

# Clinical Laboratory COVID-19 Response Call

- **Welcome and Introductions**  
Jasmine Chaitram, CDC Division of Laboratory Systems
- **Performance Evaluation of Commercially Developed Serology Tests**  
Michele Owen, CDC Laboratory Task Force
- **Updates and Responses to Submitted Questions on Diagnostics and Testing**  
Tim Stenzel, U.S. Food and Drug Administration (FDA)
- **Additional CLIA Guidance for Testing Laboratories**  
Karen Dyer, Centers for Medicare & Medicaid Services (CMS)
- **COVID-19 Response – Hospital System on the Front Lines**  
James (Jim) Crawford, Donald and Barbara Zucker School of Medicine at Hofstra/Northwell Health, Lake Success, New York
- **Nebraska’s Public Health Laboratory Response**  
Peter Iwen, Nebraska State Public Health Laboratory
- **Reporting Testing Data to CDC**  
Jasmine Chaitram, CDC Division of Laboratory Systems
- **Laboratory Biosafety Update for COVID-19**  
Bill Arndt, CDC Division of Laboratory Systems

# To Ask a Question

- Using the Webinar System
  - Click the **Q&A** button in the Zoom webinar system
  - Type your question in the **Q&A** box
  - Submit your question
  - Please do not submit a question using the chat button
- For media questions, please contact CDC Media Relations at [media@cdc.gov](mailto:media@cdc.gov).

# CDC Laboratory Task Force – COVID-19 Testing

CDC guidance on specimen collection and transport for COVID-19 testing

<https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html>

CDC guidance on evaluating and testing persons for coronavirus disease

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-criteria.html>

# CDC Laboratory Task Force – COVID-19 Testing

For laboratories using the CDC EUA assay, please contact [respvirus@cdc.gov](mailto:respvirus@cdc.gov) for laboratory testing guidance.

# Food and Drug Administration (FDA)

COVID-19 Emergency Use Authorization (EUA)

Information: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>

COVID-19 Frequently Asked Questions: <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/coronavirus-disease-2019-covid-19-frequently-asked-questions>

COVID-19 Updates: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#2019-ncov>

# Food and Drug Administration (FDA)

COVID-19 Diagnostic Development: [CDRH-EUA-Templates@fda.hhs.gov](mailto:CDRH-EUA-Templates@fda.hhs.gov)

Spot Shortages of Testing Supplies: 24 hour support available

1. Call 1-888-INFO-FDA (1-888-463-6332)
2. Then press star (\*)

# Centers for Medicare and Medicaid Services (CMS)

CLIA Laboratory Guidance During COVID-19 Memo and FAQs:

<https://www.cms.gov/medicareprovider-enrollment-and-certificationsurvey/certificationgeninfo/policy-and-memos-states-and/clinical-laboratory-improvement-amendments-clia-laboratory-guidance-during-covid-19-public-health>

