

Cardiovascular Innovation Institute

Cardiovascular Dynamics and Surgical Technology Laboratory

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Rm. CII 423 & 424

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Title: COVID-19 Sample Collection Kit Assembly

Document Type: Standard Operating Procedure

Purpose:

The objective of this procedure is to assemble COVID-19 culture sample collection kits.

Procedure:

Necessary Materials (to assemble 50 sampling kits; scale as needed):

Material Name	Quantity	Physical Description
Biohazard Level II Hood	1	Biosafety Cabinet, CII 424
Viral transport medium	> 150 mL	Red liquid
1000-5000 µL pipette Gilson P5000	1	Navy and gray pipette
15mL Presterilized Falcon tube (vials)	50	Conical vial with screw cap
Sterile foam tipped sample swab	50	Puritan swabs packaged in paper
Biohazard bags	50	6" x 9" Orange transparent bags
Instructions For Use labels	50	3" x 6" printed label with adhesive back
Pipetman diamond tips	5-10	Reference No. VWR76178-180
Tube holder	2-4	Holds 50 15mL Falcon tubes
Pair of clean exam gloves	2	One pair for each technician
Hairnets	2	One for each technician
Disposable lab coat with cuffed sleeves	2	One for each technician
Surgical Mask	2	One for each technician
200 mL Sterile container	1	Open container to hold viral transport medium
Biohazard waste container	1	12" x 12" x 24" container with red biohazard liner
Sample Collection Kit transport container	1	4 gallon flip-top tote

1. Execution of Process 1: Preparation of Biohazard Sample Collection Bag (lab counter, Room 424)

Step Number	Action Taken	Depiction
1.1	Gather all necessary materials.	
1.2	Cut Instructions For Use labels to size with paper cutter	
1.3	Adhere Instructions For Use label to the biohazard bag so the biohazard sign and storage indicators are visible.	

2. Execution of Process 2: Filling Falcon Tubes with Viral Transport Medium (Biosafety Cabinet, Room 424*)

Step Number	Action Taken	Depiction
2.1	In the biosafety cabinet, while dressed in PPE, set up 50 falcon tubes in a tube holder and set an empty tube holder to the side.	
2.2	Prepare viral transport medium for pipetting and loosen caps of all Falcon tubes.	
2.3	Attach the sterile Pipetman tip to the pipet. If this tip ever touches anything other than the inside of the Falcon tubes or the viral medium, discard it in the biohazard waste container and replace it with another sterile tip.	
2.4	Technician 1, draw up 3 mL viral transport fluid with the pipet.	
2.5	Technician 2, take off the lid of the first Falcon tube and hand container to Technician 1.	
2.6	Technician 1, dispense 3 mL into Falcon tube, and hand the container back to Technician 2.	
2.7	Technician 2, secure lid on the Falcon tube and place upside down on the hood countertop to check for leakage. Discard tube if leakage is observed.	
2.8	Repeat steps 2.4-2.7, until there are 50 filled Falcon tubes.	
2.9	Turn filled Falcon tubes right-side up and place into tube rack. Take rack of filled Falcon tubes to the Sampling Kit Assembly Area (hooded work bench), then dispose of pipette tip and gloves in the biohazard waste container	

3. Execution of Process 3: Filling Sample Collection Bag with All Materials (Hooded Work Bench, Room 423)

Step Number	Action Taken	Depiction
3.2	Take a labeled biohazard bag and fill it with a packaged sterile foam swab and a filled Falcon tube, then securely close the biohazard bag. Place the closed bag in the Sample Collection Kit transport container.	
3.3	Repeat step 3.2 for 50 bags.	
3.4	Once all bags are filled and in the transport container, dispose of gloves, in the biohazard waste container. Due to the current PPE shortage, if coats, hairnets, and masks are in sufficient condition to be reused, they should be saved in a labeled container and reused at a later date by the same technician.	

Maintaining Falcon Tube Sterility:

In addition to replacing contaminated tips, do not run hands or anything else over or near the open end of the tube when dispensing viral transport media. The inside cap must also say sterile. Only touch the outside of the cap. If the inside of the cap, or the inside of the tube becomes contaminated, the tube and any material inside must be discarded in the biohazard waste container. Maintaining sterility inside the tube is the most important priority.

Safety Hazards:

No sharps or virulent materials used. The PPE is for the protection and sterility of Falcon tube being used for the culture sample collection as well as protection for the technician from accidental solution splash.

