. NW Tietz, pg. 620

# Water Issues: Role of Water in Clinical Chemistry Analyser

## Critical in performance

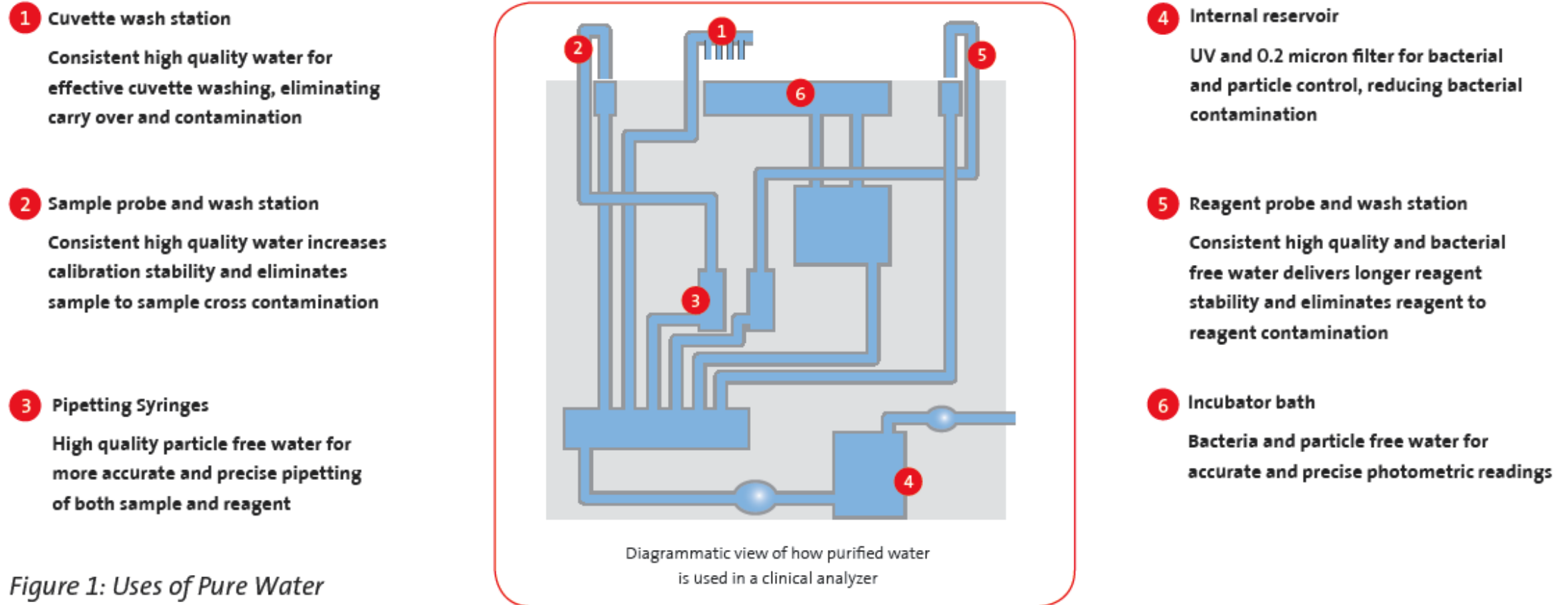


Figure 1: Uses of Pure Water

Pure Water for the Modern Clinical Laboratory; [www.elgalabwater.com](http://www.elgalabwater.com)



# Common Assays Affected by Water Quality

## Performance Impact

Clinical Test	Interferent present in water	Water purity parameter affected
Total Calcium	Oxalate, Sulphate, Calcium	Resistivity, TOC Resistivity
Alkaline Phosphatase	Fluoride, Phosphate, Zinc Manganese, Arsenate EDTA Bacteria Endotoxin	Resistivity Resistivity Resistivity, TOC TVC Endotoxin
Creatine Kinase (CK)	Oxidizing agents	Resistivity, TOC
Amylase	Oxalate, Citrate and EDTA	Resistivity, TOC
Lactate Dehydrogenase	Urea	TOC
Phosphorous	Citrate and Oxalate	Resistivity, TOC
Urea Nitrogen	Citrate	Resistivity, TOC
Iron	EDTA, Oxalate Fluoride	Resistivity, TOC Resistivity
Triglycerides	Glycerol	TOC
LDH	Hydrogen Peroxide	(Resistivity) Specific test
Peroxidase-based reactions	Hydrogen Peroxide	(Resistivity) Specific test

