



National Health and Nutrition Examination Survey (NHANES)

Oral Glucose Tolerance Test (OGTT) Procedures Manual



January 2007

TABLE OF CONTENTS

<u>Chapter</u>		<u>Page</u>
1	OVERVIEW OF THE ORAL GLUCOSE TOLERANCE TEST (OGTT).....	1-1
	1.1 Introduction.....	1-1
	1.2 Field Office Responsibilities	1-2
	1.3 MEC Overview	1-4
2	COORDINATOR APPLICATION	2-1
	2.1 Coordinator Responsibilities.....	2-1
	2.2 Application Overview	2-1
	2.3 Coordinator Progress Bar Colors	2-3
	2.4 Priorities and Verification Form	2-6
	2.5 Exclusion Criteria and Blocking.....	2-12
	2.5.1 Shared Exclusion Pregnancy Question	2-12
	2.5.2 9-Hour Fast Requirement.....	2-15
	2.5.3 No Tubes Drawn	2-17
	2.5.4 Less than 1 Hour and 40 Minute Blocking	2-18
	2.5.5 Return Time Expired Blocking	2-19
	2.6 Coordinator Messaging.....	2-20
	2.7 Assigning an Examiner and SP to the OGTT Component.....	2-26
3	TRUTOL ADMINISTRATION OGTT APPLICATION	3-1
	3.1 MEC Staff Responsibilities	3-1
	3.2 Equipment and Supplies	3-1
	3.3 Gaining Cooperation.....	3-3
	3.4 Exclusion Criteria	3-5
	3.5 OGTT Application Overview	3-6
	3.5.1 Introduce Exam to SP.....	3-7
	3.6 OGTT Section 1 - Exclusion Questions and Trutol Administration...	3-8
	3.6.1 Recording Responses to the Exclusion Questions	3-18
	3.6.2 Trutol Administer Information.....	3-22
	3.6.3 Section Status	3-34

TABLE OF CONTENTS (continued)

<u>Chapter</u>		<u>Page</u>
4	BLOOD DRAW OGTT APPLICATION.....	4-1
	4.1 OGTT Application – Section Two (Blood Draw)	4-1
5	LABORATORY PROCESSING.....	5-1
	5.1 Laboratory Overview.....	5-1
	5.2 Process the 2-mL Gray Top Tube for OGTT.....	5-1
	5.3 Record the Results of Specimen Processing.....	5-2
	5.4 Vessel 98 Storage Protocol.....	5-13
	5.5 Vessel 98 Shipping Protocol.....	5-13
6	SPANISH SPEAKING SPs.....	6-1
	6.1 Performing the OGTT on SPs Who Do Not Speak English.....	6-1
	6.2 Convert Screen Text to English or Spanish.....	6-1

List of Exhibits

<u>Exhibit</u>		
1-1	Informational flyer for Oral Glucose Tolerance Test, aged 12 years and older	1-3
2-1	Verification form – a.m. session.....	2-7
2-2	Verification form – p.m. session.....	2-8
3-1	Equipment and supplies – OGTT	3-2
3-2	Talking Points - English	3-7
3-3	Talking Points – Spanish	3-8
3-4	Trutol Calibrated Dosage Chart.....	3-23
5-1	Primary SP’s OGTT processing protocol	5-1
5-2	Storage protocol for GTT	5-13
5-3	GTT shipping protocol.....	5-13
5-4	Contract laboratory addresses.....	5-14

1. OVERVIEW OF THE ORAL GLUCOSE TOLERANCE TEST (OGTT)

1.1 Introduction

Because of the increasing occurrence of diabetes in younger ages, NHANES has added this component to the examination protocol to reassess the prevalence of diabetes and impaired glucose tolerance (IGT) in the U.S. population.

Diabetes is a large, growing, and costly public health problem in the United States and disproportionately affects racial and ethnic minorities. About 17 million Americans have diabetes and over 1 million new cases of diabetes are diagnosed each year. Diabetes is the leading cause of kidney failure, nontraumatic lower extremity amputation, and blindness in working-age adults, and an estimated \$135 billion was spent on direct and indirect medical costs for diabetes in 2002. Alarming, type 2 diabetes (formerly considered an adult disease) is now being diagnosed in children and adolescents and there has been a large increase in diagnosed diabetes among adults <40 years of age.

Persons with IGT – 15.6 percent of the U.S. population – are at high risk for developing diabetes. In addition, IGT is an important risk factor for a number of other adverse health conditions and mortality. IGT is defined on the basis of an abnormal oral glucose tolerance test (OGTT). Persons without diabetes but with an OGTT 2-hour value of 140-199 mg/dl are considered to have IGT.

Recent national and international randomized controlled trials have shown that diabetes can be delayed or prevented among persons with IGT. Furthermore, NHANES III data indicate a tremendous opportunity for the prevention of diabetes—over 12 million persons aged 45-74 have prediabetes (defined as overweight persons with either IGT or impaired fasting glucose metabolism). These data also indicate that over 50 percent of persons with prediabetes are detected only by IGT findings. As risk factors for diabetes, IGT, and prediabetes increase (e.g., physical inactivity, obesity, and aging), the prevalence of these conditions is also likely to increase.

The inclusion of OGTTs on NHANES will allow estimation of the prevalence of IGT and, thus, prediabetes in the U.S. population, surveillance of trends in the prevalence and awareness of these conditions, study of the risk factors for IGT and prediabetes, and examination of IGT as a risk factor for health conditions and mortality. Timely data on IGT and prediabetes are particularly important as the

Nation initiates efforts to prevent diabetes among persons with prediabetes. These data on IGT and prediabetes are critical to targeting, designing, and evaluating prevention efforts such as DHHS's STEPS program and efforts by the National Diabetes Education Program.

A fasting glucose blood test is performed on all participants 12 years and older who are examined in the morning session after a 9-hour fast. After the initial venipuncture, participants are asked to drink a calibrated dose (generally 75 milligrams) of Trutol® and to have a second venipuncture 2 hours (plus or minus 15 minutes) after drinking the Trutol.

There are minimal risks associated with this procedure. The package label for Trutol lists the following rare but known adverse reactions: nausea, vomiting, abdominal bloating, and headache. In addition, there is a rare incidence of hypoglycemia. The risks associated with venipuncture include excessive bleeding, fainting/feeling lightheaded, hematoma, infection, and multiple punctures to identify veins. Participants eligible for OGTT will have to endure the discomfort of a second venipuncture; however, they will benefit by the report of findings that will inform them if they have impaired glucose tolerance.

The results from the OGTT will be reported to parents of participants 12-17 years and directly to participants 18 years and older in the Final Report of Findings. If the 2-hour blood glucose values are equal to or greater than 140 mg/dL, (i.e., glucose levels consistent with impaired glucose tolerance or diabetes mellitus), an early report will be sent.

1.2 Field Office Responsibilities

The field office is responsible for instructing SPs to fast and for introducing the OGTT during the household interview by using an informational flyer (Exhibit 1-1). There is no change to the existing fasting remuneration.

Oral Glucose Tolerance Test, aged 12 years and older

Why are we asking participants to have an Oral Glucose Tolerance test (OGTT)?

We are asking teenagers and adults who are examined in the morning exam session to have an OGTT so we can learn more about how many people in the United States have diabetes.

Why is the study of diabetes in teenagers important?

Doctors and other health workers have seen an increase of type 2 diabetes in teenagers and adults over the past 20 years. This is an important problem since it can lead to many health problems such as heart disease, poor circulation, and blindness.

What is diabetes?

Diabetes mellitus is a group of diseases that cause high blood sugar levels. Type 1 diabetes was called insulin-dependent diabetes or juvenile diabetes and develops when the body's immune systems destroy the cells that make the hormone insulin that controls blood sugar levels. Type 2 diabetes was previously called non-insulin diabetes or adult-onset diabetes. Type 2 diabetes happens when the cells in our body do not use insulin right. In the past it was seen mostly in old people, overweight people, and people who were inactive. Today, type 2 diabetes is seen more and more in children and teenagers.

What will participants have to do to have the OGTT test?

Participants aged 12 years and older who are examined in the morning will be asked not to eat or drink anything (EXCEPT WATER) 9 hours before coming to the exam center. They will have their blood drawn for laboratory tests that include a fasting glucose test. They will then drink a special sugar drink. After 2 hours they will have more blood drawn to see how their body handled the sugar they drank.

What will this test tell participants about their health?

This test measures how the body handles sugar. We will be able to tell if a person is at risk for diabetes or already has it. The person or his or her parents will be told if the test shows a blood sugar problem.

Consent:

Page 3 of the consent brochure has been modified as follows:

Safety of Tests

We chose the tests and measurements because they are safe. Some of the exams or procedures may cause you slight discomfort. Examples are collecting a blood sample or fasting for 9 hours. For the blood sample, a person will have a small amount of blood drawn from a vein in his or her arm with a needle. Participants 12 years and older with a morning appointment will be asked to drink a sugar solution and have blood taken a second time. Although rare, the sugar solution can cause nausea, vomiting, bloating, or headache. We will not ask you to have any test or procedure that is wrong for you because of a health problem or condition.

1.3 MEC Overview

Diabetics taking insulin who are assigned to morning sessions are asked to fast for 9 hours so these SPs will be assigned to phlebotomy as the highest priority. They are not eligible for the GTT.

SPs aged 12 and older assigned to the morning session who have fasted for 9 hours are eligible for the GTT. It is generally important to assign SPs aged 12 and older to phlebotomy as soon as possible at the start of a session, but it is especially important during a morning session. It is also important to assess the fasting status of SPs aged 12 and older assigned to a morning session because they are not eligible for the GT examination if they have not met their 9-hour fast requirement. The coordinator gives each SP a hard-copy verification form as part of the check-in process. For SPs aged 12 and older who are examined during a morning session, it includes the question, “Did you eat or drink anything, other than plain water, after 11:30 last night?” The SP records “Yes” or “No” in a checkbox and the coordinator enters this information into the coordinator application. The coordinator application then highlights (hot pink) the names of SPs who responded “Yes.” The coordinator must queue these SPs after those who have met their fast, although judgment is always required when managing MEC flow.

If the 9-hour fast is not met but it will be met, and 1 hour and 40 minutes remains in the session, then the phlebotomist will draw all the tubes, including the 2-mL gray top for glucose. The SP will continue with other exams until the fast is met. Once the fast is met, the SP will be assigned to the GT component so that he or she can drink the Trutol and have the second blood drawn 1 hour and 40 minutes later. The phlebotomist must take care not to give the SP juice and crackers at the conclusion of the first blood draw.

The coordinator will use the “GT” component in the coordinator application to assign and track SPs. After the initial phlebotomy examination, the SP will be assigned to the phlebotomy/OGTT, BM/OGTT room in trailer 1, or the MEC Interview/OGTT room in trailer 2 for the first section of the GT component. If the SP is not excluded, then he or she will be instructed to drink a calibrated dose (generally 10 oz.) of a glucose solution (Trutol) immediately after the first venipuncture has been completed. The SP must drink the entire dose within 10 minutes. All MEC staff members, except the physician, have been trained to administer the Trutol. They monitor the time it takes for the SP to consume the Trutol using the first of two sections in the OGTT application. After the SP has consumed the solution, he or she will continue with the other MEC exams.

The SP is eligible to return to phlebotomy for a second blood draw 2 hours, -20 or +15 minutes, after he or she finished consuming the Trutol. (He or she must maintain the fast until the second blood draw is completed.) The coordinator will track the reassignment using the GT component in the coordinator application. After 100 minutes has elapsed since the SP finished drinking the solution, the coordinator will reassign the SP to the phlebotomy room for the second section of the GT component to have a second venipuncture performed. The phlebotomist will draw one additional 2-mL gray top tube for the OGTT test and any tubes that were not drawn during the first venipuncture. The second venipuncture must be complete 135 minutes after the SP finishes drinking the Trutol.

Most SPs will drink the Trutol solution in the BM/OGTT or MEC interview/OGTT rooms. Some SPs may stay in the phlebotomy room to drink the Trutol, but this will generally occur only during lightly booked sessions. The coordinator must exercise judgment to determine the best location for the SP to consume the Trutol solution. Judgment should be guided by the goal to complete all MEC exams for an SP, balance the phlebotomist's workload, and assign the SP to the GT component as soon as possible after the initial venipuncture is complete.

It is critical that the SP drink the entire calibrated dose in 10 minutes as soon as possible after the first venipuncture is complete because he or she must wait at least 100 minutes before being eligible for the second blood draw. SPs must maintain their fast until the second blood draw is complete. Therefore, the entire MEC staff must be aware that the SP must continue the fast and must be sensitive to the discomfort caused by the Trutol and the effect of being around other SPs who may be eating or drinking juice. The SP may drink water. If an SP breaks his or her fast, then he or she is not eligible for the second blood draw but must be reassigned to OGTT in the phlebotomy room to complete the examination.

As noted earlier, drinking 10 oz. of Trutol may have some unpleasant side effects. These side effects may include nausea, vomiting, abdominal bloating, and/or headache. To enhance the palatability, chill enough of each flavor to accommodate all SPs scheduled into the session. Chill the solution in the refrigerators located in the BM/OGTT, spare room in trailer 4, and phlebotomy/OGTT rooms. Protect from light, do not freeze, and discard any remaining solution. After the second blood draw, the phlebotomist will ask the SP if he or she is allergic to peanuts. If not, offer the SP peanut butter crackers and juice.

A paper label prints on the Dymo printer in the BM/OGTT, MEC Interview/OGTT, and phlebotomy/OGTT rooms. The label displays the time at which the SP is eligible for the second blood draw. Place this label on the upper right hand side of the SP's paper top. All MEC staff members are responsible for monitoring the time on this label and ensuring that the SP is taken to the coordinator in time to be reassigned to phlebotomy for the second blood draw.

The MEC lab staff will process this OGTT vessel (#98) per the glucose protocol. They will use the "gtt" module that is similar to the urine collection module to record the vessel as filled "Yes" or "No." All SPs are listed in the same window in this module. The lab staff ships the samples weekly to the contract laboratory.

2. COORDINATOR APPLICATION

2.1 Coordinator Responsibilities

The coordinator uses the hard-copy verification form and the check-in screen to determine and record an SP's initial fasting compliance.

A GT component tracks assignment to the GT component and the time between the consumption of the solution and reassignment of the SP to phlebotomy for the second venipuncture (2 hours, -20 and +15 minutes, after the SP finishes drinking the solution). The earliest reassignment time is 1 hour 40 minutes or 100 minutes. The coordinator can drag the mouse arrow over the yellow GT progress bar to view the time remaining until the reassignment to phlebotomy.

A new priority has been created for GTT SPs aged 12+ so that they are assigned to phlebotomy first, GTT second so they can drink the Trutol, and reassigned to GTT in phlebotomy for the second blood draw. A series of pop-up messages assist the coordinator in assigning and tracking SPs through the three activities.

It is the coordinator's responsibility to monitor the MEC flow, including tracking the assignment of staff and SPs, to ensure that every eligible SP completes the GT component. SPs who have successfully consumed the Trutol, but who are not assigned to phlebotomy in time for the second blood draw, will automatically be coded as "SP return time expired."

2.2 Application Overview

The coordinator application assigns SPs according to priorities, monitoring the time that an SP is eligible to return to phlebotomy for the second blood draw and for sending the appropriate messages to itself and any relevant applications. The coordinator application has a timer that runs every minute to check that an SP is eligible for either the first or the second section of the OGTT examination and if the time to return has expired. The component priority has been modified so that the names of diabetics taking insulin are displayed in red on the coordinator screen; assign these SPs to phlebotomy first. The

names of SPs aged 12 and older who have **not** met the 9-hour fast as indicated during the verification form/check-in process are indicated in hot pink on the coordinator's display.

