Welcome to #WIGWednesday
May 20, 2020

*Update on the COVID-19 Outbreak: Understanding the Impact of Diagnostic Testing Modalities*

**Moderated by:**
Representative Lisa Beck (IN)
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MAY 20, 2020
HAVE YOU HEARD?

#WIGSummerSummit
Let’s be social!
#ConnectingLegislativeLeaders
#WIGWednesdays

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Women In Government

Women In Government
Moderated by:

Representative Lisa Beck (IN)
Women In Government welcomes you to #WIGWednesday!

1. All participants are muted through the system.

2. We will have a Q&A period at the end of the presentation, be sure to use the Chat Box feature to ask questions!

3. This virtual round-table event will be recorded and provided on our website once the event is over
Featured Speaker

Jamie E. Phillips, PhD
Sr. Scientific Affairs Manager Medical and Scientific Affairs Roche Diagnostics Corporation
SARS-CoV-2
Responding to a public health emergency

JAMIE PHILLIPS PHD
SENIOR SCIENTIFIC AFFAIRS MANAGER
Who am I

Jamie Phillips, PhD
Medical and Scientific Affairs
Sr. Scientific Affairs Manager

Obtained my PhD from the University of Georgia, in Infectious Diseases. Graduate studies focused on Coronavirus viral genome annotation and identification of genes associated with pathogenicity/attenuation.
Agenda

• Background on Coronaviruses
• Epidemiology of the SARS-CoV-2 to date
• SARS-CoV-2 Diagnostic Modalities
SARS-CoV-2: A novel coronavirus

History

• World Health Organization (WHO) informed of cases of pneumonia of unknown origin in Wuhan City, Hubei Province, on 31-Dec-2019.
• WHO declares coronavirus a global emergency on 31-Jan-2020.

The Virus

• A novel coronavirus (SARS-CoV-2) was officially announced as the causative agent by Chinese authorities on 07-Jan-2020.

The Disease

• The resulting disease has been named COVID-19.
What are Coronaviruses?

- Coronaviruses are large, enveloped RNA viruses (Hepatitis B Virus – 3 kbp; Corona Virus – 30 kbp)
- Coronaviruses are zoonotic, meaning they are transmitted between animals and people.
- Animal reservoirs are ecologically diverse with the **widest variety seen in bats**, which are the **reservoirs for many of these viruses**.
- Mammals may serve as **intermediate hosts**, facilitating **recombination and mutation events** with expansion of genetic diversity.
- Not all coronaviruses are pandemic strains - endemic human coronavirus are responsible for approximately **5–10% of all upper and lower respiratory tract infections**.
- Two previous outbreaks:
  - Severe acute respiratory syndrome - SARS-CoV (2002) - China
  - Middle East respiratory syndrome - MERS-CoV (2012) - Saudi Arabia

## SARS* and MERS** - Brief History

<table>
<thead>
<tr>
<th></th>
<th>SARS-CoV</th>
<th>MERS-CoV</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Focus of Outbreak</strong></td>
<td>China (2002)</td>
<td>Saudi Arabia (2012), South Korea (2015)</td>
</tr>
<tr>
<td><strong>Animal source of human infection</strong></td>
<td>Civet cats</td>
<td>Camels</td>
</tr>
<tr>
<td><strong>Infected people</strong></td>
<td>8000</td>
<td>2494</td>
</tr>
<tr>
<td><strong>% severe cases/mechanical ventilation</strong></td>
<td>35%</td>
<td>50-89%</td>
</tr>
<tr>
<td><strong>Deaths (mortality rate)</strong></td>
<td>774 (&lt;10%)</td>
<td>858 (34%)</td>
</tr>
<tr>
<td><strong>Distribution</strong></td>
<td>29 countries</td>
<td>27 countries</td>
</tr>
<tr>
<td><strong>Global economy costs</strong></td>
<td>30-120 billion (USD)</td>
<td>30-100 billion (USD)</td>
</tr>
</tbody>
</table>

*SARS - Severe acute respiratory syndrome **MERS – Middle East respiratory syndrome

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SARS-CoV-2: Relationship between SARS-CoV and SARS-CoV-2

- In December 2019, a cluster of pneumonia cases related to exposure to a live animal market emerged in Wuhan City, China.
- Viral genome sequences identified novel coronavirus as causative agent (originally named 2019-nCoV)
- On February 11, 2020, the World Health Organization (WHO) announced the official name of the novel coronavirus, SARS-CoV-2, and the official name of the respiratory disease caused by the virus, COVID-19.

