



Table of contents

Introduction to Vitros Systems	4
Six Sigma	5
VITROS technologies	6
VITROS MicroSlide Technology	7
Bone health	8
Cardiac	C
Clinical chemistry	1C
Diabetes	11
Drugs of abuse / monitoring	12
Reproductive endocrinology	13
Infectious disease	14-15
Sepsis	16
Thyroid	17
VITROS systems	18
References	19



Quality assays deliver quality results

VITROS MicroSlide and MicroWell technologies enable high precision and are robust to common interferences that impact quality

We say that tests deliver "results." That sounds like an ending, but it's not. It's just the beginning.

When your lab delivers results: information is shared that will change lives. The results and the intelligence they provide help set the trajectory for the most appropriate diagnostic and treatment decisions that impact patients, families, and communities. There are consequences across your institution, too for staffing, for efficiency, for quality measures, for reimbursement, and more.

VITROS solutions are intentionally designed to deliver quality results so you are prepared to meet the challenges you face every day in your lab, including staffing, workflow, and rising costs. Our solutions empower you to focus on what matters most - patient care.

"Intelligent technology and patient-focused design deliver world-class quality and precision"

- Six Sigma Quality Design and Control, SECOND EDITION

Our menu covers over 90% of menu needs and 99% of the testing volume for typical labs with:

- More than 150 VITROS assays
- Broad, accessible menu onboard at all times
- Standardized reagents and operating interface across all VITROS platforms
- Twenty user-defined chemistry channels provide menu flexibility for MicroTip assays

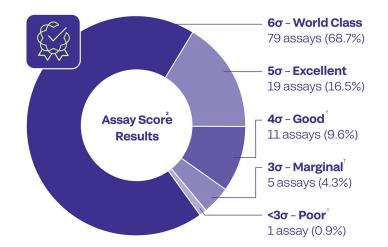


of all Vitros assays are designated World-Class or Excellent as defined by Six Sigma - the most in the industry²

A novel approach for automatically assessing laboratory Sigma metrics for a broad range of VITROS assays

Sigma metrics have been adapted for the clinical laboratory to incorporate observed accuracy, precision, and total error allowed.

Calculating Sigma metrics for assays can indicate product performance - the higher the Sigma level, the better the performance.



Confidence in your results

- Alignment to proficiency testing standards, including CLIA 2024
- Reduced material cost from fewer quality control (QC) repeats due to improved precision
- Reduced burden on and need for highly skilled lab staff to troubleshoot QC outliers
- Can run QC less often if following the Westgard Sigma QC protocols
- Fewer complaints from physicians requesting retests
- More potential for continuous improvement

QuidelOrtho big data starts with E-Connectivity® **Technology**

- Vitros systems connect to the cloud to provide anonymized patient data instrument log files, and quality control results
- Data is available for thousands of Vitros systems and billions of test results

The scale of the analysis



Countries





Months³

2,150

Vitros systems



VITROS models



Quality systems from start to finish

VITROS systems enable ongoing automated quality checks from sample quality and system processing steps through final results without additional consumables or impact to turnaround time

Your world is changing

Laboratories face unprecedented challenges: demographic changes, increasing testing volume, budgetary pressures, evolving regulatory requirements and staff training issues. Go beyond the reliable delivery of test results and demand more reliable, consistent solutions that enhance patient care decisions through:

- · Giving clinicians the confidence to make critical patient care decisions
- · Helping meet and exceed expectations for consistently on-time results
- · Simplifying your lab to easily meet operational goals
- · Delivering the reliability to be ready to go when you need it
- · Providing the savings and predictability to empower your financial success
- · Efficient solutions reduce staff time and overall costs
- Lean processes power quality results: 96.5% of test on the VITROS systems deliver results the first time without the need for repeat testing¹



Intelligent technologies power up performance



VITROS MicroSlide

Dry-slide format MicroSlide enables robust performance, filters out common interferences and provides industry-leading calibration stability of up to six months.⁴



XT MicroSlide

By placing two tests on one slide, 12 of the most common tests can be carried out on just six VITROS XT MicroSlides, doubling the testing output¹ per slide, increasing productivity and fulfilling more requests from difficult draws.



MicroWell

Our proprietary, enhanced chemiluminescence detection technology provides exceptional immunoassay precision for wide dynamic ranges across a broad test menu and disease states.



MicroTip

Provides special chemistry menu offerings and user-defined assays without the cost, maintenance, carryover, and contamination risks of traditional water-based systems.



