

The Lab Must Go On

Clinical Laboratory Management in a
World Turned Upside Down

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Clinical Laboratory Management in a World Turned Upside Down

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Key Words: Coronavirus; COVID-19; Laboratory operations; Crisis management; Information technology; SARS-CoV-2

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ABSTRACT

Objectives: The clinical laboratory community has faced unprecedented challenges in responding to the coronavirus disease 2019 (COVID-19) pandemic. Long-held assumptions about laboratory management have been reconsidered in light of these new circumstances.

Methods: Experience during the first 6 months of the COVID-19 pandemic at a clinical reference laboratory was reviewed in the context of several commonly held management principles to assess their relevance to clinical laboratory operations during a crisis.

Results: Management and operational ideas regarding different modes of communication, physical proximity and interaction, operating under a fixed budget, and maintaining a breadth of laboratory service offerings have been challenged during the COVID-19 pandemic. The importance of putting people first, maintaining collaboration, and providing effective leadership and communication throughout an organization have been highlighted.

Conclusions: The collaborative activities of highly interdependent teams and individuals have helped the clinical laboratory community respond to society's needs in the COVID-19 crisis. Not all laboratory management principles apply equally well in the course of an international respiratory pandemic. When navigating crises, leaders need to distinguish situational management principles from those that are universal.

Key Points

- The clinical laboratory community has faced unprecedented challenges in responding to the coronavirus disease 2019 (COVID-19) pandemic.
- Not all management principles designed for sustained operations are equally applicable in a crisis setting.
- A focus on people, collaboration, and communication is essential in any clinical laboratory's response to COVID-19.

The urgent demand for coronavirus disease 2019 (COVID-19) diagnostic testing in the spring of 2020 generated resource and staffing requirements beyond the scale of what clinical laboratories have previously had to face. At the same time, hospital and laboratory budgets were threatened by sharp reductions in income-generating clinical services and associated laboratory testing. This combination of events was disorienting and stressful for the laboratory industry, which has had to make large decisions quickly and based on limited and frequently changing information.

The COVID-19 era has been described by many as a "new normal" in which old management heuristics no longer apply. This perception, however, is not completely accurate, because not all management heuristics are created alike. Some are situational and depend on a particular business context, while others are more universal. Distinguishing between these two sets can free up managers to engage in flexible thinking, not just during crises but also during more gradual shifts in the business landscape. Identifying universal principles

AJCP 2021 Jan 4;155(1):4-11.

<https://pubmed.ncbi.nlm.nih.gov/33118009/>

OPEN ACCESS

Brian Jackson



Jonathan Genzen



July 2020 Perspective

1

location

100+

medical directors
& consultants

~98%

testing performed
in-house

National clinical reference laboratory
located in Salt Lake City, Utah

Clinical laboratory for University of Utah
Health (hospital and outpatient clinics)



50

states

>3,000

diagnostic tests

>70,000

specimens
processed daily

>4,000

employees

Specimen transportation via
local and regional couriers,
commercial airlines, and
FedEx

24/7

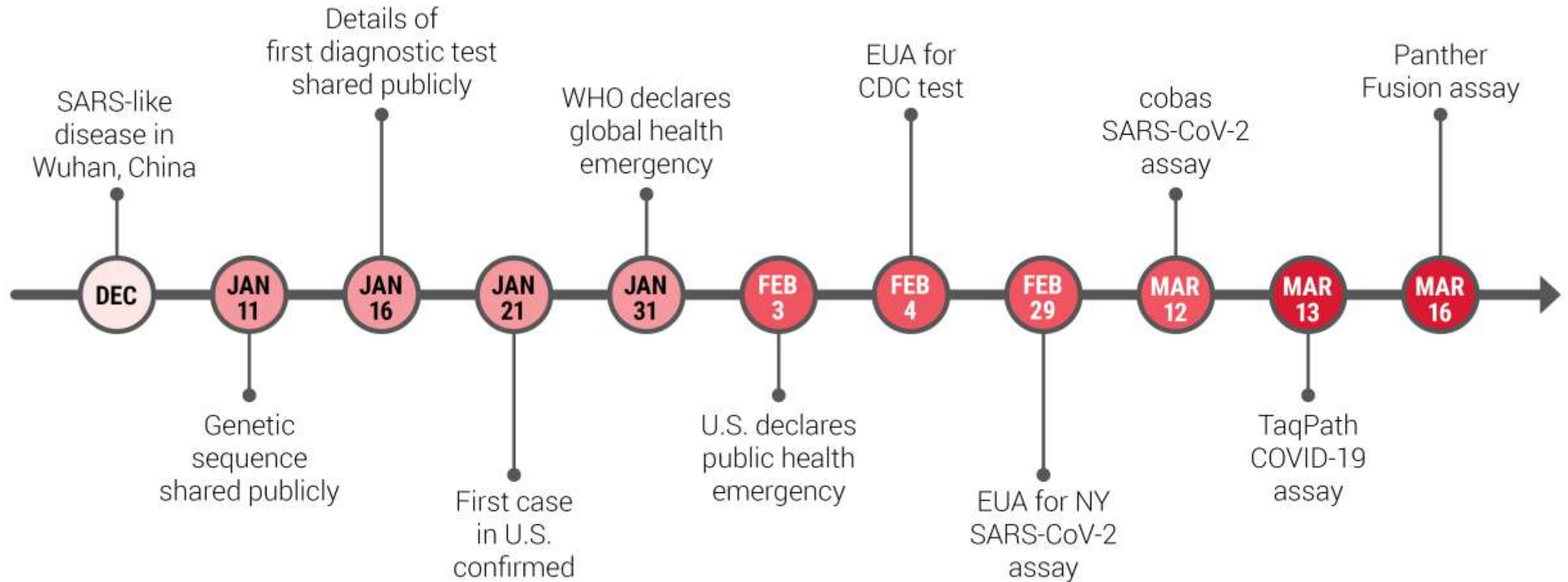
operations



Building 4 - 2021



Diagnostics Timeline



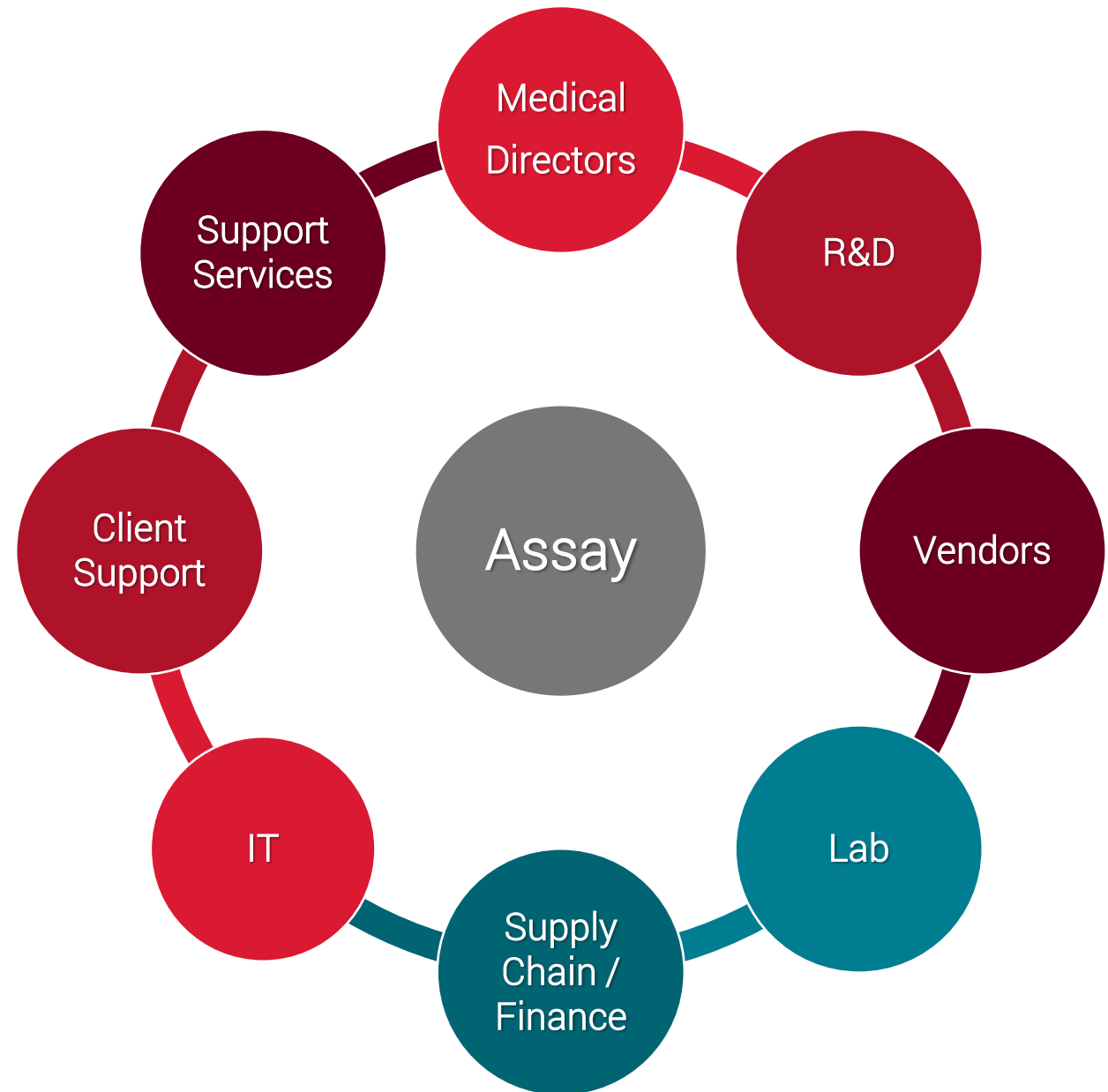
Early Pandemic Factors

- Two months from sequence to commercial tests
- Unfamiliarity with Emergency Use Authorization (EUA) process
- Regulatory uncertainty
- Prior experience with Zika
- Demand versus supply
- Competition for automated molecular platforms



