

# Laboratory Communication

## COVID-19 - UPDATE

April 6, 2020

### Lab Testing Evaluation Progress

The CommonSpirit Health National Laboratory Service Line continues to evaluate the use of COVID-19 tests being marketed in the United States. Some tests have claims that will be of little help in diagnosing and treating our patients, and some are out-right scams.

At this time the use of SARS-CoV-2 antibody testing is NOT approved for use in CommonSpirit Health.

- Antibody tests may give a false negative with the need to follow-up with a molecular test.
  - The only negative antibody test result that can be taken at face value is that from a patient “who is not suspected of having COVID-19.”
- Positives tests must also be confirmed with a subsequent molecular test.

An internal study is in place to compare the **Abbott ID NOW** molecular test with other known molecular tests. If this test proves acceptable (i.e. has a high sensitivity and specificity with little cross reactivity with flu), we will recommend its use. Completion with recommendation expected next week.

*See Appendix I for complete testing evaluations to date.*

### Specimen Collection and Transport

The FDA requires every patient being tested for COVID-19, receive a **Fact Sheet for Patients**. Lab Directors have access to these.

Swabs and Viral Transport Media supplies are at critically low levels at many of our facilities and within our distributor community. Manufacturers are increasing supply, however global shortages are expected to persist for some time based on current demands.

Specimen collection by use of oral pharyngeal swabs is NOT approved at this time. Collection by saline wash is approved. Use of saline transport media for swab collections is under evaluation, but is NOT approved at this time. We are in the process of performing a study to determine how long the RNA stays viable for test detection in saline without viral media. Findings and a recommendation are forthcoming. Preparation of all specimens for use on **any platforms** MUST be performed under a Level 2 Bio-Safety hood.

### Test Kits

All vendors (Cepheid, BioFire, GenMark, Hologic, Luminex, BD, Abbott) are **allocating test kits** for the foreseeable future. Purchase Orders for the amounts allocated will be requested by the vendors when product is available. Test kit allocations will be determined week-to-week based on product availability and national prioritization. This is a highly dynamic environment – frequent changes are occurring and expected to continue.

Cepheid and BioFire are expected to distribute their first test allocations next week, however initial quantities will be insufficient for distribution to all facilities or even the total demand at any given facility. The Laboratory Service Line team will continue to work with all of our vendor partners and will provide updates as new allocations are approved or updated.

*See Appendix II for expected **Cepheid** kit availability for all of CommonSpirit Health for the month of April.*

Note - as each kit runs 10 tests, our national capacity for testing with Cepheid will be **6,120** in totality for the month.

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### Capital Equipment

Purchase orders for new equipment and additional capacity have been coordinated with the divisions and released to the vendor. All vendors (Cepheid, BioFire, GenMark, Hologic, Luminex, BD, Abbott) are also **allocating new units - including expansion modules for existing units.**

**Cepheid** has been granted approval for SARS-COV-2 reagent use on CLIA-Waived devices (this was previously not an expected option). Due to greater equipment availability and lower price points, new POs are being requested in an effort to shorten delivery timelines. These devices will still be used within the clinical labs. **Biofire** has determined that **partial orders** will be filled against some requested equipment POs in an effort to bring up testing at a greater number of locations.

*See Appendix III for updated Cepheid model information.*

*See Appendix IV for expected Biofire shipping timeframes and initial module quantities.*

### Other Notes

Hospital laboratory distribution of test and new equipment allocations are being made by the CSH COVID sub-Task Force. The Task Forces members are Robert Wiebe, CSH CMO; Barb Pelletreau, CSH SVP Patient Safety; Roy Boukidjian, CSH VP Infection Prevention and Karen Smith, VP CSH Laboratory Operations.

The following factors are being considered:

- PPE days on hand / burn rate
- Number of positives test results
- Number of test results pending
- Test TAT from outside sources

### Additional Testing Coming

Abbott ID NOW testing units and tests are begin secured. Location of testing is forthcoming.

Antibody Testing for purposes of immunity is forthcoming

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### APPENDIX I: SARS-CoV-2 Laboratory Testing Evaluation Matrix (for Diagnostic purposes)

Manufacturer	Platform	Method	FDA Approved under EUA or Other	Approval Status for CSH	Comments
Abbott	M2000	Molecular	YES	APPROVED	
Abbott	ID NOW	Molecular	YES	Under investigation	Planned parallel study
Abbott	Allinity M	Molecular	NO	Under investigation	Approval to use may change with EUA approval
Becton Dickinson	BD Max	Molecular	NO	NOT APPROVED	May be used as a Laboratory Developed Test
BioFire	Torch	Molecular	YES	APPROVED	
BioRad		Molecular	NO	APPROVED	Approved as a Laboratory Developed Test
BioZek	Rapid Kit	Antibody	NO	NOT APPROVED	
Cepheid	GeneXpert; GeneXpert Express	Molecular	YES	APPROVED	
Coronacide	Rapid Kit	Antibody	NO	NOT APPROVED	
Diasorin	Simplexa	Molecular	YES	APPROVED	
Erpan Tech	Rapid Kit	Antibody	NO	NOT APPROVED	
Gen Mark	ePlex	Molecular	NO	NOT APPROVED	
Genesis	Rapid Kit	Antibody	NO	NOT APPROVED	
Genetic Institute of America	Thermo Fisher ABI 7500	Antibody, Lateral Flow	NO	NOT APPROVED	
Hardy	Rapid Kit	Antibody	YES	NOT APPROVED	
Hologic	Panther/Fusion	Molecular	YES	APPROVED	
Honeybee Diagnostics	Rapid Kit	Antibody	NO	NOT APPROVED	
Luminex	Aries	Molecular	NO	NOT APPROVED	
Luminex	NX Tag	Molecular	YES	APPROVED	
Quidel	Lyra	Molecular	YES	APPROVED	
Roche	Cobas	Molecular	YES	APPROVED	
Thermo Fisher	Tag Path	Molecular	YES	APPROVED	

