Infectious Disease Diagnostics

Tackling Infectious Diseases

Uppsala Health Summit - October10th, 2017

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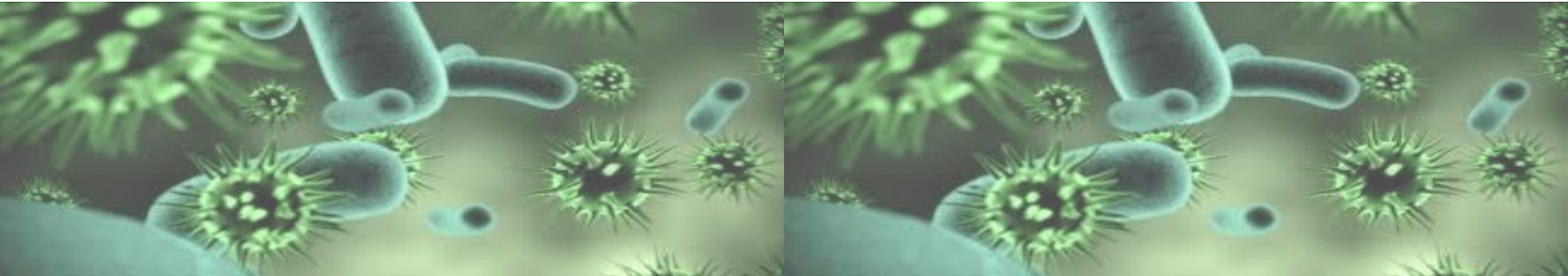


When to tackle infectious diseases

Prevention & action – contribution from Diagnostic solutions

Surveillance	**Track & prevent:** find outbreaks – pathogens – resistances – in hospital/globally – blood screening
Screening	**Identify infections:** patient screening – population at risk
Diagnosis	**What's the bug / patient response**: bacteria/viruses/fungi/parasites– resistances – severity of infection – risk for sepsis - sepsis
Treatment decision	**Act precisely & with impact:** which therapy – broad/narrow spectrum antibiotics – avoid antibiotic resistance – isolate patient – intensive care – closely monitoring
Monitoring	**React:** monitoring therapy response – change treatment – treatment duration

How to tackle Infectious Diseases

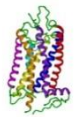
Diagnostic technologies

Infectious Diseases

Traditional

Culture

Molecular



Proteomics
(Proteins)

ELISA

Mass Spec

Genomics
(DNA/RNA)

NAAT
NGS

Live Cell Molecular
(Bio-response)

