

Roche Blood Safety Solutions

Rapid Response to Emerging Pathogens

Susan A. Galel, MD, Senior Director, Medical Affairs

A composite image showing the profile of a woman on the left and a newborn baby on the right, both looking towards the right.

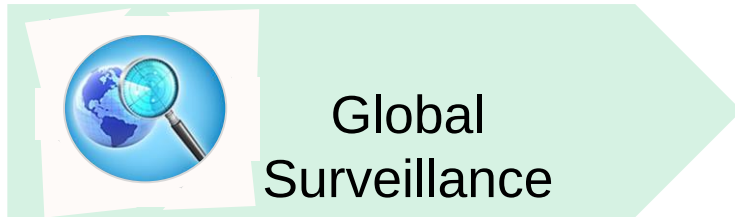
*Delivering confidence in
transfusion safety from
donor to patient*

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Considerations for regulatory
pathways and international guidelines

Responding to emerging infections

Roche's process for infectious disease assessment and response



**Emerging Infections Monitoring Team
(diagnostics and donor screening)**

Medical
Research
Business

Epidemic risk

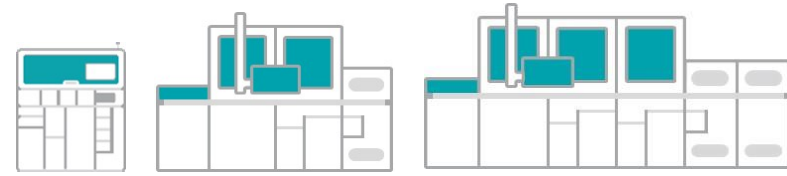
Unmet needs

Research readiness

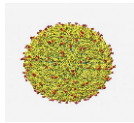
Goal: rapid assessment and response to public health emergency

cobas[®] 5800/6800/8800 Systems

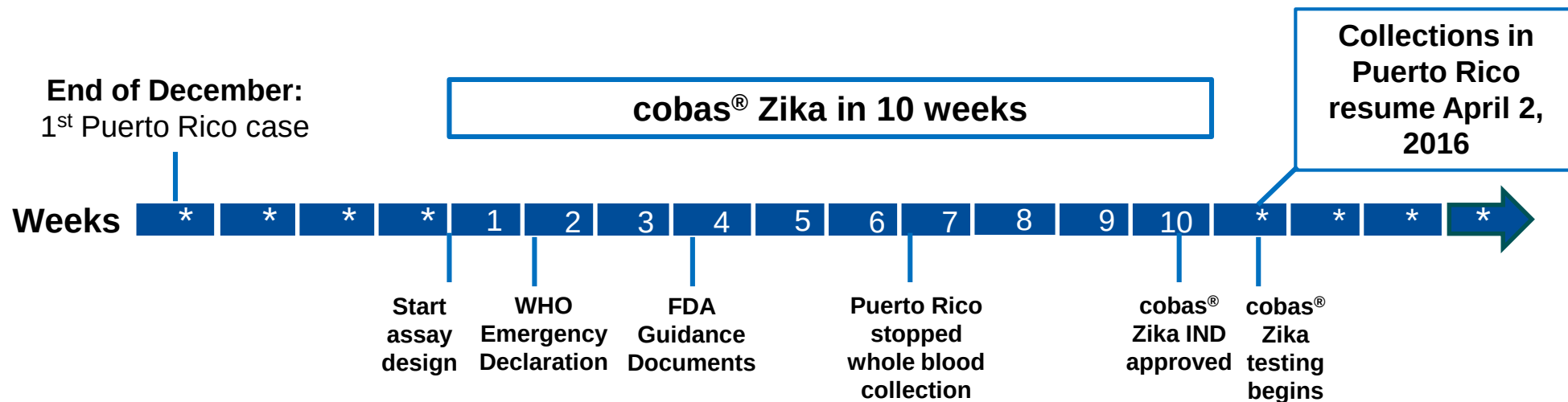
Rapid test development



- Standardized chemistry and conditions enable streamlined test development
- Agile Assay Design software predicts behavior of oligonucleotides in the standardized conditions