Table 2: Examples of Chemical Interferences

Pure Water for the Modern Clinical Laboratory; [www.elgalabwater.com](http://www.elgalabwater.com)

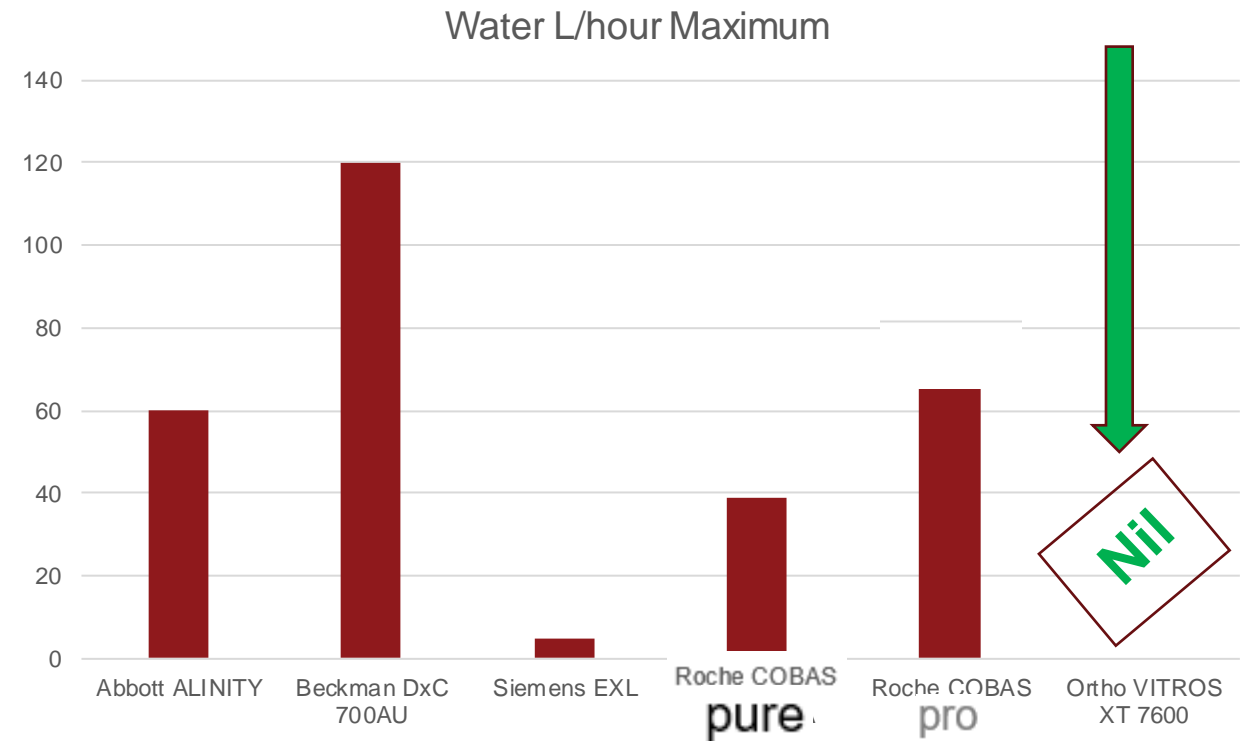
# Productivity for Today and Tomorrow

## Emergency Preparedness

### No distilled water costs/contamination

See the following for documentation :

- [The Critical Role of Water Quality in Lab Performance](#)
- [ELGA PURE LABWATER Guide](#)
- [CLSI Guideline GP 40: Preparation and Testing of Reagent Water in the Clinical Laboratory](#)



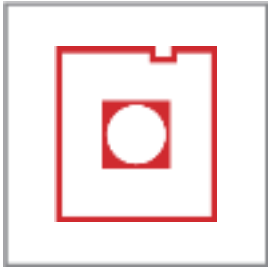
JCAHO regulations EC4.11-EC 4.20 states that a hospital must have a plan for the first 96 hours of an emergency. To serve your patient population in emergencies and maintain ER services at your hospital lab must be operational, including full availability of your water system.

