Title: Contingency planning in the clinical laboratory: lessons learned amidst COVID-19

Running head: Contingency planning in the clinical laboratory

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List of abbreviations:
COVID-19, coronavirus disease 2019
SARS-CoV-2, novel severe acute respiratory syndrome coronavirus 2
FTE, full-time equivalent

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Global transmission of the novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has faced clinical laboratories with many challenges in continuing to offer critical services. Round-the-clock laboratory testing remains essential to support patient care, both those with and without 2019 coronavirus disease (COVID-19). This pandemic is leading to an influx of hospitalized patients, while simultaneously yielding virus exposures and self-quarantines for the laboratory workforce. Thus, laboratories should prepare to operate with limited staff and may need to prioritize laboratory tests according to clinical necessity.

All laboratories will recognize the need to pay particular attention to those sections involved in SARS-CoV-2 viral testing; upstaffing areas that receive, test or send out samples, and report/call-back results. However, the laboratory should consider various staffing models to maintain healthy workers, such as altering shift hours, or even alternating staffing groups (1). Preemptive scaling back of laboratory staff and enabling them to work from home will allow for creation of a reserve labor pool that can be engaged as staff are required to quarantine with exposure. This is only possible when laboratory testing volumes for tests not relevant to COVID-19 precipitously decrease as hospitals cancel all non-emergent and elective procedures that would otherwise require maintaining higher volumes of comprehensive testing.

The laboratory should begin contingency planning by assessing baseline operational status, which benches can be offered less frequently (batched as sample stability allows), which can be closed altogether, and the resultant minimum number of staff required to support emergent testing (**Table 1**). In order to do so effectively, the laboratory should define which tests are required to support emergent care and inpatient testing. Some resources are available to determine this emergent test menu, such as the World Health Organization's *Model List of Essential In Vitro Diagnostics* (2) and the Clinical and Laboratory Standards Institute's *Planning for Laboratory Operations During a Disaster* (3). However, these resources are not specific to COVID-19, and laboratories should work with medical leadership to ensure that laboratory offerings are aligned with expected testing practices.

Tests that will need to be maintained include complete blood counts, metabolic panels, routine coagulation, troponin, liver function tests, blood gases, and inflammatory markers such as C-reactive protein, lactate dehydrogenase, and procalcitonin (4, 5). With laboratory automation, it may be best to prioritize FTEs by assay bench or analyzer as prioritization of individual tests would require additional work of scrutinizing and separating orders, and sorting, storing, and re-running a large number of samples. It may be most efficient to simply allow an automation line to run the complete battery of tests ordered unless analyte-specific technical issues arise. In times of particularly critical shortages of staff and/or reagents, with proper

agreement of hospital leadership and use of mass notification mechanisms, non-emergent tests could be temporarily masked from providers in the test ordering system and eliminate the laboratory from receiving them in the first place.

The laboratory should also evaluate reagent and supply inventory and consider increasing supplies on-hand in preparation for higher test volumes and/or possible lapses in vendor supplies or delivery mechanisms. This will need to be considered in relation to the number of tests anticipated in both critical care and general care patient populations (https://covidprotocols.org) and the likelihood of filling COVID-19 expansion beds as part of surge planning (**Table 2**). The lab should prepare for an increased number of mechanically ventilated patients. Hospital leadership can provide details about the plans to expand patient care areas for COVID-19 patients and the expected testing volumes. It may also be valuable to preemptively evaluate the potential benefit of increased point-of-care testing to ease the burden of samples sent to the laboratory. However, it is essential to consider the entire workflow, including interface work that may be required for new tests.

As elective surgical procedures are postponed, staff across the department may be available to provide support and back-up to the essential functions of the lab, particularly on off-shifts. Cross-training amongst the various core laboratory areas, ideally in advance of significant absenteeism, will yield flexibility of assignments. As universities are increasingly scaling back research operations, other able-bodied personnel such as research scientists, medical students, or Pathology residents may help the clinical laboratory as long as institutional policies and regulatory requirements are met. Non-certified personnel may assist the laboratory with, for example, internal specimen courier services, specimen accessioning, inventory, or the assembly of COVID-19 test collection kits.

Finally, open and continuous communication, both among the laboratory department and healthcare providers, should be maintained with regards to the status of laboratory services. Electronic ‘daily huddles’ can help with assessing the number of staff available, the benches that will operate each day, and where additional staff can be relocated to support intradepartmental needs. Daily assessment and communication can be automated via e-mail templates to inform the hospital of real-time lab staffing capacity and tests that will be unavailable or delayed.

