



National Health and Nutrition Examination Survey (NHANES)

Home Urine Collection



January 2011

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1. HOME URINE COLLECTION

1.1 Background

NHANES is the source of national estimates of the prevalence of chronic kidney disease in the United States. An estimated 7.69 percent of adults aged 20 or older (15.5 million adults) have physiological evidence of chronic kidney disease determined as a moderately or severely reduced glomerular filtration rate.¹ The two main causes of chronic kidney disease are diabetes and high blood pressure, which are responsible for up to two-thirds of the cases. The third most frequent cause of chronic kidney disease, glomerulonephritis, is a group of diseases that cause inflammation and damage to the kidney's filtering units. Other causes of chronic kidney diseases include:

- Inherited diseases, such as polycystic kidney disease, which causes large cysts to form in the kidneys and damages the surrounding tissue.
- Malformations that occur as a baby develops in its mother's womb. For example, a narrowing may occur that prevents normal outflow of urine and causes urine to flow back up to the kidney. This causes infections and may damage the kidneys.
- Lupus and other diseases that affect the body's immune system.
- Obstructions caused by problems such as kidney stones, tumors, or an enlarged prostate gland in men.
- Repeated urinary infections.

Microalbuminuria, also referred to as proteinuria (protein excretion in the urine), is an important indicator of early kidney disease. If a person has "persistent proteinuria" it means they have chronic kidney disease. When kidney disease progresses, it may eventually lead to chronic kidney failure, or end stage renal disease (ESRD), when the kidneys permanently fail to work. ESRD usually requires the patient to undergo dialysis or a kidney transplant.

A urine sample collected for the measurement of protein in the urine (albumin/creatinine ratio), as well as a blood test for serum creatinine, is recommended by the National Kidney Disease Education Program as the two diagnostic tests to ascertain early chronic kidney disease. The purpose of

¹ Coresh, J., Selvin, E., Stevens, L.A., Manzi, J., Kusek, J.W., Eggers, P., Van Lente, F., and Levey, A.S. Prevalence of chronic kidney disease in the United States. *Journal of the American Medical Association*. 2007;298(17): 2038–2047.

the Home Urine Collection is to measure the albumin/creatinine ratio to assess persistent microalbuminuria in the U.S. population. This requires the collection of a second urine specimen collected within 14 days of the mobile examination center (MEC) exam to compare the level of protein excretion with the first urine sample obtained when the SP was examined on the MEC. This second collection is also particularly important to determine proteinuria in children. Children commonly exhibit a benign finding referred to as “orthostatic proteinuria.” Many children have a positive urine finding for protein in random urine samples, but don’t have protein present in their urine when the first morning void is collected. Orthostatic proteinuria must be excluded by repeat measurement on a first morning specimen if the initial finding of proteinuria was obtained on a random specimen.

The 2009-2010 albumin/creatinine ratio component of NHANES is sponsored by the following organizations:

- The Centers for Disease Control and Prevention (CDC)/National Center for Chronic Disease Prevention and Health Promotion/Division of Diabetes Translation, and
- The CDC National Center for Health Statistics (NCHS).

1.2 Overview of the Home Urine Collection Component (HUC)

All primary SPs aged 6 years and older who have vessel 45 (urine albumin and creatinine) marked as filled in the urine processing module of the Laboratory Subsystem are eligible for a second urine collection in their home. The participant is asked to take a kit home, fill the sample cup, and mail it to the contract lab as soon as possible - ideally within 14 days after the MEC exam. However, if they cannot collect it within 14 days, then they are asked to collect and ship it at their earliest convenience. The kit contains instructions on how to collect and mail the urine specimen to the testing laboratory.

In the MEC, the examiner opens the kit; explains the contents; and provides verbal, written, and visual instructions to reinforce these procedures. A self-addressed stamped shipping envelope containing a U.S. Postal Service Priority Mail shipping label is provided. The air bill number is used to track the urine shipment to the contract laboratory. Most MEC examination staff, including the MEC manager, are trained to perform the HUC. Exceptions are the lab staff, coordinator, and physician. The exam takes place in trailer #3. The complete protocol is described in Chapter 2.

Warehouse staff members prepare the HUC kits. This includes printing the USPS shipping label. This shipping label routes the kit from the SP to the contract laboratory. This label contains an air bill number which is used to track the shipment from the SP's home to the analysis laboratory. This process is described in Chapter 3.

The HUC module in the FFMS (Field Follow-up Management System) supports the tracking and management of the HUC component. The complete protocol is described in Chapter 4.

A HUC appointment is created daily at the end of the MEC sessions for each eligible HUC participant.

- If the SP does not agree to take a kit or does not receive the component the appointment status is set to Final Non-Response (FNR) with a comment of 'Primary Appt. Not Complete.'
- If the SP agrees to take a kit, the appointment status is set to "Scheduled, tentative."
 - A nightly procedure creates a PF appointment record for 14 days following the MEC Exam appointment. The PF Appointment Status is set to "Scheduled, Tentative."
- Once the mailperson scans the kit into the USPS system showing that the kit was picked up, the PF appointment is set to "Scheduled, Firm."
 - "Scheduled, Firm" records get checks cut.
- If 14 days have elapsed since the SP was initially given the kit and there is no tracking activity then the PF appointment is "Not scheduled, broken."
 - A nightly procedure looks to see if there are appointments that are "Scheduled, tentative" and 14 days past their appointment date and then marks the record as broken which triggers the reminder postcard.
- Once the USPS system marks the air bill as "received," meaning they delivered it, the PF appointment status is "Complete."
 - This triggers the creation of efiles that are emailed to the laboratory as well as the expectations of data to be received back.
- If after 30 days the air bill has not been marked as "delivered" then the PF appointment status is marked as FNR (final nonresponse), SP refusal.
 - A nightly procedure looks for all records where the status is "Scheduled, tentative" and >30 days past MEC appt. and marks them as FNR.

MEC lab shipments are sent by FedEx and HUC kits are sent by USPS Priority Mail. Tracking emails are sent daily to home office staff. This process is described in Chapter 6. Once the air bill is marked by the USPS as “Processed through Sort Facility” (meaning they scanned the kit into their system), a remuneration check for \$40 is mailed to the participant. The check generation process is described in Chapter 5.

The ISIS system generates and sends an Efile with all relevant information that the lab needs to analyze the sample. This file can be used by the lab to return the results.

The SRMS (System Result Management System) calculates a Urine Albumin Creatinine Ratio (UACR) from the Albumin and Creatinine Results received from the first urine collection (vessel 45) and the second home urine collection (vessel 124). An Early Reporting Letter is generated for SPs with a UACR > 300 mg/g on their first collection only. The FFMS Report of Findings provides findings for both the first and second UACRs. Examples are illustrated in Appendix E.

2. MEC PROTOCOL

2.1 Overview

All primary SPs aged 6 years and older who have vessel 45 marked as filled in the urine processing module of the Laboratory Subsystem are eligible for a second urine collection in their home. The participant is asked to take a kit home, fill the sample cup, and mail it to the contract lab as soon as possible - ideally within 14 days after the MEC exam. However, if they cannot collect it within 14 days, then they are asked to collect and ship it at their earliest convenience. The kit contains instructions on how to collect and mail the urine specimen to the testing laboratory.

In the MEC the examiner opens the kit; explains the contents; and provides verbal, written, and visual instructions to reinforce these procedures. A self-addressed stamped shipping envelope containing a U.S. Postal Service (USPS) Priority Mail shipping label is provided. The air bill number is used to track the urine shipment to the contract laboratory.

Blank white Tyvek envelopes, stamps, and address labels are sent to the field individually and are assembled in the MEC as needed. On a weekly basis the MEC examiners make up a set number (as determined by the chief health tech) of shipping envelopes by putting a preprinted Avery USPS air bill label and a postage stamp on the white Tyvek envelope. At the end of a stand the remaining envelopes are counted as part of the end of stand inventory process, left onboard the MEC, and continue onto the next MEC site. The stamps are counted and then returned to the warehouse via "transfer inventory to warehouse inventory sheet." The remaining preprinted address labels are discarded at the end of each stand.

Most MEC examination staff members including the MEC manager are trained to perform the HUC. Exceptions are the lab staff, coordinator, and physician. The exam takes place in trailer #1.

2.2 Eligibility Criteria

Sample persons (SPs) aged 6 years and older are eligible for the Home Urine Collection (HUC) component. There are no safety exclusion criteria for HUC. The coordinator is only able to assign

an SP to the HUC component if the SP has submitted a urine specimen and (1) the urine specimen volume is sufficient to fulfill the SPs urine processing protocol; or (2) the urine specimen volume is not sufficient to fulfill the SPs protocol, but the lab has enough urine to process vessel no. 45. If the SP submitted a small quantity of urine, but vessel no. 45 has not been processed by the MEC laboratory staff, the coordinator will not be able to assign the SP to HUC.

Parents or guardians of children aged 16 years and younger are required to respond for the children due to the detailed instructions for the specimen collection and mailing procedures. The children may accompany the parent to the component, but they are not required to be present.

When the examiner attempts to recruit an SP who does not speak English and the examiner does not speak the language of the SP, a translator who does speak the language of the SP assists the examiner. The interpreter stays with the examiner and the SP for the entire examination.

The successful recruitment of the SP is an important aspect of this examination. Recruitment requires careful patience on the part of the examiner. Encourage the SP to accept the kit and follow through with the collection and shipment of the home specimen. To assist the examiner, talking points and labeling summary documents have been developed (Appendix A).

Gaining the cooperation of an SP is easier if the atmosphere in the examination room is pleasant and makes the SP feel comfortable. Below is a list of suggestions for creating a pleasant atmosphere in the examination room.

- Maintain a clean and uncluttered work area.
- Be aware of body image; a positive body image inspires confidence. Maintain a tidy appearance, erect posture, and a smile.
- Speak face-to-face with the subject and maintain eye contact. Staring at other areas in the room may cause the SP some uneasiness since it implies that he or she is not important. It also implies disinterest.
- Avoid nervous behaviors such as squirming and tapping that can be distracting. The SP may begin to feel nervous, hurried, and anxious because of such behaviors.

2.3 Equipment and Supplies

The equipment and supplies used in the Home Urine Collection (HUC) are described below.

2.3.1 Equipment

- Dymo label printer.

2.3.2 Supplies

- Home specimen collection kit (pre-assembled in the HANES warehouse)
 - White cardboard outer box;
 - Styrofoam shipping container with date/time label affixed to top of lid;
 - Refrigerant gel pack pouch (Cold Ice™);
 - One 60 milliliter plastic specimen cup with screw on lid;
 - One 5”X 5” zip closable plastic bag with absorbent pad; and
 - Temperature monitoring strip (affixed to the inside lid of Styrofoam container).
- White Tyvek self-addressed postage-paid shipping envelope, containing:
 - “Exempt Human Specimen” label;
 - Preprinted Avery USPS air bill label;
 - USPS postage stamp; and
 - Priority Mail sticker.
- 10” x 13” zip closable plastic bag;
- Hard-copy color “WHAT TO DO Urine Collection and Shipping Instructions” (Appendix C) in English and Spanish;
- Wall aid - Laminated hard-copy “Talking Points”;
- Wall aid – “Label the Kit” summary;

- Recruitment aid - Laminated hard-copy color “WHAT TO DO Urine Collections and Shipping Instructions” in English and Spanish;
- Wall aid – Laminated hard-copy informational letter (Appendix B) from DHHS/CDC in English and Spanish;
- Permanent markers, heavy point;
- Dymo polyester labels—1” x 2 1/8,” 500 labels per roll;
- Jumbo paper clips;
- Poly tote hand bag w/ handle 20" x 20" x 5" (2 cases / 200 each);
- Confidentiality label English (1 box, 600 per box);
- Confidentiality label Spanish (1 box, 600 per box);
- Sani Cloth towelettes (1 bottle); and
- Temperature monitoring Strips (extras/replacements, 20 each)

Component Tools - Non Consumables

- Metal foot stool (1 each)
- Temperature monitor strip storage box w /lid (1 each)

2.3.3 Inventory Management

The HUC component is managed by the health technologists. The par level for the consumables is set at the levels shown in Exhibit 2-1. A mid-stand inventory request for additional urine collection kits will be necessary to complete the stand.

Exhibit 2-1. Inventory par levels: Home Urine Collection Component

Supply	Par level
Home specimen collection kits	200
White Tyvek shipping envelopes with Exempt Human Specimen label and Priority Mail label	375
Preprinted Avery USPS air bill label - 5 1/2" x 8 1/2"	375
USPS Postage Stamp - 1st Class stamp	375
WHAT TO DO Urine Collection and Shipping Instructions, English/Spanish	375
Confidential Label – Spanish (600)	1 box
Confidential Label – English (600)	1 box
Poly tote hand bag - white - 200 bags/case	2 cases
10" x 13" – zip closable bag, clear (100 bags/bundle)	4 bundles
Dymo polyester labels—1"x 2 1/8"	4 rolls
Temperature monitoring strip - Range C: 54-65C	20
Paper clip, jumbo	2 boxes
Permanent markers, black heavy point	2
SORTKWIK – Finger Moistener – 3/8 ounce container	2
Purell Handsoap (Waterless)	1

During the stand, store the stamps in the safe at the coordinator's station. On a weekly basis make up a set number (as determined by the chief health tech) shipping envelopes by putting a preprinted Avery USPS air bill label and a stamp on the white Tyvek envelope. When it is time to make more envelopes each week, the tech should ask the MEC manager for stamps (usually 100 at a time.) Toward the end of the stand, track how many additional stamps and envelopes will be needed to complete the stand. Avoid putting postage on envelopes that will not be used.

At the end of every stand, discard unused preprinted Avery air bill labels. Count and record the separate, unlabeled envelope on the end of stand inventory sheet. Send any unused stamps back to the warehouse at the end of the stand.

2.3.4 Urine Collection Kit Storage

A limited number of urine collection kits (200) are shipped from the warehouse with the start of stand supplies. Due to the temperature sensing strips, kits cannot be stored in the belly compartments. Store the kits in the HUC room. At mid-stand inventory, submit a request for the number of kits needed for the rest of the stand.

2.4 Examination Procedures

The Home Urine Collection ISIS application allows the examiner to (1) record that the participant consented to take a kit; (2) print the label for the specimen cup; (3) print three picture stickers; and (4) scan the USPS air bill number into the system.

Using the standard ISIS format, open the HUC application and log the SP into the exam by scanning the bar code on the SP ID bracelet or manually typing the SP ID when the SP arrives in the examination room.

2.4.1 Recruiting the Participant to Accept the Home Collection

Invite the SP to participate in the home urine collection with the assistance of the following talking points:

English

“NHANES is determining how many people have protein in their urine. To be sure if your urine has increased protein, we need a second urine specimen. Take this urine collection kit home with you so you can collect a urine specimen and mail it to the laboratory. Once the lab has received the urine, we will send you a check for \$40. If the sample is not received, you will not be paid.

Protein detected in urine may be an indicator of weak kidneys. This measure and a blood test for creatinine are recommended by the National Kidney Disease Education Program to detect early chronic kidney disease. You will get results of your urine tests.”

Spanish:

“NHANES está tratando de determinar cuántas personas tienen proteína en la orina. Para estar seguros que la proteína en su orina ha aumentado con el tiempo, necesitamos una segunda muestra de orina. Llévase a su casa estos materiales para tomarse una muestra de orina en su casa y mandarla por correo al laboratorio. Una vez que el laboratorio reciba la muestra le enviaremos un cheque por \$40.00.