Intellicheck® Technology

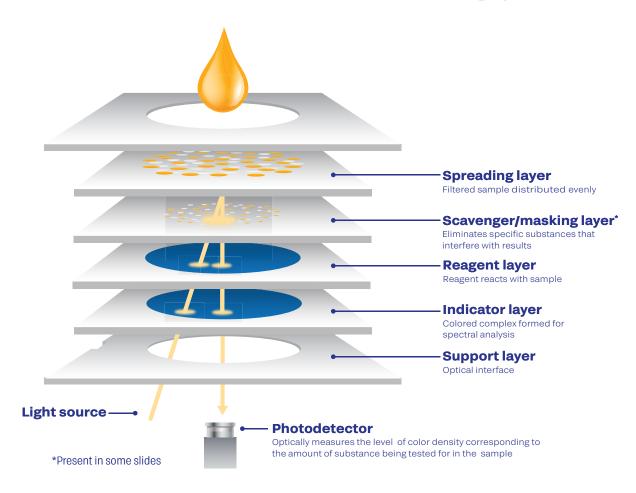
VITROS Intellicheck technology with Smart Metering automatically checks for clots and bubbles and reports on diagnostic checks throughout the testing process, limiting manual intervention.



MicroSensor

Our MicroSensor technology automates detection of HIT interferences on every sample in less than one second, without the use of any additional sample or reagent.

MicroSlide technology



Trusted solutions

- The unique design of VITROS MicroSlide and XT MicroSlide minimizes the impact of endogenous and exogenous interfering substances that could impact the quality of assay results
- The MicroSlide spreading layer's unique and proprietary technology eliminates monoclonal/paraprotein and heterophilic antibody interference, which have been documented in several competitor's analyzers in journal articles^{5,6}

Quality results

 Eliminates carryover associated with reagent probe and incomplete washing from one assay to another with the use of disposable tips and disposable cuvettes

Productivity

- Enables consistent and efficient delivery of accurate and reliable results while simplifying your lab workflow
- XT MicroSlide speeds the time to first result for key stat assays with a 6.0-minute Basic Metabolic Profile (BMP) and a 7.5-minute Comprehensive Metabolic Profile (CMP). These times are among the fastest in the industry. CAP Today July 2019 Product Summary

VITROS direct ISEs7-11

- Direct potentiometry methods report results with more physiologically correct values than indirect potentiometry or flame photometry
- Direct methods do not dilute serum samples and are not impacted by the electrolyte exclusion effect as seen in patients with high lipid and protein concentrations
- VITROS direct ISEs are single-use electrodes, eliminating any risk of drift due to high lipid or protein concentrations





Bone health



Focused experience on bone health diagnostics

The VITROS menu of bone metabolism assays helps clinicians better manage bone disease for improved patient outcomes.

VITROS Vitamin D Assay ¹²		Sample 25- OH Vitamin D concentration		Mean 25-OH Vitamin D result of cross- reactant pool		
Compound	Concentration	ng/mL	nmol/L	ng/mL	nmol/L	% Cross- reactivity
Vitamin D ₂ (Ergocalciferol)	100 ng/mL	8.81	22.0	9.77	24.4	1.0
Vitamin D ₃ (Cholecalciferol)	100 ng/mL	8.81	22.0	9.66	24.2	0.9
25-OH Vitamin D ₂	100 ng/mL	8.10	20.3	113	283	104.9
25-OH Vitamin D ₃	100 ng/mL	8.10	20.3	107	268	98.9
1,25 (OH)2 Vitamin D ₂	0.2 ng/mL	8.81	22.0	10.1	25.3	>100
1,25 (OH)2 Vitamin D ₂	0.2 ng/mL	26.8	67.0	28.5	71.3	>100
1,25 (OH)2 Vitamin D ₃	0.2 ng/mL	8.10	20.3	8.09	20.2	-5.0
24,25 (OH)2 Vitamin D ₂	10 ng/mL	26.8	67.0	30.2	75.5	34.3
24,25 (OH)2 Vitamin D ₃	10 ng/mL	7.92	19.8	11.4	28.5	34.8
3-epi 25-OH Vitamin D ₃	100 ng/mL	7.92	19.8	45.3	113	37.4

Excellent overall design

VITROS assay design delivers a clinically useful

- Equimolar detection of both vitamin D₂ and vitamin D₃ means more accurate results key for monitoring patients in prescription D therapy¹⁻³
- VITROS monoclonal assay design delivers better specificity for more accurate results¹⁻³

Calibration simplicity

VITROS MicroWell assay architecture delivers

- Two-level liquid in duplicate versus 6 levels in up to quadruplicate
- Extended calibration and reagents stability provides improved efficiency for the laboratory

Sample and reagent handling simplicity

VITROS Vitamin D assay is easier to use.