Smarticles

Detection of Live Bacteria Phenotypic Test Direct from Clinical Samples

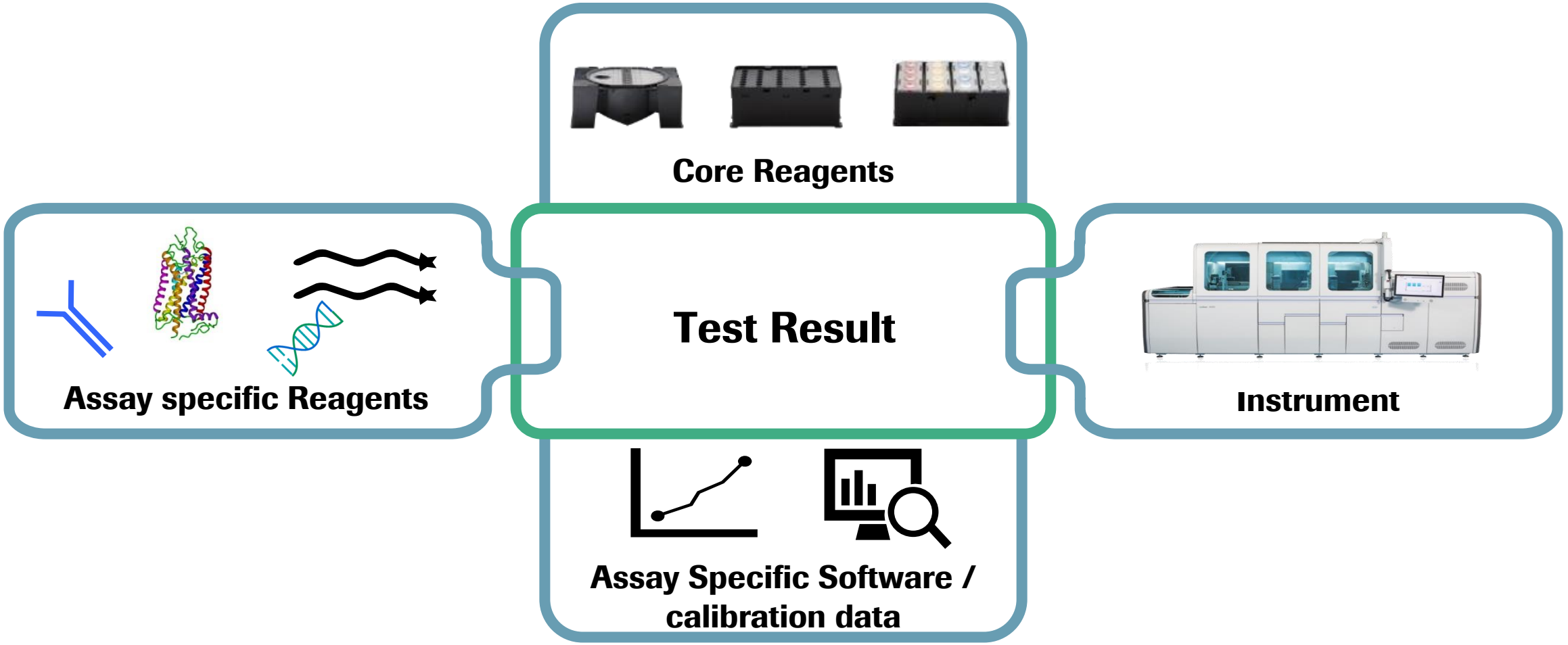
others

Optical
(Morphokinetic, digit, fluorescence)

Accelerate Dx, First Light, QuantaMatrix

Diagnostic Solutions

A test result depends on four elements



Instruments and software

Customers need solutions from point of care to high throughput lab

Research Lab / Academia | **Physician's office** | **ER / ICU** | **Microbiology Lab** | **Hospital / Commercial Lab**

Provide Dx solution as customer need

Point of Care | Central Lab | Bloodscreening

cobas® Liat® System

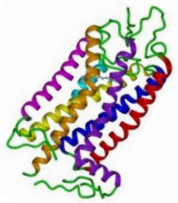
cobas® 4800 System

cobas® 6800 System

cobas® 8800 System

User Defined Functionality (UDF)

cobas omni Utility Channel



cobas® 4000 System

cobas® 6000 System

cobas® 8000 System

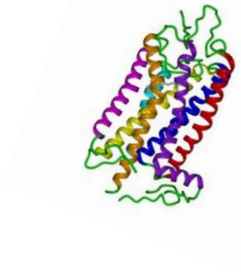
Infectious Disease assay portfolio strategy

Rapidly increase menu across instruments

Genomics

- Influenza A/B
- Influenza A/B + RSV
- HIV-1
- HIV-2
- HBV
- HCV
- HCV GT
- HSV-1/2
- HPV
- CMV
- WNV
- DPX
- HEV
- Zika (IND)
- chikV/denV*
- MRSA/SA
- CT/NG
- C. diff
- Strep A
- TV/MG*
- MTB*
- MAI*
- RIF/INH*
- Babesia

Proteomics



- HAV
- HBV
- HCV
- HIV-1
- HTLV 1+2
- HSV-1
- HSV-2
- CMV
- Rubella
- HIV-2*
- Syphilis
- Toxo
- Chagas