# Technological Advancements To Ensure Lab Performance

Eliminating Errors

# The result of quality

VITROS® Systems are built on proven & proprietary technologies  
....& enhance these technologies



MicroSlide

Digital detection enables commonly requested tests to be paired on ONE slide, while maintaining the proven quality and accuracy of our proprietary dry slide technology.



MicroWell



MicroTip



MicroSensor



Intellicheck®

Digital detection deliver benefits to our other technologies, and helps make the VITROS® XT System\*\* more:

- Productive\*\*\*
- Efficient \*\*\*
- Reliable\*\*\*\*

\*\*\*DATA GENERATED THROUGH VITROS SIMULATOR, E10108-PRD-413

\*\*\*\*[http://cool.conservation-us.org/byorg/us-doe/lifetime\\_white\\_leds\\_aug16\\_r1.pdf](http://cool.conservation-us.org/byorg/us-doe/lifetime_white_leds_aug16_r1.pdf)

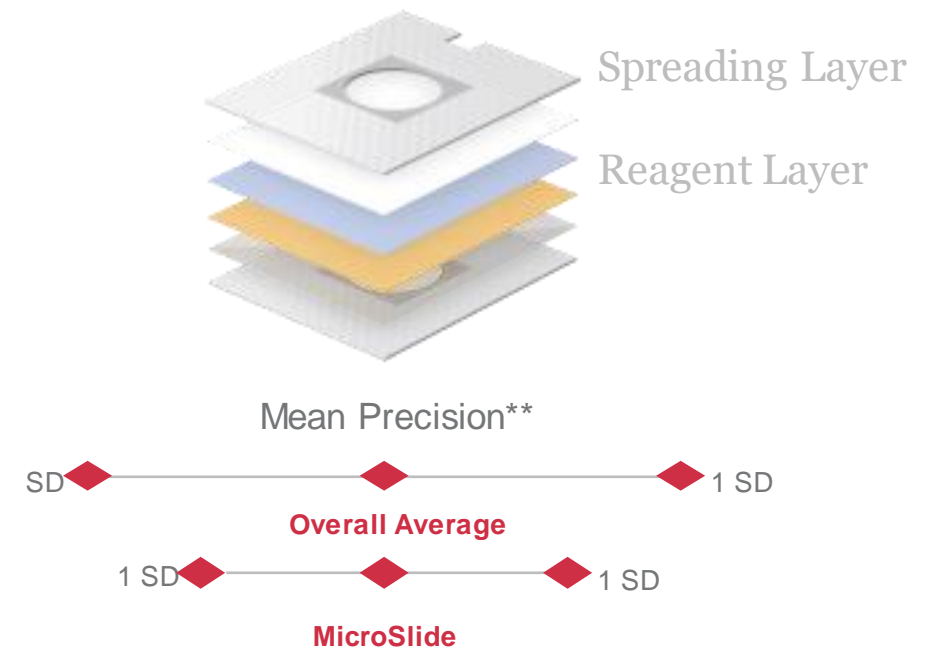
# The result of quality



## VITROS® MicroSlide: delivering trusted chemistry results

### Spreading layer traps selected interferences\*

- Spreads the sample uniformly
- Acts as a reflective surface during reading
- Can minimize interference from endogenous substances such as lipids, bilirubin, hemoglobin and drugs