- · One-step assay no sample pretreatment
- No need to inspect samples for clots or bubbles

Equimolar detection of both D2 and D3¹²

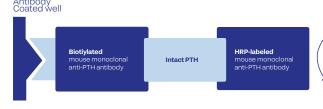
Allows for a complete total vitamin D measurement.

VITROS iPTH II Assay

World-class² assays built on our proprietary MicroWell technology, delivering accurate results necessary to expedite diagnosis and treatment decisions

- · Long calibration time up to 56 days
- · Follows world-class Six Sigma methodology
- · It has an intraoperative claim
 - · Rapid time to reporting (18 minute time to first result)
- · Supports testing of patients with chronic kidney disease
- · Excellent precision and sensitivity

Reaction Scheme



 Eliminated biotin interference, ensuring confidence in patient results (iPTH II improvement from previous assay)

VITROS bone health assay menu ¹²			
AlkPhos	NTx		
Calcium	Phosphorous		
iPTH II	Vit D		

Cardiac



Exceptional assay performance for critical treatment decisions

Rely on the VITROS system to deliver sensitivity, accuracy, and reliability with a menu of cardiac assays on one fully automated random-access system.

VITROS Troponin I ES Assay

Improved assay sensitivity and precision delivers reliable short-term and long-term risk information for patients with acute coronary syndrome and supports single-sample testing with serum/plasma equivalence.

- Guideline-acceptable precision. Meets ACC/ESC guidelines for acceptable imprecision in a high sensitivity assay (≤10% coefficient of variation at the 99th percentile)
- Analyzer-automated sample indices help ensure that actionable results are reported



VITROS NT-proBNP II Assay

Provides confidence to physicians for the diagnosis of heart failure, improving patient care. Enables consolidated cardiac testing on one fully automated, random-access system.

Adopted in clinical practice guidelines and included in ESC/ACC/AHA practice guidelines.

- · ICON age-specific cutoffs first to market in the U.S.
- Excellent NPV for confident rule-out 15-minute turnaround time
- · Long calibration interval (70 days)
- Excellent correlation to competitive assay (Roche)43
- Excellent correlation between VITROS NT-proBNP and VITROS NT-proBNP II assays⁴³
- · No biotin interference

VITROS cardiac assay menu ¹²	
Apolipoprotein A1	hsCRP
Apolipoprotein B	LDH
Cholesterol	Myoglobin
CKMB (Activity)	NT-proBNP
CKMB (Mass)	СК
Direct HDL	Triglycerides
Direct LDL	Troponin I ES
Homocysteine	

Clinical chemistry



Delivering accurate and precise results for your patients

With the fully automated VITROS systems, your lab can feel confident that it is delivering accurate, reliable results across a range of clinical conditions and patient populations.

VITROS electrolytes (Na+, Cl-, and K+)

Direct ISEs with accurate results even when faced with challenges such as dilutions, interferents or presence of abnormal proteins or elevated lipids - with lower overall costs.

- Diabetes¹⁶
- Hypercholesterolemia¹⁸
- Dehydration¹⁷
- Multiple Myeloma¹⁹

VITROS BuBc Assay

The Vitros BuBc assay is a unique assay that directly measures the unconjugated and conjugated bilirubin fractions in comparison with calculated indirect bilirubin values available in the market.

Small sample volume and less impact of hemolysis, lipemia and paraprotein interference due to the asking and spreading layers in the BuBc slide makes it ideal for testing **BOTH ADULTS AND PEDIATRIC SAMPLES**.

VITROS clinical chemistry	/ assay menu¹²
VITROS BuBc assay	VITROS electrolytes

Product availability subject to local regulatory requirements



Diabetes



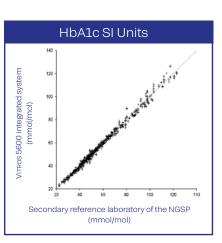
We take diabetes personally

Every patient depends on reliable diagnostic tests to improve outcomes over the course of this lifelong condition. QuidelOrtho is dedicated to diabetes care, providing a comprehensive menu of assays on the trusted VITROS systems.

VITROS HbA1c Assay

QuidelOrtho optimizes our assay design around performance that matters.

