

Hello!

Here are brief instructions on how to use this kit to transfer and send your sample of plasma to Delve Bio. For more details, please visit www.delve.bio/start

Warnings, Precautions, and Safety Information

Read all instructions carefully before performing sample collection and transfer. Failure to follow these instructions may result in inaccurate test results.

For use as a laboratory developed test only.

Treat all biological material and used kit supplies as contaminated and potentially hazardous.

This sample transfer kit and instructions should only be applied to the Delve Detect laboratory developed test.

Do not use this kit past its expiration date (the expiration date is printed on the kit box).

Do not use this kit if any of the components or packaging are damaged or missing.

Do not mix or interchange any components from other Delve kits as components are uniquely barcoded for traceability.

Once opened, the kit and its components should be used immediately.

All kit components are single-use items. Do not use the components more than once, or with more than one patient specimen.

Each sample must be shipped in its own secondary safety bag and in its own kit box. **Do not ship multiple samples in the same kit box.**

The Delve Tube is pre-filled with a stabilization buffer. Do not remove or discard the stabilization buffer; it is required to stabilize the sample for shipment. Use gloves when handling. Avoid contact with skin, eyes, and clothing; avoid ingestion and inhalation. Clean up any spills with 70% ethanol. Do not use bleach with the buffer.

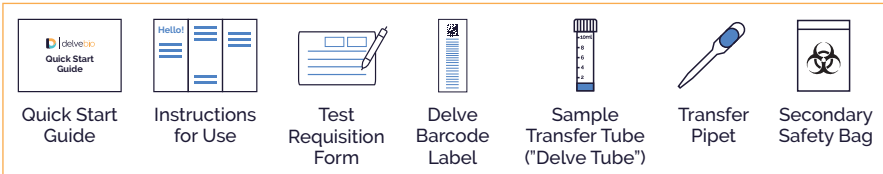
The stabilization buffer within the Delve Tube normally appears clear to yellowish in color. This variation in color is expected and does not affect performance.

Transfer the plasma specimen to the Delve Tube under clean and, if possible, sterile conditions. Specimens should be handled with gloves and appropriate PPE, and kept free of environmental contamination.

Ensure that the Delve Tube is closed tightly. Place the tube into the secondary safety bag and securely seal the bag prior to shipping.

Kit Box Components

Your Delve Detect kit contains the following components:

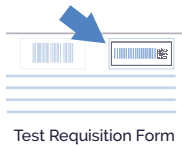


Assemble Materials

1. Gather a new, unopened Delve Detect kit box.
2. Remove the tamper-evident, plastic wrapping. Remove the kit box from the sleeve. Dispose of the wrapping and sleeve.
3. Open the kit box and place the plastic compartment pouch on a clean and if possible, sterile surface.
4. Unfold the compartment pouch to reveal its components, including the Test Requisition Form in the left pocket.

Complete the Test Requisition Form

5. Before transferring the specimen, please complete the Test Requisition Form.
6. Remove the Delve Barcode Label that is attached to the compartment pouch (inner, left pocket). Affix the Delve Barcode Label to the top of the Requisition Form.
7. Affix your institution's specimen ID label to the top of the Test Requisition Form AND to the Delve Tube. Please affix the labels in the locations indicated by the dotted lines. **DO NOT COVER** the barcode on the Delve Tube.



Transfer Specimen to Delve Tube

8. After completing the Test Requisition Form, put on appropriate gloves and PPE and prepare to transfer the specimen.
9. Retrieve the patient specimen and verify that the patient information on the specimen matches the Test Requisition Form and Delve Tube.
10. Remove the Delve Tube from the compartment pouch. Gently tap the bottom to ensure the buffer is at the bottom of the tube.
11. Place the Delve Tube in the built-in tube holder located on the flap of the kit box (highlighted with a yellow ring). Alternatively, you may use your own tube holder/rack.