La detección de proteína en la orina podría indicar que los riñones son débiles. El Programa de Educación Nacional sobre la Enfermedad de los Riñones recomienda esta medición y un análisis de sangre para creatinina para detectar enfermedades crónicas del riñón en una fase temprana. Usted recibirá los resultados de los análisis de su orina.”

If an SP initially refuses the component, ask questions to determine the reason for the refusal and try to address any of their specific concerns. Provide reassurance and encouragement. Review the questions and answers in the informational letter (Appendix B). Show the SP the urine collection kit, and describe the procedures. If he or she still refuses, code the exam as an SP refusal.

2.4.2 Procedures When the SP Agrees to Take a Kit

Conveying clear and concise specimen collection instructions and shipping procedures is essential to the response rate and to specimen integrity. Assemble the following materials when an SP accepts the home urine component:

- One urine collection kit
- One pre-assembled packet that contains:
 - One “WHAT TO DO: Urine Collection and Shipping Instructions” (English or Spanish)
 - One Tyvek self-addressed stamped envelope
 - One 10” x 13” zip closable plastic bag.
- One SP ID label for the urine cup from HUC ISIS application

- Three printed Dymo labels from HUC ISIS application
- One preprinted 3 1/3" X 4" confidentiality label for the larger zip closable bag

2.4.3 Application Screens

Exhibit 2-2 illustrates the Home Urine Collection screen. It includes one drop-down list and one text box.

Exhibit 2-2. Home Urine Collection screen

Home Urine Collection: Stand:430 Session:430122 12/15/2004 05:30 pm - 09:30 pm

SP ID: 921039 Name: DELANEY, JACOB Age: 17 years Gender: Male Date: 06/25/2009 Time: 08:21 PM

Home Urine Collection

Did the SP take a kit home with them?

Scan airbill barcode here

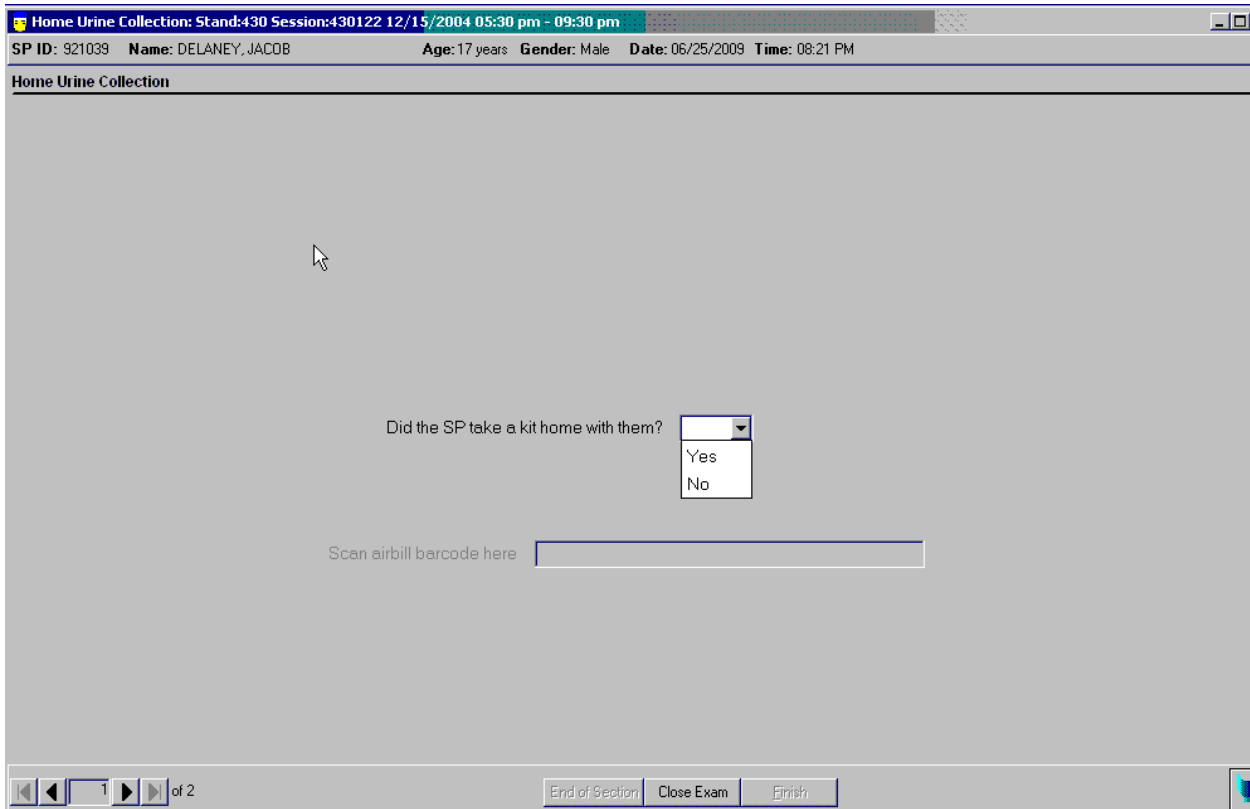
1 of 2

End of Section Close Exam Finish

Access the ISIS application drop-down box adjacent to the question, “Did the SP take a kit home with them?”

The choices in the Home Urine Collection screen drop-down list are illustrated in Exhibit 2-3.

Exhibit 2-3. Access the drop-down list



The drop-down box options are either Yes or No. If No is selected, the reason must be identified on the Section Status screen.

If the SP agrees to take a kit, select “Yes.” The following screen (Exhibit 2-4) will display with the text box activated for the shipping envelope bar code.

Exhibit 2-4. HUC Screen—SP answers “Yes.”

The screenshot shows a web browser window titled "Home Urine Collection: Stand:430 Session:430122 12/15/2004 05:30 pm - 09:30 pm". The browser address bar shows "SP ID: 921039 Name: DELANEY, JACOB Age: 17 years Gender: Male Date: 06/25/2009 Time: 08:21 PM". The main content area of the page is titled "Home Urine Collection" and contains the following text and form elements:

Did the SP take a kit home with them?

Scan airbill barcode here

At the bottom of the page, there is a navigation bar with the following elements:

- Navigation icons: back, forward, and a page indicator showing "1 of 2".
- Buttons: "End of Section", "Close Exam", and "Finish".

Use the bar-code gun to scan the USPS bar code into the text box.

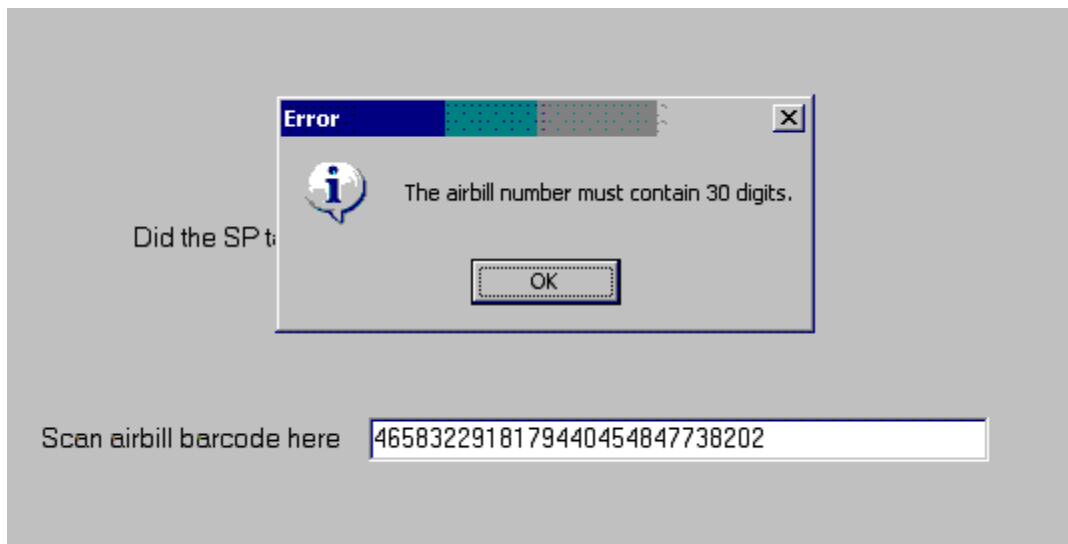
Exhibit 2-5 illustrates the air bill number which is located on the white Tyvek shipping envelope.

Exhibit 2-5. USPS air bill on white Tyvek shipping envelope



All USPS air bill numbers contain 30 numerals. If the air bill field does not contain the requisite number of characters, a hard-edit stop (Exhibit 2-6) will alert the examiner to review the field, and the application will not advance to the next screen.

Exhibit 2-6. Hard-stop edit



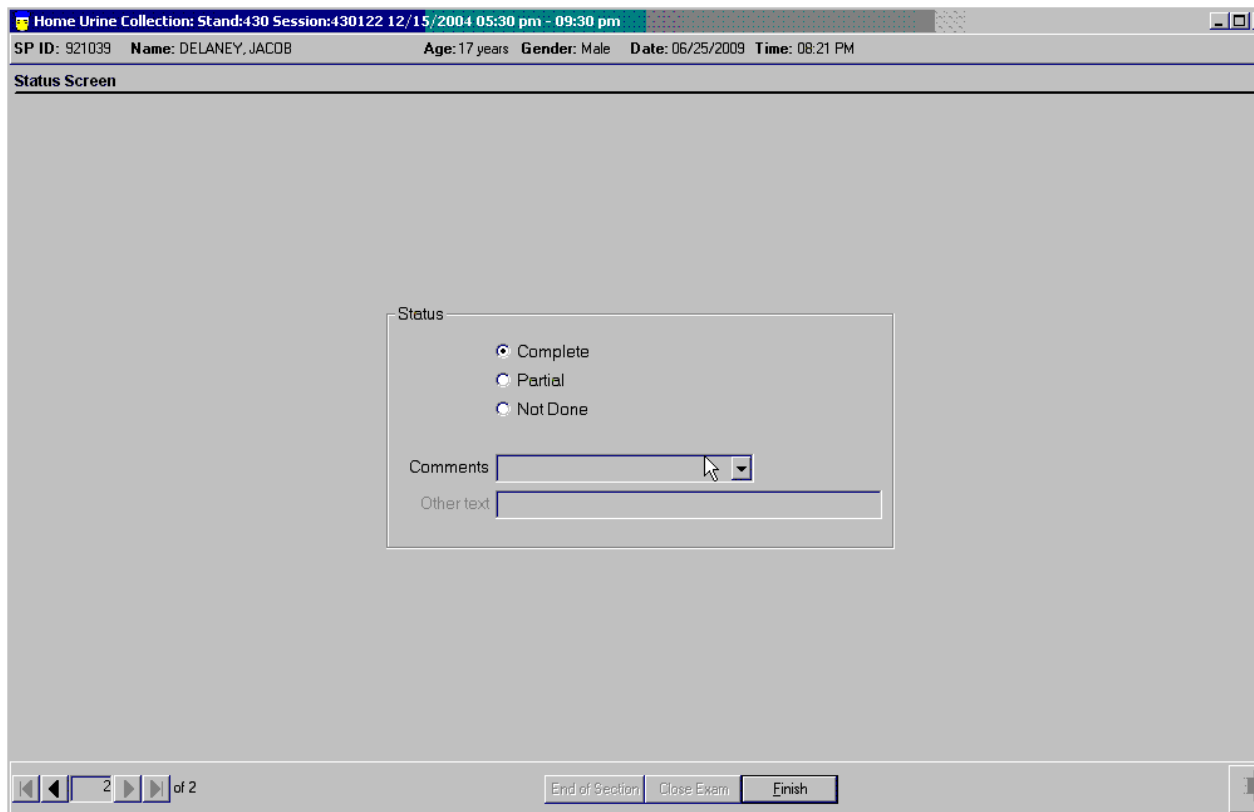
When a hard edit occurs, delete the air bill entry, and re-scan the air bill. If the bar code on the envelope cannot be scanned, set this envelope aside and retrieve another Tyvek envelope. Return the envelope to the warehouse with an explanation that the bar code is not able to be scanned.



When the USPS bar code has been successfully scanned into the application, select the arrow in the bottom right corner to launch the final examination screen.

Exhibit 2-7 illustrates the HUC Status screen.

Exhibit 2-7. Status Screen - Complete



Home Urine Collection: Stand:430 Session:430122 12/15/2004 05:30 pm - 09:30 pm

SP ID: 921039 Name: DELANEY, JACOB Age: 17 years Gender: Male Date: 06/25/2009 Time: 08:21 PM

Status Screen

Status

Complete
 Partial
 Not Done

Comments

Other text

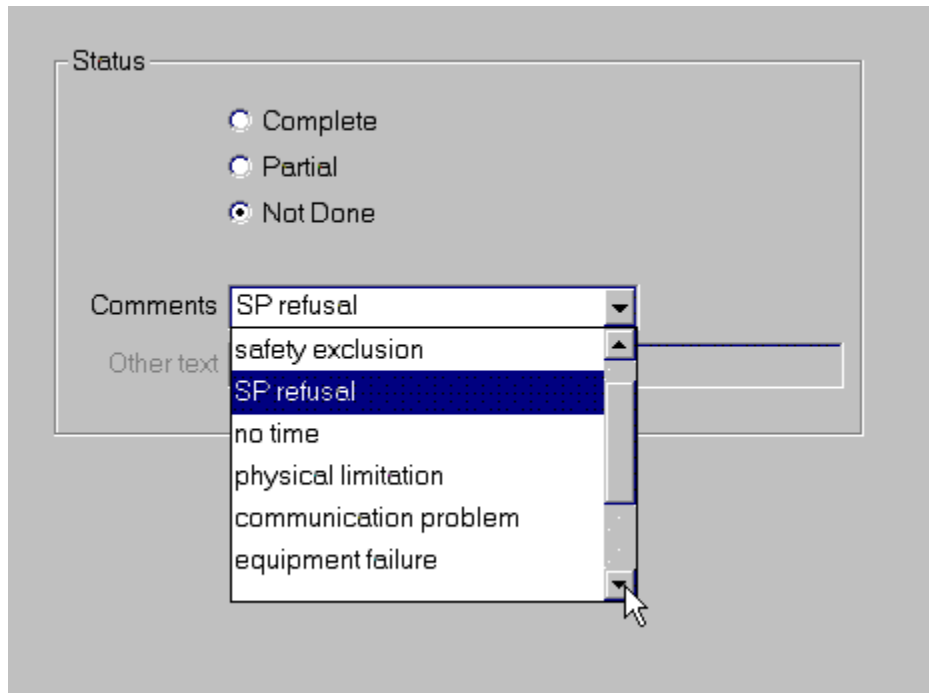
2 of 2

End of Section Close Exam Finish

Choose and enter the appropriate comment code when the HUC section status is Not Done.

Exhibit 2-8 illustrates the Not Done comment text box and Exhibit 2-9 lists all the possible comment codes and their intended use.

Exhibit 2-8. Status Screen – Not Done comments



To record a comment in the Comment text box, use the mouse to direct the mouse arrow to the scroll arrow on the drop-down list, left click, drag the mouse arrow to the desired choice, and left click. Use the scroll bar to view all choices. Alternatively, use the up and down keyboard arrows to scroll through the choices or type the first letter of the desired comment code.