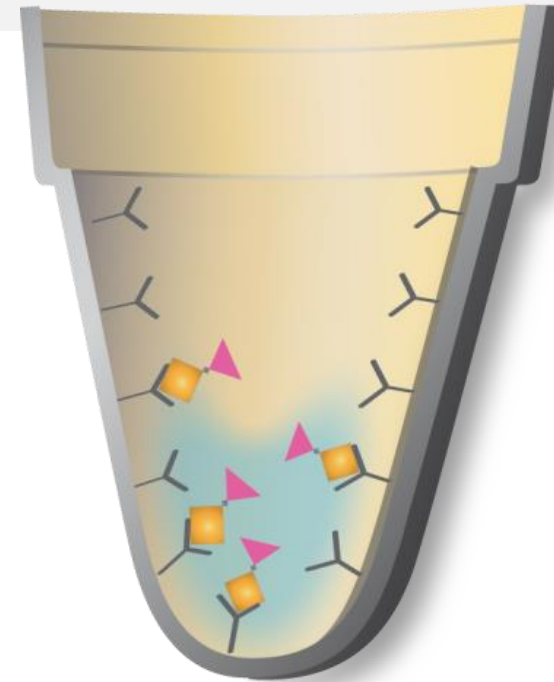


# The result of quality



## VITROS® MicroWell: Exceptional immunoassay precision and accuracy\* on VITROS® XT 5600 Integrated System

- Excellent assay sensitivity and precision
- Capability for small sample volumes
- Minimal waste
- Include Enhanced Chemiluminescence Detection
  - Improved light signal output, even at low analyte concentrations, for better detection\*
  - Broad dynamic range



\* Compared to direct and other indirect chemiluminescence methods

1. Summers M, Booth T, Brockas H, et al. Luminogenic reagent using 3-chloro 4-hydroxy acetanilide to enhance peroxidase/luminol chemiluminescence. Clin Chem. 1995;41:S73.

2. Thorpe GH, Kricka LJ, Moseley SB, Whitehead P. Phenols as enhancers of the chemiluminescent horseradish peroxidase-luminol-hydrogen peroxide reaction: application in luminescence-monitored enzyme immunoassays. Clin Chem. 1985;31(8):1335-1341.

\*\*Product not available for sale in all countries.



# The result of quality



## VITROS® MicroTip: providing high quality results in diverse patient settings\* on VITROS® 5600 Integrated System\*\*\*

- Liquid, **ready-to-use reagents** - no preparation\*\*
- Refrigerated storage maximizes on-system **stability**
- Reagent packs are **automatically opened and closed**
  - Limits contamination, evaporation, and reagent cross-contamination or carryover
  - Enhances reagent and calibration stability

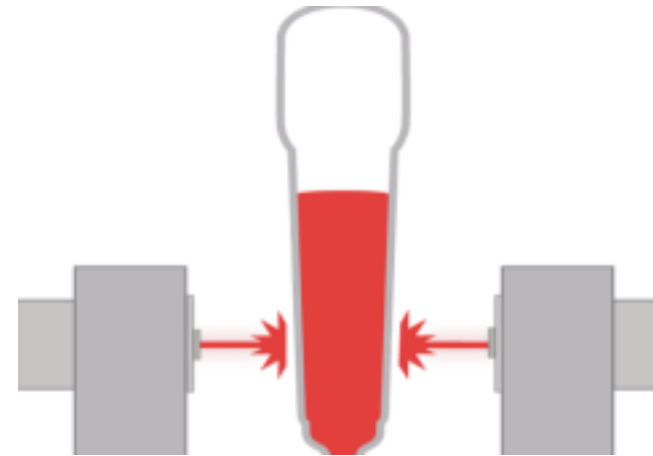


# The result of quality



## VITROS® MicroSensor: Detects endogenous interferences\*

- Fiber-optic wavelength scan of sample
- Detects and flags results affected by hemolysis, icterus, and turbidity
- No reagent or additional sample volume requirements
- Analysis time of <1 second
- No impact on system workflow or result turnaround time\*



*Cost-effective reporting without impacting workflow*

# The result of quality



## VITROS® INTELLICHECK®: Accurate and efficient result reporting

- IntelliReport™ provides full traceability, operator notification, and real-time exception documentation
- SMART Metering featuring single-use tips and Save-the-Sample Clot Detection Management and bubble detection to avoid reporting erroneous interferences
- Integrated process control that verifies the integrity of the sample processed and results reported
- VITROS® Intellicheck outputs MicroSensor results in report



