

TEMPUS

SalivaDirect™ At-Home Collection Kit Ordering Playbook

Tempus is Yale's supplier for SalivaDirect's™ At-Home Collection Kits. Tempus is responsible for providing packaged kits to labs to sell, distribute, and process. Each lab is responsible for marketing to customers, distributing the kits to their customers, processing patient samples, and delivering results in accordance with Yale's EUA authorizations. Yale is responsible for questions about or maintenance of the assay.

Before you place your first kit order

1. Create a Kit Activation Form website

- This is the website where your patients will be instructed to activate their kit before specimen collection. This activation form must include the following components to allow for specimen processing.
- Required fields:
 1. Specimen barcode ID
 2. Patient date of birth (as secondary specimen identifier)
 3. Date, time, and timezone of collection
- Additional Recommended fields:
 1. Patient name or identifying information
 2. Patient email address
 3. Image of where the patient can find the specimen barcode
 4. Instructions to mail back specimen
 5. Should integrate with your lab information system



1. ACTIVATE YOUR KIT

Before collecting your sample, activate your kit online using the link on the activation card. Follow the instructions on the page to fill in the necessary contact information to tie your sample to your results.

2. Create patient support resources, including a website, phone number, and an email support line. This will be included on the Activation Card (*see Appendix 1*), which is in each kit sent to the patient.

3. Confirm Fulfillment Center partnership: We recommend partnering with a fulfillment center to distribute kits to patients.

- [ALOM](#) is Tempus' partner for kit distribution. If you are interested in using them for your kit distribution, please contact Tami Strickland at tstrickland@alom.com.
- If you already have an established relationship with a fulfillment center, you can continue working with them.

4. **Confirm that you have a FedEx Express account for the return shipments of samples back to your lab. Outbound kit shipment to patients can be done using any carrier.** Note: you will need to work with your FedEx representative to obtain the legal addendum for shipment of At-Home collection kits and UN3373 Paks (Part Number 163034) for the number of kits you would like to order.

Ordering Kits

5. **Complete the Tempus Kit Order Form at sd-onboarding.securetempus.com to initiate your kit order.**
6. **Once complete, Tempus will reach out with the following steps, including confirming Activation Card details (see Appendix 1) and the FedEx Return Label (see Appendix 2) creation process.** We anticipate 3-4 weeks* from order placement until kits are shipped out to your lab or your fulfillment center. The timeline will depend on several factors, including how quickly each lab can confirm activation card design, and provide us Fedex Return Labels & UN3373 Paks.

*Orders placed immediately following authorization (April 2021) may require an additional 1-2 weeks for fulfillment.

Reordering Kits

7. **Submit your next order using the same form link sd-onboarding.securetempus.com.** If you are using the same support contact, fulfillment center, and activation link as the first order, we anticipate it will take 1-2 weeks to ship your re-order. When you reorder, we will assemble your additional kits using the same activation card, billing, and shipping information from your initial order. If you need to change any of this information, contact sd-onboarding@tempus.com, and please be aware that it will be considered a new order and follow our 3-4 week lead time.

Billing

When you order kits, you will be asked to provide necessary billing information such as legal name, billing address, and accounts payable contacts. You will have the opportunity to provide a Purchase Order (PO) number and upload a copy of the PO if one is required to be referenced on your invoice. Tempus Labs will send invoices after your order is shipped and must be paid within 30 days of invoice receipt. Please see the Terms and Conditions in the ordering form for specific information. Please send any billing-related questions to ar@tempus.com.

Distribution to Patients

Tempus is not responsible for distribution to patients. Labs should work with their fulfillment centers to develop a process to send kits to patients.

Some components to consider for the distribution of kits to patients:

- Shipping Carton: The kit will need to be sent out in an outer corrugated cardboard box. This box's costs can vary from \$0.40 to \$0.75 per item, depending on the number of boxes purchased.
- FedEx Label: You will need to print a shipping label to deliver kits to patients. The fulfillment center will affix this label to the shipping carton outlined above with the patient's name and address.
- ALOM has an API so you can set up an integration to automatically trigger a kit shipment when a provider places an order. (This is only available to labs that utilize ALOM for patient order fulfillment).

Frequently Asked Questions

How many kits can I order at a time?

You can order kits in the following quantities:

- 2.5k
- 5k
- 10k
- 25k
- 100k

Note: if you order 10k or more kits, Tempus can store them and ship a specified quantity to your Fulfillment Center on a monthly cadence.

Can my lab assemble our kits?

No. Tempus Labs must assemble SalivaDirect™ At-Home Collection kits.

What is included in a kit?

Please review the SalivaDirect™ At-Home Collection kits card insert for specific components. Parts and sample photos are listed in Appendix 3.

Why do we need custom activation cards and an activation form?

The activation cards include two key important pieces of information:

- The activation link for sample collection details that are needed for specimen processing
- Lab specific support information to help patient's answer any questions about the kit, including how to use it, how they send it back, and how they can see their results.