Exhibit 2-9. Comment codes

Comment code	Use when:
Safety exclusion	Not applicable.
SP refusal	The SP refuses to take a kit home.
No time	Not applicable.
Physical limitation	Not applicable.
Communication problem	SP is unable to understand and follow the instructions for the component due to cognitive impairment or other problem, and is unable to complete the test.
Equipment failure	Not applicable.
Language Barrier	SP is unable to understand and follow the instructions for the component due to language and interpreting difficulties, and is unable to complete the test.
SP ill/emergency	The SP became ill or an emergency occurred and the test was not performed on the SP.
Interrupted	An exam is interrupted, usually for a MEC-wide emergency, and cannot be completed by the SP.
Other, specify	If the above reason for a status code of Not Done is not explained by one of the comment codes, the examiner must choose Other, specify and record a comment in the text field.

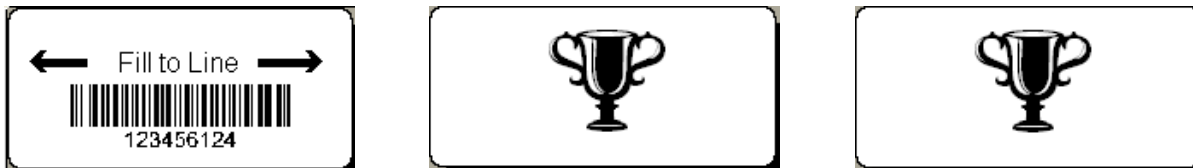
When finished, use the mouse to direct the mouse arrow to the bright blue arrow in the bottom right corner and left click to exit or select [Enter] when this blue arrow is highlighted.

2.4.4 Specimen and Assorted Labels

Experience has demonstrated that SPs tend to write their name somewhere on the kit. To assist the SP, a specimen cup identification system using computer-generated images has been developed to assure that the SP is using the correct specimen cup.

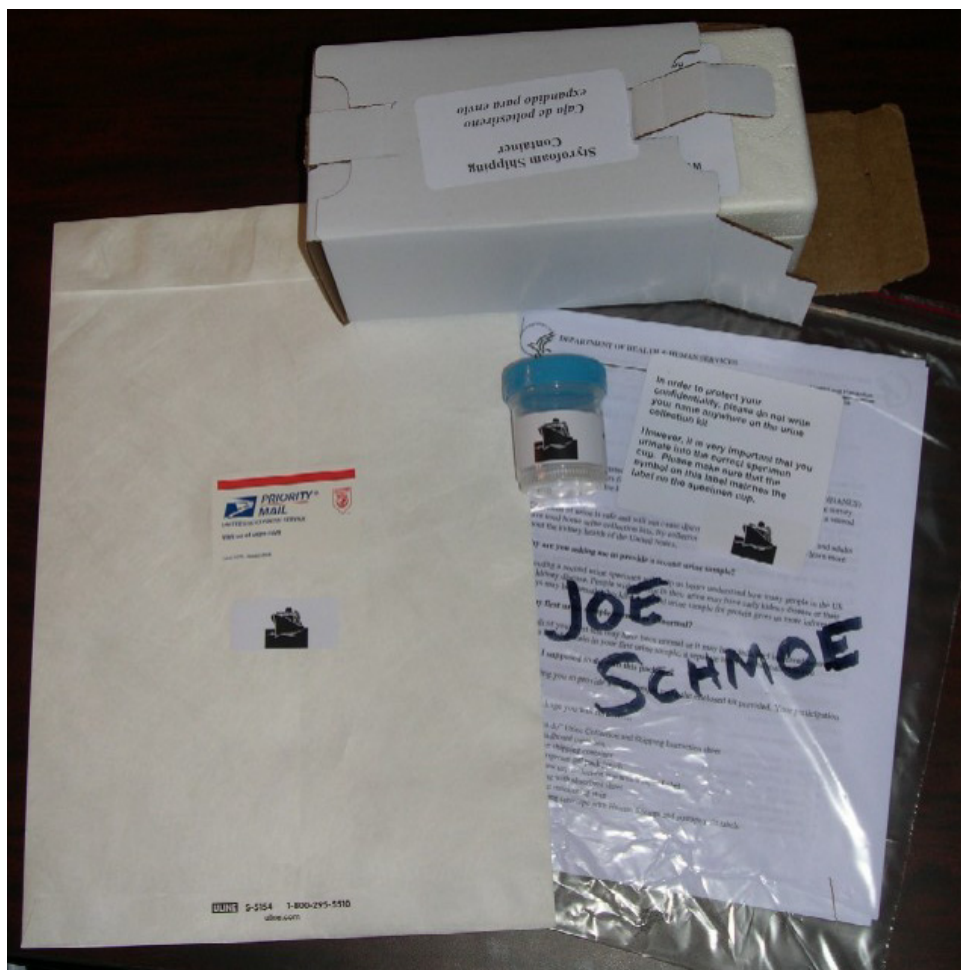
When the screen is advanced to the Finish screen, the Dymo printer will automatically print four labels on waterproof polyester material. One label contains the SP ID number and bar code, and a line that indicates the fill line on the specimen cup. Three other labels contain matching pictorial (picture stickers) images. An example of these two label types is illustrated in Exhibit 2-10. It is important to note that under no circumstance should the specimen cup display any identifiable SP personal information, including the age, first name, last name, or initials.

Exhibit 2-10. Dymo label examples



Four labels automatically print per SP, using the household data to ensure that no two SPs in the dwelling unit are given the same picture image. Apply one picture sticker to the large 10 x 13 zip closable plastic bag beside the confidentiality label. Apply the second picture sticker to the specimen cup beside the SP ID label on the side of the specimen cup. (Do NOT place the picture sticker on the lid of the specimen cup.) Apply the third picture sticker to the back side of the Tyvek shipping envelope. Exhibit 2-11 illustrates the label placement.

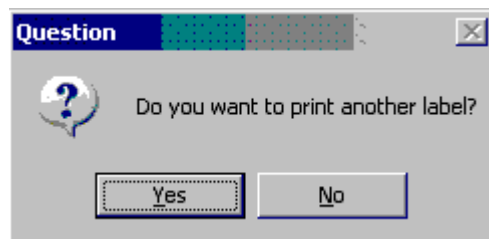
Exhibit 2-11. Image label placement



To reprint a label set, use the back navigation arrow to move back to the first Home Urine Collection screen.

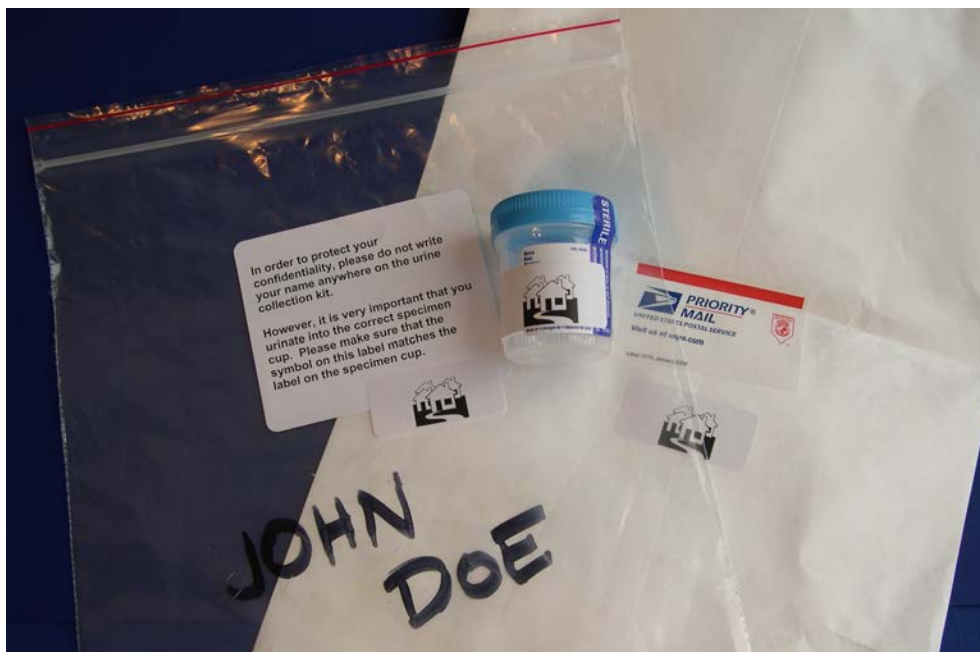
A pop-up box (Exhibit 2-12) displays asking if you want to print another label set. Select “Yes” to reprint the labels or “No” to move forward without reprinting the labels.

Exhibit 2-12. Reprint labels



There are two additional labels used on each kit: Confidentiality label (Exhibit 2-13) and Date/Time label (Exhibit 2-14). Both the confidentiality and date/time labels are printed at the Westat home office. The date time label is affixed to the top of the Styrofoam box by the warehouse staff. The confidentiality label is included in the component inventory list and should be placed on outside of the zip closable bag.

Exhibit 2-13. Confidentiality label



Provide verbal and written instructions by way of a label (Confidentiality Label):

- English: In order to protect your confidentiality, please do not write your name anywhere on the urine collection kit. However, it is very important that you urinate into the correct specimen cup. Please make sure that the symbol on this label matches the label on the specimen cup.
- Spanish: Para proteger su confidencialidad, por favor no escriba su nombre en ninguna parte de los materiales para tomar la muestra de orina. Sin embargo, es muy importante que orine dentro del envase correcto para tomar la muestra. Por favor asegúrese de que el símbolo de esta etiqueta coincide con la etiqueta en el envase para la muestra.

A date/time label is affixed to the outside lid of the Styrofoam shipping container. This label contains fields for the SP to write the date and time of the specimen collection.

Exhibit 2-14. Date/Time label



English: Please write the date and time you collected the urine specimen.

Spanish: *Por favor anote la fecha y la hora en que tomó la muestra de orina.*

2.4.5 Kit Preparation

After the SP has been successfully recruited, the USPS air bill has been scanned, and the Dymo labels have printed, prepare the kit by following the instructions below.

Labeling the Kit

- Open the urine collection kit. Confirm that the temperature monitoring strip is affixed to the inside lid of the Styrofoam shipping container.
- Apply the Dymo bar-code label to the specimen cup, aligning the fill line on the label with the 30 ml line of the specimen cup.
- Write the SP's name with permanent black marker on the 10" x 13" plastic zip closable bag. NOTE: this is the **only** location on the kit where the SP name is identified.
- Apply the appropriate language confidentiality label to the 10" X 13" zip closable bag.
- Apply the first picture sticker to the large plastic bag beside the confidentiality label.
- Apply the second picture sticker to the specimen cup beside the SP ID label on the side of the specimen cup.
- Apply the third picture sticker to the back side of the Tyvek shipping envelope.

While the kit is being labeled, present the urine collection and shipping instructions. All points below are contained in the Urine Collection and Shipping Instructions.

2.5 Urine Collection and Shipping Instructions

Present the urine collection and shipping instructions at the same time the kit is being prepared. The WHAT TO DO instruction document contains all of the information the SP needs to successfully understand the procedure and collect and ship the sample. Use the hard copy laminated examples to discuss the procedure, and follow this guideline:

Label the parts of the kit and show the SP their unique picture sticker. Show the SP the “WHAT TO DO, Urine Collection and Shipping Instructions.”

Maintain good eye contact as you stress the following specimen collection points:

- Specific details about how to collect and ship the sample is contained in this document. It is included in the kit you are taking home.
- It is very important not to mix up specimen cups when there are multiple participants in one family.
- Remember to urinate (pee) into the cup **when you wake up**.
- Collect your urine sample as soon as possible and ideally within the next 14 days. However, if you cannot collect it within 14 days then please collect and ship it at your earliest convenience.
- Fill the cup to the line on the label and screw the lid tightly on the specimen cup.
- Remember to write the date and time you collected the urine sample on the label on the top of the Styrofoam lid.
- Place the Cold Ice gel refrigerant pack in the freezer overnight or for at least 6 hours.
- Whenever possible, mail the kit the same day the urine was collected.
- If the urine specimen has not been received by the laboratory in 14 days, then a reminder postcard will be sent to you. If you have already sent your urine then ignore this postcard.
- Do **not** mail the large outer plastic bag to the laboratory.
- We will send you a check for \$40.00 as soon as you ship the package.
- If you have any questions then call the toll-free telephone number on the Urine Collection and Shipping Instructions sheet.

2.5.1 Packing the Urine Collection Kit for the SP to Take Home

1. Place the urine collection kit into the zip closable bag.
2. Fold the “WHAT TO DO Urine Collection and Shipping Instructions” and place it into the plastic bag with the urine collection kit and seal the plastic bag.
3. On the Session Preview Report, put a check beside the SP’s name that you made a kit for.
4. SPs carry their kits home in a tote bag that we provide them. Kits for the same family are put together in one bag. Approximately 4 kits fit in one tote bag.
 - a. If you are making the first kit for a family, get a new tote bag and write the SP’s last name on the bag. Place the SP’s kit in the tote bag. On the Session Preview Report, write the word “bag” beside the SP’s name so that other staff will know that a bag has been made for the family. (Exhibit 2-15)
 - b. If the notes on the session preview report indicate that a bag has already been made for the family, do not make another tote bag unless four kits are already in the family’s bag. In that case, get another tote bag, write the SP’s last name on it, and write the word “bag” on the Session Preview Report beside the SP’s name.
 - In Exhibit 2-15, a tote bag has been made for the Tsai family and it has four kits in it. When a kit is made for Christa Tsai, the examiner will need to make another tote bag for the Tsai family.
5. After the examination is completed and the SP is released from the component hang the tote bag on the wall in trailer 1 near the coordinator with the SP’s name facing the wall. If you did not make a new tote bag for the family, place the SP’s kit in the existing family’s bag already hanging on the wall.

Exhibit 2-15. Example Session Preview Report with notes

Session Preview Report				12/02/10 16:01	
Stand: 614					
<hr/>					
Session: 614640 05/13/2010 08:30 AM - 12:30 PM					
SP	SP Type	SP Name	Age	Gender	Special Considerations
614-01-0003-10-04	187554	Primary	CHRIS N	21 years	Male
614-01-0003-15-01	911561	Primary	MARY MCNEIL	15 years	Female
614-01-0003-15-04	954779	Primary	NICKI MCNEIL ✓ <i>Bag</i>	8 years	Female
614-01-0005-01-03	923804	Primary	SELENA GRENADO ✓ <i>Bag</i>	40 years	Female
614-01-0025-01-02	824799	Primary	BOB M SMOTH	40 years	Male
614-02-0001-01-01	431218	Primary	STANLEY TSAI ✓	70 years	Male
614-02-0001-01-03	319131	Primary	STELLA TSAI ✓	16 years	Male
614-02-0001-01-04	441765	Primary	GEORGE TSAI ✓ <i>Bag</i>	42 years	Male
614-02-0001-01-07	872562	Primary	CHRISTA TSAI	24 years	Male
614-02-0001-01-09	730051	Primary	BELLA TSAI ✓	40 years	Female
614-03-0001-01-04	554728	Primary	HOSEA THURSTON	59 years	Female

3. USPS LABEL PRINTING UTILITY

3.1 Warehouse Responsibility

Warehouse staff members prepare the HUC kits. This includes printing the USPS shipping label. This shipping label routes the kit from the SP to the contract laboratory. This label contains an air bill number which is used to track the shipment from the SP's home to the analysis laboratory.