12. Uncap the Delve Tube.
13. Remove the transfer pipet from the plastic pouch. *NOTE: the pipet is auto-metered to transfer 1 mL of sample; please squeeze the pipet bulb completely when withdrawing the sample.*
14. Use the transfer pipet to withdraw 1 mL of plasma from the patient sample and transfer into the Delve Tube. Please only transfer 1 mL. Requests for testing volumes < 1 mL require review and approval by Delve Bio ((844) 221-7423 or support@delve.bio). Samples received with excess volume (>1.5 mL plasma) will not be accepted.
15. After transfer, dispose of the transfer pipet in the appropriate waste container.
16. Cap and screw the cap tightly onto the Delve Tube.
17. Place the Delve Tube (containing specimen) into the provided safety bag. Seal the safety bag securely.



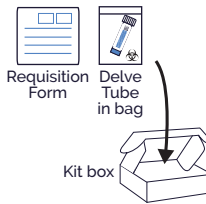
Send Test Requisition Form

18. Prior to shipping the sample, please **FAX** the completed Test Requisition Form to Delve Bio (**1-833-556-5216**).



Ship the Sample to Delve

19. Place the sealed safety bag (with Delve Tube) and the completed Test Requisition Form in the kit box. These TWO items should be the only items remaining in the kit box. All other items may be disposed of.
20. Seal the kit box by removing the cover strip at the bottom of the box, which exposes the adhesive tape.
21. Close the kit box and **PRESS FIRMLY** along the tape to ensure the kit box is sealed. The kit box will serve as the packaging to ship your sample to Delve Bio and is already pre-addressed with a prepaid shipping label that is attached to the exterior of the box.
22. Deposit the kit box to your appropriate shipping pickup location.



Questions? For support, contact us at 1-844-221-7423 or support@delve.bio

Specimen Requirements

Specimen	Plasma	
Specimen Volume	The minimum aliquot volume of plasma is 1 mL.	
	<i>We recommend only 1 mL of plasma is transferred; Requests for testing volumes < 1 mL require review and approval by Delve Bio. Samples received with > 1.5 mL plasma will not be accepted.</i>	
Transfer Container	Sample transfer tube ("Delve Tube"), which contains 1 mL stabilization buffer.	
Specimen Collection and Handling	In all settings in which samples are collected and prepared for testing, laboratory and health care personnel should follow current recommended aseptic or if possible, sterile techniques, including:	
	Perform sample collection and transfer in a clean area.	Only use the sterile pipets and tubes provided by Delve in the sample transfer kit; do not unwrap the pipet until it is ready to be used.
	Wear gloves when handling samples.	
	To reduce the risk of sample contamination, avoid touching or breathing directly on tubes, pipet tips, or surfaces that may contact the sample.	When opening sample tubes, place the cap with the opening facing down on a decontaminated surface. Cap the tubes after specimen transfer to prevent microorganisms and airborne contaminants from gaining entry.
	Perform the specimen transfer as rapidly as possible to minimize contamination.	
	Take care to minimize bubbles when transferring the specimen.	Minimize the time that tops are removed from tubes containing plasma.
Specimen Preparation, Storage and Stability	<i>Preparation of plasma:</i> Whole blood collected in EDTA or PPT tubes shall be spun per manufacturer's instructions prior to transfer.	
	<i>Prior to transfer to Delve Tube:</i> Plasma can be stored ≤ 24 hrs at room temperature, ≤ 24 hours at 2-8°C, ≤ 21 days at -20°C, ≤ 180 days at -70°C. No more than 2 freeze/thaw cycles.	
	<i>After transfer to Delve Tube:</i> Samples in the Delve Tube can be stored ambient for 1 month, up to 2 months at 2-8°C, or up to 90 days at < -20°C.	
Shipping	Plasma samples must be transferred into the Delve Tube prior to shipment and sealed in the safety bag to safely transport it to Delve Bio. The stabilization buffer within the Delve tube stabilizes the sample, ensures safe shipping as a non-infectious material, and enables samples to be shipped at ambient temperature.	
	Samples not received in the Delve tube with stabilization buffer will be rejected.	
Causes for Rejection	Specimen not aliquoted into the provided Delve Tube with stabilization buffer.	Leaking specimen.
		Gross hemolysis.
	Delve Test Requisition Form is not submitted.	Inadequate volume provided.



Plasma Transfer Kit

Instructions for Use

