

COVID-19 Requisition and Label Preparation

NOTICE

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The testing guide below has been developed to align with guidelines provided by federal and state public health authorities. Parties adopting this guide should work with their clinical operations, environmental health and safety teams, and their state and local authorities to ensure compliance with relevant laws.

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COVID-19 Requisition and Label Preparation

1. Background

This process description describes the process for printing labels, requisitions, and assembling kits for COVID-19 testing for all franchises.

2. Scope

This process instruction applies to the printing of labels and requisitions and their assembly into kits for COVID-19 testing only.

3. Suggested Summary of Responsibilities

Function/Contributor	Responsibility
Approving Physician's Group / Test Orderer	Provides PDFs of requisitions
Kit Assembly Lead	Coordinates volunteers for the label party, has access to site requisitions and labels, prints the requisitions prior to kit assembly, prints labels prior to kit assembly, cross-checks assembled kits with manifest, communicates status with site leadership, is responsible for hand offs of assembled kits to site lock box or directly to station 2 for immediate use, and trains volunteers
Kit Assembly Team	Cut labels and organize labels into binned stacks. The onsite team is composed of volunteers and Kit Assembly Lead.
Volunteer 01	Pairs requisition with matching label and checks that requisition and label details match
Volunteer 02	Double-checks that requisition and label details match
Volunteer 03	Kits requisitions and labels, triple checks that details match
Volunteer 04	Groups kits into alphabetical sets
Site Leadership	Site Leads, Ops Lead, Planning & Logistics Chief

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4. Terminology

Term/Acronym	Definition
DOB	Date of birth
Hot Zone	Area of site where participants in vehicles lower window and potentially expose workers to contamination. For our purposes 'Hot Zone' refers to the area surrounding and including Station 3 (Sample Collection Station).
Kit	A requisition and at least three copies of a label in a specimen bag
Pat #	Participant number
Req #	Requisition number
SPII	Sensitive Personal Identifiable Information

5. Materials

5.1. Equipment

- 2 laptops
- 2 label printers
- 2 Laser printers, minimum 4,000 page monthly duty cycle, connected by USB, prints to letter size paper
- 2 Scissors
- 2 Shredding bins
- 2 Barcode scanners
- 2 USB 2.0 Travel Hubs

5.2. Consumables

- Labels for label printer (stable to -80 °C)
- Label printer ink ribbon
- Appropriate toner cartridge
- Letter sized plain paper
- Specimen bags (e.g., ULIN-S2968)
- Paperclips
- Manilla folders
- Hanging file folders
- Rubber bands
- Alcohol wipes

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6. Setting up Labeling Capabilities

6.1. Onboarding Kit Assembly Leads

- 6.1.1. A site needs to identify 2-3 people to become Kit Assembly Leads - it will be required to have one onsite per day and the day prior to any appointments. Access to SPII should be limited to these individuals. These individuals need to be trained appropriately for their role.
- 6.1.2. The Site Lead will need to determine how lab requisition and label data will be transferred to the Kit Assembly Leads.

6.2. Kit Assembly Station Set Up

- 6.2.1. Printing Station will be set up by the IT and site ops team. Since printing is a critical site work stream it is imperative to have duplicate Printing Stations as a contingency plan should any equipment fail. The printing station should be located **outside** the hot-zone and distanced from patient flow so that non-PPE donned volunteers can support kit assembly. The printing station is comprised of:

- 2 - Laptops

- 2 - Label printers

- 2- Laser printers, minimum 4,000 page monthly duty cycle, connected by USB, prints to letter size paper

- 2 - Scissors

- 2 - Shredding bin

- 2 - Barcode scanners

- 2 - USB 2.0 Travel Hubs

- 6.2.2. Site ops will need to set up a Kit Assembly Station. The Kit Assembly Station consists of long lines of tables to support an assembly line of volunteers with appropriate social distancing. These tables should be covered in plastic sheets to facilitate a daily wipe down following kit assembly.
- 6.2.3. Have Label Stations set up at least 6 feet apart for social distancing.
- 6.2.4. Assign Label Station #s to each Label Station.
- 6.2.5. At Label Station 2 and Label Station 5, spread out and place laminated alphabet signs: "ABCD", "EFGH", "IJKL", "MNOP", "QRST", "UVWXYZ". Give enough space to allow for stacks of folded requisitions.

