

Roche Blood Safety Solutions

Sustaining the link from donor to patient

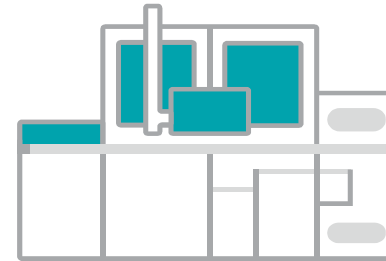
Susan Galel, MD, Senior Director, Medical Affairs



*Delivering confidence in
transfusion safety from
donor to patient*

An agile solution that can grow as your lab grows

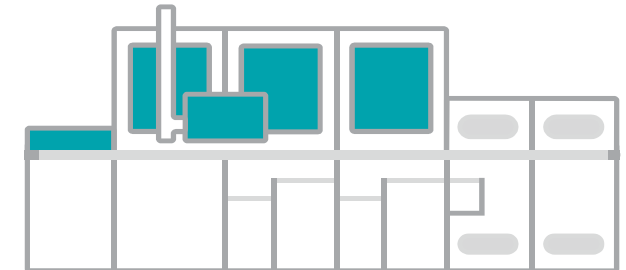
- Ready to use reagents**
 No thawing, mixing, or pouring = no prep
- On-board refrigeration**
 Long term on-board reagent stability and storage
- Flexible testing**
 Simultaneous testing from 1 donation or pool
- Validated full automation**
 Track connectable with pre & post-analytics, NAT, & Serology
- cobas omni Utility Channel**
 Develop LDTs to monitor for emerging infectious diseases



cobas[®] 6800 System

Up to 384 tests/shift*

**First 96 results in 3 hours
 +96 results every 90 minutes**



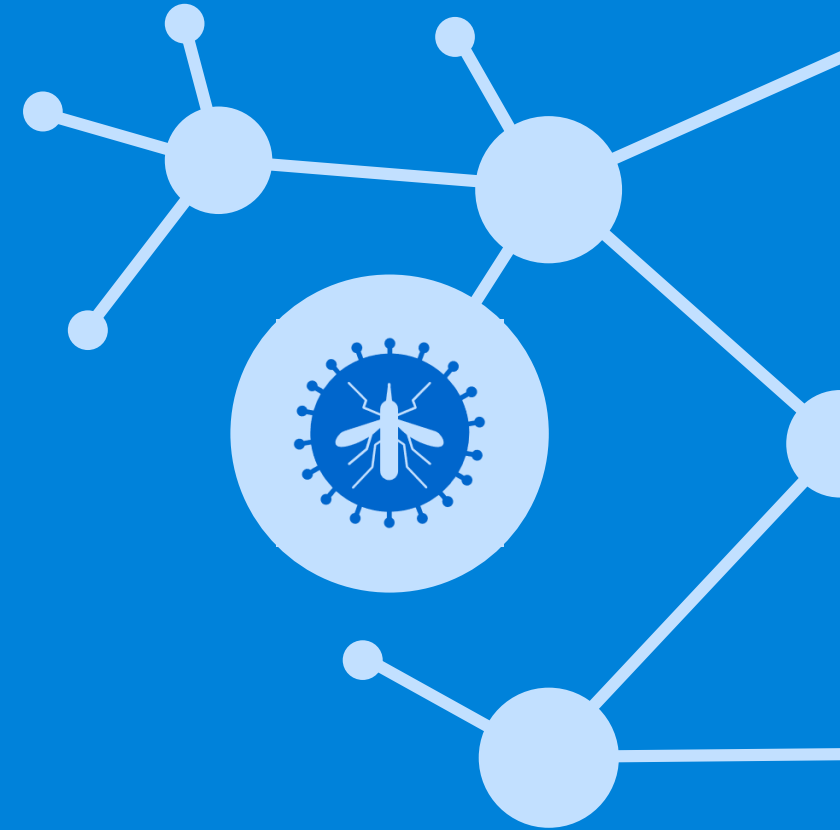
cobas[®] 8800 System

Up to 1,056 tests/shift*

**First 96 results in 3 hours
 +96 results every 30 minutes**

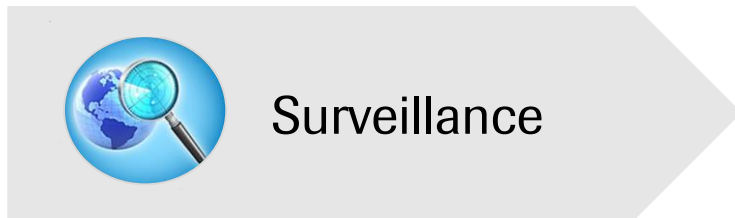
Coming soon! cobas[®] 5800 System

Responding to emerging infections



Infectious Disease Emergency Response

Pathway for pathogen alert and assessments



Monitoring Team

- Medical (diagnostics and donor screening)
 - Research
 - Business

Epidemic risk

Unmet needs

Research readiness

Regular reassessments

Testing needs assessment

Examples of considerations

Assay type

- Molecular
- Antigen
- Antibody

Body fluid

- Respiratory
- Blood
- Other (eg, GI, urine)

