

CATALOGUE (2020-21)



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"Medical Monitoring Everywhere"

Abstract

State of art. (*Point of Care from Int. Reports*)

The incipient growth of chronic diseases and other drivers like aging population and more asking needs of quick results in some critical areas, are becoming crucial in terms of Point of Care solutions widespread and ever more in a cost-conscious market.

Reduce complexity in POC testing is a claim and end-users demands some kind of external control for the pre-analytical process prior sampling and data collection, having a friendly use system to be manage on remote.

Decentralization in remote locations has taken Lab testing beyond the hospital, to other places like Doctor Offices or pharmacies, even in a search of chronic disease monitoring using some king of wearable devices, not always valid.

What's POC products must deliver?

- Of course, testing sensibility as expecting when is accesible in remote locations.
- simplicity in use and acute results
- Almost real-time results
- Minimizing cost per determination
- Connected data and Lab. support.
- More Improved and available Molecular testing

Is the space always premium? Why do POCT devices have to get smaller and smaller?

It depends on the single test, but having all the systems at the same point and remotely controlled, ensures the use of resources when necessary and confirms user access in terms of following the sampling procedure, not just for control, but to be proactive in the training of the personnel that take care of it.

Modular and Scalable Design.

"Modular POC systems where the throughput of a system can be configured as needed to suit testing volume by adding modules to a base system, offer the flexibility for higher volume production by expanding the market opportunity".

Connectivity.

"Always on" connectivity solutions at the point of care areas, whether they are in large hospitals, doctors' clinics or even at home, are becoming standard and expected.

Process and sample validation.

To establish processes to identify the critical points in systems union and in certain parameters that should need to be IT controlled within permitted tolerances in order to be automatically validated by the laboratory. .

Multiple Regulatory Regions.

Achieving regulatory approval across multiple regions - particularly those larger markets with similar requirements, such as the US and Europe

However, any kind of POCT approach as a diagnostic tool, poses design-challenges for developing platforms that provide rapid, reliable, fit for purpose test results.