# COVID-19 Signs and Symptoms

### Symptoms
- Fever, respiratory symptoms, abdominal pain, diarrhea, vomiting, headache, myalgia

### Clinical presentation
- Asymptomatic infection, mild illness, or fatal disease

### Transmission
- Person-to-person via respiratory secretions

### Incubation
- Range of 2-14 days (median – 5 days)

### Clinical progression
- Can cause severe respiratory disease

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Clinical Stages of COVID-19
Symptoms, biomarkers and potential therapies

COVID-19 Global Cases
27 January 2020

Total Confirmed: 2,886
Total Deaths: 81
Total Recovered: 59

Source: https://gisanddata.maps.arcgis.com/apps/opsdashboard/index.html#/bda7594740fd40299423467b48e9ecf6
COVID-19 Global Cases
26 March 2020

Total Confirmed: 531,860

Confirmed Cases by Country/Region/Sovereignty:
- 85,653 US
- 81,782 China
- 80,589 Italy
- 57,786 Spain
- 43,938 Germany
- 29,566 France
- 29,406 Iran
- 11,812 United Kingdom
- 11,811 Switzerland
- 9,241 Korea, South
- 7,469 Netherlands
- 6,999 Austria
- 6,235 Belgium

Active Cases: 175

Cumulative Confirmed Cases:

- 2,234 deaths Iran
- 1,696 deaths France
- 578 deaths United Kingdom
- 434 deaths Netherlands

Total Deaths: 24,057

- 8,215 deaths Italy
- 4,365 deaths Spain
- 3,169 deaths Hubei China
- 1,696 deaths France
- 1,492 deaths Germany

Total Recovered: 122,203

- 61,201 recovered Hubei China
- 10,457 recovered Iran
- 10,361 recovered Iran
- 7,015 recovered Italy
- 5,673 recovered Spain

Data sources: WHO, CDC, ECDC, NHIC, DXY, 1point3acres, Worldometers.info, BNO, state and national government health departments, and local media reports. Read more in this blog.
COVID-19 Global Cases
7 April 2020

Coronavirus COVID-19 Global Cases by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University (JHU)

Total Confirmed: 1,381,014

Total Deaths: 78,269

Total Recovered: 292,467

Confirmed Cases by Country/Region/Sovereignty

- US: 1,071,289
- Spain: 141,240
- Italy: 132,547
- Germany: 105,519
- France: 98,784
- China: 82,718
- Iran: 62,589
- United Kingdom: 35,840
- Turkey: 30,217
- Switzerland: 22,242
- Belgium: 22,194
- Netherlands: 19,703
- Canada: 17,046
- Austria: 12,592
- Portugal: 12,442
- Brazil: 12,345
- Korea, South: 10,331

Source: https://gisanddata.maps.arcgis.com/apps/opsdashboard/index.html#/bda7594740fd40299423467b48e9ecf6
COVID-19 Global Cases
5 May 2020

Total Confirmed
3,573,864

Confirmed Cases by Country/Region/Sovereignty

1,177,784 US
218,018 Spain
311,928 Italy
191,832 United Kingdom
169,589 France
165,914 Germany
145,263 Russia
127,659 Turkey
105,223 Brazil
98,647 Iran
83,565 China
61,814 Canada
50,267 Belgium

Data sources: WHO, CDC, ECDC, NHC, DXY, 1point3acres, Worldometers.info, BNO, the COVID Tracking Project testing and

Lancet Inf Dis Articles: Here, Mobile Version: Here.
Lead by JHU CSSE, Automation Support: Eni Living Atlas team and JHU APL, Contact US, FAQ.
Testing Formats and Purpose

Molecular testing and serology
PRIORITY FOR COVID-19 TESTING
(Nucleic Acid or Antigen)

High Priority

• Hospitalized patients with symptoms
• Healthcare facility workers, workers in congregate living settings, and first responders with symptoms
• Residents in long-term care facilities or other congregate living settings, including prisons and shelters, with symptoms

Priority

• Persons with symptoms of potential COVID-19 infection, including: fever, cough, shortness of breath, chills, muscle pain, new loss of taste or smell, vomiting or diarrhea, and/or sore throat.