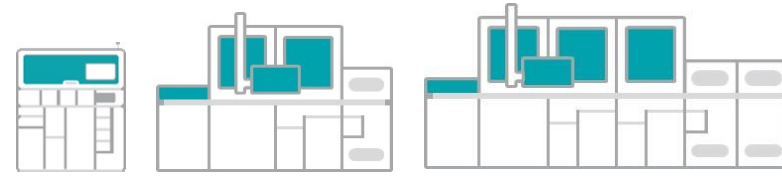


Zika Virus (2016): “From A to cobas[®] Zika in 10 weeks”

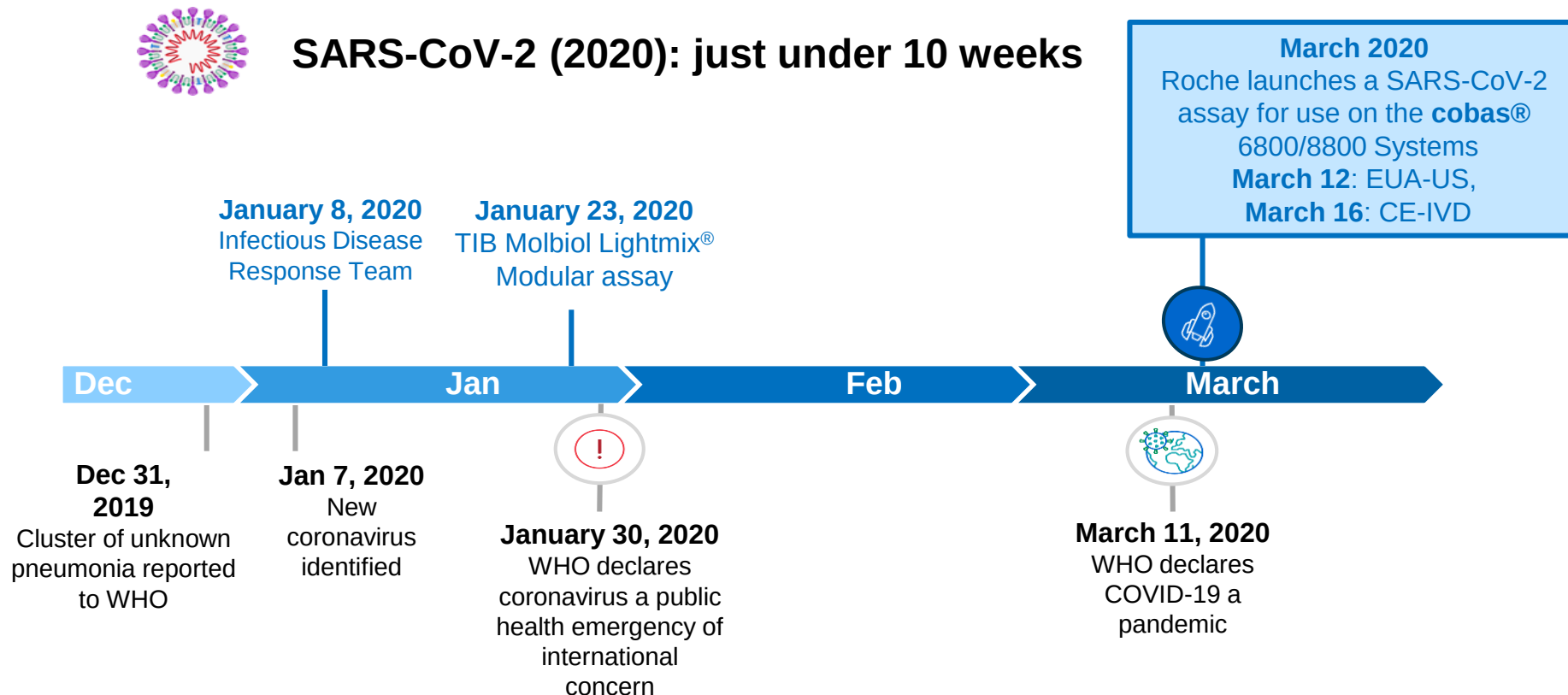


cobas® 5800/6800/8800 Systems

Rapid test development



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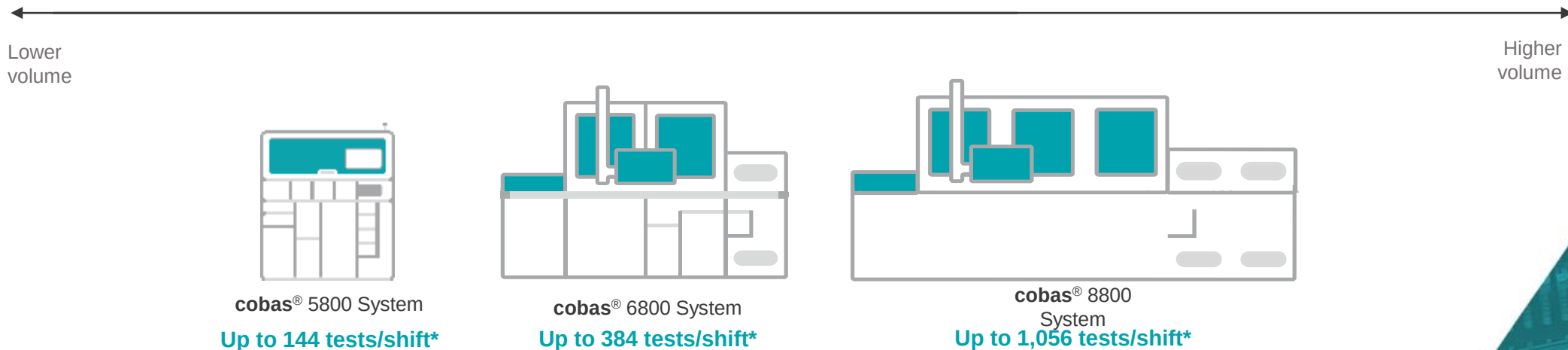