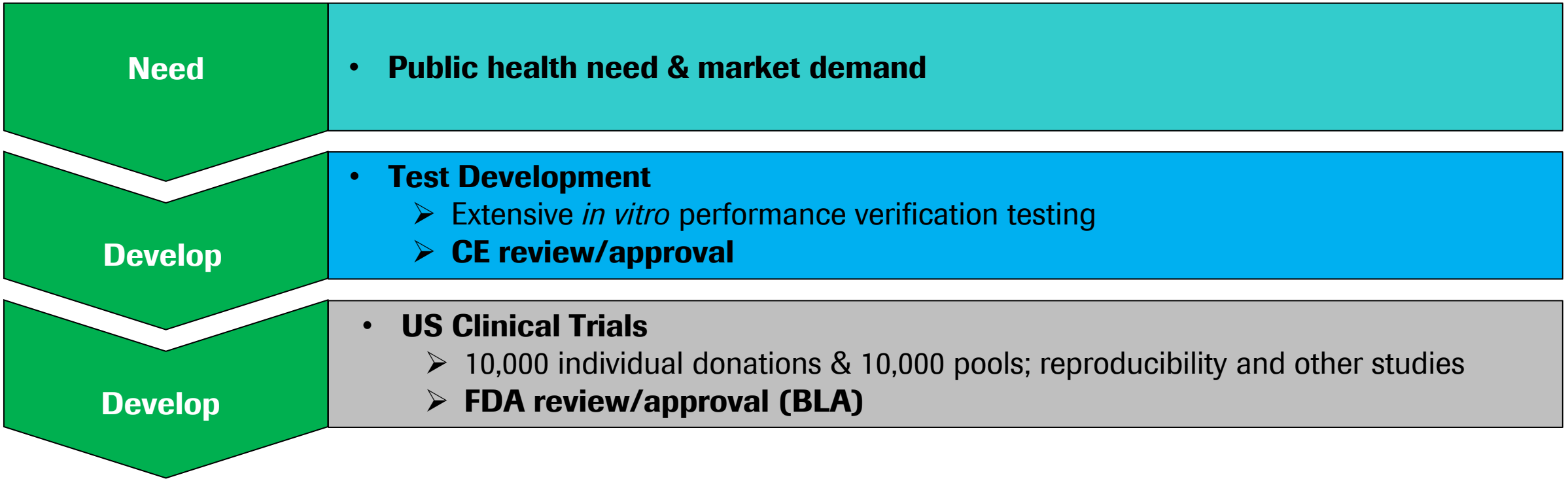
>10 assay other pathogens in development or planned

✱ In development or under discussion

Virus | Bacteria | Parasite

IVD Assay development requires extensive performance validation

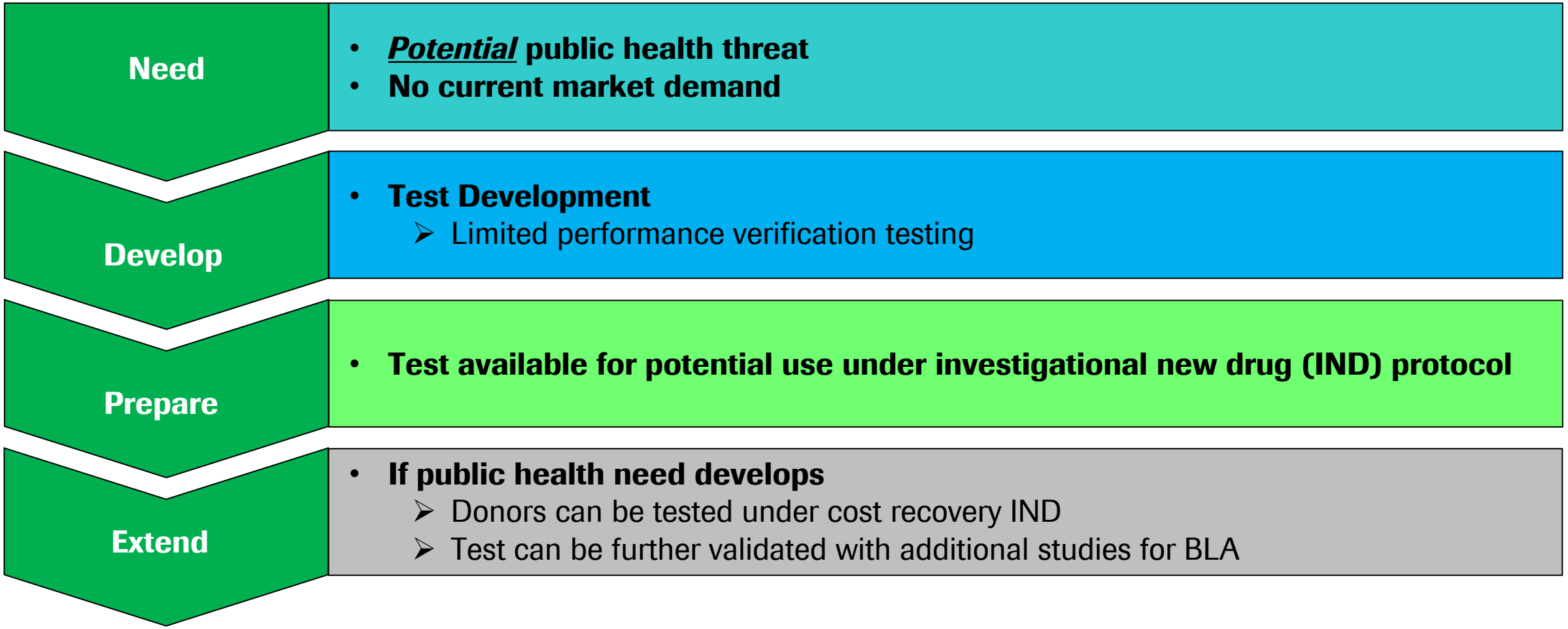
The usual assay development pathway in blood screening