SPs who have successfully consumed the Trutol are reassigned to phlebotomy for the second blood draw. A pop-up message alerts the coordinator that an SP is due to return to phlebotomy. If an SP wants to exit the MEC before the required 1 hour and 40 minutes has elapsed, then reassign him or her to phlebotomy immediately so that the second blood draw can be conducted (provided no primary exams would be missed). SPs who have successfully consumed the Trutol but who are not assigned to phlebotomy in time for the second blood draw will automatically be coded as "SP return time expired." If there is less than 1 hour and 40 minutes left in the session and the SP has not been assigned to phlebotomy yet, he or she is no longer eligible for GT. The coordinator application will automatically code the SP as not done and attach the comment code, "Less than 1 hour 40 minutes remaining."

2.3 Coordinator Progress Bar Colors

The GT component is included in the list of examinations and the OGTT component has been added to the Phlebotomy, Body Measures, and MEC Interview rooms, making these “dual” component rooms.

The screenshot displays the 'Coordinator Console' application window. At the top, it shows the session information: 'Stand:410 Session:410100 28-Aug-2004 08:30 am - 12:30 pm'. Below this is a table listing patients with columns for SP Name, Status, Ref, G, Age, and various examination components (LB, MD, PH, BM, OH, DR, MI, VI, AU, BC, OP, GT, SP, BR, BS). The 'GT' column is highlighted in green for several patients.

SP Name	Status	Ref	G	Age	LB	MD	PH	BM	OH	DR	MI	VI	AU	BC	OP	GT	SP	BR	BS
Cornelius, Keith	●	M	2																
Aul, Kristen	●	F	5																
Datanzerite, Brian	●	M	8																
Oyster, Michelle	●	F	12																
Carroll, Hope	●	F	14																
Becker, Margaret	●	F	18																
Costanzo, Michael	●	M	42																
Dewick, Cory	●	M	49																
Delach, Jennifer	●	F	59																
Balk, Jason	●	M	60																

Below the patient list, there are several examination room status indicators with icons and labels: Audiology (Open), Oral Health (Open), Body Composition (Open), Laboratory (Open), Phleb (Available), OGTT (Busy), Lbl/Shp (Open), Staff Area (Open), Ophthalmology (Open), Dietary 2 (Open), Dietary 1 (Available), MEC Int 2 (Available), OGTT (Busy), MEC Int 1 (Available), OGTT (Busy), Physician (Available), Broncho (Busy), Body Measures (Open), OGTT (Open), BPMS (Open), Spirometry (Open), Vision (Open), and Coordinator Puckett T. (Open).

On the right side, there is a 'Technician Skill' table:

Technician	Skill
✓ Matthew G. E.	Dietary Interviewer
♦ Grunby D. M.	Health Tech
♦ Louise R. O.	Health Tech
♦ Macnamara J. W.	Health Tech
♦ Mossey S. F.	Health Tech
♦ Spedaro O. J.	Health Tech
✓ Cheney J. M.	Lab Tech
✓ Lacey S.	Lab Tech
✓ Nesbitt R. F.	Lab Tech
✓ Vitner M.	Lab Tech
✓ Gonzales M.	MEC Interviewer
✓ Neves E.	MEC Interviewer
✓ Brown F. K.	Phlebotomist
✓ Carolyn S.	Physician

The bottom of the window shows the Windows taskbar with the Start button, the application name 'Coordinator C...', and the system tray showing 'MEC Layer: 10/10/2006', 'Application: 7.0.0', 'Connected to server', and the time '12:23 AM'.

The progress bar colors represent the following conditions:

Color	Corresponds to:
White	<p>Unblocked</p> <ol style="list-style-type: none"> 1. The SP is eligible for the component.
Teal	<p>Blocked if they are:</p> <ol style="list-style-type: none"> 1. On insulin –”safety exclusion.” 2. Taking oral medications for diabetes – “safety exclusion.” 3. Have hemophilia, as determined in phlebotomy – “safety exclusion.” 4. Received cancer chemotherapy in the past 4 weeks, as determined in phlebotomy – “safety exclusion.” 5. Pregnant, as reported in the shared exclusion question – “safety exclusion.” 6. Have not fasted at least 9 hours and will not meet their fast in time to complete the exam – “Fast less than 9 hours.” <p>If an SP refuses one or more of the blood tubes during the initial venipuncture or the phlebotomy is not attempted due to the lack of a suitable vein then he or she is “Blocked: Not done (No blood tubes).”</p>
Yellow	<p>Waiting</p> <ol style="list-style-type: none"> 1. SP has completed the initial phlebotomy and is waiting for assignment to the OGTT examination for the Trutol administration. “Eligible for Trutol administration for the next _hr. and __min.” 2. SP is waiting for the required 1 hour and 40 minute time restriction to expire so that he or she can return to the phlebotomy room for the second blood draw section of the OGTT examination. “_hr. and __min. until eligible for OGTT blood draw.”
Orange	<p>Waiting</p> <ol style="list-style-type: none"> 1. SP is waiting for 9-hour fast to be met in order to be assigned to the phlebotomy/OGTT, BM/OGTT or MEC interview/OGTT rooms for the Trutol administration section of the OGTT examination. “_hr. and __min. until eligible for OGTT Trutol administration.”

Color	Corresponds to:
Green	Eligible <ol style="list-style-type: none"> <li data-bbox="418 380 1411 457">1. SP has completed phlebotomy and is eligible for the first section of the OGTT examination (Trutol administration). <li data-bbox="418 474 1411 552">2. SP can be reassigned to the phlebotomy room for the second section of the OGTT examination (blood draw).
Blue	Complete <ol style="list-style-type: none"> <li data-bbox="418 621 1411 644">1. Completed OGTT examination.

2.4 Priorities and Verification Form

New priorities have been established so that insulin-dependent diabetics must be assigned to phlebotomy ahead of all other eligible SPs. The names of these SPs are indicated in red on the coordinator's display.

When an SP arrives at the MEC, he or she is given a hard-copy verification form (Exhibit 2-1). If the SP is 12 years or older and is scheduled into a morning session, then the verification form includes a question to assess fasting status. If the SP is less than 12 years, or is scheduled into an afternoon or evening session, the form does not include this question (Exhibit 2-2).



WELCOME / BIENVENIDO

National Health and Nutrition Examination Survey *Encuesta Nacional de Examen de Salud y Nutrición*

Your participation is important to us. Please check all of the information shown below to ensure it is accurate. If you find mistakes, please tell the Coordinator or write the correct information on this form and return it to the Coordinator.

Su participación es importante para nosotros. Por favor revise toda la información que se muestra abajo para asegurarse de que es precisa. Si encuentra errores, por favor dígaselo al Coordinador o escriba la información correcta en este formulario y devuélv

Name:	JENNIFER ANISTON	
Nombre:		
Date of Birth:	9/14/1968	
Fecha de Nacimiento:		
Gender:	Female	
Sexo:		
Consents Required:	Exam SP Consent (12+)	Research SP Consent (18+)

Check this box if the above information is correct
Marque esta casilla si la información de arriba es correcta

Did you eat, or drink anything other than plain water, after 11:30 last night?

¿Comió o bebió algo que no haya sido agua sola, después de las 11:30 de anoche?

Yes

Check one box

No

Marque una casilla

Thank you!

¡Gracias!

Jennifer Aniston, 762833, October 01, 2004.

 National Center For Health Statistics, 3311 Toledo Road, Rm 4323, Hyattsville, Maryland 20782.



WELCOME / BIENVENIDO

National Health and Nutrition Examination Survey *Encuesta Nacional de Examen de Salud y Nutrición*

Your participation is important to us. Please check all of the information shown below to ensure it is accurate. If you find mistakes, please tell the Coordinator or write the correct information on this form and return it to the Coordinator.

Su participación es importante para nosotros. Por favor revise toda la información que se muestra abajo para asegurarse de que es precisa. Si encuentra errores, por favor dígaselo al Coordinador o escriba la información correcta en este formulario y devuélvase.

Name:	JEN CALHOUN	_____
Nombre:		
Date of Birth:	1/2/1954	_____
Fecha de Nacimiento:		
Gender:	Female	_____
Sexo:		
Consents Required:	Exam SP Consent (12+)	Research SP Consent (18+)
<input type="checkbox"/>	Check this box if the above information is correct	
	<i>Marque esta casilla si la información de arriba es correcta</i>	

Thank you!
¡Gracias!

Jen Calhoun, 318374, September 29, 2004.

NCHS National Center For Health Statistics, 3311 Toledo Road, Rm 4323, Hyattsville, Maryland 20782.

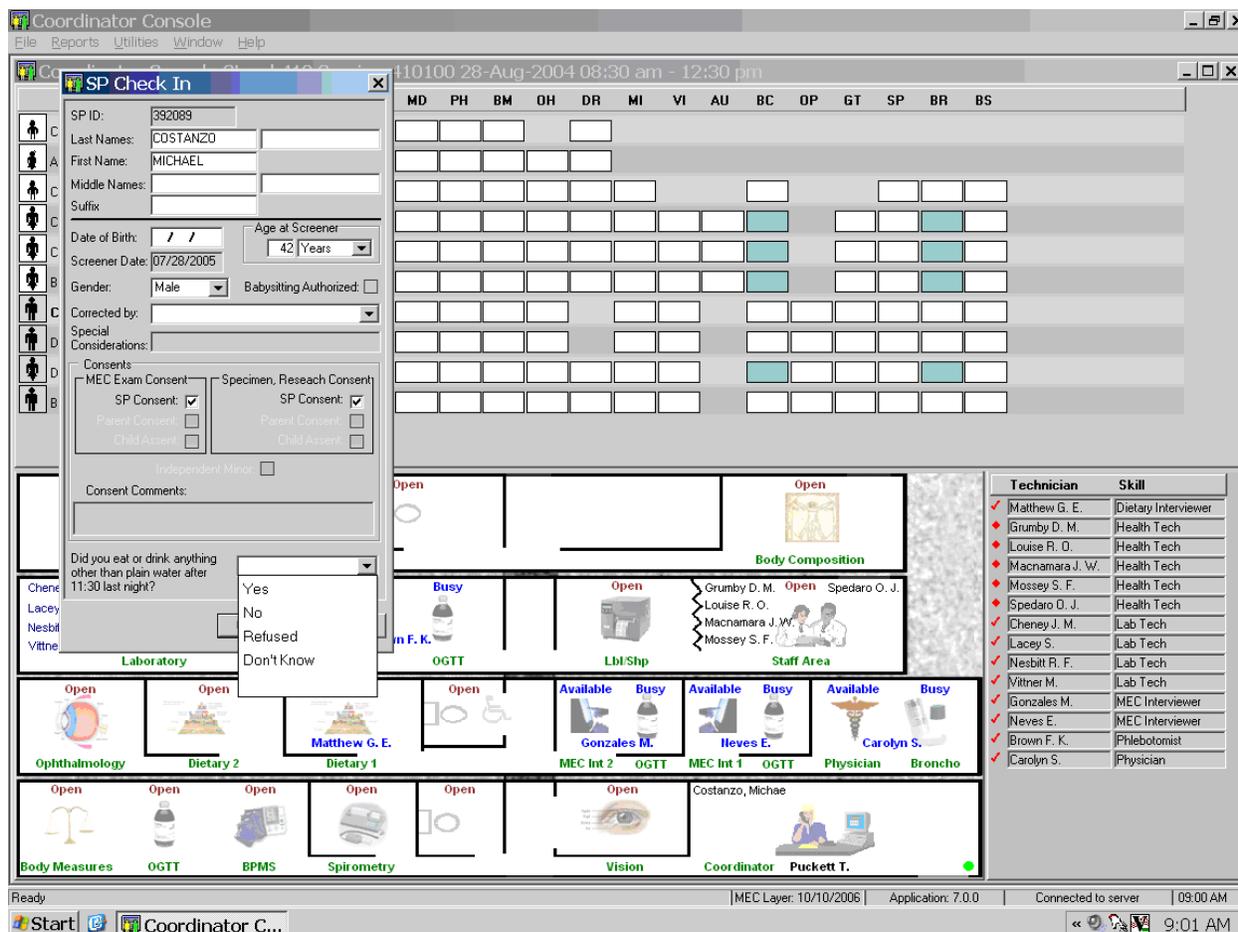
Access the SP Check In screen as part of the routine check-in process. For SPs aged 12 and older who are assigned to a morning session, the verification form includes the fasting question;” Did you eat or drink anything other than plain water after 11:30 last night?” The SPs marks one of two checkboxes: “Yes” or “No.”

The screenshot shows a software window titled "SP Check In" with a close button (X) in the top right corner. The form contains the following fields and controls:

- SP ID: 330740
- Last Names: CRYSTER
- First Name: MICHELLE
- Middle Names: (empty)
- Suffix: (empty)
- Date of Birth: / /
- Age at Screener: 12 Years (dropdown menu)
- Screener Date: 07/28/2005
- Gender: Female (dropdown menu)
- Babysitting Authorized:
- Corrected by: (dropdown menu)
- Special Considerations: (text area)
- Consents section:
 - MEC Exam Consent:
 - SP Consent:
 - Parent Consent:
 - Child Assent:
 - Specimen, Research Consent:
 - SP Consent:
 - Parent Consent:
 - Child Assent:
 - Independent Minor:
 - Consent Comments: (text area)
- Did you eat or drink anything other than plain water after 11:30 last night? (dropdown menu)
- Buttons: Check in, Cancel

The coordinator enters this information into the check-in screen.

Review the verification form and enter the SP's response to the fasting question.

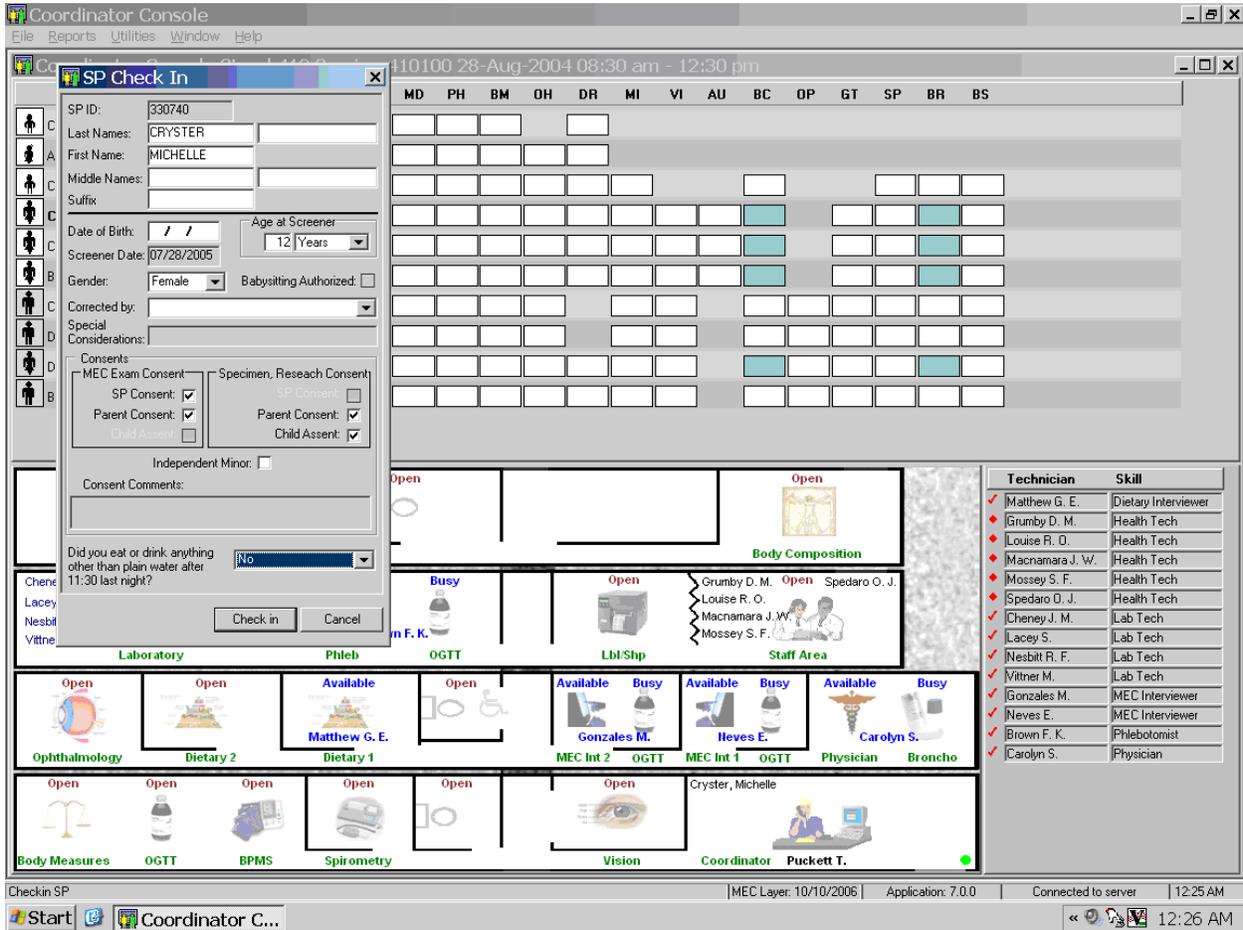


The response options are “Yes,” “No,” “Refused,” and “Don’t know.”