The blank white Tyvek envelopes, stamps, and address labels are sent to the field individually and assembled in the MEC as needed. On a weekly basis, the MEC examiners make up a set number (as determined by the chief health tech) of shipping envelopes by putting a preprinted Avery USPS air bill label and a postage stamp on the white Tyvek envelope. At the end of a stand, the remaining envelopes are counted as part of the end of stand inventory process, left onboard the MEC, and continue on to the next MEC site. The stamps are counted and then returned to the warehouse via "transfer inventory to warehouse inventory sheet." The remaining preprinted address labels are discarded at the end of each stand.

3.2 USPS Label Utility

The purpose of the USPS Label Printing Utility is to provide the warehouse staff with an easy way to print USPS mailing labels when preparing the HUC kits.

To print the USPS air bills, click on the **USPS Label Generation** icon on the desktop. The application screen is illustrated in Exhibit 3-1.

Select a Return Address (this is the Westat Mailing Address) and Destination Address (this is the address of the Contract Lab) by selecting a choice from the two “saved” drop-down lists. Access the drop-down box.

Exhibit 3-1. Shipment Tracking Label Maker blank

Shipment Tracking Label Maker

Return Address

Saved

Name

Company

Address 1

Address 2

City

State

Zip 5

Zip 4

Destination Address

Saved

Name

Company

Address 1

Address 2

City

State

Zip 5

Zip 4

Weight

Quantity

The window displays with the correct data in the various fields as illustrated in Exhibit 3-2.

Exhibit 3-2. Shipment Tracking Label Maker completed

The screenshot shows a window titled "Shipment Tracking Label Maker" with a blue header bar and a close button in the top right corner. The window is divided into two main sections: "Return Address" and "Destination Address".

Return Address:

- Saved: NHANES Warehouse (dropdown menu)
- Name: NHANES Warehouse
- Company: (empty)
- Address 1: 15835 Gaither Road
- Address 2: GA-W10
- City: Gaithersburg
- State: MD
- Zip 5: 20877
- Zip 4: (empty)

Destination Address:

- Saved: Department of Pediatrics (dropdown menu)
- Name: Microalbumin Laboratory
- Company: Department of Pediatrics
- Address 1: 420 Delaware St. S.E.
- Address 2: MMC 491
- City: Minneapolis
- State: MN
- Zip 5: 55455
- Zip 4: (empty)

Weight: 12

Quantity: 3 (spin button)

Buttons: Print, Clear

Enter the quantity of labels and select the print button.

Once the print button has been selected, the system will connect to the USPS web site and generate and print the requested number of air bills.

A sample air bill is illustrated in Exhibit 3-3.

Exhibit 3-3. Sample air bill


P

USPS PRIORITY MAIL®

WESTAT
1450 RESEARCH BOULEVARD
ROCKVILLE MD 20850

SHIP TO:
JOE SCHMOE
DUKE ST
EPHRATA PA 17522-2031

ZIP -e/ USPS DELIVERY CONFIRM



420 17522 9101 8052 1390 7842 7057 94

Electronic Rate Approved #805213907

Instructions

1. Please use a laser or laser-quality printer.
2. Adhere shipping label to package with tape or glue. **DO NOT TAPE OVER BARCODE.** Be sure all edges are secure. Self-adhesive label is recommended.
3. Place label so that it does not wrap around the edge of the package.
4. Affix Priority Mail service postage. There is no extra fee for Delivery Confirmation service.
5. Stamped packages weighing 16 ounces or more may not be placed in Postal Service collection boxes. For information on pickup options, go to the Pickup page on www.usps.com.
6. Each shipping label printed in this book can be used only once - **DO NOT PHOTO-COPY.**
7. Please use this shipping label on the "ship date" indicated when you requested the label.

Online e-Label Record

Delivery Confirmation™ Service Number: 9101 8052 1390 7842 7057 94
 Priority Mail® with electronic option
 Delivery Confirmation service fee
 Price Code: 02724038
 Electronic Open Delivery Confirmation Service Fee: 0.00

From: WESTAT
 WESTAT
 1450 RESEARCH BOULEVARD
 ROCKVILLE MD 20850

To: JOE SCHMOE
 217 DUKE ST
 EPHRATA PA 17522-2031

Regular Priority Mail Service postage rates apply. There is no fee for electronic return shipping label. Delivery information is not available by phone for the electronic option.

UNITED STATES POSTAL SERVICE Thank you for shipping with the United States Postal Service!
 Check the status of your shipment on the Track & Confirm page at www.usps.com

4. FIELD FOLLOW-UP MANAGEMENT SYSTEM PROTOCOL

4.1 Overview

The HUC module in the FFMS (Field Follow-up Management System) supports the tracking and management of the HUC component. A HUC appointment is created daily at the end of the MEC sessions for each eligible HUC participant.

- If the SP does not agree to take a kit or does not receive the component, the appointment status is set to Final Non-Response (FNR) with a comment of ‘Primary Appt. Not Complete.’
- If the SP agrees to take a kit, the appointment status is set to “Scheduled, Tentative.”
 - A nightly procedure creates a PF appointment record for 14 days following the MEC Exam appointment. The PF Appointment Status is set to “Scheduled, Tentative.”
- Once the mailperson scans the kit into the USPS system showing that the kit was picked up, the PF appointment is set to “Scheduled, Firm.”
 - “Scheduled, Firm” records get checks cut.
- If 14 days have elapsed since the SP was initially given the kit and there is no tracking activity, then the PF appointment is “Not Scheduled, Broken.”
 - A nightly procedure looks to see if there are appointments that are “Scheduled, Tentative” and 14 days past their appointment date and then marks the record as broken which triggers the reminder postcard.
- Once the USPS system marks the air bill as “received,” meaning they delivered it, the PF appointment status is “Complete.”
 - This triggers the creation of efiles that are emailed to the laboratory, as well as the expectations of data to be received back.
- If after 30 days the air bill has not been marked as “delivered,” then the PF appointment status is marked as FNR (Final Non-Response), SP refusal.
 - A nightly procedure looks for all records where the status is “Scheduled, Tentative” and >30 days past MEC appt. and marks them as FNR.

If the participant has not sent the sample to the lab within 14 days from the day he or she was recruited in the MEC, then the FFMS generates a reminder postcard list and updates the FFMS

contact history indicating that the reminder postcard was sent. Support staff print the labels and mail the postcards.

Once the air bill is marked by the USPS as “Processed through Sort Facility” (meaning they scanned the kit into their system), a remuneration check for \$40 is mailed to the participant. This process is described in Chapter 5.

Use the **Call History** option to document contact(s) with an SP and/or other activities like sending a replacement kit.

Use the **Reports** option to (1) print labels for the reminder postcards; (2) calculate and display the response rate; and (3) access information about the check status for an SP.

Use the **Supervisor** option to (1) view a report that lists SPs by appointment status and stand and (2) assign employees to the HUC component within the FFMS. The Interview Scheduler link is not applicable to the HUC component.

4.2 Supplies and Equipment

Store enough kits and shipping supplies to respond to requests for replacement kits. The warehouse staff provides all these supplies, except for the reminder postcards and the Avery USPS air bill label. Reminder postcard are printed once per year, so notify the technical supervisor when it is time to reorder; allow 6 weeks lead time. The tracking numbers on the Avery USPS air bill labels expire over time; therefore, they are requested from ISIS as needed.

Equipment

- Dymo label printer.

Supplies

- Home specimen collection kit (pre-assembled in the NHANES warehouse)
 - White cardboard outer box;
 - Styrofoam shipping container with date/time label affixed to top of lid;
 - Refrigerant gel pack pouch (Cold Ice™);

- One 60 milliliter plastic specimen cup w/ screw-on lid;
- One 5”X 5” zip closable plastic bag with absorbent pad; and
- Temperature monitoring strip (affixed to the inside lid of Styrofoam container).
- White Tyvek self-addressed postage-paid shipping envelope, containing:
 - “Exempt Human Specimen” label;
 - Avery USPS air bill label;
 - USPS postage stamp; and
 - Priority Mail sticker.
- 10” x 13” zip closable plastic bag;
- Hard-copy color “WHAT TO DO Urine Collection and Shipping Instructions” (Appendix C) in English and Spanish; and
- Reminder postcard (Appendix D) in English and Spanish.

The supplies and par level are listed in Exhibit 4-1.

Exhibit 4-1. FFMS inventory and par levels

Supply	Par level
Home specimen collection kits	10
White Tyvek shipping envelopes with Exempt Human Specimen label and Priority Mail label	10
Avery USPS air bill label - 5 1/2" x 8 1/2"	0*
USPS postage stamp - 1 st class stamp	10
WHAT TO DO Urine Collection and Shipping Instructions, English/Spanish	10
Confidential Label – Spanish (600)	1 box
Confidential Label – English (600)	1 box
10" x 13" – zip closable bag, clear (100 Bags / Bundle)	1 bundle
Permanent markers, black heavy point	2
12” x 15” FedEx padded pak envelope	30
Reminder postcard – English	800
Reminder postcard – Spanish	400
Dymo polyester labels—1” x 2 1/8”	2 rolls

*Air bills are requested from ISIS as needed.

4.3 Logon to the FFMS

To launch the FFMS, click on the **FFMS** icon on the desktop. The first screen is the **Connect to nhprodweb** screen, shown below. Enter the **User name** and **Password** and then select the **OK** button to move forward to the login screen or the **Cancel** button to exit. Exhibit 4-2 illustrates the Logon window.

Exhibit 4-2. FFMS connect to nhprodweb window



The FFMS **Log-in** screen displays and it is shown below in Exhibit 4-3. Enter the **User ID** and **Password** and press either **Enter** or click on the **Log in** button to launch the application.

Exhibit 4-3. FFMS Log-in screen

Field Follow-Up Management System - Version 9.2.0

Please Login

User ID
Lindstrom_b

Password
•••••

Remember My Login

[Login](#)

Please Read Entirely Before Agreeing to Proceed:

Information contained on this site is confidential and subject to protections specified in the Privacy Act of 1974 and Section 308(d) of the Public Health Service Act (42 USC 242M). Unauthorized access to this information and/or disclosure is a violation of these laws and regulations and subjects the violator to fines and possible incarceration. Note that any files downloaded to your PC must also be protected. You must delete these when they are no longer needed and cannot be transferred to media, other computers that are unprotected, (or to other Westat staff or external people not working for Westat on the NHANES project. Any questions regarding the transfer of this data will be referred to the Director of the NCHS Division of Health Examination Statistics and the NCHS Confidentiality Officer). Activity on this site is logged and monitored. If you do not have official business to conduct on this site, do not attempt to log-in.

Version Details

Version 9.2.0

ITS Num. Description

The session times out after 60 minutes.

4.4 Access the HUC Module

After logging in, the system defaults to the **Dietary Appointment Manager** screen. Select the **HUC** header (far right) to access to the HUC module. Exhibit 4-4 illustrates the default opening screen.

Exhibit 4-4. System default opening screen

Field Follow-Up Management System - Version 9.2.0

You signed in as Barbara Lindstrom [Log Out](#)

Dietary Hepatitis C STD FFQ PAM PSA Allergy ER ROF HUC

Contact Manager Appointment Manager Reminder Calls Call History Reports Supervisor

Dietary Appointment Manager

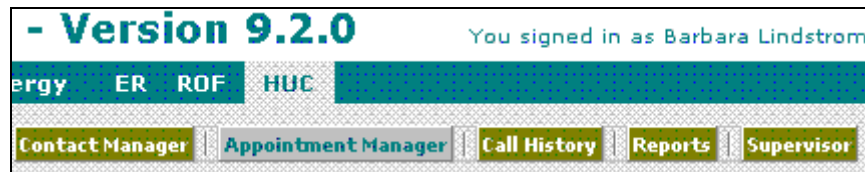
Filter Criteria (Optional)

4.5 Appointment Manager

The **Appointment Manager** module is designed to track scheduled appointments. However, this functionality is not necessary for the HUC component. It is useful to look at these data by day, week or month to get a sense of the number of SPs by appointment type.

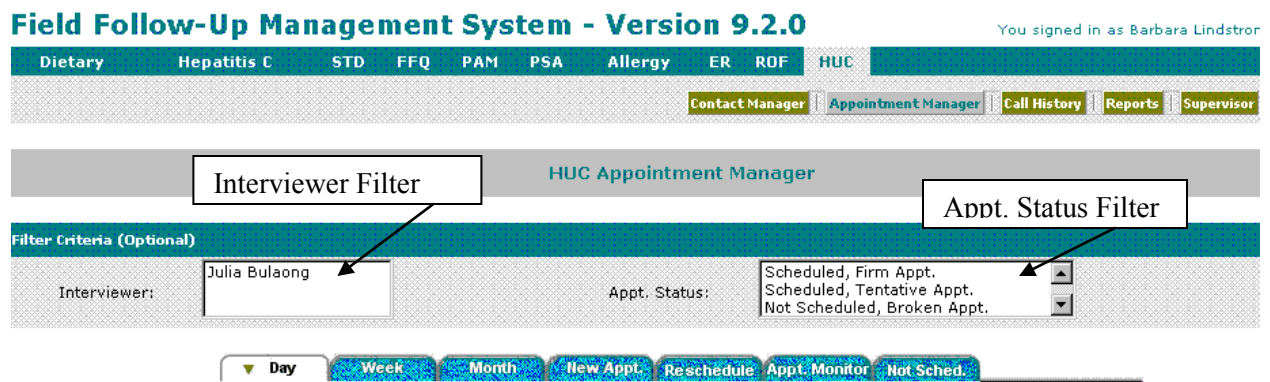
Select the HUC **Appointment Manager** button as shown below in Exhibit 4-5.

Exhibit 4-5. HUC Appointment Manager button



The **HUC Appointment Manager** screen displays and it is shown below in Exhibit 4-6.

Exhibit 4-6. Appointment Manager HUC screen



The screen will open to the **Day** tab. **Day** and **Week** tabs list all SPs who are scheduled and their appointment status. If there are no appointments, then the screen will include only the statement, "There are no appointments for 'today's date,' for the given criteria." Exhibit 4-7 illustrates the Day opening tab screen.

Exhibit 4-7. Day opening tab

▼ Day Week Month New Appt. Reschedule Appt. Monitor Not Sched.

Select A Day to View Appts

July 2009						
Sun	Mon	Tue	Wed	Thu	Fri	Sat
28	29	30	1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	31	1
2	3	4	5	6	7	8

Tuesday, July 28, 2009						
9:00 AM	163028	MARY SMITH2	50yrs	English	Appt. Completed	Rem:
9:00 AM	203468	MARY SMITH4	8yrs	English	Appt. Completed	Rem:
9:00 AM	254693	MARY SMITH1	61yrs	English	Scheduled, Tentative Appt.	Rem:
9:00 AM	278394	MARY SMITH5	9yrs	English	Appt. Completed	Rem:
9:00 AM	385150	MARY SMITH6	44yrs	English	Scheduled, Tentative Appt.	Rem:
9:00 AM	408725	MARY SMITH3	85yrs	English	Appt. Completed	Rem:

The appointment list includes a default time of 9:00 AM, SP ID, SP name, SP age, appointment status, and Rem:.

Select the **Month** tab to view a monthly calendar of all appointments by appointment type. Exhibit 4-8 is an example of the appointments by month screen. Use the links on the right and left side of the teal top border to go to the previous or next month.

Exhibit 4-8. Appointments by month screen

Field Follow-Up Management System - Version 9.2.0 You signed in as Barbara Lindstrom [Log Out](#)

Dietary Hepatitis C STD FFQ PAM PSA Allergy ER ROF **HUC**

Contact Manager Appointment Manager Call History Reports Supervisor

HUC Appointment Manager

Filter Criteria (Optional)

Interviewer: Carrie Humbertson
Julia Bulaong

Appt. Status: Scheduled, Firm Appt.
Scheduled, Tentative Appt.
Not Scheduled, Broken Appt.