In summary, there are a number of steps the laboratory can preemptively take as part of disaster planning that involve cross-specialty collaboration within laboratory medicine and with the support of hospital leadership (**Table 3**).

References:

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Table 1. Example contingency planning FTE assignment tool. Using the Chemistry section as an example, a similar contingency planning tool can be used across core clinical lab specialties to assess benches/testing that can be performed depending upon available staffing. Its design affords managers to use this tool daily to assign benches, considering priority of assays and specimen stability for assays that are batched. Notably, increased risks of staffing concerns are seen on off-shifts (weekend days, evenings, and nights) and may be addressed by identifying staff who would volunteer to be on-call to cover these shifts as needed. A similar tool can be used to automate communication within the department and help reallocate staffing where it is needed, while also providing updates to clinical care teams. Data for the Chemistry section is offered as an example of information to collect, which is dependent on testing volumes, breadth of testing offered, as well other lab-specific needs. Lab Control/Receiving, Hematology, and Lab Management sections are provided as a place holder, with blank, shaded cells indicating additional data to be entered. A downloadable Excel file of this table is available as **Supplemental Table 1**. FTE: baseline full-time equivalent (FTE) staff number; DS: preemptive down-staffing to create alternating labor pools; Min: minimum number of FTE required to support only emergent testing; %Min: minimum percentage of full staffing capacity to perform testing; Float: no dedicated staff, staff from other benches to cover as able; d/c: discard and cancel; 1+: requires supervisor review and sign-off.

			Sample Stabilities				Day Shift				Weekend Days				Evening				Nights			
CORE LAB	**Prior**	**Bench or testing area**	**20-**	**2-**	**-**	**Contingency/Back-Up**	**FTE**	**DS**	**Min**	**%M**	**FT**	**DS**	**Min**	**%M**	**FT**	**DS**	**Min**	**%M**	**FT**	**DS**	**Min**	**%M**
Lab Control/Receiving	1	Pneumatic Tube																				
	2	Manual Processing, Problem Samples																				
	3	Automation Line Loader																				
	4	Send Out																				
Chemistry	1	Blood Gas				Essential Testing	2	2	1	25%	1	1	1	25%	2	1	1	25%	2	1	1	25%
	2	Osmolality (Serum and Urine)					0.5	Float	Float	25%	0.5	Float	Float	25%	0.5	Float	Float	25%	0.5	Float	Float	25%
	3	Core Chemistry Automation				1. batch and run as possible 2. d/c testing without staffing (blood gas for emergent testing)	3	3	2	25%	3	3	2	50%	3	3	2	75%	3	2	2	50%
	4	Fetal Fibronectin Testing	8 hrs	3 days	3 mo	1. batch and run as possible 2. d/c when > 2 days delay (notify physician)	0.5	Float	Float	25%	0.5	Float	Float	25%	0.5	Float	Float	25%	0.5	Float	Float	25%
	5	Therapeutic Drug Monitoring Mass Spectrometry Testing	12 hrs	14 days		1. batch and run as possible, store 2-8°C and run within 14 days 2. send out when > 2 days delay (notify physicians) 3. d/c if unable to send out (notify physician)	1+	1+	1+	50%	1+	0	0	75%	0	0	0		0	0	0	
	6	Serologic Hepatitis Testing	3 days	7 days	6 mo	1. batch and run as possible, store 2-8°C and run within 7 days 2. freeze when > 5 days, review pending log for Occupational	1	1	Batch	50%	0	0	0		0	0	0		0	0	0	
	7	Immunoglobulins and Free Light Chains		7 days	6 mo	1. batch and run as possible, store 2-8°C and run within 7 days 2. freeze when > 5 days	1	1	Batch	50%	0	0	0		0	0	0		0	0	0	
	8	Ancillary Non-Emergent Chemistries Vitamin D TPO Insulin C3 C4	8 hrs 4 days 2 days	4 days 3 days 24 hrs	6 mo 1 mo 6 mo 3 mo	1. batch and run as possible, 2-8°C and run within limits per analyte: freeze when > 2 days delay, run within 6 months freeze when > 3 days delay, run within 1 month d/c when > 3 days delay, non-essential given delay (notify physician)	1	Batch	Batch	50%	0	0	0		0	0	0		0	0	0	
	9	Protein Electrophoresis/ Immunofixation Serum	4 days	2 wks 72 hrs	6 mo 1 mo	1. batch and run as possible 2. send to reference lab when > 7 delay 3. freeze when > 2 days, run within 1 mo (irretrievable sample)	2	Batch	Batch	75%	0	0	0		0	0	0		0	0	0	
	10	Toxicology Mass Spectrometry Testi	24 hrs	7 days	3 mo	1. batch and run as possible 2. freezing when > 2 days delay (irretrievable sample)	1+ M,W,F	Batch	Batch	75%	0	0	0		0	0	0		0	0	0	
	11	Reports and QA (Supervisor)					2	2	1	75%	1	Float	Float	25%	1	Float	Float	25%	1	Float	Float	25%
	12	Contingency Work					0	Float	Float		0	Float	Float	25%	0	Float	Float	25%	0	Float	Float	25%
						TOTAL FTEs	15	11	6		7	5	4		7	5	4		9	4	4	
						75% Staffed	11.25				5.25				5.25				6.75			
						50% Staffed	7.5				3.5				3.5				4.5			
						25% Staffed	3.75				1.75				1.75				2.25			
Hematology	1	Core Hematology Automation																				
	2	Core Coagulation																				
	3	Automated Urinalysis																				
	4	Manual hCG																				
	5	Manual Differential and Slide Review																				
	6	Bone Marrow																				
	7	Body Fluids																				
	8	Flow																				
	9	Reports and QA (Path Review, etc.)																				
	10	Contingency Work																				
						TOTAL FTEs																
						75% Staffed																
						50% Staffed																
						25% Staffed																
Lab Management	1	Inventory and Stocking																				
	2	Ordering																				