■ COVID-19 Molecular Testing at ARUP

Assay Collaboration



Automated Molecular Platforms in Infectious Disease

Initial Approach

PANTHER FUSION

EXTRACTION AND
AMPLIFICATION

RT-PCR
(reverse-transcriptase
polymerase chain reaction)

PANTHER

EXTRACTION AND
AMPLIFICATION

TMA
(transcription-mediated
amplification)

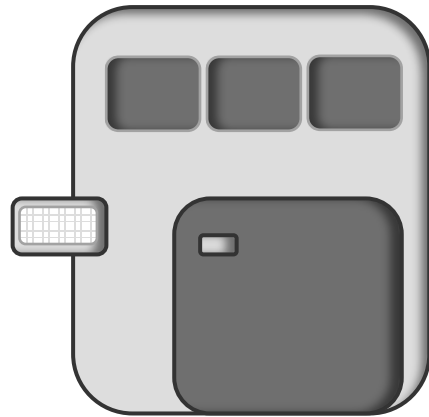
ROCHE 6800

EXTRACTION AND
AMPLIFICATION

RT-PCR
(reverse-transcriptase
polymerase chain reaction)

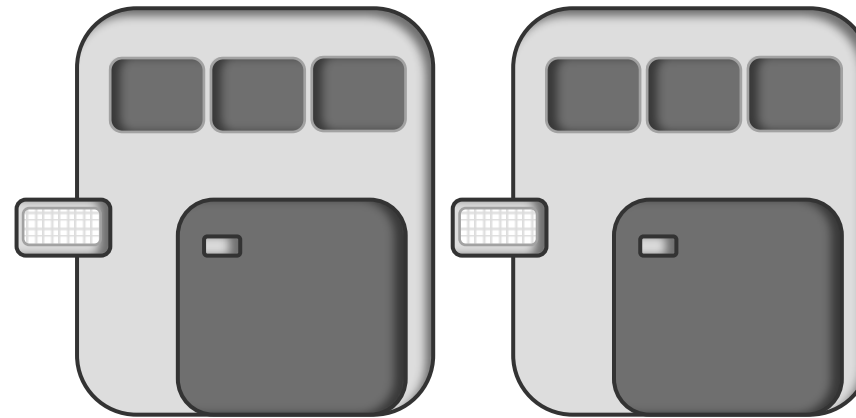
Capacity – All Automated Instrumentation

Specifications



Instrument X
"1,000" tests/day

Clinical Lab



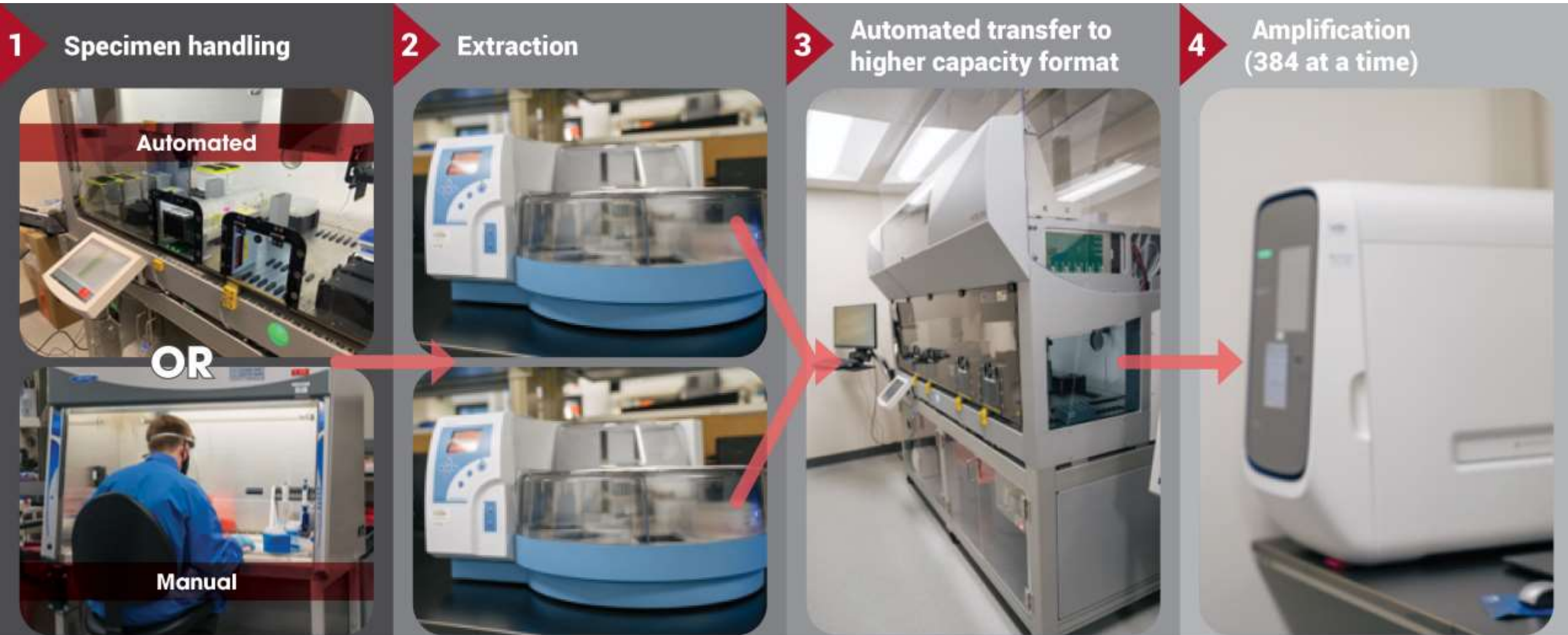
<1000 tests/day

<1000 tests/day

- Running instruments hard (service)
- Preventive maintenance and updates
- Specimen loading (batch versus random access)
- Other critical tests competing for capacity
- 24/7 staffing

+ PHASE II

COVID Rapid Response Laboratory



Planning for Pandemic Lab Space

MODEL 1

Lab space with significant excess capacity

- Long-term budgetary commitment and cost
- Memory fades, markets turns
- “Nature abhors a vacuum”

MODEL 2

Maintain or acquire external space capacity

- Difficult in high-complexity CLIA setting for infectious disease testing if continually unused

MODEL 3

Office space built out for future laboratory use

- “Office in-lab concept”
- Initial investment

Fill with teams that can work from home during a pandemic

- IT
- HR
- Client Services



Laboratory Management During a Pandemic

Some rules are made to be (situationally) broken.

Some rules are there for a reason.

Minimize Meetings and Emails

Meetings
can be the
bane of
organizational
life.

Critical during a pandemic!

- COVID planning meetings
- Management update meeting
- Frequent department meetings and discussions
- Virtual formats
- Safety communications
- Leadership communications

- 
- Operations
 - Safety
 - Clinic
 - HR
 - R&D
 - Marketing
 - Transportation
 - Supply Chain
 - Finance
 - IT

Communication Matters— With All Stakeholders

ARUP Intranet



Management Update Meeting (MUM)

“Mini-MUM”

- Announcements
- Operations
- Safety
- Clinic and Wellness Center
- Finance
- HR
- Quality

Communicating Purpose

Interim Guidance for Healthcare Facilities: Preparing for Community Transmission of COVID-19 in the United States

Key Goals for the U.S. healthcare system in response to the COVID-19 outbreak are to:

- 1. Reduce morbidity and mortality ✓
- 2. Minimize disease transmission ✓
- 3. Protect healthcare personnel ✓
- 4. Preserve healthcare system functioning ✓

