



DIABETES & WOMEN'S HEALTH

A Study of the National Institutes of Health

Biospecimen Collection Instructions & Information Please Read!

We want to thank you for your participation and steadfast support of the Nurses' Health Study II and additionally for completing the Diabetes and Women's Health (DWH) study questionnaire. As you know, the DWH Study includes women, such as yourself, with a history of gestational diabetes mellitus (GDM). Part of the study will involve the collection of biological specimens including blood samples, a urine sample and a saliva sample.

All of the information you need to complete the biospecimen collection is outlined in this packet of instructions. If you have any questions related to the collection or the study, please give us a call or send us an email!

Email: nhs2dwh@channing.harvard.edu

Phone: 617-432-7214

Our office hours are Monday through Friday, EST 8:00 A.M. - 5:00 P.M. We remain on call during off hours and make our best effort to respond to urgent calls within the same business day. Please leave a voicemail. If at any point you decide not to participate, please call us before discarding your collection materials.

As always, all information collected will be kept strictly confidential and used for research statistical purposes only.

Thank you in advance for your participation!

Collection Materials

I. Forms

- a. 1 – Biospecimen Collection Instructions (this form)
- b. 1 – Research Consent Form
- c. 1 – Blood Spot, Urine and Saliva Collection Questionnaires

II. Blood Spot Collection Supplies

- a. 1 – Pair of Gloves
- b. 2 – Alcohol Wipes
- c. 2 – Band Aid
- d. 2 – Gauze Pad
- e. 2 – Blood Spot Cards
- f. 4 – Lancets (there are 2 extra lancets if needed)
- g. 2 – Lancing Devices
- h. 2 – Gauze Pads
- i. 1 – Desiccant Pack (labeled silica gel – this will be placed with your samples when shipping)

III. Urine Collection Supplies

- a. 1 – Urine Collection Cup (120ml)
- b. 1 – Towelette
- c. 1 – Pair of Gloves
- d. 1 – Absorbent Strip (250ml)

IV. Saliva Collection Supplies

- a. 2 – Saliva Collection Containers
- b. 2 – Saliva Collection Aids
- c. 1 – Pair of Gloves

V. Shipping Supplies

- a. 3 – Specimen Bags with Absorbent Material (for blood spot cards, saliva and urine samples)
- b. 1 – 4 Pocket Absorbent Sheet (for 2 saliva containers)
- c. 2 – Gel Packs
- d. 1 – FedEx Preprinted Return Airway Bill (prepaid)

Collection Instructions

**** Read through this entire instruction packet prior to collecting any samples****

1-2 Days *Before* Your Sample Collection

1. **Plan to collect and ship your samples Monday – Thursday.** FedEx does not pick up on Saturday, Sunday or national holidays. In addition, the lab is unable to process samples received during the weekend.
2. **If you need to collect your samples during the weekend** - Put the samples in the refrigerator and send the samples on Monday morning.
3. **Freeze Gel Packs** - Put the gel packs into the freezer overnight or 2 days prior to collection.
4. **Dental Work** - If you had dental work or a dental injury within 24 hours of scheduled saliva collection, please reschedule the entire collection for another time.
5. **Illness** - If you have cold or flu-like symptoms, please wait to collect your samples.
6. **Call FedEx** - Call FedEx to arrange for FedEx pickup. Return shipping postage has been paid. They can pick up from your home or work. Call 1-800-463-3339 (1-800-GO-FEDEX) and dial 0 to speak with an operator. Tell the operator that you are shipping via **Priority Overnight** method using a **billable stamp** and give them the address where you would like the pick-up to be made. You may also drop off your parcel at a manned FedEx location, which can be found by calling FedEx or visiting <http://www.fedex.com>. You do not need to make prior arrangements to drop off your samples.
7. **Read through the Research Consent Form (included in this packet)** - This form explains the procedures involved in the study, potential risks and benefits to you, and information about confidentiality. It is essential that you sign and date the consent form and return the form with your samples.

The Day *Before* Your Collection – Sample Collection Reminders

- Eat a small meal no later than 10 PM the day before you collect your samples.
- Following the small meal, if your health permits, we recommend you not eat or drink (except water) the day before collecting your samples. **You should be fasting for 9-10 hours before collecting your samples.**
- We recommend you not be physically active from 10 PM the day before collecting your samples.
- If you have cold or flu-like symptoms, please wait to collect your samples.
- If you had dental work or a dental injury within 24 hours of the saliva collection, please collect your saliva and other samples another time.

On The Day of Your Sample Collection

Urine Collection

We recommended that your urine sample is a first morning void. If you forget to collect a first-morning urine sample, a sample collected later in the day is also valuable.

