

collection 3

Follicular - Luteal Blood and Urine

Thank you for your participation!

Thank you for your contribution of time, energy, and specimens to the Nurses' Health Study 3!

For this collection, we are requesting blood and urines samples timed to the follicular(days 3,4 or 5) and luteal phases (days 20, 21, or 22) of your menstrual cycle. By collecting samples during both phases of the menstrual cycle, you will help us develop a fuller understanding of how fluctuating hormones levels influence long term health.

QUESTIONS:

If at any point you have questions about how to schedule or collect your samples, please contact us! Our staff can be reached Monday through Friday, EST 8:00A.M. - 5:00P.M.

Email: NHS3specimens@partners.org

Phone: 617-432-7078

Website: http://www.nhs3.org/collection2

If we are unable to answer your call please leave a voicemail. We make every effort to respond to urgent calls within the same business day.

FOLLICULAR

BLOOD SUPPLIES



COLLECTION KIT CONTENTS

To ensure your confidentiality during this collection, we have assigned you an alias ID that is different from your actual NHS3 ID number. Please confirm that the NHS alias ID on your blood and urine tube labels match the NHS alias on your packet envelope. If they do not, or you are missing any of the below supplies, contact us immediately.

Paperwork

- □ Cover letter and Collection Calendar (PINK)
- ☐ Biospecimen Collection Instruction Form
- Follicular Paperwork Envelope
 - 2 Research Consent Forms (BLUE and WHITE)
 - 1Health and Diet Questionnaire (WHITE)
 - 1 Follicular Questionnaire(GREEN)
 - 1 Phlebotomy Reimbursement
- Luteal Paperwork Envelope
 - 1 Luteal Questionnaire (YELLOW)
 - 1 Phlebotomy Reimbursement
 - 1 Postcard (Start of next menstrual cycle)

II. Follicular Blood Collection Supplies(GREEN)

- \Box 4 10mL green top sodium heparin tubes (1 is extra)
- ☐ Venipuncture supplies

☐ Urine collection cup

☐ Small Urine Tube

☐ Pipette

- ☐ White four-pocket tube sleeve for return packaging (Aqui-pak)
- ☐ Sealable plastic bag containing materials above, to be reused for packing

FOLLICULAR

☐ Castile Soap Towelette IV. Luteal Blood Collection Supplies (YELLOW)

III. Follicular Urine Collection Supplies(GREEN)

- \Box 4 10mL green top sodium heparin tubes (1 is extra)
- ☐ Venipuncture supplies
- ☐ White four-pocket tube sleeve for return packaging (Aqui-pak)
- ☐ Sealable plastic bag containing materials above, to be reused for packing

V. Luteal Urine Collection Supplies (YELLOW)

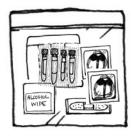
- ☐ Urine collection cup
- ☐ Small Urine Tube
- ☐ Pipette
- ☐ Castile Soap Towelette

VI. Shipping Supplies

- ☐ 2-Foam cooler
- ☐ 2-Cardboard box for cooler
- ☐ 2-Biohazard ziploc bag
- ☐ 2-Bubble sheet
- ☐ 2-Exempt Human Specimen label
- ☐ 2-Tape strips
- ☐ 2-FedEx Return Airway Bill
- ☐ 2-Cold pack



