

May 1, 2022

TO: ALL NATIONAL CLINICAL TRIALS NETWORK (NCTN) MEMBERS AND NCI COMMUNITY ONCOLOGY RESEARCH PROGRAM (NCORP) AFFILIATES AND SUBAFFILIATES; CTSU

FROM: SWOG Operations Office (E-mail: protocols@swog.org)

RE: Blood Specimen Collection Tube Shortage Guidance

MEMORANDUM – Blood Specimen Collection Tube Shortage Guidance

The purpose of this memorandum is to notify sites of alternatives for specimen submission on SWOG protocols given the ongoing blood specimen collection tube shortage.

The FDA has expanded the Medical Device Shortage list to include all blood specimen collection tubes.

Please note the following **SWOG guidance for site participation in SWOG trials**:

- Review SWOG protocol Section 15 to determine if collection kits are being supplied or if sites are to utilize institutionally-supplied collection materials; Institutional-supply is common for FFPE tissue slide preparation, EDTA, SST, heparin, and other collection tubes that participating sites commonly have in stock as part of regular institutional activities.
- **If the protocol utilizes institutionally-supplied collection materials and there is a shortage:**
 - Based upon available site materials, sites may use multiple smaller volume tubes of the same type (e.g., two 5-mL K2EDTAs may be used in place of one 10-mL K2EDTA) to collect the total protocol-specified sample (blood, plasma, serum) volume, as long as the total sample volume collected matches the total sample volume indicated in the protocol for that specimen type and timepoint.
 - Important: When using different sized tubes than specified in the protocol, this difference must be noted on the specimen packing slip and in the "Comments" section in the Specimen Tracking System, e.g., "Due to the blood specimen collection tube shortage, alternate tubes were utilized."
- Reminder: For questions pertaining to utilization of alternate collection tubes (e.g., K3EDTA for K2EDTA tubes), delayed specimen collection or submission, or specimen collection procedures, contact the Translational Medicine (TM) Chair via the E-mail address indicated on the title page of the protocol or the Protocol Contact Information Page. Substitution of alternate types of tubes may vary per protocol (dependent upon the protocol objectives and planned analyses), so it is important to verify any substitutions of TYPE of collection tube with the TM Chair for the respective SWOG protocol.
 - In event that a TM Chair or supporting contact is not yet included on the protocol (banking only), please contact the Study Chair via the E-mail address indicated in the protocol.
- For more information on specimen collection – reference the [SWOG Protocol Conduct FAQs](https://www.swog.org/faqs-protocol-conduct) (<https://www.swog.org/faqs-protocol-conduct>).

Updated **FDA guidance for Health Care Providers and Laboratory Personnel** is accessible from links below:

- [Blood Specimen Collection Tube Conservation Strategies - Letter to Health Care and Laboratory Personnel | FDA](https://www.fda.gov/medical-devices/letters-health-care-providers/update-blood-specimen-collection-tube-conservation-strategies-letter-health-care-and-laboratory?msclkid=df9ec1bdbce311ecb5f032de94d62218)
(<https://www.fda.gov/medical-devices/letters-health-care-providers/update-blood-specimen-collection-tube-conservation-strategies-letter-health-care-and-laboratory?msclkid=df9ec1bdbce311ecb5f032de94d62218>)
- [Medical Device Shortages During the COVID-19 Public Health Emergency](https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/medical-device-shortages-during-covid-19-public-health-emergency)
(<https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/medical-device-shortages-during-covid-19-public-health-emergency>).

This memorandum serves to notify the NCI, CIRB, and SWOG Statistics and Data Management Center.

cc: PROTOCOL & INFORMATION OFFICE