Day Week **Month** New Appt. Reschedule Appt. Monitor Not Sched.

Select A Month to View Appts, Day to View Details

Jun	July 2009						Aug
Sun	Mon	Tue	Wed	Thu	Fri	Sat	
			1 9:00 AM <u>Mary Smith 1</u> 9:00 AM <u>Mary Smith 2</u>	2 9:00 AM <u>Mary Smith 3</u>	3 9:00 AM <u>Mary Smith 5</u>	4 9:00 AM <u>Mary Smith 6</u>	

Names are displayed in color and the color represents their appointment status. The appointment status legend (Exhibit 4-9) is listed below.

Exhibit 4-9. Appointment status legend

Green	Scheduled, Firm Appt. Mailperson scanned the kit into their system showing that it was picked up. Processed through Sort Facility (USPS data)
Black	Scheduled, Tentative Appt. SP said "Yes" in the MEC exam. Electronic Shipping Info Received (USPS data)
Red	Not Scheduled, Broken Appt. 14 days have elapsed since the SP was initially given the kit and there has been no tracking activity.
Blue	Appt. Completed USPS system marks the air bill as "received" meaning they delivered the kit. Delivered (USPS data)
Brown	Appt. Final-Nonresponse 30 days have elapsed since the SP was initially given the kit and there has been no tracking activity.

4.6 Call History

Document all contacts with an SP. To access the call history, click on his or her underlined name on the monthly appointment schedule or select the **Call History** button on the top of the module. If the link on the monthly calendar in Appointment Manager is selected, then the Call History screen for that SP displays.

If the **Call History** button on the top of the module is selected, then only blank text fields for SP ID, Last Name, and First name display. Enter the relevant information and select the **Search** button to access the call history for that SP. Exhibit 4-10 is an example of the HUC Call History search screen.

Exhibit 4-10. HUC Call History search screen

The screenshot displays the 'Field Follow-Up Management System - Version 9.2.0' interface. At the top right, it indicates the user is signed in as 'Barbara Lindstrom' with a 'Log Out' link. The main navigation bar includes modules: Dietary, Hepatitis C, STD, FFQ, PAM, PSA, Allergy, ER, ROF, and HUC. Below this, a secondary menu highlights 'Contact Manager', 'Appointment Manager', 'Call History', 'Reports', and 'Supervisor'. The central heading is 'HUC Call History'. Below the heading is a search form titled 'Enter Search Criteria' with the following fields: 'SP ID:', 'Last Name:', 'First Name:', 'Suffix:', and 'Stand:'. There are also 'Search' and 'Clear' buttons.

This module tracks the date and time of each call and the contact code if contact was unsuccessful.

Once the search criteria have been successfully entered and the search executed, the Call History screen displays. The screen displays the history of the calls for the SP identified on the **Call Information** screen. An example of the Call History screen is illustrated in Exhibit 4-11.

Exhibit 4-11. Call History screen

HUC Call History

Enter Search Criteria

SP ID: Last Name: First Name: Suffix: Stand:

Current Appointment: [Wednesday - 6/3/2009 9:00 AM](#) Initial Exam: [Saturday - 5/23/2009](#)

Current Appointment Status: [Appt. Completed, Updated on 6/9/2009](#)

Phone No.: (555)555-5555 Location: [Home](#) Comment: SP Will Call In:

Age: [36](#) Gender: [Female](#) Language: [English](#)

Dietary: [C](#) STD/HIV: [C](#) FCBS: [C](#)

Record Call History for SMITH ()

Appointment Date/Time: 6/3/2009 9:00 AM

Contact Made with SP: Yes No

Reschedule Appointment Yes No

Contact Status:

Other, Reason:

The features of this screen include:

- **Search Criteria bar.** Use this feature to access information about another SP. Enter the SP ID or the first and last name in the search criteria boxes at the top of the screen.
- **Contact Information box.** This top box provides contact information specific to the SP. It includes current appointment date and time, initial exam date, current appointment status and last update date, phone number, location, comments, age, gender, language, and appointment status for all components. (C = complete, S = scheduled [either tentative or firm], B = broken, FNR = Final non-response)
- **Record Call History table.** This table lists the history of call attempts for the SP. Record all contacts by marking **Contact Made with SP** yes or no and **Reschedule Appointment** yes or no, and recording **Contact Status** and **Other, Reasons**.
- **Update Call Info button.** This button updates the contact status information, after it's been entered into the FFMS (described below).

Note that for this SP the **Current Appointment Status** is Appt. Completed.

Documenting these status codes allows all interviewers to see what has transpired with previous call attempts to a particular SP. Assign a contact status for every attempt to contact the SP. Two contacts were made to the particular SP shown in Exhibit 4-12.

Exhibit 4-12. Example of contact attempts

Attempt No.	Date/Time	Contact Made	Contact Status	Other, Reason	Rescheduled
1	6/22/2009 6:12 PM	No	Reminder Postcard Sent		
2	7/7/2009 1:02 PM	No	Other	USPS envelope sent	

The contact status will automatically update with the date and time the reminder postcard was sent once the SP's postcard has been marked as sent.

Select a **Contact Status** from the list of possible choices. Exhibit 4-13 illustrates the various codes.

Exhibit 4-13. Contact status codes

Appointment Date/Time: 6/18/2009 9:00 AM

Contact Made with SP: Yes No

Reschedule Appointment: Yes No

Contact Status:

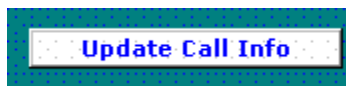
Other, Reason:

- Reminder Postcard Sent
- Replacement Kit Sent
- Other
- Appt. Rescheduled (DO NOT USE)

The contact codes are described below.

- **Reminder Postcard Sent** – The contact status will automatically update with the date and time the reminder postcard was sent once the SP’s postcard has been marked as sent.
- **Replacement Kit Sent** – Select this option when a replacement kit has been sent.
- **Other** – If none of the above contact codes applies, select “Other” and type in the reason.
- **Appt. Rescheduled (DO NOT USE)** – this choice is not applicable to the HUC.

After entering the information, select the **Update Call Info** button before exiting the module.

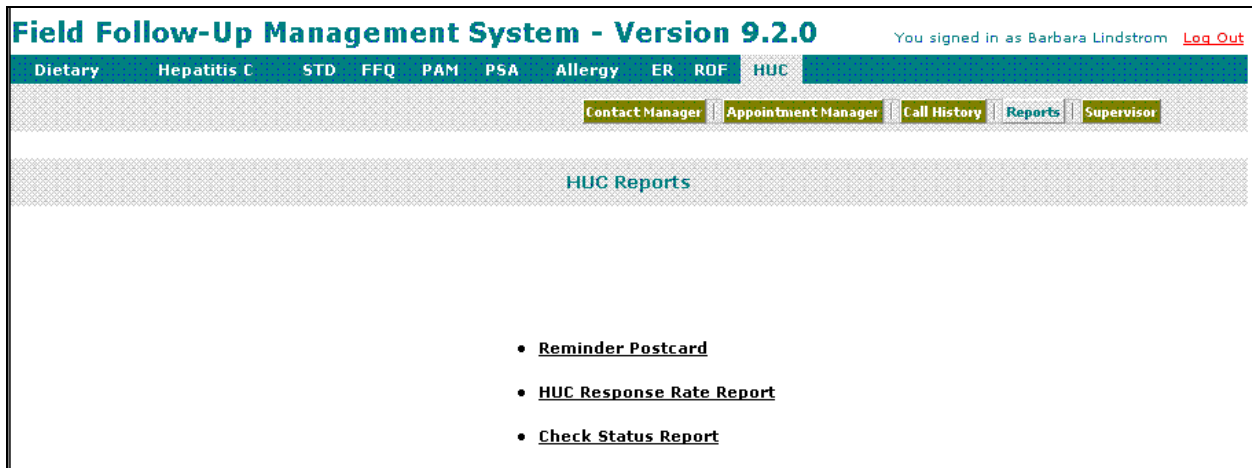


The button is highlighted in pink and is located above the updated information.

4.7 Reports

Use the **Reports** functionality to print labels for the reminder postcards, run the HUC Response Rate Report, and investigate the status of a particular payment check. Exhibit 4-14 illustrates the Reports screen and links.

Exhibit 4-14. HUC Reports screen and links



To access one of the three options, click on the desired link.

4.7.1 Reminder Postcard

At least daily, access the Reminder Postcard list, print labels, and mail the postcards. Select the [Reminder Postcard](#) link to access this functionality. Exhibit 4-15 illustrates the HUC Reminder postcard screen.

Exhibit 4-15. HUC Reminder Postcard screen

HUC Reports

Reminder Postcard

Print Label(s)
Mark Postcards as Mailed
 Print All

<u>SP ID</u>	<u>Name</u>	<u>Age</u>	<u>Stand</u>	<u>Initial Exam</u>	<u>Language</u>	<u>Generate Label</u>
184869	ERIC JONES	41	410		English	<input type="checkbox"/>
243260	JASON BALK	60	410		English	<input type="checkbox"/>
334755	JOSEPH OT	10	410		English	<input type="checkbox"/>
360722	CORY DEWICK	49	410		English	<input type="checkbox"/>
381736	JENNIFER DELACH	59	410		English	<input type="checkbox"/>
386651	HOPE CARROLL	14	410		English	<input type="checkbox"/>
392089	MICHAEL COSTANZO	42	410		English	<input type="checkbox"/>
411725	STEPHEN BREYER	33	410		English	<input type="checkbox"/>
437875	REUBEN OT	10	410		English	<input type="checkbox"/>
534770	BRIAN CATANZERITE	8	410		English	<input type="checkbox"/>
603252	JENNY BLOCK	42	410		English	<input type="checkbox"/>

The **Reminder Postcard** screen includes buttons for **Print Label(s)**, and **Mark Postcards as Mailed**, a check box for **Print All**, and columns for SP ID, Name (first, last), Age, Stand number, Initial Exam date, Language, and a checkbox for Generate Label.

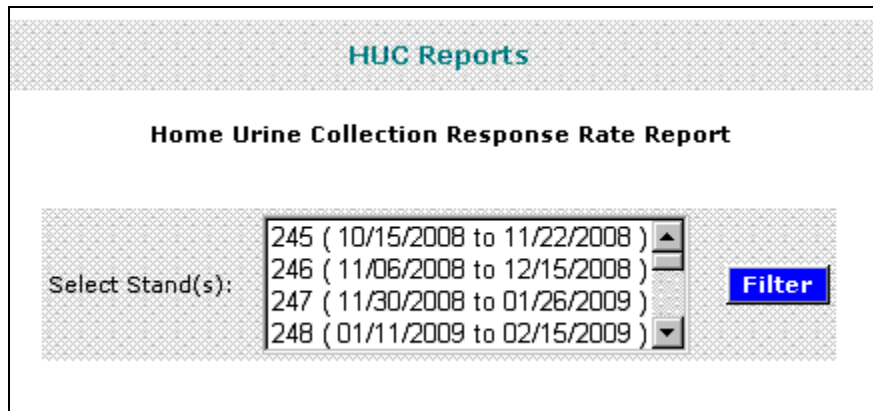
To individually mark each SP, check each **Generate Label** checkbox or, to print labels for all SPs in the list, select the **Print All** checkbox.

Use the language displayed for each SP to select the correct English or Spanish postcard. Affix the label to the postcard and mail the postcard through Westat’s routine mail system.

4.7.2 HUC Response Rate Report

Select the **HUC Response Rate Report** link to access this functionality. The first screen is illustrated in Exhibit 4-16.

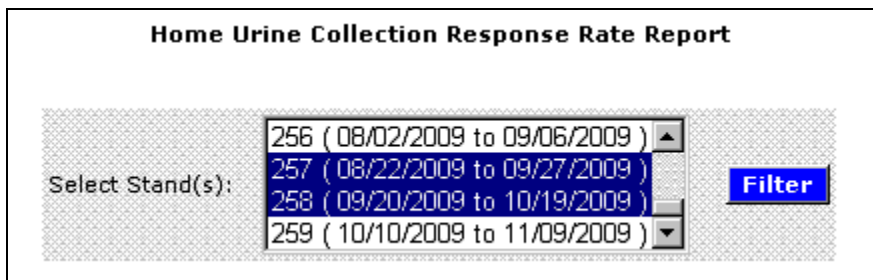
Exhibit 4-16. Response Rate Report first screen



The screenshot shows a web interface titled "HUC Reports" with a sub-header "Home Urine Collection Response Rate Report". Below the header is a selection area labeled "Select Stand(s):" containing a list of four stands with their respective date ranges: 245 (10/15/2008 to 11/22/2008), 246 (11/06/2008 to 12/15/2008), 247 (11/30/2008 to 01/26/2009), and 248 (01/11/2009 to 02/15/2009). Each stand entry has a small arrow icon to its right. To the right of the list is a blue button labeled "Filter".

The Response Rate Report includes a **Select Stand(s)** filter. Select or highlight the stand or stands. To select more than one stand, hold down the **Ctrl** key and click on the desired stands. Exhibit 4-17 illustrates an example where multiple stands were selected.

Exhibit 4-17. Response Rate Report multiple stands selected



The screenshot shows the same "Home Urine Collection Response Rate Report" selection screen. In this instance, the second, third, and fourth stands are highlighted with a blue background, indicating they have been selected. The selected stands are: 257 (08/22/2009 to 09/27/2009), 258 (09/20/2009 to 10/19/2009), and 259 (10/10/2009 to 11/09/2009). The "Filter" button remains visible to the right.

Once the stands have been selected, click on the **Filter** button to generate the report.

Exhibit 4-18 is an example of a HUC Response Rate Report.

Exhibit 4-18. HUC Response Rate Report example

Home Urine Collection Response Rate Report for stands: 252,253												
Select Stand(s):		245 (10/15/2008 to 11/22/2008) 246 (11/06/2008 to 12/15/2008) 247 (11/30/2008 to 01/26/2009) 248 (01/11/2009 to 02/15/2009)						Filter				
	All Ages		6 - 11 yrs		12 - 19 yrs		20 - 49 yrs		50 - 74 yrs		75+ yrs	
	#	%	#	%	#	%	#	%	#	%	#	%
SPs Eligible for MEC Urine Collection	592		63		106		229		138		56	
SPs Eligible - no urine collected	11	1.9	0	0	3	2.8	2	0.9	4	2.9	2	3.6
SPs Eligible - no vessel 45 collected	0	0	0	0	0	0	0	0	0	0	0	0
SPs Eligible for Home Urine Collection	581	98.1	63	100	103	97.2	227	99.1	134	97.1	54	96.4
SPs with Not Done HUC Status	13	2.2	1	1.6	1	1	5	2.2	3	2.2	3	5.6
SPs Provided Home Urine Collection Kit	568	97.8	62	98.4	102	99	222	97.8	131	97.8	51	94.4
Samples Outstanding <= 10 Days	1	0.2	0	0	0	0	1	0.5	0	0	0	0
Samples Outstanding > 10 Days	6	1.1	0	0	2	2	4	1.8	0	0	0	0
Broken Appointments with Reminder Postcards Sent	6	1.1	0	0	2	2	4	1.8	0	0	0	0
Samples in Transit	1	0.2	0	0	0	0	1	0.5	0	0	0	0
Samples Received by Contract Lab	469	82.6	46	74.2	81	79.4	174	78.4	120	91.6	48	94.1
Samples Marked as Final Non-Response	92	16.2	16	25.8	19	18.6	43	19.4	11	8.4	3	5.9

The report breaks down the response rate by number and percent for the following age groups: All ages, 6-11, 12-19, 20-49, 50-74, and 75+. It includes the following data:

- SP eligible for MEC urine collection by:
 - SPs eligible – no urine collected
 - SPs eligible – no vessel 45 collected
- SPs eligible for home urine collection (SP eligible for MEC Urine Collection minus SPs eligible – no urine collected and SPs eligible – no vessel 45 collected)
- SPs with Not Done HUC status
- SPs provided home urine collection kit
 - Samples outstanding <= to 10 days
 - Samples outstanding > 10 days
 - Broken appointments with reminder postcard sent
 - Samples in transit
 - Samples received by contract lab
 - Samples marked as Final Non-Response

4.7.3 Check Status Report

Use the **Check Status Report** functionality to check the status of HUC payments.