“cobas[®] x800 family”: cobas[®] 5800/6800/8800 Systems

Common assays, ready-to-use reagents and user experience across platforms

Consistent patient results

Built-in scalability to adapt to growing test volumes

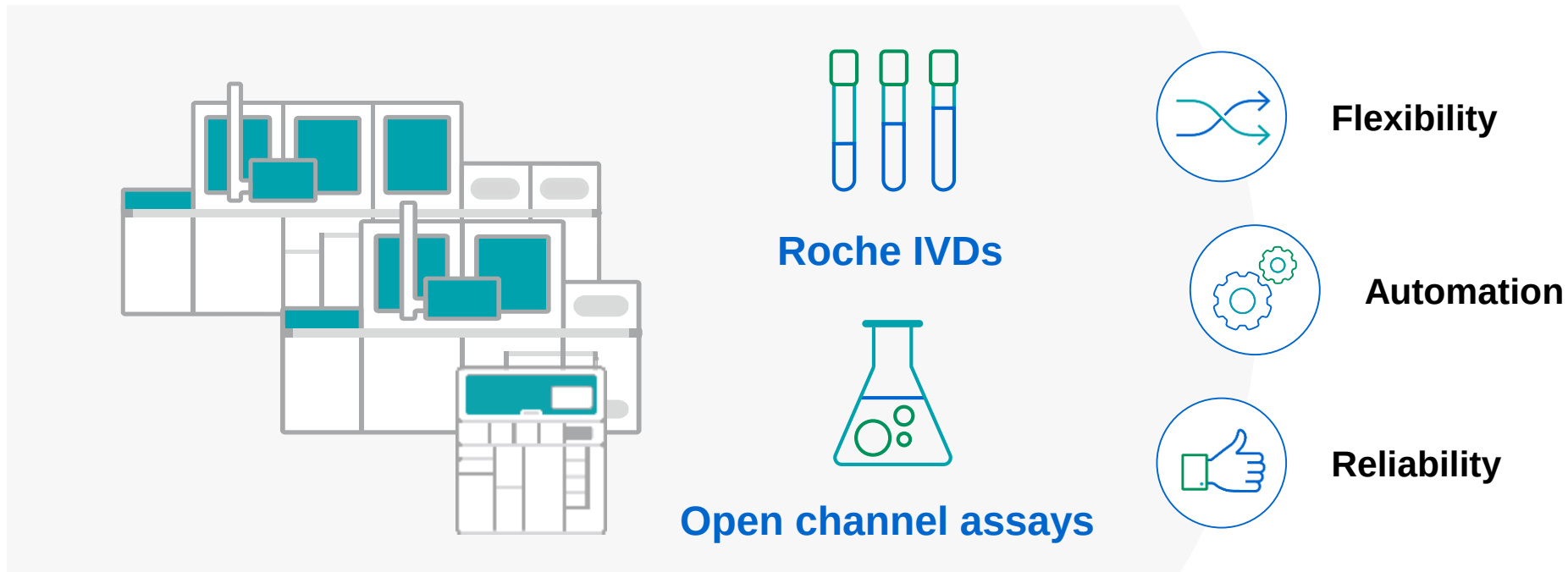
cobas omni Utility Channel on all Systems