FAQs Only

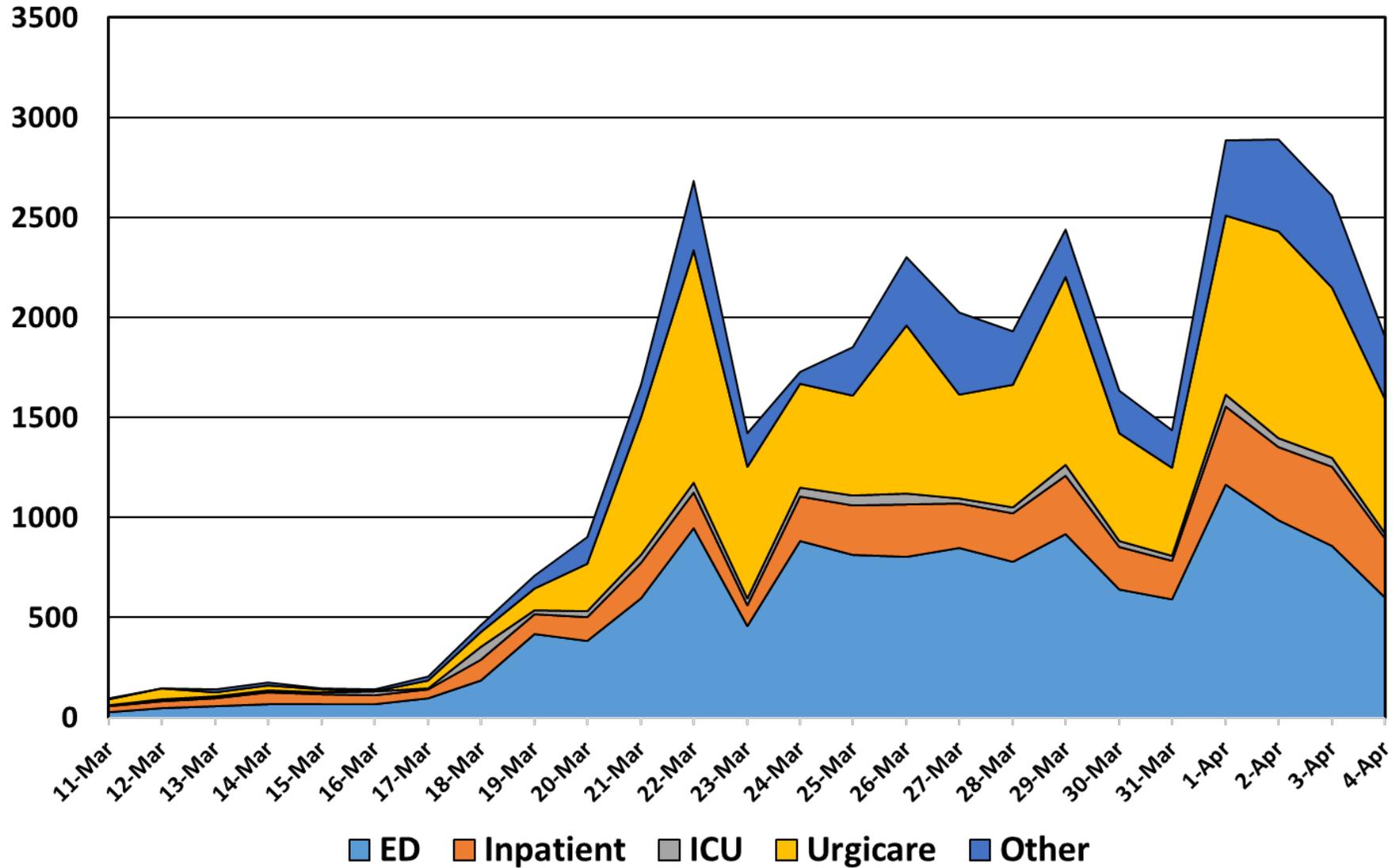
<https://www.cms.gov/medicare/quality-safety-oversight-general-information/coronavirus>