- The Vitros HbA1c assay is robust against interference from hemoglobin variants C, D, E, and S. Anti-HbA1c antibodies used in the assay do not cross-react with HbA0, HbA1a, or HbA1b. The assay is unaffected by the presence of acetylated hemoglobin, carbamylated hemoglobin, and labile glycated hemoglobin
- · High-quality results with traceability to NGSP and IFCC standards
- · The QuidelOrtho Vitros HbA1c assay has a diabetes diagnostic claim
- Long calibration stability provides stable performance and minimizes workload to maintain performance



The Vitros HbA1c assay is certified by the National
Glycohemoglobin Standardization Program and is traceable to the
Diabetes Control and Complications Trial Reference Method

VITROS Immunodiagnostic Products: Insulin Assay

- Insulin level elevation is associated with obesity, Cushing's syndrome, acromegaly, insulinoma, administration of contraceptives, and the early stage of Type 2 diabetes
- Conditions associated with decreased insulin levels are Type 1 diabetes and chronic pancreatitis²¹
- The Vitros Insulin assay uses an antibody highly specific for insulin detection, which has insignificant or no cross-reactivity to insulin analogs commonly used in diabetes treatment

Vitros diabetes menu ¹⁵	
Beta-Hydroxybutyrate*	Glycated Serum Protein*
BUN/Urea	HbA1c
C-peptide	Insulin
Creatinine	Microalbumin
Glucose	

VITROS Immunodiagnostic Products: C-peptide Assay

- C-peptide is a preferred biomarker for assessing beta cell function in patients on insulin therapy²²
- Helps differentiate Type 1 diabetes from LADA (latent autoimmune diabetes) and type 2 diabetes²²
- Can aid in identifying patients with MODY (maturity onset diabetes of the young)²²

Product availability subject to local regulatory requirements.

^{*} MicroTip Partnership Assay (MPA); reagents and validated applications available directly from QuidelOrtho; product availability subject to third party's or their agent's capability to support the laboratories.

Drugs of abuse / monitoring



Patient testing

Therapeutic drug monitoring²³

Intended use: Quantitative determination of therapeutic drugs in human serum or plasma

- · Confirm adequacy of treatment
- Patient exhibits toxicity on anormal therapeutic drug monitoring dosage
- · Noncompliance is suspected
- · Drug-drug interaction is suspected
- · Changing dosage formulations
- · Patient is not responsive to treatment



VITROS therapeutic drug monitoring assay menu		
Amikacin*	Methotrexate*	
Caffeine	Phenobarbital	
Carbamazepine	Phenytoin	
Digoxin	Theophylline	
Gentamicin	Tobramycin	
Lithium	Valproic Acid	
	Vancomycin	

Drugs of abuse

	Illicit drugs	Prescription drugs
Reason for testing	Make sure patient is not taking drug	Compliance: confirm patient IS taking drug
Patient background	Patient may be a known drug abuser or is suspected of being on drugs (e.g., ER admittance, child custody cases, liability insurance claims)	Some patients will "pretend" they are in pain to obtain drugs to sell on the black market
Confirmation testing	Not all positive results are confirmed, especially if patient admits to the abuse	All positive results confirmed by mass spectrometry

VITROS drugs of abuse (urine) assay menu ¹²		
Amphetamines	Hydrocodone*	
Barbiturates	Methadone	
Benzodiazepines	Methadone Metabolite (EDDP)*	
Buprenorphine/Suboxone*	Opiates	
Cocaine Metabolites	Oxycodone*	
Ecstasy*	PCP	
Ethyl Glucuronide (ETG)* For criminal justice and forensic use only in the U.S.	Propoxyphene*	
Heroin Metabolite (6-AM)*	THC	
Fentanyl For criminal justice and forensic use only in the U.S.	Tricyclic antidepressants	

*MicroTip Partnership Assay (MPA); reagents and validated applications available directly from QuidelOrtho.

Reproductive endocrinology



Improve efficiency without compromising quality

VITROS systems deliver an unparalleled level of sensitivity and accuracy – limiting uncertainty and ensuring reliable patient outcomes.

VITROS Estradiol Assay

Sensitivity with broad dynamic range delivers the accuracy and turnaround times physicians depend on to track hormonal cycles and make treatment decisions.

