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DIAGNÓSTICO PARA A VIDA

Where we were and where we are now after COVID Pandemic?

The Brazilian perspective

Carlos Gouvêa -Oct/23


ALDIMED


INSTITUTO
ÉTICASAÚDE


LONDON
SCHOOL of
HYGIENE
&TROPICAL
MEDICINE


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The
International
Diagnostics
Centre


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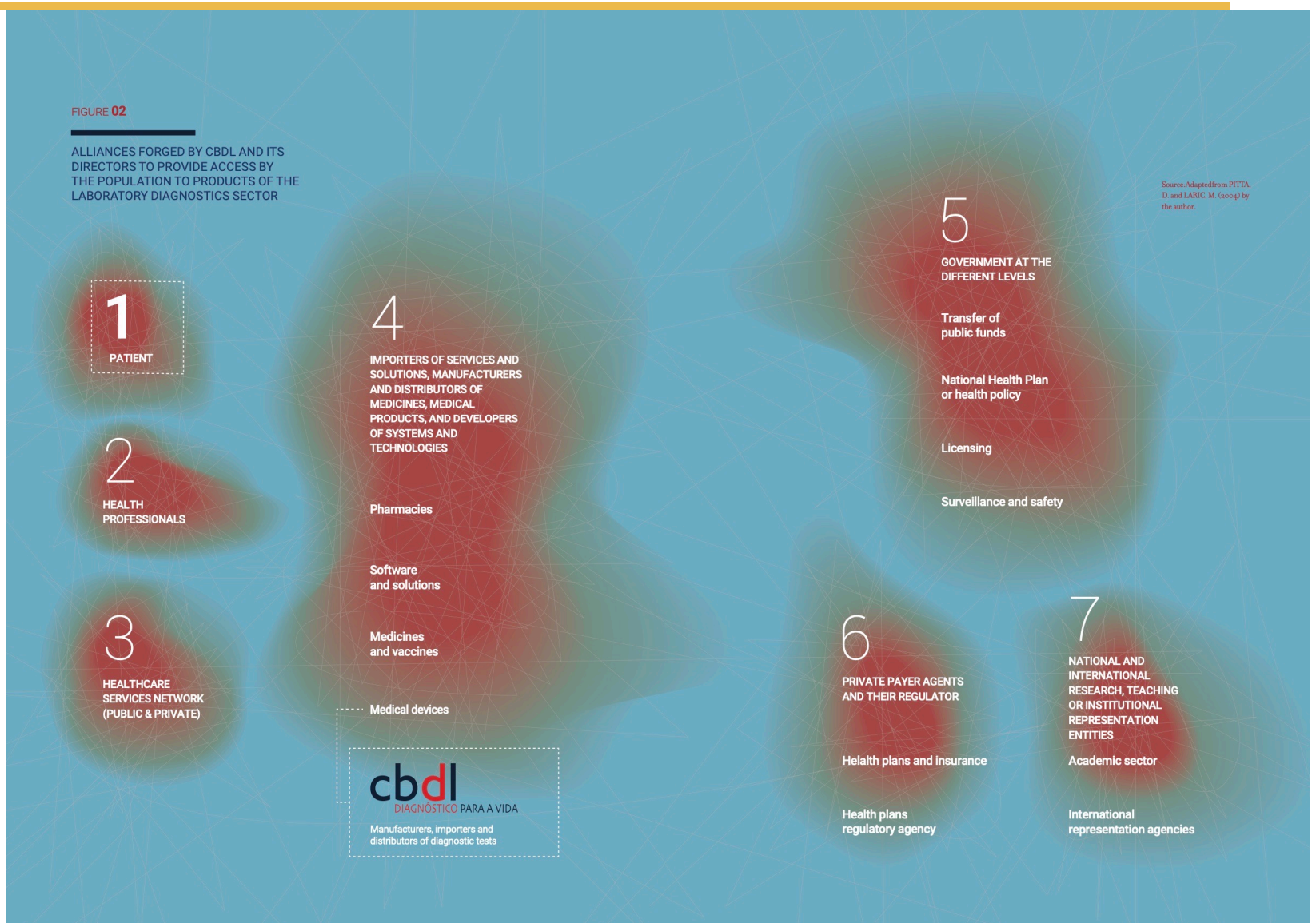
GLOBAL DIAGNOSTICS ALLIANCE


ABIIS
Aliança Brasileira da
Indústria Inovadora
em Saúde

Strategic Alliances in Health




Organización
Panamericana
de la Salud
WORKSHOP
"Testes de Diagnóstico in Vitro Acessíveis e com Qualidade Assegurada para Programas de Saúde Pública"
17 e 18 de Abril de 2012 - Brasília/ Brasil
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ANVISA
II WORKSHOP INTERNACIONAL
" Testes de Diagnóstico in Vitro Acessíveis e com Qualidade Assegurada para Programas de Saúde Pública"
19 e 20 de Novembro de 2012 - Brasília- Brasil
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III WORKSHOP INTERNACIONAL
Testes de Diagnóstico com Qualidade Assegurada e Acessíveis para Programas de Saúde Pública
30 e 31 de outubro e 01 de novembro de 2013 - Curitiba-PR
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TECPAR


TECPAR


PLANTA DE DESENVOLVIM
PRODUÇÃO DE INSUMOS PARA
DIAGNÓSTICOS


TECPAR


ALAD DiV
V TALLER INTERNACIONAL
PRUEBAS DE DIAGNÓSTICO CON CALIDAD ASEGURADA
Y ACCESIBLE PARA PROGRAMAS DE SALUD PÚBLICA
Hotel Meliá Lima, 14 y 15 de mayo 2015


Caminho Açoriano

IX INTERNATIONAL - WORKSHOP

" Testes de Diagnóstico com Qualidade Assegurada e Acessíveis para Programas de Saúde Pública"

2 e 3 de setembro de 2019 - Brasília/DF Brasil

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE · ALADDiV · The International Diagnostics Centre

Apoio: cbdl DIAGNÓSTICO PARA A VIDA · Brasil · ALDIMED

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LABORATORY DIAGNOSTICS WHITE BOOK 2021-2022

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https://cbdl.org.br/cbdl-whitebook/

Pilars

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Access

Intelligent Regulation

Ethics & Compliance

Perspectives for Healthcare

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SDGs / WHO

- **Most governments think of diagnostics as a cost to the healthcare system and not of value**
- **Diagnostics, unlike drugs and vaccines, are not considered life-saving commodities**

WHO Sustainable Development Goals.
http://www.who.int/sdg/targets/en/

- **All WHO member states pledged to leave no one behind and achieve universal healthcare by 2030**
- **47% of the global population has little to no access to diagnostics, including imaging**

Fleming et al. The *Lancet* Commission on diagnostics: transforming access to diagnostics. *The Lancet*, Vol. 398, No. 10315, October 6, 2021
https://www.thelancet.com/commissions/diagnostics

Fonte: IPEA e Valor.

O BRASILEIRO VAI VIVER MENOS

PROFESSOR HOC: HENI OZI CUKIER

ARRASTE PARA O LADO

Life expectancy: 4,4 years lost due to COVID-19

Before 2019: avg 76,6 years old
After 2022: avg 72,2 Years old

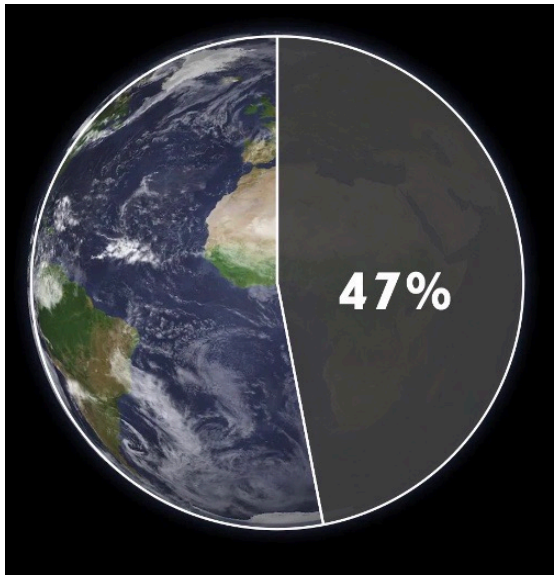
Source: IPEA

Reason: many young active people died and many couples gave up or postponed their pregancies

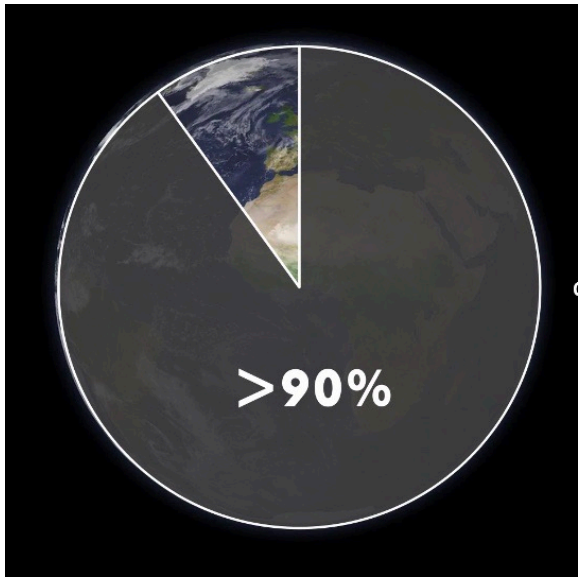
Labor will be impacted as there will be less active workers generating income

Active aged population:
2020 = 136 million people
2025 – 142.7 million
2030 = 138.8 million
2035 = 133.1 million

Source: IPEA



47% of the population has no or limited access to diagnostics



90% of the IST cases occur in LMIC where access to appropriate diagnostics is limited or non existent

Acquired Syphilis

213,482 cases in 2022

~585 cases/day

˜24 cases/hour

2 cases each 5 minutes!

