LabCoP ECHO Session – maintaining HIV & TB Testing in the context of COVID 19

Discussion Questions & Answers

Date: April 23, 2020

SN	Questions	Answer/ Response / Comments
Sample Management		
1.	What are the safety measures and the requirements for sample stability for Covid-19 test during transportation to the testing sites?	Specimens for virus detection should reach the laboratory as soon as possible after collection. Correct handling of specimens during transportation is essential. Specimens that can be delivered promptly to the laboratory can be stored and shipped at 2-8°C. When there is likely to be a delay in specimens reaching the laboratory, the use of viral transport medium is strongly recommended. Specimens may be frozen to - 20°C or ideally -70°C and shipped on dry ice if further delays are expected. It is important to avoid repeated freezing and thawing of specimens. Transport of specimens within national borders should comply with applicable national regulations. International transport of potentially COVID-19 virus containing samples should follow the UN Model Regulations, and any other applicable regulations depending on the mode of transport being used. More information may be found in the WHO Guidance on regulations for the Transport of Infectious Substances 2019-2020 and WHO interim guidance for laboratory biosafety related to coronavirus disease See also https://apps.who.int/iris/rest/bitstreams/1272454/retrieve https://www.who.int/ihr/publications/WHO-WHE-CPI-2019.20/en/ https://apps.who.int/iris/bitstream/handle/10665/331639/WHO-2019-nCoV-laboratory_shipment-2020.3-eng.pdf

2.	What are some of the specific measures that can be taken to ensure VL sample inflow continues amidst COVID	VL testing should continue as is because this is currently fully funded. What we should be considering is how to accommodate COVID-19 testing in the midst of VL and EID. Key critical molecular diagnostic tests should be prioritized are early infant diagnosis (EID), TB testing of all suspected, and viral load testing for people living with advanced HIV disease; those suspected of failing treatment, including pregnant and breastfeeding women; and infants, children, and adolescents. During the presentation, we talked of integrated testing to include multiplex testing, sample transport systems, data systems, consider work shift, overtime etc. Funding should be made available from COVID-19 supported funds to support additional cost of sample transport, overtime payment, and HR needs.
Biosafety Measures		
3.	Most of the laboratories in Africa, do not meet the required standard, with the COVID pandemic what is the way forward, using this current platform for COVID testing. So what is the minimal laboratory standard needed to effectively handle COVID testing and biosafety requirements	New biosafety guidance to replace the one at https://www.who.int/publications-detail/laboratory-biosafety-guidance-related-to-coronavirus-disease-2019-(covid-19) is expected very soon. This will clarify and reduce the minimum requirements when procedures that do not generate droplets or aerosols are used in diagnosis, allowing for more decentralized testing. Please watch this space.
Diagnosis		
4.	~~When should the serology test kit be used in testing COVID-19 patients?~~	
5.	What mitigating steps are being made to triage cases as they come for testing at sites with both COVID/TB/HIV testing facilities? Preventing mixing of patient populations would be critical to prevent confections.	Yes, indeed this is recommended; see : https://www.who.int/news-room/detail/04-04-2020-updated-who-information-note-ensuring-continuity-of-tb-services-during-the-covid-19-pandemic Further, early infant HIV diagnosis and viral load testing for people living with advanced HIV disease; those suspected of failing treatment, including pregnant and breastfeeding women; and infants, children, and adolescents should remain top priorities.
6.	Massive house to house testing for covid-19 to commence soonest[real-time],with insufficient kits on ground in AFRICA-NIGERIA in particular....how is this going to	Diagnosis of COVID based on suggestive syndrome during the pandemic may still be possible. See also here : https://www.who.int/publications-

	be possible considering the daily escalation in number of infected people	detail/considerations-in-the-investigation-of-cases-and-clusters-of-covid-19
7.	Is there a list of WHO approved HIV self-testing kits that is available, do we have self-testing videos to help with training and implementation thank you	See here: https://www.who.int/hiv/topics/self-testing/en/ Additional considerations on HIV testing in COVID should be available shortly.
8.	What about prioritization of pregnant and breastfeeding women for HTS testing and maternal retesting?	
9.	Regarding self-testing for HIV diagnosis, based on the stigma that still exists, I can see many barriers to obtaining truthful answers and also subject to abuse, or avoiding testing - is there any experience on implementing self-testing successfully?	
10.	In the case of self-testing how do we get those tested positive, get confirmatory test and treatment in this period of lockdown	
11.	Which Rapid diagnostic tests have been recommended by WHO?	The three NAT tests have been listed on the WHO emergency use list for COVID-19 as of right now are the following : https://www.who.int/diagnostics_laboratory/eual/listing/en/ However, additional manual NAT tests have been approved by the technical team at WHO. Rapid diagnostic tests, using antigen or antibodies, are not currently recommended for clinical management.
12.	Please what does it take to ensure the Genexpert machine accommodates the investigation of COVID-19 without interrupting TB assay routinely?	This requires advance planning to provide for sufficient capacity to continue TB tests uninterruptedly. See also here http://www.euro.who.int/en/health-topics/communicable-diseases/tuberculosis/publications/2020/rapid-communication-on-the-role-of-the-genexpert-platform-for-rapid-molecular-testing-for-sars-cov-2-in-the-who-european-region-2020
Treatment		
13.	What are the monitoring mechanism of TB treatment adherence during this pandemic?	Apart from monitoring, it is important to ensure patients feel supported to continue treatment by improving communication between in-person encounters with healthcare staff.
Procurement and supply		