The lab benefits from:

- · Wide dynamic ranges resulting in fewer dilutions
- Small sample volumes
- · Less operator intervention

Vitros β-hCG II Assay

Wide dynamic range and equivalent results in serum and plasma minimize dilutions, provide flexibility, and may improve turnaround time. Leading high-dose hook protection ensures the accuracy of results.

VITROS Progesterone Assay

Full random-access availability allows for fast turnaround, which is especially important for treatment decisions. Low-end sensitivity enables accurate tracking of hormonal cycles.



VITROS reproductive endocrinology assay menu ¹²		
Estradiol	Prolactin	
FSH	Testosterone	
LH	Total β-hCG II	
Progesterone		

Infectious disease



You deliver more than results. You deliver trust.

Offering a menu of high-performing assays to meet your hepatitis and HIV testing needs. These combine the MicroWell technology with the enhanced chemiluminescence detection technology that improves signal detection with outstanding precision. These technologies lead to assay performance valued by laboratories:

- · Highly sensitive and specific assay performance
- Exceptional separation between positive and negative results
- Confidence in assay performance is further enhanced by the MicroSensor and Intellicheck® technology available only on VITROS systems
- VersaTip technology is designed to eliminate carryover and cross contamination by using disposable tips
- · Streamlined workflow makes laboratories more efficient
- Low sample volume requirements
- Efficient testing algorithms eliminate repeat testing for most initial assay positive results²⁴

A comprehensive hepatitis panel

The fully automated VITROS systems support the hepatitis assays providing continuous random access with results reported in under 60 minutes. Reflex testing protocols enable positive results to be automatically retested on another clinically relevant test on the same system. When combined with proven VITROS technologies, labs can be confident in the results to provide appropriate patient care as soon as possible.



Infectious disease (continued)



Screening leads to diagnosis and treatment

The VITROS HIV Combo test provides early detection of acute HIV-1 infection²⁵ with class-leading²⁶ fourth-generation antigen sensitivity combined with uncompromised specificity.

VITROS HIV Combo Test

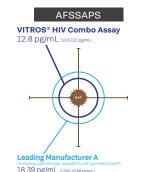
The VITROS HIV Combo, a fourth-generation test, detects HIV-1 infection earlier than third-generation tests.²⁶

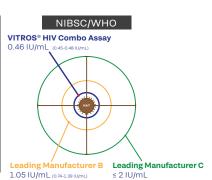
- In 2014, the CDC (Centers for Disease Control and Prevention) and the APHL (Association for Public Health Laboratories) updated recommendations to fourth-generation tests for initial HIV screening. ²⁶ Fourth-generation tests simultaneously detect HIV-1 and 2 IgM/IgG antibodies, as well as the p24 antigen. Compared with third-generation HIV tests, which only detect antibodies, p24 antigen detection allows fourth-generation assays to detect an acute HIV infection approximately seven to 11 days earlier^{26,27}
- Seroconversion panel data shows that VITROS HIV Combo test delivers even earlier detection than a leading fourth-generation test¹
- VITROS HIV Combo test became reactive earlier for six of 32 seroconversion panels (agreement for 25 of 32 panels) when compared with a leading commercially available fourth-generation Ag/Ab test²⁸

Sequence of apperance of laboratory markers for HIV - 1 infection 24 HIV RNA (plasma) HIV antibody HIV-1 p24 antigen HIV-1 p24 antigen Autibody Antibody detection Nucleic sold Antibody Antibody Antibody detection Himminosissiy Antibody detection Antibody detection Himminosissiy Himminosissiy Himminosissiy

Building trust with performance

- With class-leading²⁸ antigen sensitivity that doesn't sacrifice specificity
- VITROS HIV Combo test delivers the utmost confidence in results and can save costs, time, and labor in repeat and confirmatory testing²⁶





Not drawn to scale. NAT does not measure p24 antigen and is shown above for relative sensitivities only.

VITROS infectious disease assay menu ¹²			
Hepatitis	HIV	Other	
Anti-HAV IgM	Ani-HIV 1+2	Rubella IgG	
Anti-HAV Total	HIV Combo	Anti-SARS-CoV-2 IgG*	
Anti-HBc		Anti-SARS CoV-2 Total†	
Anti-HBc IgM		Anti-SARS-CoV Tot N‡	
Anti-HBe		Anti-SARS-CoV-2 IgG Quantitative‡	
HBeAg		SARS CoV-2 Antigen‡	
Anti-HBs		Syphilis	
Anti-HCV			
HBsAg			
HBsAg Confirmatory			

Sepsis



Thyroid



A beacon for better-informed decisions

VITROS B·R·A·H·M·S PCT Assay

VITROS B·R·A·H·M·S PCT assay is the timely and illuminating test that can help clinicians make better-informed antibiotic treatment decisions.