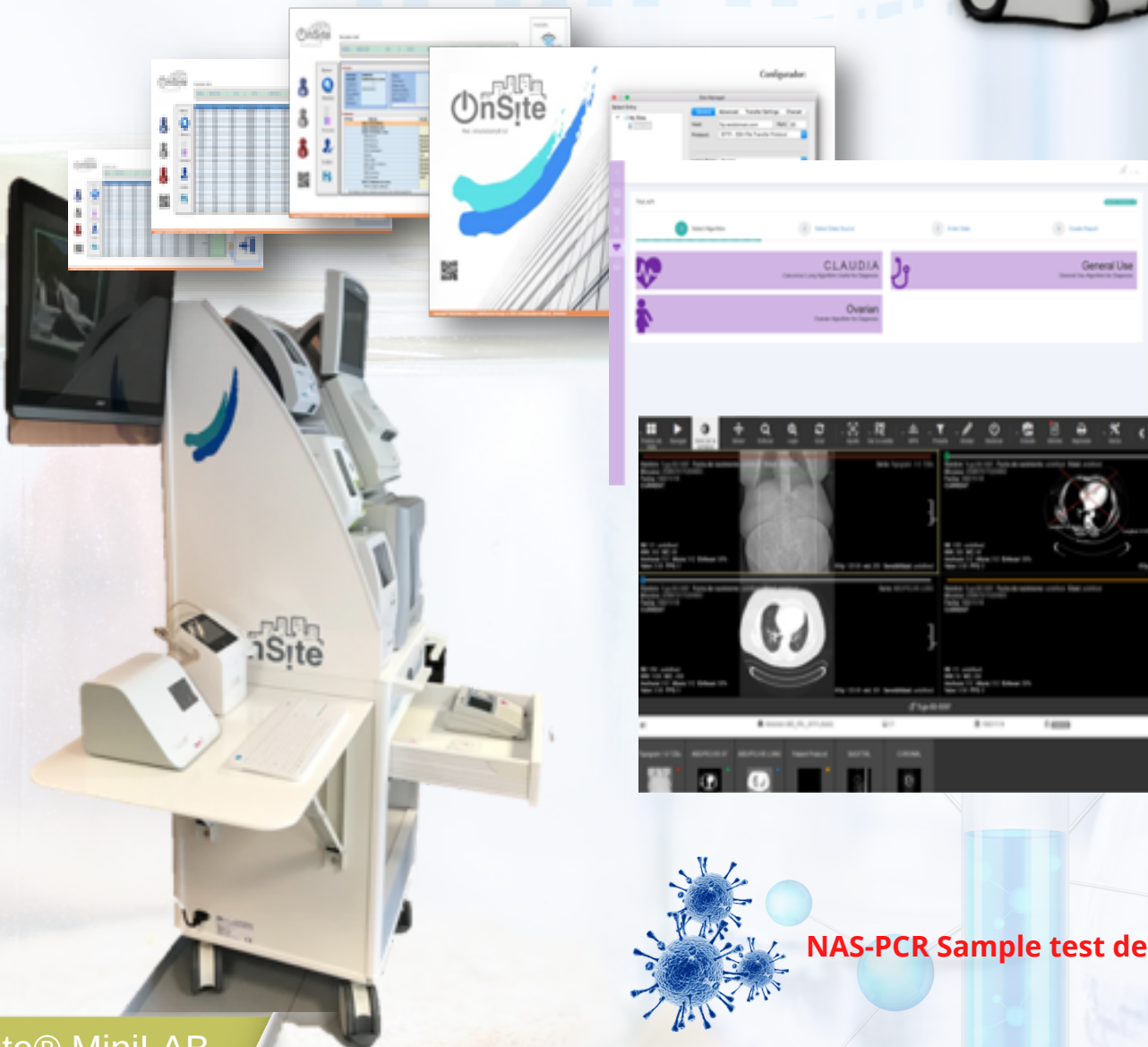
MEDICAL GROUP
"MEDICAL MONITORING EVERYWHERE. FOR EVERYONE"

MiniLAB OnSite®

The new OnSite®

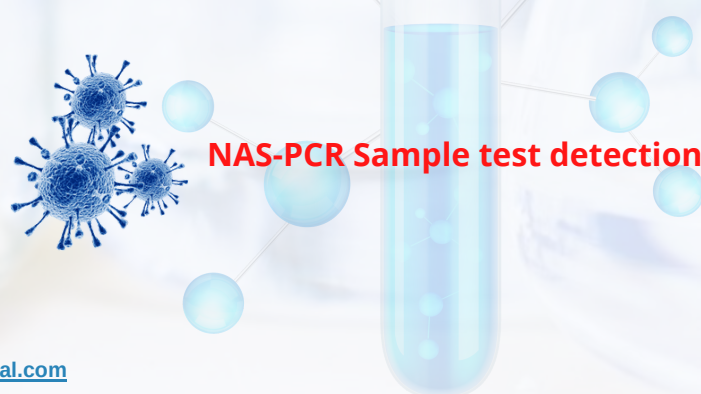
A new concept of portable mini laboratory called **OnSite® Plus**, a high-performance system that delivers clinical results of IVD diagnostic tests in real-time, in distant units outside the central laboratory that controls it. Specially designed for its portability and autonomy, it makes it possible for the Laboratory's clinical results to be available at the patient's side wherever that may be required, representing its maximum service extension.

Permanently connected to the reference center. With minimal connection requirements, it allows remote patient monitoring by means of immediate validation of the tests and remote management of the systems that compose it, in addition to the transferability of results for immediate incorporation into the patient's medical history.