Fonte: LANCET 2021/ MoH Brazil

Technological Horizon

- Everything we know is in a permanent state of flow

- The more stability we search in the comfort of our routine, the more we realize that the world around us is changing in a even faster mode

http://www.maurilioamorim.com/2012/01/are-you-adapting-to-the-change-accelerators/
Fonte: Gabriela Tannus

The Medical Technology (MedTech) Industry

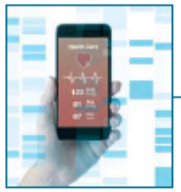
What does Medical Technology mean?

It is a term used to encompass:

MEDICAL DEVICES

IN VITRO DIAGNOSTICS

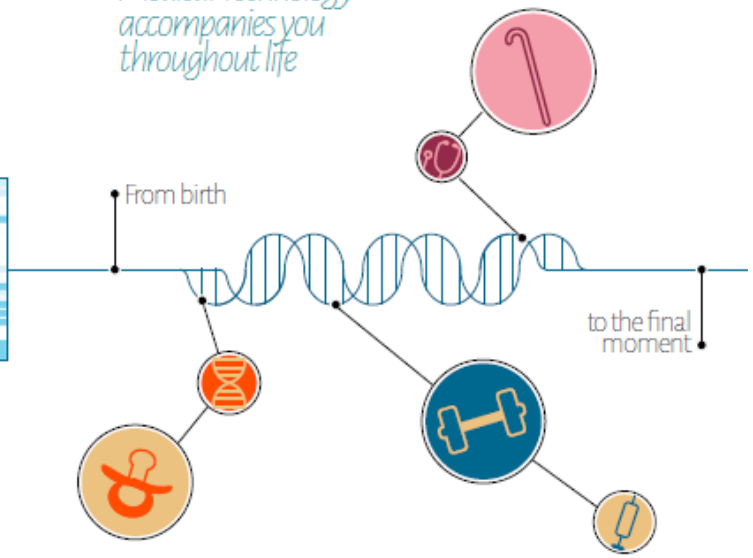
MEDICAL EQUIPMENT



E-HEALTH

500,000 Medical Technologies currently exist

Medical Technology accompanies you throughout life



Source: Adapted by the Webeditorial MedtechEurope http://www.medtecheurope.org/publications/55/84/Infographic-The-MedTech-Industry-in-Europe published on 9 September, 2015

http://www.abiis.org.br/abiis-health-4.0.html

Benefits of MedTechs

How do they reduce the costs of healthcare?

Limit care costs of patients with chronic diseases

- EARLY DIAGNOSIS + MONITORING
- TREATMENT
- HOSPITAL COSTS

Limit the use of unnecessary and ineffective treatments, allowing customization of care based on prevention

ENABLE PATIENT RISKS TO BE IDENTIFIED (PERSONALIZED MEDICINE)

Limit treatment costs

- **MORE** EFFICIENT TREATMENT
- **REDUCED** HOSPITAL STAYS

IMPROVE HOSPITAL CARE QUALITY

HELP TO DIRECT CARE TO THE LOCATION WITH BEST COST-BENEFIT

Reduce treatment costs

- **GREATER** EFFICIENCY
- **LESS** DUPLICATION

E-HEALTH

- Remote self-monitoring
- Cost-effectiveness of access to healthcare

E-health for better health system management

E-health can also enable big-data to be incorporated for identifying the need for new product development, tracking, inventory control/ re-stocking and maintenance data.

What is big-data?

A term to describe large amounts of data. Society faces an unprecedented increase in the daily amount of information generated.

Source: Adapted by Webstorial from MedtechEurope: (http://www.medtecheurope.org/publications/93/84/Infographic-The-MedTech-Industry-in-Europe). Access on: 9 September 2013.

http://www.abiis.org.br/abiis-health-4.0.html

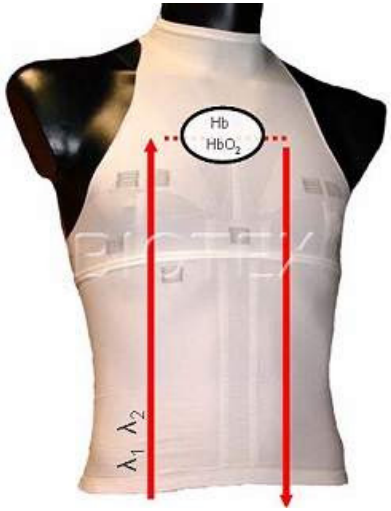
IVD Life Cycle

Fiction or Reality?

Fonte: Gabriela Tannus/AxiaBio

Future trends

- Supportive technologies
  - Smaller and lighter devices
  - Advanced materials
  - Wearable health monitors
  - IT improvements



Fonte: Gabriela Tannus/AxiaBio

Evolution in Molecular POCT

Explosion in near-patient molecular platforms


PositiveID


STATDiagnostica


Great Basin


Cepheid


BioCartis


IdahoTechnologies


BioFire


Alere


Veredus


Epistem


iCubate


Osmetech


Curetis


Roche


Enigma


Gentura


Atlas Genetics


Molbio


Rheonix

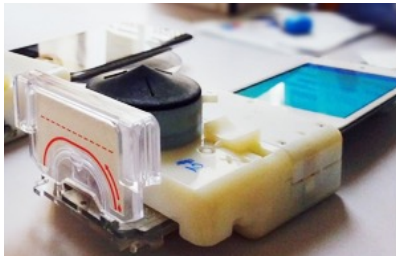

QuantumDx


Spartan


Fluidigm


Qiagen


Micronics



Evolution in COVID Selftests

The right test…

Different test formats that are adequate to every need, from the Central Lab to the most remote places

