

Clinical Laboratory COVID-19 Response Call

Monday, November 2nd, 2020 at 3:00 PM ET

- **Welcome**

- Jasmine Chaitram, CDC Division of Laboratory Systems (DLS)

- **CMS Reimbursement Update**

- Sarah Harding, Centers for Medicare & Medicaid Services (CMS)

- **College of American Pathologists (CAP) Letter: Caution Must Be Used in Interpreting the Cycle Threshold (Ct) Value**

- Daniel Rhoads, Cleveland Clinic

- **FDA Update**

- Sara Brenner and Toby Lowe, U.S. Food and Drug Administration (FDA)

Schedule for Clinical Laboratory COVID-19 Response Calls

The next call will be on **Monday, November 16th**
from **3:00 PM to 4:00 PM ET.**



We Want to Hear From You!

Training and Workforce Development

Questions about education and training?

Contact LabTrainingNeeds@cdc.gov

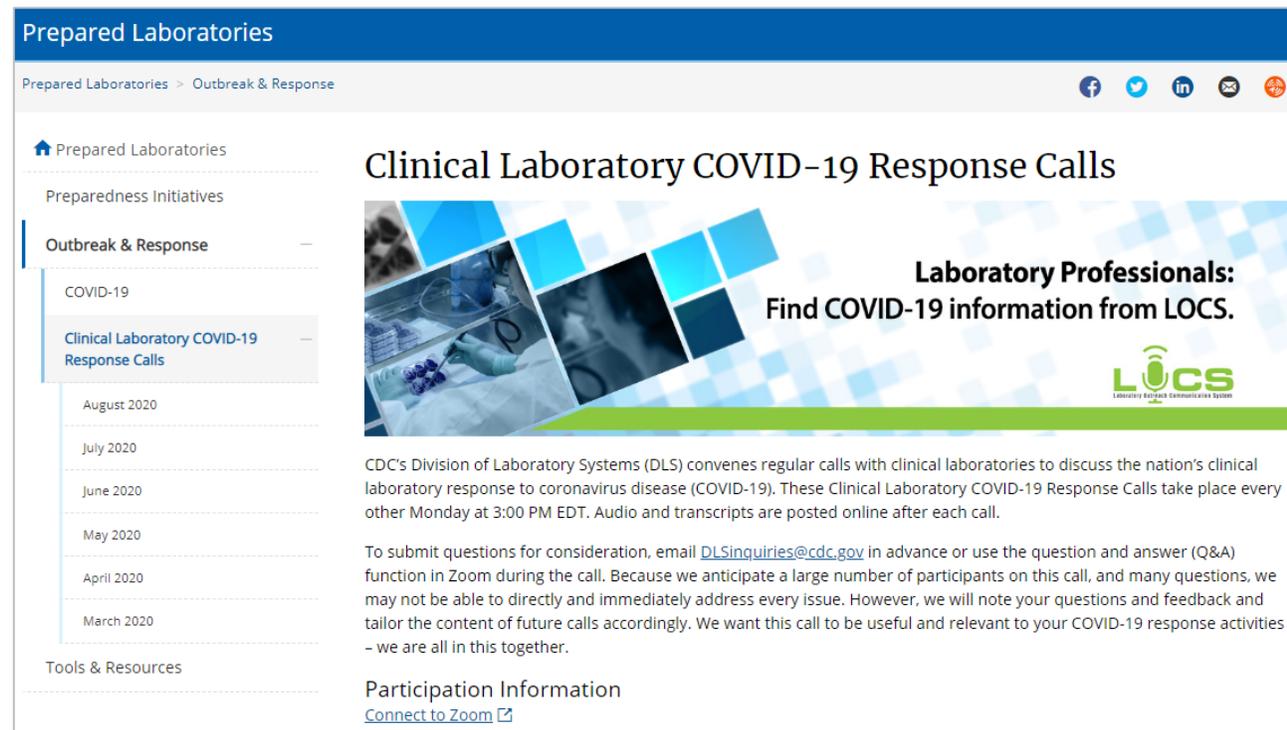


COVID-19 Resources for Laboratories

- **LOINC In-Vitro Diagnostic (LIVD) Test Code Mapping for SARS-CoV-2 Tests**
<https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html>
- **IVD Industry Connectivity Consortium**
<https://ivdconnectivity.org/livd/>
- **Antigen Testing Guidance**
<https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html>
- **Frequently Asked Questions about COVID-19 for Laboratories**
<https://www.cdc.gov/coronavirus/2019-ncov/lab/faqs.html>
- **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 Laboratory Outreach Communication System (LOCS)**
<https://www.cdc.gov/csels/dls/locs/>

CDC Preparedness Portal

<https://www.cdc.gov/csels/dls/preparedlabs/covid-19-clinical-calls.html>



The screenshot shows the 'Prepared Laboratories' section of the CDC Preparedness Portal. The main heading is 'Clinical Laboratory COVID-19 Response Calls'. Below the heading is a banner image with the text 'Laboratory Professionals: Find COVID-19 information from LOCS.' and the LOCS logo. The page includes a sidebar with navigation options: 'Prepared Laboratories', 'Preparedness Initiatives', 'Outbreak & Response', 'COVID-19', 'Clinical Laboratory COVID-19 Response Calls', and 'Tools & Resources'. The main content area contains a paragraph explaining that CDC's Division of Laboratory Systems (DLS) convenes regular calls with clinical laboratories to discuss the nation's clinical laboratory response to COVID-19. It also provides contact information for submitting questions and a link to 'Participation Information' with a 'Connect to Zoom' button.

Prepared Laboratories

Prepared Laboratories > Outbreak & Response

Prepared Laboratories

Preparedness Initiatives

Outbreak & Response

COVID-19

Clinical Laboratory COVID-19 Response Calls

August 2020

July 2020

June 2020

May 2020

April 2020

March 2020

Tools & Resources

Clinical Laboratory COVID-19 Response Calls

**Laboratory Professionals:
Find COVID-19 information from LOCS.**

CDC's Division of Laboratory Systems (DLS) convenes regular calls with clinical laboratories to discuss the nation's clinical laboratory response to coronavirus disease (COVID-19). These Clinical Laboratory COVID-19 Response Calls take place every other Monday at 3:00 PM EDT. Audio and transcripts are posted online after each call.

