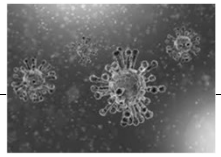
Coronavirus: The Clinical Lab Perspective



BETH P. LANDRY, MHA, MT(ASCP)

Objectives:

1. Identify the origin of the 2019 novel Coronavirus outbreak.

2. Describe the clinical symptoms that are associated with patient illness.

3. Discuss the measures taken by the Louisiana Office of Public Health and CDC to assist clinical laboratories and hospitals.

Once upon a time…..

- In December 2019, patients with "pneumonia of unknown etiology" were reported in Wuhan, China.
- "Pneumonia of unknown etiology" – surveillance mechanism was established after the 2003 SARS (Severe Acute Respiratory Syndrome) outbreak with the goal of timely identification of novel pathogens.
- Criteria:
  - Illness without a causative pathogen
  - Fever >100.4°F
  - Radiographic evidence of pneumonia
  - Low/normal WBC or low lymphocyte count
  - No symptomatic improvement after antimicrobial treatment for 3-5 days

Once upon a time…..

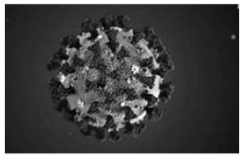
- 2003: SARS → SARS-CoV
  - Viral respiratory illness caused by a coronavirus.
  - First reported in Asia in February 2003.
  - Within a few months, it spread to more than two dozen countries in North America, South America, Europe, and Asia before it was contained.
  - 8,098 people worldwide were infected.
  - 774 deaths
  - U.S.: only 8 people tested positive – all had travel history to countries associated with outbreak
  - Since 2004, there have been no reported cases.

Once upon a time…..

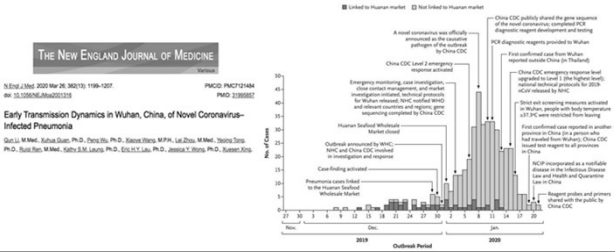
- 2012: MERS (Middle East Respiratory Syndrome → MERS-CoV
  - Viral respiratory illness caused by a coronavirus.
  - First reported in Saudi Arabia in September 2012.
  - Looking back, it was discovered that the first case occurred in Jordan in April 2012.
  - All cases of MERS have been linked through travel to, or residence in, countries in and near the Arabian Peninsula.
  - 2,519 cases worldwide
  - 866 deaths
  - U.S.: only 2 people tested positive in May 2014 – both were HCP who worked in Saudi Arabia (Indiana - 1 and Florida - 1)

Coronavirus Family

- Named for their crown-like spikes on their surface.
- First identified in the mid-1960s.
- Common human coronaviruses:
  - 229E
  - NL63
  - OC43
  - HKU1
- "New" to humans:
  - SARS-CoV (2003)
  - MERS-CoV (2012)
  - SARS-CoV-2 (2019)



COVID-19 Origin



COVID-19: Arrives in the United States

- 1/19/20: 35 yo male presents to urgent care in Snohomish County, Washington
- 4-day history of cough and fever
- Checked in and put on a mask
- Returned to Washington after traveling to visit family in Wuhan, China
- Decided to see HCP after seeing the health alert from the CDC about the novel coronavirus outbreak in China
- 1/20/20: CDC confirms that the patient's nasopharyngeal and oropharyngeal swabs tested positive for 2019-nCoV by real-time reverse-transcriptase-polymerase chain reaction.

COVID-19: What is my name?

- The World Health Organization originally called this illness "novel coronavirus-infected pneumonia" (NCIP).
- The virus was named "2019 novel Coronavirus" (2019-nCoV).
- On 2/11/20, the WHO officially renamed the clinical condition **COVID-19**, which is an abbreviation of **CO**rona**VI**rus **D**isease-19.
- Also on 2/11/20, the Coronavirus Study Group of the International Committee on Taxonomy of Viruses renamed the virus "**S**evere **A**cute **R**espiratory **S**yndrome **Co**rona**v**irus **2**" (SARS-CoV-2).
- To prevent confusion with SARS-CoV-1, the WHO decided to use "COVID-19 virus" when communicating with the public.