- Strip

Cassette

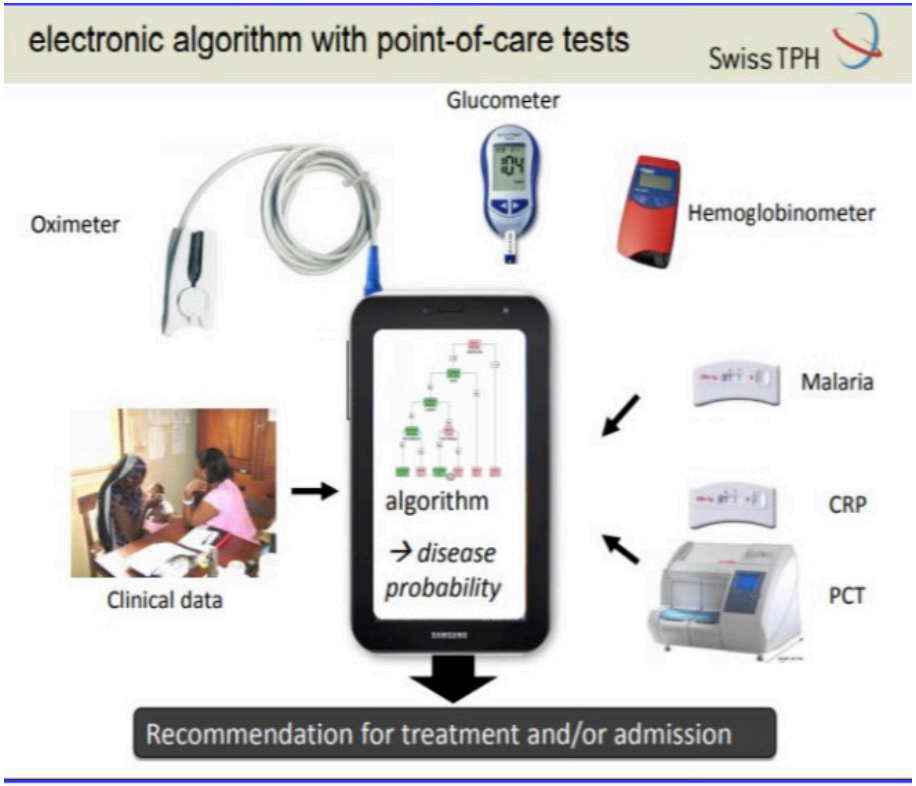
Card

Dipstick

Multi-assay instruments

Source: Alere

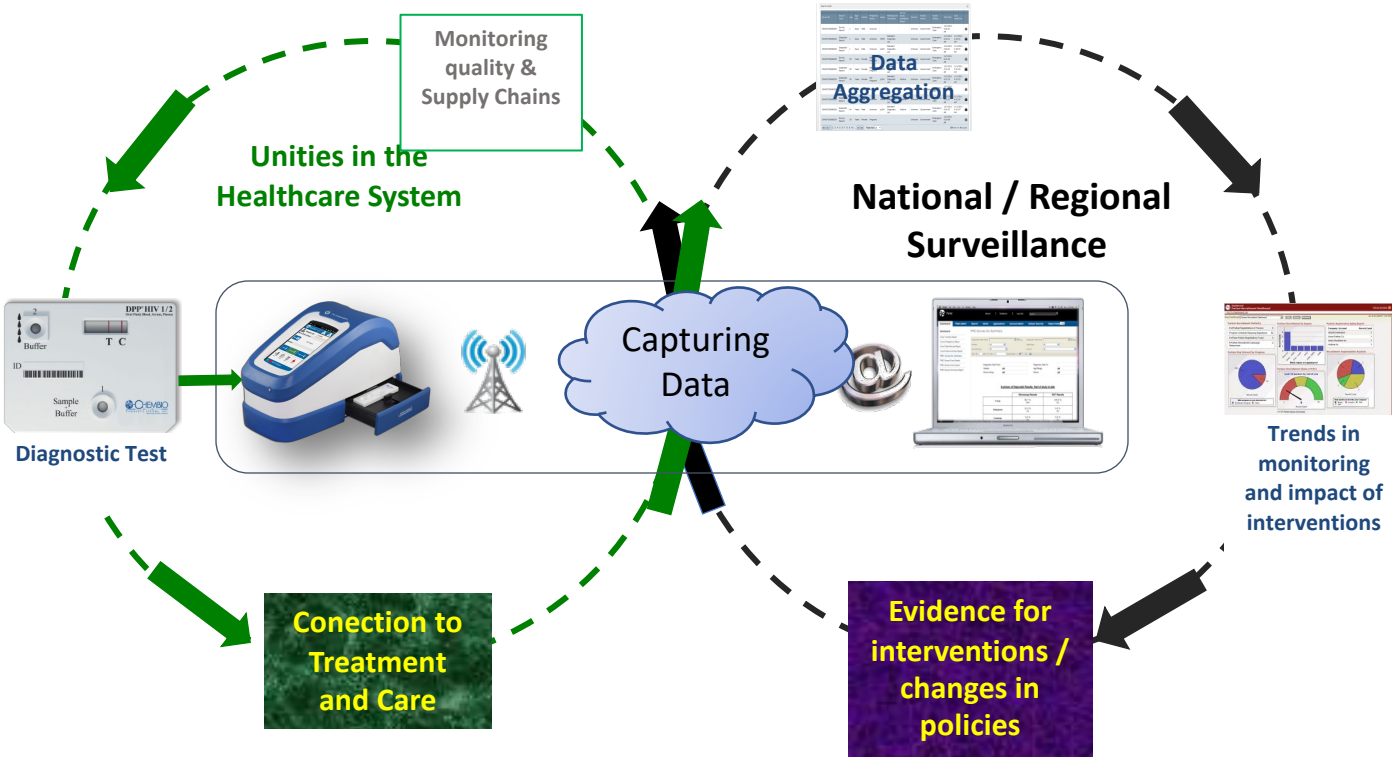
Integrating solutions



Source: Rosanna Peeling

Connectivity

Readers: Connecting Results of PoCT to Surveillance



Source: Rosanna Peeling

COVID-19: a good example of full cooperation

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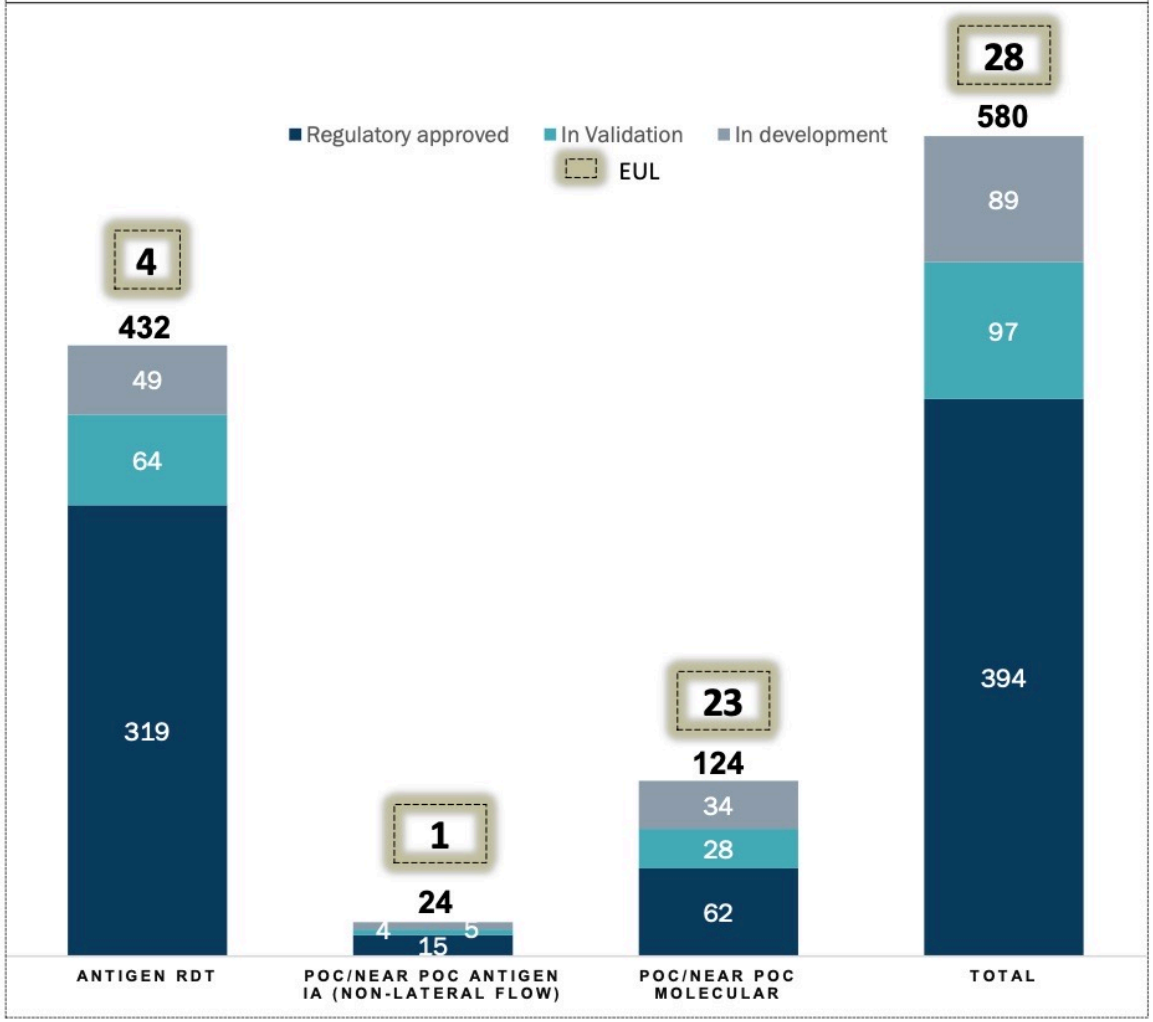
The pipeline of diagnostic tools remains robust with progress still needed on affordability and EUL

ACTaccelerator
ACCESS TO COVID-19 TOOLS
Hosted by World Health Organization

COVID-19 Antigen and Molecular Diagnostic Tools *(Number of tools)*



Tools in market

Ag RDTs
Multiple suppliers
EUL=4
~US$3 per test, with goal of $1 per test

Near-patient molecular/PCR
Only one supplier with EUL; *pricing still high (US$15–20+)*