If the SP responds:

- “No,” then he or she **has met** the 9-hour fast. Assign phlebotomy as the first priority and GTT as the second priority.
- “Refused” or “Don’t know,” then the actual fasting time is unknown. Prioritize these SPs for phlebotomy after SPs who responded “No.”
- “Yes,” then he or she has not met the fast or the actual fasting time is unknown. The name is indicated in hot pink on the coordinator display. Assign these SPs to phlebotomy after all other SPs.

After a response has been recorded, continue to check the SP into the session.



To continue the check-in process, use the mouse to direct the mouse arrow to the Check In button and left click or select [Enter]. To cancel the check-in process, use the mouse to direct the mouse arrow to the Cancel button and left click. The check-in process cannot continue until a response has been recorded.

SPs who respond “Yes” indicated that they may not have met their fast. Their names are displayed in hot pink.



Assign SPs whose names are not hot pink to phlebotomy as their first priority. Assign SPs whose names are hot pink to phlebotomy so that they have enough time to complete the OGTT exam. SPs frequently misread this screening question or check the wrong answer box. The phlebotomist will assess the SP's actual fasting status as part of the initial blood draw process.

2.5 Exclusion Criteria and Blocking

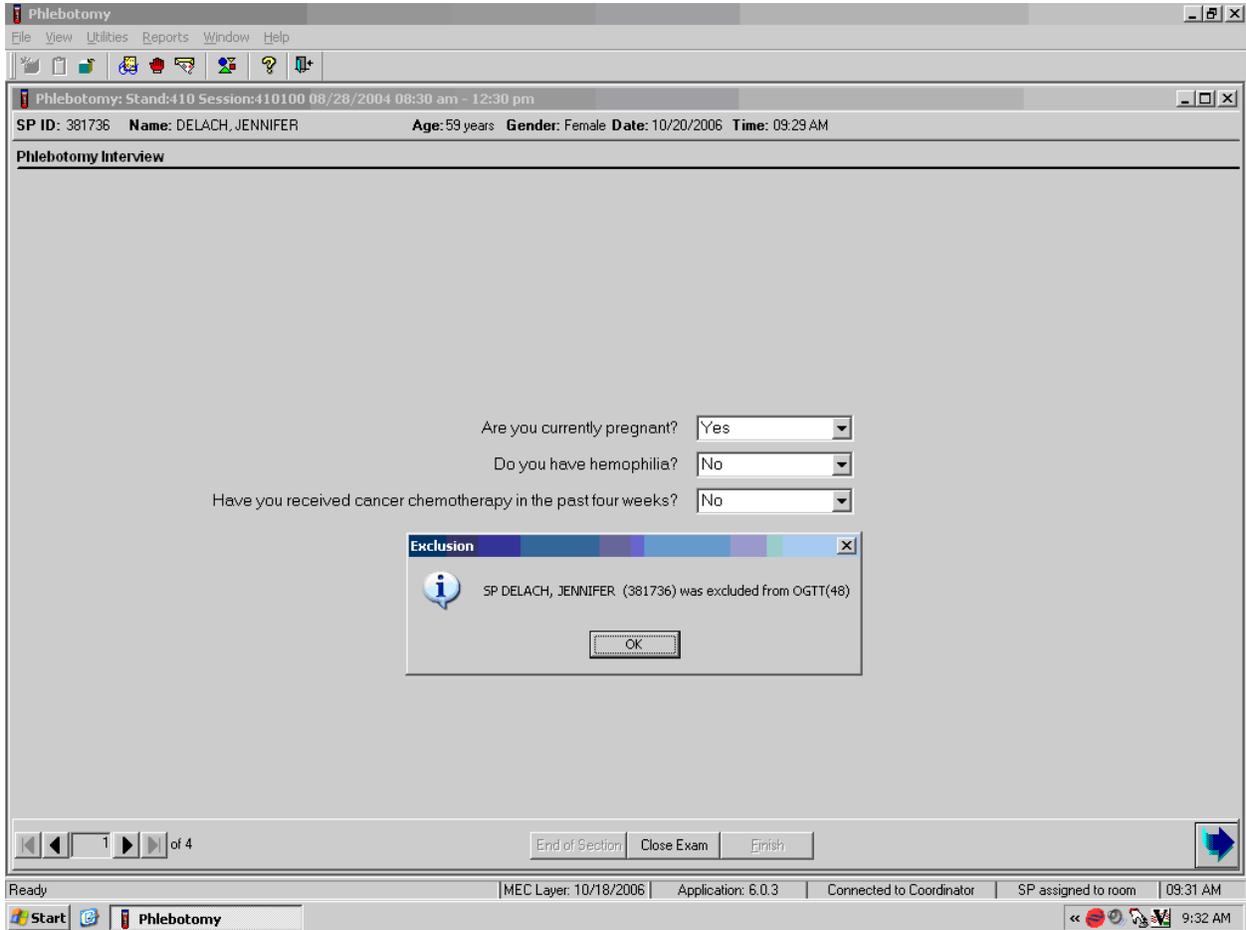
There are seven exclusion criteria. The questions are displayed and asked in phlebotomy and body composition for SPs aged 12-59. Hemophilia and chemotherapy safety exclusion questions are asked and fasting status is assessed in phlebotomy as a prelude to the initial venipuncture examination. Only SPs who responded "No" to the hemophilia and chemotherapy questions in phlebotomy are eligible for the GT examination. SPs who respond to these questions with a response other than "No" are blocked from GT and are coded as safety exclusion. To view the reasons why an SP is blocked, drag the mouse arrow over the teal progress bar and review the text. The examiner's name, current status, and reason will display. If the SP has not met the 9-hour fast, and will not meet the fast with 1 hour and 40 minutes remaining in the session, then he or she is blocked. If the SP refuses one or more of the initial venipuncture blood tubes, he or she is excluded from the GTT. (The other two exclusion criteria, taking insulin or oral medications for diabetes, are listed in the first screen of the first section of the OGTT examination.)

2.5.1 Shared Exclusion Pregnancy Question

Female SPs aged 12-59 are blocked from GT until the SP provides an answer to the shared exclusion question, "Are you currently pregnant?" Female SPs aged 12-59 are asked these questions during the MEC examination in the first examination where shared exclusions are asked. Each question is asked only once, even when the question is relevant for more than one component. If the shared exclusion pregnancy question was answered during the body composition examination, the answers appear in the text boxes and the questions are disabled for the phlebotomy examination, as well as any other component where the questions are relevant. (The shared exclusion question is, SEQ060 "Are you currently pregnant?" The responses are, 1=Yes, 2=No, 3=Don't know.) The coordinator application uses the answer to this question to block SPs who report that they are currently pregnant from the GT examination. The

responses given during any component cannot be changed after the answer is recorded and the screen advanced.

If the answer to the shared exclusion pregnancy question is “Yes,” then the SP is blocked from the GT component.



The GT component is blocked and the status defaults to “Not Done” with the comment “Safety exclusion.”

To view the reasons why an SP is blocked, drag the mouse arrow over the teal progress bar and review the text. The examiner's name, current status, and reason will display.

Coordinator Console
 File Reports Utilities Window Help

Coordinator Console Stand:410 Session:410100 28-Aug-2004 08:30 am - 12:30 pm

SP Name	Status	Ref	G	Age	LB	MD	PH	BM	OH	DR	MI	VI	AU	BC	OP	GT	SP	BR	BS	
Cornelius, Keith	●	M		2																
Aul, Kristen	●	F		5																
Catanzerite, Brian	●	M		8																
Cryster, Michelle	✓	F		12																
Carroll, Hope	●	F		14																
Becker, Margaret	●	F		18																
Costanzo, Michael	◆	M		42																
Dewick, Cory	●	M		49																
Delach, Jennifer	⊗	F		59																
Balk, Jason	●	M		60																

Examiner 1: Francesca Brown
 Examiner 2: None None
 Blocked: Not done (safety exclusion)

Technician Skill

- ✓ Matthew G. E. Dietary Interviewer
- ◆ Grunby D. M. Health Tech
- ◆ Louise R. O. Health Tech
- ◆ Macnamara J. W. Health Tech
- ◆ Mossey S. F. Health Tech
- ◆ Spedaro D. J. Health Tech
- ✓ Cheney J. M. Lab Tech
- ✓ Lacey S. Lab Tech
- ✓ Nesbitt R. F. Lab Tech
- ✓ Vitner M. Lab Tech
- ✓ Gonzales M. MEC Interviewer
- ✓ Neves E. MEC Interviewer
- ✓ Brown F. K. Phlebotomist
- ✓ Carolyn S. Physician

If the response to the question “Are you currently pregnant?” is “No” or “Don’t Know,” the SP is **not excluded** from the GTT.

2.5.2 9-Hour Fast Requirement

Only SPs who have fasted for 9 hours are eligible for the GT examination. During the phlebotomy examination, the fasting time is calculated. It is based on the date and time that the SP reports that he or she ate or drank anything other than plain water. If the 9-hour fast is not met, but it will be met, and 1 hour and 40 minutes remains in the session, then the phlebotomist will draw all the tubes, including the 2-mL gray top for glucose. The SP will continue with other exams until the fast is met.

SP Name	Status	Ref	G	Age	LB	MD	PH	BM	OH	DR	MI	VI	AU	BC	OP	GT	SP	BR	BS	
Cornelius, Keith	●	M	2																	
Aul, Kristen	●	F	5																	
Catanzerite, Brian	●	M	8																	
Cryster, Michelle	●	F	12																	
Carroll, Hope	●	F	14																	
Becker, Margaret	●	F	18																	
Costanzo, Michael	✓	M	42																	
Dewick, Cory	●	M	49																	
Delach, Jennifer	●	F	59																	
Balk, Jason	●	M	60																	

Once the fast is met, the orange progress bar will turn green, indicating that the SP should be assigned to the GT component in order to drink the Trutol and have the second blood drawn 1 hour and 40 minutes later.

If the fast cannot be met during the session and 1 hour and 40 minutes does not remain in the session, then the coordinator application automatically blocks the GT component and attaches the comment code “fast less than 9 hours.”

The screenshot displays the Coordinator Console interface. At the top, the title bar reads "Coordinator Console Stand:410 Session:410100 28-Aug-2004 08:30 am - 12:30 pm". Below this is a staff schedule table with columns for SP Name, Status, Ref, G, Age, and various service codes (LB, MD, PH, BM, OH, DR, MI, VI, AU, BC, OP, GT, SP, BR, BS). The row for Michael Costanzo shows a blocked status (red circle with slash) and a teal progress bar in the GT column. A tooltip for Michael Costanzo displays: "Examiner 1: Francesca Brown", "Examiner 2: None None", and "Blocked: Not done (Fast less than 9 hours)".

A "Message Center" window is open, showing a message from SP COSTANZO, MICHAEL (392089) stating "SP COSTANZO, MICHAEL (392089) was excluded from OGTT(48)". The message is dated 00:38:21. Below the message, it indicates "Total: 1 Unread: 1 1:46".

At the bottom right, a "Technician Skill" table lists various staff members and their roles:

Technician	Skill
✓ Matthew G. E.	Dietary Interviewer
✓ Grumby D. M.	Health Tech
✓ Louise R. O.	Health Tech
✓ Macnamara J. W.	Health Tech
✓ Mossey S. F.	Health Tech
✓ Spedaro D. J.	Health Tech
✓ Cheney J. M.	Lab Tech
✓ Lacey S.	Lab Tech
✓ Nesbitt R. F.	Lab Tech
✓ Vitner M.	Lab Tech
✓ Gonzales M.	MEC Interviewer
✓ Neves E.	MEC Interviewer
✓ Brown F. K.	Phlebotomist
✓ Carolyn S.	Physician

The interface also features several service icons such as "Audiometry", "Oral Health", "Laboratory", "Phleb", "Ophthalmology", "Dietary 2", "Dietary 1", "Body Measures", "OGTT", "BPMS", "Spirometry", "Vision", "Coordinator", and "Puckett T.". The bottom status bar shows "MEC Layer: 10/10/2006", "Application: 7.0.0", "Connected to server", and the time "12:38 AM".

To view the reasons why an SP is blocked, drag the mouse arrow over the teal progress bar and review the text. The examiner’s name, current status, and reason will display.

2.5.3 No Tubes Drawn

If an SP refuses one or more blood collection tubes or the phlebotomist is unable to draw any blood tubes during the phlebotomy examination, then the SP is blocked from the GT component.

The screenshot shows the Coordinator Console interface. At the top, a menu bar includes 'File', 'Reports', 'Utilities', 'Window', and 'Help'. Below the menu bar, the window title is 'Coordinator Console Stand:410 Session:410100 28-Aug-2004 08:30 am - 12:30 pm'. The main area contains a table with columns for 'SP Name', 'Status', 'Ref', 'G', 'Age', and various exam components (LB, MD, PH, BM, OH, DR, MI, VI, AU, BC, OP, GT, SP, BR, BS). A tooltip is visible over the 'GT' column for 'Carroll, Hope', displaying: 'Examiner 1: Francesca Brown', 'Examiner 2: None None', and 'Blocked: Not done (No Tubes Drawn)'. Below the table is a grid of exam components with status indicators (Open, Busy, Available) and technician names. A 'Technician Skill' list is on the right, showing names and roles like 'Dietary Interviewer', 'Health Tech', 'Lab Tech', 'MEC Interviewer', 'Phlebotomist', and 'Physician'. The bottom status bar shows 'Ready', 'MEC Layer: 10/10/2006', 'Application: 7.0.0', 'Connected to server', and '10:39 AM'.

To view the reasons why an SP is blocked, drag the mouse arrow over the teal progress bar and review the text. The examiner's name, current status, and reason will display.

2.5.4 Less than 1 Hour and 40 Minute Blocking

If an eligible SP has not been assigned to GT and less than 1 hour and 40 minutes remains in the session, then the SP's GT exam will automatically be blocked once the SP is assigned to phlebotomy because there is not enough time to complete the entire exam.

The screenshot displays the Coordinator Console interface. At the top, a menu bar includes 'File', 'Reports', 'Utilities', 'Window', and 'Help'. Below the menu is a status bar showing 'Coordinator Console Stand:410 Session:410100 28-Aug-2004 08:30 am - 12:30 pm'. The main area features a grid with columns for SP Name, Status, Ref, G, Age, LB, MD, PH, BM, OH, DR, MI, VI, AU, BC, OP, GT, SP, BR, and BS. The grid lists several SPs with their respective status and assigned components. A Message Center window is open in the center, displaying a message from SP BALK, JASON (243260) regarding exclusion from OGTT. To the right, a 'Technician' list shows names and skills, with a 'Blocked: Not done (Less than 1 hour 40 min left in session)' notification. The bottom of the screen shows a taskbar with the Start button, 'Coordinator C...', and 'Printkey4', along with system information like 'MEC Layer: 10/10/2006', 'Application: 7.0.0', and 'Connected to server'.