# COVID-19 Data Northwell Health Laboratories Update April 6, 2020

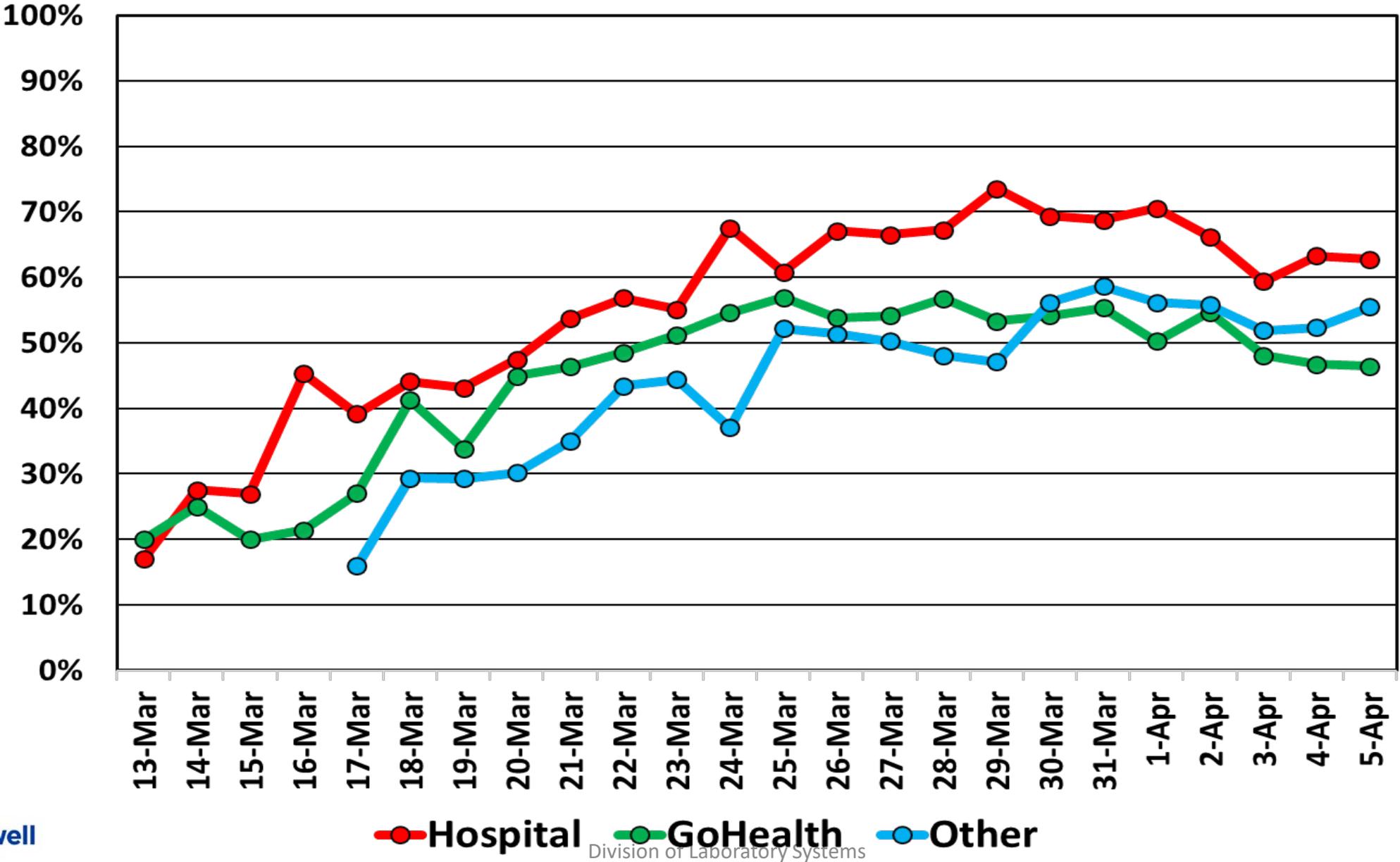
James M Crawford, MD PhD  
[jcrawford1@northwell.edu](mailto:jcrawford1@northwell.edu)