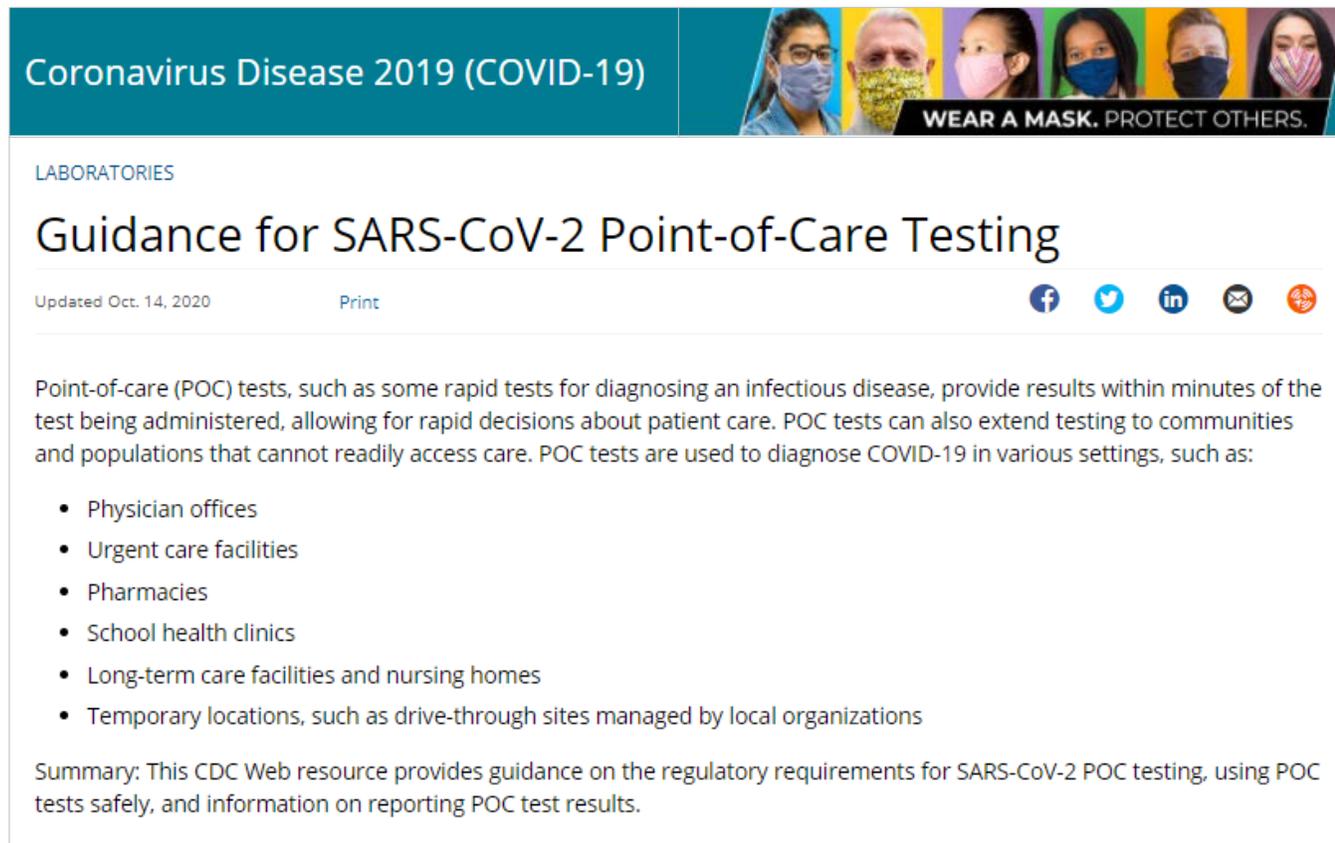
To submit questions for consideration, email DLInquiries@cdc.gov in advance or use the question and answer (Q&A) function in Zoom during the call. Because we anticipate a large number of participants on this call, and many questions, we may not be able to directly and immediately address every issue. However, we will note your questions and feedback and tailor the content of future calls accordingly. We want this call to be useful and relevant to your COVID-19 response activities - we are all in this together.

Participation Information
[Connect to Zoom](#)

Find CLCR call information, transcripts, & audio recordings on the Preparedness Portal

Guidance for SARS-CoV-2 Point-of-Care Testing

<https://www.cdc.gov/coronavirus/2019-ncov/lab/point-of-care-testing.html>



The screenshot shows the top of a CDC webpage. At the top left, it says "Coronavirus Disease 2019 (COVID-19)". To the right is a banner with six diverse people wearing face masks and the text "WEAR A MASK. PROTECT OTHERS." Below this, the page is categorized under "LABORATORIES" and has the main title "Guidance for SARS-CoV-2 Point-of-Care Testing". It includes a date "Updated Oct. 14, 2020" and a "Print" button. There are social media icons for Facebook, Twitter, LinkedIn, Email, and RSS. The main text explains that Point-of-care (POC) tests provide rapid results for diagnosing infectious diseases and lists several settings where they are used. A summary at the bottom states that the resource provides regulatory requirements for POC testing, safety information, and reporting procedures.

Coronavirus Disease 2019 (COVID-19)

WEAR A MASK. PROTECT OTHERS.

LABORATORIES

Guidance for SARS-CoV-2 Point-of-Care Testing

Updated Oct. 14, 2020 [Print](#) [f](#) [t](#) [in](#) [✉](#) [RSS](#)

Point-of-care (POC) tests, such as some rapid tests for diagnosing an infectious disease, provide results within minutes of the test being administered, allowing for rapid decisions about patient care. POC tests can also extend testing to communities and populations that cannot readily access care. POC tests are used to diagnose COVID-19 in various settings, such as:

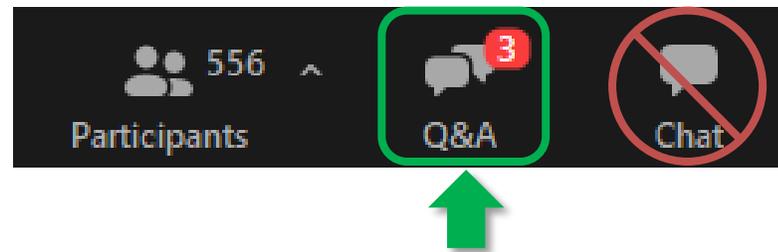
- Physician offices
- Urgent care facilities
- Pharmacies
- School health clinics
- Long-term care facilities and nursing homes
- Temporary locations, such as drive-through sites managed by local organizations

Summary: This CDC Web resource provides guidance on the regulatory requirements for SARS-CoV-2 POC testing, using POC tests safely, and information on reporting POC test results.