*Proprietary technology provides unique results integrity*

# The result of quality

## Metering

- VersaTip eliminates carryover
- No fixed probes - No probe maintenance
- Pressure transducer ensures sample & result integrity
- Save-the-Sample Clot Management
- Deep tube sampling



# VITROS® Integrated Immunoassay and Chemistry Systems addressing laboratory testing needs

## Efficiency

Solutions that meet your operational and cost efficiency objectives

## Confidence

Confidence in the accuracy and treatment impact of results you deliver

## Reliability

A system you can rely on to be ready to deliver accurate results when you need them

## Ownership

Fully supported and worry free



VITROS® XT 7600  
Integrated System



VITROS® 5600  
Integrated System



VITROS® 3600  
Immunodiagnostic  
System



VITROS® 4600  
Chemistry System



VITROS® XT 3400  
Chemistry System



## Superior Reagent Efficiency

=====

96% Efficiency incl. ISEs , consumables

96.5% Other items

(Calibration - 0.1%, Q.C. - 2.9%. Re-test-0.5%)

## Low Sample Volume

=====

MicroSlide : 2.7 ~ 11µl

MicroWell: 10 ~ 80 µl

MicroTip : 2 ~ 16.7µL

## Short TAT

=====

ISE s : ~ 2.5Min / Routines : ~ 5Min

Special Proteins : ~ 9Min

MicroTips : ~ 8 – 16Min

# Technology harnessed

## Smart automation: driving your workflow efficiency

### The key characteristics of VITROS® Automation Solutions:

The VITROS® Systems enhance our smart automation offering by increasing possible configurations and possibly reducing capital requirements, which:

- Relieve the pressure on your staff
- Make efficiency gains throughout the lab
- Focus on the tasks where you make your impact





# The total solution

What powers your lab?

Ortho Care™

The value of service

Menu

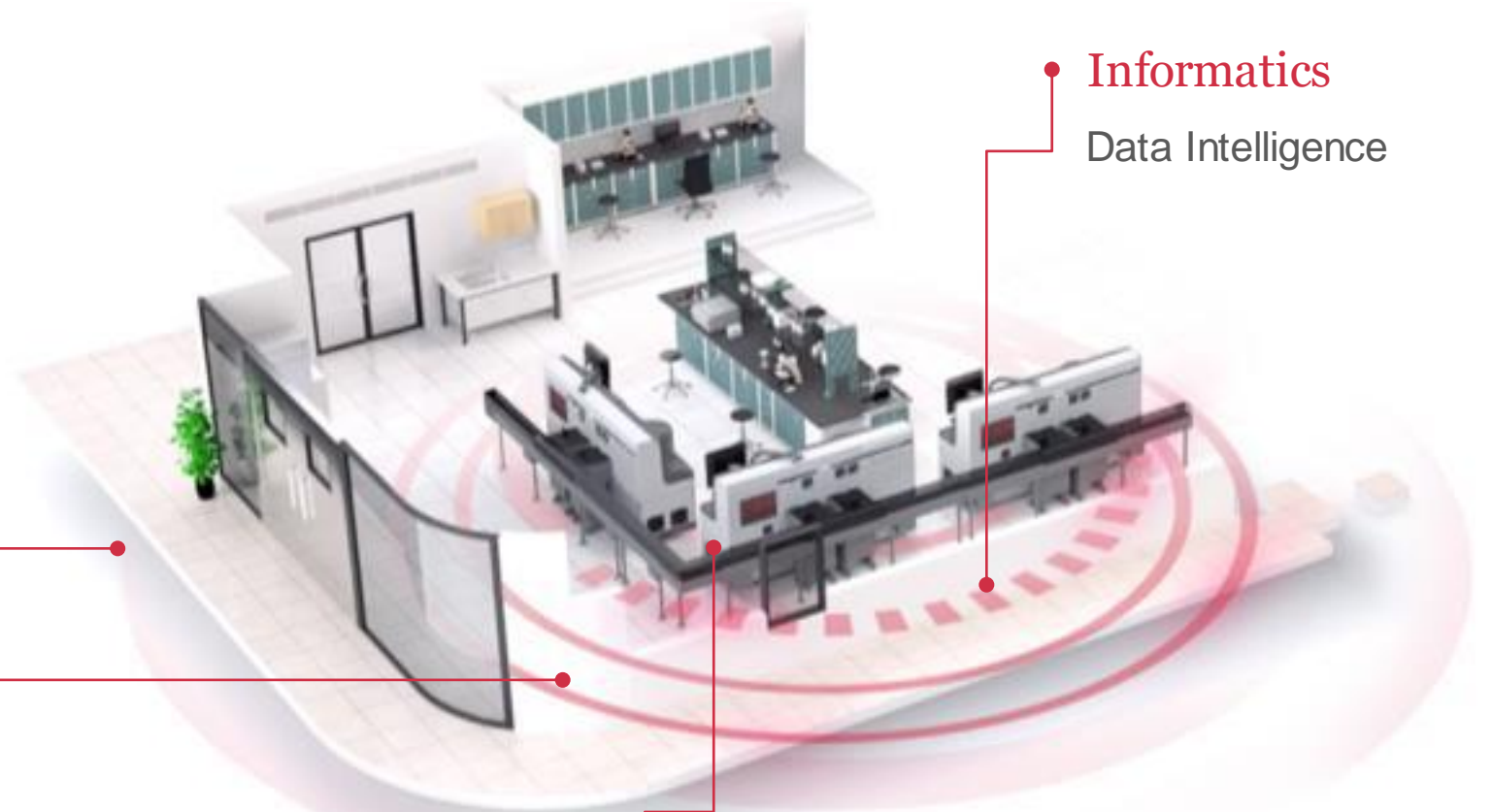
Key assays for  
critical disease  
states

