



COLLEGE of AMERICAN PATHOLOGISTS

June 7, 2021

Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Sent via email: Secretary@HHS.gov; Xavier.Becerra@HHS.gov

Dear Secretary Becerra:

The College of American Pathologists (CAP) lauds your leadership and dedication in combatting the coronavirus (COVID-19) and preparing for future global health threats. We request the Administration take **immediate action** to resolve the supply shortage of sodium citrate light blue top tubes. To keep our country on its current trajectory to recovery, the Administration must be diligent in addressing supply shortages caused by the pandemic in other areas of clinical laboratory testing. As was outlined in the Administration's National COVID-19 strategy, we request the administration abide by its goals and invoke the Defense Production Act (DPA) as well as provide clear guidance to clinical laboratories for actions to perform testing in the interim until the blue top tube supply levels are adequate.

Blue top tubes are used for specimen collection for coagulation testing. Coagulation tests measure the blood's ability to clot, and how long it takes to clot. This testing determines the risk of excessive bleeding or developing clots (thrombosis) in blood vessels. Clotting disorders can cause a dangerous amount of bleeding or clotting and, for many patients, are life threatening. These are fundamental laboratory studies and correct treatment decisions rely on these tests. Without them, physicians are reduced to guessing. The urgency to guarantee the supply of blue top tubes cannot be overstated.

Given the importance of these tubes to patient care, the CAP believes it is critical for the Administration to dedicate additional resources and focus its attention on increasing supplies of blue top tubes. In the interim, the Administration needs to provide guidance so clinical laboratories can identify and/or create alternative collection methods, including validation processes for development of sodium nitrate tubes within clinical laboratories.

As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the CAP serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide. The CAP offers its expertise and assistance in developing resources and educating the clinical laboratory on best practices during this time of blue top tube shortages.



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For any questions, concerns, please contact Helena Duncan (hduncan@cap.org).

Sincerely,

Patrick Godbey, MD, FCAP
CAP President

CC: Jeff Zients, White House COVID Coordinator, Carole Johnson, COVID Testing Coordinator, Tim Manning, Supply Coordinator; Chiquita Brooks-LaSure, CMS Administrator, Janet Woodcock, M.D. Acting Commissioner of Food and Drug Administration