• Persons without symptoms who are prioritized by health departments or clinicians, for any reason, including but not limited to: public health monitoring, sentinel surveillance, or screening of other asymptomatic individuals according to state and local plans.

STAGES OF TRANSIENT VIRAL INFECTIONS

SARS–CoV-2/COVID-19 Testing Objectives
What Are We Trying to Find Out?

Is a person **currently infected** with SARS–CoV-2?

Has a person **previously been infected** with SARS–CoV-2?

or
## Tests for SARS-CoV-2/COVID-19 Potential Uses

<table>
<thead>
<tr>
<th>Type of test</th>
<th>Measure</th>
<th>Value</th>
<th>Beneficiary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nucleic acid amplification test</td>
<td>Direct detection of infection i.e.</td>
<td>Inform individual of infections status so they can anticipate course of illness and take action to prevent transmission</td>
<td>Individual</td>
</tr>
<tr>
<td>for viral RNA</td>
<td>Current infection with SARS-CoV-2</td>
<td>Inform patient management and actions needed to prevent transmission</td>
<td>Healthcare or long term care facility</td>
</tr>
<tr>
<td>(Nasopharyngeal swab, oropharyngeal</td>
<td></td>
<td>Inform actions needed to prevent transmission</td>
<td>Public health</td>
</tr>
<tr>
<td>swab, sputum, bronchoalveolar lavage</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>fluid, others)</td>
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<tr>
<td>Antibody detection</td>
<td>Detection of immune response i.e.</td>
<td>Detect susceptible individuals (antibody negative) and those previously infected</td>
<td>Identify those potentially immune to SARS-CoV-2 if tests can detect protective immunity individuals could return to work</td>
</tr>
<tr>
<td></td>
<td>Past exposure to SARS-CoV-2</td>
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<tr>
<td></td>
<td></td>
<td>Identify individuals with neutralizing antibodies</td>
<td>Healthcare facilities: experimental therapy</td>
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<tr>
<td></td>
<td></td>
<td>Facilitate contact tracing and surveillance</td>
<td>Public health</td>
</tr>
</tbody>
</table>
**LightMix® Modular SARS and CoV Assays**

*Launched February 14, 2020*

- **Assay Design**
  - PCR Technology
  - 3 RUO Assays targeting CoV strain
    - E-gene
    - N-gene
    - RdRP-Gene

- **Instrumentation**
  - MagNA Pure 96 Sample Extraction
  - z480 Sample Analysis

- **Performance**
  - 96 samples per run
  - ~ 2.5 hours throughput
Emergency Use Authorization (EUA)

What does this mean?

The FDA Medical Countermeasures Initiative (MCMi) legal, regulatory, and policy framework ensures that U.S. laws, regulations and policies help support preparedness and response for potential chemical, biological, radiological, nuclear (CBRN) and emerging infectious disease threats the FDA Commissioner may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN threat agents when there are no adequate, approved, and available alternatives.