SP Name	Status	Ref	G	Age	LB	MD	PH	BM	OH	DR	MI	VI	AU	BC	OP	GT	SP	BR	BS	
Cornelius, Keith	●	M		2																
Aul, Kristen	●	F		5																
Datanzerite, Brian	●	M		8																
Cryster, Michelle	○	F		12																
Carroll, Hope	✓	F		14																
Becker, Margaret	✓	F		18																
Costanzo, Michael	○	M		42																
Dewick, Cory	✓	M		49																
Delach, Jennifer	✓	F		59																
Balk, Jason	○	M		60																

The coordinator application will automatically code the component as “Blocked: Not Done (Less than 1 hour 40 minutes left in session).” The comment code will automatically be added to all SPs who have not been assigned to GT by 10:50 AM.

Continue to review the coordinator screen and assign SPs to the GT component as soon as possible after their current examination is complete.

2.5.5 Return Time Expired Blocking

If an eligible SP has completed the first section (Trutol administration) section of the GT component and more than 2 hours and 15 minutes has elapsed, then the SP's GT exam will automatically be Blocked: Partial (Return Time Expired).

The screenshot shows the 'Coordinator Console' interface. At the top, it displays 'Stand:410 Session:410100 28-Aug-2004 08:30 am - 12:30 pm'. Below this is a table of SPs with columns for Name, Status, Ref, G, Age, and various exam components (LB, MD, PH, BM, OH, DR, MI, VI, AU, BC, OP, GT, SP, BR, BS). The 'GT' column for Jennifer Delach is highlighted in yellow and labeled 'Blocked: Not done (Return Time Expired)'. Below the table are several icons representing different exam sections: Audiology, Oral Health, Body Composition, Laboratory, Phleb, OGTT, Lbl/Shp, Staff Area, Ophthalmology, Dietary 2, Dietary 1, MEC Int 2, OGTT, MEC Int 1, OGTT, Physician, Broncho, Body Measures, Vision, and Coordinator. A technician roster on the right lists names and skills, including Matthew G. E. (Dietary Interviewer), Grumby D. M. (Health Tech), Louise R. O. (Health Tech), Macnamara J. W. (Health Tech), Mossey S. F. (Health Tech), Spedaro O. J. (Health Tech), Cheney J. M. (Lab Tech), Lacey S. (Lab Tech), Nesbitt R. F. (Lab Tech), Vitner M. (Lab Tech), Gonzales M. (MEC Interviewer), Neves E. (MEC Interviewer), Brown F. K. (Phlebotomist), and Carolyn S. (Physician).

SP Name	Status	Ref	G	Age	LB	MD	PH	BM	OH	DR	MI	VI	AU	BC	OP	GT	SP	BR	BS	
Cornelius, Keith	●	M		2																
Aul, Kristen	●	F		5																
Datanzerite, Brian	●	M		8																
Cryster, Michelle	●	F		12																
Carroll, Hope	●	F		14																
Becker, Margaret	⊗	F		18																
Costanzo, Michael	✓	M		42																
Dewick, Cory	✓	M		49																
Delach, Jennifer	✓	F		59																
Balk, Jason	●	M		60																

Continue to review the coordinator screen and assign SPs to the blood draw section of the GT component as soon as possible after 1 hour and 40 minutes has expired.

2.6 Coordinator Messaging

The progress bar turns green when the SP has completed phlebotomy and is ready for the first section of the OGTT examination (Trutol administration) or the SP is eligible to return to phlebotomy for the second section of the OGTT examination (blood draw).

SP Name	Status	Ref	G	Age	LB	MD	PH	BM	OH	DR	MI	VI	AU	BC	OP	GT	SP	BR	BS	
Cornelius, Keith	●	M		2																
Aul, Kristen	●	F		5																
Datanzerite, Brian	●	M		8																
Cryster, Michelle	○	F		12																
Carroll, Hope	○	F		14																
Becker, Margaret	✓	F		18																
Costanzo, Michael	✓	M		42																
Dewick, Cory	✓	M		49																
Delach, Jennifer	✓	F		59																
Balk, Jason	●	M		60																

Examiner: Eligible for OGTT Trutol administration for the next 0h 40m

Technician	Skill
✓ Matthew G. E.	Dietary Interviewer
♦ Grumby D. M.	Health Tech
♦ Louise R. O.	Health Tech
♦ Macnamara J. W.	Health Tech
♦ Mossey S. F.	Health Tech
♦ Spedaro D. J.	Health Tech
✓ Cheney J. M.	Lab Tech
✓ Lacey S.	Lab Tech
✓ Nesbitt R. F.	Lab Tech
✓ Vitner M.	Lab Tech
✓ Gonzales M.	MEC Interviewer
✓ Neves E.	MEC Interviewer
✓ Brown F. K.	Phlebotomist
✓ Carolyn S.	Physician

To view the timer, use the mouse to direct the mouse arrow to the progress bar and hold the arrow over the progress bar until the text containing the timer appears.

The progress bar turns yellow to indicate that the SP is waiting (1) for the first section of the OGTT examination or (2) to be assigned to phlebotomy for the second section of the OGTT examination.

SP Name	Status	Ref	G	Age	LB	MD	PH	BM	OH	DR	MI	VI	AU	BC	OP	GT	SP	BR	BS	
Cornelius, Keith	●	M		2																
Aul, Kristen	●	F		5																
Catanzerite, Brian	●	M		8																
Oyster, Michelle	●	F		12																
Carroll, Hope	●	F		14																
Becker, Margaret	⊗	F		18																
Costanzo, Michael	✓	M		42													●			
Dewick, Cory	✓	M		49																
Delach, Jennifer	✓	F		59													●			
Balk, Jason	●	M		60																

To view the timer, use the mouse to direct the mouse arrow to the progress bar and hold the arrow over the progress bar until the text containing the timer appears.

A pop-up message indicating that an SP is eligible to continue with either the first section (Trutol administration) or second section (second blood draw) of the OGTT component displays. The message also indicates when 1 hour and 40 minutes has elapsed since the SP finished drinking the Trutol solution.

Technician	Skill
✓ Matthew G. E.	Dietary Interviewer
✓ Grunby D. M.	Health Tech
✓ Louise R. O.	Health Tech
✓ Macnamara J. W.	Health Tech
✓ Mossey S. F.	Health Tech
✓ Spedaro O. J.	Health Tech
✓ Cheney J. M.	Lab Tech
✓ Lacey S.	Lab Tech
✓ Nesbitt R. F.	Lab Tech
✓ Vitner M.	Lab Tech
✓ Gonzales M.	MEC Interviewer
✓ Neves E.	MEC Interviewer
✓ Brown F. K.	Phlebotomist
✓ Carolyn S.	Physician

To close or remove the coordinator Message Center box, use the mouse to direct the mouse arrow to the Close button and left click, or use the mouse to direct the mouse arrow to the upper right hand corner to the x and left click.

If the SP will meet the fast during the session and 1 hour and 40 minutes remains in the session then the SP is eligible to continue with their other MEC exams until the fast is met. A pop-up box displays indicating the time at which the SP is eligible to begin the OGTT examination.

The screenshot displays the Coordinator Console interface. At the top, the title bar reads "Coordinator Console Stand:410 Session:410100 28-Aug-2004 08:30 am - 12:30 pm". Below this is a grid with columns for SP Name, Status, Ref, G, Age, LB, MD, PH, BM, OH, DR, MI, VI, AU, BC, OP, GT, SP, BR, BS. The grid lists several patients, including Carroll, Hope, with colored cells indicating exam status.

A "Message Center" pop-up window is open, showing a message from "Reception Coordinator" at 10:21:26: "Please return HOPE CARROLL (SPID 386651) at 12:01 PM to OGTT." Below the message, it shows "Total: 1 Unread: 1 | 0.50" and buttons for "Send" and "Close".

At the bottom right, a "Technician Skill" table is visible:

Technician	Skill
✓ Matthew G. E.	Dietary Interviewer
♦ Grumby D. M.	Health Tech
✓ Louise R. O.	Health Tech
✓ Macnamara J. W.	Health Tech
✓ Mossey S. F.	Health Tech
✓ Spedaro D. J.	Health Tech
✓ Cheney J. M.	Lab Tech
✓ Lacey S.	Lab Tech
✓ Nesbitt R. F.	Lab Tech
✓ Vittner M.	Lab Tech
✓ Gonzales M.	MEC Interviewer
✓ Neves E.	MEC Interviewer
✓ Brown F. K.	Phlebotomist
✓ Carolyn S.	Physician

The bottom of the interface shows a taskbar with "Start", "Coordinator C...", and system tray icons for "MEC Layer: 10/10/2006", "Application: 7.0.0", "Connected to server", and "10:22 AM".

To close or remove the coordinator Message Center box, use the mouse to direct the mouse arrow to the Close button and left click, or use the mouse to direct the mouse arrow to the upper right hand corner to the x and left click.

Once the fast has been met, the orange progress bar turns green indicating that the SP is eligible to be assigned to the GT component.

Coordinator Console

File Reports Utilities Window Help

Coordinator Console Stand:410 Session:410100 28-Aug-2004 08:30 am - 12:30 pm

SP Name	Status	Rof	G	Age	LB	MD	PH	BM	OH	DR	MI	VI	AU	BC	OP	GT	SP	BR	BS	
Cornelius, Keith	●	M		2																
Aul, Kristen	●	F		5																
Catanzerite, Brian	●	M		8																
Cryster, Michelle	○	F		12		■	■									■	■			
Carroll, Hope	●	F		14																
Becker, Margaret	✓	F		18			■													
Costanzo, Michael	✓	M		42			■										■			
Dewick, Cory	✓	M		49			■										■			
Delach, Jennifer	✓	F		59			■										■			
Balk, Jason	●	M		60																

Examiner:
Eligible for OGTT Trutol administration for the next 0h 47m

Audiometry (Open) **Oral Health** (Open) **Body Composition** (Open)

Cheney J. M. (Open) Lacey S. (Open) Nesbitt R. F. (Open) Vittner M. (Open)

Laboratory (Open) **Phleb** (Cryster, Michelle) **OGTT** (Brown F. K.) **Lbl/Shp** (Open) **Staff Area** (Spedaro O. J., Louise R. O., Mossey S. F., Macnamara J. W., Grunby D. M.)

Ophthalmology (Open) **Dietary 2** (Open) **Dietary 1** (Available: Matthew G. E.) **MEC Int 2** (Available: Gonzales M.) **OGTT** (Available: Neves E.) **MEC Int 1** (Available: Neves E.) **Physician** (Carolyn S.) **Broncho** (Busy: Carolyn S.)

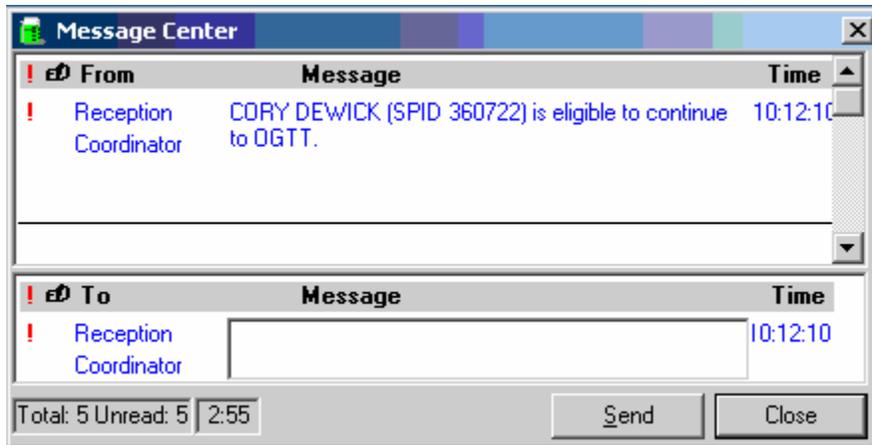
Body Measures (Open) **OGTT** (Open) **BPMS** (Open) **Spirometry** (Open) **Vision** (Open) **Coordinator** (Dewick, Cory; Costanzo, Michee; Delach, Jennifer) **Puckett T.** (Becker, Margaret)

Technician	Skill
✓ Matthew G. E.	Dietary Interviewer
♦ Grunby D. M.	Health Tech
♦ Louise R. O.	Health Tech
♦ Macnamara J. W.	Health Tech
♦ Mossey S. F.	Health Tech
♦ Spedaro O. J.	Health Tech
✓ Cheney J. M.	Lab Tech
✓ Lacey S.	Lab Tech
✓ Nesbitt R. F.	Lab Tech
✓ Vittner M.	Lab Tech
✓ Gonzales M.	MEC Interviewer
✓ Neves E.	MEC Interviewer
✓ Brown F. K.	Phlebotomist
✓ Carolyn S.	Physician

Ready MEC Layer: 10/10/2006 Application: 7.0.0 Connected to server 10:02 AM

Start Coordinator Co... 10:02 AM

A pop-up message box also displays alerting the coordinator and phlebotomist that the SP is eligible to continue with the OGTT examination.



To close or remove the coordinator Message Center box, use the mouse to direct the mouse arrow to the Close button and left click, or use the mouse to direct the mouse arrow to the upper right hand corner to the x and left click.

2.7 Assigning an Examiner and SP to the OGTT Component

Assign unblocked SPs aged 12 and older to the phlebotomy component and then immediately assign eligible SPs to OGTT after phlebotomy is complete. Generally, assign an SP to the BM/OGTT or MEC Interview/OGTT workstations. Assign an SP to the phlebotomy/OGTT workstation only if the session is lightly booked and the phlebotomist's workload will accommodate all exams, without fail.

The screenshot displays the Coordinator Console interface. At the top, it shows the session details: "Coordinator Console Stand:410 Session:410100 28-Aug-2004 08:30 am - 12:30 pm". Below this is a grid for staff scheduling with columns for SP Name, Status, Ref, G, Age, and various exam components (LB, MD, PH, BM, OH, DR, MI, VI, AU, BC, OP, GT, SP, BR, BS). Staff members listed include Cornelius, Keith; Aul, Kristen; Catanzerite, Brian; Cryster, Michelle; Carroll, Hope; Becker, Margaret; Costanzo, Michael; Dewick, Cory; Delach, Jennifer; and Balk, Jason. A yellow callout box indicates that Margaret Becker is an "Examiner: Eligible for OGTT Trurol administration for the next 0h 40m".

Below the grid is a workstation status area with icons and labels for various components: Audiometry, Oral Health, Body Composition, Laboratory, Phleb, OGTT, Lbl/Shp, Staff Area, Ophthalmology, Dietary 2, Dietary 1, MEC Int 2, OGTT, MEC Int 1, OGTT, Physician, Broncho, Body Measures, OGTT, BPMS, Spirometry, Vision, Coordinator, and Puckett T.

On the right side, there is a "Technician Skill" table:

Technician	Skill
✓ Matthew G. E.	Dietary Interviewer
♦ Grumby D. M.	Health Tech
♦ Louise R. O.	Health Tech
♦ Macnamara J. W.	Health Tech
♦ Mossey S. F.	Health Tech
♦ Spedaro D. J.	Health Tech
✓ Cheney J. M.	Lab Tech
✓ Lacey S.	Lab Tech
✓ Nesbitt R. F.	Lab Tech
✓ Vitner M.	Lab Tech
✓ Gonzales M.	MEC Interviewer
✓ Neves E.	MEC Interviewer
✓ Brown F. K.	Phlebotomist
✓ Carolyn S.	Physician

The bottom status bar shows "Ready", "MEC Layer: 10/10/2006", "Application: 7.0.0", "Connected to server", and the time "10:08 AM".

Use the PH and GT progress bar colors and the timing description to manage the SPs. To view the timing description, use the mouse to direct the mouse arrow to the progress bar. The timing text will display.

Assign an SP to OGTT.

SP Name	Status	Ref	G	Age	LB	MD	PH	BM	OH	DR	MI	VI	AU	BC	OP	GT	SP	BR	BS	
Cornelius, Keith	●	M		2																
Aul, Kristen	●	F		5																
Catanzerite, Brian		M		8																
Cryster, Michelle		F		12																
Carroll, Hope		F		14																
Becker, Margaret		F		18																
Costanzo, Michael		M		42																
Dewick, Cory		M		49																
Delach, Jennifer		F		59																
Balk, Jason		M		60																

Technician	Skill
✓ Matthew G. E.	Dietary Interviewer
♦ Grumby D. M.	Health Tech
✓ Louise R. O.	Health Tech
♦ Macnamara J. W.	Health Tech
♦ Mossey S. F.	Health Tech
♦ Spedaro D. J.	Health Tech
✓ Cheney J. M.	Lab Tech
✓ Lacey S.	Lab Tech
✓ Nesbitt R. F.	Lab Tech
✓ Vitner M.	Lab Tech
✓ Gonzales M.	MEC Interviewer
✓ Neves E.	MEC Interviewer
✓ Brown F. K.	Phlebotomist
✓ Carolyn S.	Physician

To assign an SP to the GT component in the BM/OGTT room (after the phlebotomy examination is complete), use the mouse to direct the mouse arrow to the highlighted OGTT selection on the flying box and double click.

