

BIOPSY & SHIPPING INSTRUCTIONS | USING ICE PACKS

Enclosed is an **Invitae Preimplantation Genetic Testing (PGT)** kit. Our platform uses next-generation sequencing (NGS) to detect chromosome abnormalities; it does not assess all changes within or between chromosomes. Please contact Invitae to determine if this is the most appropriate test for your patient.

For the best test outcome, please follow your laboratory's standard sterile procedures and the steps listed below. This kit and its components may be stored at room temperature prior to use. **The included ice packs must be frozen for a minimum of 24 hours prior to shipping patient samples to Invitae.**

Before sending in this kit, please ensure that the ordering medical professional (or appropriate staff) has completed the following documents:

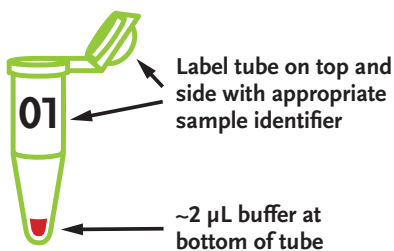
- Test requisition form (TRF)
- Biopsy worksheet form (included in this kit)
- (For PGT-SR only) A completed PGT referral form and medical review

To download these forms, please visit www.invitae.com/forms.

SAMPLE REQUIREMENTS

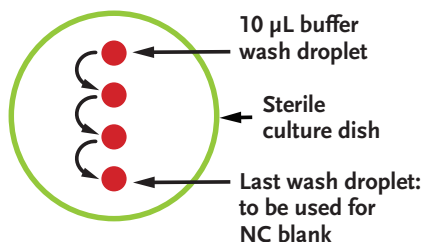
- Invitae PGT can be performed on trophectoderm/blastocyst biopsy samples **only**.
- No fresh transfers can be accommodated.
- All samples **must** arrive in the Invitae tubes (0.2 mL) provided.
- All samples **must** arrive in ~2.5 to 3.5 μ L of the Invitae buffer provided.
- All samples **must** be frozen prior to shipping and remain frozen during the shipping process. Samples stored at room temperature may render samples unable to be tested.
- All samples **must** be received within two weeks of biopsy.

Please reach out to Invitae with any questions at www.invitae.com/contact.



1. Prepare samples in a sterile environment (wipe down hood or tube loading area prior to use).

- Prepare 1 tube per biopsy sample by adding ~2 μ L of the Invitae buffer to the bottom of each tube. At room temperature, the buffer should be **RED** in color.
- Prepare 1 tube of control buffer (NC blank) to be taken from the last wash droplet.
- Please send 1 NC blank per case/embryologist/day.

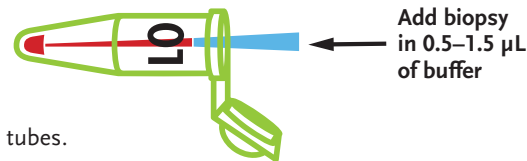


2. For each biopsy, extraneous (cell-free) DNA must be removed from the outside of the cells.

- Place 3–4 10 μ L droplets of Invitae buffer into a sterile culture dish.
- Move/wash the biopsy sequentially through each of the droplets, minimizing the volume transferred from one droplet to the next.
- Rinse the stripper/pipette tips between droplets.

3. Transfer the biopsy to the buffer on the bottom of the 0.2 mL Invitae tube.

- Using a permanent marker, clearly label the tube cap and the sidewall with the appropriate embryo # and complete the **Biopsy worksheet form** accordingly. It is suggested to label the tubes prior to loading.
- Transfer the biopsy in 0.5–1.5 μ L of the Invitae buffer.
- The color of the buffer should not change.
- Tightly close the lid: it will snap and lock.
- Once all samples and controls have been collected, briefly centrifuge or shake down all tubes.
- Samples should be placed in the rack inside the Invitae kit.
 - Affix the large Invitae barcode sticker to the outside of the rack and label with the patient's name and DOB (MM/DD/YYYY).
 - The medium barcode stickers are for any patient-related paperwork included in the shipment (e.g., Biopsy worksheet form, Test requisition form, etc.).
 - The small barcode stickers are optional and can be used to associate each tube with the appropriate kit. If using, each label should be wrapped around the tube so that it sticks to itself. Please ensure that the embryo # is visible on the tube or on the tube label.
 - Place the rack into a biohazard bag.



4. Immediately place the Invitae rack upright in a freezer.

- Invitae buffer will turn **YELLOW** to indicate that it is frozen.
- Samples may be stored frozen for up to one week.
- When ready, use ice packs provided to ship to Invitae.
- Place the ice packs in a -20 °C freezer for a minimum of **24 hours** before desired shipping date.

KIT PACKAGING

Note: When removed from the freezer, the ice packs should be frozen solid (no liquid sound or movement when removed from the freezer). Ensure all samples remain frozen prior to packing the shipper indicated by the **YELLOW** buffer color.

Small shipper (1–2 patients)

- Remove the ice packs from the freezer.
- Place 2 ice packs in the bottom of the styrofoam container.
- Place a foam insert with cutout on top of the ice packs.
- Place the biohazard bag containing the PCR rack inside the cutout. It should fit tightly in the cutout. You may ship an additional sample rack if you wish, however it is not necessary. **Ensure the rack(s) are upright in the cutout.**
- Place 3 ice packs on top.
- Place cooler lid on styrofoam container.
- Seal kit and follow shipping steps below.

Large shipper (up to 4 patients)

- Remove the ice packs from the freezer.
- Place 2 ice packs in the bottom of the styrofoam container.
- Place a foam insert with cutout on top the ice packs.
- Place 2 biohazard bags containing the PCR racks in the cutout. **Ensure the racks are upright in the cutout.**
- Place 1 ice pack on top.
- Place a foam insert with cutout on top of the ice pack.
- Place remaining biohazard bags containing the PCR racks in the cutout. **Ensure the racks are upright in the cutout.**
- Place 3 ice packs on top.
- Place foam plug on top.
- Place cooler lid on styrofoam container.
- Seal kit and follow shipping steps below.

SHIPPING

- Place the styrofoam container in the cardboard shipping box.
- Seal the kit and affix the prepaid FedEx shipping label to the box.
- Schedule a pickup by visiting [fedex.com](https://www.fedex.com) or bring your kit to your local FedEx office.
- Samples cannot be processed without:
 - Test requisition form (TRF)
 - Biopsy worksheet form (included in kit)
 - (For PGT-SR only) A completed PGT referral form and medical review
- We do not accept shipments on Sundays. Please ensure your shipment arrives Monday–Saturday, otherwise your shipment will be rejected. Please send your sample within two weeks of biopsy.
- Ship samples for overnight delivery to:
Invitae Corporation, 1400 16th Street, San Francisco, CA 94103