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

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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

Source: Alere
Integrating solutions

Source: Rosanna Peeling
Readers: Connecting Results of PoCT to Surveillance

Source: Rosanna Peeling
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

https://app.powerbi.com/view?r=eyJrIjoiNTY5NGJmZWQtMWU3YS00ZTNjLTllZWRtNnFjZWUtYyJ9
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
Protocol

Common to all participants
Kits and Labs

PERFORMANCE Analysis
- Sensitivity
- Specificity
- Predictive value Pos and Neg
- Likelihood Ratio Pos and Neg
- Diagnostic Probability Ratio

REPRODUCIBILITY analysis
- intra test
- inter test

Source: Alvaro Pulchinelli

www.testecovid19.org
Key Figures

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

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!
The future is in our hands...
Obrigado!

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