*Based on an 8-hour shift

Expand your menu on the cobas® 5800/6800/8800 Systems

Open channel and Roche IVD assays on the same platform



*Leverage the workflow efficiencies of the **cobas®** 5800/6800/8800 Systems*

Expand your menu on the cobas® 5800/6800/8800 Systems

Open channel and Roche IVD assays on the same platform



Monkeypox!

medRxiv
THE PREPRINT SERVER FOR HEALTH SCIENCES



BMJ Yale

Posted June 07, 2022.

- **May 2022:** multiple cases of monkeypox identified in several non-endemic countries
- **June 7, 2022:** Report posted on medRxiv describing the design and utilization of an assay for monkeypox using the **cobas omni** Utility Channel (now published: Nörz D, et al., Emerg Infect Dis. 2022;28(9):1765-1769)

Rapid adaptation of established high-throughput molecular testing infrastructure for detection of monkeypoxvirus

Dominik Nörz, Hui Ting Tang, Petra Emmerich, Katja Giersch, Nicole Fischer, Marylyn M. Addo, Martin Aepfelbacher, Susanne Pfefferle, Marc Lütgehetmann

doi: <https://doi.org/10.1101/2022.06.05.22276011>

*Leverage the workflow efficiencies of the **cobas** 5800/6800/8800 Systems*

International Standards and Regulatory Challenges

What may need to be changed to optimize blood bank laboratory responses to threats?

Regulations and Standards potentially impacting blood establishment responses to an emergent threat