# Daily Tests by Clinical Site



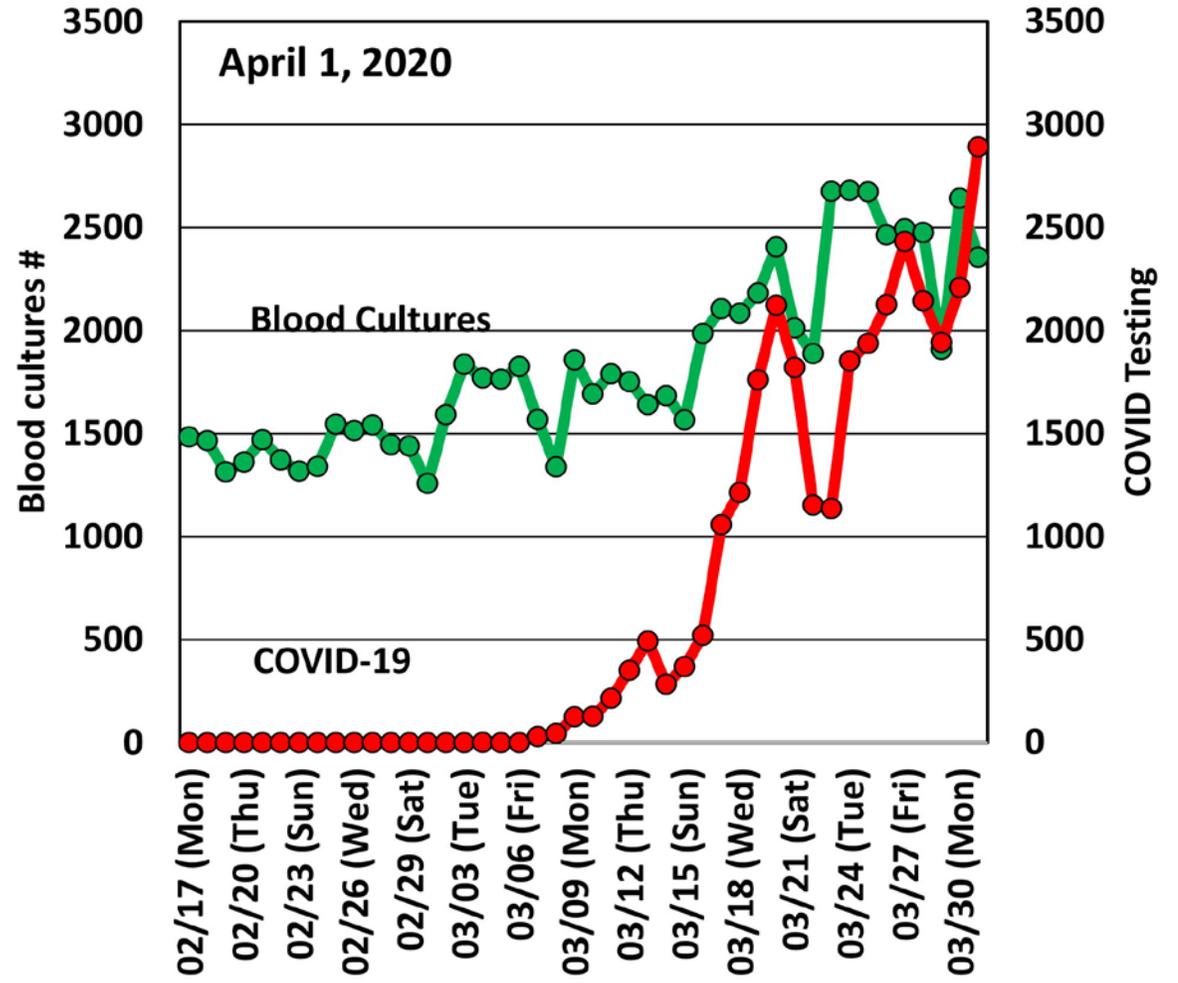
