

**Beyond vaccines: mapping other COVID-19 essential
health technologies and trade**

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ALDIMED+



LONDON
SCHOOL of
HYGIENE
& TROPICAL
MEDICINE



cbdI
DIAGNÓSTICO PARA A VIDA



ALAD **DiV**

The
**International
Diagnostics
Centre**

gda
GLOBAL **DIAGNOSTICS** ALLIANCE

ABIIS | Aliança Brasileira da
Indústria Inovadora
em Saúde



Explosion in near-patient molecular platforms



Seegene



KH Medical



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



• Strip



Cassette



Card

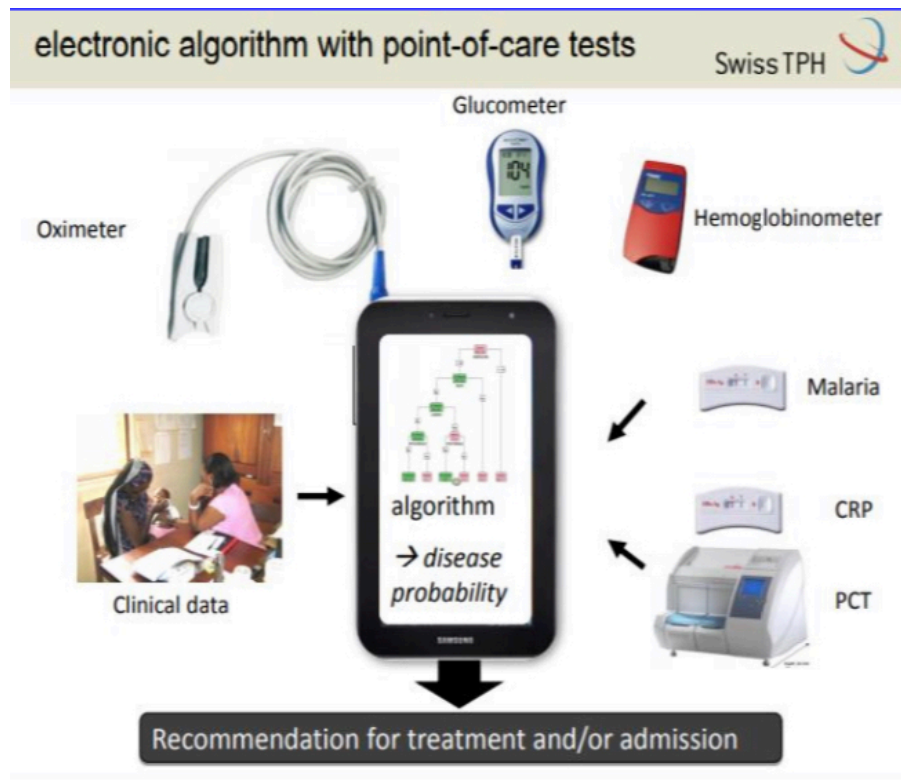


Dipstick

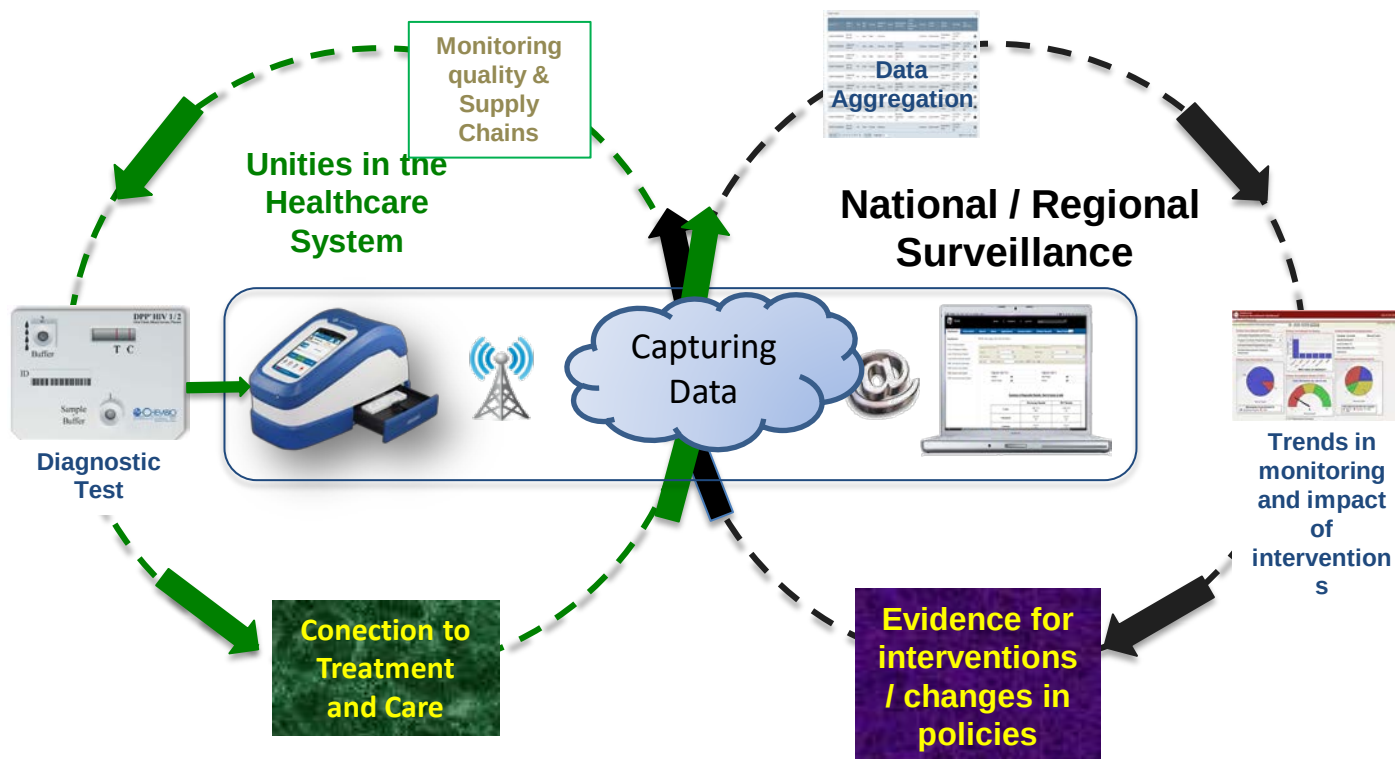


Multi-assay instruments

Integrating solutions



Readers: Connecting Results of PoCT to Surveillance