How to Ask a Question

- **Using the Zoom Webinar System**

- Click the **Q&A** button in the Zoom webinar system
- Type your question in the **Q&A** box and submit it
- **Please do not submit a question using the chat button**



- For media questions, please contact CDC Media Relations at media@cdc.gov
- If you are a patient, please direct any questions to your healthcare provider

CMS Reimbursement Update

Sarah Harding
Centers for Medicare & Medicaid Services (CMS)



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**

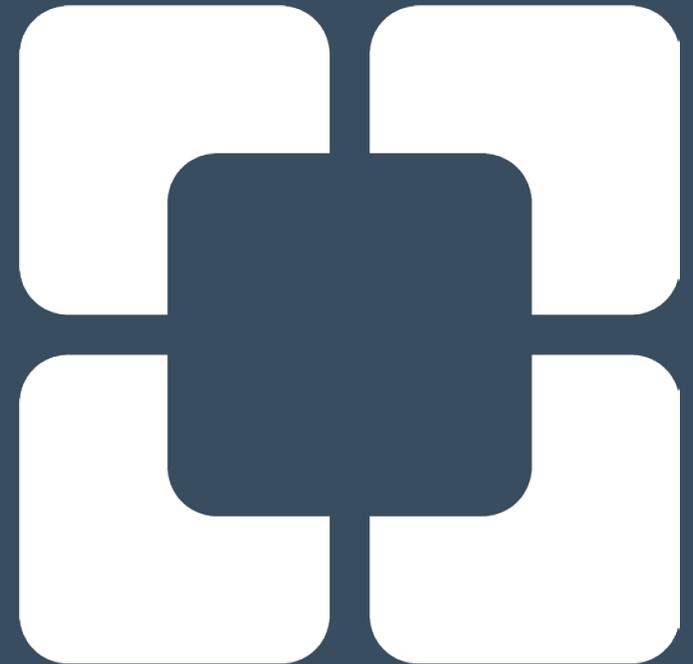
<https://www.cms.gov/medicare/quality-safety-oversight-general-information/coronavirus>