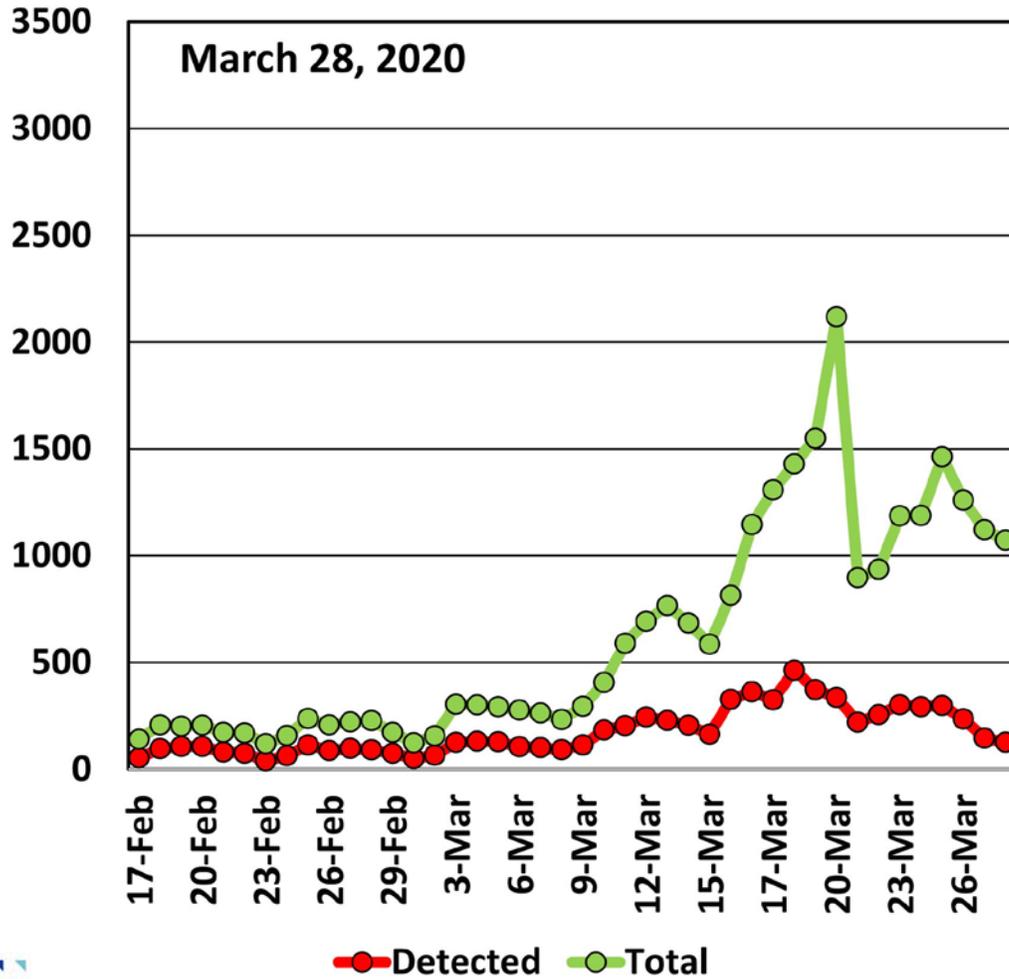
# Northwell: COVID-19 Daily Test Positivity Rates