VITROS® Automation Solutions

Optimize your process

Informatics

Data Intelligence



# The total solution



## Ortho Care™: The value of service

Will my analyzer be ready whenever I need it?

How quickly will I be able to solve an issue?

Is my lab achieving all it can?

How can you help me manage my inventory?

How can Ortho help me and my staff be better?



# Clinical Chemistry Assays

## Ortho Assays

Sr. No.	LFT
1	ALT
2	AST
3	ALP
4	Albumin
5	Total Protein
6	Bilirubin Total
7	Bilirubin Direct
8	GGT
9	LDH

Sr. No.	KFT
10	Urea
11	Calcium
12	Creatinine
	Chloride
	Sodium
	Potassium

Sr. No.	Lipids
13	Tg
14	Chol
15	HDL
16	LDL
17	APO A1
18	APO B
19	LP a

Sr. No.	Others Routine
20	Glucose
21	HbA1c
22	Iron
23	MG
24	Phosphorus
25	TIBC/UIBC
26	Uric Acid
27	CRP
28	RF
29	Amylase
30	Cholinesterase
31	CK-NAC
32	CK-MB
33	Lipase
34	Micro Albumin
35	Micro Protien
36	D Dimer
37	Lactate
38	Ammonia
39	Hs CRP
40	CO2 (Bicarbonate)

Sr. No.	Others 2
41	Carbamazepine
42	Phenobarbital
43	Valproic Acid
44	Lithium
45	ASO
46	C3
47	C4
48	IgA
49	IgG
50	IgM
51	Transferrin
52	Lithium (Li)

Sr. No.	Others 3
53	Alpha-1-Antitrypsin (AAT)
54	Haptoglobin (HPT)
55	Prealbumin (pALB)
56	Amphetamine (AMPH)
57	Barbiturates (BARB)
58	Benzodiazepines (BENZ)
59	Cannabinoid (THC)
60	Cocaine Metabolite (COCM)
61	Methadone (METD)
62	Opiate (OP)
63	Phencyclidine (PCP)
64	Caffeine (CAFFN)
65	Gentamicin (GENT)
66	Tobramycin (TOBRA)
67	Vancomycin (VANC)
68	Acetaminophen (ACET)
69	Digoxin (DIGXN)
70	Phenytoin (PHYT)
71	Salicylate (SALI)
72	Theophylline (THEO)
73	Theophylline (THEO)
74	Phenobarbital (PHBR)