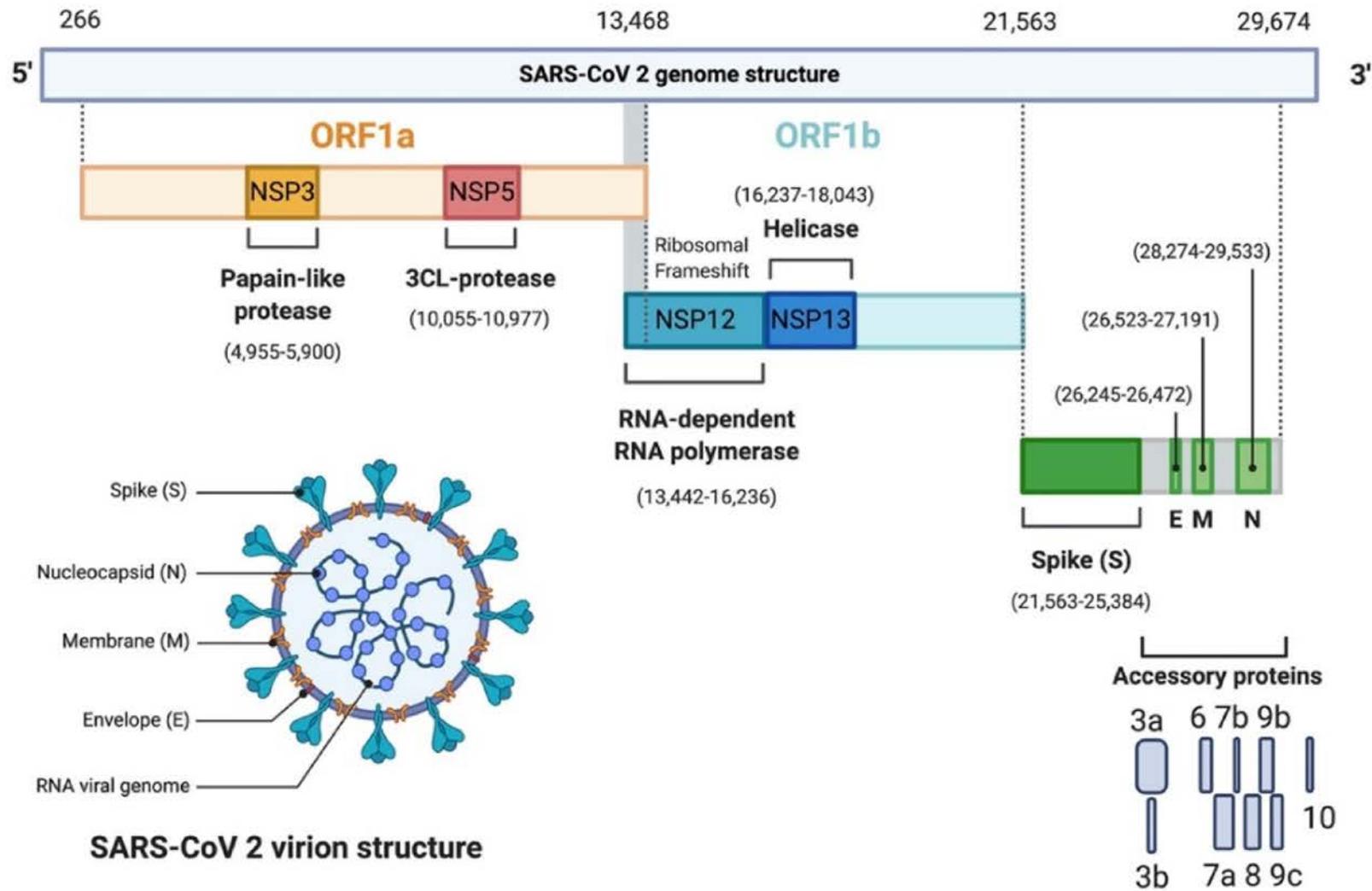


SARS-CoV-2 Ct-values

CDC's Clinical Laboratory COVID-19 Response Call
2 November 2020

Daniel D. Rhoads, MD, FCAP, D(ABMM)
Section Head of Microbiology
Cleveland, Ohio





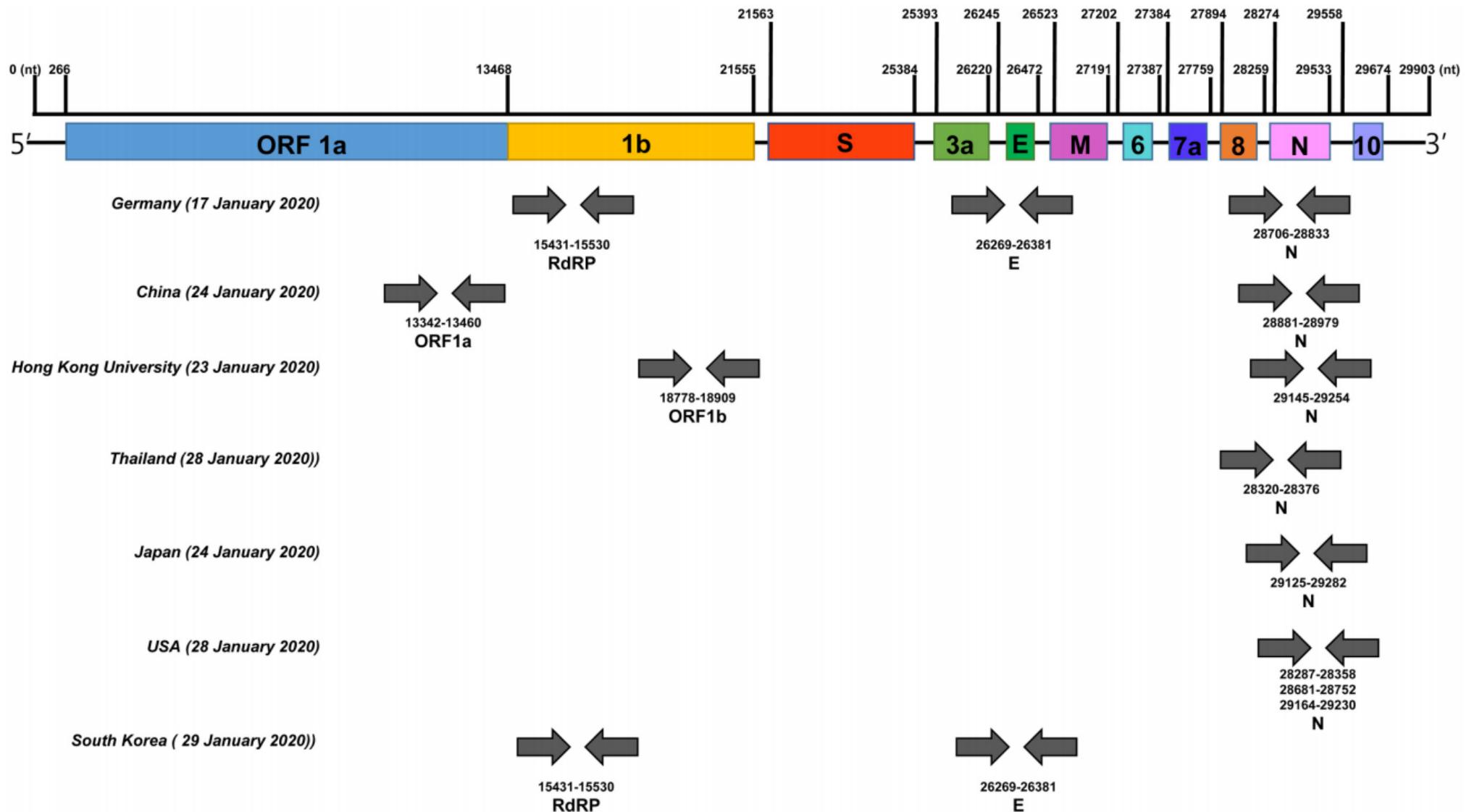
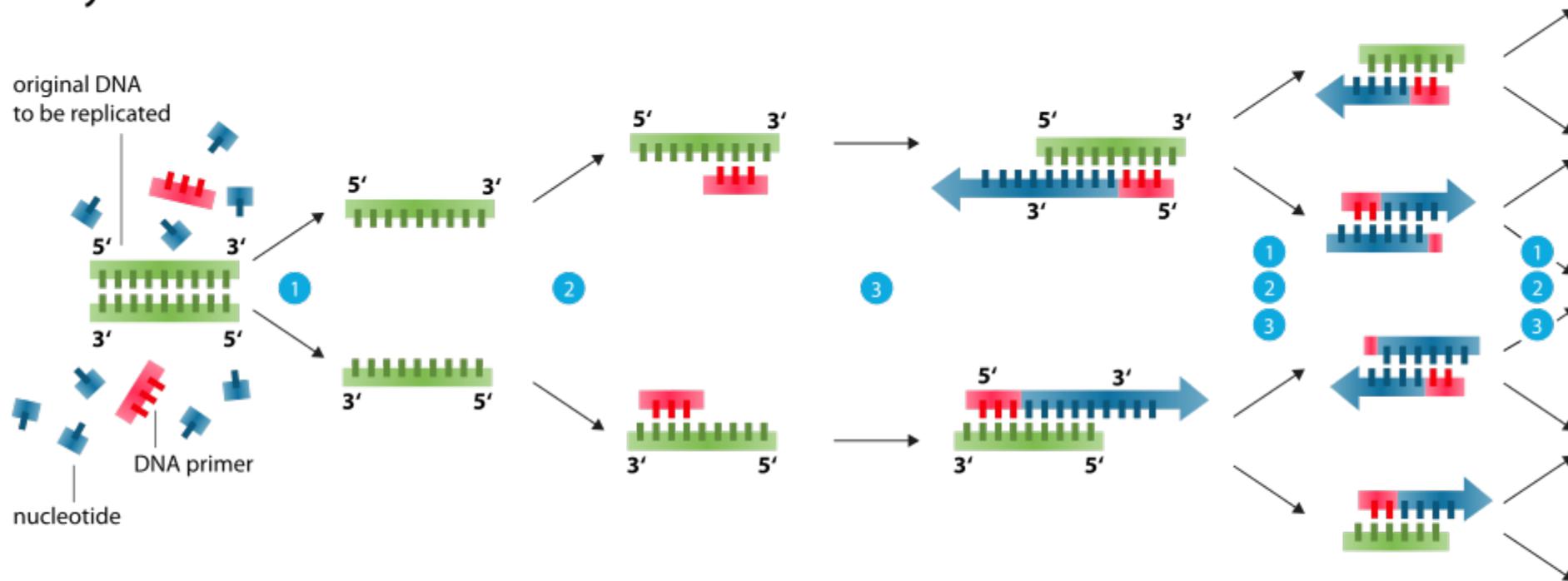


Fig. 5. A representative diagram showing currently available diagnostic primer sets on SARS-CoV-2 genome. Numbers represent genome positions according to SARS-CoV-2 isolate Wuhan-Hu-1 (GenBank: MN908947.3). Each primer set for the diagnosis was indicated by grey arrows.