To assign the SP to the OGTT component in the MEC Interview/OGTT or phlebotomy/OGTT room, drag the phlebotomist or MEC interviewer's name to the bathroom area, and then drag the name back to OGTT.

The screenshot shows the 'Coordinator Console' interface. At the top, it displays 'Stand:410 Session:410100 28-Aug-2004 08:30 am - 12:30 pm'. Below this is a table with columns for 'SP Name', 'Status', 'Ref', 'G', 'Age', and various room codes (LB, MD, PH, BM, OH, DR, MI, VI, AU, BC, OP, GT, SP, BR, BS). The table lists staff members like Cornelius, Keith; Aul, Kristen; Catanzerite, Brian; Cryster, Michelle; Carroll, Hope; Becker, Margaret; Costanzo, Michael; Dewick, Cory; Delach, Jennifer; and Balk, Jason.

Below the table are several room status panels with icons and labels:

- Audiometry:** Cryster, Michelle (Open), Spedaro D.J. (Open), Body Composition (Open).
- Laboratory:** Cheney J. M. (Open), Lacey S. (Open), Nesbitt R. F. (Open), Vittner M. (Open).
- Phleb/OGTT:** Brown F. K. (Available/Busy).
- Lbl/Shp:** Louise R. O. (Open), Mossey S. F. (Open), Macnamara J. W. (Open), Grumby D. M. (Open).
- Staff Area:** Staff Area (Open).
- Ophthalmology:** Open.
- Dietary:** Dietary 1 (Available), Dietary 2 (Open).
- MEC Int 2/OGTT:** Matthew G. E. (Available), Carroll, Hope (Busy).
- MEC Int 1/OGTT:** Gonzales M. (Busy), Neves E. (Available).
- Physician/Broncho:** Carolyn S. (Available/Busy).
- Body Measures/OGTT/BPMS/Spirometry/Vision/Coordinator:** Body Measures (Open), OGTT (Open), BPMS (Open), Spirometry (Open), Vision (Open), Coordinator (Open), Puckett T. (Open).

On the right side, there is a 'Technician Skill' table:

Technician	Skill
✓ Matthew G. E.	Dietary Interviewer
♦ Grumby D. M.	Health Tech
♦ Louise R. O.	Health Tech
♦ Macnamara J. W.	Health Tech
♦ Mossey S. F.	Health Tech
♦ Spedaro D. J.	Health Tech
✓ Cheney J. M.	Lab Tech
✓ Lacey S.	Lab Tech
✓ Nesbitt R. F.	Lab Tech
✓ Vittner M.	Lab Tech
✓ Gonzales M.	MEC Interviewer
✓ Neves E.	MEC Interviewer
✓ Brown F. K.	Phlebotomist
✓ Carolyn S.	Physician

The bottom of the screen shows system information: 'Ready', 'MEC Layer: 10/10/2006', 'Application: 7.0.0', 'Connected to server', and '10:10 AM'.

After the phlebotomist or MEC interviewer is assigned to the OGTT side of the phlebotomy or MEC interview room, it is then possible to assign the SP to the OGTT component.

3. TRUTOL ADMINISTRATION OGTT APPLICATION

3.1 MEC Staff Responsibilities

The MEC phlebotomist completes the initial blood collection procedure, which consists of (1) administering a questionnaire to screen for conditions that exclude the participant from the blood draw; (2) determining fasting status; and (3) performing a blood draw.

The OGTT application has been created to (1) calculate and display the amount of Trutol that an SP should drink (calibrated dose); (2) monitor the time it takes for an SP to consume the Trutol solution; and (3) record the second venipuncture results. This application has been installed in the phlebotomy/OGTT, BM/OGTT, and MEC Interview/OGTT rooms. All MEC staff members who administer the Trutol are responsible for using the first section of this application to administer the correct amount of Trutol for the weight of the SP and monitor the time it takes for the SP to drink the Trutol. After 100-135 minutes have elapsed since the SP consumed the Trutol, the phlebotomist is responsible for drawing a second 2-mL gray top tube and for using the second section of the OGTT application to record the results of the second blood draw.

After the first venipuncture is complete, the phlebotomist will escort the SP to the location identified in the message window. All MEC staff members with the exception of the physician are eligible to administer the Trutol in the BM/OGTT room. The coordinator can also assign the SP to phlebotomy or the MEC interview rooms where the respective staff can administer the Trutol. When the SP is reassigned to phlebotomy for the second blood draw, the phlebotomist will draw one 2-mL gray top tube and any tubes that were missed during the first venipuncture.

3.2 Equipment and Supplies

The equipment and supplies used in the OGTT are listed in Exhibit 3-1. The average number of examined SPs aged 12 and older is 232 per stand.

At the start and end of each stand, the phlebotomist will take a complete inventory using procedures described in Chapter 11, Section 11.3 in the Laboratory Procedures Manual. The OGTT supplies are included in the phlebotomy start and end of stand inventory sheets.

Exhibit 3-1. Equipment and supplies – OGTT

OGTT	Par level
Trutol	
Orange (part number 401223)	12 cases of 12
Lemon-Lime (part number 401421)	8 cases of 12
Cola (part number 401025)	5 cases of 12
Peanut butter crackers	4 packages of 80
2-mL gray top Vacutainer tube	3 trays of 100
Plastic drinking straws	2 boxes of 100
Dymo labels	7 rolls of 500 (for use in phlebotomy and BM and MEC Interview rooms)
Small graduated medicine cups	2 sleeves

The Trutol can travel from one stand to the next; it does not need to be sent back to the warehouse. Do not store the Trutol in the belly compartments as they are not climate controlled and there is the possibility that the Trutol could freeze. However, it is acceptable to pack the Trutol in boxes in the BM/OGTT exam room.

The Trutol is good through the end of the month listed as the expiration date. If, at the end of the stand, any of the Trutol expires before the start of the next stand then it should be discarded on site and the end of stand par level adjusted accordingly.

The phlebotomist should empty and clean the GTT refrigerators at the end of each stand and should prepare them for transit (block the door open like the other refrigerators.) The FES will need to secure the refrigerator so that it does not get moved around or get damaged in transit.

It is acceptable to refrigerate the Trutol, let it warm to room temperature, and then refrigerate it again.

3.3 Gaining Cooperation

The coordinator will introduce the SP to the OGTT examination and briefly explain the examination process. The coordinator can answer any general questions the SP has about venipuncture or the OGTT. However, the entire MEC staff must be prepared to answer all the questions the SP poses about the OGTT procedure and must convince the SP of the importance of participating in the OGTT component of the examination.

Prepare to answer questions about the rationale for the OGTT component, the discomfort involved and the side effects, and the composition of the Trutol. It is essential to create a pleasant atmosphere and maintain a pleasant attitude. To address SPs' concerns effectively, know the following information about the procedures used for the study:

Rationale

- Although the SP has provided much useful information in the household and individual interviews, the successful completion of the OGTT component of NHANES is critical to the success of the pilot. This information is contained in the introduction to this chapter. Diabetes is a large, growing, and costly public health problem in the United States and disproportionately affects racial and ethnic minorities. About 17 million Americans have diabetes and over 1 million new cases of diabetes are diagnosed each year. It is the leading cause of kidney failure, non-traumatic lower extremity amputation, and blindness in working-age adults, and an estimated \$135 billion was spent on direct and indirect medical costs for diabetes in 2002. Alarmingly, type 2 diabetes (formerly considered an adult disease) is now being diagnosed in children and adolescents and there has been a large increase in diagnosed diabetes among adults <40 years of age.
- Persons with impaired glucose tolerance (IGT) – 15.6 percent of the U.S. population – are at high risk for developing diabetes. In addition, IGT is an important risk factor for a number of other adverse health conditions and mortality. IGT is defined based on an abnormal oral glucose tolerance test (OGTT). Persons without diabetes but with an OGTT 2-hour value of 140-199 mg/dl are considered to have IGT. Recent national and international randomized controlled trials have shown that diabetes can be delayed or prevented among persons with IGT. Furthermore, NHANES III data indicate a tremendous opportunity for the prevention of diabetes - over 12 million persons aged 45-74 have prediabetes (defined as overweight persons with either IGT or impaired fasting glucose metabolism). These data also indicated that over 50 percent of persons with prediabetes are only detected by IGT findings. As risk factors for diabetes, IGT, and prediabetes increase (e.g., physical inactivity, obesity, and aging), the prevalence of these conditions is likely to increase.

- The inclusion of OGTTs on NHANES will allow estimation of the prevalence of IGT and, thus, prediabetes in the U.S. population, surveillance of trends in the prevalence and awareness of these conditions, study of the risk factors for IGT and prediabetes, and examination of IGT as a risk factor for health conditions and mortality. Timely data on IGT and prediabetes are particularly important as the Nation initiates efforts to prevent diabetes among persons with prediabetes. These data on IGT and prediabetes are critical to targeting, designing, and evaluating prevention efforts, such as DHHS's STEPS program and efforts by the National Diabetes Education Program.

Discomfort and Side Effects

- Venipuncture causes only minimal discomfort. A certified, experienced phlebotomist performs venipunctures. A variety of blood collection needles are available so that the most appropriate size can be selected for each SP.
- Side effects of drinking the Trutol can include nausea, vomiting, abdominal bloating, and/or headache. To enhance the palatability, chill before serving. Protect from light, do not freeze, and discard any remaining solution.

Composition of the Trutol

Ten ounces of Trutol contains 75 grams of dextrose and 300 calories. The following items contain approximately the same amount of sugar:

- 2 cans of Pepsi or Coke (66 grams)
10 ounces of Coke or Pepsi has 33 grams of sugar and 121 calories
- 3/4 cup of raisins (86 grams)
1 cup contains 115 grams of sugar and 435 calories
- 1 cup of dried apricots (80 grams)
1 cup contains 80 grams of sugar and 310 calories
- A small McDonalds sundae (61 grams)
A 6.4-ounce McDonald's hot caramel sundae contains 61 grams of sugar and 360 calories

- A small McDonalds M&M McFlurry (90 grams)

A 12-ounce (small) McDonalds M&M McFlurry contains 90 grams of sugar and 630 calories

- A small McDonalds vanilla shake (67 grams)

A 12-ounce (small) McDonald's vanilla shake contains 67 grams of sugar and 430 calories

- A small Dairy Queen Misty slush (56 grams)

A small Dairy Queen Misty slush contains 56 grams of sugar and 454 calories

Creating a Pleasant Atmosphere and Positive Attitude

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.

3.4 Exclusion Criteria

There are seven exclusion criteria. The phlebotomist will ask SPs aged 12-59 the shared exclusion pregnancy question if the question has not already been asked elsewhere in the MEC. Hemophilia and chemotherapy safety exclusion questions are asked and fasting status is assessed in phlebotomy as a prelude to the initial venipuncture examination. If the SP refuses one or more of the blood tubes, then he or she is excluded. The other two exclusion criteria are listed in the first screen of the first section of the OGTT examination.

Persons will be **excluded** from this component if they:

- Report that they are taking oral medications for diabetes (asked during the household interview or in OGTT);
- Report that they are taking insulin (asked during the household interview or in OGTT);
- Report that they are pregnant (shared exclusion question);
- Report that they have hemophilia (asked in phlebotomy);
- Report that they have received cancer chemotherapy in the last 3 weeks (asked in phlebotomy);
- Report that they have not fasted at least 9 hours (as determined by the fasting questionnaire in phlebotomy); and
- Refuse one or more blood tubes in phlebotomy during the initial venipuncture or if the phlebotomist is unable to draw at least one tube.

3.5 OGTT Application Overview

The OGTT application consists of two sections and five total screens. The first section contains the safety exclusion questions and monitors the time it takes the SP to drink the Trutol. This application is active in the BM, phlebotomy, and MEC Interview rooms. The second section is used by the phlebotomist to record the results of the second blood collection.

The first Trutol Administration Information section includes three screens. The first Exclusion Question screen includes the two exclusion questions and a 'Length of Fast' read-only text box. The second Trutol Administer Information screen contains instructions, a 'Length of Fast' read-only text box, a 'Your weight is' text box, an 'Amount to drink' calculation (in oz. and mL), a 'Please drink this solution within 10 minutes' script, a 10:00 timer, Start button, Start and Stop read-only text boxes, a timer Reset button and an 'Amount of solution the SP drank' text box. The Trutol Administer Information section status screen displays after the first screen if the SP is excluded or after the second screen if the SP is not excluded.

The second blood draw section contains two screens. The first blood draw screen includes the second 2-mL gray top tube in the upper section and any tubes that were not drawn during the first venipuncture in the lower section. The second screen is the blood draw section status screen.

3.5.1 Introduce Exam to SP

Introduce the OGTT component as the “next component” in the SP’s exam profile. The first section of the OGTT application is used by the phlebotomist, MEC interviewers, health technologists, dietary and MEC interviewers, the medical technologist assigned to workstation 3, and the MEC manager to screen for safety exclusions and to administer and monitor the time it takes the SP to drink the Trutol solution.

The following “Talking Points” in Exhibits 3-2 and 3-3 have been developed to ensure that each examiner provides the same critical information to every SP.

Exhibit 3-2. Talking Points - English

OGTT Talking Points - English

- This test measures how your body handles sugar.
- We will be able to tell if you are in danger for getting diabetes or if you already have it.
- Diabetes is important because it is the leading cause of kidney failure, blindness in working-age adults, and almost 16 percent of the US population is in danger of developing diabetes.
- We need you to drink 10 ounces of a chilled carbonated sugar solution. We have three flavors—cola, lemon-lime, and orange.
- You must drink all 10 ounces within 10 minutes, although most people drink the solution in less than 4 minutes. I will use this computer to record the time you start and stop drinking and the amount that you drank.
- It’s very important that you do not eat or drink anything, other than plain water, for the next 2 hours.
- In 2 hours you will return to the blood draw room to have one small blood tube drawn. We will give you juice and crackers once the blood tube has been drawn.
- The sugar solution can make some people feel thirsty. Feel free to ask any staff member for a glass of water at any time.

- After you finish drinking the solution, I will place a paper sticker on the outside of your top. This is the time at which you are eligible to return for the second blood draw. It helps the staff keep track of when the 2 hours are up and you need to go back and have the second blood draw.

Exhibit 3-3. Talking Points – Spanish

OGTT Talking Points - Spanish

- Esta prueba mide cómo su cuerpo procesa el azúcar.
- Podremos decirle si usted está en peligro de contraer diabetes o si ya la tiene.
- La diabetes es importante porque es la causa principal del fallo renal, la ceguera en adultos en edad productiva, y casi el 16 por ciento de la población de Estados Unidos está en peligro de desarrollar diabetes.
- Necesitamos que tome 10 onzas de agua gaseosa fría con una solución de azúcar. Tenemos tres sabores—cola, lima - limón, y naranja.
- Usted tiene 10 minutos para tomar las 10 onzas, aunque la mayoría de las personas toman la solución en menos de 4 minutos. Usaré esta computadora para anotar el tiempo en que empieza y deja de tomar la solución y la cantidad que toma.
- Es muy importante que en las próximas dos horas usted no coma ni tome nada aparte de agua sola.
- En dos horas usted volverá al cuarto donde le hicieron el examen de sangre para que le saquen un tubito de sangre. Le daremos jugo y galletas una vez que le hayan sacado el tubito de sangre.
- La solución de azúcar puede hacer que algunas personas sientan sed. Por favor pídale a cualquier miembro del personal que le dé un vaso de agua cuando desee.
- Después que termine de tomar la solución de azúcar, le pondré un papel adhesivo en la parte de arriba, por fuera de su camisa. Esta indica el tiempo en que usted podrá volver para la segunda muestra de sangre. También ayuda a que el personal lleve la cuenta de las dos horas transcurridas para que usted vuelva nuevamente a sacarse sangre por segunda vez.