URINE SUPPLIES



<insert image of paperwork>

LUTEAL BLOOD

LUTEAL URINE





SPECIMEN COLLECTION OVERVIEW



& CHECKLIST

Before the follicular collection	1)	Review and sign the BLUE Research Consent Form.	
	2)	Use the Collection Calendar to track your menstrual cycle for at least ONE month and schedule your collection	
	3)	Make the appointments for both of the blood draws (FOLLICULAR and LUTEAL).	
	4)	Complete the white Health and Diet Questionnaire.	
	5)	2 days before the follicular blood draw: Call FedEx (1-800-463-3339) to arrange for package pick-up to occur on the day of collection.	
	6)	1 day before collection: Put the cold gel pack in the freezer.	
FOLLICULAR COLLECTION DAY	7)	Collect urine sample from first morning void on same day as blood draw.	
	8)	Bring your urine sample and all supplies with you to the blood draw.	
	9)	Have your fasting follicular blood sample drawn (Mon –Thurs).	
	10)	Complete the green Follicular Questionnaire.	
	11)	Pack your follicular samples and paperwork for return shipment via FedEx.	
Before the luteal	11)	Pack your follicular samples and paperwork for return shipment via FedEx. 2 days before luteal blood draw: Call FedEx (1-800-463-3339) to arrange for package pick-up to occur on the day of collection.	
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luteal collection	12)	 2 days before luteal blood draw: Call FedEx (1-800-463-3339) to arrange for package pick-up to occur on the day of collection. 1 day before collection: Put the refrigerant gel pack in the freezer. 	
luteal collection LUTEAL COLLECTION	12) 13)	 2 days before luteal blood draw: Call FedEx (1-800-463-3339) to arrange for package pick-up to occur on the day of collection. 1 day before collection: Put the refrigerant gel pack in the freezer. Collect urine sample from first morning void on same day as blood draw. 	
luteal collection LUTEAL COLLECTION	12) 13) 14) 15)	 2 days before luteal blood draw: Call FedEx (1-800-463-3339) to arrange for package pick-up to occur on the day of collection. 1 day before collection: Put the refrigerant gel pack in the freezer. Collect urine sample from first morning void on same day as blood draw. Bring your urine sample and all supplies with you to the blood draw. 	
luteal collection LUTEAL COLLECTION	12) 13) 14) 15)	 2 days before luteal blood draw: Call FedEx (1-800-463-3339) to arrange for package pick-up to occur on the day of collection. 1 day before collection: Put the refrigerant gel pack in the freezer. Collect urine sample from first morning void on same day as blood draw. Bring your urine sample and all supplies with you to the blood draw. Have your fasting luteal blood sample drawn on a Mon-Thurs 	



1) REVIEW & SIGN THEBLUE RESEARCH CONSENT FORM

Please confirm your willingness to participate in this study by reviewing and signing the Research Consent Form. We have provided a **BLUE** and a **WHITE** copy of the **Research Consent Form**. It is essential that you sign and date the consent statement at the end of the BLUE form and <u>return the entire form</u> with your samples. The WHITE copy is for your records.

2) SCHEDULE YOUR COLLECTIONS (MON-THURS)

Use the included **Collection Calendar**(PINK)to mark the days on which you can collect your samples. If you have any questions about how to schedule your collection please contact us directly at MHS3specimens@partners.org or 617-432-7078.



Why do I need to ship my samples Monday - Thursday?

Unfortunately, we **CANNOT** receive or process samples on Saturdays and Sundays and **FedEx does not** pick up on Saturday, Sunday, or national holidays

If you MUST collect your luteal samples on a Sunday please put the sample in the refrigerator (do not freeze) and ship on Monday with a note indicating the luteal samples were refrigerated for a day before shipping.

3) MAKE BLOOD DRAW APPOINTMENTS (BOTH FOLLICULAR & LUTEAL)

Use your charted days on your **Collection Calendar**(PINK) to help schedule your blood draw appointments. Call the lab or doctor's office where you will have your blood drawn to confirm they will draw blood for a research study and release the blood sample to you, or arrange with a friend or colleague to have your blood drawn.

If you are having your blood drawn at a lab or doctor's office, **make an appointment 2 weeks in advance** and confirm that they will draw blood for a participant of a research study and that they will release the samples to you after the draw. If the lab requires a formal doctor's order, please contact the study staff. Plan to ship your samples on the same day of collection.

4) COMPLETETHE HEALTH AND DIETQUESTIONNAIRE (WHITE)

Please verify the NHS3 alias ID on your questionnaire matches the ID on your kit and complete this general questionnaire prior to collecting your follicular samples.



5) ARRANGE FOR YOUR FOLLICULAR SHIPMENT WITH Fed Ex

It is a good idea to arrange for your FedEx shipment at least 2 days before you plan to collect your samples. You can either schedule a pick—up or you may drop off your package at a <u>staffed</u> FedEx Location. If you decide to schedule a pick-up, you must speak with an agent to ensure they have the correct pick-up location!

SCHEDULE A PICK-UP

Call 1-800-463-3339 (1-800-GO-FEDEX) and say "agent" to speak to a live person. You **MUST** speak with an agent to schedule your pickup.

Have the provided FedEx airbill (found in the white shipping box) handy when you call. You will be shipping via **Priority Overnight** method using a **prepaid stamp.** They can pick up the package from your home or work.

DROP OFF

OR

Locate a <u>staffed</u> FedEx location on online (<u>http://www.fedex.com/us</u>) or by calling FedEx.

Be sure to find out the cutoff time for Express packages.

6) FREEZE COLD PACK

Fill to 20ML line

Put the cold pack into the freezer the day before your blood and urine collection and don't forget it in when you go to the lab!

7) COLLECT FIRST MORNING URINE

Collect your first morning urine sample. If you wake in the night to void, collect your sample **when you wake up for the day.** If you forget to or cannot collect a first-morning urine, collect whenever you can.