Blood Safety

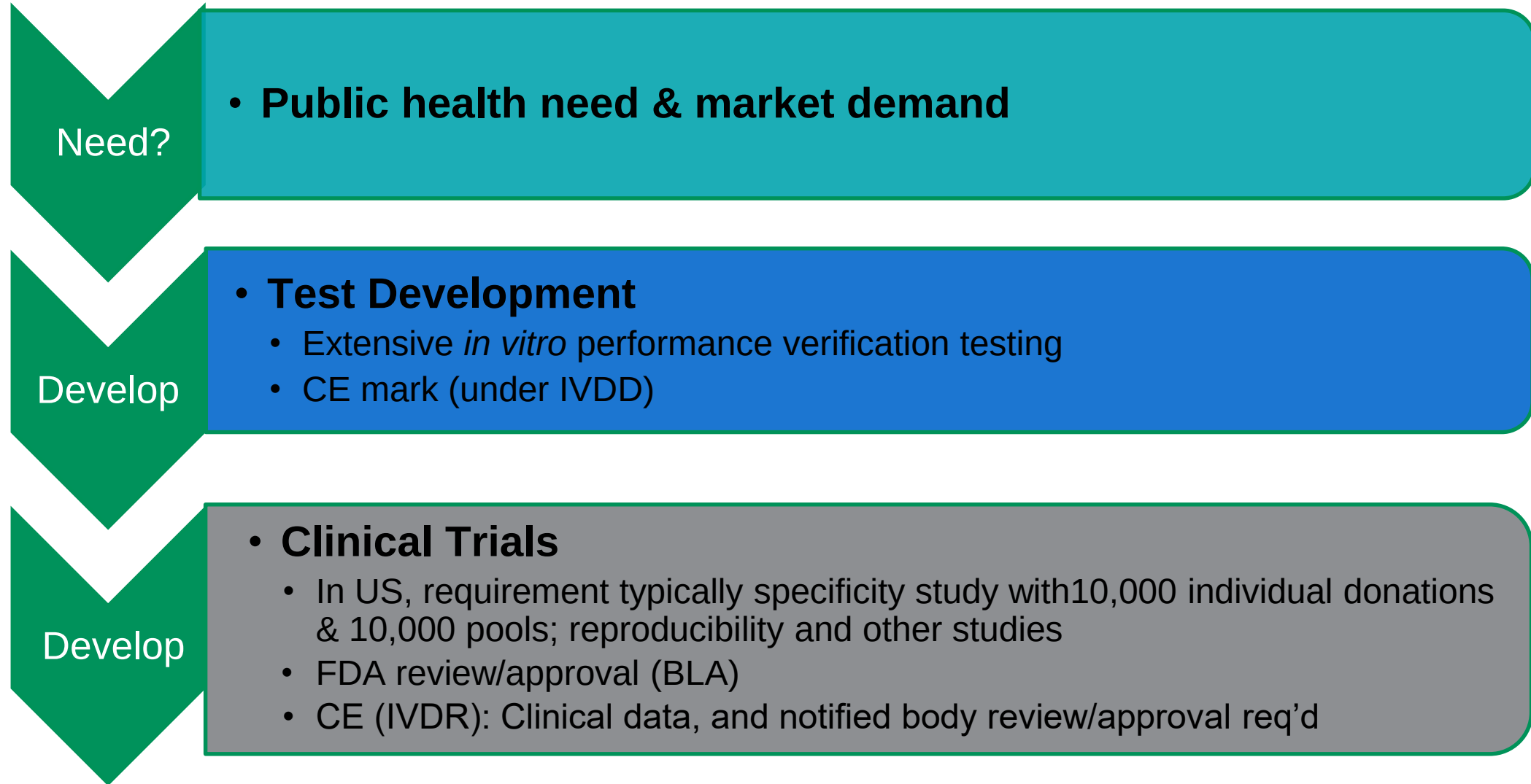
Regulatory pathway for urgent deployment of a donor screening test under IVDR