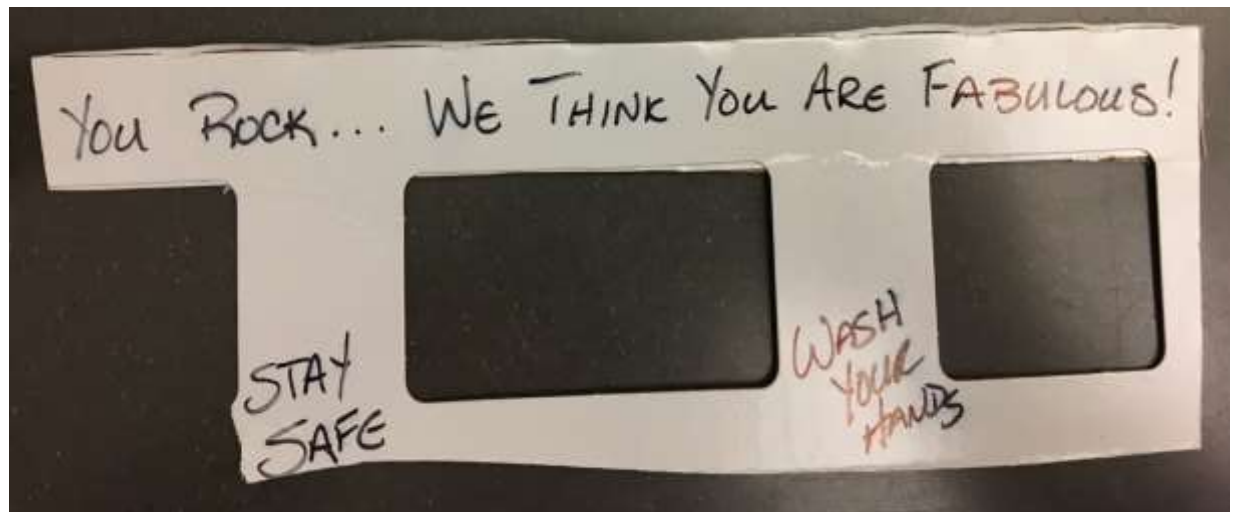
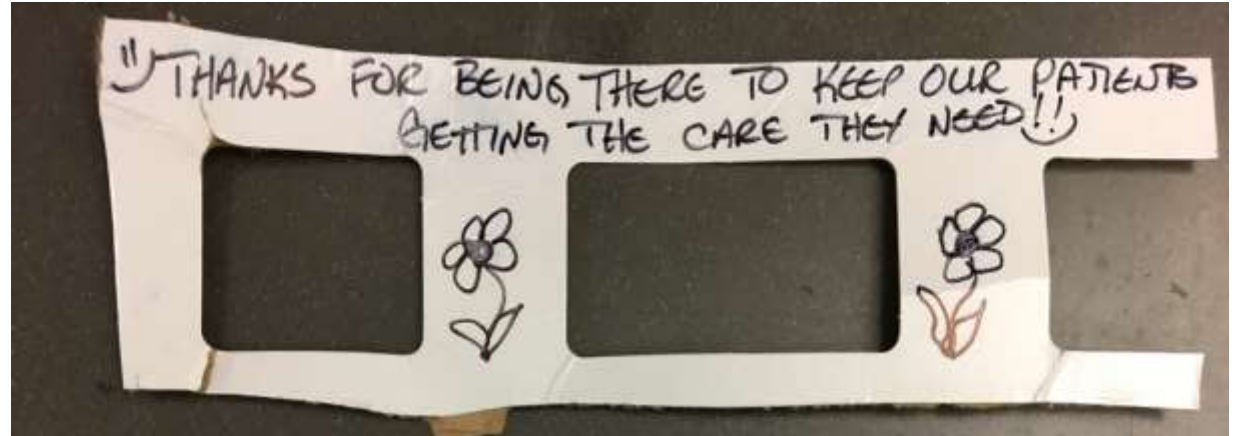


CLIENTS • REGION • UTAH • UNIVERSITY HEALTH • ARUP



<https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/guidance-hcf.html>

Communicating Kindness



Communicating Safety

PPE Policies and Procedures

- Laboratory areas
- Non-laboratory areas
- Hallways
- Offices
- Cubicles
- Face shields
- Breaks and lunches