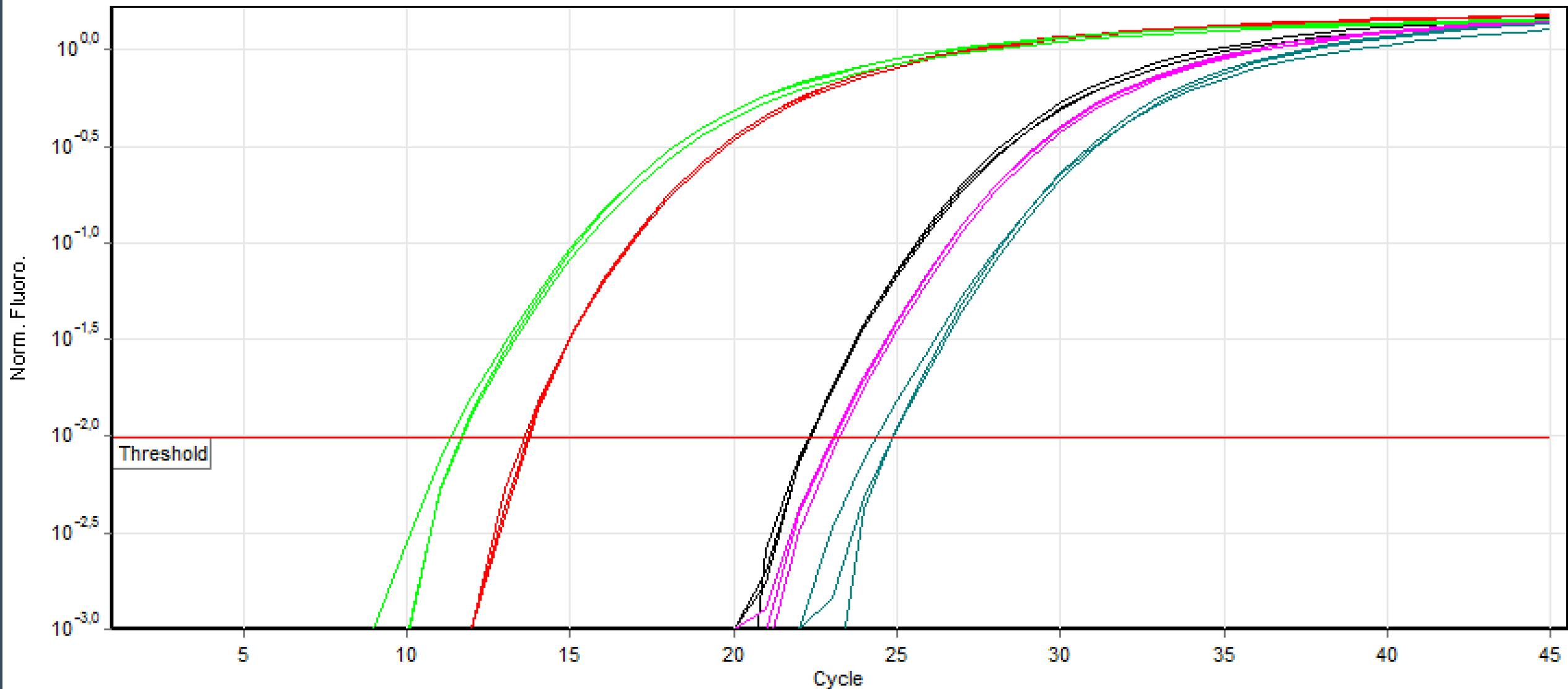
PCR

Polymerase chain reaction - PCR



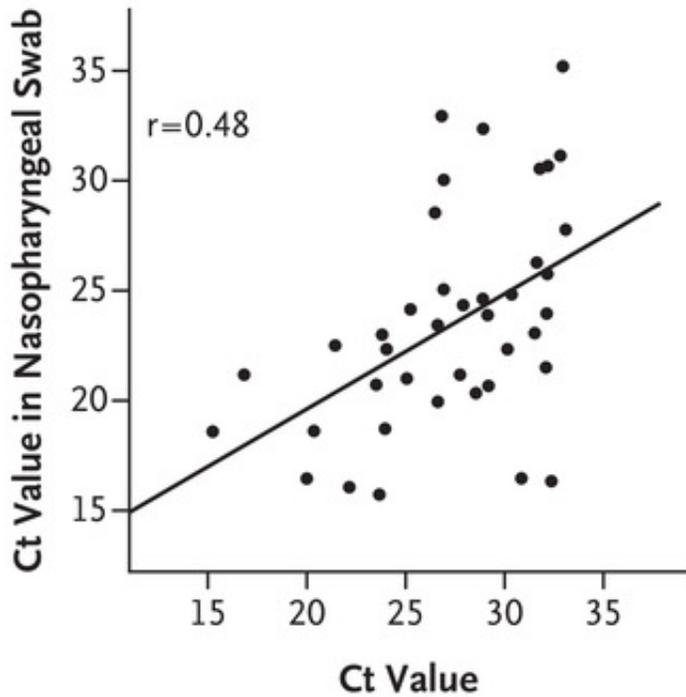
- 1 **Denaturation** at 94-96°C
- 2 **Annealing** at ~68°C
- 3 **Elongation** at ca. 72 °C