74 Assays

# Immuno Assays

## Ortho Assays

THYROID
Free T3 (FT3)
Free T4 (FT4)
T3 Uptake (T3U)
Total T3 (TT3)
Total T4 (TT4)
TSH
Intact PTH (iPTH)

REPRODUCTIVE ENDOCRINOLOGY
AFP
Estradiol (E2)
FSH
LH
Progesterone (PROG)
Prolactin (PROL)
Testosterone (TESTO)
Total $\beta$ -hCG II (B-hCG)

ANAEMIA
Ferritin (FERR)
Folate 1/2 (FOL)
Red Cell Folate (RCFOL)
Vitamin B12 1/2 (B12)
Vitamin B12/Folate 3

BONE
NTx
25-OH Vitamin D (tVITD)

SEPSIS
Procalcitonin (PCT)

CARDIAC
CK-MB
Myoglobin (MYOG)
NT-ProBNP II (NTBNP)
Troponin I ES (TROPI)
High-Sensitive Troponin I (hsTROPI)

RENAL
Nephrocheck (TIMP-2 & IGFBP-7) (NCHECK)

ONCOLOGY
CA 125 II™ (CA125)
CA 15-3™ (CA15-3)
CA 9-9™ (CA19-9)
CEA
Total PSA II (tPSA)
Free PSA (fPSA)

DIABETES
Insulin (INS)
C-Peptide (C-PEP)

OTHER TESTS
Anti HAV IgM (HAVM)
Anti-HAV Total (HAVT)
Anti-HBc (aHBc)
Anti-HBc IgM (HBcM)
Anti-HBe (aHBe)
Anti-HBs (aHBs)
Anti-HCV (aHCV)
Anti-HIV 1+2 (aHIV)
HIV Combo (HIVc)
CMV IgG (CMVG)
CMV IgM (CMVM)
HBeAg
HBsAg
HBsAg ES (HBsAg)
HBsAg ES Confirmatory Kit (HBCon)
Rubella IgG (RUBG)
Rubella IgM (RUBM)
Syphilis TPS (SYPH)
Toxoplasma IgG (TOXG)
Toxoplasma IgM (TOXM)
Anti-SARS-Cov-2 IgG
Anti-SARS-Cov-2 IgG Version 2
Anti-SARS-CoV-2 Total
Anti-SARS-CoV-2 Total Version 2
SARS-CoV-2 Antigen
IL-6
Cortisol (CORT) 100 Wells

64 Assays

Ortho Clinical Diagnostics

Because Every Test Is A Life™

**Commercial  
Efficiency**

# Commercial Efficiency

## Understanding of cost

### ■ Tangible Costs –

- **Labour cost** – Evaluation of labor cost for non-value-added activity
- **Cost of space** – Bigger footprint of analyzer and space required for water plant, water tank, plumbing, drainage and other accessories
- **Cost of reagents and consumables** – Calculation of all the items required to run a test, it's beyond only reagent
- **Cost of water and biomedical waste management** – Cost of water, purification system, plumbing, water and biomedical waste management