Available in CE and U.S.

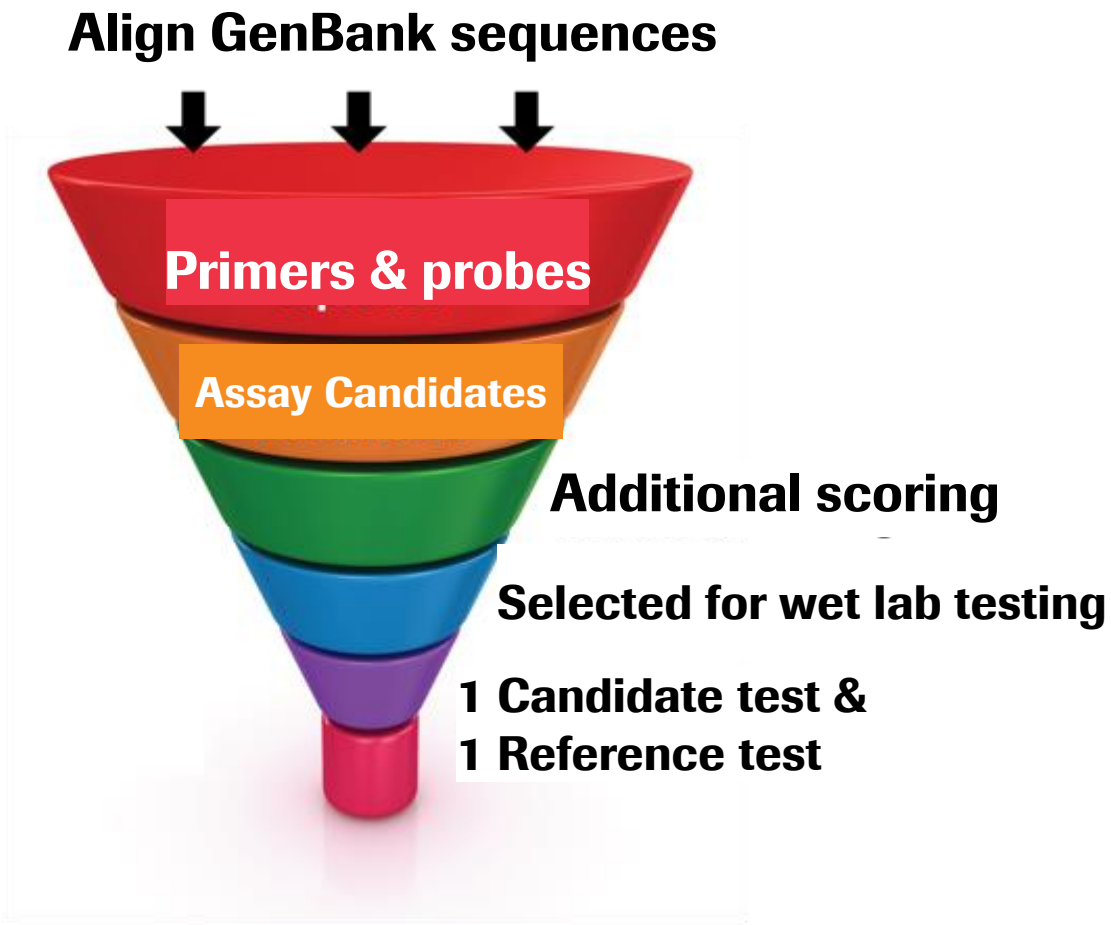
Emerging pathogens may require a different approach

