Inter-American
Coalition for
Regulatory Convergence

MEDICAL TECHNOLOGY SECTOR

Virtual Meeting "Engagement with External Stakeholders"

December 1, 2020

Inter-American
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Welcome Message

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TIME	AGENDA – Part I (Aprox. duration: 2 hrs., 10min.)
9:00 – 9:05	**Virtual Meeting Opening: Housekeeping message** Andrew Blasi, Technical Secretariat
9:05 – 9:10	**Welcome Message** Sandra Ligia González, Executive Secretary
9:10 – 9:50	**COVID-19 – Impact, response, recovery (40 min.)** Moderator: Sandra Ligia González – IACRC *Rosanna Peeling - London School of Hygiene and Tropical Medicine* (15 min.) Q&A (5 min.) *Katherine M. Serrano – Regional Director – FDA LATAM OFFICE* (15 min.) Q&A (5 min)
9:50 – 10:30	**Lessons learned from COVID -19 (40 min.)** Moderator: Sandra Ligia González – IACRC *Adriana Velázquez, Group Lead Medical Devices and In Vitro Diagnostics, MDD, WHO* (10 min.) *Alexandre Lemgruber, Regional Advisor, Health Technologies – PAHO* (10 min.) *Carlos Gouvêa – Executive President CBDL and ALADDIV* (10 min.) Q&A (10 min.)
10:30 – 11:00	**The Role of the WTO TBT Agreement & GRPs in support of Medical Device Regulatory Convergence (30 min.)** Moderator: Renata Amaral – IACRC Juliana Ghizzi Pires, General Coordinator of Regulatory Convergence and Barriers to Exports, Special Secretary for Foreign Trade and International Affairs Ministry of Economy, Brazil (10 min.) Jennifer Stradtman, Director, Technical Barriers to Trade, Office of the U.S. Trade Representative (10 min.) Q&A (10 min.)
11:00 – 11:10	**Closing Remarks** Sandra Ligia González - IACRC

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COVID-19 – Impact, response, recovery

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Rosanna Peeling
Professor and Chair of Diagnostic Research
London School of Hygiene and Tropical Medicine

COVID-19: Impact, Response and Recovery

Rosanna W Peeling
Professor and Chair, Diagnostic Research
Director, International Diagnostics Centre

www.idx-dx.org

COVID-19 Pandemic: Test, Test, Test

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

The Director-General of the World Health Organization urged countries to “test, test, test”. He says testing, isolation, and contact tracing should be the backbone of the global pandemic response.

COVID-19 Pandemic: Impact

- √ Recognition of diagnostics as critical tools in the pandemic response

- ➢ COVID exposed fault-lines and inequities in health care systems
- ➢ Fragmentation between public health and political decisions to save the economy led to confusion about how to fight the pandemic
- ➢ A parallel pandemic of mis-information through social media

COVID-19 Pandemic: Response

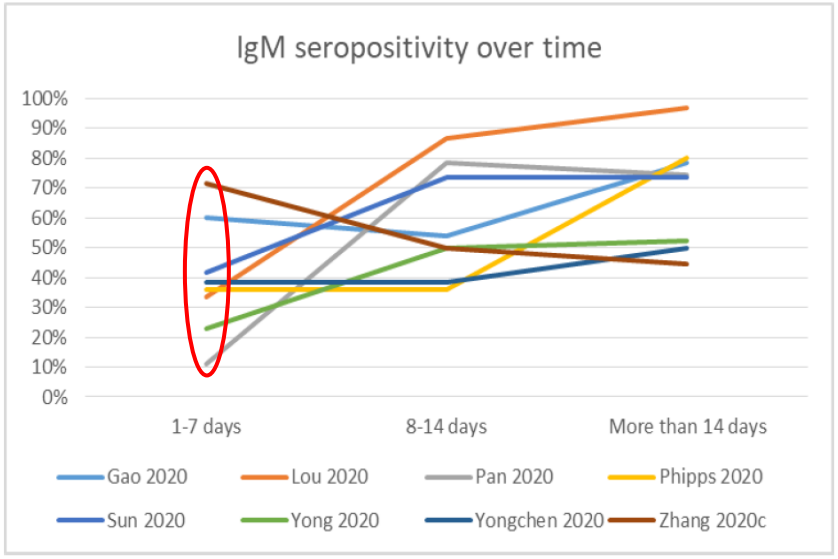
- √ Sharing of genomic sequence data and open access to all COVID publications
- √ Unprecedented response from the diagnostic Industry with >850 tests commercialised and more in the pipeline, despite late development of Target Product Profiles

- ➢ Global competition for molecular test kits, reagents and supplies
- ➢ Countries had to innovate on use of diagnostic tests

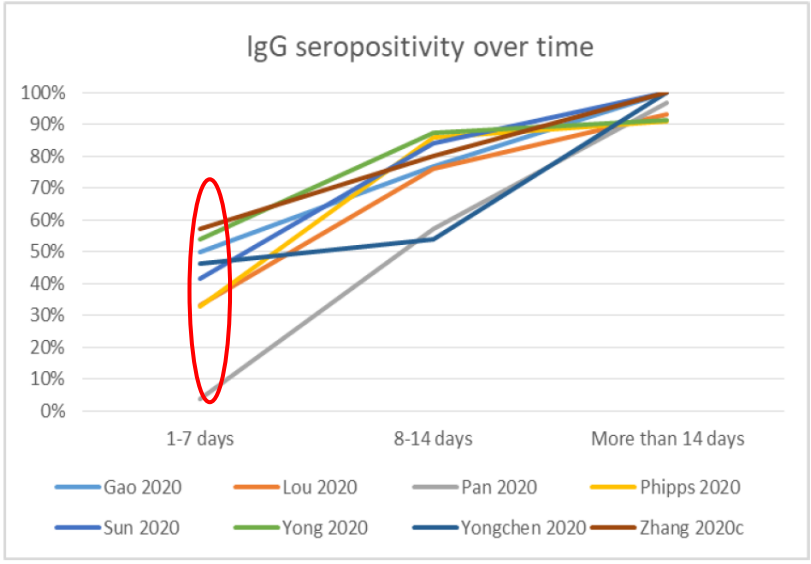
The right test for the right patient at the right time in the right setting

Diagnostic Tests	Target	Optimal time for use post onset symptoms	Use Case
Molecular: Lab POC	Viral RNA	day 0-7	confirm infection
Antigens: Lab POC	Viral Proteins	day 0-10	confirm infection
Serology: Lab POC	Host Antibodies	day 7-40	exposure, surveillance

IgM and IgG Responses in Symptomatic COVID-19 Patients



Note – Zhang 2020 collected data at following time points: <10 days, 10-20 days and 20-30 days.



Note – Zhang 2020 collected data at following time points: <10 days, 10-20 days and 20-30 days.

Source: Health Information and Quality Authority, Ireland, 2020

Use of Tests in Combination: RNA/Antigen + Serology Tests

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

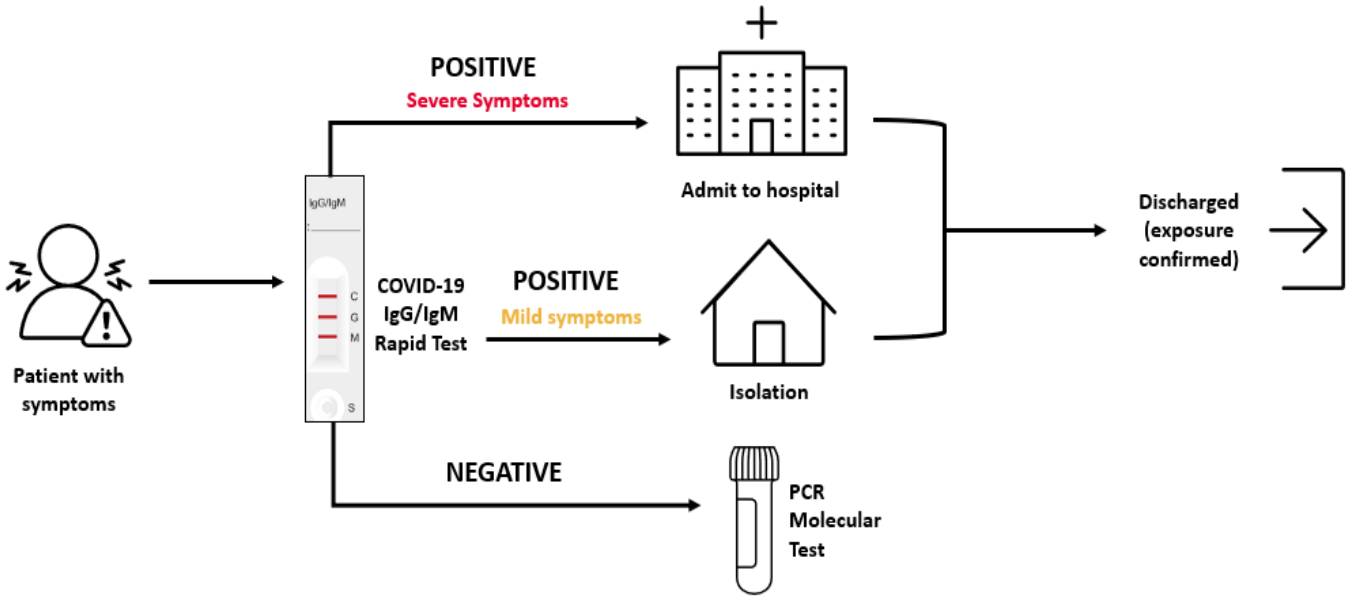
- Patients typically present late as symptoms for a variety of reasons
- A combination of molecular/antigen + serology tests may be useful for delayed case finding and contact tracing

