COLLEGE of AMERICAN PATHOLOGISTS

BLUE TOP TUBE RECOMMENDATIONS
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Background
Currently, there is a shortage of 3.2% sodium citrate blue top tubes. The shortages of these tubes have occurred due to several recalls along with unprecedented levels of demand for Citrate products due to surges in COVID-19 infection rates, COVID-19 vaccines, and treatment development. Since sodium citrate tubes supplies are not expected to meet demand until the end of the year, the CAP developed mitigation strategy recommendations to guide clinical laboratories and federal regulators in reducing the clinical impact of these shortages.

CAP MITIGATION STRATEGY RECOMMENDATIONS
Ordering Providers
- Evaluate clinical necessity of all coagulation testing orders to ensure only vital tests are ordered.
- Where possible, reduce the frequency and/or extend the timing of standing PT/INR orders, especially for stable patients on long term warfarin.
- Reduce routine coagulation testing where not clinically necessary (eg, Avoid routine preoperative testing for low-risk surgeries without a clinical indication.[1])

Nursing/Phlebotomy
- Immediately stop drawing light blue top tubes
  - as part of any a "hold" request - only draw a tube when actual testing has been ordered
  - as part of any “rainbow draw” – only draw a tube when actual testing is likely to be ordered
- Avoid using sodium citrate tubes as discard tubes
  - Use another appropriate source for a discard tube; importantly, discard tubes should lack any substance which could affect coagulation testing (eg, clot activator or EDTA)
- Reserve the use of smaller volume 1.8mL coagulation tubes for patient populations that cannot be drawn with larger volume 2.7mL coagulation tubes.

Clinical Laboratories
- Validate or develop alternative sodium citrate tubes; however, the clinical laboratory must have written procedure for this process, document training for this process, and follow GEN.40942 Specimen Container Analytic Interference to ensure this change does not impact patient results.
  - Clinical laboratories can use 3.2% sodium citrate tubes from an alternative manufacturer if a validation is performed.[2]
  - Clinical laboratories should AVOID 3.8% tubes as a replacement for 3.2% tubes.
- Use POCT devices; but must follow the manufacturer’s instructions (COM.40250). If the laboratory uses the method outside of the intended use (i.e., monitoring of patients on warfarin), the test is then modified, and the laboratory will need to perform a validation of test performance specifications as outlined in COM.40350 and ensure that operators are qualified to perform high complexity testing (GEN.54750).
- Use expired tubes as a last resort. Only during the public health emergency declaration, CMS will allow laboratories to use expired test kits and reagents if they pass quality control tests with each assay run. There is language in CMS Interpretive Guidelines (IGs) stating, “When in-date reagents are unavailable, it may become necessary to frame written policies for their temporary use beyond their expiration dates until non-expired supplies become available.

1. American Society for Clinical Pathology. Choosing Wisely: An Initiative of the ABIM Foundation, 2013.
2. Lima-Oliveira, G., Lippi, G., Salvagno, G. L., Montagnana, M., Picheth, G., & Guidi, G. C. (2013). Sodium citrate vacuum tubes validation: preventing preanalytical variability in routine coagulation testing. *Blood Coagulation & Fibrinolysis: An International Journal in Haemostasis and Thrombosis*, *24*(3), 252–255. https://doi.org/10.1097/MBC.0b013e32835b72ea.