When used in combination with standard laboratory tests and clinical assessment, VITROS B-R-A-H-M-S PCT assay delivers the insightful information your physicians need with the rapidity with which they need it, enabling them to gain a clear understanding of the clinical scenario from diagnosis, through treatment, to resolution.²⁹⁻³² Being more informed, they can make appropriate decisions every step of the way – improving outcomes while reducing costs and antibiotic use.^{29-31, 33-35}

VITROS B·R·A·H·M·S PCT assay delivers:

- High analytical sensitivity and specificity¹²
- Delivering results the first time for 96.5% of tests without intervention or repeat testing, only on VITROS systems¹
- Analytical performance: LOD at 0.007 ng/mL, LOQ (20% CV, observed) at 0.013 ng/mL
- · Fast turnaround time: 24 minutes to first result

Procalcitonin is currently the best biomarker for early bacterial infection diagnosis and antibiotic stewardship^{33, 38-40}

Trust in results for laboratories:

- Reliability: Fulfill more requests from difficult draws with small sample volume (30µL)
- Accuracy: Trust your results through a quantification of endogenous interferences, hemolysis, icterus, and turbidity
- Efficiency: Maximize efficiency with long calibration intervals of 56 days

Confidence in decisions for clinicians:

- Early diagnosis of severe bacterial infections and sepsis³⁶⁻³⁸
- Therapeutic guidance for starting and safely stopping antibiotic treatment^{33,40}
- Excellent analytical correlation and clinical concordance to B-R-A-H-M-S method



Thyroid panel to meet clinical needs

VITROS systems offer a complement of thyroid assays delivering fast, accurate and reliable results to expedite diagnosis and treatment decisions.

The thyroid affects so many body systems, common symptoms considered in isolation can lead to misdiagnosis. Even when reviewing symptoms together, thyroid issues may still be unexplored. Quickly receiving an accurate diagnosis and treatment of thyroid disease will positively impact patient care and improve quality of life. QuidelOrtho offers world-class Six Sigma quality thyroid assays you can trust for your patients.



More accurate by design

FT4 assay is designed to be insensitive to protein binding capacity.

- VITROS FT4 assay does not include BSA, ensuring that equilibrium of free/bound hormone is maintained and the level of free hormones in the sample is not affected
- Published studies show no bias in populations such as pregnant women or critically ill, hospitalized patients with protein binding abnormalities⁴¹
- Insensitive to abnormal serum proteins (e.g., patients with cancer and pregnant populations)

VITROS thyroid assay menu ¹²		
FT3	TSH	
FT4	TT3 II	
T3 Uptake II	TT4	

Product availability subject to local regulatory requirements.

VITROS TSH and FT4 assays – part of a high-performing thyroid panel

- TSH, FT4 and all of the high-performing thyroid menu from QuidelOrtho are on the same platform
- · Predictable, trusted results

VITROS TSH assay provides decision confidence in diagnosing thyroid and/or pituitary disorders

Wide reportable range

- · Better precision than competitors at clinical decision points¹
- \cdot Reportable range covers the clinically relevant reference range



A broad portfolio of award-winning VITROS solutions for your clinical laboratory testing needs

Integrated

Chemistry

Immunodiagnostic



VITROS XT 7600



VITROS 5600



VITROS XT 3400



VITROS 4600



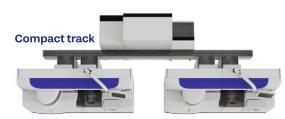
VITROS 3600



VITROS ECIQ

VITROS Duo or Duo+42 — designed to grow with your lab

Think of this as the beginning of your automation journey. As your lab grows, you can add modules and tracks to meet your needs. With the addition of automation, you will take advantage of the full Vitros solution, including integrated systems, quality assays and enabling technologies.

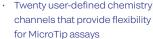


VITROS Duo or Duo+ What's the difference?

Duo+ configurations include an automated centrifuge.

Our extensive menu caters to more than 90% of testing requirements and encompasses 99% of the testing volume for standard laboratory operations, offering:

- More than 150 VITROS Assays
- · Broad, accessible menu on board at all times
- · Standardized reagents and operating interface across all VITROS platforms



Twenty user-defined chemistry

Contact your local QuidelOrtho representative for more information today!