3.6 OGTT Section 1 - Exclusion Questions and Trutol Administration

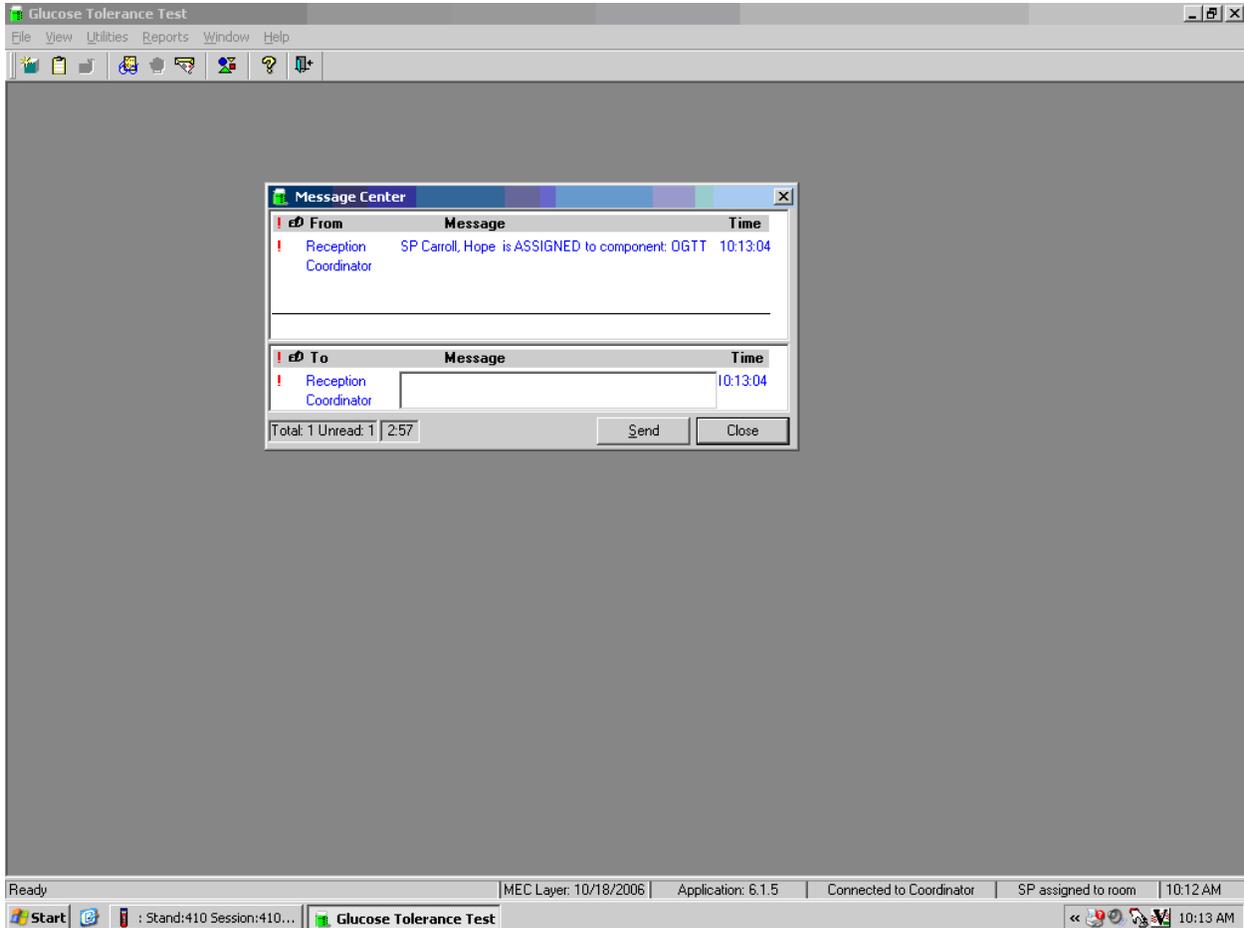
Two safety exclusion questions are asked in the Trutol administration section of the OGTT application. The first question asks the SP if he or she is taking insulin, and the second question asks if he or she is taking oral medications for diabetes. The insulin question is asked during the household

interview. The oral medications question may be asked during the household interview, but in the event that it is not, then it is asked in the OGTT examination. Only a “Yes” response to either question will exclude the SP from the OGTT examination.

SPs who weigh less than 94 pounds must have a calibrated dose of Trutol. If the SP has been weighed in body measures, then the weight is pulled into the Trutol Administration screen and displayed in the “Your weight is” text box. If the SP has not been weighed in body measures, then the self-reported weight will be pulled into the Trutol Administration screen and displayed in the text box. (The self-reported weight is WGQ020 “How much do you weigh without clothes or shoes?”) If the self-reported weight is less than 100 pounds, then weigh the SP on the Body Measures scale.

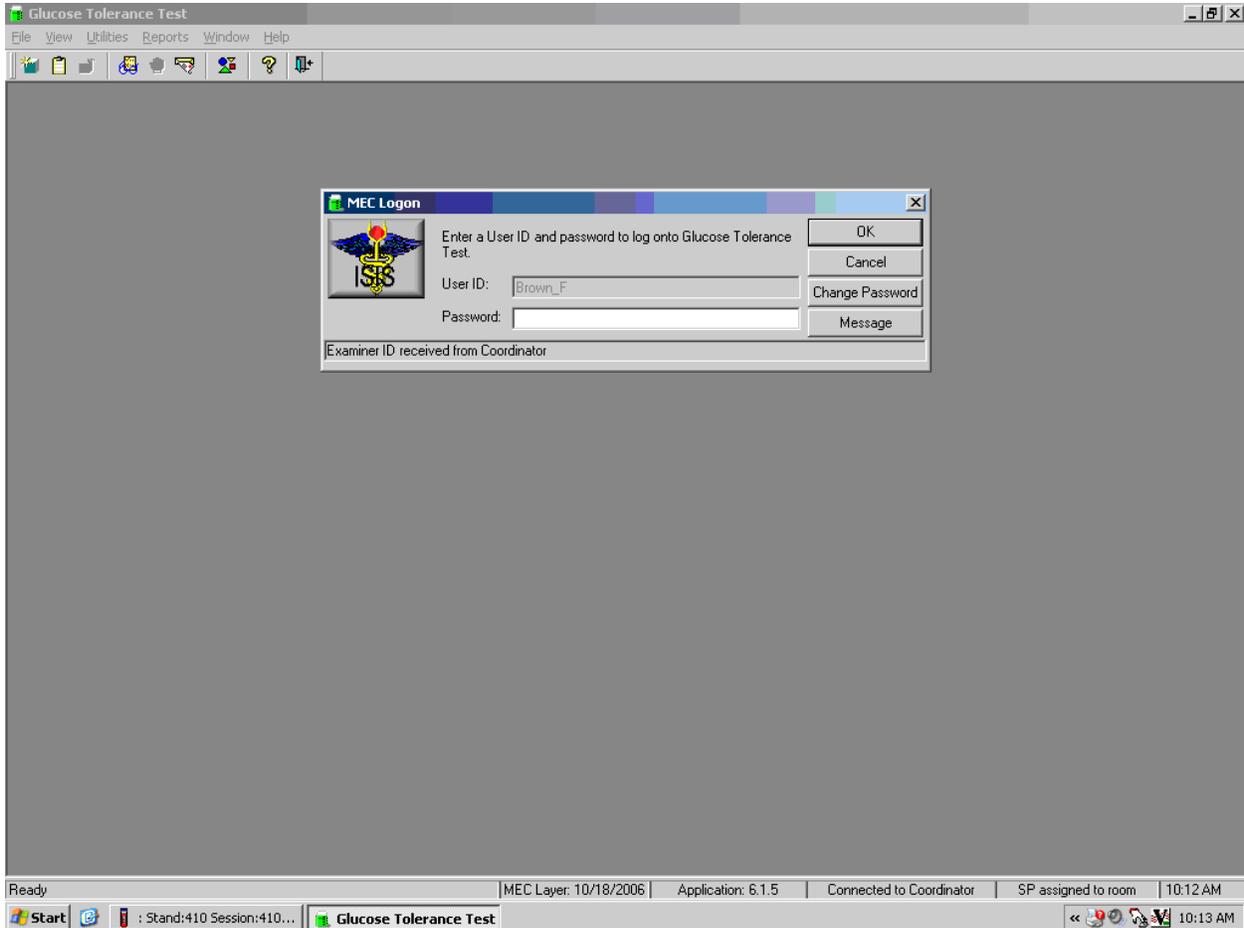
The SP must meet the 9-hour fast requirement before he or she is eligible for the OGTT. The fasting time is based on information given during the fasting interview that was administered before the first venipuncture in phlebotomy.

The Message Center window displays once an examiner and SP are assigned to the OGTT component.



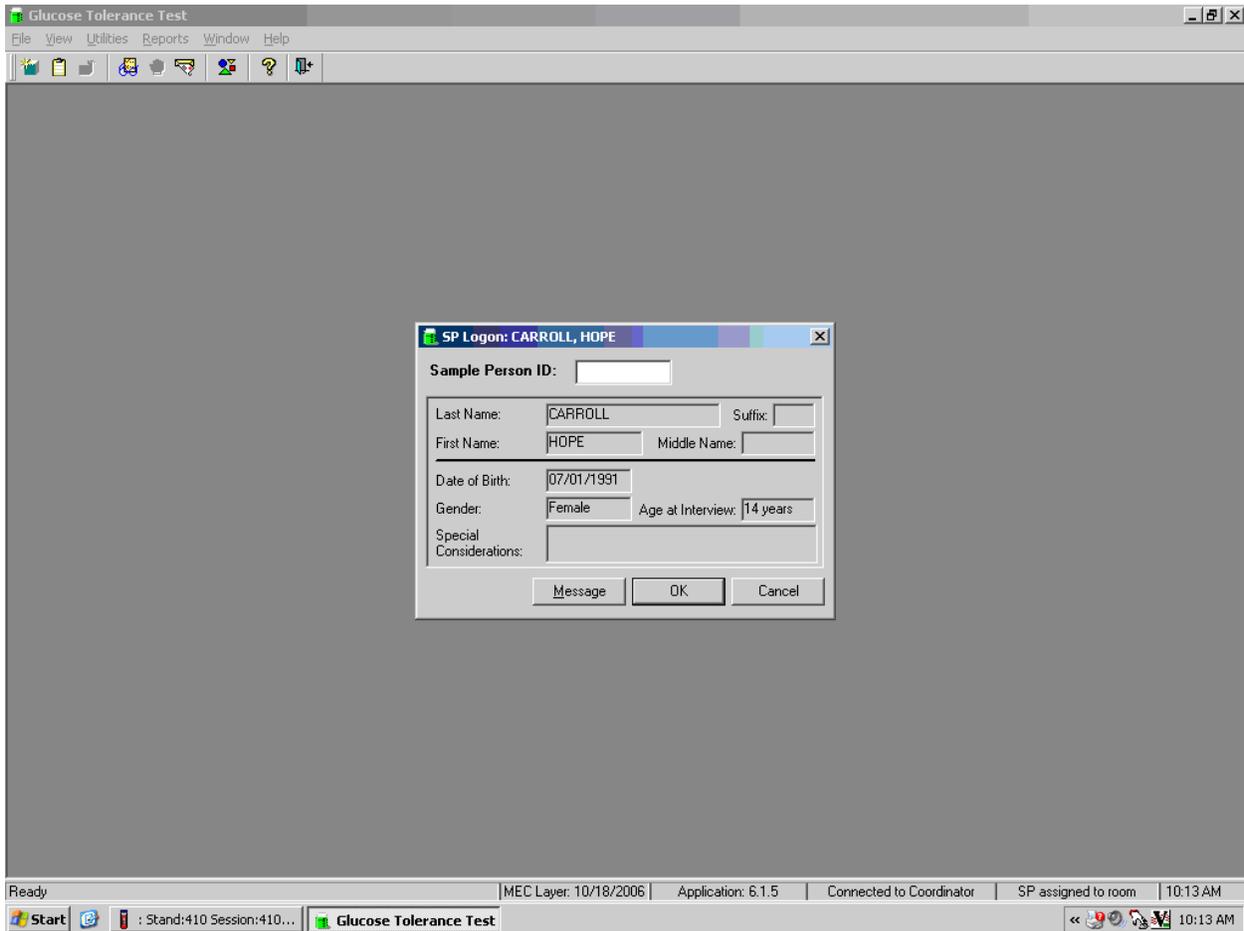
A Message Center message text box displays containing a message from the coordinator indicating the name of the SP who is assigned to the OGTT component. Enter an optional text message and, to send the message to the coordinator, use the mouse to direct the mouse arrow to the Send button and left click. To exit without sending a message to the coordinator, use the mouse to direct the mouse arrow to the Close button and left click, or select [Enter].

The logon screen, shown below, appears after the coordinator assigns the examiner to the component and the assigned examiner accesses the OGTT application.



The MEC Logon window displays. The User ID (Last Name_First Initial) will automatically appear and cannot be changed. Type last name, underscore, first initial in the User ID space, and [Tab] or [Enter]. Enter the password using the keyboard keys and press [Tab], [Enter], or use the mouse to direct the arrow to the OK button and left click. To exit this screen without entering a password, use the mouse to direct the arrow to the Cancel button, and left click. Examiner logoff is automatic at the end of each examination.

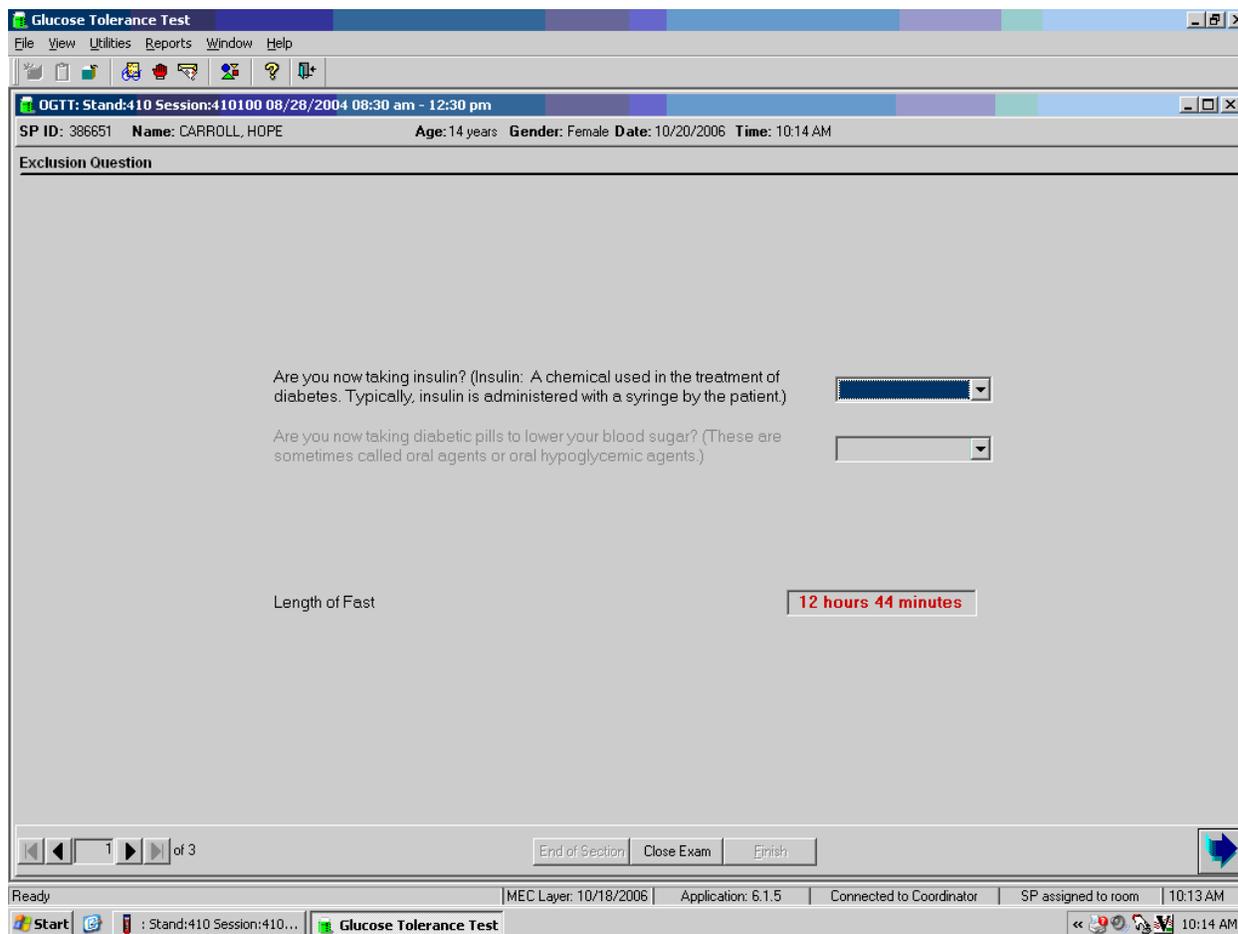
Open the OGTT exam. To open an exam, use the mouse to direct the mouse arrow to {File} in the menu bar, left click, drag the arrow to {Open} and left click, or type [Alt] [F/f], [O/o], or [Ctrl] [O/o]. Log the SP into the exam component.