### ■ Intangible Costs –

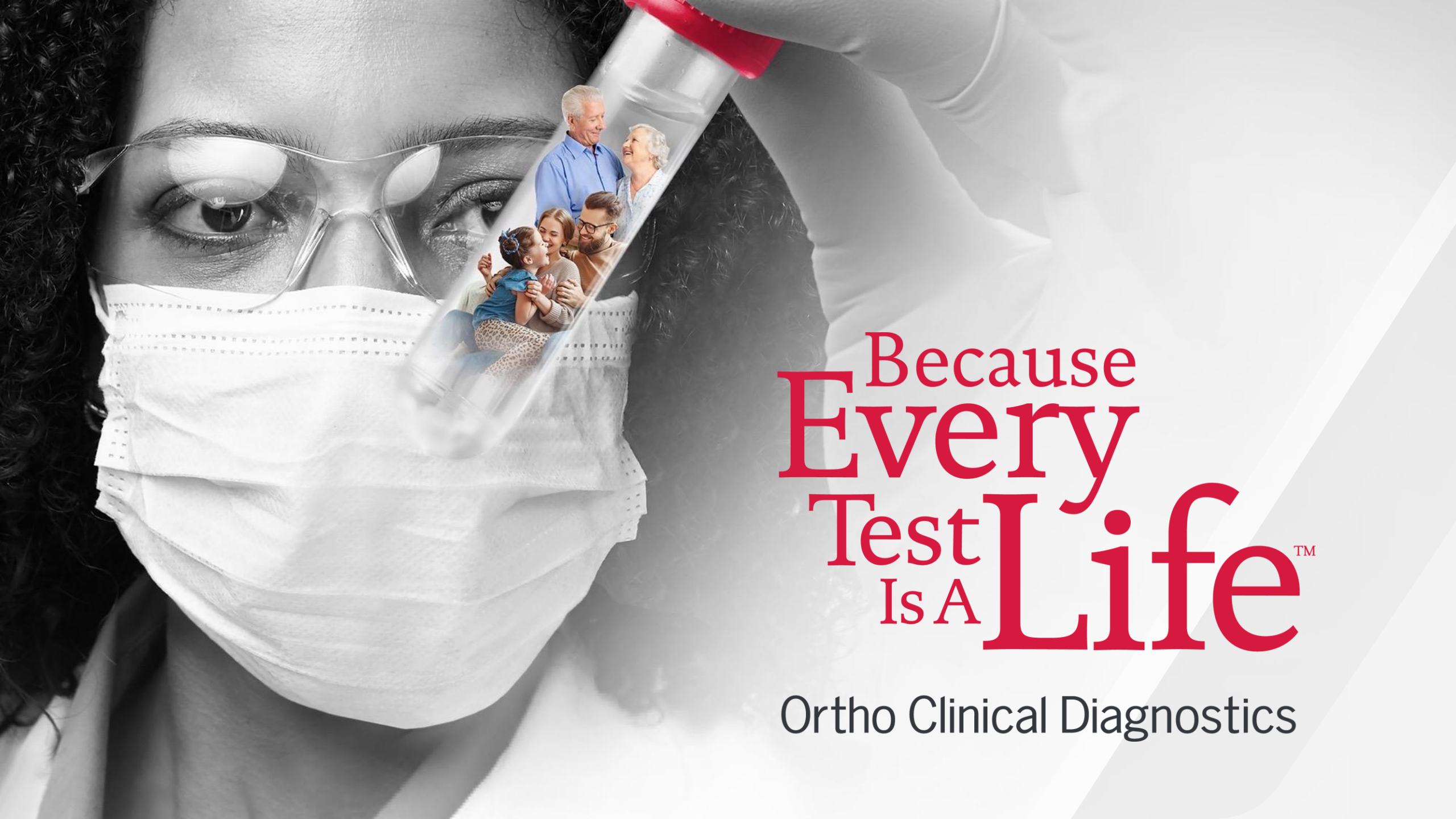
- **Cost of Non-productive time of analyzer** – During maintenance, Breakdown, Service, Calibration, QC, Stand by etc.
- **Cost of TAT impact** – FPY and 24/7 analyzer availability
- **Result Quality** – Impact of a wrong result or % of tests require review, repeat, rerun etc.



# Commercial effectiveness

## Ortho's unique capability

- **Industry leading First Pass Yield (FPY)** – Higher 1<sup>st</sup> time reportable result ensure lower manual intervention, reruns, repeats and improve productivity
- **Reagent efficiency:** Industry leading Reagent efficiency
- **Pack-size:** Smaller pack-size ensure minimal wastage and more tests can be performed in-house without wastage
- **Excellent calibration stability** – maximum utilization of reagents for patient sample testing
- **Higher on-board stability of the reagents** – Utilization without wastage specially for IA parameters
- **Analyzer time for patient sample testing** – Low maintenance, no standby time, less time spend for calibration, more assay on board etc. ensure better availability of analyzer for patient sample testing
- **Manpower utilization** – Less time spend of skilled manpower on analyzer maintenance, water quality check, calibration, troubleshooting on results require review etc.



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**Every**  
Test  
Is A **Life**<sup>TM</sup>

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# Ortho Clinical Diagnostics

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