Ct-value

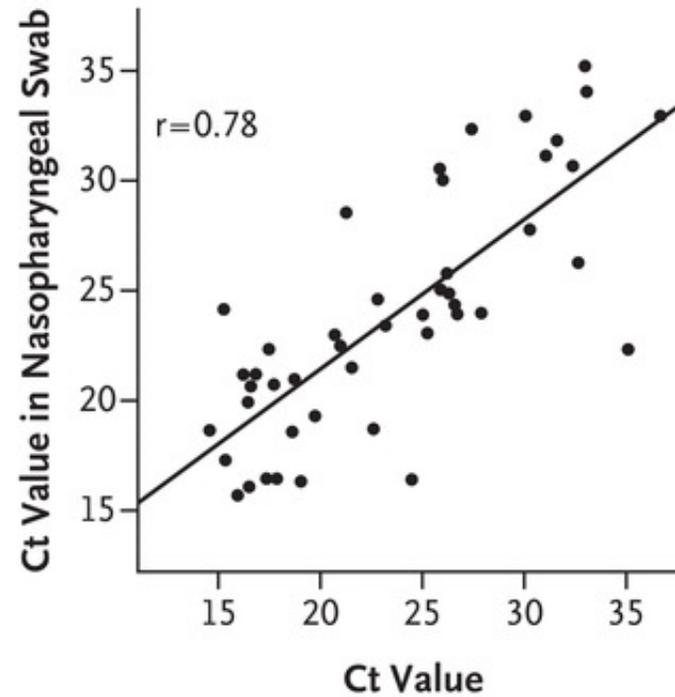


Specimen type & Ct-value

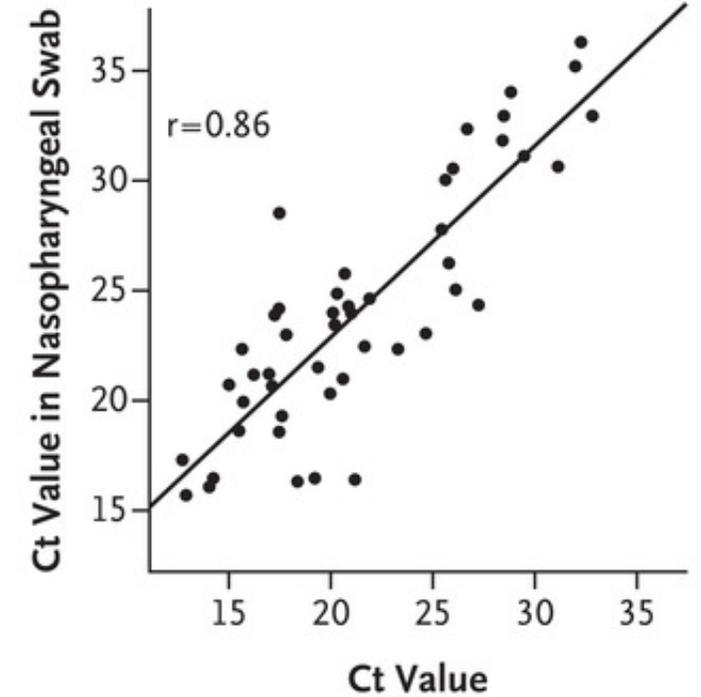
A Patient-Collected Tongue Swab



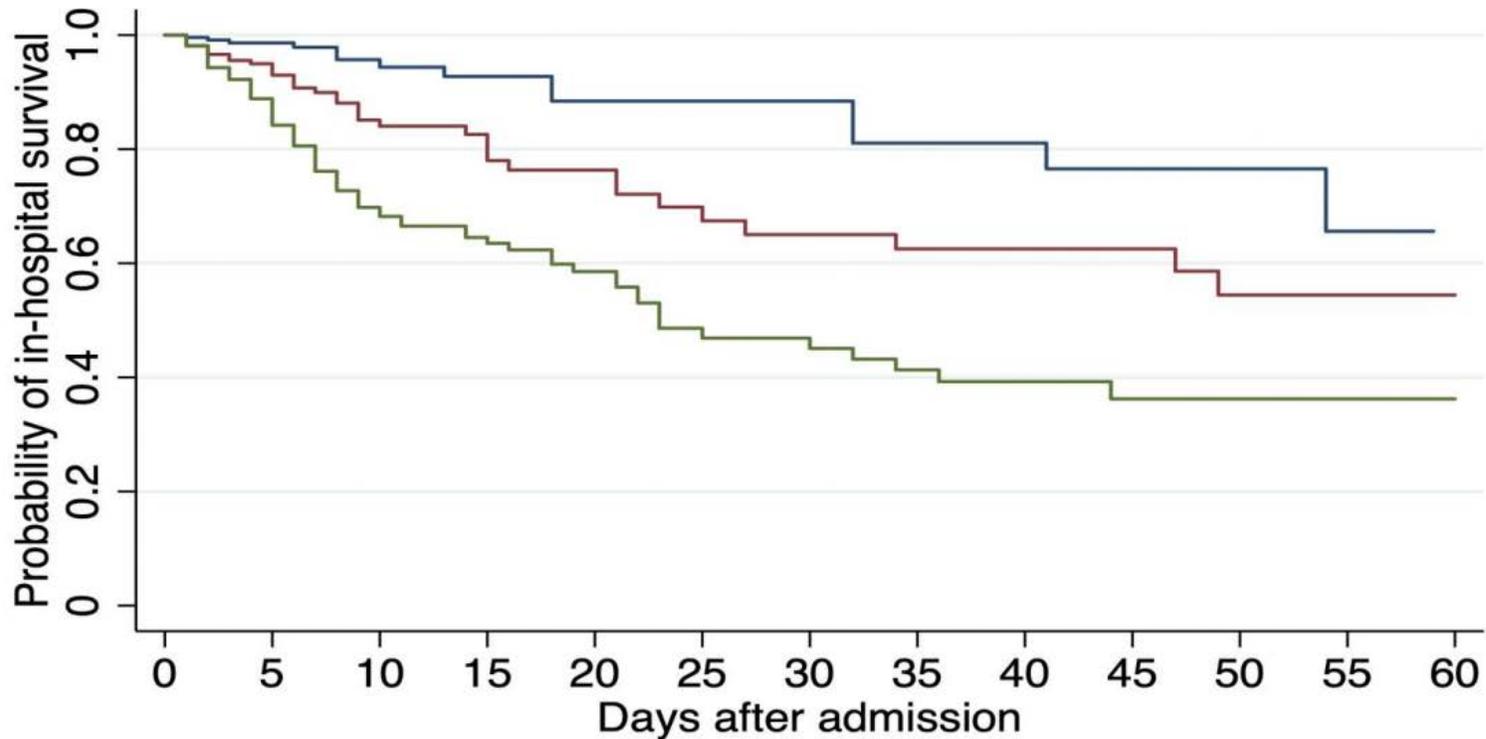
B Patient-Collected Nasal Swab



C Patient-Collected Mid-Turbinate Swab



Ct-value & prognosis



Low load: Ct > 30
 Medium load: Ct 25-30
 High load: Ct <25

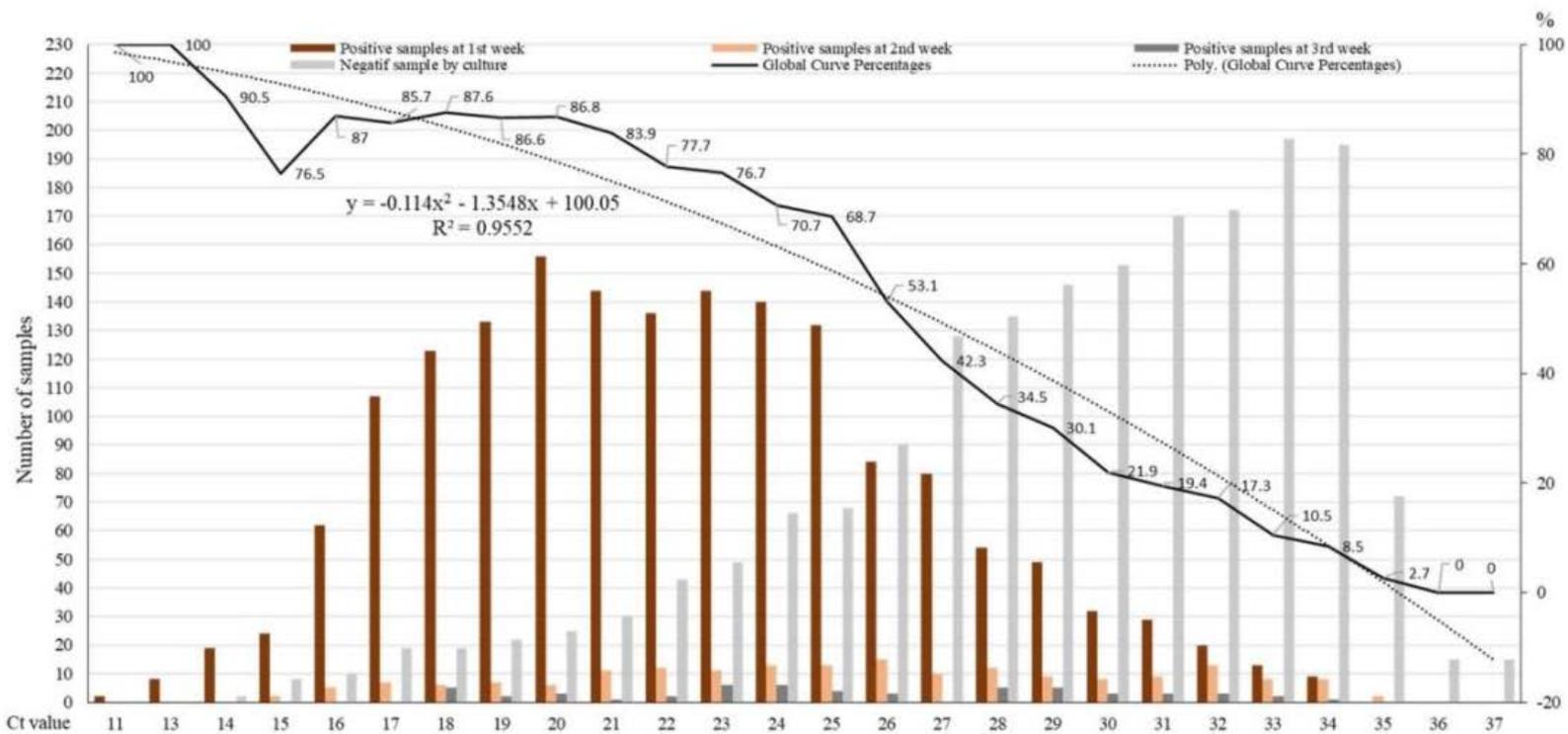
- NP swab
- UTM
- ORF1ab target
- Roche 6800