1. Wash hands thoroughly with soap and water.
2. Using the sanitary towelette provided, cleanse the genital area well, passing the towelette from front to back.
3. Remove the urine container from packaging and remove the lid. Be careful to not touch the inside of the container or lid.
4. Start to urinate directly into the toilet. Stop, position the container, and collect the mid-stream urine specimen. Do not touch the container to the genital area. Do not fill to the top.
5. Void any additional urine into the toilet. Secure the lid tightly on the container.
6. **Refrigerate!** Place the specimen cup in the refrigerator (face up) until you are ready to ship your samples.
7. Complete the urine collection questionnaire included in this packet of information.
8. **Shipping** - When you are ready to ship all of your samples, refer to the shipment instructions on the last page of this packet.

Saliva Collection

If you had dental work or a dental injury within 24 hours of scheduled saliva collection, please reschedule the collection to another time.

Avoid vigorous physical activity or smoking for at least 30 minutes before saliva collection.

Avoid brushing or flossing your teeth or undergoing other oral hygiene/cosmetic procedures (e.g. using mouthwash, teeth whitening strips) within 45 minutes prior to saliva collection.

- 1. Rinse Mouth.** Before collecting the samples, use cold water to rinse your mouth three times for 20 seconds each time (Note: DO NOT use mouthwash or other oral hygiene products, such as LISTERINE®).
- 2. Wait at least 10 minutes after rinsing** before collecting saliva, to avoid sample dilution.
- 3. Fill saliva container.** You will use the saliva collection container and the saliva collection aid to collect your saliva sample.
- 4.** Remove the cap from the saliva collection container.
- 5.** Remove the saliva collection aid from packaging and place securely into the saliva collection container (see picture).
- 6.** With head tilted forward, drool through the saliva collection aid to collect saliva in the saliva collection container. DO NOT blow into the saliva collection aid. It may help with the saliva flow if you imagine that you are chewing your favorite food, and move your jaws as if you were chewing that food. It may take 15-20 minutes to completely fill the saliva collection container.
- 7.** Carefully fill the container with saliva to the **top of the label** without bubbles. If bubbles build up, tap the bottom of the tube a few times on a hard surface to remove bubbles.
- 8. Close saliva container.** Securely place the cap onto the saliva collection container.
- 9.** Repeat steps 3-5 to collect the second saliva sample.
- 10. Refrigerate!** Place the saliva samples into the refrigerator until you are ready to ship your collection.
- 11.** Complete the saliva collection questionnaire included in this packet of information.
- 12. Shipping** - When you are ready to ship all of your samples, refer to the shipment instructions on the last page of this packet.

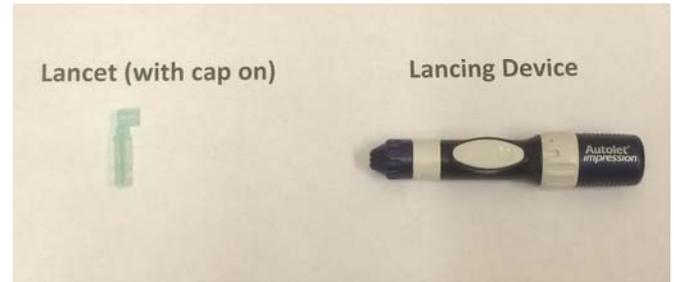


Dried Blood Spot Collection

Plan to collect your blood in the morning when you are fasted (no eating or drinking, except water) for at least 9-10 hours.

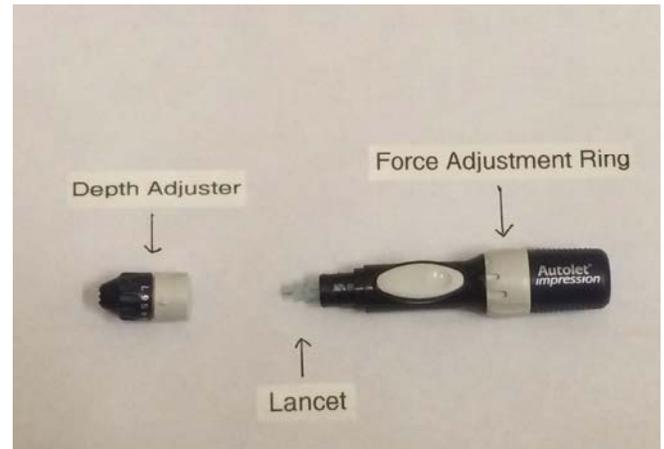
Lay out the collection supplies in front of you on a tabletop or counter.

Read all the instructions provided below before proceeding with the dried blood spot collection.