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OnSite® MiniLAB



NAS-PCR Sample test detection

MiniLAB OnSite®

The new OnSite®

The OnSite® Plus system is perfectly configured to facilitate the creation of rapid laboratory response points (ad-hoc) with greater capacities and handling guarantees than a simple Point of Care (POCT). It is available for:

- Isolation plants to avoid contagion by external personnel due to sample inputs and outputs and system maintenance, with the consequent use of personal protection material: masks, suits, gloves, etc.
- Peripheral Hospitals and Campaign (Battlefield) Hospitals.
- Emergency entrances in Hospitals for rapid screening of patients.

- Primary Care Centers
- Doctor Offices
- Specialized Clinics
- Rural medicine
- Hotels
- Maritime
- Army Deploy
- Others.

Allocated centers outside the physical reach of sample transport by the centers that must offer their support. **It eliminates the need to transport samples to a central laboratory, as they are processed On-Site.**



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OnSite® MiniLAB

MiniLAB OnSite®

The new OnSite®

It has the technical capability to measure **more than 600 available parameters**, covering areas such as **Hematology, Complete Blood Gases, Immunology, Biochemistry, Informed Glucometry (IT), Coagulation, Cardiac Markers, Toxicology, PCR, Infectious Diseases and a host of other complementary tests.**

Also, with optional add ons such as the RX PAC, SW for Cancer screening and the link to the AWE diagnostic briefcases it can provided real-time telemonitoring of vital signs, ultrasound, guided endoscopy, spirometry and others.

Always On-line, validated and supported by the central Laboratory and the staff who control it in remote.

In addition, it is equipped with a proprietary Multiple Management Software that allows Control Guides to be established, Determination Patterns (DPD) by specialized algorithms (Artificial Intelligence) for Rapid Diagnostic Orientation; Two-way Checking of results, Diagnostic Profiles, remote Control Management, Operator Profiles, Third-party Systems linked, Detailed Use Statistics, eLearning platform and Double Confirmation Systems for correlation with the Laboratory.

Approvals:

All the system pertained are TUV Listed, CSA, IEC/EN 61010-1, IEC 60825-1:2007 with IVD tests categorized by the Food and Drug Administration's (FDA), Clinical Laboratory Improvement Amendment (CLIA).

With regards to the patented Determination Pattern for Diagnosis Orientation (DPD), indicate that it allows to combine suspicion indicators added to the specific tests to establish a more efficient screening of patients without the repeated use of confirmation tests, in addition to facilitating stages of the disease in its evolution. It typifies the clinical picture for its subsequent management including for the case that concerns us at the present time: **the COVID19.**



MiniLAB OnSite[®]

Measurement & System features (Modules):

Module of Gasometry

Blood Gas Systems leverage proven Siemens technology to deliver fast, accurate and comprehensive test **results in approximately 60 seconds.**

These flexible, easy-to-use analyzers help free your clinicians to focus on improved patient care without reliability or maintenance worries.

- Test blood gas, electrolytes, glucose, lactate and full CO-oximetry including neonatal total bilirubin (nBili) and total hemoglobin (tHb)
- Multiple sample types including whole blood (arterial and venous), pleural fluid and dialysate
- Intuitive touch-screen interface and integrated bar-code reader—just scan, insert, and analyze with results in approximately 60 seconds
- Bio-safe hands-free automatic sampling with clot detection and clot management
- Maintenance-free, cartridge-based system incorporates automatic QC to help assure quality
- Fully integrated system on the OnSite[®] software with remote monitoring and control.

Hematology

Hematology System from Siemens H. specially designed to meet the specific needs of lower-volume testing environments. It efficiently generates reliable and accurate results.

With Easy-to-use interface and fully integrated system OnSite[®] offering multiple settings as a primary analyzer in smaller labs and as a backup in larger labs.

- Runs up to 60 samples per hour
- Processes aspiration volumes as low as 100 µL
- Facilitates efficient sampling of both open and closed tubes
- Measure 22 parameters, including a 3-part white blood cell differential
- Unlimited results storage capacity within OnSite[®]
- Streamlines result reporting via OnSite[®] Printer
- Fully integrated system on the OnSite[®] software with remote monitoring and control.