Lab-based molecular/PCR
Multiple suppliers
<US$15 per test

Near-POC automated PCR
Single supplier (Cepheid)
US$14.90 per test

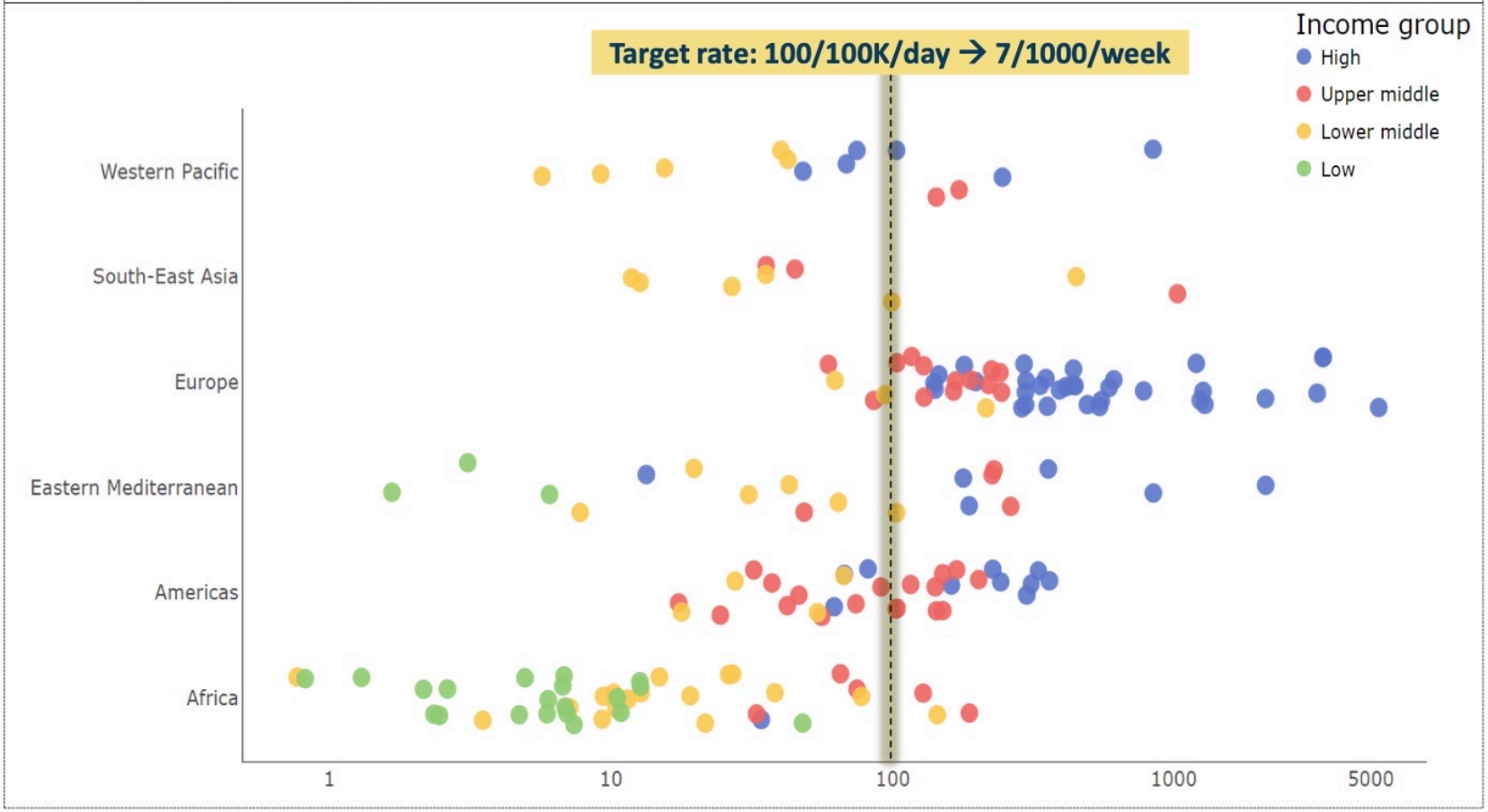
Source: FIND market research, WHO EUL for IVDs Detecting SARS-CoV2 as of 30 Apr 2021

Despite the availability of tools, testing remains inadequate in LMICs

ACTaccelerator
ACCESS TO COVID-19 TOOLS
Hosted by World Health Organization

Average daily COVID-19 testing rates (Jan-Jul 21)

Number of tests per 100K population



Source: Avg daily tests per capita pulled from FIND test tracker (as of 12 August 2021)

ACT-A Dx partners are coordinating to address these barriers and ensure adequate testing to limit transmission, support test & treat strategies, and link to care

ACT-A Dx pillar refreshed priorities for 2021-22

01 Ensure a **reliable supply of accurate, affordable diagnostic tools** through expanded local manufacturing and support for market entry.

02 Scale **procurement of diagnostic tools** based on policy and the evolving evidence of their optimal use.

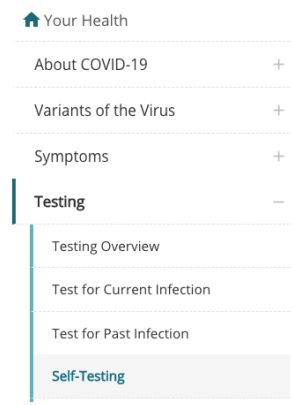
03 **Expand capacity** for countries to deploy quality-assured diagnostic tools throughout the health system and **increase community-based testing with clear link to public health interventions.**

04 Support the expansion of global disease surveillance, including strengthening the integration of epidemiological and genomic sequencing data.

Ensure equitable access to tests by supporting the procurement and use of **1 bn tests in LMICs in 2021-22**

Ensure increased testing is part of a comprehensive testing **strategy linked to public health action**

Strengthen linkages between testing, surveillance, treatment, and vaccination strategies



Self-Testing

Updated Nov. 4, 2021 Languages Print

Summary of Recent Changes

Updates as of November 4, 2021

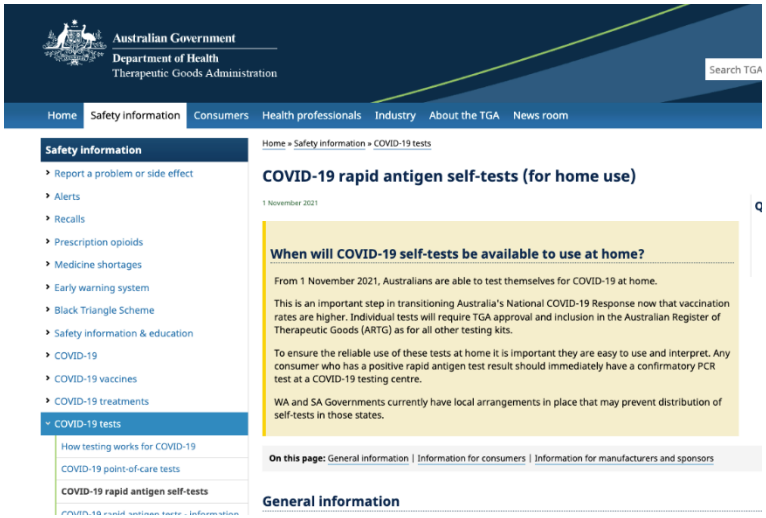
- Self-testing videos are now available to assist with how to use and interpret self-tests.
- Removed recommendation to report test results to healthcare providers or health departments.
- Added guidance about seeking assistance from a healthcare provider if the test result seems incorrect.

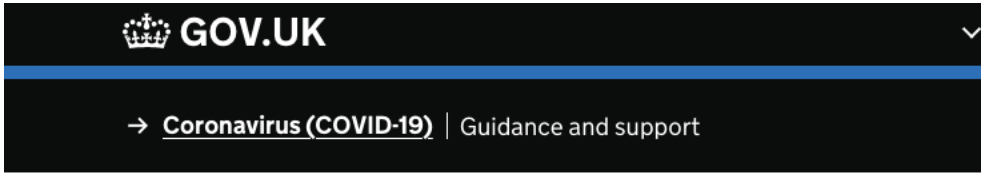
Public Health Ontario | Santé publique Ontario

Coronavirus Disease 2019 (COVID-19)

Testing Yourself for COVID-19

Self-test kits are now available in Ontario and can be used to test yourself for COVID-19 at home or elsewhere. This fact sheet explains what steps to follow based on the result of your self-test. For information on when to test yourself for COVID-19, please see the Ministry of Health: COVID-19 Test and Testing Location Information.





Home > Coronavirus (COVID-19) > Testing for coronavirus (COVID-19)