Table 2. Example surge planning tool for emergent laboratory testing. Using a surge planning model of 670 general care and 280 intensive care unit (ICU) beds, the anticipated volume of laboratory testing during an anticipated suge can be estimated following testing protocols outlined by the institution (e.g. https://covidprotocols.org/protocols/02-ed-inpatient-floor-management-triage-transfers). A downloadable Excel file of this table is available as **Supplemental Table 2**. GC: general care unit; ICU: intensive/critical care unit; SCT: stem sell transplant; ABG/VBG: arterial/venous blood gas; CK: creatinine kinase; LFT: liver function tests; LDH: lactate dehydrogenase; CRP: C-reactive peptide; PT/INR: prothrombin time/international normalized ratio; +: additional testing expected, unpredictable volumes.

	Typical (pre-COVID)	Estimated COVID		On Admission		Daily		Every Other Day			Weekly
COVID-19 Order set	**Daily Volume**	**Daily Volume**									
Test				All	High Risk	Unstable	ICU	Stable	Worsening On Propofol		Heme malignancy/SCT patients
CBC with differential	1218	779	+	137	20	+	280	343	+		
BMP	1000	779	+	137	20	+	280	343	+		
Magnesium	850	779	+	137	20	+	280	343	+		
ABG/VBG	205	840	+			+	840		+		
Troponin	120	779	+	137	20		280	343	+		
NT-proBNP	55	779	+	137	20		280	343	+		
CK	33	779	+	137	20		280	343	+		
LFT	350	499	+	137	20			343	+		
Triglycerides	170	126								126	
LDH	115	499	+	137	20			343	+		
CRP	110	499	+	137	20			343	+		
PT/INR	750	157	+	137	20				+		
D-dimer	16	499	+	137	20			343	+		
Fibrinogen	62	0	+						+		
Procalcitonin	42	157	+	137	20				+		
Ferritin	70	499	+	137	20			343	+		
Extended Respiratory Viral Panel		20			20						
Glucan		16									16
Galactomannan		16									16
Inpatient CoV2 testing		155		155							

Adult and Pediatric Estimates:											
Peak # Daily Admissions				*157*							
General Care				137							
ICU					20						
Peak Occupancy							*965*				
General Care								685			
ICU							280				

Assumptions

Assume 20% for GC and 7% for ICU of peak occupancy for daily admissions
Assume 90% ICU patients on mechanical ventilation, requiring propofol
Assume 3x blood gasses per day for each ICU COVID positive patient
Assume 11.5% of all admissions are heme malignancy/SCT patients
Assume 1x CoV testing on admission

Table 3. Strategies for contingency planning in the clinical laboratory amidst the COVID-19 pandemic