Fast and reliable hematology solution that helps the labs optimize and manage workflow.

Parameters

22 parameters, including 3-part WBC differential: WBC, LYM, MID, GRA, LYM%, MID%, GRA%, RBC, MCV, HCT, HGB, MCH, MCHC, PLT, MPV, RDW-SD+, RDW-CV, PCT+, PDW-SD,+ PDW-CV,+ P-LCR,+ P-LCC+

Urinalysis

That system integrated provides automated reading of urinalysis strips:

- Leukocyte
- Nitrite
- Protein
- Blood
- Glucose
- Ketone
- Bilirubin
- Urobilinogen
- pH
- SpecificGravity
- Creatinin
- Protein-to-Creatinine Ratio
- Albumin
- Albumin-to-Creatinine Ratio (ACR)
- hCG Pregnancy Test

MiniLAB OnSite®

Measurement & System features (Modules):

Chemistry

Basic Profile: 6ALT, AST, CRE, GGT, GLU, URE

13 Test-kit: ALT, ALB, ALP, AMY, AST, Ca⁺⁺, CRE, GGT, GLU, TBIL, TP, URE, AUMetlyte

8 Test-Kit: GLU, URE, CRE, CK, Na⁺, K⁺, Cl⁻, Tco2Lipídico

Plus-Kit: CHOL, CHOL/HDL, LDL, TRIG, VLDL, GLU, AST, ALTHepático

7 Test-Kit: ALT, ALB, ALP, AST, DBIL, TBIL, TP

Metabolic complete: GLU, URE, CRE, Ca⁺⁺, Na⁺, K⁺, Cl⁻, tCO₂, ALT, AST, ALP, AST, TBIL, TP.

Lipid Test-Kit: CHOL, CHOL/HDL, LDL, TRIG, VLDL, GLU

Renal Kit: ALB, Ca⁺⁺, GLU, URE, CRE, Na⁺, K⁺, Cl⁻, tCO₂, PCR

Metabolic 8P: GLU, URE, CRE, Ca⁺⁺, Na⁺, K⁺, Cl⁻, tCO₂, PCR

Metabolic Basic: GLU, URE, CRE, Na⁺, K⁺, Cl⁻, tCO₂, Ca⁺⁺, LDH, Mg

Cardiac Markets

Different panels, with troponine detection, Ck-Mb, Myoglobin, BNP, Pro-BNP, D-DimerBNP Test, BNP Test per inmunoassay, Cardio2 and Cardio3 Panel, Profiler SOB Panel

Diabetes

Monitor glycemic control in a variety of environments in a multisite practices—in order to manage diabetes patients more effectively, improve clinical workflow, and simplify HbA1c testing.rug testing (GLU + Hb1Ac)

Coagulation

Fast, reliable, and accurate PT/NR testing for oral anticoagulation therapy (OAT) with warfarin. In a regular testing, with (IT) Data:

PT/INR, APTT

Rapid Test

The module that accurately reads and interprets lateral flow tests in just seconds, delivering automated, objective results in any healthcare setting.

Respiratory Infection

Flu A/B, Legionellosys, Pneumonia, RSV, Faringitis per streptococcus group A, Streptococcus pneumonia. MRSA

MRSA-Kit: PBP2a proteine detection from cultives of S. áureos as guided to find Staphylococcus aureos ceps Meticiline Resintance (MRSA).

SARS-CoV-id 2 (19) Rapid-Test from Antibodies or Antigen detection.

RT-PCR p

To rapidly virus detection in low sample volumen and less than 20 minutes, to discard patient under the maximum guarantees of sensibility and test specificity.

Drug Testing

Test designed for rapid drug screening and detection in oral fluid. With test results in minutes, this handheld analyzer is lightweight, compact, and easy to use.