Select the **Check Status Report** link to access this functionality. This search screen is illustrated in Exhibit 4-19.

Exhibit 4-19. Check Status Report search screen

Enter the SP ID or the first and last name in the search criteria boxes at the top of the screen. Select the **Search** button to initiate the search. Select the **Clear** button to clear the fields.

The Report displays after the search button has been selected. An example is illustrated in Exhibit 4-20.

Exhibit 4-20. Check Status Report example

SP ID	Name	Component	Appt Status	Check Date	Batch No	Check Amount
111111	MARY SMITH1	HUC	Appt. Completed	06/15/09	100058	\$40.00
111111	MARY SMITH1	Dietary	Appt. Completed	07/09/09	101173	\$30.00
111111	MARY SMITH1	ER	Not Scheduled			
111111	MARY SMITH1	FCBS	Appt. Completed	07/09/09	10757	\$15.00

The screen includes the SP ID, Name, Component, Appt Status, Check Date, Batch No, and Check Amount.

4.8 Supervisor

Use the **Supervisor** functionality to (1) view a report that lists SPs by appointment status and stand and (2) assign employees to the HUC component within the FFMS. There are three links: **Appointment Monitoring Report**, **Interviewer Scheduler**, and **HUC Module Security**. The Interview Scheduler link is not applicable to the HUC component. The main screen is illustrated in Exhibit 4-21.

Exhibit 4-21. Supervisor main screen



To access one of the two applicable options, click on the desired link.

4.8.1 Appointment Monitoring Report

Use the **Appointment Monitoring Report** to view a report that lists SPs by appointment status and stand. To access the module, select the link. The search criteria screen displays and it is illustrated in Exhibit 4-22.

Exhibit 4-22. Appointment Monitoring Report – select criteria

The screenshot shows a web interface for a HUC Supervisor. At the top, it says "HUC Supervisor" in blue. Below that is the title "Appointment Monitoring Report". A red message says "Please select a stand.". The main area is titled "Select Criteria" and contains a "Filter" button in the top right. Under "APPOINTMENT STATUS:", there are six radio button options: "Scheduled", "Appts. Not Completed within 10 days of Primary" (which is selected), "All Broken Appts.", "Complete Appts.", "All Final, Non-Response Appts.", and "Not Scheduled". To the right, under "STAND(S):", there is a list box containing "Year 1 Stands", "Year 10 Stands", "Year 11 Stands", and "Year 2 Stands".

Select the **APPOINTMENT STATUS** by clicking on the desired radio button and then select or highlight the stand or stands. To select more than one stand, hold down the **Ctrl** key and click on the desired stands. When finished, select the **Filter** button to run the report.

The appointment status for all SPs who meet the criteria displays with each SP contained in a separate box. Exhibit 4-23 is an example of an appointment monitoring report.

Exhibit 4-23. Appointment Monitoring Report example

Field Follow-Up Management System - Version 9.2.0 You signed in as Barbara Lindstrom [Log Out](#)

Dietary Hepatitis C STD FFQ PAM PSA Allergy ER ROF HUC

Contact Manager Appointment Manager Call History Reports Supervisor

HUC Supervisor

Appointment Monitoring Report for Stand(s): 253

Select Criteria Filter

APPOINTMENT STATUS:

- Scheduled
- Appts. Not Completed within 10 days of Primary
- All Broken Appts.
- Complete Appts.
- All Final, Non-Response Appts.
- Not Scheduled

STAND(S):

- Year 1 Stands
- Year 10 Stands
- Year 11 Stands
- Year 2 Stands

Update Changes

SP ID	Name	Age	Initial Exam	Current Appt.	Stand ID	
111111	MARY SMITH	16	5/28/2009	6/8/2009 9:00 AM	253	
Appt. Status: Appt. Final-Non-Response Reason: SP Refusal Other Text: <input type="text"/>						
	<u>Attempt No.</u>	<u>Date/Time</u>	<u>Contact Made</u>	<u>Contact Status/Description</u>	<u>Contact By</u>	<u>Rescheduled</u>
	1	6/10/2009 4:50 PM	No	Reminder Postcard Sent	Sandra Ayala	

The criteria box remains on the top of the screen. The teal header includes the SP ID, Name, age, initial exam date, current appointment date, and stand number. The lower section includes text boxes for Appt Status, Reason, and Other Text.

Change the appointment status, reason, and/or enter free text. Exhibit 4-24 shows the appointment status change options.

Exhibit 4-24. Appointment Status change options

Appt. Status: Appt. Final-Non-Response

- Scheduled, Firm Appt.
- Scheduled, Tentative Appt.
- Not Scheduled
- Not Scheduled, Broken Appt.
- Appt. Completed
- Appt. Final-Non-Response

To change the appointment status, select or highlight the correct choice from the drop-down list.

The default reason for HUC exams coded as final non-response is **SP Refusal**. Do not change this to any of the other options. Exhibit 4-25 illustrates the various reason options.

Exhibit 4-25. Appointment Status reason options

Reason: SP Refusal

- SP Refusal
- Language Problem
- Hearing Impaired
- Unable to contact SP
- End of Feasibility
- Other

Any **Call History** attempts display under the lower section as illustrated by Exhibit 4-26.

Exhibit 4-26. Call History displays at bottom of SPs window

Field Follow-Up Management System - Version 9.2.0 You signed in as Barbara Lindstrom [Log Out](#)

Dietary Hepatitis C STD FFQ PAM PSA Allergy ER ROF HUC

Contact Manager Appointment Manager **Call History** Reports Supervisor

HUC Supervisor

Appointment Monitoring Report for Stand(s): 254

Select Criteria [Filter](#)

Scheduled
 Appts. Not Completed within 10 days of Primary
 All Broken Appts.
 Complete Appts.
 All Final, Non-Response Appts.
 Not Scheduled

APPOINTMENT STATUS: STAND(S):

[Update Changes](#)

SP ID	Name	Age	Initial Exam	Current Appt.	Stand ID
111111	MARY SMITH1	63	6/1/2009	6/12/2009 9:00 AM	254
Appt. Status: <input type="text" value="Appt. Completed"/>		Reason: <input type="text"/>		Other Text: <input type="text"/>	
Attempt No.	Date/Time	Contact Made	Contact Status/Description	Contact By	Rescheduled
1	6/15/2009 4:31 PM	No	Reminder Postcard Sent	Pat Soto	

Select the **Update Changes** button to save the changes to the database.

[Update Changes](#)

4.8.2 HUC Module Security

Use the **HUC Module Security** link to assign employees to the HUC component within the FFMS and to give them permission to access the various modules within the HUC component. To access the module, select the link. Exhibit 4-27 illustrates the HUC Module security screen.

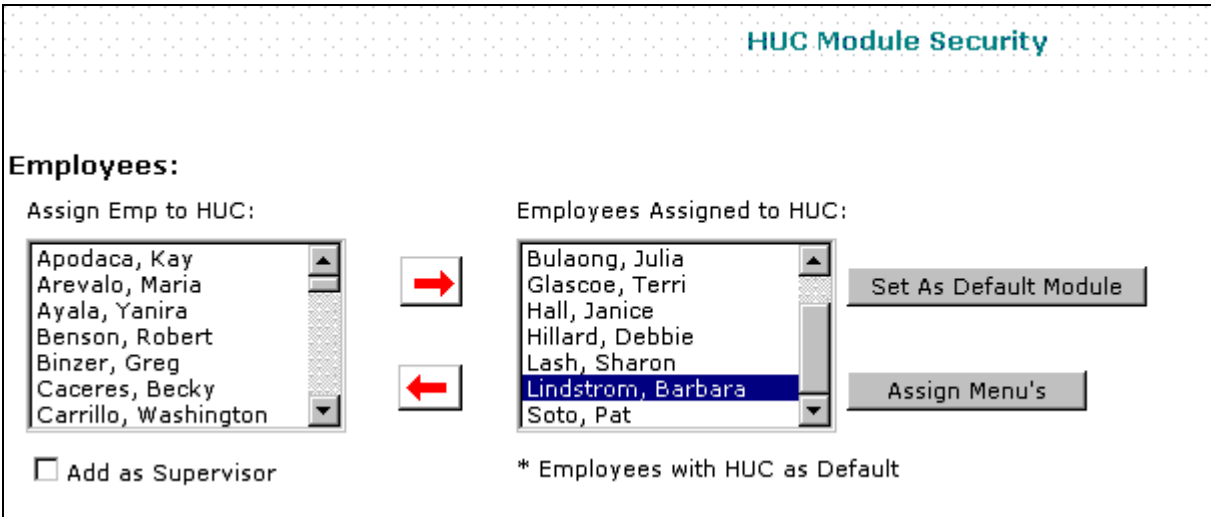
Exhibit 4-27. HUC Module security screen

The screenshot displays the 'HUC Module Security' interface. At the top, the system title is 'Field Follow-Up Management System - Version 9.2.0' and the user is signed in as 'Barbara Lindstrom'. The navigation bar includes links for 'Dietary', 'Hepatitis C', 'STD', 'FFQ', 'PAM', 'PSA', 'Allergy', 'ER', 'ROF', and 'HUC'. Below this, there are buttons for 'Contact Manager', 'Appointment Manager', 'Call History', 'Reports', and 'Supervisor'. The main content area is titled 'HUC Module Security' and contains two columns of employee names. The left column, labeled 'Assign Emp to HUC:', lists: Apodaca, Kay; Arevalo, Maria; Ayala, Yanira; Benson, Robert; Binzer, Greg; Caceres, Becky; and Carrillo, Washington. The right column, labeled 'Employees Assigned to HUC:', lists: Ayala, Sandra; Bernas, Stephen; Bulaong, Julia; Glascoe, Terri; Hall, Janice; Hillard, Debbie; and Lash, Sharon. Between the columns are two red arrows: a right-pointing arrow above and a left-pointing arrow below. To the right of the right column are two buttons: 'Set As Default Module' and 'Assign Menu's'. At the bottom left, there is a checkbox labeled 'Add as Supervisor'. At the bottom center, there is a note: '* Employees with HUC as Default'.

Two employee text boxes display. The left text box includes the names of employees who are eligible to be assigned to the HUC module. The right text box includes the names of employees who have been assigned to the HUC FFMS module. Use the bright red arrows to move the employees between the two boxes.

Assign specific menus to specific individuals who have been assigned to the module. This screen is illustrated in Exhibit 4-28.

Exhibit 4-28. HUC Module security - assign menus



To assign specific menus to specific individuals select or highlight the employee from the right box and then select the **Assign Menu's** button. The menu options text boxes display. These additional text boxes are illustrated in Exhibit 4-29.

Exhibit 4-29. HUC Module security - available menus

HUC Module Security

Employees:

Assign Emp to HUC:

- Apodaca, Kay
- Arevalo, Maria
- Ayala, Yanira
- Benson, Robert
- Binzer, Greg
- Caceres, Becky
- Carrillo, Washington

Employees Assigned to HUC:

- Ayala, Sandra
- Bernas, Stephen
- Bulaong, Julia
- Glascoe, Terri
- Hall, Janice
- Hillard, Debbie
- Lash, Sharon

Add as Supervisor

* Employees with HUC as Default

HUC Menus for Lindstrom, Barbara:

Available Menus:

Menus Assigned to Lindstrom, Barbara:

- Appointment Manager *
- Call History
- Contact Manager
- Reports
- Supervisor

The interface includes two sets of list boxes with red arrows for moving items between them. Buttons for 'Set As Default Module' and 'Assign Menu's' are located to the right of the 'Employees Assigned to HUC' list. A checkbox for 'Add as Supervisor' is located below the 'Assign Emp to HUC' list.

To move one or more of the menu options from one box to the other, click on the bright red arrow.

To designate someone as a supervisor, highlight the name and add a checkmark to the **Add as Supervisor** checkbox. This option is illustrated in Exhibit 4-30.

Exhibit 4-30. HUC Security Module – assign supervisor status

Employees:

Assign Emp to HUC:

Apodaca, Kay	→	Ayala, Sandra	Set As Default Module
Arevalo, Maria		Bernas, Stephen	
Ayala, Yanira		Bulaong, Julia	
Benson, Robert		Glascoe, Terri	
Binzer, Greg		Hall, Janice	
Caceres, Becky	←	Hillard, Debbie	Assign Menu's
Carrillo, Washington		Lash, Sharon	

Add as Supervisor

* Employees with HUC as Default

Use the **Set as Default Module** button to set the module that is displayed when the application opens. However, if the application is opened in the same browser window that it was opened in previously, meaning logged out and back in without closing the window, then the application remembers the module that was displayed when logging out regardless of the default.

5. CHECK PROTOCOL

5.1 Overview

Remuneration checks for \$40 are generated once the mailperson scans the kit into the USPS system showing that the kit was picked up. The PF appointment is “Scheduled, Firm.” The ISIS check application is used to send check information to Westat accounting for the generation of checks to respondents who sent in their urine sample.

The check application generates a unique batch ID each time it generates a group of checks. The check extraction application first determines the list of participants that need checks. Then the check application retrieves the name of the participant from the nh_person table along with the address. The check is mailed from the same address sources used by the HUC kit generation page. This information is placed in the Access database specified by Accounting and emailed to them. Accounting then cuts the necessary checks. The SP ID and check batch number appear in the memo field of each check for tracking purposes.

The email to Accounting is generated and checks are mailed twice a week, on Monday and Thursday. The home office dietary phone staff are responsible for mailing the checks. They place the check in an envelope with a letter (Exhibits 5-1 and 5-2) and mail the checks. Checks are sent to an address instead of an individual, similar to the other components.

Exhibit 5-1. English letter – check enclosure

Dear Participant:

Thank you for participating in the National Health and Nutrition Examination Survey (NHANES) by sending us your urine collection kit.

Enclosed is a check for \$40 as a token of appreciation. If additional family members also received a urine kit, they will receive their check once we receive their kit.

Thank you once again for taking part in this important study. If you have any questions regarding this payment, please call **1-888-458-4762** Monday through Friday between the hours of 8:00 AM and 4:30 PM Eastern Time.

Sincerely,

Sharon Lash
Senior Study Manager

Enclosure

Exhibit 5-2. Spanish letter – check enclosure

Estimado(a) participante:

Gracias por participar en la Encuesta Nacional de Examen de Salud y Nutrición (NHANES) al mandarnos los materiales de su muestra de orina.

Adjunto hay un cheque por \$40 dólares como muestra de agradecimiento. Si otros familiares también recibieron materiales para una muestra de orina, ellos recibirán su cheque una vez que nosotros recibamos sus materiales.

