**COVID-19 ECHO Session #19 _July 15, 2020: Public Health Laboratory Networks and Sars-Cov-2 Testing: Challenges, Strategies? And Lessons Learned From USA**

| SN | Questions | Answer/ Response / Comments |
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| **Sample management** | | |
| 1. | When you say contaminated VTM, what were specifically the contaminants? Is it contaminated with SARS-COV-2 and giving false positive results or what? | The contamination of VTM in the example discussed was bacterial likely due to lack of cleanroom conditions in the manufacturing process. |
| 2. | Does the contaminated VTM affect the quality of Results? | Bacterial contaminated VTM would be unfit for use. |
| 3. | If contamination is discovered during the verification process, what then are the next actions and recommendations to the manufacturer? | Manufacturers should replace contaminated VTM without cost to the user. |
| 4. | What are your thoughts on pooling in the current environment of reagent and test kit shortages? | Pooled testing is a procedure commonly used to reduce the cost of screening for a large number of individuals for infectious diseases such as blood donation screening, chlamydia and gonorrhea opportunistic testing in medical clinic, influenza surveillance through blood donations, and West Nile virus surveillance in mosquitoes. Pooling is a valid option to consider for SARS-CoV-2 testing. However, determining the pool size for group testing of specimens is critical. The test sensitivity, specificity and Limit of Detection are important as is a highly sensitive test needed to avoid missing low positive specimens. The positivity rate among the population and specimens submitted for testing affects the efficiency of the assay and at higher positivity rates pooling does not offer an advantage in reduced use of reagents and personnel time. In addition to the analysis to estimate the pool size for the specific conditions of the test system to be used, a well-planned validation study is required that includes all steps in the testing procedure. This is a link to the recent CDC guidance on specimen pooling strategy. https://www.cdc.gov/coronavirus/2019-ncov/lab/pooling-procedures.html |
| 5. l | What might be causing specimen backlog in US | This is a very important question globally. “Backlogs” or specimen testing demand greater than testing capacity is often seen in diagnostic testing. The laboratory must be managing all aspects of the testing workflow and test turnaround time is a key quality indicator. The |

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| | | TAT required for a test depends on the use of the data. Backlog of specimens awaiting test is an indication of a problem that must be addressed. For specimens being tested in the commercial labs, which provide the largest percentage of SARS-CoV-2 PCR tests in the U.S, the TAT average has been 7 days or longer for many of the tests although some are tested in less than one day. Obviously, all the factors from specimen collection through testing and reporting of a final test result must be reviewed and action taken on one or more means to increase the throughput of specimens or control the demand side of the system. It may be the wide fluctuations from day to day in test demand and the very large numbers of test requests cannot be accomplished without changes to the current system for diagnostic testing. I don't have the data and information to with accuracy point to a main reason for the long TAT. The point I would make is that the laboratory must be a leader and advocate to provide data and information on the issue, commit to a TAT that meets the purposes of the various test results, and make or require others to make the changes necessary to provide the testing services needed in a timely manner, by increasing testing capacity, prioritize testing that requires fast TAT or a combination of these actions. |
| 6. | I see you indicate "Sending to external labs" as a strategy to manage workload... does this mean sending to labs outside the US? | In the context of the presentation, the reference was to sending specimens from outside the service area of the laboratory. Specimen transport time and cost are limiting factors on accessing distant lab testing. For the U.S., options outside its borders are very limited. As a note, the State of Hawaii location leaves it with very limited options for accessing timely testing services off Island. |
| 7. | stability for GeneXpert samples, either on VTM or saline | See Journal of Clinical Microbiology, Evaluation of Transport Media and Specimen Transport Conditions for the Detection of SARS-CoV-2 by Use of Real-Time Reverse Transcription-PCR, Rogers et al., August 2020 Volume 58 Issue 8. Available free on Web. |
| 8. | Clearly time and cost savings are some of the advantages of pooling specimens, what are the disadvantages of pooling? | Disadvantages are the need to do additional validation if any component such as an extraction method is changed; need to monitor positivity of the population being tested as this affects the |

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| | | efficiency of the method and may render the method not worth the effort or even less efficient than individual specimen testing; the need to monitor test sensitivity to assure low positive specimens are not missed. |
| **Reagents and consumables** | | |
| 9. | Regarding screening kits for COVID-19 is there any approved one for the purpose? | In the US, Abbott, Biofire and Cepheid and a few others have approval for tests that can be one outside of laboratories. |
| **Diagnosis** | | |
| 10. | Is there an algorithm to determine ideal testing rate to contain the disease? | Testing is a means to identify and quarantine infected persons and test their contacts to decide on recommendations. Widely different recommendations have been offered on how many tests should be done. WHO suggests a metric to estimate if enough tests are being done, which is a 10% benchmark of positive tests. WHO suggests that if positivity rate of testing exceeds 10% there is not enough testing to capture all the infected people in the community. |
| 11. | In commercial laboratories do patients pay for the test or are they funded by government | Health insurance companies or the government pays for most testing. |
| 12. | What is USA doing to ensure almost everyone is tested, Do you consider having Rapid diagnostic test kit for Covid-19 to allow large numbers of people are tested? before using the PCR technique | There is no recommendation to test everyone, nor is it necessary in order to control the pandemic. Rapid diagnostic tests are in use and more in development. This technology has an important role in testing in areas where access is limited and are used in some settings such as nursing homes and other uses. However, laboratory PCR platforms have a throughput capability much greater than RDTs for testing specimens than RDTs and are essential to meeting testing demands. |
| **Result interpretation /Reporting** | | |
| 13. | Has the US implemented electronic result delivery directly to patients to lower TAT and reduce lab/clinic workload? | Electronic test result reporting directly to patients is in place in some hospital networks and from some other testing providers but not all. |
| 14. | I need expert opinion regarding these positive COVID-19 results with high CT values of between 37-40. Would you recommend repeat before release of such results? | I can't comment on your specific question. However, the QC/QA checks in the SOP should include sufficient checks such as visual inspection of curves to compare with instrument interpretation, and when to repeat tests for cause. |
| **Method Validation/ Verification and Evaluation of Kits** | | |

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| 15. | Does any of your validation activity identify kit related malfunction? Is the contaminated VTM related to the whole lot? Thanks | For VTM, visual checking is usually done on all tubes and sterility testing on a sample of tubes from each lot. |
| 16. | Validating additional test types as strategy to manage work load: like what? | The reference was for validation of extraction kits and PCR test kits from more than one manufacturer, for example, Roche and Abbott. |
| 17. | Any comments on saliva validation for PCR? | There is published data that saliva may be as sensitive as NPS for detection of SARS-CoV-2. |