Number at risk

High viral load	237	153	73	50	38	31	28	20	18	13	9	6	5
Medium viral load	209	143	80	54	37	29	27	23	21	18	12	10	9
Low viral load	217	153	89	63	45	28	26	21	16	12	12	10	7



Ct-value & *in vitro* infectivity



Ct value	11	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37
Number of samples (N = 3790)	2	8	21	34	77	133	153	164	190	186	193	210	225	217	192	218	206	209	196	211	208	220	213	74	15	15
Total positive (n = 1941)	2	8	19	26	67	114	134	142	165	156	150	161	159	149	102	90	71	63	43	41	36	23	18	2	0	0
Week 1: number of positive (n = 1700)	2	8	19	24	62	107	123	133	156	144	136	144	140	132	84	80	54	49	32	29	20	13	9	0	0	0
(% by total positive)	(100)	(100)	(100)	(92.3)	(92.5)	(93.9)	(91.8)	(93.7)	(94.5)	(92.3)	(90.7)	(89.4)	(88.1)	(88.6)	(82.4)	(88.9)	(76.1)	(77.8)	(74.4)	(70.7)	(55.6)	(56.5)	(50.0)	(0)	(-)	(-)
Week 2: number of positive (n = 187)	0	0	0	2	5	7	6	7	6	11	12	11	13	13	15	10	12	9	8	9	13	8	8	2	0	0
(% by total positive)	(0)	(0)	(0)	(7.7)	(7.5)	(6.1)	(4.5)	(4.9)	(3.6)	(7.1)	(8.0)	(6.8)	(8.2)	(8.7)	(14.7)	(11.1)	(16.9)	(14.3)	(18.6)	(22.0)	(36.1)	(34.8)	(44.0)	(100)	(-)	(-)
Week 3: number of positive (n = 54)	0	0	0	0	0	0	5	2	3	1	2	6	6	4	3	0	5	5	3	3	3	2	1	0	0	0
(% by total positive)	(0)	(0)	(0)	(0)	(0)	(0)	(3.7)	(1.4)	(1.8)	(0.6)	(1.3)	(3.7)	(3.8)	(2.7)	(2.9)	(0)	(7.0)	(7.9)	(7.0)	(7.3)	(8.3)	(8.7)	(5.6)	(0)	(-)	(-)
Negative cultured (n = 1849)	0	0	2	8	10	19	19	22	25	30	43	49	66	68	90	128	135	146	153	170	172	197	195	72	15	15