Gracias nuevamente por participar en este importante estudio. Si desea hacer alguna pregunta relacionada con este estudio, por favor llame al **1-888-458-4762** de lunes a viernes entre las 8:00 de la mañana y las 4:30 de la tarde, hora del Este.

Atentamente,

Sharon Lash
Administrador de alto cargo del estudio

Se adjunta cheque

6. AIR BILL TRACKING AND DELIVERY STATUS

6.1 Overview

Tracking emails are sent daily to home office staff (Exhibit 6-1). MEC shipments are sent by FedEx USPS Priority Mail. Shipments that are not marked as delivered within 24 hours are tracked as “In Transit.” Home office FFMS (Field Follow-Up Management System) support staff investigate all shipments where the “No (number) of Days Pending” is greater than 8 days. They email the analysis lab and include the SP ID and number of days pending. If the analysis lab indicates that they received the sample, then the home office system analysis is notified and the database is updated accordingly.

Exhibit 6-1. Sample tracking email

From: FedexTracking@westat.com Sent: Mon 8/10/2009 12:17 PM
 To: Kimberly Sun; Stephen Bernas; Lakshmi Venkateraman; Debbie Hillard; Barbara Lindstrom; Renee Storandt
 Cc:
 Subject: NHANES Airbill tracking

Lab airbills in transit:

Lab

Airbill No	Lab ID	Shipped DT	Container/SP ID	No of Days Pending	e-mail address
420554559101805213907474795408	16	8/7/2009	959167	3	microalb@umn.edu sawye014@umn.edu
420554559101805213907616083325	16	8/9/2009	147984	1	microalb@umn.edu sawye014@umn.edu
420554559101805213907513125890	16	8/8/2009	189089	2	microalb@umn.edu sawye014@umn.edu
420554559101805213907544196494	16	8/7/2009	433159	3	microalb@umn.edu sawye014@umn.edu
420554559101805213907544196630	16	8/8/2009	401070	2	microalb@umn.edu sawye014@umn.edu
420554559101805213907575612895	16	8/9/2009	205195	1	microalb@umn.edu sawye014@umn.edu

Selecting any air bill number links to the USPS web site where track and confirm information is available. Exhibits 6-2 through 6-4 illustrate the three examples.

Exhibit 6-2. Example Status 1 Electronic Shipping Info Received

The screenshot displays the USPS Track & Confirm interface. At the top left is the United States Postal Service logo. On the top right are links for Home, Help, and Sign In. Below the header is a navigation bar with buttons for Track & Confirm and FAQs. The main content area is titled 'Track & Confirm' and contains a 'Search Results' section. The search results show a label/receipt number of 4205 5455 9101 8052 1390 7338 3116 21, a class of Priority Mail, a service of Delivery Confirmation, and a status of Electronic Shipping Info Received. A text block explains that the USPS was notified by the shipper on May 19, 2009, to expect the package for mailing, but no further information is available. To the right of the search results is a 'Track & Confirm' search box with a text input field labeled 'Enter Label/Receipt Number.' and a 'Go >' button. Below the search results is a 'Notification Options' section with a sub-section 'Track & Confirm by email' and a 'Go >' button.

UNITED STATES POSTAL SERVICE® [Home](#) | [Help](#) | [Sign In](#)

[Track & Confirm](#) [FAQs](#)

Track & Confirm

Search Results

Label/Receipt Number: **4205 5455 9101 8052 1390 7338 3116 21**
Class: **Priority Mail®**
Service(s): **Delivery Confirmation™**
Status: **Electronic Shipping Info Received**

The U.S. Postal Service was electronically notified by the shipper on May 19, 2009 to expect your package for mailing. This does not indicate receipt by the USPS or the actual mailing date. Delivery status information will be provided if / when available. No further information is available for this item.

Track & Confirm

Enter Label/Receipt Number.

[Go >](#)

Notification Options

Track & Confirm by email

Get current event information or updates for your item sent to you or others by email. [Go >](#)

Exhibit 6-3. Example Status 4 Processed through Sort Facility



[Home](#) | [Help](#) | [Sign In](#)

[Track & Confirm](#)

[FAQs](#)

Track & Confirm

Search Results

Label/Receipt Number: **4205 5455 9101 8052 1390 7382 9367 88**

Class: **Priority Mail®**

Service(s): **Delivery Confirmation™**

Status: **Processed through Sort Facility**

Your item was processed through and left our BETHPAGE, NY 11714 facility on June 15, 2009. The item is currently in transit to the destination. Information, if available, is updated periodically throughout the day. Please check again later.

Detailed Results:

- **Processed through Sort Facility, June 15, 2009, 6:36 pm, BETHPAGE, NY 11714**
- **Electronic Shipping Info Received, April 24, 2009**

Notification Options

Track & Confirm by email

Get current event information or updates for your item sent to you or others by email. [Go >](#)

Track & Confirm

Enter Label/Receipt Number.

[Go >](#)

Exhibit 6-4. Example Status 2 Delivered



[Home](#) | [Help](#) | [Sign In](#)

[Track & Confirm](#)

[FAQs](#)

Track & Confirm

Search Results

Label/Receipt Number: **4205 5455 9101 8052 1390 7359 1422 73**

Class: **Priority Mail®**

Service(s): **Delivery Confirmation™**

Status: **Delivered**

Your item was delivered at 10:37 AM on June 13, 2009 in MINNEAPOLIS, MN 55414.

Detailed Results:

- **Delivered, June 13, 2009, 10:37 am, MINNEAPOLIS, MN 55414**
- **Acceptance, June 06, 2009, 9:49 am, NORTH KINGSTOWN, RI 02852**
- **Electronic Shipping Info Received, May 19, 2009**

Notification Options

Track & Confirm by email

Get current event information or updates for your item sent to you or others by email. [Go >](#)

Track & Confirm

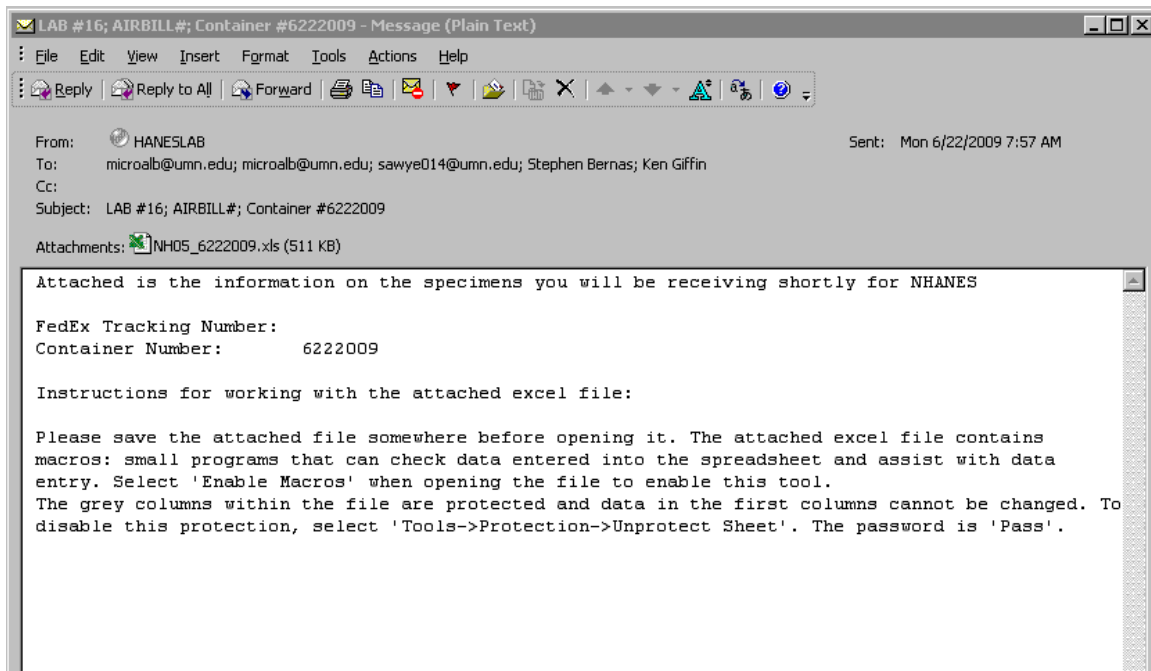
Enter Label/Receipt Number.

[Go >](#)

6.2 Email Sent Weekly to Analysis Lab

On occasion USPS does not mark a package as delivered in their tracking system so the analysis lab emails a file weekly. This file contains a list of every SP ID marked as received in the database in the past week. The contact lab staff use this file to reconcile the samples they received with the list of samples that were marked by the USPS as delivered. Exhibit 6-5 is an example of this email.

Exhibit 6-5. Example emailed file sent to analysis lab



No action is required.

Appendix A

Talking Points
English and Spanish
and
Home Collection Kit Preparation

Talking Points

Label the parts of the kit and show the SP their unique picture sticker. Show the SP the “WHAT TO DO, Urine Collection and Shipping Instructions.”

Maintain good eye contact as you stress the following specimen collection points:

- * Specific details about how to collect and ship the sample is contained in this document. It is included in the kit you are taking home.
- * It is very important not to mix up specimen cups when there are multiple participants in one family.
- * Remember to urinate (pee) into the cup when you wake up.
- * Collect your urine sample as soon as possible and ideally within the next 14 days. However, if you cannot collect it within 14 days then please collect and ship it at your earliest convenience.
- * Fill the cup to the line on the label and screw the lid tightly on the specimen cup.
- * Remember to write the date and time you collected the urine sample on the label on the top of the Styrofoam lid.
- * Place the Cold Ice gel refrigerant pack in the freezer overnight or for at least 6 hours.
- * Whenever possible, mail the kit the same day the urine was collected.
- * If the urine specimen has not been received by the laboratory in 14 days, then a reminder postcard will be sent to you. If you have already sent your urine then ignore this postcard.
- * Do **not** mail the large outer plastic bag to the laboratory.
- * We will send you a check for \$40.00 as soon as you ship the package.
- * If you have any questions then call the toll-free telephone number on the Urine Collection and Shipping Instructions sheet.

Talking Points

Marque las partes del paquete de materiales para tomar la muestra y muéstrela a la persona que da la muestra (SP) la etiqueta con su imagen única. Muéstrela a esta persona las páginas “QUÉ HACER, Instrucciones para recolección y envío de una muestra de orina”.

Mantenga un buen contacto visual mientras explica los siguientes aspectos de la recolección de la muestra:

- * Este documento contiene los detalles específicos de cómo tomar y enviar la muestra. Se incluye en el paquete de materiales para tomar la muestra que usted se llevará a su hogar.
- * Es muy importante no mezclar los envases de la muestra cuando hay varios participantes en una familia.
- * Recuerde orinar en el envase cuando usted se levante.
- * Tome la muestra de orina tan pronto como sea posible e idealmente dentro de los próximos 14 días. Sin embargo, si no puede tomar la muestra dentro de los siguientes 14 días, entonces tómela y envíela tan pronto como pueda.
- * Llene el envase hasta la línea de la etiqueta y ponga y ajuste fuertemente la tapa del envase.
- * Recuerde anotar la fecha y la hora en que se tomó la muestra en la etiqueta que hay en la tapa de la caja de poliestireno.
- * Ponga el paquete blanco de hielo-gel Cold Ice en el congelador durante la noche o por lo menos durante 6 horas.
- * Si es posible, envíe el paquete con los materiales el mismo día que tomó la muestra de orina.
- * Si el laboratorio no recibe las muestras en 14 días, se le enviará una tarjeta para recordárselo. Si usted ya ha enviado su muestra de orina, ignore esa tarjeta.
- * **No** envíe al laboratorio la bolsa plástica exterior.
- * Le mandaremos un cheque por \$40.00 dólares tan pronto como envíe el paquete.
- * Si desea hacer alguna pregunta, llame al número gratis que hay en las Instrucciones para recolección y envío de una muestra de orina.

Labeling the Kit Summary

- Open the urine collection kit. Confirm that the temperature monitoring strip is affixed to the inside lid of the Styrofoam shipping container.
- Apply the Dymo bar code label to the specimen cup, aligning the fill line on the label with the 30 ml line of the specimen cup.
- Write the SP's name with permanent black marker on the 10" x 13" plastic zip closable bag. **NOTE:** this is the only location on the kit where the SP name is identified.
- Apply the appropriate language confidentiality label to the 10" X 13" zip closable bag.
- Apply one picture sticker to the large plastic bag beside the confidentiality label.
- Apply the second picture sticker to the specimen cup beside the SP ID label on the side of the specimen cup.
- Apply the third picture sticker to the back side of the Tyvek shipping envelope.

Appendix B

Informational Letters English and Spanish



Dear Participant,

Recently, you participated in the National Health and Nutrition Examination Survey (NHANES) operated by the Centers for Disease Control and Prevention. When you took part in the survey we tested your urine for kidney health. We are writing to ask that you provide us with a second urine sample.

Collection of urine is safe and will not cause discomfort. Many studies with children and adults have used home urine collection kits. By collecting this second sample we hope to learn more about the kidney health of the United States.

Why are you asking me to provide a second urine sample?

Collecting a second urine specimen will help us better understand how many people in the US have kidney disease. People with protein in their urine may have early kidney disease or their kidneys may be normal. Checking a second urine sample for protein gives us more information.

Was my first urine sample normal or abnormal?

The result of your first test may have been normal or it may have indicated increased protein. If you had a lot of protein in your first urine sample, a separate letter will be mailed to you.

What am I supposed to do with this package?

We are asking you to provide a urine sample using the enclosed kit provided. Your participation is voluntary.

Inside the package you will find

- Large plastic bag with an instruction label and a picture sticker
- “WHAT TO DO” Urine Collection and Shipping Instruction” sheet
- White cardboard outer box
- Styrofoam shipping container with date and time label
- White refrigerant gel pack pouch
- Plastic screw cap collection cup with a picture sticker
- Zip closable bag with absorbent sheet
- White shipping envelope with Exempt Human Specimen label, postage paid and picture sticker



What should I do with the Cold Ice™ ice pack?

Place the Cold Ice pouch in your freezer overnight (or at least 6 hours) **before** collecting the urine.

What am I supposed to do with the cup?

You will use the cup to collect the urine specimen. Please read and follow the instructions on the “WHAT TO DO” Urine Collection and Shipping Instruction sheet provided with the kit.

How do I mail the kit?

Give the envelope containing your kit to your mailperson or place it in your mailbox or in any United States Postal Service mailbox as soon as possible after collection. When we receive the box, we will mail you a check for \$40.

Is there a special time of day to collect the specimen?

This is very important. You should urinate (pee) into the cup first thing in the morning. Fill the cup to the line as soon as you get out of bed.

What do I do after I have I have urinated (peed) into the cup?

Put the lid on tightly, wipe off the outside, and follow the instructions for mailing the cup.

Who do I contact if I have questions?

Our staff will answer any questions you have Monday-Friday from 8:30 AM to 6:00 PM Eastern Time at 1-888-458-4762.

You will get the results of your urine test by mail in 3 months.



Estimado(a) participante:

Recientemente, usted participó en la Encuesta Nacional de Examen de Salud y Nutrición (NHANES por sus siglas en inglés), que administran los Centros para el Control y la Prevención de Enfermedades. Cuando participó en la encuesta le hicimos una prueba de orina para examinar la salud del riñón. Le estamos escribiendo para pedirle que proporcione una segunda muestra de orina.