References

- *The Vitros Anti-SARS-CoV-2 IgG test has been cleared by FDA, with De Novo grant. The test has been authorized only for the detection of IgG antibodies from SARS-CoV-2, not for any other viruses or pathogens and results should not be used as the sole basis for diagnosis.
- † The Vitros Anti-SARS-CoV-2 Total test has been cleared by FDA, with De Novo grant. The test has been authorized only for the detection of total antibodies from SARS-CoV-2, not for any other viruses or pathogens, and results should not be used as the sole basis for diagnosis.
- ‡ The Vitros-SARS-CoV-2 Antigen Assay, Vitros Anti-SARS-CoV-2 Total N and Vitros Anti-SARS-CoV-2 IgG Quant Antibody Tests have not been cleared or approved by the FDA. They have been authorized by the FDA under an Emergency Use Authorization (EUA) and testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate- or high-complexity tests. The VITROS antigen test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. The Vitros antibody tests have been authorized only for the detection of either total or IgG antibodies from SARS-CoV-2, not for any other viruses or pathogens, and results should not be used as the sole basis for diagnosis. These tests are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.
- Data on file. QuidelOrtho.
- 2. Per competitive Six Sigma published data. Data on file
- 4. Stability claim based on publicly available data for select competitive systems. Data on file.
- 5. Sheppard CA, Allen RC, Austin GE, Young AN, Ribeiro MA, Fantz CR. Paraprotein interference in automated chemistry analyzers. Clin Chem. 2005;51:1077-1078.
- 6. Dalal BI, Brigden ML. Factitious biochemical measurements resulting from hematologic conditions. Am J Clin Pathol. 2009;131(2):195-204.
- 7. Toffaletti J. Blood Gases and Electrolytes. AACC Press; 2001.
- 8. Oh MS. Pathogenesis and Diagnosis of Hyponatremia. Nephron. 2002;92(suppl 1):2-8.
- 9. Turchin A, Seifter JL, Seely EW. Clinical problem-solving. Mind the gap. N Engl J Med. 2003;349:1465-1469.
- 10. Aw TC, Kiechle FL. Pseudohyponatremia. Am J Emerg Med. 1985;3:236-239.
- 11. Estilo A, McCormick L, Rahman M. Using Tolvaptan to Treat Hyponatremia: Results from a Post-authorization Pharmacovigilance Study. Adv Ther. 2021;38(12):5721-5736.
- 12. Refer to individual instructions for use for additional information
- 13. Cavalier et al. Clin Chem Lab Med (2013); doi: 10.1515/cclm-2013-0138.
- 14. Kleerekoper M, et al. Clinical applications for vitamin D assays: what is known and what is wished for, Clin Chem. 2011; 57:1227. 3. Practical Laboratory Medicine 7 (2017); 27-35.
- 15. QuidelOrtho Instructions for Use
- 16. Liamis G. Liberopoulos E. Barkas F. Elisaf M. Diabetes mellitus and electrolyte disorders. World J Clin Cases. 2014:2(10):488-496.
- 17. Ashraf M, Rea R. Effect of dehydration on blood tests. Practical Diabetes. 2017;34(5):169-171. Doi: 10.1002/
- 18. Turchin A, Seifter JL, Seely EW. Clinical problem-solving. Mind the gap. N Engl J Med. 2003;349:1465-1469.
- 19. Lyon AW, Baskin LB. Pseudohyponatremia in a myeloma patient: direct electrode potentiometry is a method worth its salt. Laboratory Medicine. 2003; 5(34):357-360.
- 20. Refer to individual instructions for use for additional information
- 21. QuidelOrtho Instructions for Use Pub. No. GEM1430 EN WW Version 1.0.
- 22. QuidelOrtho: QuidelOrtho Instructions for Use Pub. No. GEM1440_EN_WW.
- 23. Thermo Scientific Reagent Training for VITROS® System Applications. PR-01710.
- 24. Refer to Instructions for Use for interpretation algorithm