The FDA provides guidance to manufacturers and labs on requirements needed for approval for EUA; Roche follows these guidelines for their submission.
COVID-19 and cobas® SARS-CoV-2 Timelines

Dec

12/31/2019
Cluster of unknown pneumonia reported to WHO

01/07/20
New Coronavirus Identified

01/23/20
Wuhan city shut down

01/30/20
WHO declares coronavirus a public health emergency of international concern

Jan

01/08/20
RMD Infectious Disease Emergency Response Team

01/23/20
TIB LightMix® Modular Wuhan CoV available (CE)

Feb

02/03/20
RMD Project team was formed

02/14/20
TIB LightMix® Modular Wuhan CoV available (US)

02/24/20
MSA Grand Rounds on COVID-19

02/27/20
cobas® omni channel assay published

02/25/20
Daily new cases outside China exceed China numbers

March

03/11/20
WHO declares COVID-19 a pandemic

03/13/20
RMD launches a COVID-19 assay (EUA/CE-IVD) for use on the 6800/8800-

First commercial assay

02/29/20
FDA releases Guidance on EUA Procedure for labs
EUA cobas® 6800/8800 SARS-CoV-2

Specific nucleic acid sequences from the non-structural Open Reading Frame (ORF 1a/b) in the genome of the SARS-CoV-2 virus in the FAM channel

The conserved sequences in the structural envelope (E) gene common to all Sarbecoviruses including SARS-CoV-2 with a pan-Sarbecovirus assay in the HEX channel to provide a high degree of robustness.

Tracking ID: MCM2020-00043
The cobas® 6800/8800 SARS-CoV-2 assay

Intended Use

- **cobas®** SARS-CoV-2 for use on the **cobas® 6800/8800 Systems** is a **real-time RT-PCR** test intended for the qualitative detection of nucleic acids from SARS-CoV-2 in clinician-instructed self-collected nasal swab samples (collected on site), and clinician-collected nasal, nasopharyngeal, and oropharyngeal swab samples from patients who meet COVID-19 clinical and/or epidemiological criteria in **nasopharyngeal and oropharyngeal swab** samples from patients who meet **COVID-19** clinical and/or epidemiological criteria.

- **Positive** results are indicative of the **presence of SARS-CoV-2 RNA**; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status.
Roche Solution: cobas® 6800/8800 Systems
Supporting cobas SARS-CoV-2 EUA Assay

384 results FROM AN 8 HOUR SHIFT

1,824 results FROM AN 8 HOUR SHIFT

*The cobas® 6800/8800 Systems are not available in all markets. *May vary based on workflow demands
COVID-19 Timeline

1 Roche

01/07/20: New Coronavirus Identified
01/08/20: RMD Infectious Disease Emergency Response Team
01/23/20: TIB LightMix® Modular Wuhan CoV available
02/27/20: cobas® omni channel assay published
03/13/20: RMD launches a COVID-19 assay (EUA/CE-IVD) for use on the 6800/8800
03/11/20: WHO declares COVID-19 a pandemic
05/05/20: 250,687 confirmed deaths due to SARS-CoV-2
05/02/20: CPS launches a Elecsys® Anti-SARS-CoV-2 assay

First commercial assay

12/31/2019: Cluster of unknown pneumonia reported to WHO
Uses of Serology Assays

What we don’t know

- Is the immunological response protective?
- Does the presence of antibodies indicate immunity?
- How long does the immunity last?
- What kind of antibodies will a safe and effective vaccine generate? How fast will this happen? How long will the vaccine be protective for?
- How long will it take to reach “herd” immunity?
- How many times will an individual need to be tested?
Roche is working in alignment with the government and have allocation measures in place that offers testing to all 50 states and Puerto Rico across a combination of hospitals and large reference labs (for PCR).

For additional questions, healthcare providers can call 1-866-987-6243 for general information and updates regarding COVID-19.
Doing now what patients need next
Questions & Answers

Jamie E. Phillips, PhD
Sr. Scientific Affairs Manager Medical and Scientific Affairs Roche Diagnostics Corporation
We hope you enjoyed our #WIGWednesday session

Please join us for these upcoming #WIGWednesday programs:

**May 27, 2020:** Mental Health Resources for You and Your Constituents in the Time of COVID-19 Moderated by Senator Nancy Todd (CO) Featuring Paul Gionfriddo, President and CEO, Mental Health America

**June 3, 2020:** Amazon’s Response to COVID-19: Supporting Employees, Customers, and Communities Featuring Jane Bourke, Worldwide Senior Manager, Health and Safety Technical Solutions, Amazon and Anya Malkov, Senior Manager, Public Policy, Amazon; stay tuned for the Moderator!