Strategy



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

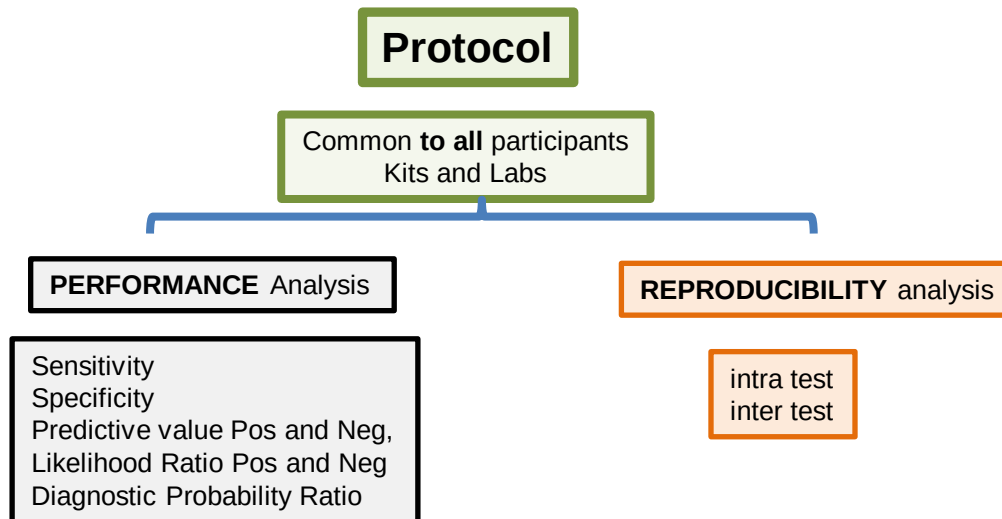
Series of Actions

- Development of New Products
 - RT PCR
 - Rapid Tests – Antigen and Antibody (ex: immunochromatographic tests)
 - POCT – Point of Care Testing
 - ELISA, CLIA, Fluorescence, etc.
- ANVISA
 - GMPC – Good Manufacturing Practice Certificate
 - Product Registration (Risk Class III) = 633 Registrations Approved (June/21) (*)
 - Imports
- Resource Mapping

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



- Consortium with 13 labs (public/private)



INICIATIVA

Entidades do setor laboratorial unidas no programa de avaliação dos kits diagnóstico para Covid-19