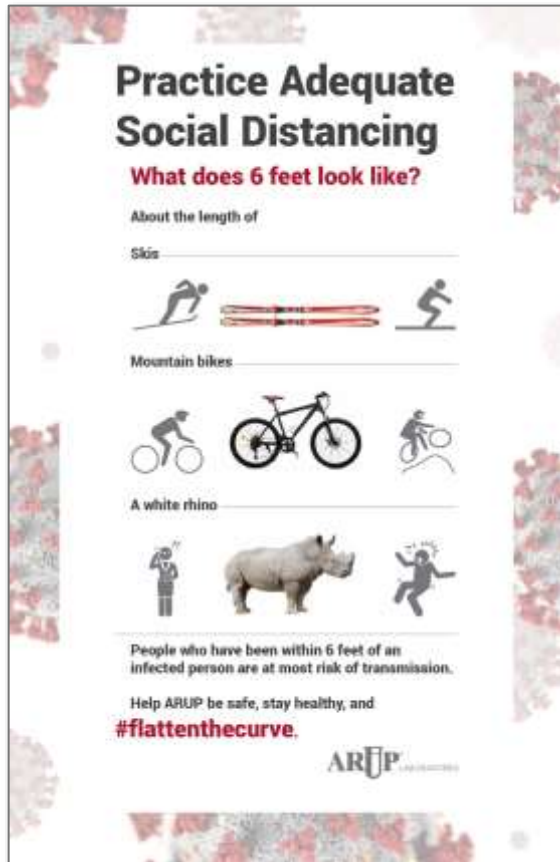
Overall Tone

- Be supportive
- Be kind
- Be safe
- Be consistent



Communicating Safety

Signage



Information Overload



Communicating Safety

Strange Can Be Effective



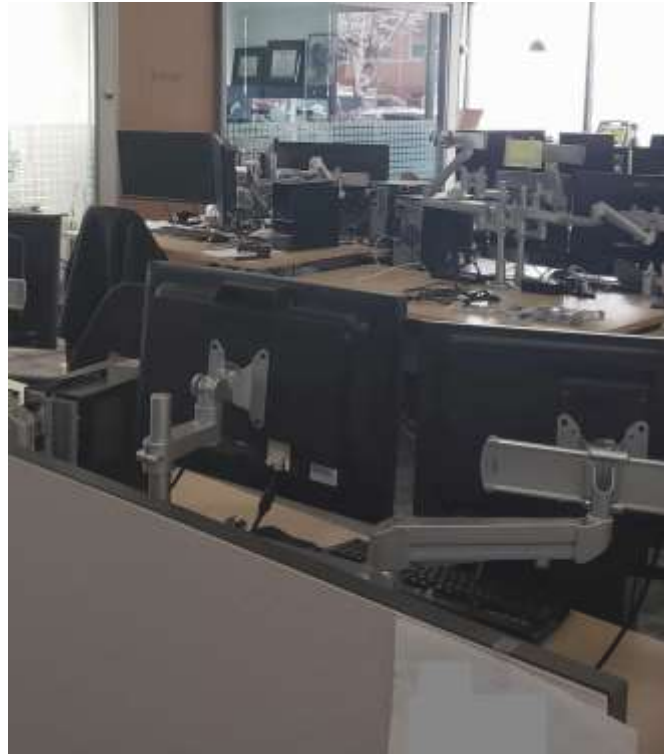
RULES TO BE (SITUATIONALLY) BROKEN

Manage Physical Spaces to Maximize Social Interactions

2019



Open Collaborative Spaces



Separated Cubicles







MAXIMUM OCCUPANCY

CHAIRS ONLY: 472 PERSONS

TABLES & CHAIRS: 220 PERSONS

Work From Home

Information
Technology

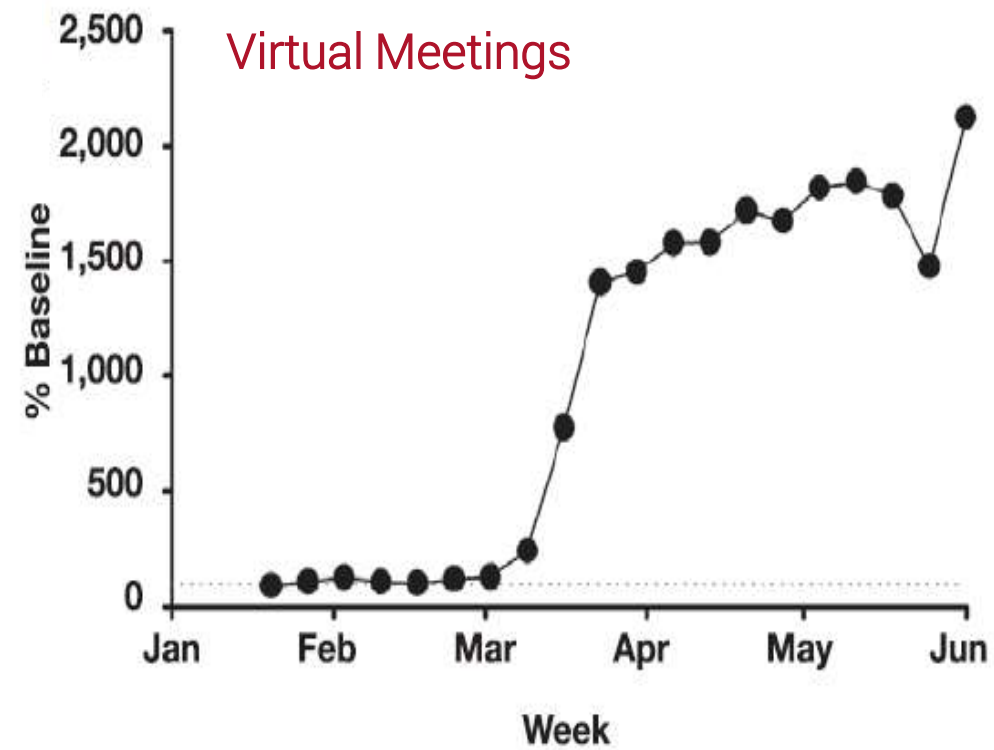
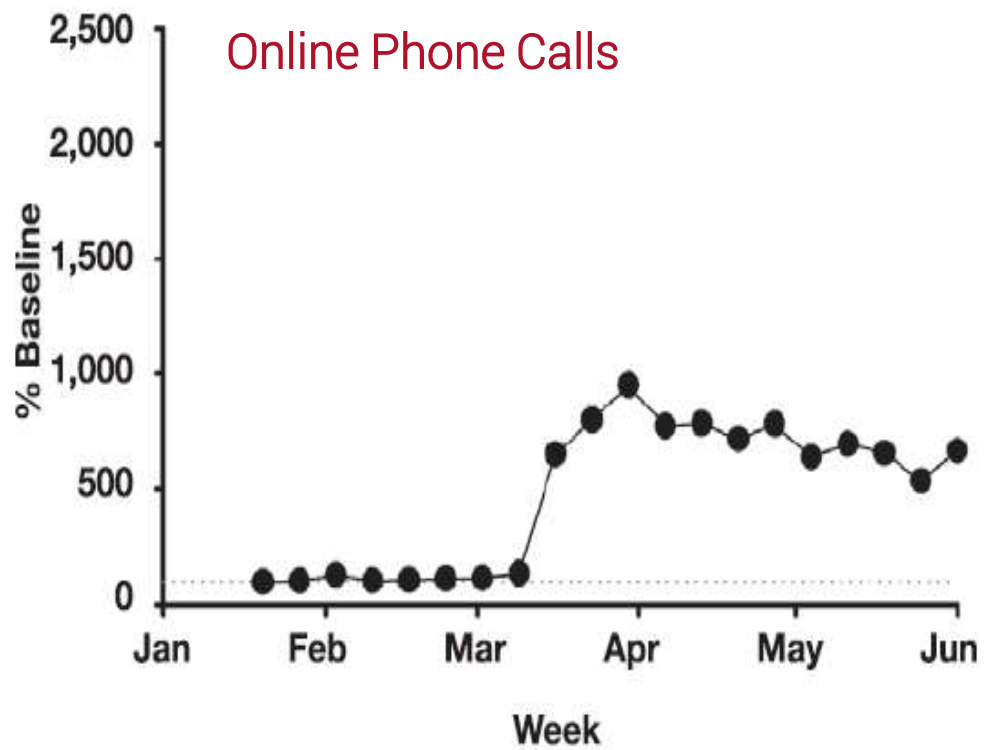
Client Services

Business
Development

Medical
Directorship

Quality





Am J Clin Pathol. 2021 Jan 4;155(1):4-11.

Laboratory Processes Must Accommodate the Full Clinical Spectrum of Inpatient, Outpatient, and Subspecialty Care

Solutions Shops

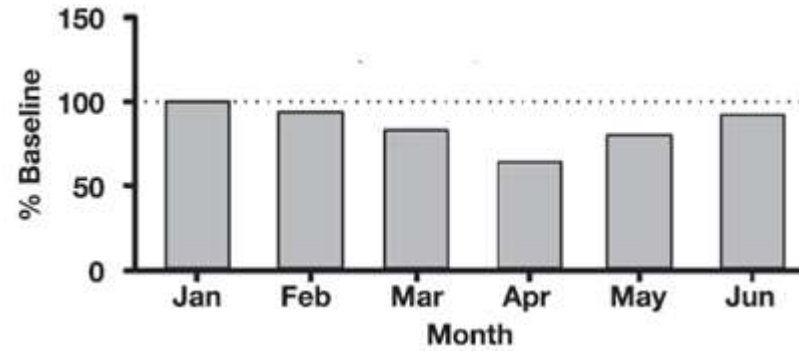
(Generalist)

Focused Factories

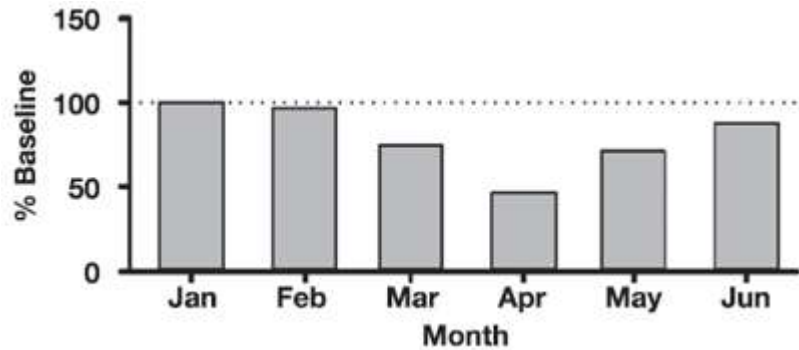
(Specialist)

- Diversion of resources to COVID-19
- Leveraging available instrumentation
- Cross-training of current employees

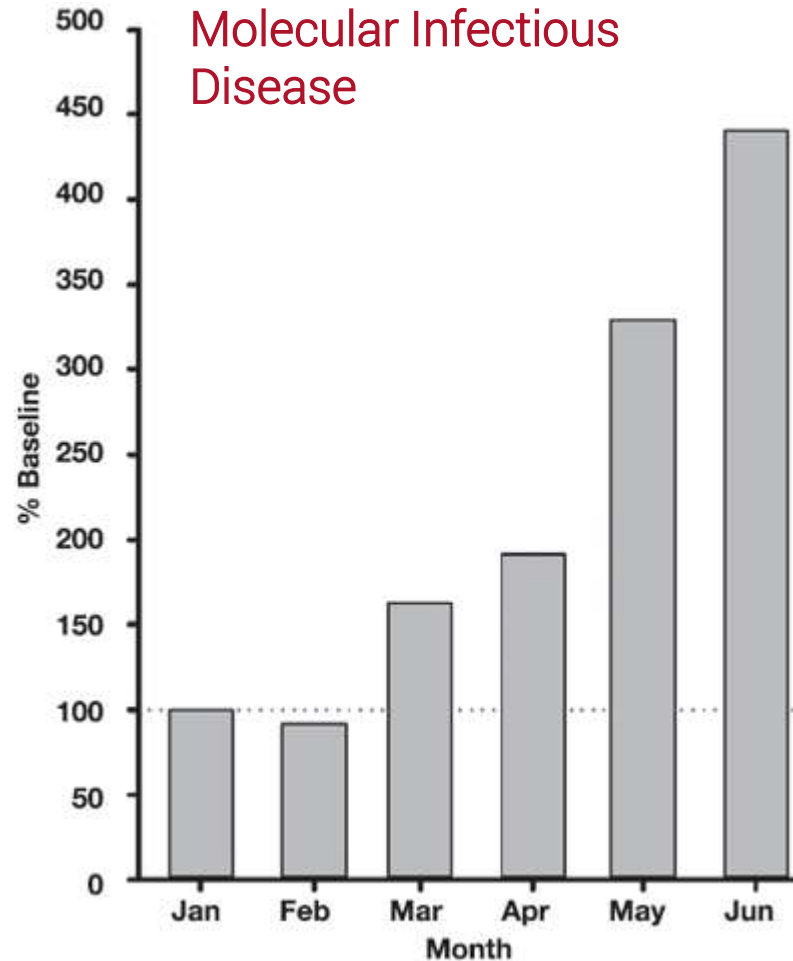
University Hospital



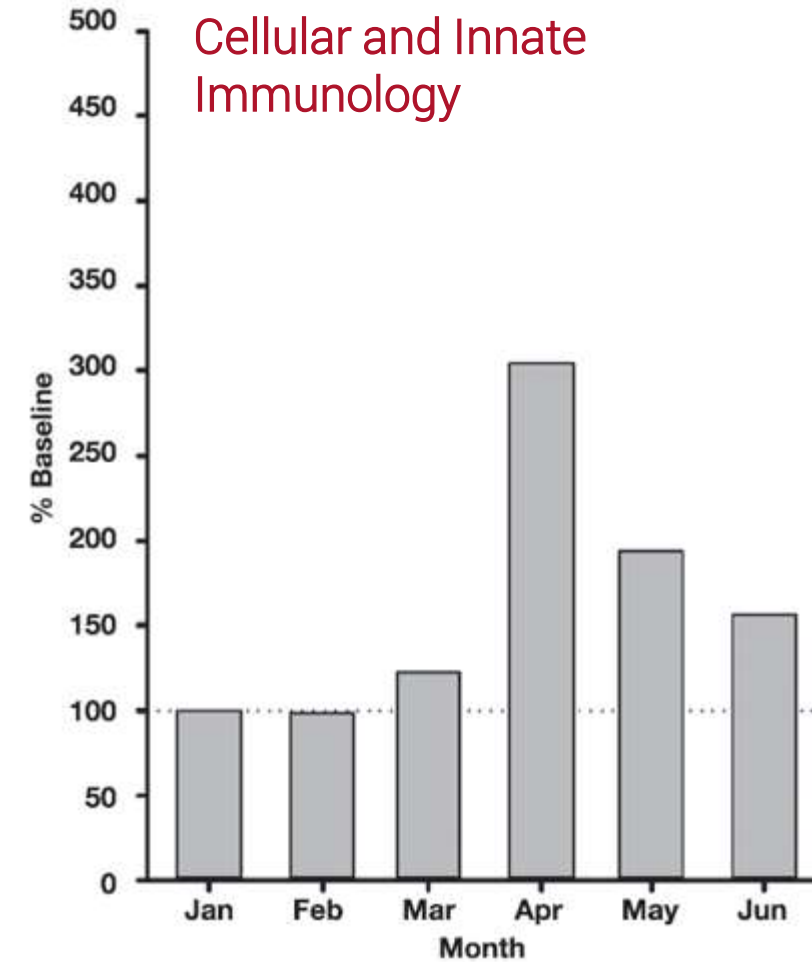
Automated Core Laboratory



Molecular Infectious Disease

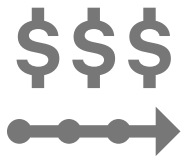


Cellular and Innate Immunology



Am J Clin Pathol. 2021 Jan 4;155(1):4-11.

