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VIRAL TRANSPORTATION IN COVID-19 PANDEMIC: INACTIVATED VIRUS TRANSPORTATION

SHOULD BE IMPLEMENTED FOR SAFE TRANSPORTATION AND HANDLING AT DIAGNOSTICS

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The potential for a laboratory-acquired SARS-CoV-2 infection, causing COVID-19 disease, from accidental exposure grows as the pandemic progresses making the biosafety of samples during transportation and laboratory diagnosis vital. Therefore, the Centers for Disease Control's (CDC) recommendation to transport diagnostic specimens in viral transport media (VTM) that preserve viability and infectivity of the SARS-CoV-2 virus is unexpected. ¹ Additionally, some healthcare professionals and transport personnel may not be aware that they are handling specimens with live viruses collected in CDC recommended media.

Modern molecular nucleic acid (NA) tests, unlike traditional virology tests, do not require viable virus, but rather only intact NA particles of the viral genome. These tests also have improved test performance with better turnaround time, sensitivity, specificity, precision and reproducibility as compared to traditional tests. Indeed, majority of currently approved SARS-CoV-2/COVID-19 tests in the world are NA based molecular tests.

A variety of transport media have previously been shown to effectively inactivate/kill viral, bacterial and fungal pathogens while preserving stability of the released DNA and RNA for diagnosis. ^{2,3,4} These media include ones with a surfactant (e.g. Guanidine thiocyanate) or molecular grade Ethanol.^{2,3,4} One such medium has been extensively analyzed and is approved by the USA Federal Drug Administration (FDA).^{2,3,4} Moving to virus-inactivating VTM at collection allows risk mitigation from transportation and handling of bio-specimens for diagnosis and can potentially reduce the need for special packaging and transportation measures for SARS-CoV-2/COVID-19 test samples.

Although current CDC recommendations, classify SARS-CoV-2/COVID-19 test samples in media that keeps virus intact as International Air Transport Association (IATA) Category B (UN3373- for diagnostic testing), some have raised concerns that these specimens should be classified as IATA Category A (UN2814- potential to cause severe harm).⁵ In addition, CDC recommendations impose additional burden on aircraft carriers as alcohol based hand sanitizers, recommended by CDC for use by transportation staff, are in themselves a dangerous good and specifically not permitted by IATA, requiring special authorization by the civil aviation authority. Furthermore, even the lower IATA-B rating imposes significant packing and coldchain requirements which may be difficult to maintain in low resource settings. Use of traditional VTM's also leaves open the possibility of an accidental population outbreak from a vehicular accident, which could release large amounts of viral particles into the atmosphere.

The CDC's recommendation for using virus- preserving VTM's may have been intended to allow for identification and tracking strain evolution for epidemiologic studies. However, as the approved molecular nucleic acid tests do not inform on strain identification, this goal cannot be met. Therefore, the current VTM requirements only end up posing unnecessary risk on transportation and laboratory professionals without any epidemiological benefits. The CDC should therefore reconsider their recommendation for transportation of SARS-CoV-2/COVID-19 specimens in virus- preserving VTM to reduce the risk to laboratory and transportation professionals who are battling this pandemic.

References

- Center for Disease Control. CDC interim guideline for specimen handling and transportation for COVID-19 testing. <u>https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-</u> <u>specimens.html</u>. Accessed on March 30, 2020.
- Luinstra K, Petrich A, Castriciano S, et. al. Evaluation and clinical validation of an alcoholbased transport medium for preservation and inactivation of respiratory viruses. J Clin Microbiol. 2011;49(6):2138-2142.
- Daum LT, Choi Y, Worthy SA, Rodriguez JD, Chambers JP, Fischer GW. A molecular transport medium for collection, inactivation, transport, and detection of Mycobacterium tuberculosis. Int J Tuberc Lung Dis. 2014;18(7):847-849.
- Federal Drug Administration. Evaluation of automatic class III designation for for PrimeStore MTM. <u>https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN170029.pdf</u>. Accessed on March 30, 2020.
- International Air Transport Association. Air Transport & COVID-19 Coronavirus. https://www.iata.org/en/programs/safety/health/diseases. Accessed March 30, 2020.