LABORATÓRIOS PARTICIPANTES



<https://www.aladdiv.org.br>

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

Key Figures

Source: Alvaro Pulchinelli

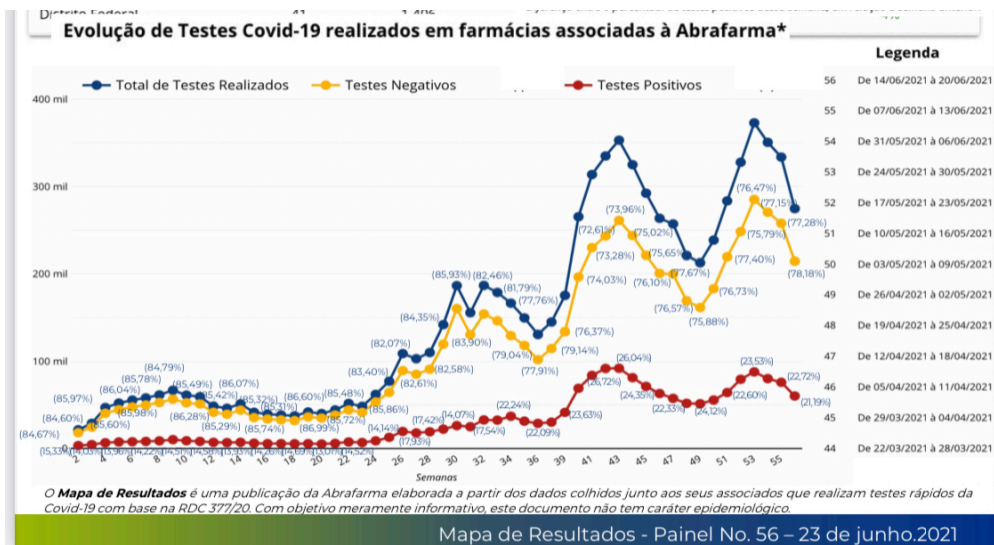
www.testecovid19.org

Mass Testing

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

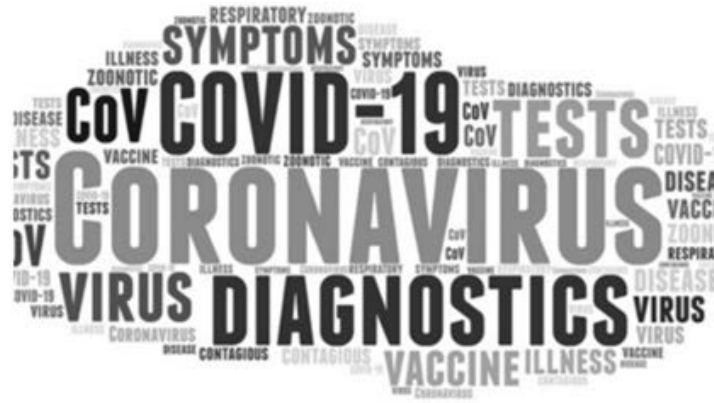
Mass Testing

- 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
 - Control Spread of the Infection



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!**
- **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? What about the “One Health Approach”?
 - Better integration of Academy + Industry + Government
 - Self-sufficiency or new production arrangements = Global Value Chains in a new format (global and/or local)
 - Regional collaborative networks by different stakeholders (public x private) = Regulatory Convergence is key!

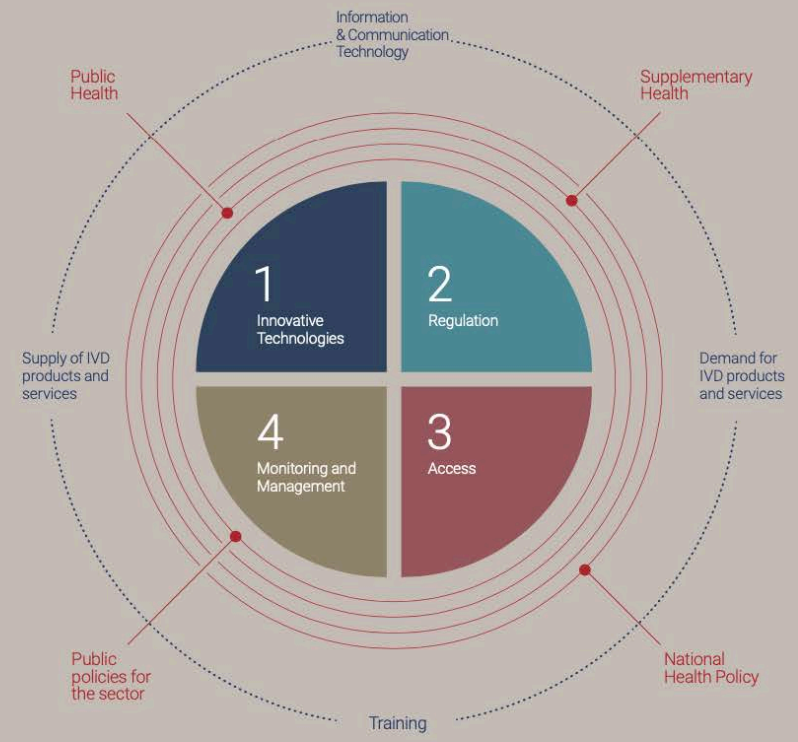
LABORATORY DIAGNOSTICS WHITE BOOK 2021-2022

cbdl
CONSELHO BRASILEIRO
DE DIAGNÓSTICO LABORATORIAL



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

LIFE CYCLE OF MEDICAL AND LABORATORY DIAGNOSTIC DEVICES IN THE CONTEXT OF THE NATIONAL HEALTH SYSTEM





The future is in our hands...





Obrigado!

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