Manage Laboratory Budgets Based on Annual Projections of Income Versus Expense



Extremely large purchases, contracts, and commitments



Requests to commit prior to evaluations



Unknown volumes



Unknown future reagent availability



Wide array of pricing for similar supplies



Year-over-year rolling forecast models



Decisions based on patient care

IT Matters, Even If You Don't Think You're an IT Company



Data center



Support



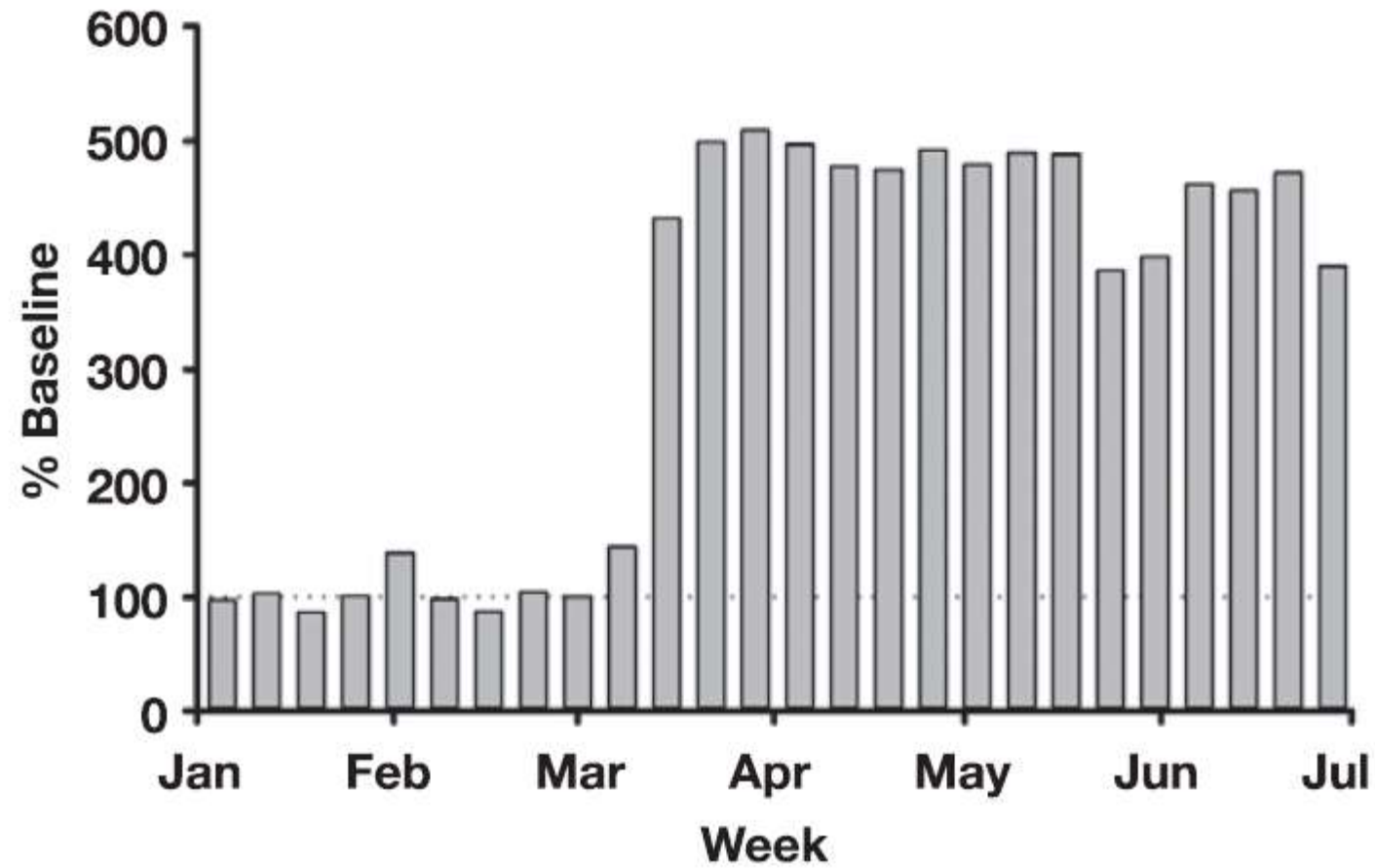
Repair



Analytics

- VPNs/VDIs
- Telephony (Client Services)
- Hardware
- Software
- Online collaboration tools
- Test builds and interfaces
- PHI/HIPAA

WEEKLY AVERAGE VPN CONNECTIONS



Key Issues

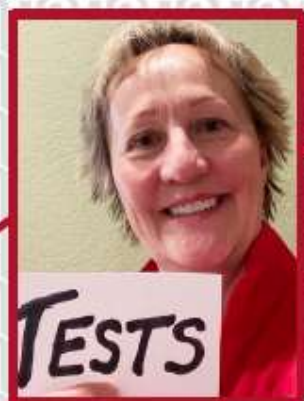
- Licenses
- Security
- Support

Am J Clin Pathol. 2021 Jan 4;155(1):4-11.

RULES THAT ARE THERE FOR A REASON

People Come First







Goals

Maintain patient testing.

Keep employee base intact and safe during the pandemic.



Highly trained, valuable, and talented workforce



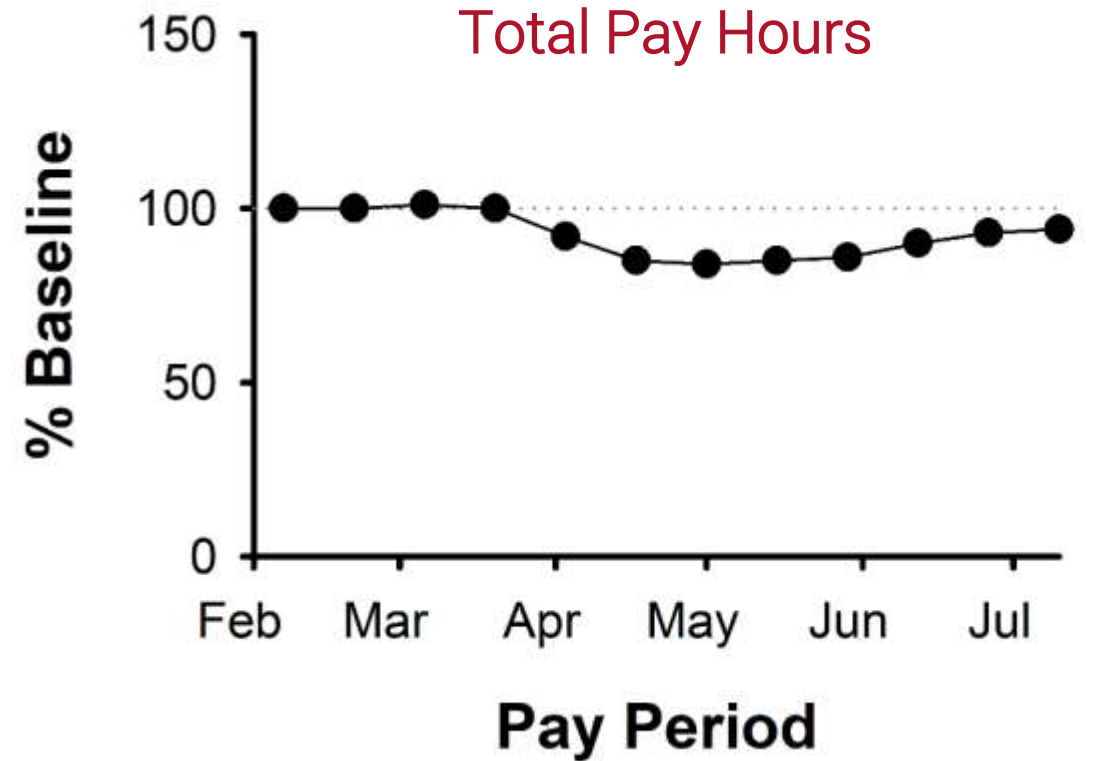
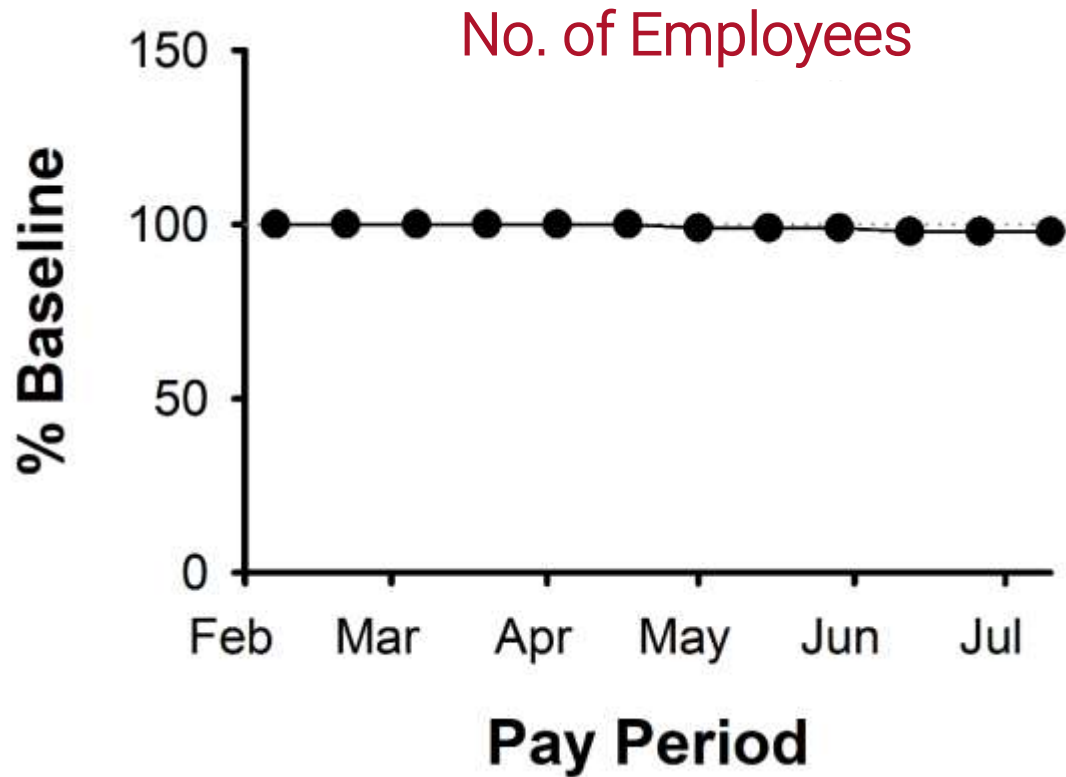
Getting through this together