Tomar una muestra de orina es seguro y no le causará malestar. Muchos estudios en niños y adultos han usado materiales para tomar muestras de orina en el hogar. Al tomar esta segunda muestra esperamos saber más acerca de la salud del riñón de las personas que viven en Estados Unidos.

¿Por qué se me pide que proporcione una segunda muestra de orina?

Recolectar una segunda muestra de orina nos ayudará a saber cuántas personas en Estados Unidos tienen una enfermedad de los riñones. Las personas que tienen proteína en la orina posiblemente tienen una enfermedad de los riñones en la fase inicial, o puede que sus riñones sean normales. Observar una segunda muestra de orina en busca de proteína nos dará más información.

¿Fue mi primera muestra de orina normal o anormal?

El resultado de su primera prueba puede haber sido normal o puede haber indicado aumento de la proteína. Si usted tenía mucha proteína en su primera muestra de orina, se le informará en una carta separada.

¿Qué debo hacer con este paquete?

Le pedimos que proporcione una muestra de orina usando los materiales que se adjuntan. Su participación es voluntaria.

Dentro del paquete encontrará...

- Una bolsa grande de plástico con una etiqueta con instrucciones y una etiqueta con un símbolo
- Hoja de instrucciones “QUÉ HACER” para recolección y envío de la muestra de orina
- Caja de cartón blanco
- Caja de poliestireno expandido para envío con etiqueta para fecha y hora



- Paquete blanco de hielo-gel PolarPack™
- Envase de plástico con tapa y una etiqueta con un símbolo
- Bolsa con cierre (Zip-lock) con toalla absorbente
- Sobre blanco para envío con etiqueta “EXEMPT HUMAN SPECIMEN” y costo pre pagado y una etiqueta con un símbolo

¿Qué debo hacer con el paquete blanco de hielo-gel Cold Ice™?

Ponga el paquete blanco de hielo-gel “Cold Ice” en el congelador durante la noche (o por lo menos durante 6 horas) **antes** de tomar la muestra de orina.

¿Qué debo hacer con el envase de plástico para la muestra de orina?

Use el envase de plástico para poner la muestra de orina. Por favor lea y siga las instrucciones para tomar y enviar la muestra de orina de la hoja “QUÉ HACER” que se proporciona junto con los materiales.

¿Cómo envío el paquete?

Entréguele el sobre con los materiales de la muestra a su cartero o póngalo en su buzón o en cualquier buzón del Servicio Postal de Estados Unidos tan pronto como sea posible después de tomar la muestra. Cuando recibamos la caja, le enviaremos un cheque por \$40 dólares.

¿Hay una hora especial del día para tomar la muestra de orina?

Esto es muy importante. Debe orinar en el envase de plástico para la muestra de orina tan pronto como se despierte por la mañana. Inmediatamente después de levantarse, orine en el envase de plástico llenándolo hasta la línea.

¿Qué hago después de orinar en el envase de plástico para la muestra de orina?

Ponga y ajuste firmemente la tapa, limpie la parte de afuera y siga las instrucciones para enviar el envase de plástico por correo.

¿Con quién me puedo comunicar si deseo hacer alguna pregunta?

Nuestro personal responderá cualquier pregunta que desee hacer de lunes a viernes desde las 8:30 de la mañana a las 6:00 de la tarde, hora del Este, en el 1-888-458-4762.

Recibirá los resultados de su prueba de orina por correo dentro de 3 meses.

Appendix C

“What To Do”

**Urine Collection and Shipping Instructions
English and Spanish**

“WHAT TO DO”

Urine Collection and Shipping Instructions

Collect a urine sample and ship it to the laboratory using these instructions.

Collect your urine sample as soon as possible - ideally within the next 14 days. However, if you cannot collect it within 14 days then please collect and ship it at your earliest convenience.

We will send you a check for \$40.00 as soon as you ship the package.

The bag you received in the mobile examination center includes:

- Large zip closable bag with a confidentiality statement, your name written on the bag, and your personal picture sticker
- “WHAT TO DO” Urine Collection and Shipping Instructions sheet
- Department of Health and Human Services Cover Letter
- The home urine collection kit



Your Personal Picture Sticker:

Your picture sticker is unique to you and it is found on:

- The large zip closable bag with your name written on it
- Your urine collection cup
- The back of your shipping envelope

The picture sticker identifies your kit from kits assigned to other people in your household. When collecting and shipping your urine, make sure you use the collection cup and shipping envelope marked with your unique picture sticker.



Home Urine Collection Kit Contents:

- A.** White cardboard outer box
- B.** Styrofoam shipping container
- C.** Temperature monitoring strip
- D.** White shipping envelope with Exempt Human Specimen, picture sticker, and postage paid labels
- E.** White refrigerant gel pack pouch
- F.** Plastic screw cap urine collection cup with your picture sticker
- G.** Small zip closable bag with absorbent sheet



Kit Preparation:

1. Remove kit from the large zip closable bag.
2. Open the white cardboard box.
3. Slide the Styrofoam shipping container out of the cardboard box.
4. Open the Styrofoam container.
5. Remove the white refrigerant gel pack pouch and place it in the freezer compartment of your home freezer for at least 6 hours.
6. Remove the small zip closable bag from the Styrofoam container.
7. Remove the plastic screw cap collection cup from the small zip closable bag (Do not remove the absorbent sheet.)



Collect the Urine Sample:

Collect the sample when you first wake up for the day.

Whenever possible, mail the sample on the same day you collect the sample.

1. Before you collect your urine, verify that the picture sticker on the cup matches the picture sticker on the zip closable bag that has your name written on it.
2. Wash hands with soap and water.
3. Take the cap off the cup before urinating.
4. Urinate (pee) into the collection cup until it is half full. The inside of the cup and cap should not touch or come into contact with any part of the body, clothing, or external surfaces.
5. Tighten the cap on the half-filled urine cup and wipe off the outside of the cup.
6. Write the date and time you collected the urine on the label on the top of the Styrofoam container.



Pack the Urine Sample:

Pack the sample in the shipping container with the ice pack immediately after collection, even if you do not mail the package until later in the day.

Do not include these instructions, the cover letter, or the large zip closable bag with your name in the shipping envelope. Do not add additional packaging.

1. Place the half-filled urine cup back into the zip closable bag.
2. Push the air out of the zip closable bag and securely seal the bag.
3. Place the sealed bag into the Styrofoam container.
4. Place the frozen gel pack from your freezer into the Styrofoam container.



Pack the Urine Sample *continued*:



5. Place the Styrofoam lid onto the top of the Styrofoam bottom.
6. Slide the Styrofoam container into the white cardboard shipping box, fold the flaps down, and tuck in the tabs.

7. Verify that the picture sticker on the shipping envelope matches the picture sticker on the bag that has your name written on it.
8. Place the white shipping box inside the white shipping envelope.
9. Remove the adhesive strip, fold the edge over, and seal shut.



Ship the Urine Sample:

Use the US Postal Service (USPS) to send the package.

The best way to send the package is to take it to the Post Office.



Or, send the package by one of the following methods:

- Place the kit in your mailbox
- Give the kit to a USPS mail carrier
- Drop the kit in a USPS mailbox



If you have any questions call 1-888-458-4762.

“QUÉ HACER”

Instrucciones para recolección y envío de la muestra de orina

Recolecte una muestra de orina y use estas instrucciones para enviarla al laboratorio.

Tome su muestra de orina tan pronto como sea posible - idealmente dentro de los próximos 14 días. Sin embargo, si no puede tomar la muestra dentro de los siguientes 14 días entonces tómelala y envíela tan pronto como pueda.

Le mandaremos un cheque por \$40.00 dólares tan pronto como envíe el paquete.

La bolsa que recibió en el centro móvil de examen incluye:

- Una bolsa grande con cierre (Ziploc) con una declaración de confidencialidad, su nombre escrito en la bolsa y una calcomanía impresa con un símbolo elegido únicamente para usted.
- Hoja “QUÉ HACER” Instrucciones para recolección y envío de la muestra de orina
- Carta del Departamento de Salud y Servicios Humanos
- Materiales para tomar la muestra de orina en el hogar



Calcomanía con su símbolo personal:

El símbolo impreso en la calcomanía es únicamente para usted y se encuentra en:

- La bolsa grande con cierre (Ziploc) que lleva su nombre escrito
- El envase para la muestra de orina
- El sobre de envío para devolver los materiales

El símbolo distingue sus materiales de los materiales asignados a otras personas de su hogar. Cuando tome y envíe su muestra de orina, asegúrese de que usa el envase para la muestra y el sobre marcado con el símbolo asignado únicamente para usted.



Los materiales para tomar la muestra de orina en el hogar contienen:

- A.** Caja de cartón blanco
- B.** Caja de poliestireno para envío
- C.** Cinta de monitoreo de la temperatura
- D.** Sobre blanco de envío con etiquetas marcadas “Exempt Human Specimen”, el símbolo suyo y franqueo pre pagado
- E.** Paquete blanco de hielo-gel refrigerante.
- F.** Envase de plástico con tapa para poner la muestra, marcado con su símbolo.
- G.** Bolsa pequeña con cierre (Zip-lock) con toalla absorbente



Preparación de los materiales:

1. Saque los materiales de la bolsa grande con cierre (Zip-lock).
2. Abra la caja de cartón blanco.
3. Saque la caja de poliestireno para envío, de la caja de cartón
4. Abra la caja de poliestireno.
5. Saque la bolsa blanca de hielo-gel refrigerante y póngala en el congelador de su casa por no menos de 6 horas.
6. Saque la bolsa pequeña con cierre (Zip-lock) de la caja de poliestireno.
7. Saque el envase para la muestra de orina de la bolsa pequeña con cierre (Zip-lock). (No saque la toalla absorbente.)



Recolección de la muestra de orina:

Tome la muestra de orina cuando usted se levante.

Si es posible, envíe el paquete con los materiales el mismo día que tome la muestra de orina.

1. Antes de tomar la muestra de orina, verifique que el envase lleva el mismo símbolo que la bolsa con cierre (Zip-lock) con su nombre escrito.
2. Lávese las manos con jabón y agua.
3. Quite la tapa del envase de plástico antes de orinar.
4. Orine dentro del envase de plástico para la muestra y llene hasta la mitad. Ni el interior del envase ni el de la tapa deben tocar o estar en contacto con ninguna parte del cuerpo, ropa o superficies externas.
5. Ajuste la tapa del envase de plástico lleno hasta la mitad y limpie la parte de afuera del envase.
6. Anote la fecha y la hora en que se tomó la muestra en la etiqueta que hay en la tapa de la caja de poliestireno.



Empaque la muestra de orina:

Empaque la muestra en la caja de envío con la bolsa de hielo-gel refrigerante inmediatamente después de tomar la muestra, incluso si no la va a enviar hasta más tarde en el día.

No incluya en el sobre de envío estas instrucciones, la carta informativa ni la bolsa grande con cierre (Zip-lock) con su nombre. No añada material adicional de empaque.

1. Ponga el envase de plástico con la orina lleno hasta la mitad en la bolsa con cierre (Zip-lock).
2. Saque el aire de la bolsa con cierre (Zip-lock) y ciérrela bien.
3. Ponga la bolsa cerrada dentro de la caja de poliestireno.
4. Ponga la bolsa blanca de hielo-gel de su congelador dentro de la caja de poliestireno.



Empaque la muestra de orina *continuación*:



5. Tape la caja de poliestireno para envío
6. Ponga la caja de poliestireno dentro de la caja de cartón blanco, doble las aletas de la caja hacia abajo y métalas en las ranuras.
7. Verifique que el sobre de envío lleva el mismo símbolo que la bolsa con su nombre escrito.
8. Ponga la caja de cartón blanco dentro del sobre blanco para envío.
9. Quite la cinta adhesiva, doble en el borde y selle para cerrar.



Envíe la muestra de orina:

Use el Servicio Postal de Estados Unidos (USPS) para mandar el paquete.

La mejor manera de enviar el paquete es llevarlo a la Oficina de Correos.



O, mandar el paquete por uno de los siguientes métodos:

- Poner el paquete en su buzón de correo
- Darle el paquete a uno de los carteros del correo USPS
- Echar el paquete en un buzón de correo del USPS



Si desea hacer alguna pregunta llame al 1-888-458-4762.

Appendix D

Reminder Postcards English and Spanish

Reminder

NHANES Urine Collection Kit



You recently completed a health examination as part of the National Health and Nutrition Examination Survey (“NHANES”). You received a urine collection kit before you left the exam center.

Please remember to mail the urine sample to the laboratory using the kit that was given to you.

Once the laboratory receives the urine sample, we will mail you a check for \$40.00, as promised.

We appreciate your participation and interest in NHANES.

If you have any questions, please call the toll free number 1-888-458-4762.

NHANES
RP 5055F
1600 Research Blvd.
Rockville, MD 20850-9973
Project #8056.00.01.04



Recordatorio

Materiales de NHANES para tomar la muestra de orina



Recientemente usted completó un examen de salud como parte de la Encuesta Nacional de Examen de Salud y Nutrición ("NHANES"). Antes de irse del centro de examen usted recibió los materiales para tomar una muestra de orina.

Por favor recuerde enviar la muestra de orina al laboratorio usando los materiales que se le dieron.

Tan pronto como el laboratorio reciba la muestra de orina, le enviaremos un cheque por \$40 dólares, como prometimos.

Agradecemos su participación e interés en NHANES.

Si desea hacer alguna pregunta, por favor llame gratis al número 1-888-458-4762.

NHANES
RP 5055F
1600 Research Blvd.
Rockville, MD 20850-9973
Project #8056.00.01.04



Appendix E

**Early Reporting Letter
and
Urine Final Report of Findings**



7/31/2009

Mary Smith 1
555 No Street
Anywhere, US

Dear **Mary Smith 1**,

Recently, you participated in a voluntary health examination at special mobile facilities operated by the Centers for Disease Control and Prevention. We reviewed your test results from your examination on 3/31/2009, and found that some values were abnormal and require your immediate attention.

We cannot be sure whether or not these test results represent illness. Only your doctor can determine that. We **strongly recommend** that you talk to your doctor and give him or her your test results on the enclosed sheet. He or she can evaluate your findings and help you understand what they mean for your health. The NHANES program will not pay for further test or treatment you may require.

The examination was not intended to be a complete physical examination nor a substitute for a visit to a doctor. Our survey physicians are not authorized to administer treatment or engage in any follow-up with examinees.

You will receive a full report of your examination findings in the future, but we thought you should know about these results right away.

If you have any questions, you may call me at our toll-free number, **1-800-452-6115**, between 8:30 AM and 6 PM Eastern Time, Monday through Friday.

Sincerely yours,

Kathryn S. Porter, M.D., M.S.
Medical Officer

Enclosure

111111



National Health and Nutrition Examination Survey

Early Report of Findings

Laboratory - Urine Tests

	Abnormal Value(s)		Flag	Reference Range
	Result	Units		
Albumin Creatinine Ratio - 1st Collection	540.13	mg/g	High	< 30.00
Other Values				
Albumin Creatinine Ratio - 2nd Collection*	469.33	mg/g	High	< 30.00

--- Test not done

^^^ Results Still Pending

vvv Delayed Results

<<< Lower than the limit of detection

>>> Above the limit of detection

*2nd Urine Collected in home 1 - 10 days after the health examination.



Centers for Disease Control and Prevention, NCHS 3311 Toledo Road, Room 4323, Hyattsville, Maryland 20782

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