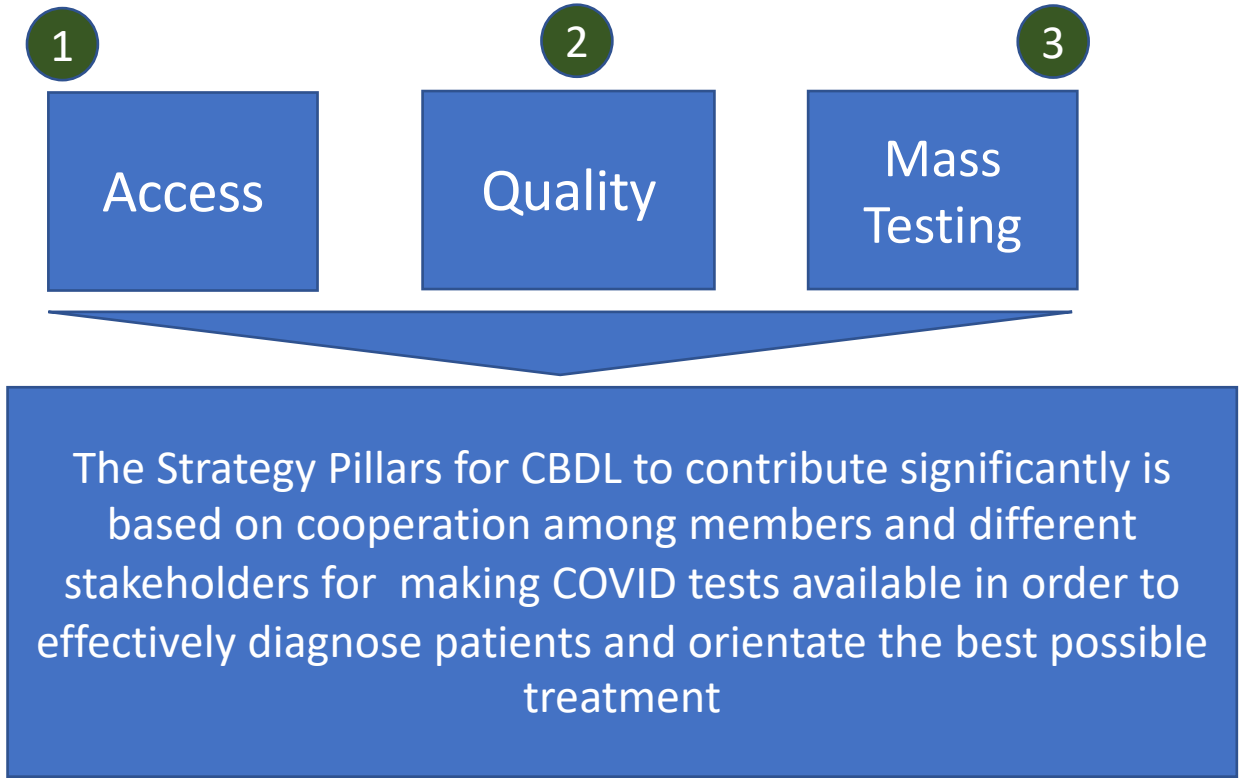
Guidance

COVID-19 rapid lateral flow test kit instructions: throat and nose test

How to do a rapid throat and nose test for COVID-19 and report the results. This test is only for people who do not have symptoms of COVID-19.

From: UK Health Security Agency

The Brazilian Strategy



1

Series of Actions

- Development of New Products
  - RT PCR
  - Rapid Tests – Antigen and Antibody (ex: immunochromatographic tests)
  - POCT – Point of Care Testing
  - ELISA, CLIA, Fluorescense, etc.

- ANVISA
  - GMPC – Good Manufacturing Practice Certificate
  - Product Registration (Risk Class III) = 633 Registrations Approved (June/21) (*)
  - Imports

- Resource Mapping

https://app.powerbi.com/view?r=eyJrIjoiNTY5NGJmZWQtMWU3YS00ZTNjLTllZWUtNmFlZWUyODFkYTQ5IiwidCI6ImI2N2FmMjNmLWMzZjMtNGQzNS04MGM3LWI3MDg1ZjVlZGQ4MSJ9 (*)

Access

- SARS-CoV-2
  - Unkown Virus
  - No IVD product available with long stability studies (RDC 36)
- Development from Feb2020 onwards
  - Asia: China and Korea
  - Europe
  - USA and Canada
- ANVISA
  - RDC 346 (GMP) and 348/20 (Registration)
  - RDC 356, 379/20 and 483/21(Imports)
  - Results: more than 1,253 submissions / 867 registrations (*)

Fonte: Fila Completa de Produtos de Diagnóstico in Vitro para COVID-19 (31/07/23): https://app.powerbi.com/view?r=eyJrIjoiNTY5NGJmZWQtMWU3YS00ZTNjLTllZWUtNmFlZWUyODFkYTQ5IiwidCI6ImI2N2FmMjNmLWMzZjMtNGQzNS04MGM3LWI3MDg1ZjVlZGQ4MSJ9

Quality

- New products of new suppliers
  - Concern on quality and performance
  - How to deal with so many factors?
- Solution:

- Consortium with 13 labs (public/private)

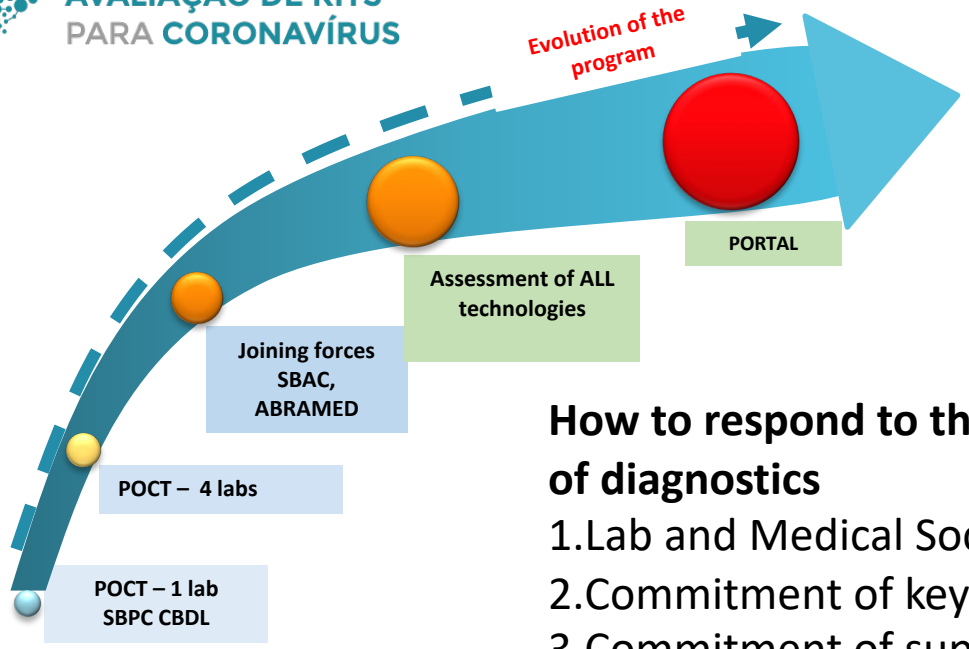
www.testecovid19.org

PROGRAMA DE AVALIAÇÃO DE KITS PARA CORONAVÍRUS

https://testecovid19.org

Assessment Program

PROGRAMA DE
AVALIAÇÃO DE KITS
PARA CORONAVÍRUS



How to respond to the challenge of diagnostics

1.Lab and Medical Societies
2.Commitment of key labs
3.Commitment of suppliers
4.Scientific knowledge

Fuente: Alvaro Pulchinelli

https://testecovid19.org

PROGRAMA DE
AVALIAÇÃO DE KITS
PARA CORONAVÍRUS

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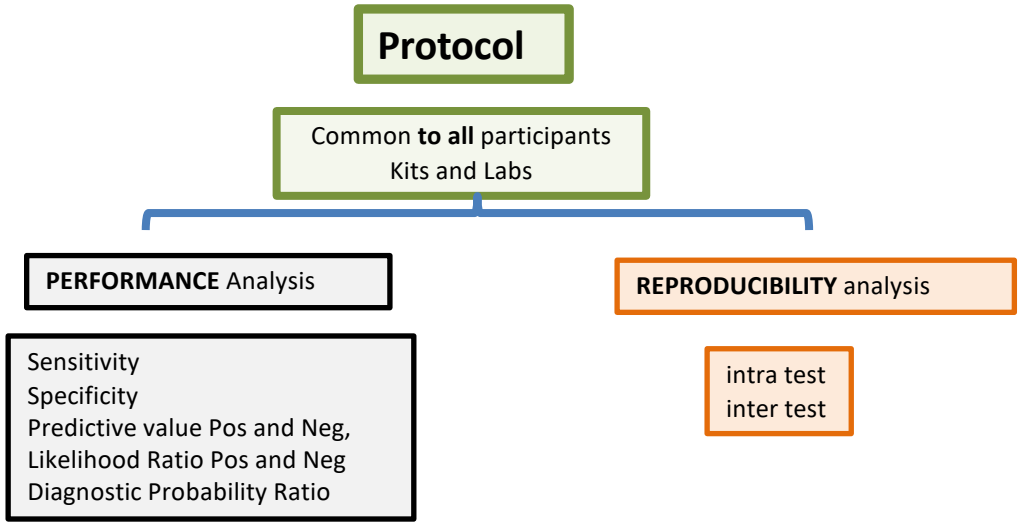


Source: Alvaro Pulchinelli

- 13 labs
  - Private and Public
- More than 70 kits evaluated
- Over 16,000 samples analyzed

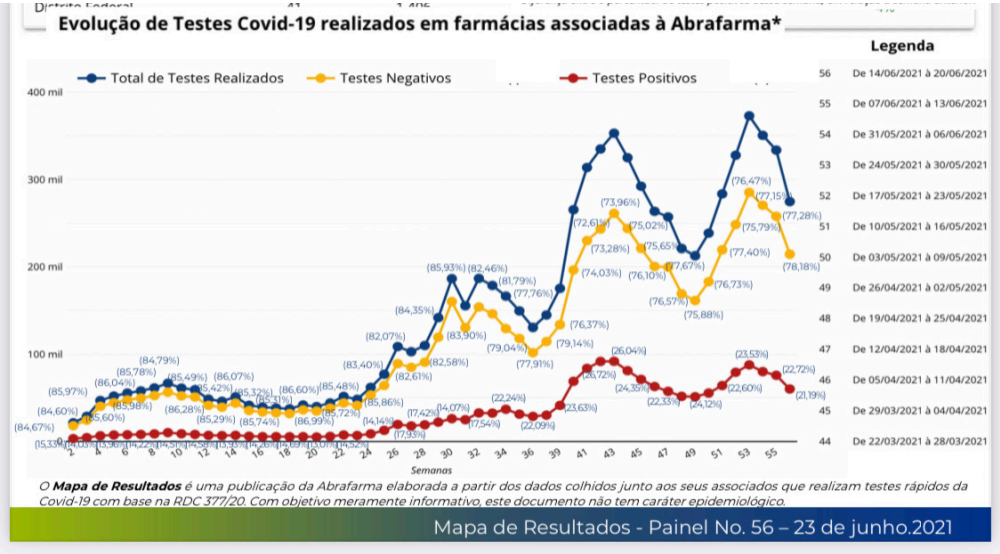
Key Figures

Source: Alvaro Pulchinelli

www.testecovid19.org

Mass Testing

- Pandemic
  - Hospitals (> 6,000)
  - Laboratories (> 18,000)
- How to take the next step?
  - Pharmacies / Drugstores (>93,000)
    - RDC 377/20
  - Companies
    - If served by Clinical Analysis Lab
      - (RDC 302/05)
- Goals:
  - Epidemiological Study
  - Information about the individual status
  - Support for the return to work
  - Control Spread of the Infection