Family safety

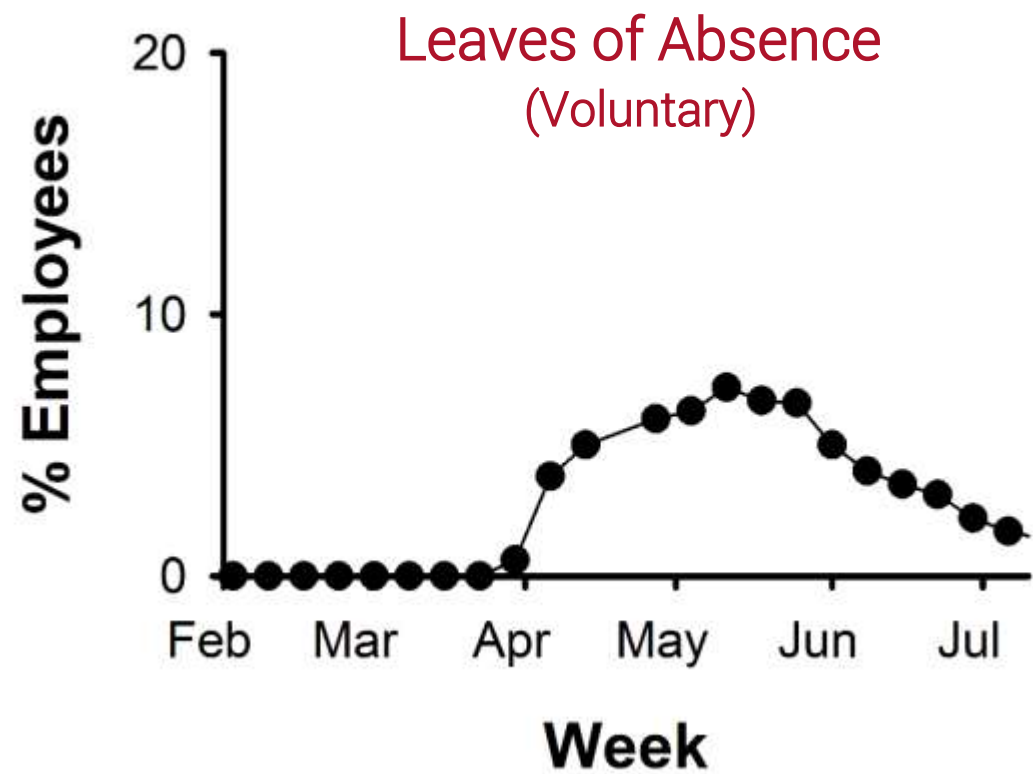
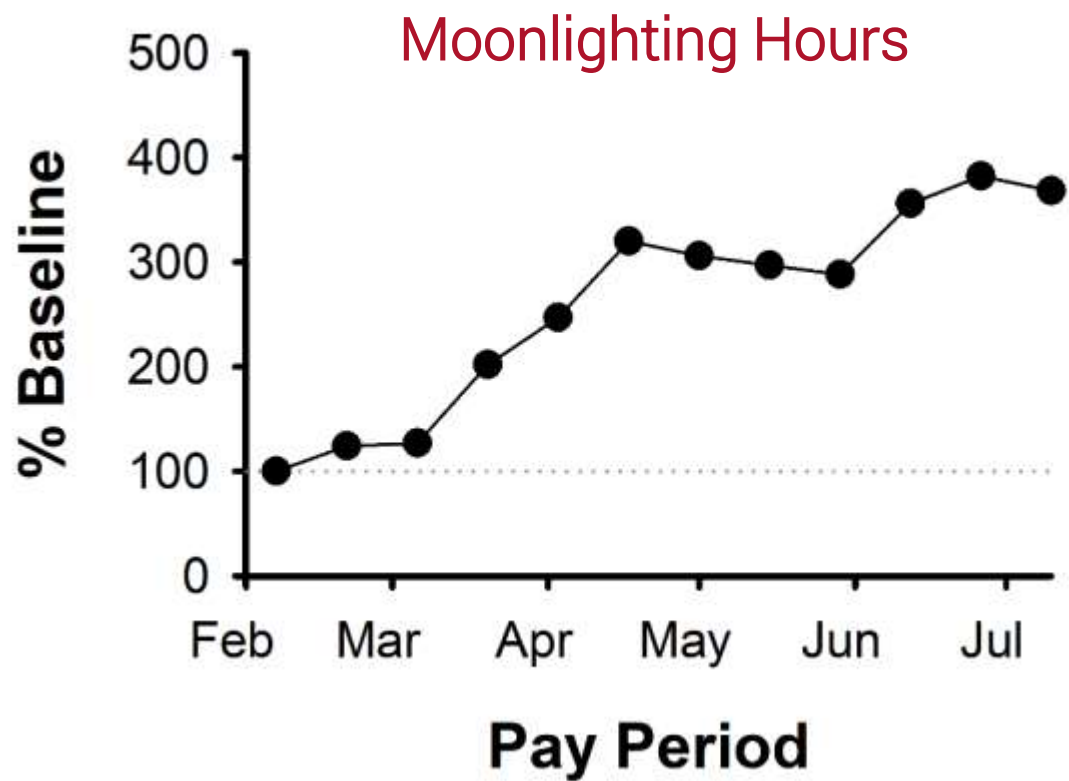