Days post onset of symptoms	# patients	RNA+ (%)	AB+ (%)	RNA +Ab (%)
1-7	94	66.7	38.3	78.7
8-14	135	54.0	89.6	97.0
15-39	90	45.5	100	100

Zhao et al. Antibody responses to SARS-CoV-2 in patients of novel corona virus disease. CID 2020

Rapid Triage of Suspect Cases in Peru using Serology + Molecular Tests

- Population: 32 million; 500 ICU beds; backlog of molecular testing due to limited number of testing facilities;
- A MOH hotline and website allow those who have symptoms to call/connect



(http://elbuho.pe/2020/04/coronavirus-peru-ultimas-noticias-y-casos/)

Results:

1. Rapid community triage of symptomatic individuals
2. Relieve backlog and waiting time for molecular testing
3. Prevent the health care system from being overwhelmed

Rapid Antigen Tests for COVID-19

Company	Test	Specimens; time of collection*	Result	Sens/Spec (%)	Comment
Abbott, USA	BinaxNOW	NS; 0-7 days	Visual, 15 min	97/99	App for -ve results; Flu A+B
	PanBIO	NS, NP	Visual, 15-20min	93/99	
BD, USA	Veritor	NS	Instrument, 30 min	84/100	Flu A+B, RSV
Lumira, UK	LumiraDx	NS; 0-12 days	Instrument 12 min	98/97	
Quidel, USA	Sofia Antigen FIA with and without Flu test	NS, NP; 0-5 days	Instrument, 20 min	97/100	Does not differentiate between SARS-CoV and SC2
SD BioSensor	Standard Q	NS	Visual, 15 min		




NS = nasal swab; NP = nasopharyngeal swab; *days after onset of symptoms

WHO Target Product Profile: performance thresholds for antigen Tests: ≥80% sensitivity and ≥97% specificity

Scaling up Testing in the COVID-19 Response

Access options:

Health Facilities

Community Venues

Diagnostic options:

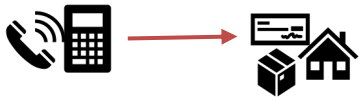
Lab based Molecular Tests

Rapid Molecular/Antigen Tests

- Testing of contacts of cases
- Surveillance:
  - Health care workers
  - Care home workers
  - Essential workers

Mass Gatherings

Online

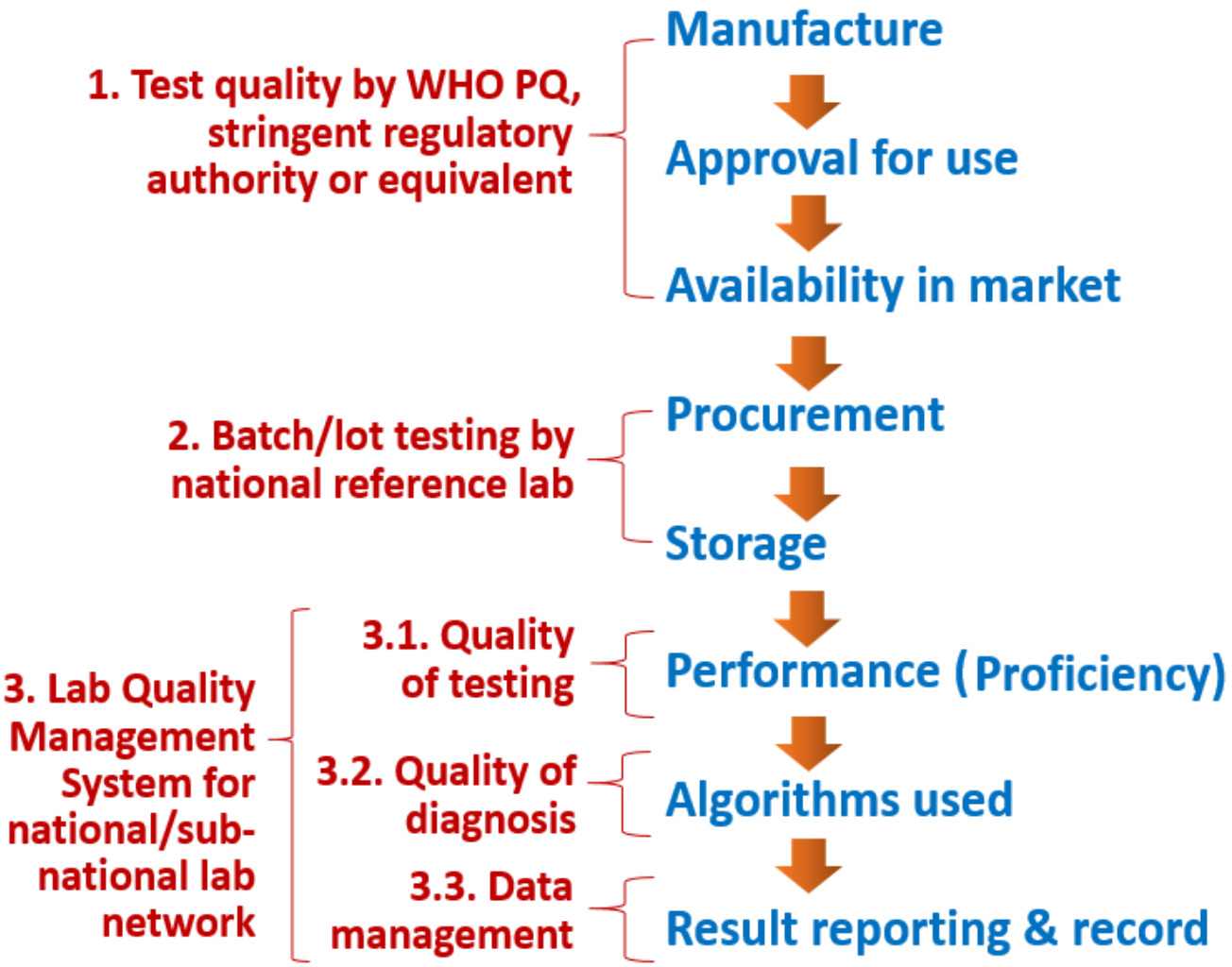


Border Crossings

? Routine COVID-19 screening of asymptomatic people

- in schools
- in workplaces, gyms, restaurants, shops
- mass gatherings e.g. sports events, concerts
- travel