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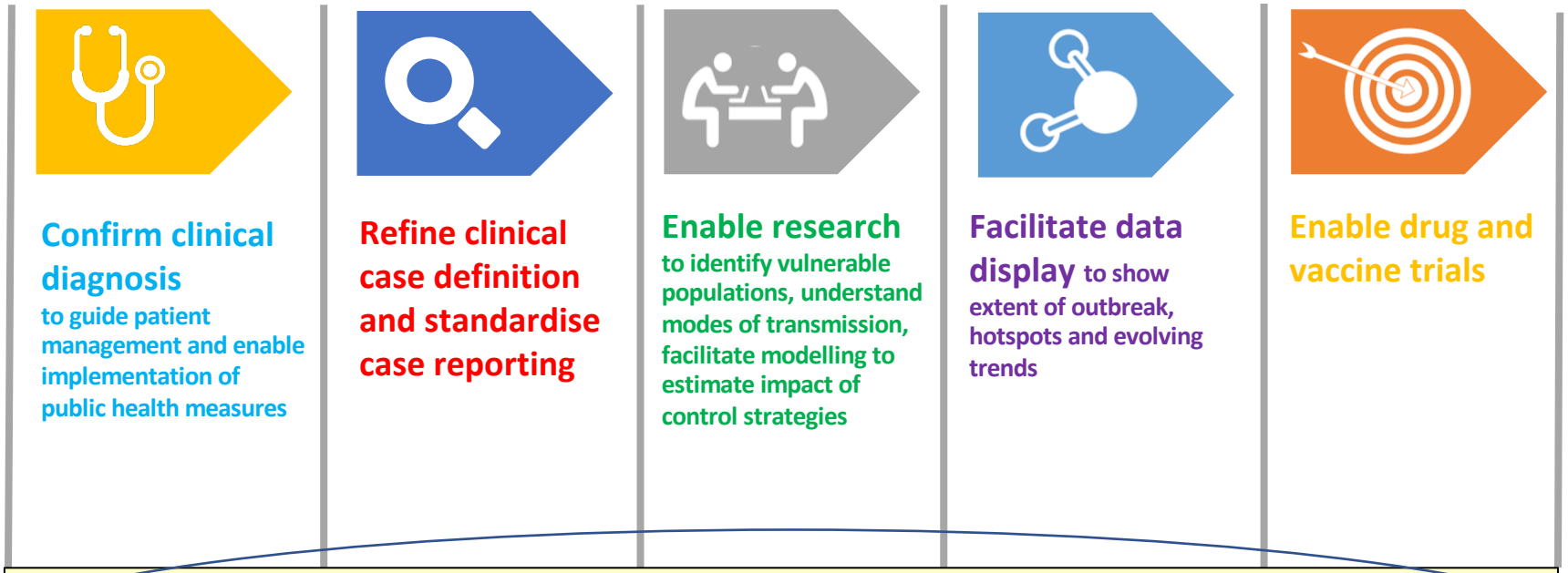
Post COVID solutions

Role of Diagnostics for Emergency Response



Before availability of drugs and vaccines, diagnostic testing for case detection to enable the implementation of public health measures is the only means of controlling disease transmission

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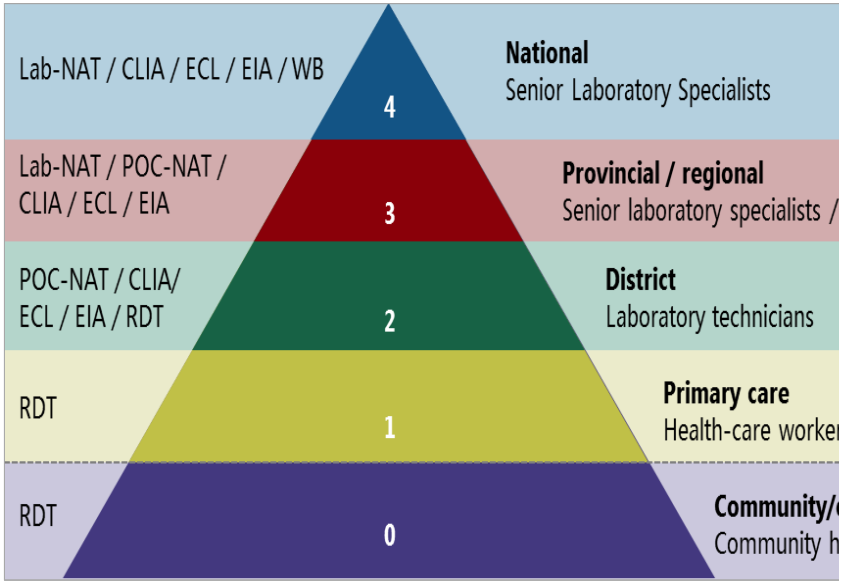
Ref: Peeling RW, Heymann DL, Teo YY, Garcia PJ. Lancet. 2022 Feb 19;399(10326):757-768.

Access x Sensitivity



	Sensitivity			
Access	**100**	**90**	**80**	**70**
100	100	90	80	70
90	90	81	72	63
80	80	72	64	56
70	70	63	56	49
60	60	54	48	42
50	50	45	40	35
40	40	36	32	28
30	30	27	24	21
20	20	18	16	14
10	10	9	8	7

Source: WHO Hepatitis Testing Guidelines 2017
NAT: Nucleic acid tests: Lab-NAT: laboratory-based; POC-NAT: at point-of-care; CLIA: chemiluminescence immunoassay; ECL: electrochemiluminescence immunoassay;
EIA: enzyme immunoassay; RDT: rapid diagnostic test

A new role for pharmacies

- Use of pharmacies in the COVID-19 pandemic
  - Sale of test kits for self-testing
  - testing
  - vaccinations
  - others

- Investing in pharmacies for enhanced health services:
  - Pandemic preparedness
  - Antimicrobial resistance (AMR)

A new role for pharmacies

The authors mapped current practices on **31 pharmacy interventions on COVID-19 in 32 countries in Europe**. Almost all preventive measures **to reduce health risks** have been provided in most countries. Other frequent interventions **reflected preparedness for stockpiling, increased demand for services and products, and important patient care interventions exceeding dispensing role**.

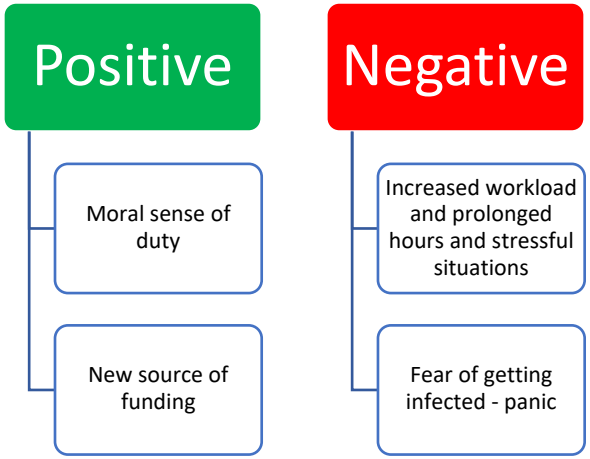
Expanded powers granted to pharmacists or legislation passed in 11 countries: (Austria, Belgium, Croatia, Czech Republic, Germany, Italy, The Netherlands, Poland, Portugal, Spain, and UK). Interventions included:

- relaxation of regulations on dispensing controlled medicines
- extension of emergency supply of medications (without prescription)
- increased demand/ changes to repeat dispensing
- e-prescribing
- substitution rights when in short supply due to shortages
- supply of medicines usually supplied in hospitals
- administration of oxygen to patients
- preparing alcohol sanitizers
- home delivery to vulnerable patients
- protocol for reporting domestic violence
- access to patient electronic health care records

Ref: Costa S, et al. Pharmacy interventions on COVID-19 in Europe: Mapping current practices and a scoping review. Research in Social and Administrative Pharmacy 18(8):3338-49, 2022. https://doi.org/10.1016/j.sapharm.2021.12.003.