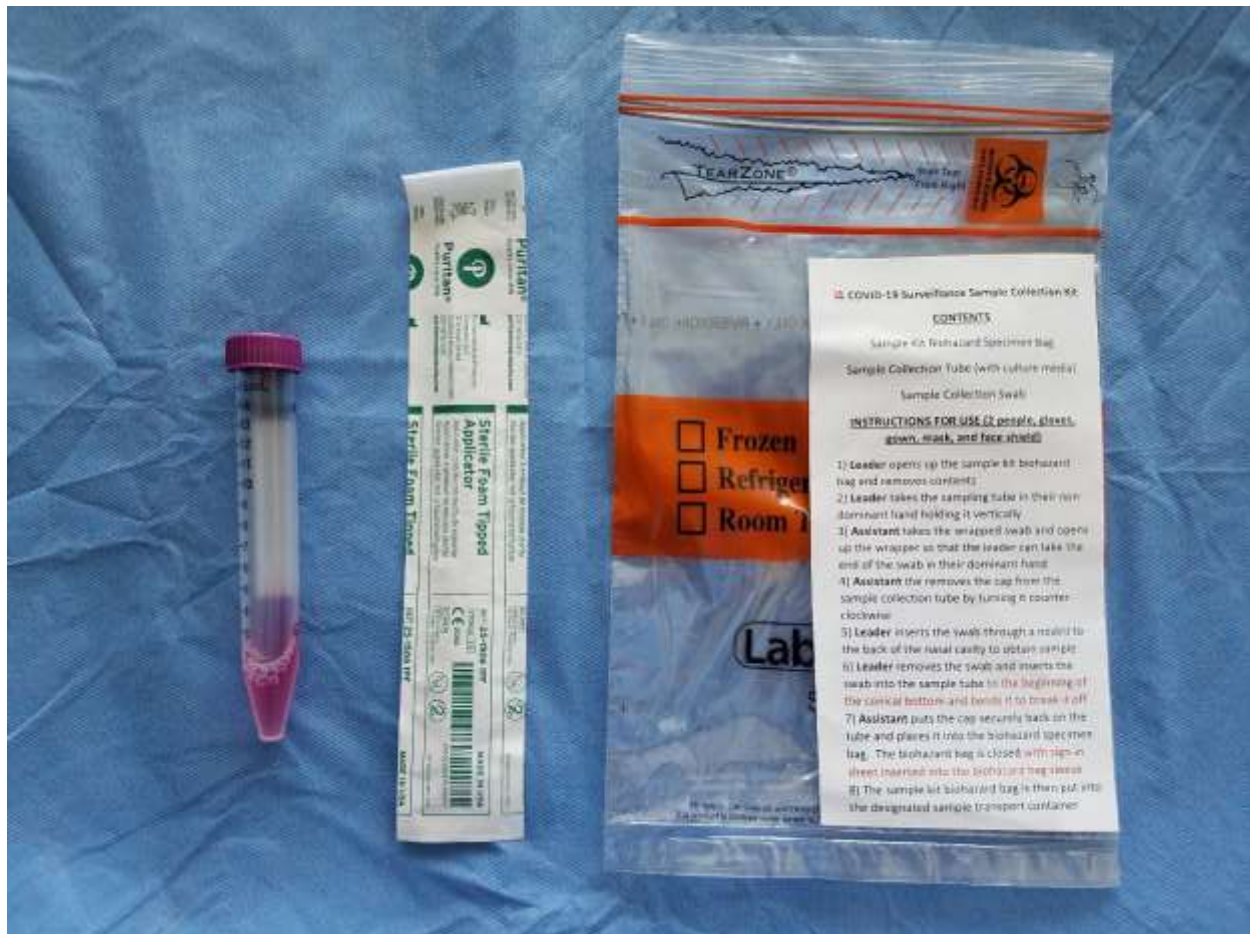
Notes:

- 1) An additional biosafety cabinet (Class II hood) is available in the CII Room 512.
- 2) The kit assembly process (tube with media and sterile swab into labeled biohazard bag) does not need to take place in a hooded bench. If additional space is needed for production scale-up purposes, it can occur on a lab countertop covered with plastic-backed absorbent material.

Document Concurrence:

Clara Jones _____ date _____

Sienna Shacklette _____ date _____



Example Sample Collection Kit including (left) the 15 mL Falcon Tube vial with 3 mL of viral transport media, (middle) sterile collection swab in sterile wrapper, and (right) the biohazard bag with Instructions For Use label attached to the right hand side of the front of the bag. A completed Sample Collection Kit has the 15 mL Falcon Tube and swab sealed inside of the biohazard bag for transport to the sampling site.