Vary staffing models
Alter shift hours
Preemptively scale back on-site workers
Alternate teams for remote vs. on-site work
Approve overtime to call in off-shift workers
Cross-train professionals from other clinical lab areas
Prioritize testing menu for emergent testing
Define necessary/urgently needed tests
Prioritize FTEs to necessary tests
Batch or temporarily discontinue non-prioritized tests
Mask non-prioritized tests from provider order system
Prepare for surge of COVID-19 patients
Amplify inventory of reagents for prioritized tests
Support point-of-care testing
Recruit medical trainees or researchers for lab assistant roles
Maintain communication with hospital and medical leadership
Define expected practices for laboratory testing
Communicate daily lab staffing status and test menu availability

S	Priority	Bench or testing area	Sample Stabilities 20-22°C	2-8°C	-20°C	Contingency/Back-Up	Day Shift FTE	DS	Min	%Min	Weekend Days FTE	DS	Min	%Min	Evening FTE	DS	Min	%Min	FTE
	1	Pneumatic Tube																	
	2	Manual Processing, Problem Samples																	
	3	Automation Line Loader																	
	4	Send Out																	
	1	Blood Gas				Essential Testing	2	2	1	25%	1	1	1	25%	2	1	1	25%	
	2	Osmolality (Serum and Urine)					0.5	Float	Float	25%	0.5	Float	Float	25%	0.5	Float	Float	25%	0.5
	3	Core Chemistry Automation				1. batch and run as possible 2. d/c testing without staffing (blood gas for emergent testing)	3	3	2	25%	3	3	2	50%	3	3	2	75%	
	4	Fetal Fibronectin Testing	8 hrs	3 days	3 mo	1. batch and run as possible 2. d/c when >2 days delay (notify physician)	0.5	Float	Float	25%	0.5	Float	Float	25%	0.5	Float	Float	25%	0.5
	5	Therapeutic Drug Monitoring Mass Spectrometry Testing	12 hrs	14 days		1. batch and run as possible, store 2-8°C and run within 14 days 2. send out when >2 days delay (notify physicians) 3. d/c if unable to send out (notify physician)	1+	1+	1+	50%	1+	0	0	75%	0	0	0		
	6	Serologic Hepatitis Testing	3 days	7 days	6 mo	1. batch and run as possible, store 2-8°C and run within 7 days 2. freeze when >5 days, review pending log for Occupational Health	1	1	Batch	50%	0	0	0		0	0	0		
	7	Immunoglobulins and Free Light Chains		7 days	6 mo	1. batch and run as possible, store 2-8°C and run within 7 days 2. freeze when >5 days	1	1	Batch	50%	0	0	0		0	0	0		
	8	Ancillary Non-Emergent Chemistries				1. batch and run as possible, 2-8°C and run within limits per analyte:	1	Batch	Batch	50%	0	0	0		0	0	0		
		Vitamin D	8 hrs	4 days	6 mo	freeze when >2 days delay, run within 6 months													
		TPO		3 days	1 mo	freeze when >3 days delay, run within 1 month													
		Insulin		24 hrs	6 mo	d/c when >3 days delay, non-essential given delay (notify physician)													
		C3	4 days	8 days		d/c testing when >7 days delay (notify physicians)													
		C4	2 days	2 days	3 mo	freeze when >2 days delay, run within three months													
	9	Protein Electrophoresis/ Immunofixation				1. batch and run as possible	2	Batch	Batch	75%	0	0	0		0	0	0		
		Serum	4 days	2 wks	6 mo	2. send to reference lab when >7 delay													
		Urine		72 hrs	1 mo	3. freeze when >2 days, run within 1 mo (irretrievable sample)													
	10	Toxicology Mass Spectrometry Testing	24 hrs	7 days	3 mo	1. batch and run as possible 2. freezing when >2 days delay (irretrievable sample)	1+ M,W,F	Batch	Batch	75%	0	0	0		0	0	0		
	11	Reports and QA (Supervisor)					2	2	1	75%	1	Float	Float	25%	1	Float	Float	25%	
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EXAMPLE

COVID-19 Order set	Typical (pre-COVID) Daily Volume	Estimated COVID Daily Volume		On Admission		Daily		Every Other Day		Weekly
Test				**All**	**High Risk**	**Unstable**	**ICU**	**Stable**	**Worsening On Propofol**	**Heme malignancy/SCT patients**
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CRP	110	499	+	137	20			343	+	
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Galactomannan		16								16
Inpatient CoV2 testing		155		155						
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