The Quality Continuum



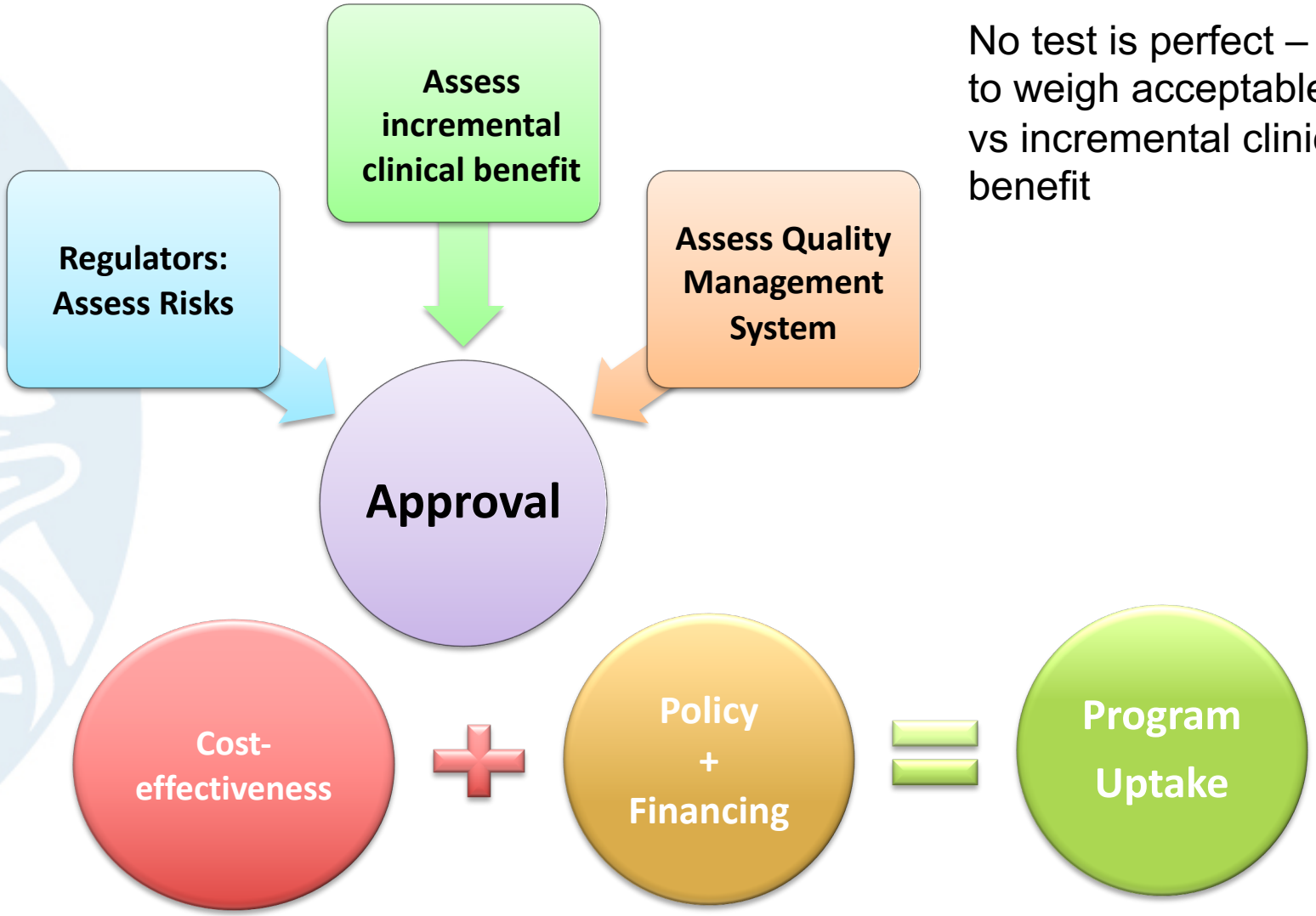
WHO Laboratory evaluation and assessment Guidance, checklists and tools Aug 2020

No Time to Lose

The most urgent needs for global public health today are for quality-assured medical devices to address epidemic preparedness and AMR:

- **Regulatory standardization: adoption existing standards and not reinvent the wheel**
- **Harmonization/convergence: GHTF, IMDRF**
- **Joint review of risk and benefit: Accelerating Diagnostic Access Project**
- **Data sharing: avoid duplication and delays**

Joint Review of Performance data to Accelerate Regulatory Approval and Policy development and Program Uptake

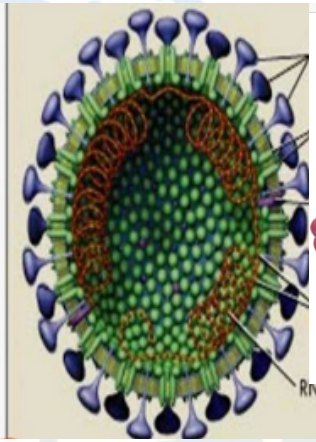


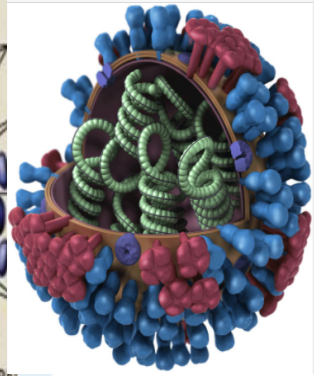
No test is perfect – need to weigh acceptable risks vs incremental clinical benefit

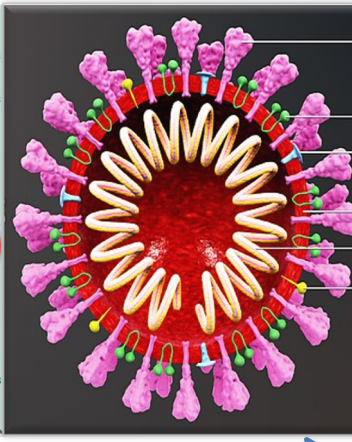
LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

COVID-19 Pandemic: Recovery

Global Health Emergencies:
Viral epidemics - more frequent and severe







2003-4 SARS

new tests

2009 Flu

2012 MERS-CoV

new tests

2013-6 Ebola

faster NAT and more sensitive Ag tests

2015-6 Zika

more sensitive Ag tests and more specific antibody tests

2019-20 COVID

new tests

COVID-19 Pandemic: Recovery

- √ **No one is safe until everyone is safe: Greater global cooperation, including regulatory aspects**
- √ **More resilient health systems that provide people-centred and inclusive services**

- Digitalization Need for guidance on data governance, access and sharing

PACIFIC HEALTH SUMMIT
SEATTLE - LONDON

Faster, Better, Safer, Cheaper Regulation of Health Products

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

Rosanna Peeling, Professor, London School of Hygiene & Tropical Medicine

Trevor Mundel, President of the Global Health at the Bill & Melinda Gates Foundation

Michael Watson , VP of Global Immunization Policy at Sanofi Pasteur

Rhona Applebaum, VP and Chief Scientific & Regulatory Officer, Coca-Cola Company

The purpose of this panel is to examine the relationship between regulation and innovation, and explore ways in which regulation can be utilized to stimulate innovation, avoid regulatory bottlenecks, inefficiencies, and inconsistency to reduce costs and to accelerate access.

Regulators should add value and be a part of the quality system, not an audit system, which comes after the fact and tries to establish guilt.

Trevor Mundel, President, Global Health, Bill & Melinda Gates Foundation


Thank you

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Katherine M. Serrano
Regional Director
USFDA LATAM Office

Q&A

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Lessons learned from COVID-19

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Adriana Velázquez Berumen
Group Lead Medical Devices and In-Vitro Diagnostics
WHO

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Alexandre Lemgruber
Regional Advisor, Health Technologies
PAHO

A Regional approach on Medical Device Regulation

Alexandre Lemgruber

Virtual Session of the Inter-American Coalition for Regulatory Convergence for the Medical Technology Sector | 1 December 2020

PAHO Pan American Health Organization

World Health Organization Americas
REGIONAL OFFICE FOR THE Americas

Regional Working Group on Medical Devices Regulation

- **Established in 2012**
- ***24 countries* are currently members**

Argentina	Belize	Bolivia	Brazil	Canada
Chile	Colombia	Costa Rica	Cuba	Dominican Republic
Ecuador	El Salvador	Guatemala	Guyana	Honduras
Jamaica	Mexico	Nicaragua	Panama	Paraguay
Peru	Trinidad & Tobago	Uruguay	Venezuela	

Activities of the Regional Working Group

Regional Meetings

- Annual Face to Face Meetings
  - Open Session with stakeholders
- Virtual Meetings

Training

- Annual virtual courses in collaboration with CECMED and INVIMA
- Face to face workshops on defined priority topics

Collaboration with IMDRF

- Regional Meetings in conjunction with the IMDRF Meetings
- Participation in the Working Groups
- Mirror Working Groups
- Translation of technical documents

Technical Groups

- Reuse and reprocessing of Medical Devices
- National Implant Registry

Medical Device Indicators

- Development of Basic Indicators
- Advanced Indicators pilot
- Participation in the Global Benchmarking Tool + Medical Devices

Community of Practices

- Regulation of Medical Devices
- REDMA Program

Regional Meetings

Open sessions of the Regional Working Group with stakeholders

I Open Session 21 October 2016 – Mexico City	II Open Session 21 September 2017 - Ottawa, Canada	III Open Session 23 October 2018 – Santa Tecla, El Salvador	IV Open Session 5 September 2019 – Bogota, Colombia
• Activities of the **Regional Working Group** • Medical Devices **Postmarket surveillance** • Software as Medical Device • Reuse and reprocessing of Medical Devices	• Medical Devices use in public health programs • Regulation of Medical Devices in the Americas (regulators and manufacturers perspective) • Use of standards for regulatory purposes • Standards Alliance Survey	• Challenges of the Regulation of Medical Devices in the Americas (regulators and manufacturers perspective) • Medical Devices Postmarket Surveillance in the USA • Medical Devices Regulatory framework in Europe • Experiences on Medical Devices Regulatory framework in the Region • Cibersecurity • Results of the Standards Alliance Survey	• Perspectives of the Medical Device Single Audit Program (MDSAP) • Medical Devices Nomenclature • Cibersecurity • Regulation of Personalized Medical Devices • Improving the quality of international medical device standards for regulatory use • Findings of the Standards Alliance Project

