

GW COVID-19 Specimen Guidance Document

Updated May 9, 2023

The purpose of this Guidance Document is to describe the standard procedures to be followed for the collection and transport of blood, specimens and urine samples collected at the George Washington University Hospital and transported to the GW Biorepository in Ross Hall Room 119 for the COVID19 research bank. Banking of clinical specimens and data from coronavirus (SARS-CoV-2) patients and controls is critical to facilitate research to understand the pathogenesis of the virus in order to move towards improved diagnostics and therapeutics. The specimen bank is intended to be a resource to provide de-identified biospecimens to fast track immunology and virology work critically needed to end transmission of SARS-CoV-2.

Samples will be collected from confirmed SARS-CoV-2 positive patients and control patients identified at the George Washington University Hospital. The specimens will include blood, urine, oro- or naso-pharyngeal swabs, respiratory fluid, penile, anal and vaginal swabs.

RESPONSIBILITY:

Principal Investigator

The principal investigator will be responsible for the overall oversight of the study and ensuring the proper transfer of samples collected from the hospital, regulatory management and document control.

Research Coordinator

The research coordinator is responsible for consenting the patient identified as COVID19 positive and controls at the hospital, maintain regulatory documents and managing REDCap

Nurse

The nurse responsible for the patient at the hospital will be responsible for collecting the Day 1-11 samples including blood, urine and other specimens. The nurse will give the research staff the samples once they are collected.

Biorepository Associate (BA)

The BA will be responsible for receiving the samples from the coordinator and storing them in the BSL2 lab according to standard lab practices.

Other considerations

Where appropriate, the following information should be on the document:

- Consent must be obtained prior to samples being collected
- If patient is unable to provide consent, LAR must sign the consent on behalf of the patient prior to sample collection
- If patient is less than 18 years of age, an assent must be collected
- Instruction brochure should be given to the patient detailing how to collect vaginal, penile and anal swabs (See Appendix A & B)

A chain of custody must be maintained for specimen transport (See appendix C)

PROCEDURE:**Acute Sample Day 1-11**

1. The Infectious Disease attending notifies the COVID Research Coordinator of a positive hospitalized case via Tiger Text and the coordinator will add the PHI to a link file that will be kept locked in Dr. Chang's office.
2. The coordinator arrives to the hospital with a pre-assembled package including brochure, consent, sample collection supplies with numbered labels, sample transfer container and coordinates with nurse manager and nurse for passage of consent materials sharing with them the sample collection cheat sheet.
3. The coordinator calls the patient from outside the room to perform the consent.
4. Wearing the double gloves, the coordinator inspects the consents to ensure they are properly completed and signed.
5. The nurse assists in sample collection and then places all the samples into the transfer container. Meanwhile, the coordinator notifies the lab that a sample is coming so that they can label the aliquot tubes and ready the lab to receive the samples
6. He or she then sprays the outside of the sample transfer container with freshly prepared 10% bleach and allowed it to sit for 10 minutes. (Coronavirus is inactivated with 0.1% sodium hypochlorite within 1 minute (*Journal of Hospital Infection, 2020*)). The coordinator then removes one layer of gloves and wipes off the bleach solution.
7. The coordinator then removes his/her gloves and calls the lab to notify of a delivery en route.
8. The coordinator delivers the sample to the GW Biorepository Room 119 in Ross Hall where the BA will be waiting. The coordinator will not enter the lab in order to preserve PPE. The BA will be wearing an impervious lab coat, double gloves, face shield and goggles. The BA will place the sample transfer container into the BSC.
9. The chain of custody forms is completed by the coordinator and BA outside of the lab.
10. Wearing proper PPE, the BA will then remove the samples from the transfer container in the biosafety cabinet and again decontaminate the sample transfer container with freshly prepared 10% bleach with 10 minute contact time on the inside and outside of the container and return the decontaminated sample transfer container to the coordinator.
11. The coordinator will leave and enter all the patient information into REDCap.
12. The BA will follow the standard operating procedures that will be approved by the IBC for sample preparation.
13. The samples will be banked in GW Biorepository following standard GW Biorepository protocol related to inventory control with the exception of 2 15 ml conicals with urine at each timepoint and 5 ml of whole blood at timepoint 1 and 2 that will be provided to Dr. Sen's lab.

Follow up Visits (1 month, 6 months, and 12 months)



1. The coordinator will contact the patient by phone to ensure that the patient is afebrile without respiratory symptoms. The patient will be instructed to arrive to the 3rd floor clinical trials unit where the coordinator will assist in sample collection and completion of the case report form.
2. The coordinator will contact the lab technician and transfer the samples to the lab as per above

Principal Investigator:

IRB #:

[Project Title]

CHAIN OF CUSTODY

Subject ID	Date & time collected	Transported by	Received by	Date/Time Received	SPECIMEN
	Date:	Name/Title:	Name/title:	Date:	<input type="checkbox"/> WHOLE BLOOD <input type="checkbox"/> URINE <input type="checkbox"/> SWABS <input type="checkbox"/> STOOL
	Time:	Signature:	Signature:	Time:	
	Date:	Name/Title:	Name/title:	Date:	<input type="checkbox"/> WHOLE BLOOD <input type="checkbox"/> URINE <input type="checkbox"/> STOOL <input type="checkbox"/> SWABS
	Time:	Signature:	Signature:	Time:	
	Date:	Name/Title:	Name/title:	Date:	<input type="checkbox"/> WHOLE BLOOD <input type="checkbox"/> URINE <input type="checkbox"/> SWABS <input type="checkbox"/> STOOL
	Time:	Signature:	Signature:	Time:	
	Date:	Name/Title:	Name/title:	Date:	<input type="checkbox"/> WHOLE BLOOD <input type="checkbox"/> URINE <input type="checkbox"/> STOOL <input type="checkbox"/> SWABS
	Time:	Signature:	Signature:	Time:	