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### APPENDIX II: Cepheid Test Kit Allocations (April)

Facility	City	State	Kit April Allocation	Other testing ?	Other Testing Planned ?	SO TAT	CSH Priority	4/6	4/13	4/20	4/27
St Joseph's Med Ctr	Tacoma	WA	82	NO	NO	0.5-2 days	1	12	14	36	20
Dignity Health Pathology	Sacramento	CA	78	NO	NO	1-2 days	2	10	12	36	20
Baylor	Houston	TX	80	NO	NO	1-1.5 days	3	10	14	36	20
St. Rose Domin. - Siena	Henderson	NV	84	NO	NO	4-5 days	4	12	18	36	18
Marian Medical Center	Santa Maria	CA	40	NO	BioFire, Fusion	2-3 days	5	10	6	24	0
St Francis Hospital	San Francisco	CA	68	NO	NO	2-3 days	6	12	12	32	12
St John's Regional Medical Center	Oxnard	CA	32	NO	NO	2-3 days	7	0	6	20	6
Memorial Hospital - Bakersfield	Bakersfield	CA	30	NO	NO	1-2 days	8	0	6	18	6
Mercy Medical Center Redding	Redding	CA	62	NO	NO	2 days/ HCCL	9	6	18	20	18
St Anthony Hospital	Lakewood	CO	36	NO	Diasorin	10 days	10	6	8	16	6
Dominican Hospital	Santa Cruz	CA	20	NO	NO	2-3 days	0	0	0	20	0
			<b>612</b>					<b>78</b>	<b>114</b>	<b>294</b>	<b>126</b>

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### APPENDIX III: Cepheid Equipment Model Updates

Hospital name	Need	Priority	Revised Equipment
St Johns Regional Medical Ctr	GXXVI-12	1	2 express (x4)
Bakersfield Memorial Hospital	GX16ADD	2	2 express (x4)
ST JOSEPH DICKINSON	GX12ADD, GX16ADD	4	No Change
ST FRANCIS BRECKENRIDGE	GXXVI-4	4	1 express (x4)
ST JOS PARK RAPIDS	GXXVI-8	4	2 express (x4)
St Gabrielle's LITTLE FALLS	GXXVI-8	4	2 express (x4)
NPL Lab in Bismarck	GX16ADD	2	No Change
Mercy Medical Williston	GXXVI-8		2 express (x4)
LAKEWOOD HEALTH Baudette	GXXVI-8	4	2 express (x4)
GOOD SAMARITAN KEARNEY	Add 4 to Cepheid	2	No Change
Oak Community	GXXVI-4		1 express (x4)
ST ELIZABETH LINCOLN	GXXVI-12	2	2 express (x4)
Dominican Hospital Santa Cruz	GXXVI-16	1	3 express (x4)
Marian Regional	GX12ADD, GX16ADD		No Change
Mercy Medical Center Redding	GX16ADD	2	No Change
MEMORIAL Chattanooga	GXXVI-16	2	No Change
ST VINCENT Infirmary	GXXVI-8	2	No Change
St Bernardine Medical Center	GXXVI-8	2	No Change
St Rose Dominican Hosp Siena	GX12ADD, GX16ADD	3	GXXVI-8
BAYLOR ST LUKE'S	GXXVI-8	2	No Change
ST JOSEPH BRYAN	GXXVI-4	4	No Change
Mercy One Des Moines	GX12ADD, GX16ADD	4	No Change
Northridge	GXXVI-16	2	No Change
PML	GXXVI-16	2	Move from San Juan

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### APPENDIX IV: Cepheid Equipment Model Updates

Hospital name	City	State	Torch Bases Needed	Modules Needed	Priority	4/6	4/13	4/20	4/27
Marian Medical Center	Santa Maria	CA	1	6	2	6			
Chandler	Chandler	AZ	1	4	1			2	
Mercy Medical Center Redding	Redding	CA	1	4	3		4		
PML	Sacramento	CA	1	8	3			8	
BERGAN MERCY	Omaha	NE	1	6	1		4		
ST FRANCIS GRD ISLAND	Grand Island	NE	1	2	2			2	
MERCY ROSEBURG	Roseburg	OR	1	2	2		2		
MEMORIAL Chattanooga	Chattanooga	TN	1	8	3				4
ST JOSEPH LEXINGTON	Lexington	KY	1	8	2			4	
ST VINCENT Infirmary	Little Rock	AR	1	8	2				2
TRINITY STEUBENVILLE	Steubenville	OH	0	2	3				2
BAYLOR ST LUKE'S	Houston	TX	1	8	2	2			
Memorial Health System - Memorial Medical Center Hospital - Lufkin	Lufkin	TX	0	4	3		2		
Northern Plains Laboratory	Bismark	ND	0	4	3				2