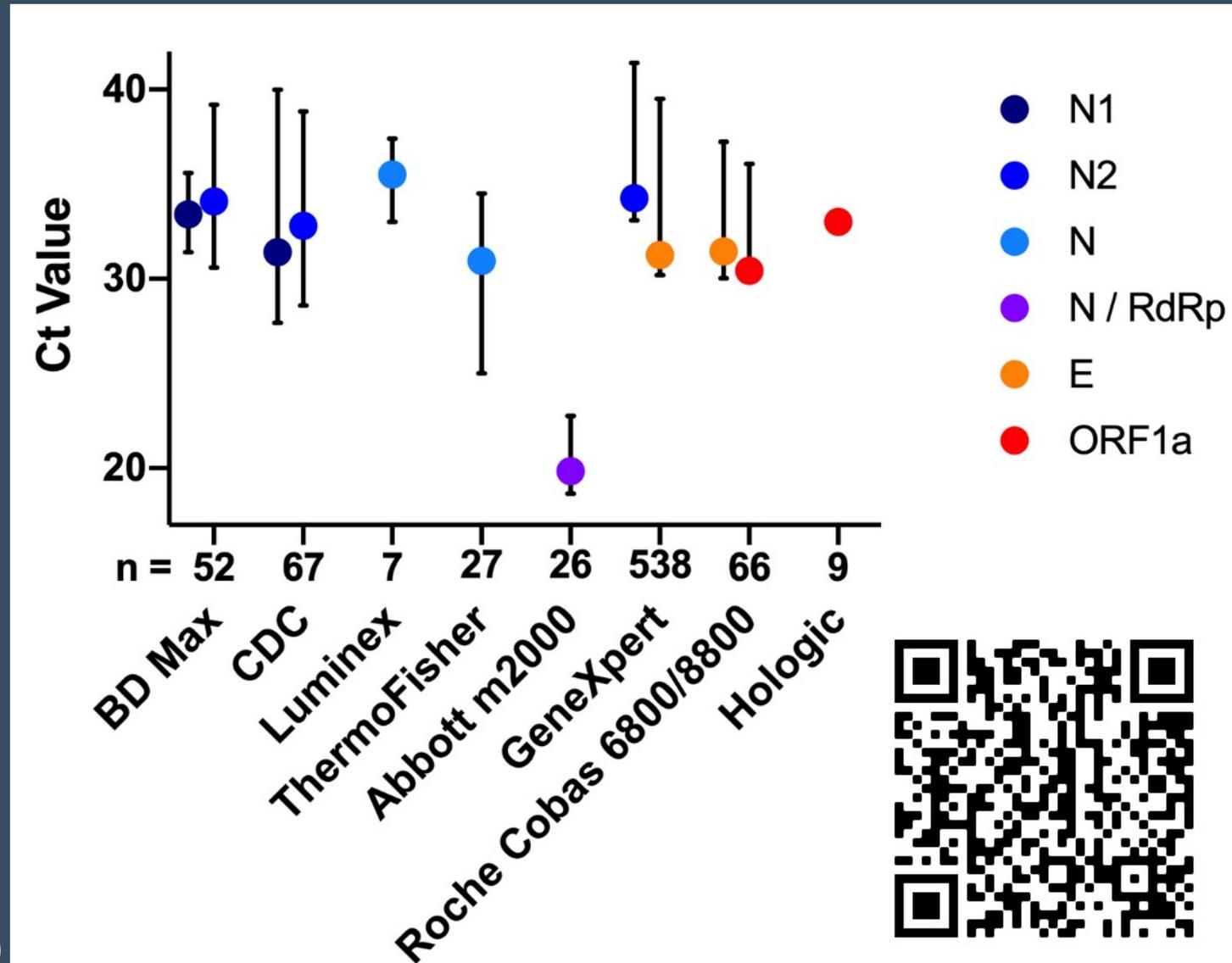
Ct-value limitations

- FDA EUA methods have qualitative interpretations
- No calibrated quantitative test is currently available
- Not all test methods generate a Ct-value
- Specimen collection impacts Ct-value
 - Time from symptom onset to collection
 - Specimen type (NP vs anterior)
 - Transport media (saline vs UTM; 1ml vs 3ml)
- Ct-values vary between test systems, between labs, & between targets



Ct-value limitations

- 3.0 cycle difference between targets (Xpert)
- 12 cycle difference between labs (TaqPath)
- 14 cycle difference between test systems (Luminex & m2000)



SARS-CoV-2 Ct-values

- Ct-values can correlate with prognosis & infectivity.
- Ct-values are not absolutely predictive of prognosis or infectivity.
- Ct-values are influenced by many pre-analytical and analytical variables.



Every life deserves world class care.

FDA Update

Sara Brenner and Toby Lowe
U.S. Food and Drug Administration (FDA)



U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention

Food and Drug Administration (FDA)

- **COVID-19 Emergency Use Authorization (EUA) Information for Medical Devices**

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

- **COVID-19 In Vitro Diagnostic EUAs**

<https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>

- **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>

- **FDA Townhall Meetings**

<https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/virtual-town-hall-series-immediately-effect-guidance-coronavirus-covid-19-diagnostic-tests-06032020>

- **Independent Evaluations of COVID-19 Serological Tests**

<https://open.fda.gov/apis/device/covid19serology/>

Food and Drug Administration (FDA)

COVID-19 Diagnostic Development: 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 (*)

CDC Social Media



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

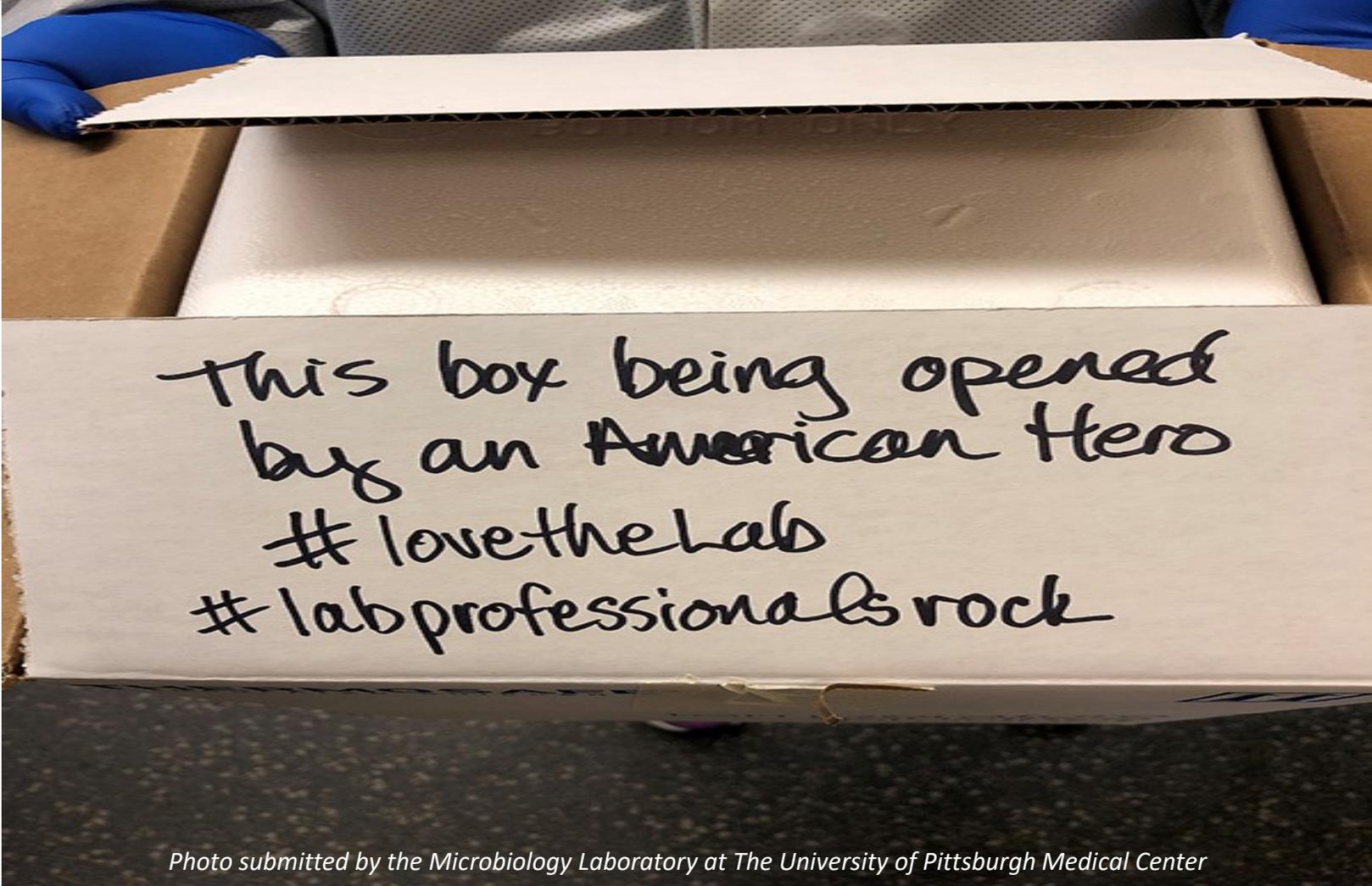


<https://twitter.com/cdcgov>



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

Thank You For Your Time!



This box being opened
by an American Hero
#lovethelab
#labprofessionalsrock

Photo submitted by the Microbiology Laboratory at The University of Pittsburgh Medical Center