

COVID-19 Updates for AFT Biorepository

Alliance Foundation Trials (AFT) Biorepository and Laboratory updates

Subject: Shipment of Biospecimens Held at Clinical Sites Due to COVID-19 Biobank Restrictions

Updated on: August 4, 2020

During the time period of March - July 2020, clinical sites participating in a number of Alliance clinical trials were asked to 'collect and hold' biospecimens (with possible on-site processing) due to COVID-19 related staffing restrictions that prevented biospecimen receipt at several of the Alliance biobanking and laboratory sites. Now that most restrictions have been lifted, these guidelines (**which take effect as of Monday, August 10th, 2020**) are intended to allow sites to ship their 'backlog' of biospecimens to the appropriate biorepository or laboratory for long term storage and eventual clinical correlative science use.

1. These guidelines do NOT necessarily apply to ALL trial specimens and all biobanks, as in some cases, biospecimen shipment did continue without interruption.
2. These guidelines apply to Alliance Foundation Trials.
3. These guidelines apply to both frozen specimens and ambiently stored biospecimens.
4. These guidelines apply to biospecimens that were collected, (processed), and held per the usual protocol as well as specimens that were exceptionally processed on site for stabilization and subsequent shipment.
5. If not done so already, all biospecimens should be logged into BioMS using actual / accurate collection dates.
6. If biospecimens were exceptionally processed outside of the standard protocol, the specimen (in its original form) should still be marked as 'collected' in BioMS but with a note added as to how it was processed on site. *For example- a 10 ml Streck tube of whole blood was collected but it was subsequently centrifuged, aliquoted, and frozen as plasma aliquots on site. The 'Streck tube' should be marked as collected and 'shipped' in BioMS, adding a note that the processed plasma vials are being shipped instead. Please indicate the number of processed vials in the shipment in your note.*
7. Each specimen collection event must include its own individual BioMS manifest, listing the specimens associated with that collection, just as it would have been collected and shipped in real time. It is permissible to physically ship specimens from multiple collection events in a single shipper, but each individual BioMS manifest for each collection must be included in the shipment.
8. If sending multiple specimens from multiple patients and time points, it is important (per standard CSM instructions) that each biospecimen be physically labeled clearly and completely with the participant ID, biospecimen type (e.g. plasma or serum or buffy coat), and collection timepoint (if applicable).
9. Be certain to include all applicable paperwork (pathology reports, questionnaires, forms) for all applicable specimens in the shipment, as per the protocol requirements.
10. Frozen specimens and ambient specimens (e.g. paraffin blocks and slides) should be sent in separate shipments.
11. If biospecimens are to be shipped to multiple biorepositories or analytical laboratories, make certain that the correct specimens are placed in the correct physical shipper with the appropriate destination address.
12. **Prior to any shipment, please call or email the destination biorepository or laboratory with the number of planned specimens to ship, and reserve a shipment date (it is assumed that delivery will be made by the following day).** If you are unable to ship on the schedule date or need to cancel a shipment, please call or email to reschedule a date. This 'reservation process' is necessary to ensure that the biorepository is not overwhelmed with a large number of shipped specimens being received on the same day.
13. All biorepository- or trial-specific rules with regard to shipments on Friday, Saturday, Sunday, or the day before a holiday apply (i.e. in most cases, biospecimens should not be shipped on Friday- Sunday or the day before a holiday).
14. All biospecimens received will be reconciled and electronic feedback will be provided regarding any issues that require resolution, as per standard submissions.
15. For questions about this general process, please call the AFT BioMS Help Desk at 1(855) 642-4667 OR email at afbhelp@email.wustl.edu
16. **For specific questions about a shipment or pending shipment, or to make a shipment reservation, please call or preferably email the destination biorepository or analytical lab, below:**

Biorepository/Lab	Phone	Email
AFTBWUSTL	314-747-4402	afbhelp@email.wustl.edu

Updated on: July 2, 2020

Please visit this page frequently to see updates regarding kit requests and biospecimen submission for all Alliance trials as we will be re-opening specimen shipments in two phase process. Note that the Alliance Biospecimen Coordinating Center (i.e. BioMS and BioMS HelpDesk) will still operate normally through phone and email communication. Please contact the **AFT BioMS HelpDesk** with any questions related to these policies and procedures.

- **Effective July 13, 2020 all clinical sites should begin submission of any paraffin block or slide biospecimens from Alliance trial patients that were being previously withheld because of limited biobanking operations.** Please read the following carefully:
- **Send only paraffin block and slide specimens at this time. Please hold on to any 'backlog' of frozen specimens at this time. These will be requested shortly.**
- **All biospecimens should be logged in AFT BioMS following normal procedures.**
- **Biospecimens from multiple patients may be placed and sent in a single shipment. However, it is essential that each biospecimen is properly labeled (please see the relevant CSM) and can be specifically and uniquely linked to each participant. It is also important that all relevant paperwork (pathology reports and other forms) be included and properly labeled so that it can be associated with each unique biospecimen in the shipment.**

- Please contact the [AFT BioMS helpdesk](#) if you have any questions or concerns about this shipment process.

Updated on: June 16, 2020

- Effective June 15, 2020 the AFT Biorepository at Washington University will be entering Phase I for specimen collections and shipments on ALL AFT trials.
- PHASE I: the following SHOULD BE SHIPPED AT THIS TIME:
 - Any fresh specimen (blood, bone marrow, plasma, serum, urine, stool) collected on or after June 16,2020. Specimens should be collected and shipped per study protocol.
 - Paraffin tissue blocks, stained slides, and unstained slides should be shipped per study protocol
- The following specimens SHOULD NOT BE SHIPPED AT THIS TIME (Phase II):
 - Any specimen that was processed and stored on site per COVID-19 instructions.
- If you are uncertain as to whether to SHIP or HOLD a biospecimen, please contact the [AFT BioMS HelpDesk](#) by phone or email.