Training activities

FACE-TO-FACE

58 delegates from **31 countries**

“Medical Devices in Latin America” Seminar

July 2019 - Montevideo

Post Marketing Surveillance of Medical Devices

September 2019 - Bogota

ONLINE

413 delegates from around **32 countries**

Courses available in **Spanish** & **English**

Medical Devices Regulation, emphasis on Post market Surveillance

June – October, 2019

Regional Virtual Course on the REDMA Program

January, 2020

Virtual Module on Technovigilance

November, 2020

Collaboration with the IMDRF

Participation in the IMDRF Working Groups

Medical Device Clinical Evaluation	Personalized Medical Devices	Good Regulatory Review Practices	Principles of In Vitro Diagnostic (IVD) Medical Devices Classification
▪ Represented by • ANMAT, Argentina	▪ Represented by: • ANMAT, Argentina	▪ Represented by: • INVIMA, Colombia	▪ Represented by: • ANMAT, Argentina • CECMED, Cuba • Ministry of Health, Uruguay

Collaboration with IMDRF

Translation of documents


IMDRF MDCE WG/N55 FINAL:2019 (antes GHTF/SG5/N1R8:2007)

IMDRF International Medical Device Regulators Forum

DOCUMENTO FINAL

Foro Internacional de Organismos Regulatorios de Dispositivos Médicos

Título: Evidencia clínica. Principales definiciones y conceptos

Elaborado por: Grupo de trabajo sobre evaluación clínica de los dispositivos médicos

Fecha: 10 de octubre del 2019

Elena M. Astapenko, presidenta del IMDRF

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© Foro Internacional de Organismos Regulatorios de Dispositivos Médicos, 2019

Spanish

1. IMDRF/PMD WG/N49 FINAL:2018 | ***Definitions for Personalized Medical Devices***
2. IMDRF/Standards WG/N51 FINAL:2018 | ***Optimizing Standards for Regulatory Use***
3. IMDRF MDCE WG/N55 FINAL:2019 | ***Clinical Evidence - Key definitions and concepts***

Spanish & Portuguese

4. IMDRF/GRRP WG/N40 FINAL:2017 | ***Competence, Training, and Conduct Requirements for Regulatory Reviewers***
5. IMDRF/GRRP WG/N47 FINAL:2018 | ***Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices***
6. IMDRF/GRRP WG/N52 FINAL:2019 | ***Principles of Labelling for Medical Devices and IVD Medical Devices***


IMDRF/GRRP WG/N52 FINAL:2019

IMDRF International Medical Device Regulators Forum

DOCUMENTO FINAL

Fórum Internacional de Reguladores de Dispositivos Médicos

Título: Princípios da rotulagem de dispositivos médicos e de dispositivos médicos para diagnóstico *in vitro*

Grupo de autoria: Boas práticas de análise regulatória do IMDRF

Data: 21 de março de 2019

Elena M. Astapenko, presidente do IMDRF

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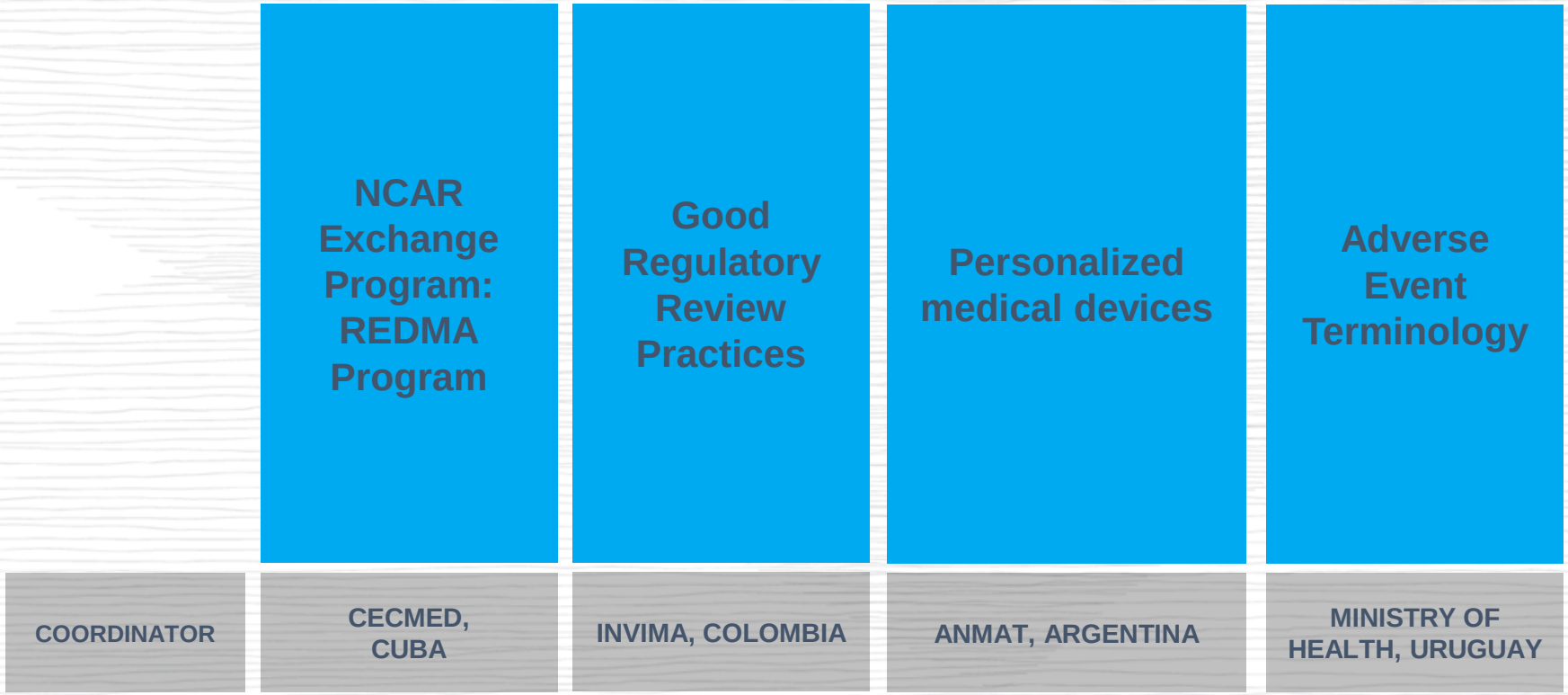
IMDRF Mirror Working Groups



Activities related to Medical Devices in the context of COVID-19

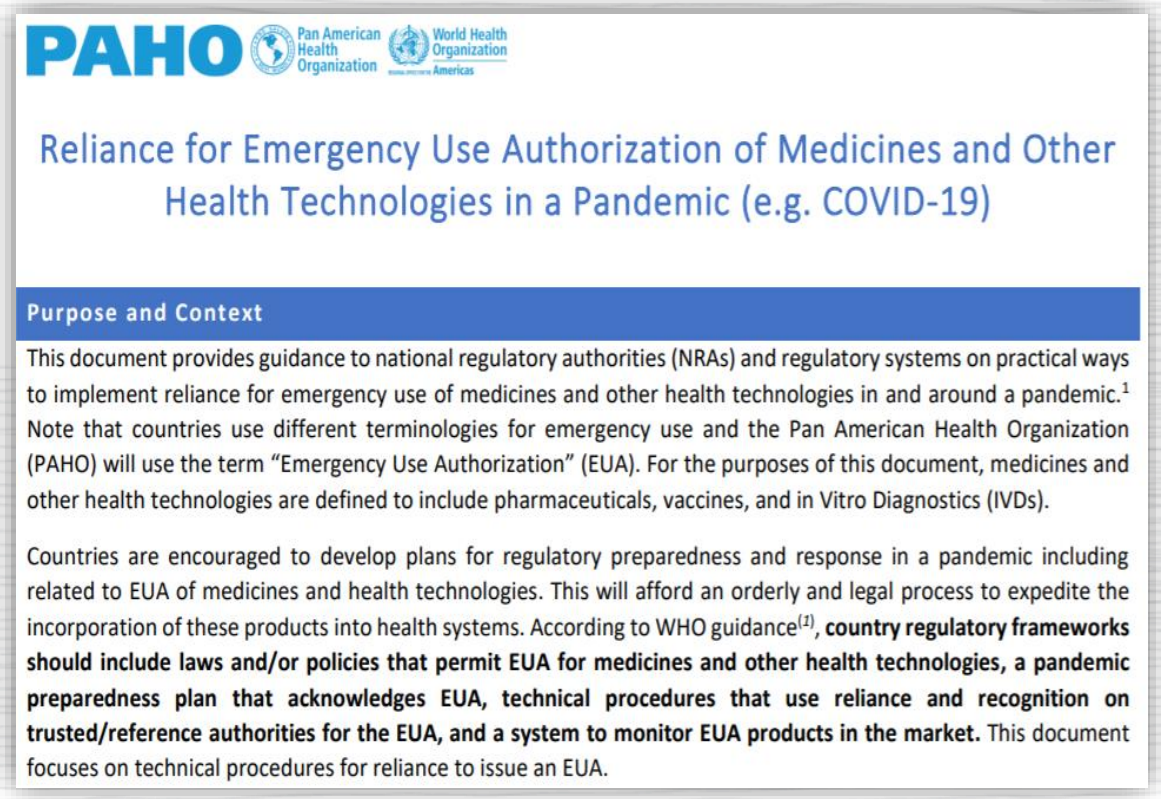
Regional coordination

- **Dissemination of information** (alerts, regulatory updates, publication of technical guidelines)
- Coordination of **webinars** and **virtual meetings** to share experiences and promote cooperation among countries of the Region
- Working group on ventilators in the context of COVID-19