Intended population

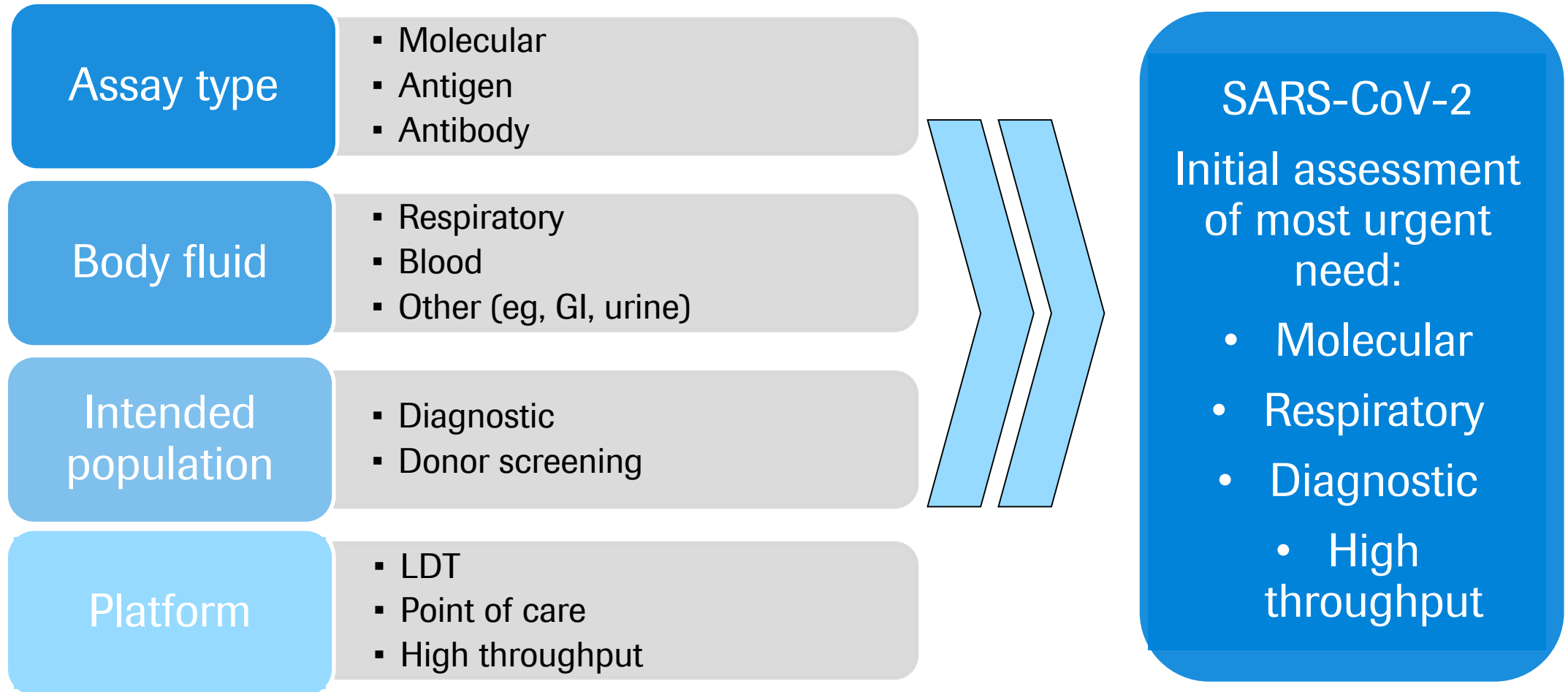
- Diagnostic
- Donor screening

Platform

- LDT
- Point of care
- High throughput

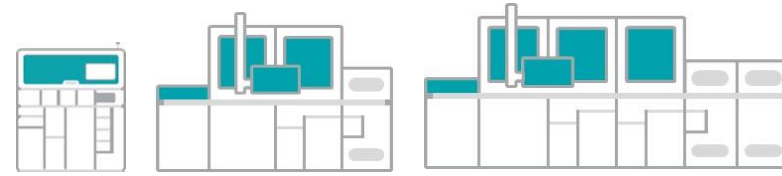
Testing needs assessment

Example: SARS-CoV-2, initial assessment

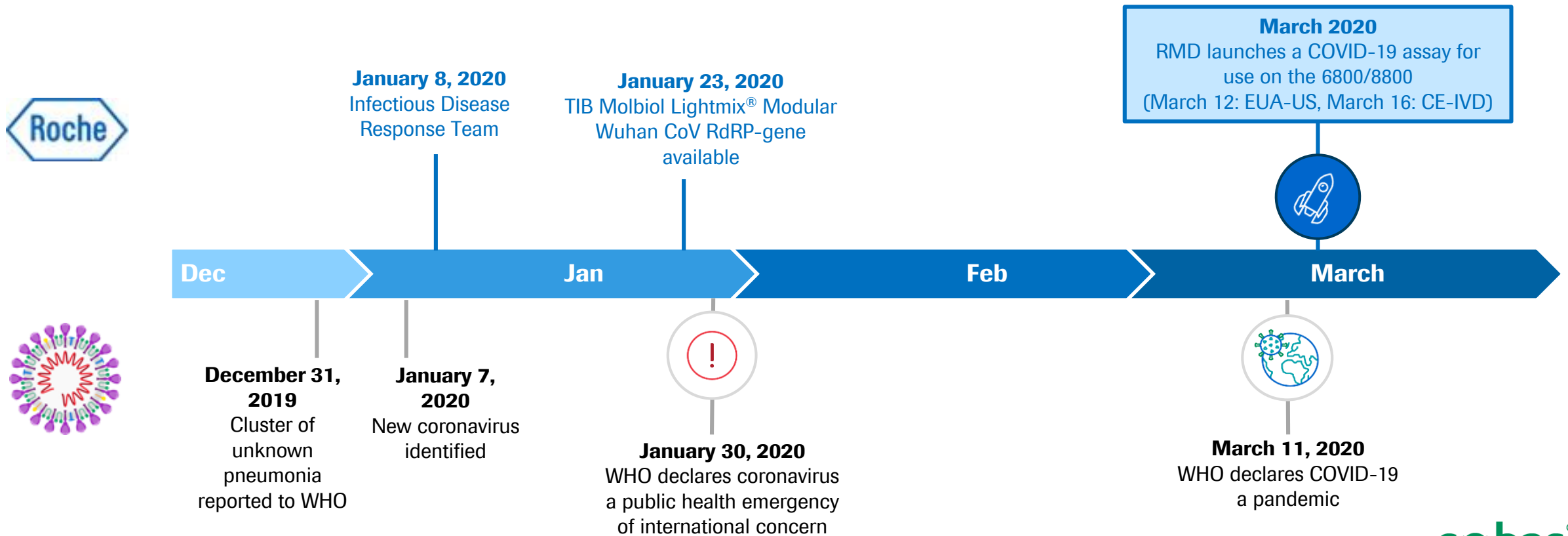


cobas[®] 5800/6800/8800 Systems

Rapid test development



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



SARS-CoV-2 continued assessment



Blood Safety

- Prepared for potential need for donor screening NAT
- Verified performance of assay in plasma to enable commercial launch if needed



Patient Dx & Monitoring

- Developed multiple additional tools for diagnosis and monitoring, including antibody tests to qualify convalescent plasma

Roche SARS-CoV-2 solutions

Solutions for point of care and laboratory testing

PCR tests