1. Select a finger from either hand. We recommend not using your index finger.
2. Wash and dry your hands thoroughly.
3. Open the lancing device package. You do not need the clear plastic cap that is included in the lancing device package.
4. With the depth adjuster of the lancing device removed (see picture below), insert the lancet. Once the lancet is fully inserted, remove the safety cap from the lancet (turn and pull cap straight up – do not snap off). **Save the lancet cap for recapping the lancet after you have completed the collection.**

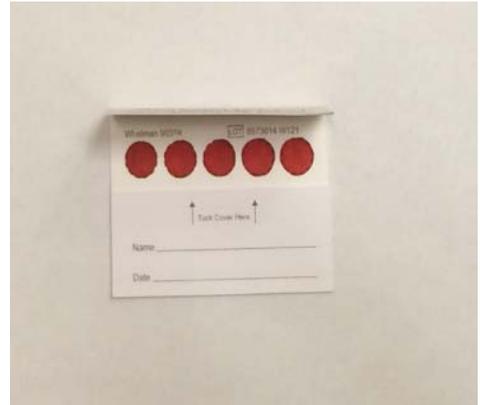
5. Replace the depth adjuster to the top of the lancing device. Set the depth of the lancing device by turning the depth adjuster to 4 unless you are familiar with the device and have a preferred setting. Next, set the force of penetration by turning the force adjustment ring to the middle or 2nd arrow unless you are familiar with the device and have a preferred setting.



6. Hold the main body of the lancing device and pull the cocking mechanism firmly until you hear a click.
7. Massage the finger to allow blood to come to the surface while holding the hand below the waist level for 30 seconds.
8. Place the hand palm side up on a flat surface. Use an alcohol wipe to clean your finger. Let the alcohol dry completely.
9. Position the lancet on your finger pad at the 3 o'clock or 9 o'clock position of your fingerprint and press down firmly. When ready to penetrate the skin, press the gray button on the lancing device.
10. The blade will puncture the skin. Put aside the lancing device.

11. Holding hand downward, gently milk the finger from the palm to the fingertip to produce blood.
12. Wipe away the first drop of blood with a gauze pad.
13. Apply gentle pressure to the finger and allow a second, larger drop of blood to collect at the puncture site.

14. Gently touch the accumulated drop of blood on one spot on the card and allow a sufficient quantity of blood to soak through and fill or saturate a full circle. Do not apply blood more than once in the same circle. Apply drops to one circle and then move on to the next, do not go back.



15. Repeat for each of the other spots or until you have collected enough blood to fill at least 3 circles on the blood collection card. **We need you to fill all circles fully if possible but three complete circles are better than five incomplete ones!**

16. Apply bandage to stop bleeding.

17. **Disposal** - Recap the lancet while the lancet is still in the lancing device. Next, replace the depth adjuster to the lancing device. Dispose of the used lancet and lancing device in a sharps container if you have access to one. If you do not, check your local listing for disposal of household sharps. In most locations it is safe to dispose of the used lancets in a hard plastic bottle such as a laundry detergent or milk bottle. Label the bottle "Do Not Recycle. Household Sharps." Ensure the top is tightly screwed on and secured with tape. Place the bottle into the trash. Do not recycle.

18. Using a different finger, repeat steps 1-17 for second blood spot card.

19. When both blood spot cards have been completed, allow the cards to fully air dry lying flat (at least 3 hours) at room temperature. Do not place cards in direct sunlight to dry. You do not need to write your name and date on the cards.

20. Place both dried blood spot cards into a specimen bag with the desiccant pack (see picture).



21. Complete the dried blood spot collection questionnaire included in this packet of information.

22. **Shipping** - When you are ready to ship all of your samples, refer to the shipment instructions on the last page of this packet.

Shipment Checklist

Make sure the below steps are completed before you ship your samples!

- Sign and date the Research Consent Form.** Place in the shipping box with your samples to be shipped.
- Complete the dried blood spot, urine and saliva collection questionnaires.** Place in the shipping box with your samples to be shipped.
- Place the frozen gel packs into the shipping box.**
- Saliva Samples** – Place the 2 saliva containers into the absorbent sheet with pockets. There will be 2 empty pockets in the absorbent sheet (see picture). Place the 2 saliva containers into a specimen bag. Seal the specimen bag and place into the shipping box.
- Urine Sample** – Place the urine sample and the large absorbent sheet (250ml) into a specimen bag. Seal the bag and place into the shipping box.
- Dried Blood Spot Cards** – Place the sealed specimen bag with the dried blood spot cards into the shipping box.
- Seal the shipping box closed.**
- Write your name and address on the blank lines of the prepaid FedEx preprinted return airbill.** Other fields have been already filled in.
- Adhere the FedEx airbill to the outside of the box.**
- Leave the package for FedEx if you have arranged for a pickup, or drop it off at a FedEx location.**



IF YOU HAVE ANY QUESTIONS OR NEED MORE SUPPLIES,
E-mail us at nhs2dwh@channing.harvard.edu or call us at 617-432-7214
For answers to frequently asked questions, visit our website at
<http://www.dwhstudy.org>.

THANK YOU!