A new role for pharmacies

Pharmacists report:



Conclusions:

A wide array of pharmacy interventions on COVID-19 was implemented in several countries within a very short time frame. Research on pharmacy interventions on COVID-19 is still in its infancy but confirmed the wide array of interventions provided and expanded powers granted to pharmacies. These findings may provide **a significant impact to improve pharmacy research, policy, and practice in response to future public health emergencies in Europe and globally.**

Ref: Costa S, et al. Pharmacy interventions on COVID-19 in Europe: Mapping current practices and a scoping review. Research in Social and Administrative Pharmacy 18(8):3338-49, 2022.

A new role for pharmacies

- “The integration of community pharmacy into the health system may translate into better access for patients to primary care services, contribute to cost effectiveness, and promulgate the sustainability of the system.
- However significant political, economic, social, and practice change would be required by all stakeholders.
- Further research is needed to underpin a consensus for a definition, the type of integration, and the model optimally suited to integrate community pharmacy into primary care.”

- The 4 constructs needed for integration were **consensus, connectivity, communication and trust**

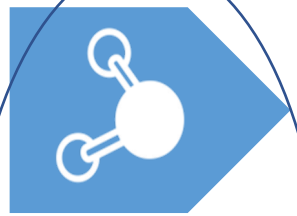
Ref: Celia Piquer-Martinez C et al. Integration of community pharmacy in primary health care: The challenge. Research in Social and Administrative Pharmacy, Vol 18 (8): 3444-7, 2022. https://doi.org/10.1016/j.sapharm.2021.12.005.

Role of the Pharmacy in Epidemic Preparedness

Strengthen surveillance to provide early outbreak alerts

Invest in open platform diagnostic technologies to build flexibility and resilience

Enable research to track known pathogens and estimate the risk of animal pathogens crossing the species barrier



Create an ecosystem for data connectivity to turn data into real-time intelligence to inform control strategies

Build capacity for community testing to increase and accelerate equitable access

Building trust and collaborative relationships among different stakeholders and with the public for a collective and effective response in infectious disease emergencies

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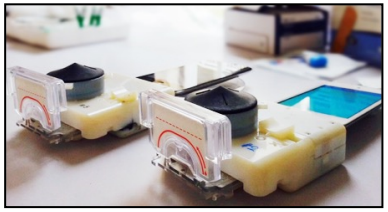
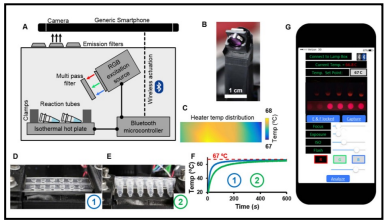
The importance of expansion of access to IVD

Plug and play format:

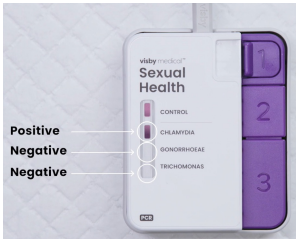
- 2-3 minutes hands-on time
- Multiplex testing
- 5 – 75 minutes to result
- Data transmission



Laksanasopin et al. *Science Transl Med* 2015:7:273



Priye, A. et al. A smartphone-based diagnostic platform for rapid detection of Zika, chikungunya, and dengue viruses. Sci Rep 2017;7:44778



1st single-use disposable Nucleic Acid Amplification Test

https://www.visbymedical.com/news/visby-medical-receives-fda-clearance-and-clia-waiver-at-the-point-of-care-for-pcr-sexual-health-test

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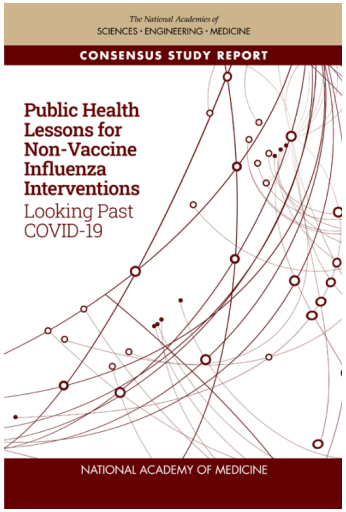
The importance of expansion of access to IVD

Countries need to invest in a robust and connected **diagnostic and laboratory infrastructure that forms the backbone of a healthcare system**, serving as the eyes and ears of the system, sounding alarms of unusual disease patterns, sending early outbreak alerts, and monitoring the effectiveness of the response.

Ref: Peeling et al. Diagnostics for COVID-19: Moving from pandemic response to control. Lancet Dec 20 2021



the U.S. Academies of Science, Engineering and Medicine published a study report entitled, "Public Health Lessons for Non-Vaccine Influenza Interventions: Looking Past COVID-19", which noted:

"Countries should institute surveillance as the backbone of their health care systems, which should include submitting aggregated clinical data feeding into public health agencies. To ensure that policy makers have access to accurate, timely, and comprehensive risk assessments, national authorities—with the advice and assistance of regional and global public health agencies—should establish more robust surveillance systems, involving public hospitals and academic medical centers, manufacturers of diagnostics, and social network platforms."

https://www.nationalacademies.org/flu-countermeasures

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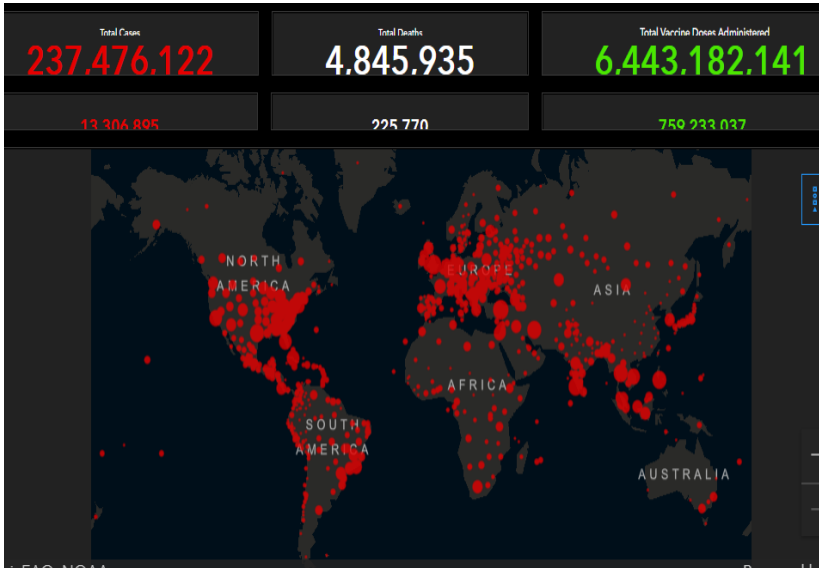
The importance of expansion of access to IVD

Digital technology adoption has the power to improve patient access, engagement, and outcomes

Data transparency (dashboards) engenders trust and empower the public with the knowledge to do their part in the public health response

- **The convergence of advances in digitisation, diagnostic technologies, artificial intelligence and machine learning means that it is possible for testing data to be turn into intelligence in real-time to inform disease control strategies**
- **Digital technology has long been thought of as a game-changer for many aspects of health care delivery. But digital technology adoption remains slow in most health care organizations due to data security concerns**



https://coronavirus.jhu.edu/map.html

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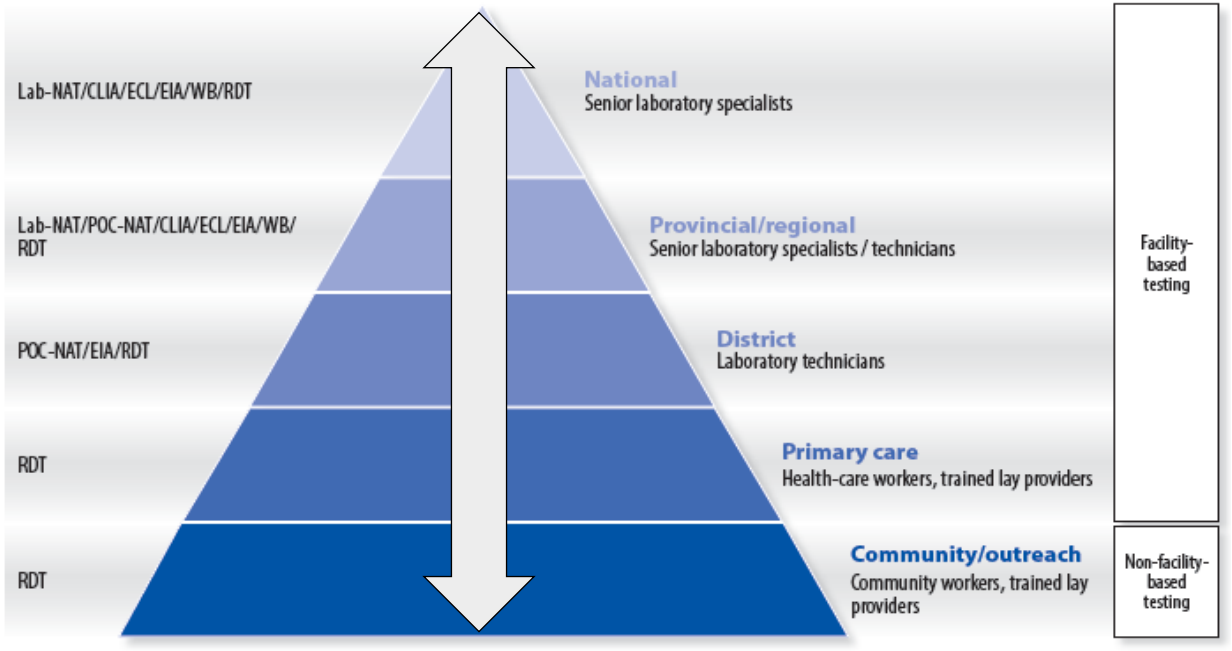
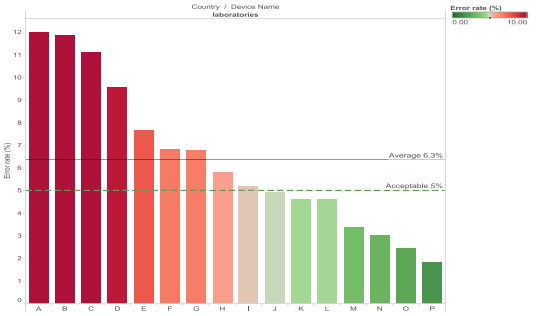
The importance of expansion of access to IVD