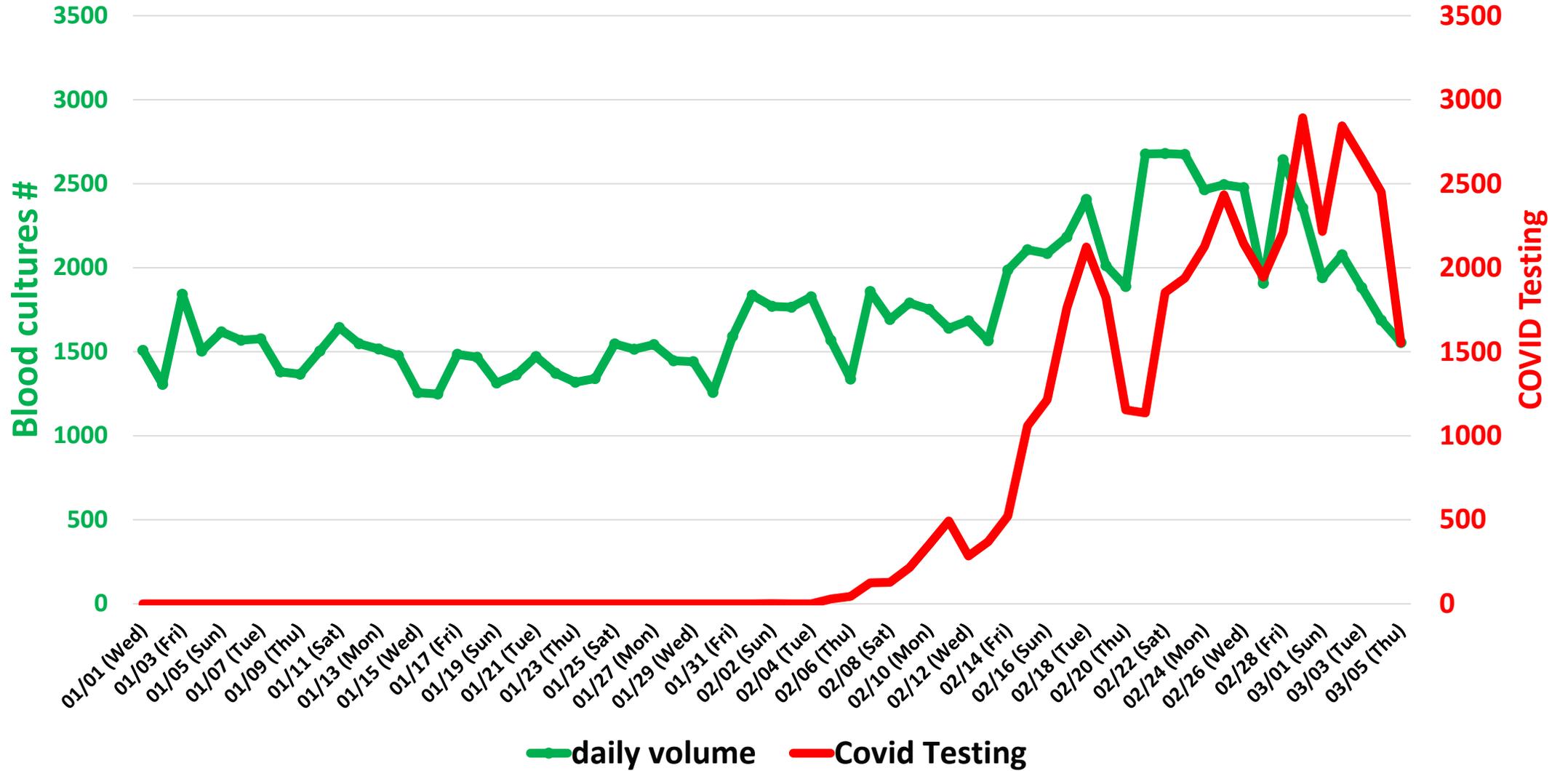
# Northwell Health Laboratories

## Blood Cultures vs. COVID-19 tests

### RVP Tests



# Blood Culture Bottles per Day, vs. COVID-19 Test Orders



# COVID-19 Laboratory Considerations (in progress)

- Negative Predictive Value (NPV) of [COVID-19 PCR] “Not Detected”
- Serologic Testing for COVID-19 Immunoreactivity
- Point-of-Care (POC) Testing for COVID-19
- [COVID-19 PCR] Testing at Hospital Sites (vs. Core Lab)
- “Need to know” [COVID-19 PCR] testing (e.g., Pre-Surgical Testing)
- Preparing for “Convalescent Plasma”

# Nebraska's Response to COVID-19



# Timeline of Important Events

- 12-01-19 First human case of nCoV (Wuhan, China)
- 01-22-20 Repatriation of Americans from China to NQU in Omaha
  - began validation of the WHO assay
- 01-29-20 Discussion to repatriate 250 individuals to Omaha
- 01-30-20 WHO declared nCoV a PH emergency of International Concern
- 02-02-20 Omaha designated as one of four sites for federal quarantine
- 02-06-20 US declared nCoV a National PH Emergency
- 02-07-20 NPHL ordered the nCoV 2019 EUA from IRR
- 02-08-20 57 people arrived in Omaha for federal quarantine
  - Received the EUA
- 02-09-20 Completed the verification process for the EUA
- 02-17-20 Received 14 people from the Diamond Princess
  - 12/14 positive for nCoV
  - 2 admitted to the Nebraska Biocontainment Unit
- 03-13-20 Governor declared a State of Emergency in Nebraska