Patient Dx & Monitoring

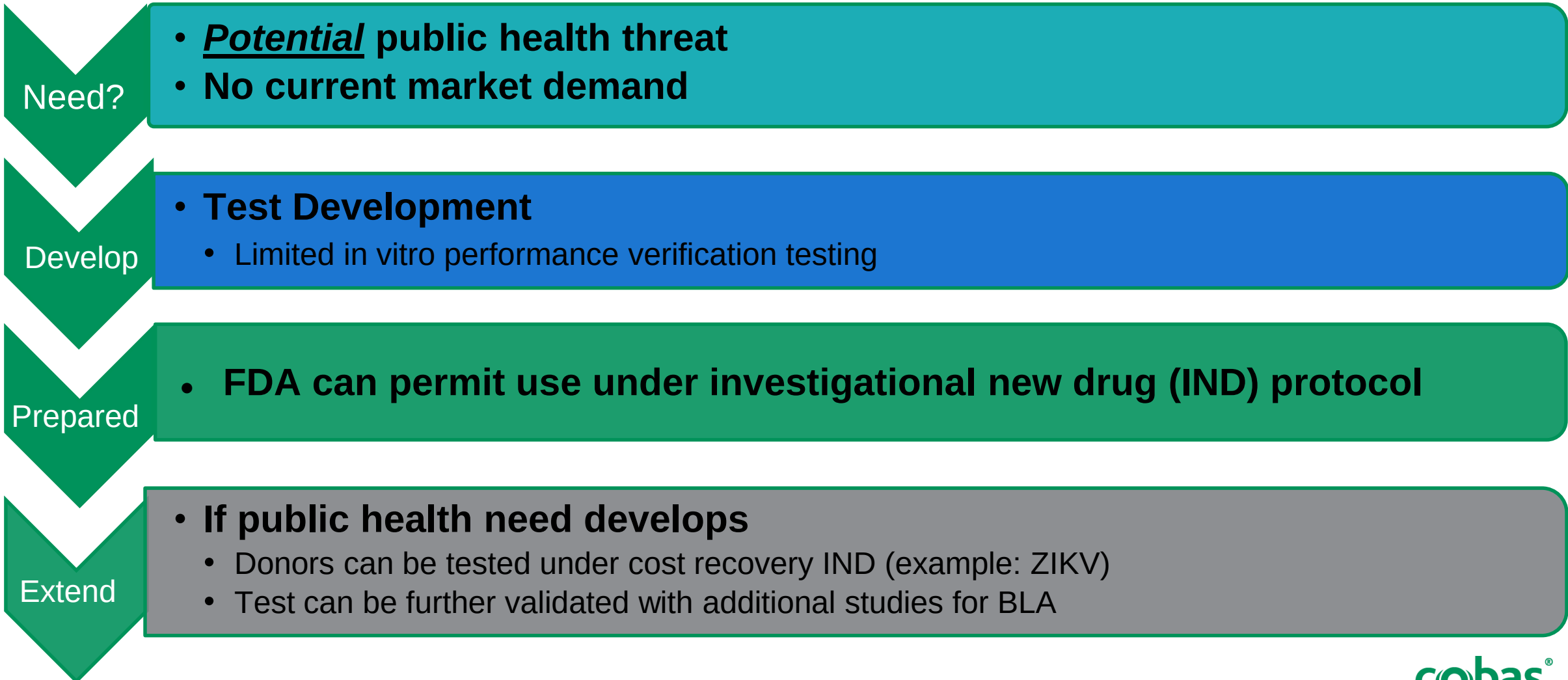
Utilization of automated test systems in blood establishments to support testing needs