Technical support

- **Quality assurance** of medical devices purchased through PAHO
- **Technical support** in the evaluation of medical devices as part of local procurement
- **Training** sessions on the evaluation and operation of medical equipment purchased through PAHO
  - ❑ 3 training sessions on quality assurance of medical equipment
  - ❑ 2 training sessions on the operation of oxygen concentrators

Reliance for Emergency Use Authorization of Medicines and Other Health Technologies in a Pandemic (e.g. COVID-19)



PAHO Pan American Health Organization World Health Organization Americas

Reliance for Emergency Use Authorization of Medicines and Other Health Technologies in a Pandemic (e.g. COVID-19)

Purpose and Context

This document provides guidance to national regulatory authorities (NRAs) and regulatory systems on practical ways to implement reliance for emergency use of medicines and other health technologies in and around a pandemic.[1] Note that countries use different terminologies for emergency use and the Pan American Health Organization (PAHO) will use the term "Emergency Use Authorization" (EUA). For the purposes of this document, medicines and other health technologies are defined to include pharmaceuticals, vaccines, and in Vitro Diagnostics (IVDs).

Countries are encouraged to develop plans for regulatory preparedness and response in a pandemic including related to EUA of medicines and health technologies. This will afford an orderly and legal process to expedite the incorporation of these products into health systems. According to WHO guidance[1], **country regulatory frameworks should include laws and/or policies that permit EUA for medicines and other health technologies, a pandemic preparedness plan that acknowledges EUA, technical procedures that use reliance and recognition on trusted/reference authorities for the EUA, and a system to monitor EUA products in the market.** This document focuses on technical procedures for reliance to issue an EUA.

"Country regulatory frameworks should include laws and/or policies that permit EUA for medicines and other health technologies, a pandemic preparedness plan that acknowledges EUA, ***technical procedures that use reliance and recognition on trusted/reference authorities for the EUA****, and a system to monitor EUA products in the market".*

The document focuses on technical procedures for reliance to issue an EUA for pharmaceuticals, vaccines and **IVDs**.

https://iris.paho.org/bitstream/handle/10665.2/52027/PAHOHSSMTCOVID19200006_eng.pdf?sequence=1&isAllowed=y

Publications on Medical Devices in the context of COVID-19

List of Priority Medical Devices in the context of COVID-19 13 August 2020 https://iris.paho.org/handle/10665.2/52580
Technical and Regulatory Aspects of the Use of Pulse Oximeters in Monitoring COVID-19 Patients 7 August 2020 https://iris.paho.org/handle/10665.2/52589
Post-authorization Surveillance of Medical Products during a Pandemic Emergency 21 July 2020 https://iris.paho.org/handle/10665.2/52578
Technical and Regulatory Aspects of the Extended Use, Reuse, and Reprocessing of Respirators during Shortages 10 June 2020 https://iris.paho.org/handle/10665.2/52431
Regulation of Medical Devices in the Context of COVID-19 14 May 2020 https://iris.paho.org/handle/10665.2/52489

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Carlos Gouvêa
Executive President
CBDL and ALADDIV

Access, Quality and Mass Testing:

Lessons learned from COVID-19

Carlos Gouvêa

Inter American Coalition for Regulatory Convergence – Dec 1st 2020

ALDIMED

INSTITUTO ÉTICASAÚDE

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

cbdl DIAGNÓSTICO PARA A VIDA

ALADDiV

The International Diagnostics Centre

gda GLOBAL DIAGNOSTICS ALLIANCE

ABIIS Aliança Brasileira da Indústria Inovadora em Saúde

www.aladdiv.org.br

How it all started…

Rosanna Peeling , Carlos Gouvea , Adele Benzaken, Graciela Russomando
Alain Mérieux, Patricia Velez Moller and Segundo Leon

International Workshops

"Accessible and Quality Assured *in Vitro* Diagnostic Tests for Public Health Programs"

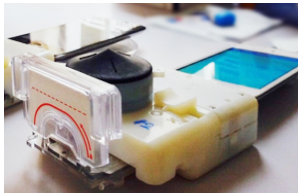
Brasília, April 2012 (PAHO)
Brasília, November 2012 (ANVISA)
Curitiba, October / November 2013 (TECPAR)
Brasília, November 2014 (ParlaMundi/LBV)
Peru, May 2015 (Universidad Cayetano Heredia)
Florianópolis, Sept 2016 (IMDRF)
Ottawa, Oct 2017 (PAHO/IMDRF)
São Paulo, April 2018 (Fleury)
Brasília, Dec 2018 (ANVISA)
Brasília, Sept 2019 (ANVISA)
Zoom/YouTube, Aug 2020 (WHO/LSHTM)

Science Fiction or Reality?