# STATE OF NEBRASKA



## Proclamation

**WHEREAS,**

*Commencing on March 6, 2020 and continuing, the Coronavirus (COVID-19) has impacted the entire State of Nebraska. COVID-19 has spread across the country with cases being confirmed within the borders of Nebraska. This emergency can strain the abilities of state and local governments to meet the needs of the citizens and respond to the pandemic; and*

**WHEREAS,**

*The actions necessary to assist in meeting the emergency conditions and subsequent impacts of these events present a burden upon the entire State of Nebraska; and*

**NOW THEREFORE,**

*Under the provisions of Neb. Rev. Stat. §81-829.40, which confers emergency responsibilities and powers upon the Governor, I, Pete Ricketts, as Governor of the State of Nebraska do hereby declare that a state of emergency exists within the State of Nebraska; and*

**NOW,**

*In addition to the powers conferred upon me by law, I may suspend the provisions of any regulatory statute prescribing the procedures for conduct of state business or the orders, rules, or regulations of any state agency if strict compliance with the provisions would prevent, hinder, or delay necessary action in coping with the emergency. This could include waiving regulations to expedite measures in order to protect the life, health, and safety of our citizens and to mitigate the impact of the pandemic; and*

**I HERBY DIRECT,**

*The Nebraska Adjutant General, who also serves as State Disaster Coordinator, to activate appropriate State emergency plans and to take such steps as he deems necessary to meet these emergencies, and to continue these actions until such time as the threat to life and property created by these situations has been alleviated; and*

**I FURTHER DIRECT  
OR REQUEST,**

*State and appropriate Federal agencies to cooperate with the and support the Adjutant General of Nebraska upon his request, as may be appropriate and lawful; and*

**I HEREBY AUTHORIZE,**

*The Adjutant General of Nebraska to activate such elements of State Government and Emergency Management resources as are appropriate to deal with this emergency and to expend such funds, within the limitations of availability, from the Governor's Emergency Fund to support these actions.*

**IN WITNESS WHEREOF,**

*I hereto set my hand and cause the Seal of the State of Nebraska to be affixed this 13th day of March, 2020.*

*Done at the State Capitol, Lincoln, Nebraska, on this Thirteenth Day of March in the Year of Our Lord, Two Thousand Twenty.*



ATTEST:

Secretary of State

Governor

# Federal Quarantined Travelers



# Federal Quarantined Travelers

14 Diamond Princess travelers quarantined  
Medium 21 days (range 14d to 33d)

Day 1      12/14 NP+      7/14 OP+

Day 10     9/14 NP+      2/14 OP+

Serial testing, 3 negative specimens before released

Total 205 specimens	100 Negative
	77 Positive
	28 Inconclusive

# Group Testing of Pooled Specimens



Pete Ricketts  
Governor

STATE OF NEBRASKA  
OFFICE OF THE GOVERNOR  
P.O. Box 94848 • Lincoln, Nebraska 68509-4848  
Phone: (402) 471-2214 • [pete.ricketts@nebraska.gov](mailto:pete.ricketts@nebraska.gov)

March 24, 2020

Dr. Jeffrey P. Gold, Chancellor  
University of Nebraska Medical Center  
987400 Nebraska Medical Center  
Omaha, NE 68198-7400

Dear Dr. Gold:

I write in response to your March 24, 2020, letter concerning the conservation of reagents used for COVID-19 testing at the Nebraska Public Health Laboratory. I give my full authorization to explore and proceed with all reasonable measures to expand testing at this time.

Thank you for all of your help.