The SP Logon window displays for the SP assigned to the component. To log the SP into the component, either read the SP ID from the SP's bracelet and manually type this number into the Sample Person ID text box, or use the bar code wand to scan the bracelet bar code. To continue, select [Enter] or use the mouse to direct the mouse arrow to the OK button, and left click. To cancel the logon process and to remove the window, use the mouse to direct the mouse arrow to the Cancel button, and left click.

Verify all information that appears on the SP Logon window. If there is an error in any of this information, inform the coordinator immediately. The coordinator will verify and correct the information as necessary.

The Exclusion Question screen displays.



The Exclusion Question screen lists the two safety exclusion questions and displays the Length of Fast timer. If the data for the first two questions was captured during the household interview, then the response is displayed in the text box and the text box is grayed out. The length of fast is initially captured by the fasting questionnaire screen in the phlebotomy application. The Length of Fast timer continues to update until this section is complete.

Use the following Q x Qs to guide the SP through the exclusion question interview.

Q1: Are you now taking insulin? (Insulin: A chemical used in the treatment of diabetes. Typically, insulin is administered with a syringe by the patient.) Yes, No, Refused, Don't know

<p>Q1: This question asks the SP if he or she is taking insulin, which is an exclusion criterion for this procedure.</p>	<p>Explain that SPs who are taking insulin are excluded due to safety concerns.</p> <p>Insulin is a hormone and therefore, a protein. Insulin is secreted by groups of cells within the pancreas called islet cells. The pancreas is an organ that sits behind the stomach and has many functions in addition to insulin production. The pancreas also produces digestive enzymes and other hormones. Carbohydrates (or sugars) are absorbed from the intestines into the bloodstream after a meal. Insulin is then secreted by the pancreas in response to this detected increase in blood sugar. Most cells of the body have insulin receptors, which bind the insulin, which is in the circulation. When a cell has insulin attached to its surface, the cell activates other receptors designed to absorb glucose (sugar) from the blood stream into the inside of the cell.</p> <p>Diabetes is a disease in which the body either fails to produce any insulin (type 1, also called insulin-dependent or juvenile-onset), or the insulin that it does produce is unable to adequately trigger the conversion of food into energy (type 2, also called non-insulin-dependent or adult-onset).</p> <p>SPs are asked to respond to DIQ050, “{Is SP/Are you} now taking insulin” during the household interview. The response choices are, 1=Yes, 2=No, 7=Refused, 9=Don't Know.</p> <p>If the SP answers, “Yes,” the SP is excluded from the OGTT.</p>
--	--

	<p>If the SP answers, “Refused” the SP drinks the Trutol and receives a 2nd venipuncture for the OGTT.</p> <p>If the SP answers “No,” the SP drinks the Trutol and receives a 2nd venipuncture for the OGTT.</p> <p>If the SP answers “Don’t Know,” the SP drinks the Trutol and receives a 2nd venipuncture for the OGTT.</p> <p>Record the response by typing [Y/y] for “Yes,” [N/n] for “No,” [R/r] if they refuse, or [D/d] for “Don’t know.” Alternatively, use the mouse to direct the mouse arrow to the drop-down arrow on the drop-down list, left click to display the responses, and drag the mouse arrow to “Yes,” “No,” “Refused,” or “Don’t Know” and left click. If the response is “Yes,” use the mouse to direct the mouse arrow to the bright blue right arrow in the bottom right corner of the screen and left click or select [Enter].</p> <p>If the answer is “No,” “Refused,” or “Don’t Know,” then continue to the next question.</p>
--	---

Q2: Are you now taking diabetic pills to lower your blood sugar? (These are sometimes called oral agents or oral hypoglycemic agents.) Yes, No, Refused, Don’t Know

<p>Q2: This question asks whether the SP is currently taking diabetic pills to lower his or her blood sugar, which is an exclusion criterion for this procedure.</p>	<p>Explain that SPs who are taking pills to lower blood sugar are excluded due to safety concerns.</p> <p>People take pills or capsules to lower the level of glucose in the blood. The pills work for some people with type 2 diabetes if their pancreas still makes some insulin. They can help the body in several ways, such as causing the cells in the pancreas to release more insulin.</p>
--	--

A great deal of research toward the development of more effective ways of treating the disease has led to the development of orally active agents, including the [sulfonylureas](#) and the [biguanides](#). These oral agents have been widely received and are primarily used for the treatment of non-insulin-dependent type of diabetes.

Types of these pills for sale in the United States are:

- [Sulfonylureas](#) (many varieties)
- Biguanides: [metformin](#) (Glucophage)
- Alpha-glucosidase inhibitors: [acarbose](#) (Precose); miglitol (Glyset)
- Thiazolidinediones (or “glitazones”): [rosiglitazone](#) (Avandia); [pioglitazone](#) (Actos)
- Meglitinides: [repaglinide](#) (Prandin); nateglinide (Starlix)

Sulfonylureas

Generic Name: Tolbutamide (*Trade Name*: Orinase)

Generic Name: Acetohexamide (*Trade Name*: Dymelor)

Generic Name: Tolazamide (*Trade Name*: Tolinase)

Generic Name: Chlorpropamide (*Trade Name*: Diabinese)

Generic Name: Glipizide (*Trade Name*: Glucotrol, Glucotrol XL)

Generic Name: Glyburide (*Trade Name*: Diabeta, Micronase, Glynase)

Generic Name: Glimepiride (*Trade Name*: Amaryl)

Metformin

Pioglitazone

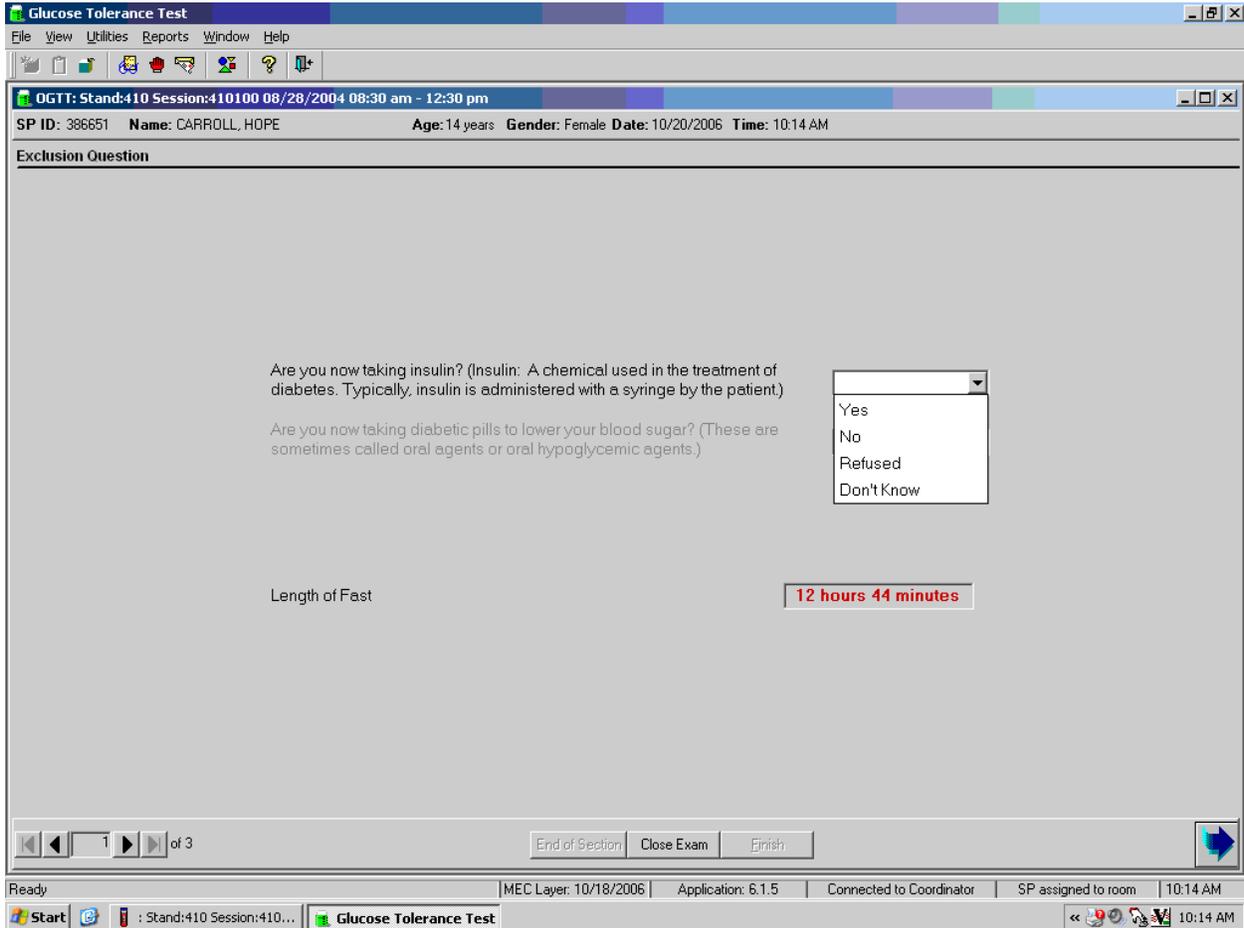
Rosiglitazone (Avandia)

Repaglinide (Prandin)

	<p>SPs may be asked DIQ070 “{Is SP/Are you} now taking diabetic pills to lower {his/her}/your} blood sugar? These are sometimes called oral agents or oral hypoglycemic agents” as part of the household interview. However, because this is dependent on a positive response to a previous question, most SPs will not be asked this question before they get to the OGTT component. The response choices are, 1=Yes, 2=No, 7=Refused, 9=Don’t Know.</p> <p><u>If the SP answers “Yes,” the SP is excluded from the OGTT.</u></p> <p>If the SP answers “Refused,” the SP drinks the Trutol and receives a second venipuncture for the OGTT.</p> <p>If the SP answers “No,” the SP drinks the Trutol and receives a second venipuncture for the OGTT.</p> <p>If the SP answers “Don’t Know,” the SP drinks the Trutol and receives a second venipuncture for the OGTT.</p> <p>Record the response by typing [Y/y] for “Yes,” [N/n] for “No,” [R/r] if they refuse, or [D/d] for “Don’t know.” Alternatively, use the mouse to direct the mouse arrow to the drop-down arrow on the drop-down list, left click to display the responses, and drag the mouse arrow to “Yes,” “No,” “Refused,” or “Don’t Know” and left click. If the response is “Yes,” use the mouse to direct the mouse arrow to the bright blue right arrow in the bottom right corner of the screen and left click or select [Enter].</p> <p>If the answer is “No,” “Refused,” or “Don’t Know,” then continue to the next screen.</p>
--	---

3.6.1 Recording Responses to the Exclusion Questions

If the text box is not grayed out, then ask the first exclusion question, “Are you now taking insulin?” Record the exact response.



Record the response by typing [Y/y] for “Yes,” [N/n] for “No,” [R/r] if he or she refuses, or [D/d] for “Don’t Know.” Alternatively, use the mouse to direct the mouse arrow to the drop-down arrow on the drop-down list, left click to display the responses, and drag the mouse arrow to “Yes,” “No,” “Refused,” or “Don’t Know” and left click. If the response is “Yes,” use the mouse to direct the mouse arrow to the bright blue right arrow in the bottom right corner of the screen and left click or select [Enter]. If the answer is “No,” Refused,” or Don’t know,” ask the next question.

If the SP has not been excluded, continue the exclusion question interview by asking the second question displayed on the screen, “Are you now taking diabetic pills to lower your blood sugar?”

Glucose Tolerance Test

File View Utilities Reports Window Help

OGTT: Stand:410 Session:410100 08/28/2004 08:30 am - 12:30 pm

SP ID: 386651 Name: CARROLL, HOPE Age: 14 years Gender: Female Date: 10/20/2006 Time: 10:14 AM

Exclusion Question

Are you now taking insulin? (Insulin: A chemical used in the treatment of diabetes. Typically, insulin is administered with a syringe by the patient.) No

Are you now taking diabetic pills to lower your blood sugar? (These are sometimes called oral agents or oral hypoglycemic agents.) Yes
No
Refused
Don't Know

Length of Fast 12 hours 44 minutes

1 of 3 End of Section Close Exam Finish

Ready MEC Layer: 10/18/2006 Application: 6.1.5 Connected to Coordinator SP assigned to room 10:14 AM

Record the response by typing [Y/y] for “Yes,” [N/n] for “No,” [R/r] if he or she refuses, or [D/d] for “Don’t know.” Alternatively, use the mouse to direct the mouse arrow to the drop-down arrow on the drop-down list, left click to display the responses, and drag the mouse arrow to “Yes,” “No,” “Refused,” or “Don’t Know” and left click. If the response is “Yes,” use the mouse to direct the mouse arrow to the bright blue right arrow in the bottom right corner of the screen and left click. If the answer is “No,” “Refused,” or “Don’t know,” continue to the next slide.

Review the length of fast; this is informational only.