Sharing of knowledge

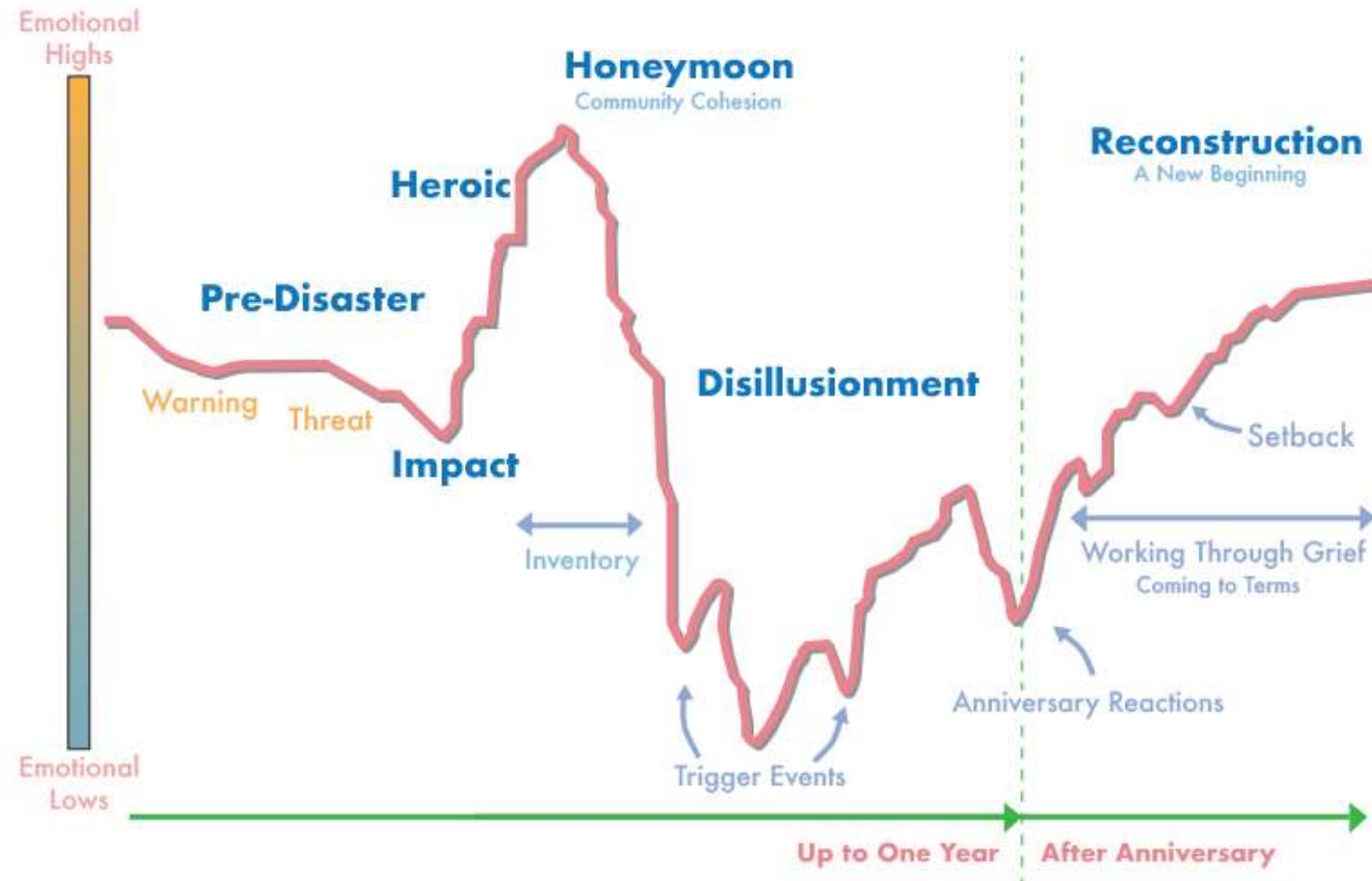


Hourly and salary reductions
across all departments and leadership

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Emotional Health and the Pandemic



Adapted from Zunin & Myers as cited in DeWolfe, D. J., 2000. (2nd ed., HHS Publication No. ADM 90-538). Rockville, MD: U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Center for Mental Health Services

Support for Employee Health

Family Health Clinic
Wellness Center

•

Health
Wellness
COVID-19 testing
Contact tracing

COVID Testing Site



Healthcare for
our employees
and their families

Promoting a safe and
healthy working
environment



Musculoskeletal Exercises

Pandemic added extra stress.

PDFs
Videos

Additional exercises for


Wrist
Elbows
Forearms

ARUP LABORATORIES | Wellness Center


Exercises for Chronic Pain While at Work

Developed chronic pain and discomfort in the body, especially in areas like the back, neck, and shoulders? Whether you're hunched over a lab bench or a desk all day, give these five exercises a try during your workday. Each stretch should be held for 30 sec – 1 min on each side.


Straight Arm Pec Stretch:
Standing next to a wall, place hand so arm is straightened, then slowly twist body away from wall until a stretch is felt in the chest, shoulder, and/or arm.




Head Tilt Trap Stretch:
Seated, place hand under thigh/butt and with opposite hand pull head away and down until a stretch is felt through the shoulder and neck.





Double Arm Lat Stretch:
Find a surface about waist height or above and place both hands on it, then drop head and chest forward towards floor until a stretch is felt in the shoulders, arms, and/or upper back.



Cross Arm Stretch:
Cross arm in front of body, then reach underneath with opposite arm, placing hand on opposite shoulder. Pull underneath arm up and away until a stretch is felt in the shoulder and/or arm.



Scapular Press:
Lean forward and place hands on table or bench, slightly wider than shoulder width apart. Maintaining extended elbows and a tight core, lower chest towards bar allowing shoulder blades to pinch together. Then reverse movement, separating shoulder blades as far as possible, and repeat 10 times. Make sure to keep shoulder blades down and back and arms extended straight.



ARUP LABORATORIES | Wellness Center


Exercises for Chronic Pain While at Home

Developed chronic pain and discomfort in the body, especially in areas like the back, neck, and shoulders? Whether you're hunched over a lab bench or a desk all day, give these five exercises a try before or after your workday. Each stretch should be held for 30 sec – 1 min, and each exercise should be performed 10 times each side.


Falling Pretzel Stretch:
Lay on back with one foot crossed over opposite thigh and both knees bent at roughly 90°. Holding the ankle of the crossed leg with opposite arm, fall over to the side so that foot being held is flat on ground. Then move hand to knee and pull until a stretch is felt in hip and/or back.




Child's Pose Stretch:
Kneeling on both knees, keep big toes touching and bring knees wider than torso. Lower torso down parallel to the ground, reaching arms overhead and allowing hips to settle between legs until a stretch is felt in the hips and/or back.




Foam Roller Pec Stretch:
Lay down on foam roller (or rolled up towel, pillow, blanket, etc.) with spine in line, knees bent, and feet wide on the floor for balance. Allow arms to fall out to your sides in a "T" shape, with palms facing up until a stretch is felt in the chest and/or arms.



Dead Bug:
Laying down with knees bent, flatten low-back into mat by tucking hips and sucking in belly button, feeling the lower abdominals engage. Lift both feet up so knees and hips are bent at 90°, then begin marching slowly, maintaining pelvis/spine positioning with low back contacting the mat. Remember to breathe and keep neck muscles relaxed, alternating marches on each side.



Bird Dog:
On all fours, engage core to flatten back. Actively squeeze the plate on one side to extend the leg back, then lift opposite arm up so that raised leg and arm are parallel to torso. Alternate each side, keeping core tight and shoulders down so torso is square to ground.



Leadership Matters

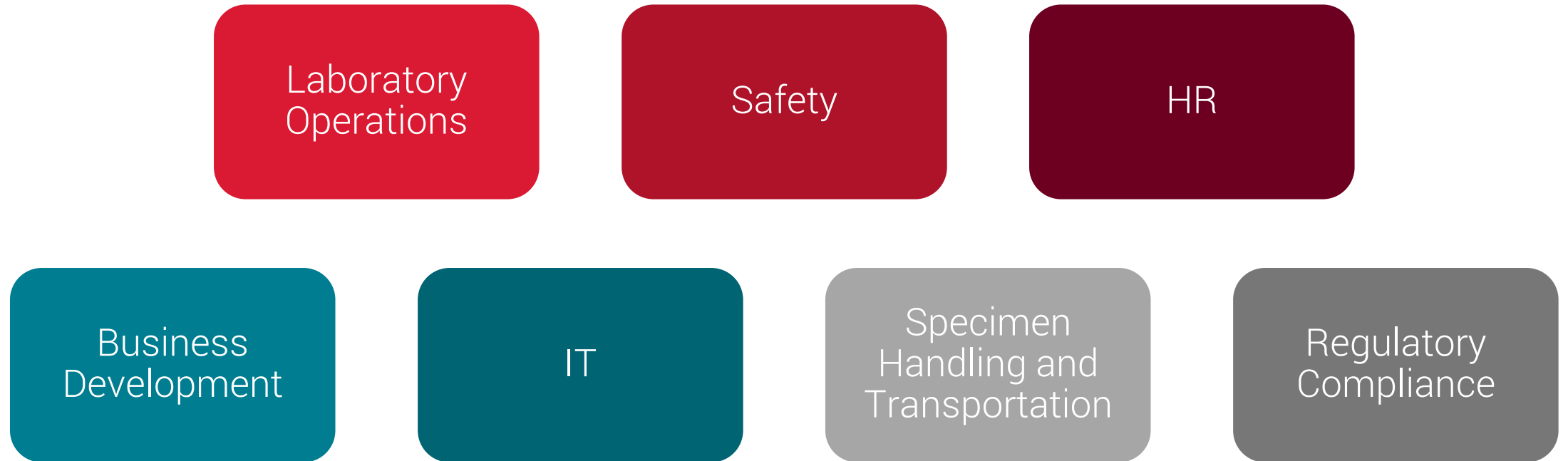
Pandemic Considerations

- Difficult decisions to make
 - Cost
 - Scale
 - Impact
- Communication
- Leading by example
- Liaison to external community