COVID-19 Symptoms

Wide range of symptoms:

Fever or chills	New loss of taste or smell
Cough	Sore throat
SOB/difficulty breathing	Congestion or runny nose
Fatigue	Nausea or vomiting
Muscle or body aches	Diarrhea
Headache	and many more….

COVID-19 Symptoms

- Symptoms may appear 2-14 days after exposure to the virus.
- Symptoms may range from mild to severe illness.
- Older adults and people who have severe underlying medical conditions (heart disease, lung disease, liver disease, HIV, immunocompromised, diabetes, etc.) are at a higher risk for developing more serious complications.

COVID-19 Complications

- Acute respiratory distress syndrome
- Pulmonary embolism
- Deep vein thrombosis
- Cardiac arrest
- Viral encephalitis
- Secondary infections: bacterial pneumonia, sepsis
- Acute kidney injury
- DIC – disseminated intravascular coagulation
- Multi-organ failure

COVID-19: Lab Results

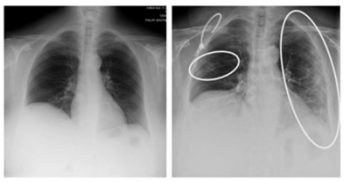
Common laboratory findings include:

- Increased PT
- Increased LDH
- Decreased Lymphocytes
- Slightly elevated inflammatory markers (CRP and ESR)
- Elevated D-dimer

COVID-19: Radiology

- 69% of patients demonstrated abnormal chest X-rays upon admission.
- Ground-glass opacities were often observed.

GGO: lighter patches that don't completely obscure the other lung structures (airways, blood vessels, lung tissue)



COVID-19: Confirmed Cases - 2/3/20

China
Hong Kong
Macau
Taiwan
Australia
Cambodia
Canada
Finland
France
Germany
India
Italy
Japan

Malaysia
Nepal
Philippines
Russia
Sri Lanka
Singapore
Spain
Sweden
Thailand
The Republic of Korea
United Arab Emirates
United Kingdom
United States
Vietnam

COVID-19: Confirmed Cases – 7/16/20

Total cases: 13,378,853
Total deaths: 580,045

COVID-19 Statistics – United States

People Under Investigation (PUI) in the United States*†

As of 2/3/2020

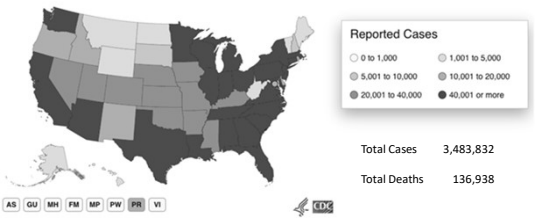
Positive	11
Negative	167
Pending‡	82
Total	260

*Cumulative since January 21, 2020.
†Numbers closed out at 7 p.m. the night before reporting.
‡Includes specimens received and awaiting testing, as well as specimens in route to CDC.

Number of states with PUI: 36

Remember when…..?

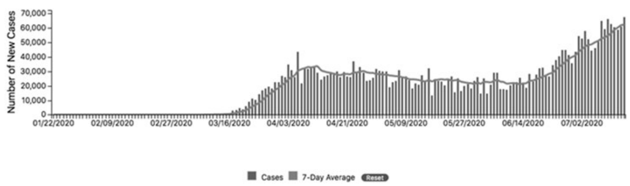
COVID-19 Statistics – United States 7/16/20



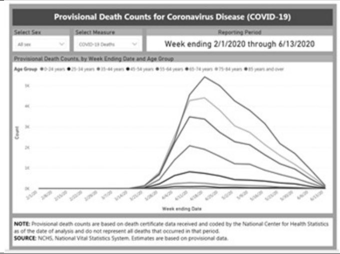
Total Cases 3,483,832

Total Deaths 136,938

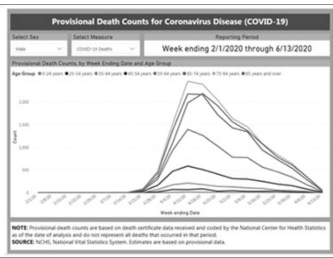
COVID-19 Statistics – United States 7/16/20