The information on the activation card has been agreed to by the FDA and cannot be changed or altered. If your lab has already created a design for the activation card, please contact sd-onboarding@tempus.com.

Can we use a different shipping provider (i.e., UPS or USPS)? How do we get shipping labels from FedEx? Is the pricing pre-negotiated?

You need to use FedEx for the return labels and UN3373 Paks (Part #163034) for the SalivaDirect™ At-Home Collection kits going from the patient back to the lab. Your Fulfillment Center will be able to help you source and send Tempus the return labels and UN3373 Paks so they can be pre-packaged into your ordered kits. It is up to you to contract your shipping costs with FedEx. The outbound shipping (from the lab to the patient) can be done with any freight vendor.

How do we get the kit back from patients?

While your lab is responsible for the distribution and processing of kits, your kits will be sent back to your lab for testing via the Fedex return label your Fulfillment Center of choice sends to our ALOM assembly team. These return labels will be pre-affixed to the FedEx UN3373 Pak, both of which are provided by your fulfillment center, as indicated in the FDA EUA.

How do I get a Fulfillment Center? How much does it cost?

While your method of distribution is up to you, we recommend using ALOM to send kits out to patients. Please contact Tami Strickland at tstrickland@alom.com for more specific information and pricing details.

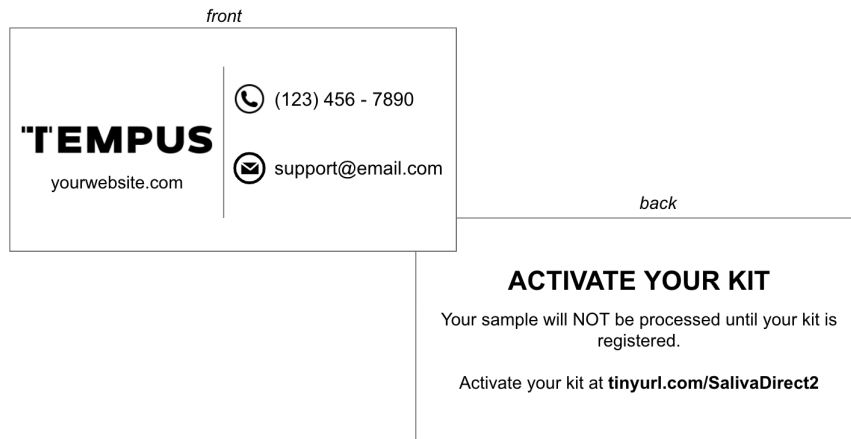
How do patients register their kits? How will they receive results?

Patients will register their kits using the link on the provided activation card. You are responsible for the activation process and delivering the test results to patients. Tempus Labs is solely the distributor of the physical kits.

Appendix 1: Lab Activation Card

Provide information for your Lab's Activation Card in the kit order form:

- These cards are included with each test kit and have your lab branding and the link to your specific Kit Activation Form.
- Once complete, Tempus will send you proof of the card to review and approve.

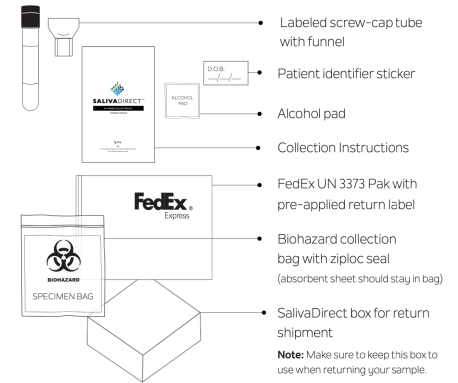


Appendix 2: FedEx Return Label and UN3373 Paks

Each lab is responsible for sourcing the FedEx return labels and UN3373 Paks, which will be packed into each kit. After the patient collects their sample and puts it in the box, the box is placed into the Pak and dropped off at a FedEx location.

- **For Labs using ALOM:** To print the return labels, work with ALOM to set up an InfoShip account and pre-print labels for order quantity. To source the UN3373 Paks, please reach out to your FedEx representative.
- **For Labs using their own Fulfillment Center:** To print the return labels, work with Fulfillment Center to create FedEx return labels and send them to ALOM for kit assembly. To source the UN3373 Paks, please reach out to your FedEx representative. Labels and UN3373 Paks should be sent to the address below and include a packing slip with part number and order quantity.

COMPONENTS



Attn: Melissa Nguyen (For Tempus Labs)
ALOM
48105 Warm Springs Blvd
Fremont CA 94539

Appendix 3: Kit Materials & Components

The **SalivaDirect™** At-Home Funnel Collection Kit includes

- SalivaDirect™ box
- Printed materials (Instructions for Use, Card Insert, Activation Card)
- 5 mL Nest tube with Medline funnel
- Biohazard bag with an absorbent sheet
- Alcohol prep pad
- Patient identifier sticker
- FedEx UN3373 Pak with the pre-applied return label

Photos below are for a sample kit and do not contain all labeling and details on the final kits.