Typical development pathway for donor screening tests

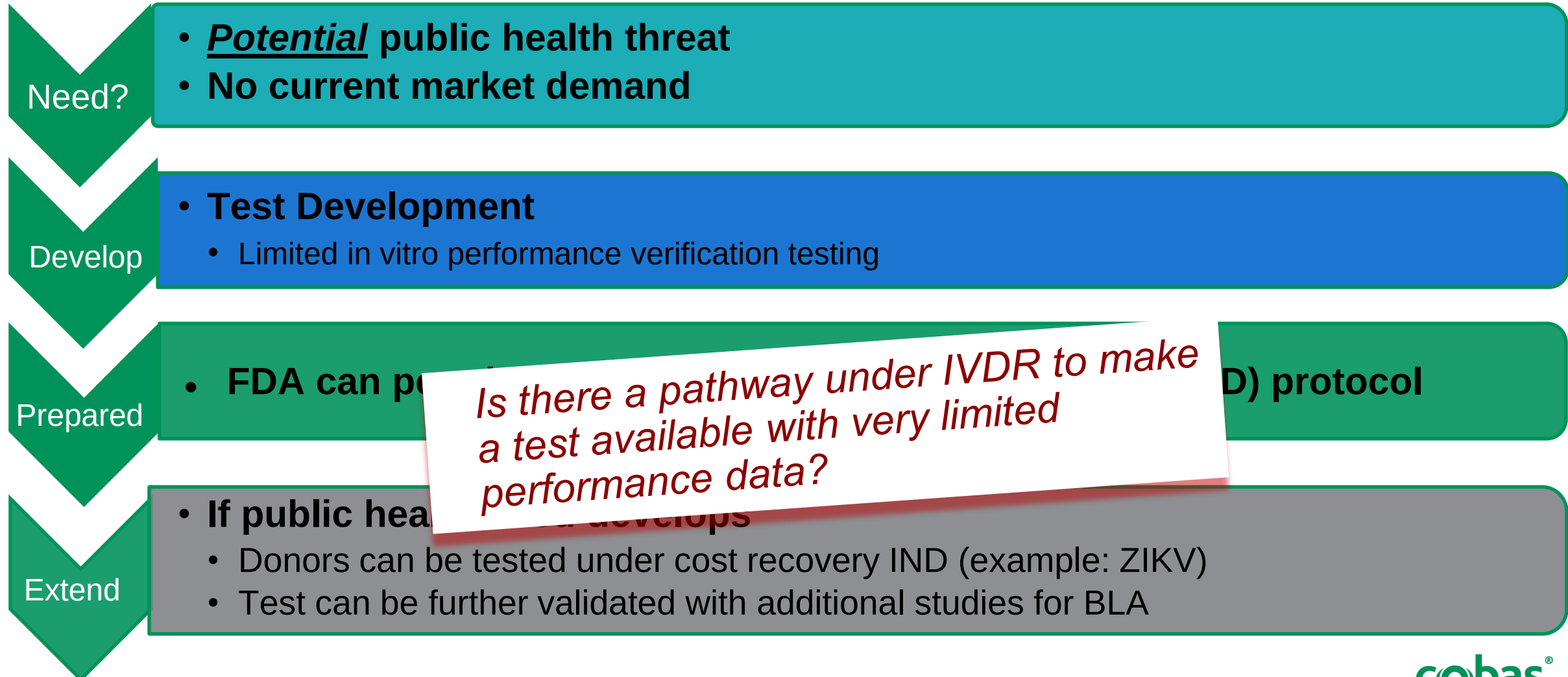


Pathway for *emerging pathogens*: US

Donor screening tests for use under IND



Pathway for *emerging pathogens*: CE ?



IVDR: is there a pathway for emergency response?

- **Challenges:**
 - Clinical samples limited or unavailable
 - Clinical validation impossible early in outbreak
 - How can a test be deployed urgently?

Use of blood bank laboratory systems to support diagnostic and monitoring needs

Example: SARS-CoV-2

- Blood bank laboratories have automated systems that can be leveraged to scale up public health testing needs.
- Numerous blood banks around the world have used their test platforms to support diagnostics and monitoring for SARS-CoV-2 by testing for RNA and/or antibody.



Guidelines requiring clarification in relation to blood bank response

Recommendations to separate blood bank and diagnostic testing

“All screening activities, handling of donor specimens, sampling, analysis and data processing should be separated from patient diagnostic testing”

- ★ WHO Technical Report Series, No. 961, 2011, p201.

“It is important that donation screening activities are totally separate from diagnostic testing activities; donation screening should be performed in dedicated Blood Service laboratories which do not undertake any diagnostic investigations”

- ★ WHO 2019 DRAFT REVISION: Screening Donated Blood for Transfusion-Transmissible Infectious Agents. Section 1.4



Guidelines requiring clarification in relation to blood bank response

Recommendations to separate blood bank and diagnostic testing

“6.3.4. All donation testing activities, handling of donor specimens, sampling, analysis and data processing should be undertaken independently of diagnostic testing of patients.”

- ★ EDQM. Guide to the preparation, use and quality assurance of blood components. 20th ed, 2020, p94



Use of automated systems to support diagnostic testing

- Blood bank laboratories have automated systems that can be, and have successfully been, leveraged to support diagnostic testing needs
- WHO and EDQM concerns seem to be:
 - GMPs are needed for blood donor testing; diagnostic labs do not follow GMPs
 - Sample contamination
- Why blood bank labs have been able to support their country's testing needs:
 - Blood bank laboratories operate under GMP; there is no risk to the quality of the diagnostics if a blood bank lab performs diagnostic tests
 - Highly automated systems minimize contamination risks within the system. Contamination can be further minimized by:
 - Using pre-analytics
 - Handling samples separately prior to loading on instruments
 - Separate runs

Sustaining the link from donor to patient

Providing novel solutions to emerging challenges

Active monitoring for emerging pathogens with large portfolio of tools for responding to diagnostic and donor screening needs

Standardized conditions for x800 family enable rapid and robust NAT design

Automated solutions facilitate response to emerging and existing challenges