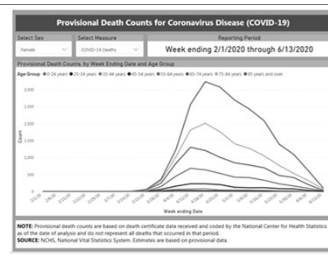
COVID-19 Statistics – United States



COVID-19 Statistics – United States



COVID-19 Statistics – United States



Non-COVID-19 Respiratory Pathogens

UMC Influenza Cases

Week of	Influenza Tests Performed	Flu A Positive	Flu B Positive	Total Positives
12/30/19	129	6	11	17
1/6/20	141	15	6	21
1/13/20	145	34	7	41
1/20/20	187	44	11	55
1/27/20	213	47	10	57
2/3/20	186	49	6	55
2/10/20	232	54	9	63
2/17/20	183	51	9	60
2/24/20	182	47	3	50
3/2/20	224	50	6	56
3/9/20	414	25	0	25
3/16/20	413	12	0	12
3/23/20	99	0	0	0
3/30/20	28	0	0	0
4/6/20	11	0	0	0
4/13/20	7	0	0	0

COVID-19 Statistics – Louisiana 7/16/20

Total cases: 86,411
Total deaths: 3,375
COVID Inpatients: 1,401 (162 on vents)

Total Number of Cases

- 0
- <20
- 37 - 241
- 242 - 384
- 385 - 487
- 488 - 912
- 913 - 2,080
- 2,081 - 11,614

COVID-19 Statistics – Louisiana 7/16/20

Race	
American Indian/Alaska N..	0.12%
Asian	0.69%
Black	51.49%
Native Hawaiian/PI	0.08%
Other	0.51%
Unknown	0.12%
White	46.92%

Ethnicity	
Hispanic/Latino	2.10%
Non-Hispanic/Latino	90.00%
Unknown	7.90%

Age (years)	
Average	74
Median	76

Underlying Conditions	
Asthma	4.09%
Cancer	7.29%
Cardiac Disease	20.64%
Chronic Kidney Disease	20.37%
Congestive Heart Failure	13.92%
Diabetes	36.38%
Hypertension	59.71%
Neurological	15.26%
Obesity	18.88%
Pulmonary	12.22%

Gender	
Female	48.00%
Male	52.00%
Unknown/Other	0.00%

COVID-19 Statistics – Louisiana 7/16/20

Cases by County

County	Total Cases	Percent of State's Cases	Cases per 100,000	Total Deaths
Jefferson	11,614	13.8%	2,685	495
Orleans	8,946	10.6%	2,293	543
East Baton Rouge	7,606	9%	1,728	279
Caddo	4,606	5.5%	1,918	249
Lafayette	4,352	5.2%	1,781	55
Calcasieu	3,705	4.4%	1,821	74
St. Tammany	3,395	4%	1,304	187
Ouachita	3,296	3.9%	2,150	92
Rapides	2,104	2.5%	1,623	81
Tangipahoa	2,081	2.5%	1,544	45
Terrebonne	1,824	2.2%	1,651	67
Lafourche	1,721	2%	1,763	91

COVID-19: UMC Timeline

- 3/10/20- First positive COVID patient at UMC
- 3/11/20 – WHO recognizes outbreak as a pandemic
- 3/11/20- UMC Incident Command enacted
- 3/11/20- Limited entry and visitor restriction
- 3/13/20- COVID bench is born

COVID-19: UMC Timeline

- 3/15/20- Masking of visitors and further visitor restrictions with safety screenings and temperature checks as required by Louisiana Department of Health
- 3/19/20- Temperature checks and symptom screeners at 1st floor entrances for all employees, faculty, residents, and contract staff reporting to work
- 3/23/20- ED Triage Tent opened
- 3/26/20- Opened additional ICU and renovated additional units for negative pressure rooms

COVID-19: UMC Timeline

Emergency Department Annex for Triage – 3/23/20

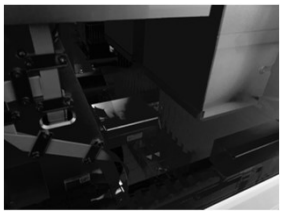
COVID-19: UMC Timeline

- 3/30/20- UMC/Tulane COVID-19 testing – Roche
- 4/07/20- Universal Masking of all employees, faculty, residents, and contract staff.
- 4/13/20- Roche Go-Live
- 4/20/20- Cepheid and Abbott Go-Live
- 4/20/20- COVID bench transitions to Microbiology
- 4/27/20- COVID-19 Pre-Procedural Testing
- 5/04/20- Employee Antibody Testing