- a) Use the Castile towelette to thoroughly cleanse yourself.
- b) Use the plastic specimen cup to catch your urine stream
- c) Transfer urine the provided pipette from the collection cup into the smaller urine tube **up to the line marked 20ml**, then recap it.
- d) Ensure that the cap is threaded properly, and cap it **tightly**. Discard the extra urine, the pipette, and the collection cup.
- e) Place the 20ml urine tube in the provided Biohazard bag. Refrigerate until you are ready to collect your blood samples.
- f) Fill in the date and time of collection on your green Follicular Questionnaire.



8) WHAT TO BRING TO THE FOLLICULARBLOOD DRAW

Put the frozen refrigerant pack into the Styrofoam box and bring the entire cardboard box with you when you go to have your blood drawn. If you are planning to ship immediately after having your blood drawn, don't forget to **take your follicular urine sample.**

WHAT TO BRING:

Follicular Blood Collection Supplies
Follicular Paperwork Packet (in white Tyvek envelope
Shipping supplies including insulated white box
Frozen cold pack
Urine sample (pack in the cooler to keep cool)

9) FASTING FOLLICULAR BLOOD DRAW

Please plan to have your blood drawn in the morning before you eat or drink (you can drink water). All supplies needed to draw your blood samples are in the venipuncture **blood collection supply bag** in your kit.

- a) Blood should be drawn from the antecubital vein
- b) To use the butterfly needle, remove the clear cap. Once the needle is in the vein, push a green-top tube into the clear needle holder until the tube stopper is punctured and blood starts to flow



- c) Once the tube is full, remove it carefully and gently insert the second green-top tube into the holder
- d) Repeat this for all three tubes. If you are unable to collect all three tubes, please move continue with the tubes you have been able to collect.

Invertthetube1 0-12timesto preventthebloo dfromclotting.

- e) Immediately after filling each tube, invert it 10-12 times to prevent the blood from clotting. We have included one extra tube in case one breaks
- f) Place the tubes into the white 4-pocket tube sleeve provided and put the sleeve back in the clear plastic zipper bag. Place the tubes in your Styrofoam box to keep them cool until you are ready to finish packing your kit. Be careful not to let the tubes touch the gel pack directly.

10) COMPLETE THE FOLLICULARQUESTIONNAIRE

Please complete the Follicular Questionnaire with information specific to your blood and urine collections.



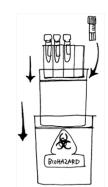
11) PACK KIT AND SHIP VIA FEDEX



- b) Ensure the both questionnaires are complete, the **Health and Diet Questionnaire** (WHITE) and the Follicular Questionnaire (GREEN).
- c) Place the **2 questionnaires** and the **BLUE** Consent Form into the Tyvek envelope and seal. (If it is necessary, also include your reimbursement form).
- d) Place the 4-pocket tube sleeve holding your blood tubes into the clear blood collection bag. Also place your container of urine into the urine collection bag. Seal the bags.
- e) Place the cold pack in the bottom of the box.
- f) Wrap the sealed blood and urine specimen bags with the bubble wrap sheet.
- g) Place the bubble wrapped specimen bags into the cooler on top of the *cold pack*. Close the cooler lid.
- h) Place the *envelope* containing the questionnaires and consent form on top of the cooler lid.
- i) Seal the outer shipping box closed with the provided tape.
- j) Place the *FedEx airway bill* into the pouch and affix to the box.
- k) Affix the **Exempt Human Specimen sticker** to the outside of the box. If it's missing, simply write "Exempt Human Specimen" on the box with a marker.
- I) Give the package to the FedEx driver, or drop it off at a FedEx location. FedEx has approved this packaging for the shipment of biological samples.

FedEx phone: 1-800-463-3339, remember to speak with an "agent"!!!

FedEx location finder: http://www.fedex.com/Dropoff/start?cc=us







Thank you!

We are incredibly grateful for the time and energy you have dedicated to submitting the follicular samples. In a few weeks you will begin the Luteal Collection. Please feel free to contact us if you have any questions.

Email: NHS3specimens@partners.org

Phone: 617-432-7078

Answers to frequently asked questions can be found online: http://www.nhs3.org/collection2









12) ARRANGE FOR YOUR LUTEAL SHIPMENT WITH FedEx

Please see the pink Collection Schedule for more information about how to schedule your collection.

OR

SCHEDULE A PICK-UP

Call 1-800-463-3339 (1-800-GO-FEDEX) and say "agent" to speak to a live person. You **MUST** speak with an agent to schedule your pick-up.

Have the provided FedEx airbill (found in the white shipping box) handy when you call. You will be shipping via **Priority Overnight** method using a **prepaid stamp.** They can pick up the package from your home or work.

DROP OFF

Locate a <u>staffed</u> FedEx location on online (<u>http://www.fedex.com/us</u>) or by calling FedEx.