TOX DS11 APAP, AMP, mAMP, BAR, BZO, COC, MTD, OPI, PCP, THC, TCA TOX DS10 AMP, mAMP, BAR, BZO, COC, MTD, OPI, PCP, THC, TCATOX DS9 AMP, mAMP, BAR, BZO, COC, OPI, PCP, THC, TCATOX DS11, AMP, mAMP, BAR, BZO, COC, MTD, OPI, PCP, THC, TCA

And others ad-hoc.

Covid -19 Testing

Rapid test (Both) & PCR platform

The essential role of laboratory diagnostics in SARS-CoV-2 infection

We fully committed to support the extended role of laboratory diagnostics in managing COVID-19 patients transmission and clinical classification

Diagnostic testing for COVID-19

As a truly emergent human pathogen, a specific test for presence of the virus did not exist with the onset of cases, necessitating rapid development. Most current testing for infection relies on detection of the viral RNA using a reverse-transcription polymerase chain reaction (rtPCR). In addition, serology testing from a blood sample can identify antibody to the virus

These tests will likely prove extremely valuable for surveillance and could potentially provide assessment for immunity, as well as aiding identification of acute infection. As availability and supplies for molecular testing for COVID-19 increase, testing turn-around times should improve, but remain contingent on sample collection, proper preanalytical handling (RNA is highly degradable), time to test result, and access to testing (point-of-care vs. lab-based).

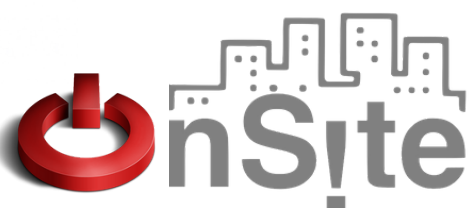
OnSite® supported.

To make it possible we complete the OnSite® platform with 3 in 1 testing solution based on 2 new COVID-19 Rapid test and 1 single or multiple Molecular Platform that delivers high-value in diagnosis in terms of clinical triage. One accurate diagnostic to manage COVID-19 detecting Antibody both IgM and IgG and Antigen to SARS-CoV-2 finally confirmed by rt-PCR in lower sample volume and faster times. Now CE-IVD validated.

Rapid testing and response, under the lab supervision that guarantees better patient screening and save money in acts, reinforcing each country healthcare systems.

FEASIBLE USE CASES

- **Workplace Screening**
- **International Travelers**
- Peripheral Hospitals and Campaign (Battlefield) Hospitals.
- Isolation plants
- Emergency entrances in Hospitals for rapid screening of patients.



OnSite® Modules

MiniLAB OnSite®

Most detailed parameters in alphabetical order (ad-hoc):