- 25. VITROS® HIV Combo Instructions for Use, GEM1256 US EN, Version 1.0.
- 26. Centers for Disease Control and Prevention and Association of Public Health Laboratories, Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations. June 27, 2014. Accessed January 5, 2024. http://stacks.cdc.gov/view/cdc/23447
- 27. Mitchell EO, Stewart G, Bajzik O, Ferret M, Bensten C, Shriver MK. Performance comparison of the 4th generation Bio-Rad LaboratoriesGS HIV Combo Ag/Ab EIA on the EVOLISTMautomated system versus Abbott ARCHITECT HIV Ag/Ab Combo, Ortho Anti-HIV 1 + 2 EIA on Vitros ECi and Siemens HIV-1/0/2 enhanced on Advia Centaur. Journal of Clinical Virology 2013.
- 28. Based on NIBSC/AFSSAPS standards data from three other fourth generation manufacturers assay Instructions for Use.
- 29. Mewes JC, Pulia MS, Mansour MK, Broyles MR, Nguyen HB, Steuten LM. The cost impact of PCT-guided antibiotic stewardship versus usual care for hospitalised patients with suspected sepsis or lower respiratory tract infections in the US; A health economic model analysis, PLoS One, 2019;14(4):e0214222, doi:10.1371/ iournal.pone.0214222
- 30. Meisner M. Update on procalcitonin measurements. Ann Lab Med. 2014;34(4):263-273. doi:10.3343/ alm 2014 34 4 263
- 31. University of Nebraska Medical Center. Procalcitonin (PCT) guidance. Accessed November 19, 2021. https:// www.unmc.edu/intmed/divisions/id/asp/procal.html
- 32. Shiferaw B, Bekele E, Kumar K, Boutin A, Frieri M. The role of procalcitonin as a biomarker in sepsis. *J Infect* Dis Epidemiol. 2016;2:006. https://clinmedjournals.org/articles/jide/journal-of-infectious-diseasesandepidemiology-jide-2-006.pdf
- 33. Schuetz P, Christ-Crain M, Thomann R, et al. Effect of procalcitonin-based guidelines vs standard guidelines on antibiotic use in lower respiratory tract infections: the ProHOSP randomized controlled trial. JAMA. 2009;302(10):1059-1066. doi:10.1001/jama.2009.1297
- 34. Balk RA, Kadri SS, Cao Z, Robinson SB, Lipkin C, Bozzette SA. Effect of procalcitonin testing on health-care utilization and costs in critically ill patients in the United States. Chest. 2017;151(1):23-33. doi:10.1016/j.
- 35. Branche A, Neeser O, Mueller B, Schuetz P. Procalcitonin to guide antibiotic decision making. *Curr Opin* Infect Dis 2019:32(2):130-135 doi:10.1097/QC0.00000000000000522
- 36. Harbarth S, Holeckova K, Froidevaux C et al. Diagnostic value of procalcitonin, interleukin-6, and interlukin-8 in critically ill patients admitted with suspected sepsis. Am J Respir Crit Care Med. 2001;164:396-402.
- 37. Müller B. Becker K. Schächinger H et al. Calcitonin precursors are reliable markers of sepsis in a medical intensive care unit. Crit Care Med. 2000;28(4):977-983.
- 38. Brunkhorst FM, Wegscheider K, Forycki ZF, et al. Procalcitonin for early diagnosis and differentiation of SIRS, sepsis, severe sepsis, and septic shock. Intensive Care Med. 2000;26(Suppl2):S148-152.
- 39. Schuetz P, Bolliger R, Merker M, et al. Procalcitonin-guided antibiotic therapy algorithms for different types of acute respiratory infections based on previous trials. Expert Rev Anti Infect Ther. 2018;16(7):555-564.
- 40. Simon L. Gauvin F. Amre D. et al. Serum procalcitonin and C-reactive protein levels as markers of bacterial infection: a systematic review and meta-analysis. Clin Infect Dis. 2004;39(2):206-217.
- 41. Christofides ND, Wilkinson E, Stoddart M, Ray DC, Beckett GJ. Assessment of serum thyroxine binding capacity-dependent biases in free thyroxine assays. Clin Chem. 1999;45(4):520-525. doi:10.1093/ clinchem/45.4.520
- 42. The Duo and Duo+ are the marketing names for specific VITROS Automation Solutions configurations which have previously obtained local registrations/approvals in the respective countries where they will be sold/ distributed
- 43. Data on File (PR-12081)



Scan here for the full VITROS Assay Menu.

New QuidelOrtho branding may not be available in all markets, subject to country-specific regulatory approval. Please confirm with your local commercial team.



At QuidelOrtho, we transform diagnostic data into answers, understanding and action, illuminating the path forward for all. For more than 80 years, we've pursued the unknown with a passion and purpose to improve health. And we'll continue to transform the power of diagnostics into a healthier future for all.

9975 Summers Ridge Road San Diego, CA 92121 USA

800-874-1517 quidelortho.com

© QuidelOrtho 2024