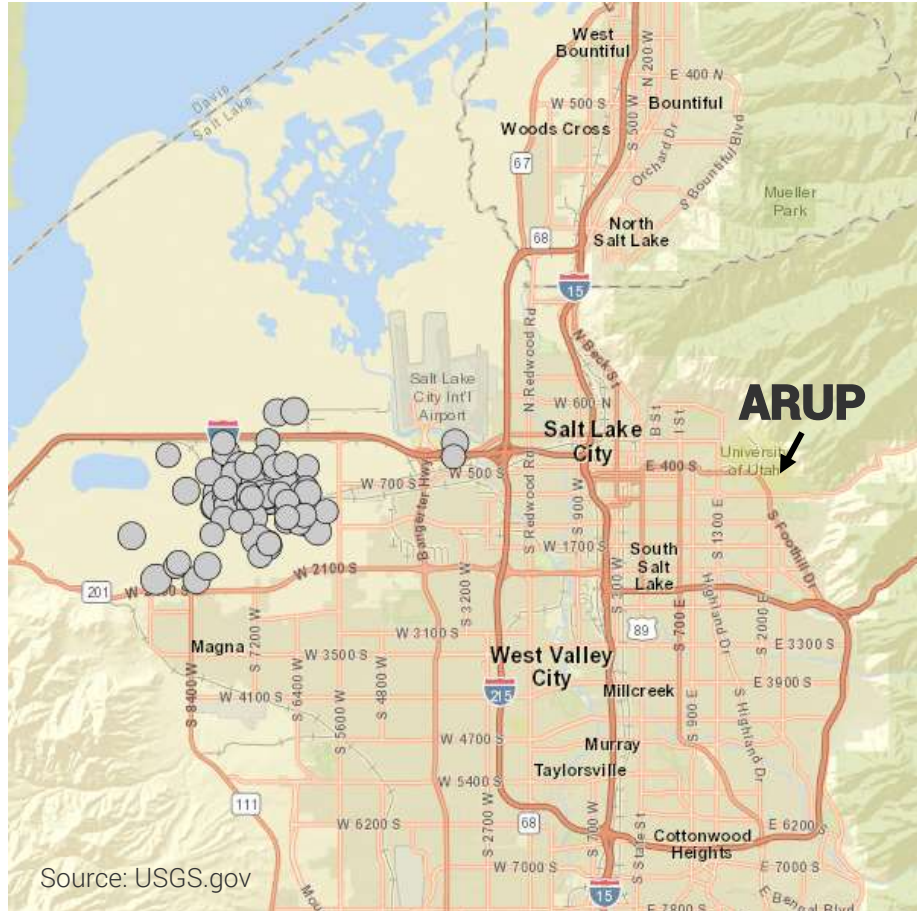
Scope

- Executives
- Managers
- Supervisors
- Clinical pathologists
- Anatomic pathologists
- PhD clinical laboratory scientists
- Clinicians
- Safety team

Pandemic Risk Assessment



Handling More Than One Crisis at a Time



5.7 Magnitude Earthquake

March 18, 2020

- No injuries
- No building damage
- ARUP maintained operations
- Temporary airport closure
- Rerouted transportation
- Aftershocks



Unexpected Lessons and Opportunities

Vice Presidential Debate

COVID-19 SPECIMEN
COLLECTIONS AT RICE
ECCLES STADIUM AND
TOWER

Testing
at ARUP

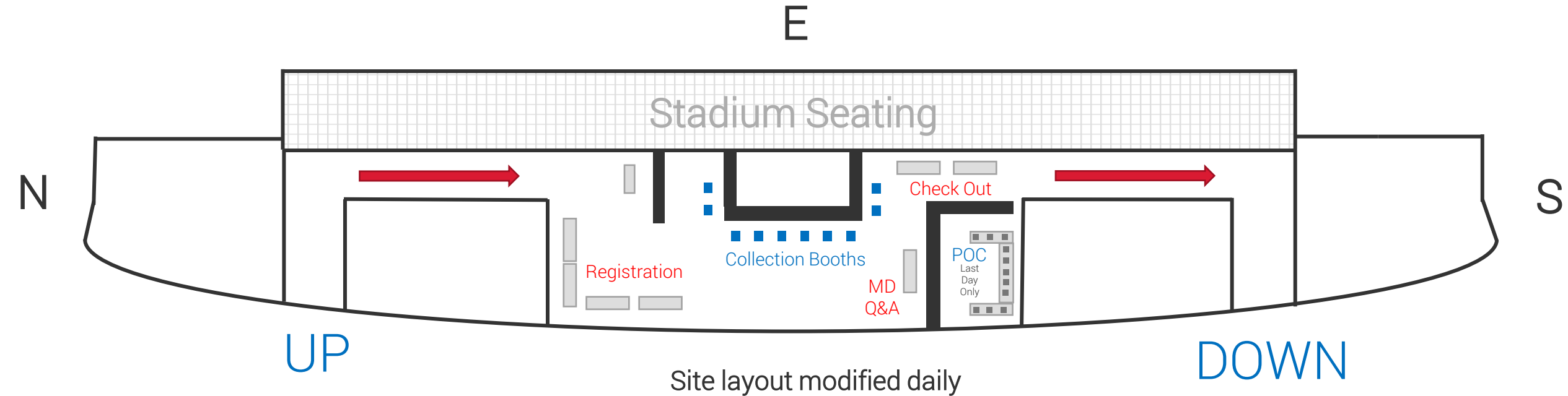
(Day of debate: POC)



Rice Eccles Stadium & Tower

Collection: Univ. of Utah Health

Testing: ARUP Laboratories



- Couriers loop to ARUP
- “Preprocessed” via the occupational health app
- Delivered directly to the testing lab

- Control of the entire process
- Reference lab-quality RT-PCR result
- Safe and successful debate

Collaboration Matters

Within organization

With external colleagues

With vendors and suppliers

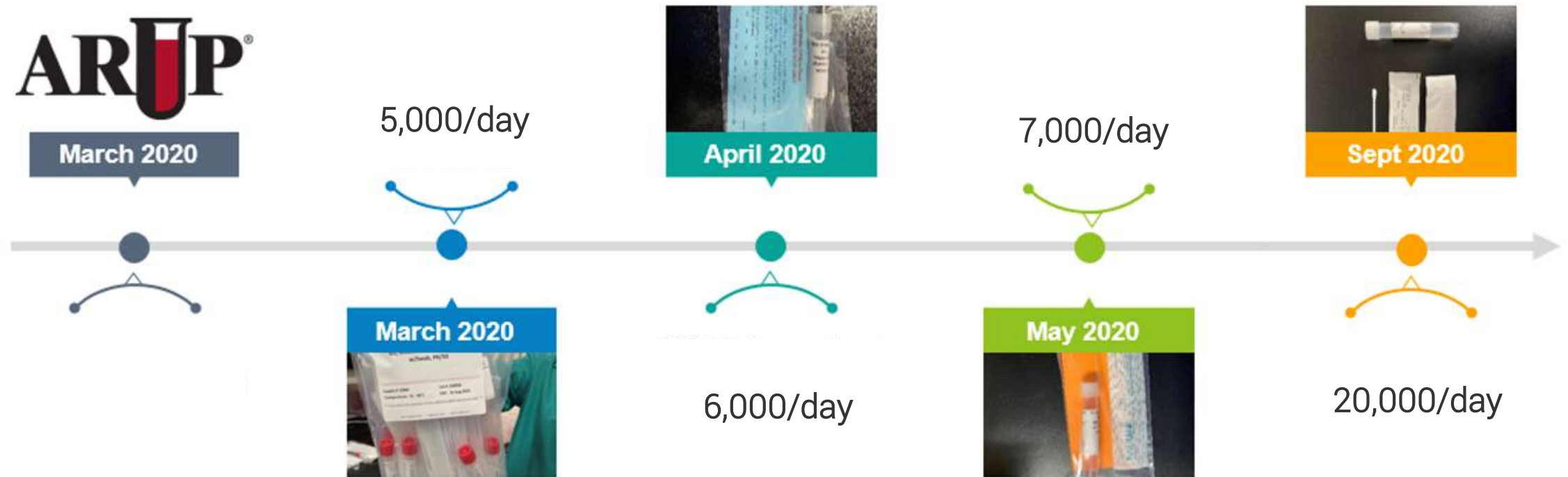
With government (local, state, federal)

Sharing experiences and knowledge
Unknowns and finite resources

Collaboration Example



Supplies for Collections







■ Concluding Thoughts

WE KNOW TESTING

Media

More clinical pathology voices are needed in public education and policy decisions

- Educate
- Advocate
- Be available



The Pandemic Challenges Core Philosophies

Culture of Quality

This is the way we **should** do things.

- CLIA, rigid, standardized, experience driven
- Extensive documentation and training

e.g., 10,000 tests, “99.9% correct”

Culture of Quantity

This is what needs to be done **quickly**.

- Urgency
- Innovation
- Competition

e.g., 100,000 tests, “89.9% correct”

Hypothetical
Examples

Diverse Legitimate Perspectives

Clinical
Pathology

Epidemiology

RT-PCR

Point of Care

Effective
Utilization

Widespread
Testing

Availability

Cost

For Future Pandemics

- Develop **pandemic response plans** based on lessons learned.
- Promote and incentivize **pre-EUA innovation**.
- Clarify and promote pathway for **pre-EUA test availability** with safeguards.
- Fund research on rapid/automatable **extraction techniques** for common categories of viruses and bacteria.
- Support **standardization efforts** to promote **swab, tube, media, and pipette tip** compatibility across automation and platforms.



Thank You

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A nonprofit enterprise of the University of Utah and its Department of Pathology