Source: Gabriela Tannus/AxiaBio

Seegene

KH Medical



Explosion in near-patient molecular platforms

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

- Strip

Cassette

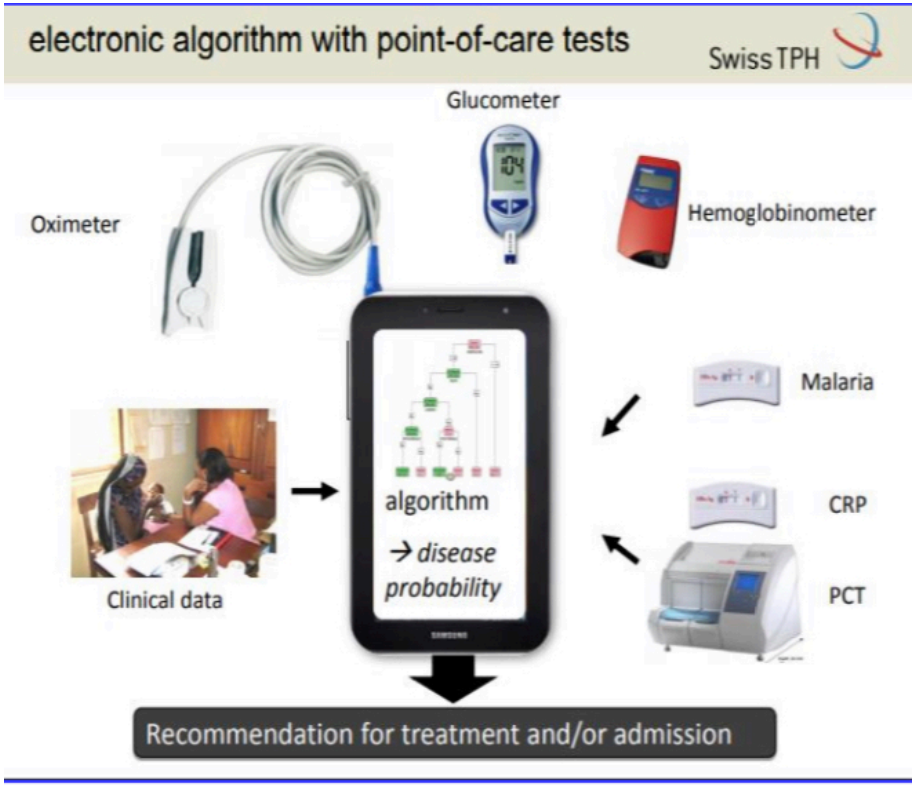
Card

Dipstick

Multi-assay instruments

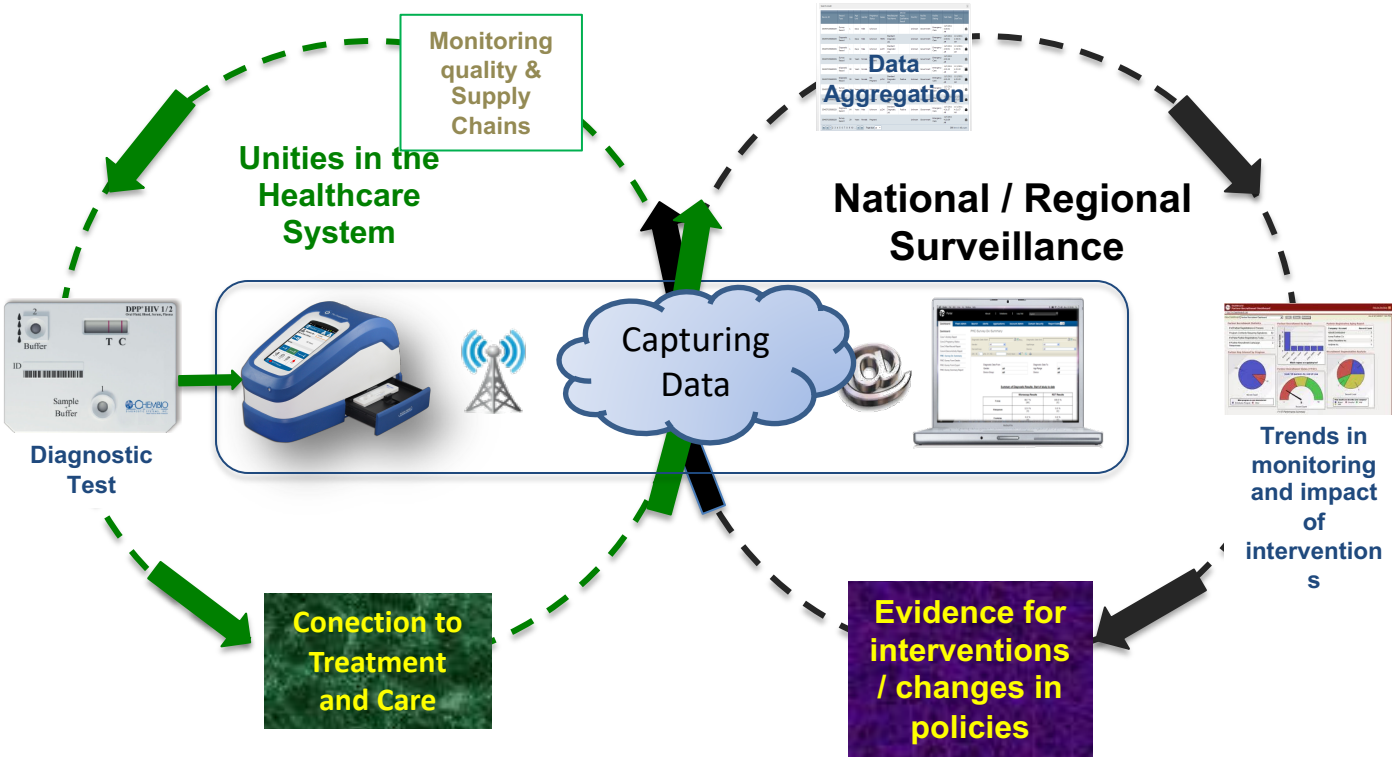
Source: Alere

Integrating solutions



Source: Rosanna Peeling

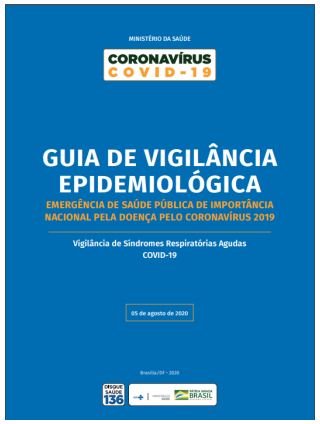
Readers: Conecting Results of PoCT to Surveillance



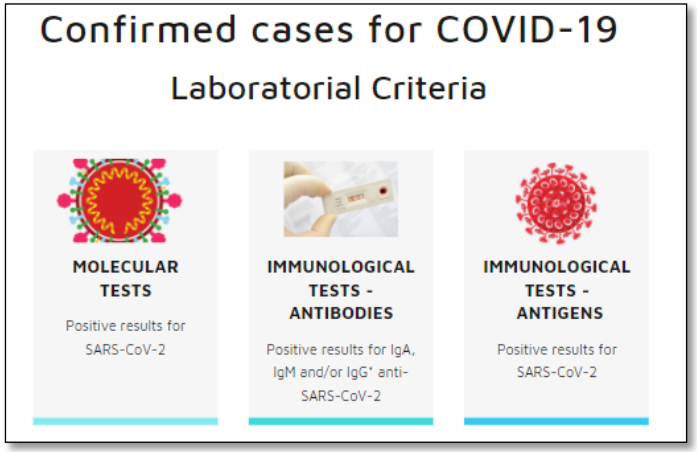
Source: Rosanna Peeling

Brazil

Diagnostic

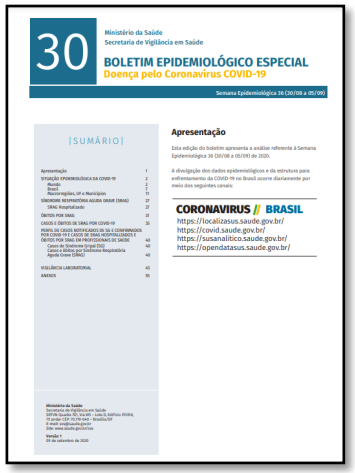


- **Clinical Diagnostic**
- **Laboratory Diagnostic**



- **Diagnostic Imaging**

- **Molecular Tests**



- 6,5 MM RT-qPCR tests
  - 27 Central Labs
  - 3 National Influenza Centers and collaborative Labs
- 2,5 MM swabs distributed
  - For the 27 states
- 1,8 MM collection tubes
  - For the 27 states

Benchmark from HIV, Hepatites and Syphilis

- Expertise, personnel, consummables and infrastructure were essential for the fast implementation of the SARS-CoV-2 molecular testing in the public services.

- Distance Learning platform used for HIV, HV and Syphilis were used for the content production of educational material for COVID-19

Epidemiology and Infection

cambridge.org/hyg

From the Field

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Increasing molecular diagnostic capacity and COVID-19 incidence in Brazil

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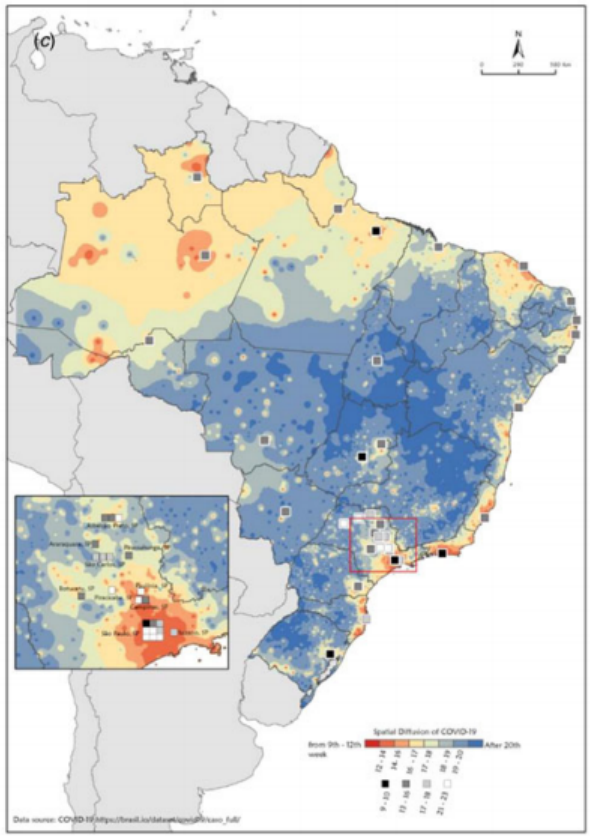
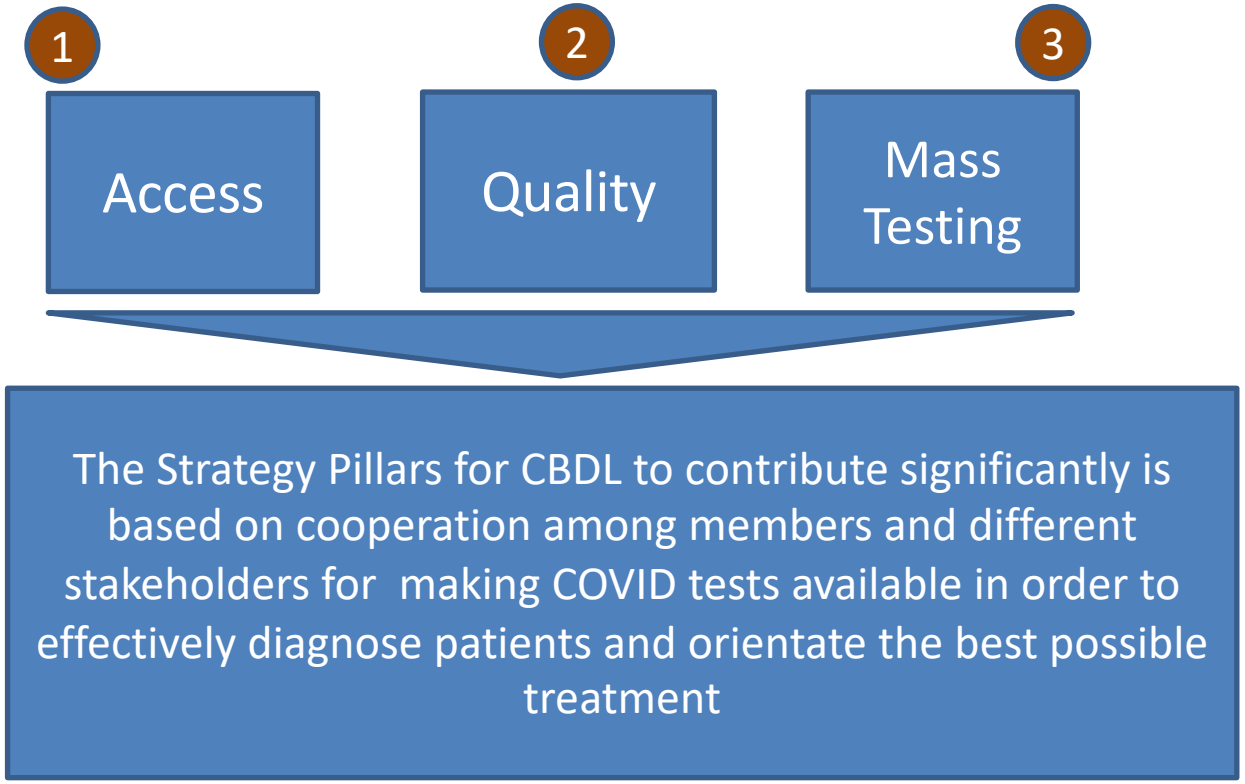
Abstract