COVID-19 Testing: Roche

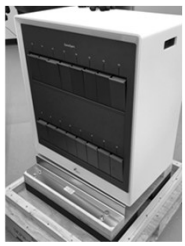
- 3/30/20- UMC/Tulane COVID-19 testing – Roche cobas 6800
- Shared reagents and instrument
- UMC instrument delivered and installed
- Go-Live 4/13/20

COVID-19 Testing: Roche



COVID-19 Testing: Cepheid

- Cepheid GeneXpert IV
  - Instrument used for Influenza, C. diff, and MTB PCR
  - Go-Live 4/20/20
- Cepheid GeneXpert XVI instrument delivered and installed on 5/8/20
  - Go-Live 5/11/20



COVID-19 Testing: Cepheid

- Unpacked and installed by UMC Lab and Biomed Staff
- Increased testing capacity

COVID-19 Testing: Abbott

- Abbott ID NOW
  - 3 instruments
  - Single test per run
  - Go-Live 4/20/20

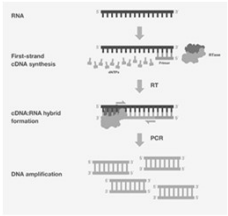
COVID-19 Testing: Methodology

Real time RT-PCR (reverse transcriptase-polymerase chain reaction):

- Method used to detect the presence of specific genetic material in any pathogen, including viruses.
- RT-PCR: converts RNA to DNA
- Originally, the method used radioactive isotope markers to detect targeted genetic materials – provided results at the end of the process
- Current methods use fluorescent dyes as special markers
- See results almost immediately while the process is ongoing – "Real Time"

COVID-19 Testing: Methodology

Real time RT-PCR (reverse transcriptase-polymerase chain reaction)



COVID-19 Testing: Methodology

SARS-CoV-2: RNA virus

Two nucleic acid targets: N2 and E

- N2: specific for SARS-CoV-2
- E: also identified in SARS-CoV-1

Result Text	N2	E
SARS-CoV-2 POSITIVE	+	+
SARS-CoV-2 POSITIVE	+	-
SARS-CoV-2 PRESUMPTIVE POSITIVE	-	+
SARS-CoV-2 NEGATIVE	-	-

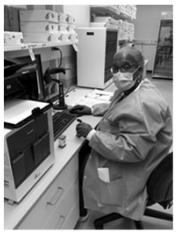
COVID-19 Testing Algorithm

ED Discharges/Trauma Activation

- **Abbott assay**
  - Testing Time: 15 minutes (analyzer time)
  - Turnaround time: 1 hour
  - Order in EPIC: SARS-CoV-2 by NAA (Abbott)

ED Admissions/Inpatients/Procedures

- **Cepheid assay**
  - Testing Time: 50 minutes (analyzer time)
  - Turnaround time: 2-3 hours
  - Order in EPIC: SARS-CoV-2 by PCR (Cepheid)



COVID-19 Testing Algorithm

Ambulatory Clinics/Healthcare Workers/System Hospitals/ Outreach

- **Roche assay**
  - Testing Time: 3-5 hours (analyzer time)
  - Turnaround time: 24-72 hours
  - Order in EPIC: SARS-CoV-2 by PCR (Roche)

COVID-19: CDC

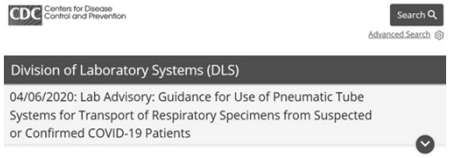
Centers for Disease Control and Prevention
National Center for Health Statistics

- CDC developed testing for SARS-CoV-2.
- Also developed testing criteria for patients.
- Distributed test reagents to state labs of hot zones.
- Performed confirmatory testing for state labs – later discontinued.
- Provided guidance for specimen collection.
- Provided guidance for lab safety.
- Maintains statistics

COVID-19: CDC

Centers for Disease Control and Prevention
National Center for Health Statistics

- Advises NOT to use pneumatic tube systems for transport of COVID specimens.



COVID-19: OPH

- OPH performed the CDC SARS-CoV-2 assay in Baton Rouge
- Developed courier system to transport systems
- Initially required PUI approval, but later gave authority to hospitals
- Developed online portal to enter patient demographics
- Test result data is reported to OPH.
- Epidemiology hotline for lab personnel

Happily ever after?

Obstacles:
- Testing reagents (shortages, allocations, etc)
- Shortages of viral transport media, sterile tubes, swabs

More to follow:
- Antibody results
- Convalescent plasma
- Drugs
- Vaccine

#ourlabrocks

Questions??

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