Table 1. Label Station # Breakdown	
Label Station #	Responsibilities
Label Station 1	Fold Requisitions & Cut Labels

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Label Station 2	Organize Labels by Alphabet Bins and Match Reqs with Labels
Label Station 3	Double Check Matched Reqs with Labels
Label Station 4	Triple Check Matched Reqs with Labels & Bag
Label Station 5	Kit Assembly Lead Scan Barcodes to Check List and Bagged Reqs

6.3. New Pop-Up Printing Site Test Checklist

- 6.3.1. To complete setup of the Printing Station, the Kit Assembly Lead must test printing of Reqs and Labels in bulk.
- 6.3.2. Following the site-specific printing process, the Kit Assembly Lead will bulk print sample requisition files.
 - 6.3.2.1. Kit Assembly Lead visually inspects printed requisitions to ensure that they are all printed accurately.
 - 6.3.2.2. Kit Assembly Lead checks that the right number of requisitions is printed.
- 6.3.3. Following the site-specific label printing process the Kit Assembly Lead will print labels using sample label data.
 - 6.3.3.1. Kit Assembly Lead visually inspects printed labels to ensure that they are all printed accurately.
- 6.3.4. Kit Assembly Lead checks if the barcode scanner is working appropriately by scanning a sample barcode (eg, on a sample requisition). Ensure that Carriage Return/Line Feed is enabled, if appropriate.

6.4. Volunteer Requirements for Kit Assembly Team

- 6.4.1. Kit Assembly Leads will need to train sufficient volunteers to support their site's capacity. We've found 50 assembled kits / hr per 1 assembly team (4 people) is a course approximation for kit assembly throughput.

6.5. Training Kit Assembly Team

- 6.5.1. Kit Assembly Lead will ensure the 5 stations are set up [Section 6.2].
- 6.5.2. Kit Assembly Lead will explain the responsibilities at each of the stations [Section 7.4 through 7.5].
- 6.5.3. Kit Assembly Lead will perform a demonstration of daily kit assembly [Section 6.3] using the sample requisition and label files.
- 6.5.4. Kit Assembly Lead will have their volunteers assemble test kits using the dummy requisition and label files and ensure each volunteer performs the responsibilities at each of the stations correctly.
- 6.5.5. Kit Assembly Lead will practice scanning the requisition barcodes into the barcode matching sheet [Section 7.6]

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7. **Daily Kit Assembly** - Kits are prepared in bulk following appointment lock to ease day-of operational burden and facilitate increased participant throughput.

7.1. Preparation

- 7.1.1. Kit Assembly Lead logs in to the computer with credentials.
- 7.1.2. Kit Assembly Lead downloads the PDFs of requisitions for printing.
- 7.1.3. Kit Assembly Lead downloads the appropriate site label sheet as an `Excel Sheet (.csv)`.
- 7.1.4. Label export files generally need to have the following columns (confirm with testing laboratory):

Collection Date: MM/DD/YYYY

Name: Last, First (Identical to the requisition)

DOB

Req #

- 7.1.5. Kit Assembly Lead ensures the laser printer has toners and paper and the label printer has toner and labels.
- 7.1.6. Kit Assembly Lead prepares alphabetical bin hanging folders for each site for the day (ie. "ABCD", "EFGH", etc.)
- 7.1.7. The whole kit assembly team can help to open the ziplock specimen bags in preparation for kitting.

7.2. Print Requisitions

- 7.2.1. Note all printing should be in black and white.
- 7.2.2. Kit Assembly Lead prints PDFs of the downloaded requisitions using the laser printer.
- 7.2.3. Kit Assembly Lead checks if any requisitions were printed twice.
- 7.2.4. Any duplicate requisitions are placed in the shredding bin.