Different countries have adopted strategies for the early detection of SARS-CoV-2 since the declaration of community transmission by the World Health Organization (WHO) and timely diagnosis has been considered one of the major obstacles for surveillance and health-care. Here, we report the increase of the number of laboratories to COVID-19 diagnosis in Brazil. Our results demonstrate an increase and decentralisation of certified laboratories, which does not match the much higher increase in the number of COVID-19 cases. Also, it becomes clear that laboratories are irregularly distributed over the country, with a concentration in the most developed state, São Paulo.



https://www.cambridge.org/core/journals/epidemiology-and-infection/article/increasing-molecular-diagnostic-capacity-and-covid19-incidence-in-brazil/D5FB1AC8785D28ABD4B01E023DDD421F

Strategy


1
Access
2
Quality
3
Mass Testing
The Strategy Pillars for CBDL to contribute significantly is based on cooperation among members and different stakeholders for making COVID tests available in order to effectively diagnose patients and orientate the best possible treatment

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) = 385 Registrations (Sept/20) (*)
  - Imports

- Resource Mapping

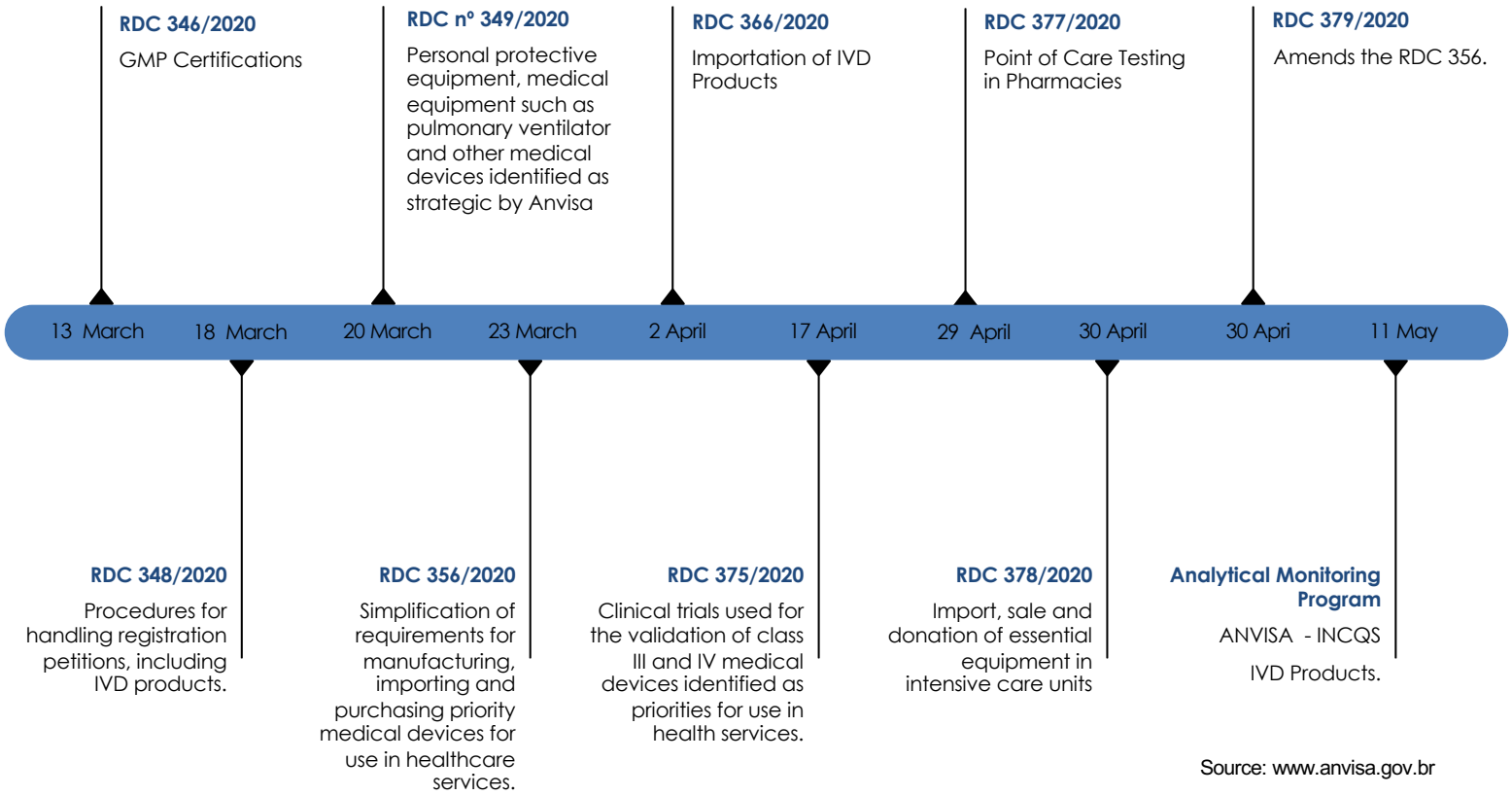
https://app.powerbi.com/view?r=eyJrIjoiNTY5NGJmZWQtMWU3YS00ZTNjLTllZWUtNmFlZWUyODFkYTQ5IiwidCI6ImI2N2FmMjNmLWMzZjMtNGQzNS04MGM3LWI3MDg1ZjVlZGQ4MSJ9 (*)

1

Access

ANVISA ACTIONS

EXTRAORDINARY AND TEMPORARY PROCEDURES



Source: www.anvisa.gov.br

RELIANCE

"A regulatory authority may take into account and give significant weight to (i.e. rely upon) assessments performed by another regulatory authority or other trusted institution in reaching its own decision". WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices

Example:

RDC nº 379/2020

"The import and purchase of protective equipment is allowed ventilators, circuits, connections and respiratory valves, monitors parametric and other medical devices, essential for combating COVID-19, new and not regulated by Anvisa, as long as they are regulated and marketed in jurisdiction member of the International Medical Device Regulators Forum (IMDRF), by bodies and public and private entities, as well as health services, when not available for the trade similar devices regularized at Anvisa.

IMDRF Members:

- Australia
- Brazil
- Canada
- China
- Europe
- Japan
- Russia
- Singapore
- South Korea, and
- the United States of America.