Be sure to find out the cutoff time for Express packages.

13) FREEZE COLD PACK

Put the cold pack into the freezer the day before your blood and urine collection and don't forget it in when you go to the lab!

14) COLLECT FIRST MORNING URINE

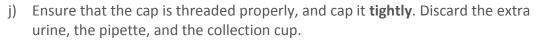
Collect your first morning void urine sample. If you wake in the night to void, collect your sample **when you wake up for the day.** If you forget to or cannot collect a first-morning urine, collect whenever you can.

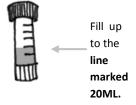




- g) Use the Castile towelette to thoroughly cleanse yourself.
- h) Use the plastic specimen cup to catch your urine stream







- k) Place the 20ml urine tube in the provided Biohazard bag. Refrigerate until you are ready to collect your blood samples.
- Fill in the date and time of collection on your green Follicular Questionnaire.



15) WHAT TO BRING TO THE LUTEAL BLOOD DRAW

Put the frozen refrigerant pack into the Styrofoam box and bring the entire cardboard box with you when you go to have your blood drawn. If you are planning to ship immediately after having your blood drawn, also take your urine and the follicular samples from your freezer.

What to bring:

Luteal Blood Collection Supplies
Collection Paperwork Packet (in white Tyvek envelope)
Shipping supplies including insulated white box
Frozen cold pack
Luteal Urine sample (pack in the cooler to keep cool)

16) FASTING LUTEAL BLOOD DRAW

Please plan to have your blood drawn in the morning before you eat or drink (you can drink water). All supplies needed to draw your blood samples are in the venipuncture **blood collection supply bag** in your kit.

- g) Blood should be drawn from the antecubital vein
- h) To use the butterfly needle, remove the clear cap. Once the needle is in the vein, push a green-top tube into the clear needle holder until the tube stopper is punctured and blood starts to flow
- i) Once the tube is full, remove it carefully and gently insert the second green-top tube into the holder
- j) Repeat this for all three tubes. If you are unable to collect all three tubes, please move continue with the tubes you have been able to collect.
- k) Immediately after filling each tube, invert it 10-12 times to prevent the blood from clotting. We have included one extra tube in case one breaks
- Place the tubes into the white 4-pocket tube sleeve provided and put the sleeve back in the clear plastic zipper bag. Place the tubes in your Styrofoam box to keep them cool until you are ready to finish packing your kit. Be careful not to let the tubes touch the gel pack directly.



Invertthetube10-12timesto preventthebloodf romclotting.

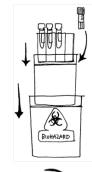
17) COMPLETE THE LUTEAL QUESTIONNAIRE

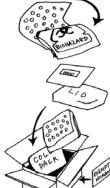
Please complete the Luteal Questionnaire with information specific to your blood and urine collections.



18) PACK KIT AND SHIP VIA FEDEX

<insert image of
paperwork>





- a) Place the **Luteal Questionnaire (YELLOW)**in to the Tyvek envelope and seal. (If it is necessary, also include your reimbursement form).
- b) Place the 4-pocket tube sleeve holding your blood tubes into the clear blood collection bag. Also place your container of urine into the urine collection bag. Seal the bags.
- c) Place the cold pack in the bottom of the box.
- d) Wrap the sealed blood and urine specimen bags with *the bubble wrap sheet*.
- e) Place the bubble wrapped specimen bags into the cooler on top of the *cold pack*. Close the cooler lid.
- f) Place the *envelope* containing the questionnaires and consent form on top of the cooler lid.
- g) Seal the outer shipping box closed with the provided tape.
- h) Place the *FedEx airway bill* into the pouch and affix to the box.
- i) Affix the Exempt Human Specimen sticker to the outside of the box. If it's missing, simply write "Exempt Human Specimen" on the box with a marker.
- j) Give the package to the FedEx driver, or drop it off at a FedEx location. FedEx has approved this packaging for the shipment of biological samples.

FedEx phone: 1-800-463-3339, remember to speak with an "agent"!!!

FedEx location finder: http://www.fedex.com/Dropoff/start?cc=us

19) MAIL IN POSTCARD

Please use the postcard to record the date on which your next menstrual cycle began following this collection. If you prefer to email this date to us, that is fine as well. Please note, this date is crucial for our research purposes.

Thank you!

We are incredibly grateful for the time and energy you have dedicated this study. Your generous participation will help to build a strong set of resources for investigating women's health issues. Please feel free to contact us if you have any questions.

Email: NHS3specimens@partners.org Phone: 617-432-7078

Answers to **frequently asked questions** can be found online:http://www.nhs3.org/collections