Donor screening tests for use under IND



Agile assay design software identifies primers and probes

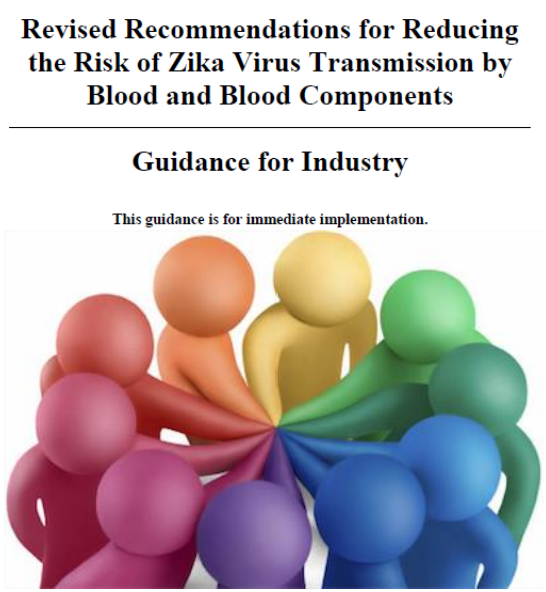
*Designed to work with **cobas omni** reagents*



- Agile assay design software is an *in silico* method to identify best candidate detection set for target pathogen RNA or DNA
- Uses standardized chemistries of **cobas** omni reagents and system thermocycling conditions to quickly winnow potential primers and probes to best choice.
- **cobas** omni reagents and standardized conditions facilitate rapid test design.