2

Quality

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

SBPC ML
Sociedade Brasileira de Patologia Clínica
Medicina Laboratorial

cbdl
DIAGNÓSTICO PARA A VIDA

SBAC
Sociedade Brasileira de Análises Clínicas

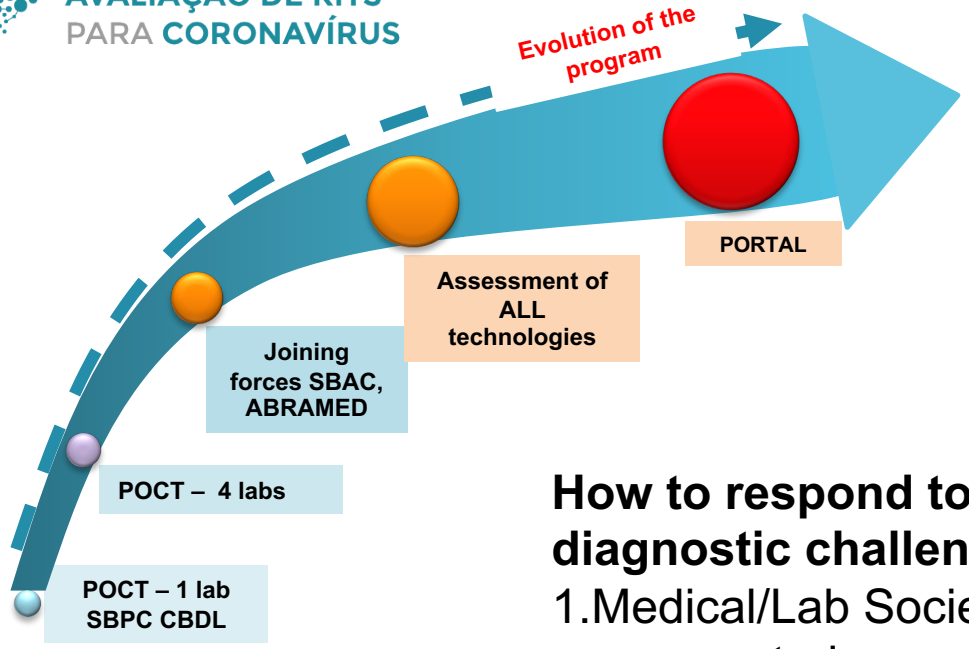
Abramed
ASSOCIAÇÃO BRASILEIRA DE MEDICINA DIAGNÓSTICA

- Consortium with 13 labs (public/private)

Program of Assessment of Kits for Coronavirus

2

PROGRAMA DE
AVALIAÇÃO DE KITS
PARA CORONAVÍRUS



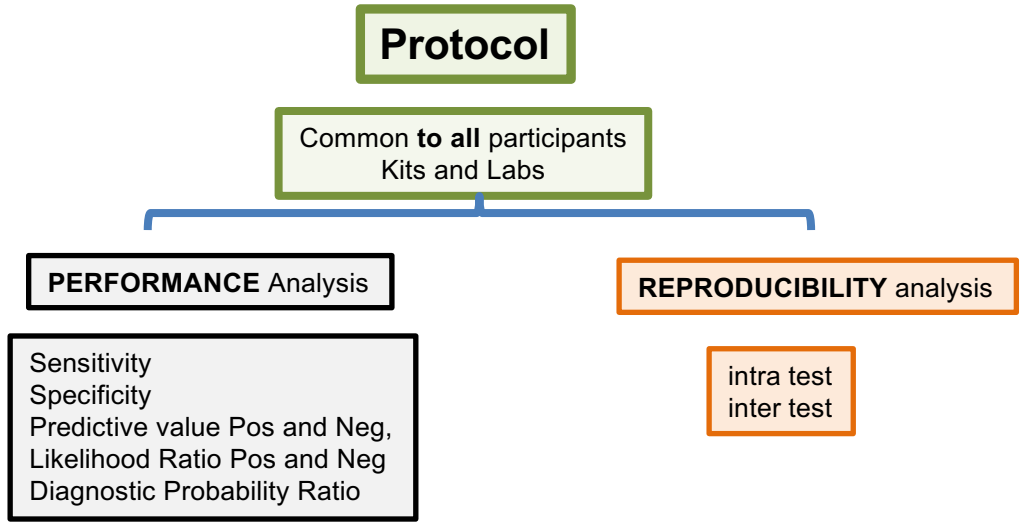
How to respond to the diagnostic challenge:

1. Medical/Lab Societies duly represented
2. Engagement of Large labs
3. Engagement of Suppliers
4. Scientific knowledge

Source: Alvaro Pulchinelli

https://testecovid19.org

PROGRAMA DE
AVALIAÇÃO DE KITS
PARA **CORONAVÍRUS**



Source: Alvaro Pulchinelli

- 13 labs
  - Private and Public
- 44 suppliers
- More than 52 kits evaluated
- Over 15,000 samples analyzed

Key Figures

Source: Alvaro Pulchinelli

Series of Actions

- International Cooperation
  - LSHTM – London School of Hygiene & Tropical Medicine
  - EU / FIND + WHO
  - Evaluation of kits available
  - Cooperate with International Publications

https://www.youtube.com/watch?v=j2SJMa7vVq8

- Local Cooperation
  - SBPC, ABRAMED and SBAC + ANVISA and MoH
  - Evaluation of kits available in the market
    - Product Reference Lists – Performance
      - Public data
      - Common Protocols
      - Top Laboratories with Access to Hospital Samples

3

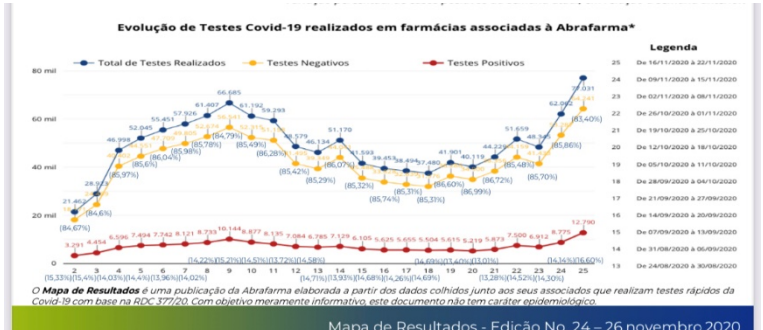
Mass Testing

- Pandemic
  - Need to have a clear picture of current situation in order to mitigate the risks
  - Public Health issue
    - Ministry of Health (MoH) role
      - Expectation of acquisition of over 46 million tests
        - » RT-PCR
        - » Rapid Tests(Ab)
    - UFPel – EpiCOVID19
      - » http://www.epicovid19brasil.org/

Mass Testing

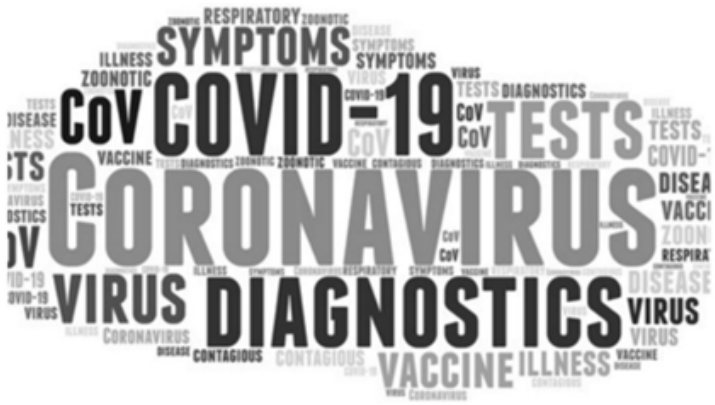
- Pandemic
  - Hospitals (> 6,000)
  - Laboratories (> 18,000)
- How to take the next step?
  - Pharmacies / Drugstores (>88,000)
    - RDC 377/20
  - Companies
    - If served by Clinical Analysis Lab
      - (RDC 302/05)

- Goals:
  - Epidemiological Study
  - Information about the individual status
  - Support for the return to work



CONCLUSION

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!**
- **Combination of molecular/antigen + serology tests** improves case detection
- **Serology tests = important to know the extent of the pandemic, map its distributions, identify hotspots and at risk populations, monitor trends**
- **Diagnostics** will be the best tool for developing **public health policy**
- Despite the great achievements in such a short time, we still have a lot to learn in order to be prepared for the next pandemic BUT

RELIANCE & COOPERATION ARE THE KEY!

The future is in our hands…

Obrigado!

Carlos Eduardo Gouvêa

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www.aladdiv.org.br

Q&A

Inter-American
Coalition for
Regulatory Convergence
MEDICAL TECHNOLOGY SECTOR

The Role of the WTO TBT Agreement & GRPs in support of Medical Device Regulatory Convergence

Inter-American
Coalition for
Regulatory Convergence
MEDICAL TECHNOLOGY SECTOR

Juliana Ghizzi Pires
General Coordinator of Reg. Convergence and Barriers to Exports
Special Secretary for Foreign Trade and International Affairs
Ministry of Economy
Brazil

Inter-American
Coalition for
Regulatory Convergence
MEDICAL TECHNOLOGY SECTOR

Jennifer Stradtman
Director, Technical Barriers to Trade
Office of the U.S. Trade Representative

Q&A

Closing Remarks