7.3. Print Labels

- 7.3.1. Note all printing should be in black and white.
- 7.3.2. Kit Assembly Lead creates labels using the template on the label printer software. (If printing for multiple sites, print labels by site.)

7.4. Prepare and match requisitions and labels

- 7.4.1. At Label Station 1:
 - 7.4.1.1. Whole team folds requisitions in half with the information facing up.
 - 7.4.1.2. Kit Assembly Lead splits labels into manageable sleeves of labels. Team members take a sleeve of labels, cut labels to separate by participant with at least 3 labels per participant, all on one sheet. Do not separate the

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multiple labels for a single participant; keep these together on a single sheet.

7.4.2. At Label Station 2:

7.4.2.1. Ensure this Label Station gets twice the space of the other Label Stations.

7.4.2.2. Whole team organizes requisitions and labels under the appropriate alphabet group based on the last name.

7.4.2.3. Volunteer 01 matches each requisition with the same participant's label set. Use a paperclip to clip together the label and the requisition and then hand it over for Volunteer 02 to review.

7.4.2.4. **Check 1:** As you are matching up the label and requisitions check for the following information:

Name

DOB

Req #

7.4.2.5. If all of these are matched correctly, hand off to Volunteer 02 for Check 2.

7.4.2.6. If these are not matched correctly, identify what is wrong (e.g., DOB mismatch). Place these in a separate pile and document the mismatch.

7.4.2.7. After Volunteer 01 completes their tasks, they should assist Volunteer 03.

7.4.3. At Label Station 3:

7.4.3.1. Volunteer 02 double checks each requisition is matched up with the participant's label.

7.4.3.2. **Check 2:** Check the requisition and label match for the following:

Name

DOB

Req #

7.4.3.3. If all of these are matched correctly, hand off to Volunteer 03 for kitting.

7.4.3.4. If these are not matched correctly, identify what is wrong. (e.g., DOB mismatch) Place these in a separate pile and document the mismatch.

7.5. Place kit requisitions and labels in specimen bag

7.5.1. At Label Station 4:

7.5.1.1. Volunteer 03 confirms that requisitions and labels match (check 3) *for each kit* and then assembles the packet.

7.5.1.2. **Check 3:** Check the requisition and label match for the following:

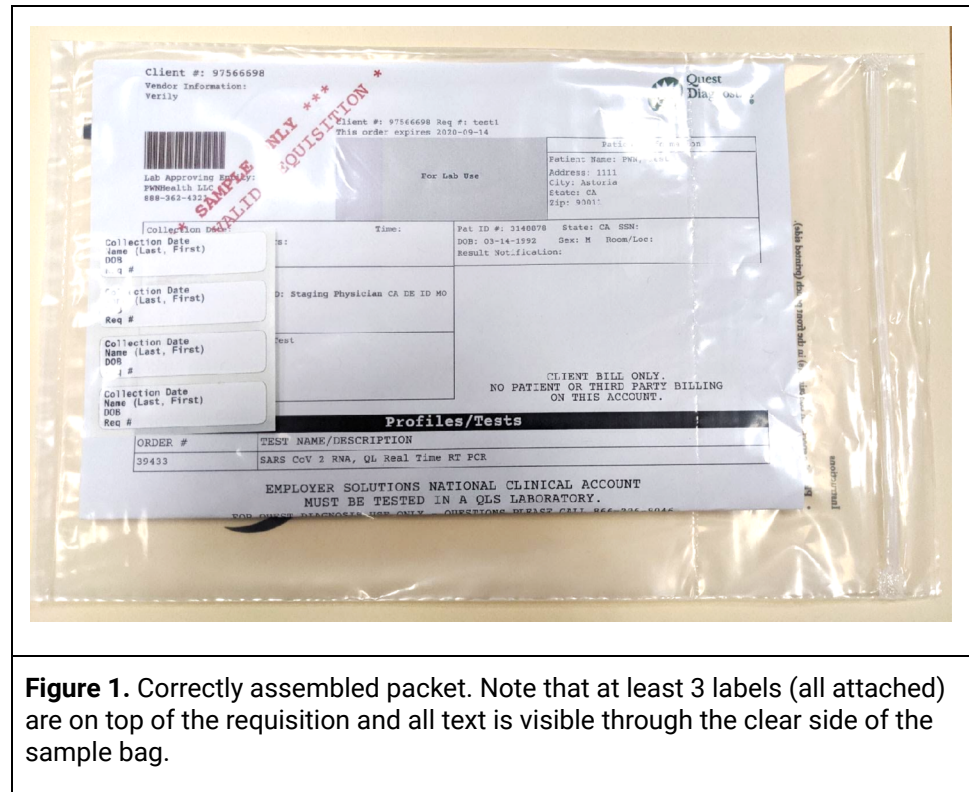
Name

DOB

Req #

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- 7.5.1.3. If any is not matched correctly, identify what is wrong. (e.g., DOB mismatch). Place these in a separate pile and document the mismatch.
- 7.5.1.4. Remove the paperclip from paper and label.
- 7.5.1.5. Place the requisition and label into the rear pocket of the specimen bag. The barcode needs to be in the bottom corner with the information facing outward on the clear side of the bag (**Figure 1**).



- 7.5.1.6. Kit assembler places the label into the same pocket on top of the requisition, so that it is visible on the clear side of the bag. Position the label in a place in which it does not block the barcode.
- 7.5.2. At Label Station 5:
 - 7.5.2.1. Volunteer 04 will group kits under the appropriate alphabetical sign based on last name.
 - 7.5.2.2. If others are done, help organize each stack of kits into alphabetical bins based on last name.

7.6. Match kits against export list

- 7.6.1. Once all requisitions and labels have been kitted, they need to be checked against the export list.
- 7.6.2. **Check 4:** Kit Assembly Lead copies the list of Pat #s from the manifest into the barcode matching spreadsheet then uses a barcode reader to scan the barcodes on each requisition to extract Pat ID #s into the spreadsheet and check for missing requisitions.

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7.7. Resolve mismatched kits

- 7.7.1. If any mismatched kits have been set aside in the separate pile during Checks 1 - 4, please contact Verily Call Center Support to resolve them.

7.8. Alphabetize and file the kits

- 7.8.1. Place each organized set of kits into the appropriate hanging folder based on the last names: "ABCD", "EFGH", "IJKL", "MNOP", "QRST", "UVWXYZ" by last name.
- 7.8.2. Make sure to maintain the alphabetical order within each stack of kits in the hanging folder. Place the full deck of hanging folders with all its content into a manila folder and wrap a rubber band over it to prevent content from falling out.
- 7.8.3. The kits contain SPII which needs to be secure and maintain a clear chain of custody. If stowing kits for the next day, the Kit Assembly Lead is responsible for placing the full set of folders into the site lock box. If the kit has been assembled for same day appointments, the Kit Assembly Lead is responsible for ensuring the kit(s) reach the plastic filer at Site Station 2.
- 7.8.4. Kit Assembly Lead is responsible for confirming with their Site Leadership that labeling for the next day has been successfully completed.
- 7.8.5. Assembled kits are used for sample collection as outlined in the **COVID-19 Participant Workflow** and **COVID-19 Sampling Collection and Transfer**.

8. Emergency Printing

- 8.1. If there is a need to print an emergency requisition, the Patient Data Specialist or Kit Assembly Lead will work with the Site Leadership to identify the one off requisition and label which need printing and will follow previous instruction [Section 7], to assemble a kit for the individual participant.

9. Post Printing Cleanup

- 9.1. After all requisitions and labels are successfully printed, the Kit Assembly Lead must remove the files from the laptop.
 - 9.1.1. Delete participant .csv file by selecting and pressing 'Shift + Delete' on the keyboard.
 - 9.1.2. Delete participant req .pdf files by doing the same.
- 9.2. When done with printing, the Kit Assembly team disinfects the reusable kit assembly station material with alcohol wipes.

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Appendix A: Flow chart of Req and Label Preparation

