Verifi™ Prenatal Test

Single kit information

Test Description	Noninvasive prenatal test
Sample Type	Whole blood, venous
CollectionTube	Streck Cell-Free DNA™ BCT (See manufacturer's website for additional information www.streck.com)
Sample Volume Requirement	7.0 to 10.0 mL, single tube, standard venipuncture technique
Storage Conditions	Store kit at room temperature (18 – 30°C, or 65 – 86°F) prior to sample collection. Refrigeration is not required
Shipping Requirements	Sample must be received by laboratory within 5 days of blood draw. Ambient temperature container is provided, no ice is required. **DO NOT FREEZE THE SAMPLES**
Kit Specifications	Can hold up to ONE (1) patient sample

Instructions for use

1. Check the NIPT kit to be sure that the collection tube has not expired, and ensure that all materials are present: Non-expired Streck BCT Tube with a space for labeling, watertight Biohazard bag, absorbent sheet or other absorbent material that can absorb the full volume of the Streck™ BCT Tube in case of breakage, and test requisition form.

2. Draw blood directly into the collection tube (do not use tubing or other transfer method), and mix by gentle inversion 8-10 times. Samples received with less than 7mL will be rejected and a cancellation report will be issued.

3. Label the collection tube with TWO patient identifiers: preferably patient full name and date of birth (MM/DD/YYYY format). The 2 patient identifiers on the tube MUST match the patient demographic information as listed on the TRF, EDI submission system, or E-TRF. For EDI submissions, one of the identifiers MUST be the Client External ID.

4. Verify that the TRF has been completed with all required elements: draw date, gestational age, patient full name, patient date of birth (DOB), provider name, provider signature, and test option & pregnancy type.

5. Insert the filled collection tube into the watertight biohazard bag with the absorbent sheet, and seal the bag. Place the completed TRF into the front pocket of the biohazard bag.

6. Insert the biohazard bag into the NIPT kit. Ensure that either the package or the outer packing material is labeled as **'Exempt Human Specimen.'** If utilizing FedEx, place the kit into the FedEx Clinical Pack, and verify that the FedEx shipping label has been affixed to the FedEx Clinical Pack. If using an alternate shipping method, please confirm that alternate shipping method requirements are in place.

7. Results will be made available via the provider portal within 3-5 business days AFTER receipt of the sample.

Requirements

Shipping: Sample must be delivered to Illumina's Testing Laboratory **within 5 days of draw.** Samples received after 5 days will not be processed and a cancellation report will be issued. For shipments originating outside the U.S., Client must complete relevant commercial invoice and other customs related documentation for product entry into the USA.

FedEx: Client is responsible for delivery to Illumina's Testing Laboratory facilities. For shipments originating outside the U.S., shipment tracking number must be emailed to verifiglobal@illumina.com upon completion of shipment processing.

Shipper's responsibility: The shipper is required to comply with the rules and guidelines for transport of Diagnostic Specimens and to ensure that shipments comply with ICAO and IATA regulations.

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