14.	What are the plans to ensure adequate supply of TB diagnostic tests such as cartridges and medicines?	Our Information Note and the communications and advocacy around it in the last months have highlighted, amongst others, the importance of protecting vulnerable individuals from further marginalization https://www.who.int/tb/COVID_19considerations_tuberculosis_services.pdf We are working with partners like Global Fund and Global Drug Facility to make sure that there are no stockouts (e.g. if patients are given a 6-month supply of TB drugs to take home at one go). Furthermore, the Diagnostics Consortium for COVID-19 is working with suppliers to ensure available stock for HIV and TB tests.
15.	With most countries on lockdown and travel restrictions, How has WHO worked with governments to make sure vulnerable HIV/TB patients continue receiving services like testing and treatments?	
Sensitivity, Specificity and detection range		
16.	There are emerging reports that are pointing out the increased rates of covid-19 FALSE NEGTIVE results (above 15% rate) from molecular tests that have been granted emergency use by FDA. Please how could this affect molecular test algorithms especially in settings with low prevalence of SARS-CoV-2 like in Africa?	Which instrument is this? Please specify. I have not seen this data from any of the FDA EUA or WHO EUL instruments. Also, the sample quality is very important for COVID and can lead to false negatives if sampled inadequately.
17.	There is evidence that COVID-19 assay using saliva has a higher sensitivity compared to other specimens (https://www.medrxiv.org/content/10.1101/2020.04.16.20067835v1). I will like to know if there are studies on sputum to know if this specimen type can be used on the GeneXpert machine for COVID-19 as well.	The currently available tests have not been evaluated for saliva nor any available data on performance yet available. Further, additional sample types must be included in the intended use claims of each test and associated data included in package inserts and provided to the necessary assessment body. There are also conflicting reports of viral loads being lower in saliva.
Cross cutting		
18.	What is OGAC thinking about current TB/HIV diagnostics budget for 2020 (COP19) and 2021 (COP 20)? Are we going to see budget reductions to fund COVID activities?	The United States government is support COVID-19 through direct funding to the country that is different from PEPFAR funding. No direct PEPFAR funds should be diverted to COVID, however, countries should use these other COVID supported funds to address any additional needs.
19.	How do we improve laboratory surveillance in resource limited set ups.	Surveillance please see here https://apps.who.int/iris/bitstream/handle/10665/331506/WHO-2019-nCoV-SurveillanceGuidance-2020.6-eng.pdf

20.	what hope have some of us in Africa that have not enough kits for Covid-19 before thinking of diagnosis of TB and HIV in the same individual	In the absence of confirmatory testing one had best consider a suggestive symptomatology as COVID and manage it accordingly. COVID can coexist with TB and HIV in the same individual.
21.	What's the timeline for availability of GXPT cartridges for Africa?	It is not yet clear how CEPHEID will provide for the demand in total numbers and distribution of XPRESS cartridge expected in the coming months. The Diagnostics Consortium for COVID-19 is trying to support LMICs countries to access tests; however, it is suggested that countries take a multi-pronged approach that includes manual assay utilization in order to meet testing needs.

Resources

1. The Stop TB document I just described: http://stoptb.org/assets/documents/covid/Considerations%20for%20selection%20of%20SARS-CoV-2%20diagnostics.pdf
2. WHO Regional Office for Europe has published a rapid communication on the use of the GeneXpert platform for SARS-CoV-2 testing which you can find under the following link: http://www.euro.who.int/en/health-topics/communicable-diseases/tuberculosis/publications/2020/rapid-communication-on-the-role-of-the-genexpert-platform-for-rapid-molecular-testing-for-sars-cov-2-in-the-who-european-region-2020