From A to cobas® Zika in 10 weeks

Response to an emergent public health need


Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components

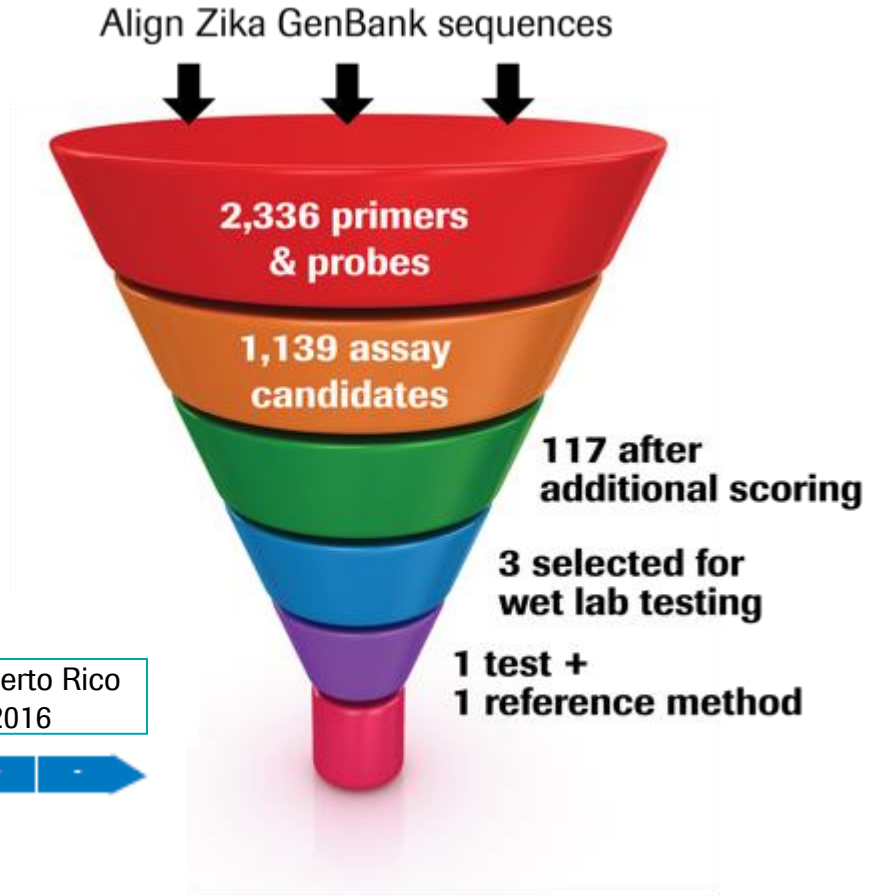
Guidance for Industry

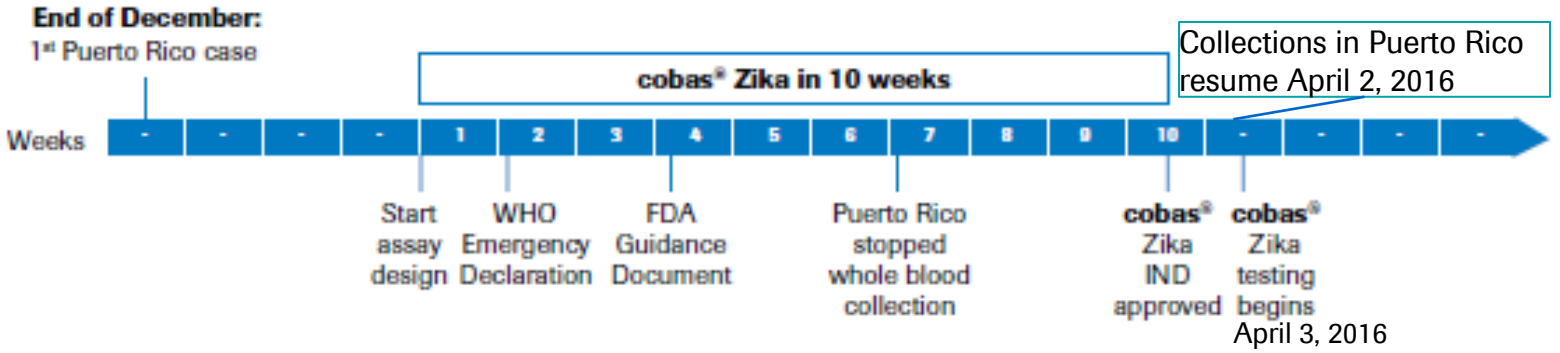
This guidance is for immediate implementation.

- Zika virus may be spread by blood transfusion.
- An apparent link between microcephaly and Zika in Brazil in **late 2015** sparked global concern.
- First Zika cases reported in Puerto Rico in **December 2015**
- In **early 2016**, FDA reached out to test manufacturers for help with Zika screening test under IND
- **February 2016:** FDA issued Guidance that prohibited use of blood collected in "Zika active areas"
  - IMPACT: Puerto Rico forced to halt blood collections & rely on import from U.S. states
  - Raised concern for spread to Gulf Coast and other states
- Concern and surveillance for the spread of Zika to U.S. states continued
  - Some blood centers and testing laboratories initiated screening in late spring and summer 2016
- First locally-acquired Zika cases detected in Miami, Florida in late **July 2016**
  - Blood screening results used to surveil and help direct vector control efforts
- On **August 26, 2016**, FDA revised its Guidance to mandate all U.S. donations be screened with NAT test or pathogen-reduction technology