Sincerely,

Pete Ricketts  
Governor

cc: Peter Iwen, Ph.D., D(ADMN), Lab Director, NPHL  
Steven H. Hinrichs, M.D., Clinical Consultant, NPHL

Iwen, Peter C

**From:** Feldblyum, Tamara <[Tamara.Feldblyum@fda.hhs.gov](mailto:Tamara.Feldblyum@fda.hhs.gov)>  
**Sent:** Friday, March 27, 2020 6:38 AM  
**To:** Hinrichs, Steven H; Sapsford, Kim E; Li, Li (CDRH)  
**Cc:** Iwen, Peter C; Goldberg, Brittany  
**Subject:** RE: New EUA for bridging to CDC EUA

Non-UNMC email

Dear Dr. Hinrichs,

Taking into consideration the current shortage of testing reagents and medical supplies and the supporting information you provided, FDA will not object to your laboratory testing pools of five specimens while the positive test rate is below 10%. However, if the positive rate for SARS-CoV-2 in the testing population exceeds 10%, pooling of clinical specimens should no longer be performed at your testing site.

Best regards,

Tamara Feldblyum, M.S., Ph.D.  
Branch Chief,  
Viral Respiratory and STI Branch  
Division of Microbiology Devices | Office of In Vitro Diagnostics and Radiological Health  
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration  
White Oak, Bldg. 66, Rm. 3106 | 10903 New Hampshire Avenue | Silver Spring, MD 20993  
Ph: (301) 796-6195  
[Tamara.Feldblyum@fda.hhs.gov](mailto:Tamara.Feldblyum@fda.hhs.gov)



# Group Testing of Pooled Specimens

24Mar – 3April

Began 24March

Pooled specimens	939
No. of pools	189
No. pools positive	50
Extraction/PCR reagents used	441
Extraction/PCR reagents saved	498 (53.0%)

\*Predictor variables Low risk specimens vs high risk

Note:

Pooling will not work if the rate of infection exceeds 15%.

Loss of sensitivity seems to be minimal (1.5 to 2.5 CTs)

Splitting any pool with late CT amplification (40 to 45 CTs)

*Number of Positive and Not Detected Tests (N = 4,618) on Nebraska Residents by Performing Laboratory – Nebraska, February-April 2020*

	Lab Status		Grand Total
	Not Detected	Positive	
	N	N	
<b>Performing laboratory</b>			
The Nebraska Medical Center Clinical Lab	1578	80	1658
Nebraska Public Health Laboratory	1240	103	1343
LabCorp	551	21	572
CHI/Creighton	328	26	354
Avera Laboratories	192	10	202
ARUP	141	2	143
Quest	132	10	142
Mayo	61	1	62
Focus Technology	58	.	58
PLAB	42	3	45
Other	33	6	39
<b>Total</b>	<b>4356</b>	<b>262</b>	<b>4618</b>

Roche Cobas

Abbott m2000

Result to 1Apr2020



WOODMEN

Bochs  
World World  
CenturyLink

# Biosafety Resources

COVID-19 Information for Laboratories page:

<https://www.cdc.gov/coronavirus/2019-ncov/lab/index.html>

Interim Laboratory Biosafety Guidelines:

<https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html>

Laboratory Biosafety Frequently Asked Questions:

<https://www.cdc.gov/coronavirus/2019-ncov/lab/biosafety-faqs.html>

Send Inquiries to: [DLSInquiries@cdc.gov](mailto:DLSInquiries@cdc.gov)

# CDC Information for Laboratories

Interim Guidance for Collecting, Handling, and Testing Clinical Specimens

<https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html>

Diagnostic Tools and Virus

<https://www.cdc.gov/coronavirus/2019-ncov/lab/tool-virus-requests.html>

Emergency Preparedness for Laboratory Personnel

<https://emergency.cdc.gov/labissues/index.asp>

CDC's Laboratory Outreach Communication System (LOCS)

<https://www.cdc.gov/csels/dls/locs/>

# CDC Social Media



Facebook: <https://www.facebook.com/CDC>



Twitter: <https://twitter.com/cdcgov>



LinkedIn: <https://www.linkedin.com/company/cdc>

# Thank You For Your Time!