Ascorbic acid	Cholesterol	Hematocrit	Paracetamol
Uric acid	Cholesterol HDL	Hemoglobin	pCO2
Acinetobacter baumannii	Cholesterol LDL	Fetal hemoglobin	PCP
Adenovirus	Cholesterol no HDL	Hemogram 3 populations	PCT
AFP	Cholinesterase	Hepatitis A	PDW
Albumin	Coronavirus 229E	Hepatitis B	Pepsinogen II
Alcohol	HKU1 coronavirus	Hepatitis B (Surface antigen)	Lipidic profile
Alpha-1 Antitrypsin	Coronavirus NL63	Hepatitis C	pH
Alpha-1 Acid Glycoprotein	OC43 coronavirus	HIV	Platelets
Alpha-2 Macroglobulin	Creatinine	HIV (Ag + Ac)	Plasmodium falciparum
ALT	Cryptococcus gattii	HIV 1/2 (AB)	pO2
Amylase	Cryptococcus neoformans	HIV 4th generation HIV HIV-QA	Potassium
Pancreatic amylase	Cryptosporidium	HIV HIV-VL IgA	pphi GFBBP-1
Ammonia	Cryptosporidium	IgA Kappa	Prealbumin
Amphetamine	Ketone bodies	IgA Lambda	Procalcitonin
Tricyclic antidepressants	Cyclospora cayetanensis	IgA1	Protein C
Antistreptolysin O (ASO)	Dengue	IgA2	C reactive protein
Apolipoprotein A1	Density	IgD	Protein
Apolipoprotein B100	Deoxyhemoglobin	IgE	PSA
AST	Digoxin	IGFBP-1	RDW
Astrovirus	D-dimer	IgG	Blood
Barbiturates	Drugs of abuse	IgG Kappa	Sodium
Basophils	Entamoeba	IgG Lambda	Staphylococcus aureus
BCR / ABL Xpert BCR / ABL Ultra	Entamoeba histolytica	IgG1	Staphylococcus aureus MRSA BC
Benzodiazepine	Enterobacter cloacae (complex)	IgG2	Staphylococcus aureus MRSA Nose
Beta-2 Microglobulin Bilirubin	Enterococcus spp	IgG3	Staphylococcus aureus MRSA NxG
Direct bilirubin	Enterovirus	IgG4	Staphylococcus aureus MRSA SSTI
BNP	Eosinophils	IgM	Streptococcus group A
Bordetella pertussis	Escherichia coli	IgM Kappa	Streptococcus group A (Direct sample)
Cl inhibitor	Escherichia coli 0111	IgM Lambda	Streptococcus group B
C3	Escherichia coli 0157	Influenza	Streptococcus group B Xpert GBS
C4	Escherichia coli 026	Influenza A	Streptococcus pneumoniae
Calcium	Escherichia coli EAEC	Influenza A+B	TCO2
Ionized calcium	Escherichia coli EIEC	Influenza A+B FIA	Prothrombin time
Calprotectin	Escherichia coli EPEC	Influenza A/H1	Activated partial thromboplastin time
Campylobacter	Escherichia coli ETEC	Influenza A/H1 2009	Transferrin
Campylobacter coli	Escherichia coli K1	Influenza A/H3	Transglutaminase
Campylobacter jejune	Escherichia coli STEC	Influenza B	Treponemapallium
Campylobacter upsaliensis	Group A streptococcus	Lactate	Trypsinogen 2
Bladder cancer	Von Willebrand factor	LDH	Troponin
Candida albicans	Rheumatoid factor	Legionella	TSH
Candida glabrata	Ferritin	Leishmania	Urea
Candida Krusei	FII Xpert FII / FV	Leptospira	Urobilinogen
Candida parapsilosis	FOB	Leucine - LAP	VCM
Candida tropicalis	Alkaline phosphatase	Leukocytes	Respiratory syncytial virus
Cannabis	Phosphoro	Lymphocytes	VLDL
Carbapenemase	FV Xpert FII / FV	Magnesium	VPM
Carboxy hemoglobin	G6PD	Malaria	Wuchereria bancrofti
CD4 cells	Galectin	Cardiac markers	
Ceruloplasmin	GGT	Methadone	
CH50	Giardia	Methemoglobin	
Chlamydia pneumoniae	GIP	Methamphetamine	
CHCM	BGP bone glaprotein	Microalbumin	
Chlamydia	Glucose	Mid	
Cystatine C	Granulocytes	Myoglobin	
Cytomegalovirus	Specific gravity	Monocytes	
CK	H-FABP	Mycobacterium tuberculosis	
CK-MB	Haemophilus influenzae Hantaan	Mycobacterium tuberculosis MTB / RIF	
Chlorine	Haptoglobin	Neutrophils	
Clostridium difficile	HbA1C	Nitrites	
Clostridium difficile Toxin A/B	HBDH	NMP22	
Clostridium difficile Toxin	HCG	NT- proBNP	
Clostridium difficile GDH	HCM	Opiates	
Clostridium perfringens	Helicobacter pylori	Osmolality	
Clostridium tetani (Tetanus toxoid) CO2	Hepatitis A	Oxyhemoglobin	
Cocaine	Red blood cells	Lipid panel	

(IVD tests categorized by the Food and Drug Administration's (FDA), Clinical Laboratory Improvement Amendment (CLIA) and CE Mark (d.)

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