From A to cobas® Zika in 10 weeks

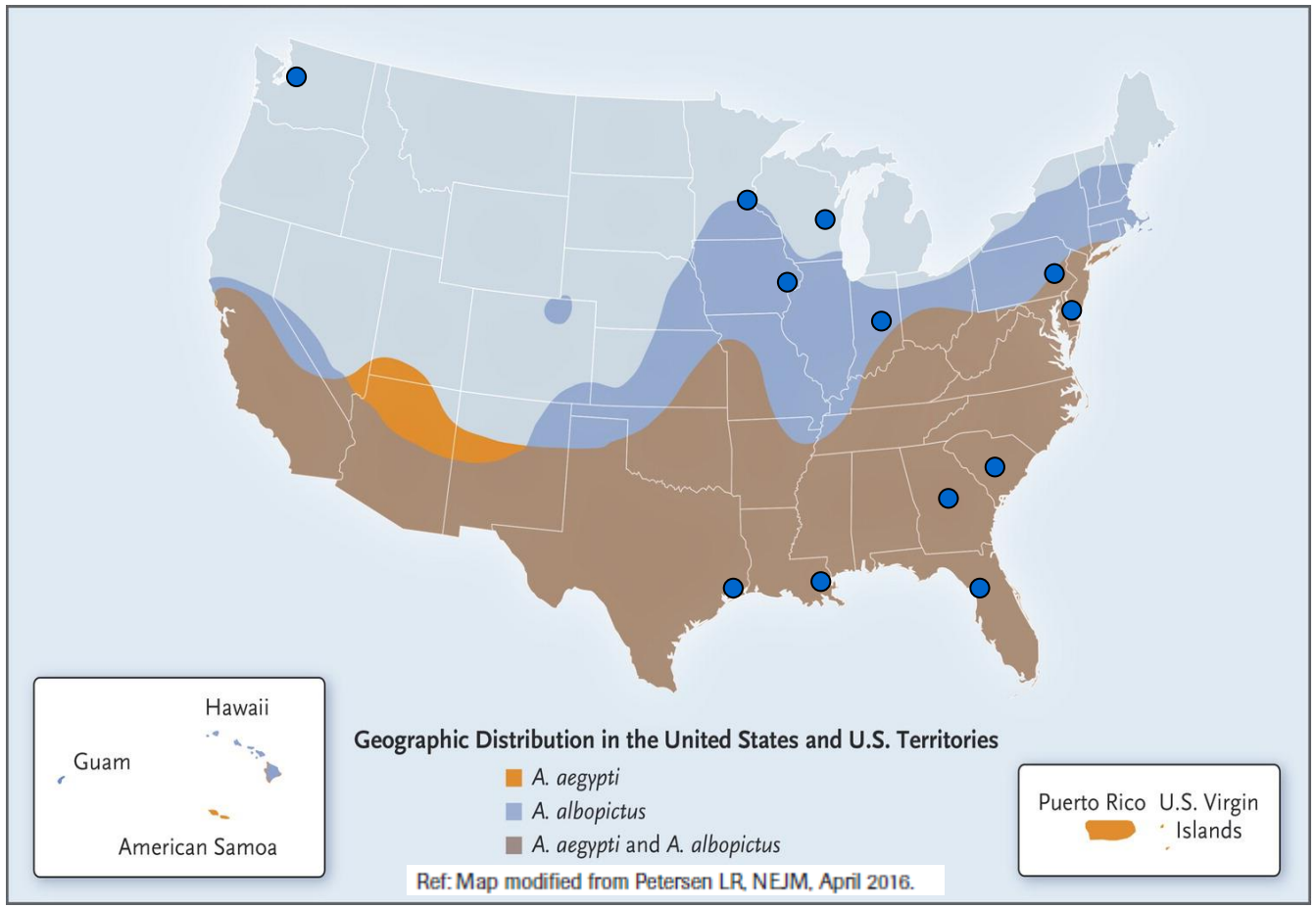
Design, development & deployment in 10 weeks





cobas® Zika is used at 12 U.S. testing laboratories

*More than 4 million donations screened with **cobas®** Zika*



	Number of Donations screened with cobas® Zika	Number of Donations with Evidence of Zika virus
Donations screened from April 3, 2016 through September 23, 2017		
Puerto Rico	**111,842**	**356**
United States*	**4,154,192**	**27**
Total	**4,265,665**	**383**

*Includes donations collected in the 50 U.S. states or at U.S. military facilities around the world.

- BLA submitted to FDA in April 2017
- Currently under FDA review

Thoughts for the workshop

Market:

- market need and demand -> actionable result
- point of care vs. central lab; especially in low income countries

Assay development and validation

- access to samples, especially for new infectious threats
- pathogen and resistance information (e.g. sequences, resistances, mutations)
- variety of relevant specimen (blood, saliva, stool, sputum, BAL, nasal / nasopharyngeal / throat swab, urine, vaginal swab, …)
- time is critical, but assays have to be safe and effective, high validation efforts

Doing now what patients need next