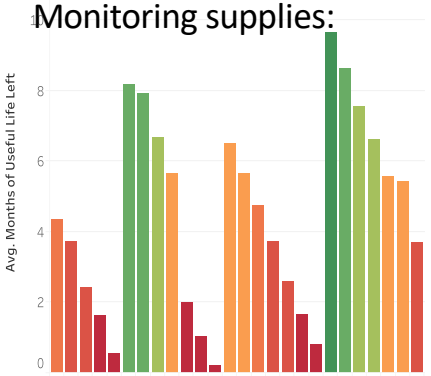
NAT: Nucleic acid tests: Lab-NAT: laboratory-based; POC-NAT: at point-of-care;
CLIA: chemiluminescence immunoassay; ECL: electrochemiluminescence immunoassay;
EIA: enzyme immunoassay; RDT: rapid diagnostic test

Source: Adapted from WHO 2017 Guidance for procurement of *in-vitro* diagnostics and related laboratory items and equipment

Monitoring error rates:



Monitoring supplies:



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DIAGNÓSTICO PARA A VIDA

Brazil: redefining the role of pharmacies and clinics

- Recent publication of the RDC 786/23 related to laboratory diagnostics.
- Main aspects:
  - Revision of the RDC 302 related to laboratory requirements and conditions
  - Creation of new spaces for testing

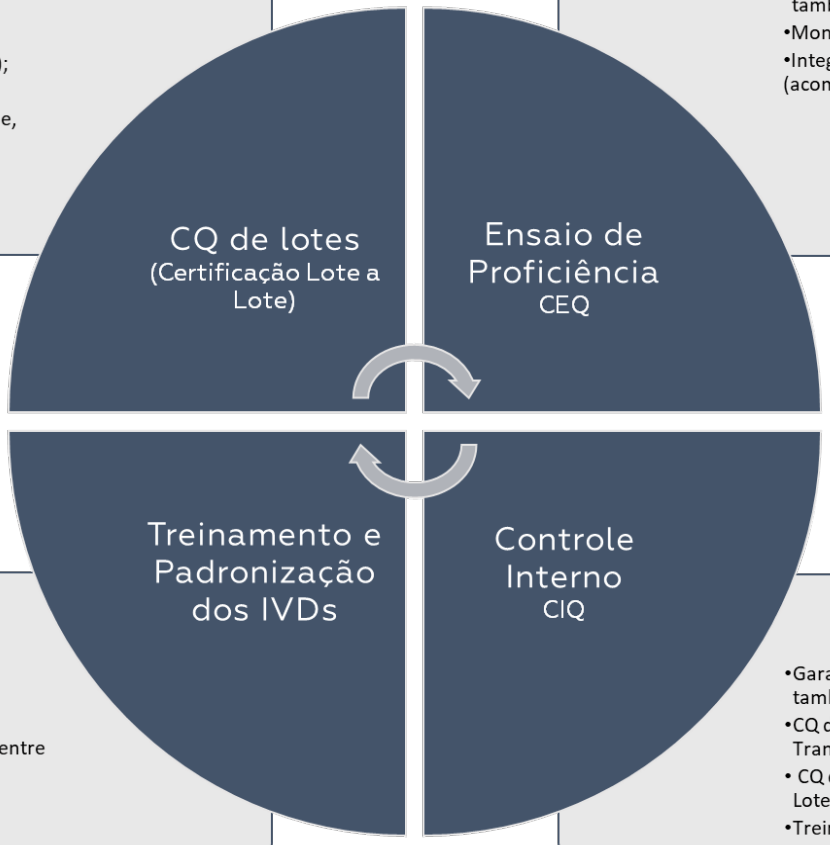
- Classification:
  - Type I = Pharmacies / Healthcare Clinics
    - Primary Sample (whole blood, oral fluid, nasal swab)
    - POCT – if supervised by a lab
  - Type II = Collection Centers
  - Type III = Clinical Labs

Quality Assurance for Rapid Tests

Segurança da qualidade dos IVDs de Teste Rápido

Garantia da Qualidade e Monitoramento Mercadológico

- Todos os exames;
- Todos os lotes do mercado;
- Qualitativos (Amostras Positivas e Negativas);
- Quantitativos (Amostras Patológicas e Normais);
- Integração amostras CEQ;
- Certificado do Lote (sensibilidade, especificidade, valor preditivo, precisão e exatidão)



- Garantia da Qualidade Analítico (erro sistemático e também aleatório)
- Monitoramento pós-venda
- Integração de amostras de CQ de lote (acompanhamento da estabilidade dos lotes)

- Treinamento para atendimento, coleta, interpretação e comunicação de resultado;
- Controle de Qualidade Analítico (objetivo, interpretações, ações corretivas e preventivas, entre outros)
- Seleção e Qualificação de IVDs
- Padronização de resultados com Sociedades Científicas utilizando Materiais de Referência

- Garantia da Qualidade Analítico (erro aleatório e também sistemático)
- CQ da Remessa ou Qualificação e Monitoramento de Transporte
- CQ da Troca de Lote ou CQ de lotes (Certificação Lote a Lote)
- Treinamentos
- Manutenções (preventivas e corretivas)

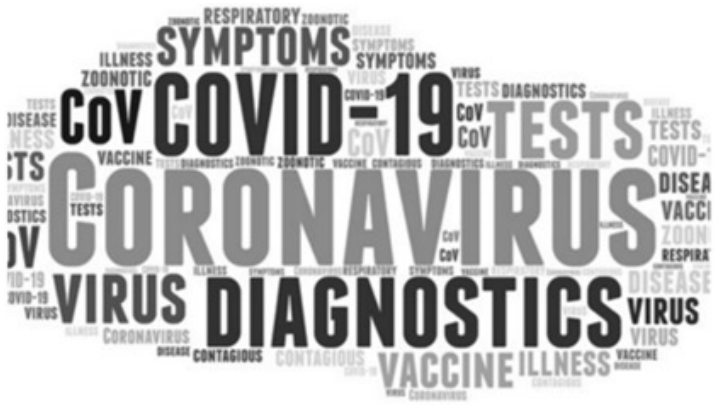
Redefining the role of pharmacies and clinics

- **Pharmacies have played a significant role in expanding access to health services during the COVID-19 pandemic** – not only for sale of self-test kits and conducting rapid antigen testing but also to provide health services for other patients
- Post-pandemic, countries should take advantage of rapid advances in diagnostic technologies, data digitisation and artificial intelligence, to **invest in a connected diagnostic system that serves as the backbone of the healthcare system, with appropriate diagnostic technologies at every level,** detecting unusual trends and turning data into intelligence in real-time to provide early alerts of outbreaks, improve supply chain management and quality of services. **Community pharmacies can provide the bedrock of this system to help countries make progress towards achieving the Sustainable Development Goals of leaving no one behind**
- Significant political, economic, social, and practice change would be required by all stakeholders. Further research is needed to **develop models for optimally integrate community pharmacy into primary care, using consensus, connectivity, communication and trust**

Conclusion

- The new Health environment – towards the XXII century!
  - Higher integration for a more sustainable health
    - With the medical specialties = responsible consumption
    - With suppliers and payors
    - With the whole Health System
    - IT = Health 4.0
  - Leadership
    - Discussion of the sector Evolution = Technological Horizon
    - Promotion of access to health for the “Invisible Patient” to the Healthcare System
    - Revision of current models of promotion of health
    - New health environments

Summary



- Diagnostics are part of the solution!
- Never forget: we always need the **right test to be used on the right patient in the right place at the right time!**
- **Diagnostics** will always be the best tool for developing **public health policy and to promote a quicker return to a normal (?) phase for the economy**
- **For the Future:**
  - **We must be prepared for the next pandemic! Are we?**
  - **Integration of Academy + Industry + Government**
  - **Self-sufficiency or new production arrangements = Global Value Chains in a new format (local x global)**
  - **Regional collaborative networks by different stakeholders (public x private)**

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Obrigado!

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