SARS-CoV-2 and influenza A/B detection and discrimination from a single sample



SARS-CoV-2 detection



SARS-CoV-2 variants (RUO)



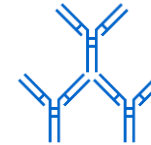
Antigen tests



SARS-CoV-2 detection



Antibody tests



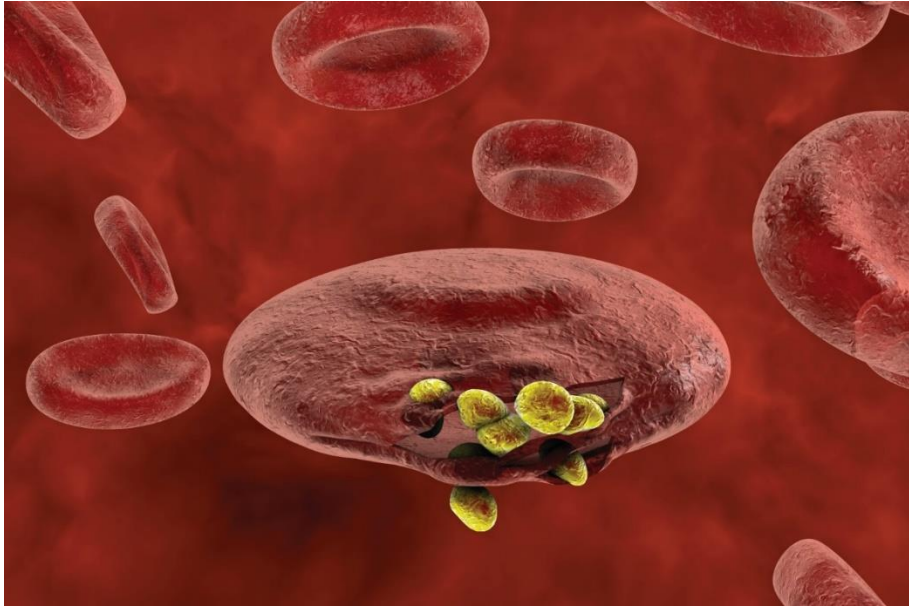
Qualitative tests



Quantitative test



NAT for Prevention of Transfusion-Transmitted Malaria



- Donor screening methods used in endemic areas (microscopy and antigen) are not sensitive enough to prevent TTM
- In non-endemic areas, donor questioning excludes a large number of non-infected donors and fails to exclude some infected donors
 - Antibody tests show variability in detection
- Highly sensitive NAT may be of benefit



Sustaining the link from donor to patient

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

Novel solutions facilitate response to emerging and existing challenges



Doing now what patients need next