Glucose Tolerance Test

File View Utilities Reports Window Help

OGTT: Stand:410 Session:410100 08/28/2004 08:30 am - 12:30 pm

SP ID: 386651 Name: CARROLL, HOPE Age: 14 years Gender: Female Date: 10/20/2006 Time: 10:14 AM

Exclusion Question

Are you now taking insulin? (Insulin: A chemical used in the treatment of diabetes. Typically, insulin is administered with a syringe by the patient.) No

Are you now taking diabetic pills to lower your blood sugar? (These are sometimes called oral agents or oral hypoglycemic agents.) No

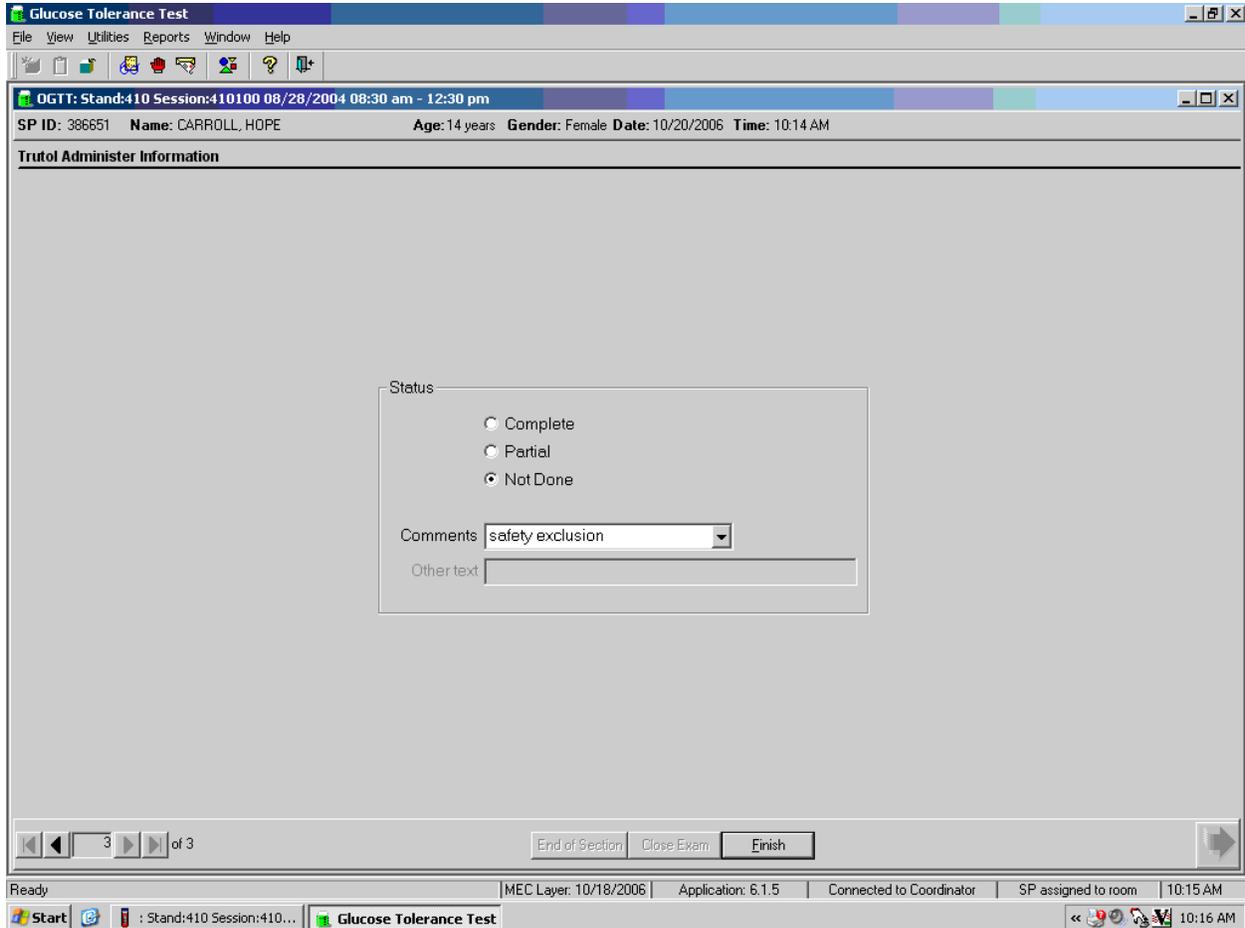
Length of Fast 12 hours 44 minutes

Ready MEC Layer: 10/18/2006 Application: 6.1.5 Connected to Coordinator SP assigned to room 10:14 AM

Start Stand:410 Session:410... Glucose Tolerance Test 10:15 AM

To progress to the Trutol Administer Information screen, use the mouse to direct the mouse arrow to the bright blue arrow in the bottom right corner and left click, or select [Enter].

SPs excluded due to a “Yes,” response to either of the two exclusion questions are automatically coded by the application as “safety exclusion.”



Escort the SP back to the coordinator or to the next component as directed by the Message Center.

3.6.2 Trutol Administer Information

If the SP is not excluded, then the Trutol Administer Information screen displays. Review the length of fast; this is informational only.

The screenshot shows a software window titled "Glucose Tolerance Test" with a menu bar (File, View, Utilities, Reports, Window, Help) and a toolbar. Below the menu bar, a status bar displays "OGTT: Stand:410 Session:410100 08/28/2004 08:30 am - 12:30 pm". The main content area is titled "Trutol Administer Information" and contains the following fields and controls:

- Length of Fast:
- Your weight is: LBs
- Amount to drink is 10 oz (295 ml)
- Please drink this solution within 10 minutes.
- Timer:
- Start:
- Stop:
- Total:
- Amount of solution the SP drank:

At the bottom of the window, there is a navigation bar with "End of Section", "Close Exam", and "Finish" buttons, and a status bar showing "Ready", "MEC Layer: 10/18/2006", "Application: 6.1.5", "Connected to Coordinator", "SP assigned to room", and "10:18 AM". The Windows taskbar at the very bottom shows the Start button, a taskbar icon for "Stand:410 Session:410...", and the "Glucose Tolerance Test" application icon, with the system clock showing "10:19 AM".

The Trutol Administer Information screen contains a 'Length of Fast' timer, a 'Your weight is' text box, an 'Amount to drink' calculation, a script ("Please drink this solution within 10 minutes.") to recite to the SP, a 10:00 timer to record the Start, Stop, Total elapse time, and a text box to record the 'Amount of the solution' (Trutol) that the SP consumed.

If the SP has been weighed in body measures, then the weight is pulled into the Trutol Administration screen and displayed in the “Your weight is” text box. If the SP has not been weighed in body measures, then the self-reported weight will be pulled into the Trutol Administration screen and displayed in the text box. (The self-reported weight is WGQ020 “How much do you weigh without clothes or shoes?”)

If the self-reported weight is less than 100 pounds, then weigh the SP on the BM scale. SPs who weigh less than 94 pounds must have a calibrated dose of Trutol. Enter the weight into the ‘Your weight is’ text box and select [TAB]. The application will calculate the amount of Trutol to remove from the Trutol bottle. Use a small medicine cup to measure the correct amount to remove and then discard the excess Trutol. Exhibit 3-4 illustrates the correct dosage per lb. or kg.

Exhibit 3-4. Trutol Calibrated Dosage Chart

Body weight		75g concentration		Remove	
lb.	kg	oz.	mL	oz.	mL
94+	42.7+	10.0	295	0	0
90-93	40.9	9.5	283	0.5	12
85-89	38.6	9.0	267	1.0	28
80-84	36.4	8.5	251	1.5	44
75-79	34.1	8.0	235	2.0	60
70-74	31.8	7.4	220	2.6	75
65-69	29.5	6.9	204	3.1	91
60-64	27.3	6.4	188	3.6	107

If the SP consumes the entire dose of Trutol, then the examiner must place a Dymo label on the outside of the SP’s top. The time displayed is the earliest time at which the SP is eligible for the GTT blood draw. The SP is eligible for the second blood draw 1 hour and 40 minutes after the time he or she consumed the Trutol, but the second blood draw must occur within 2 hours and 15 minutes after consuming the Trutol. The entire MEC staff should monitor the SP and the time displayed on the top. Encourage the SP to continue his or her fast.

Taking an SP's Weight

Follow these steps to take the SP's weight:

1. Make sure the scale weighs in pounds by checking the switch on the underside of the digital display.
2. Place the scale on the floor.
3. Switch on the scale by pressing the ON button; 888.8 will appear on the digital display.
4. Have the SP remove his or her shoes and any heavy outer clothing such as sweaters, jackets, etc.
5. As soon as the display switches to 0.0, have the SP step on the scale with his or her feet positioned in the center.
6. Ask the SP to stand straight and remain still.
7. Wait about 4 seconds for the weight to display on the digital readout.
8. Record the weight in pounds in the "Your weight is" text box.
9. Ask the SP to step off the scale. The scale switches off automatically after 30 seconds.

Enter the weight into the “Your weight is” text box and select [TAB]. The application will calculate and display the calibrated dose of Trutol.

Glucose Tolerance Test

File View Utilities Reports Window Help

OGTT: Stand:410 Session:410100 08/28/2004 08:30 am - 12:30 pm

SP ID: 386651 Name: CARROLL, HOPE Age: 14 years Gender: Female Date: 10/20/2006 Time: 10:14 AM

Trutol Administer Information

Length of Fast

Your weight is LBs

Amount to drink is 9.0 oz (267 ml), remove 1.0 oz.
Please drink this solution within 10 minutes.

Timer

Start

Stop

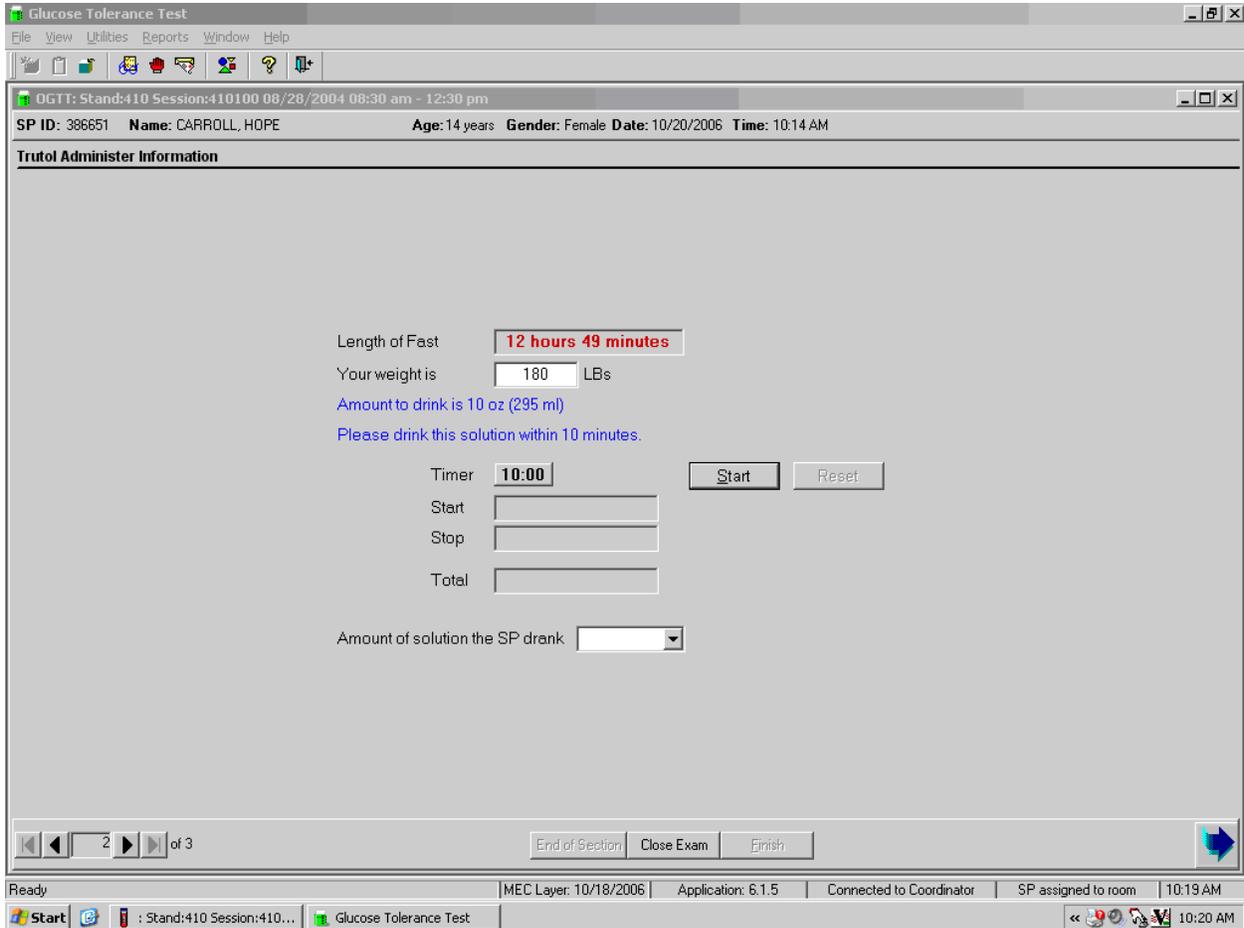
Total

Amount of solution the SP drank

Ready MEC Layer: 10/18/2006 Application: 6.1.5 Connected to Coordinator SP assigned to room 10:18 AM

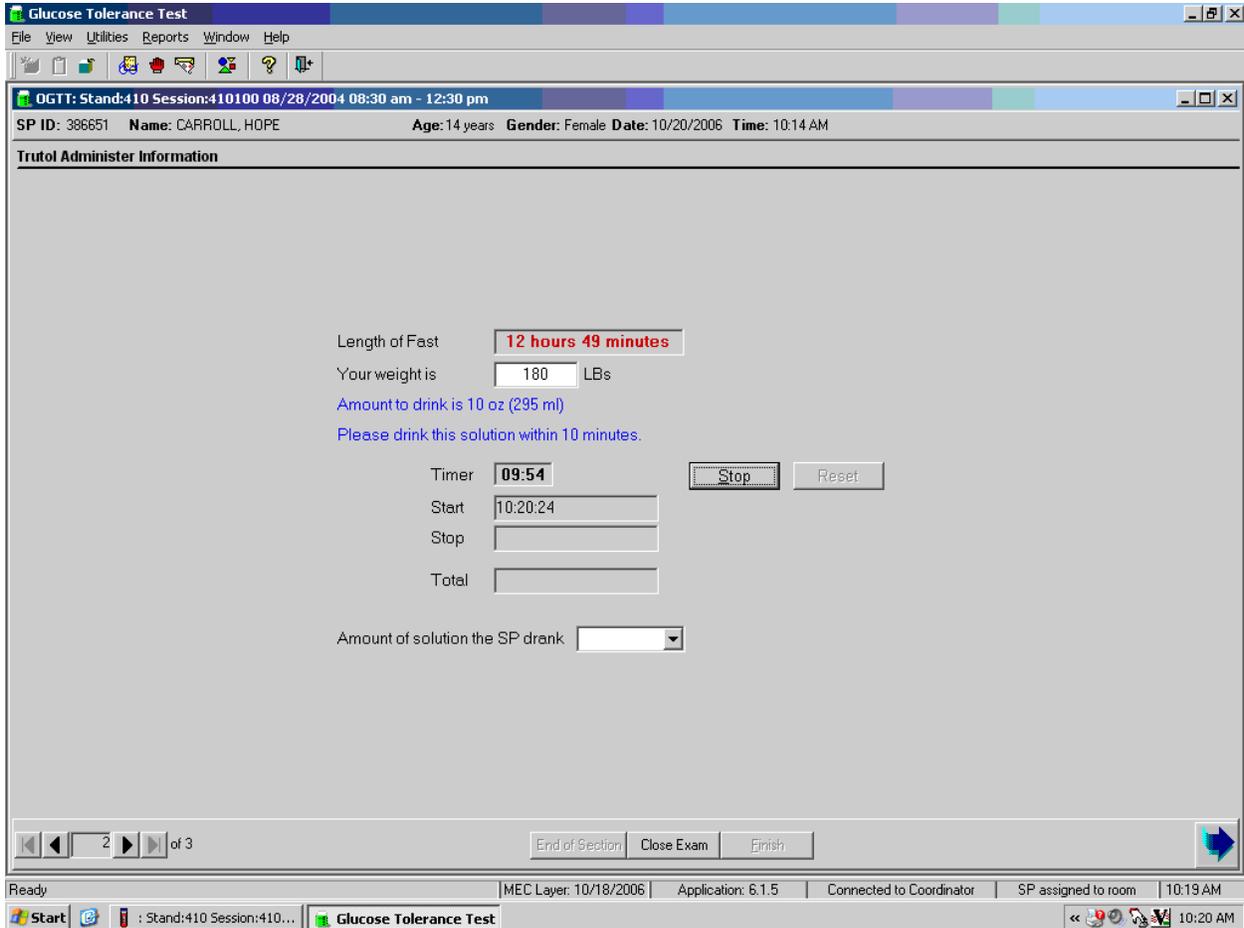
Ask the SP to indicate a preference for one of the three flavors. Choose the flavor that matches the preference of the soft drink flavor that he or she prefers. Follow the instructions; remove the correct amount of Trutol from the bottle before handing the bottle to the SP. Use a small medicine cup to measure the correct amount to remove and discard the excess Trutol. Hand the SP a cold bottle of Trutol (containing the calibrated dose) and a straw. SPs MUST consume the entire calibrated dose of the Trutol within 10 minutes.

Recite the script “Please drink this solution within 10 minutes” and start the timer. The timer counts down from 10:00 minutes.



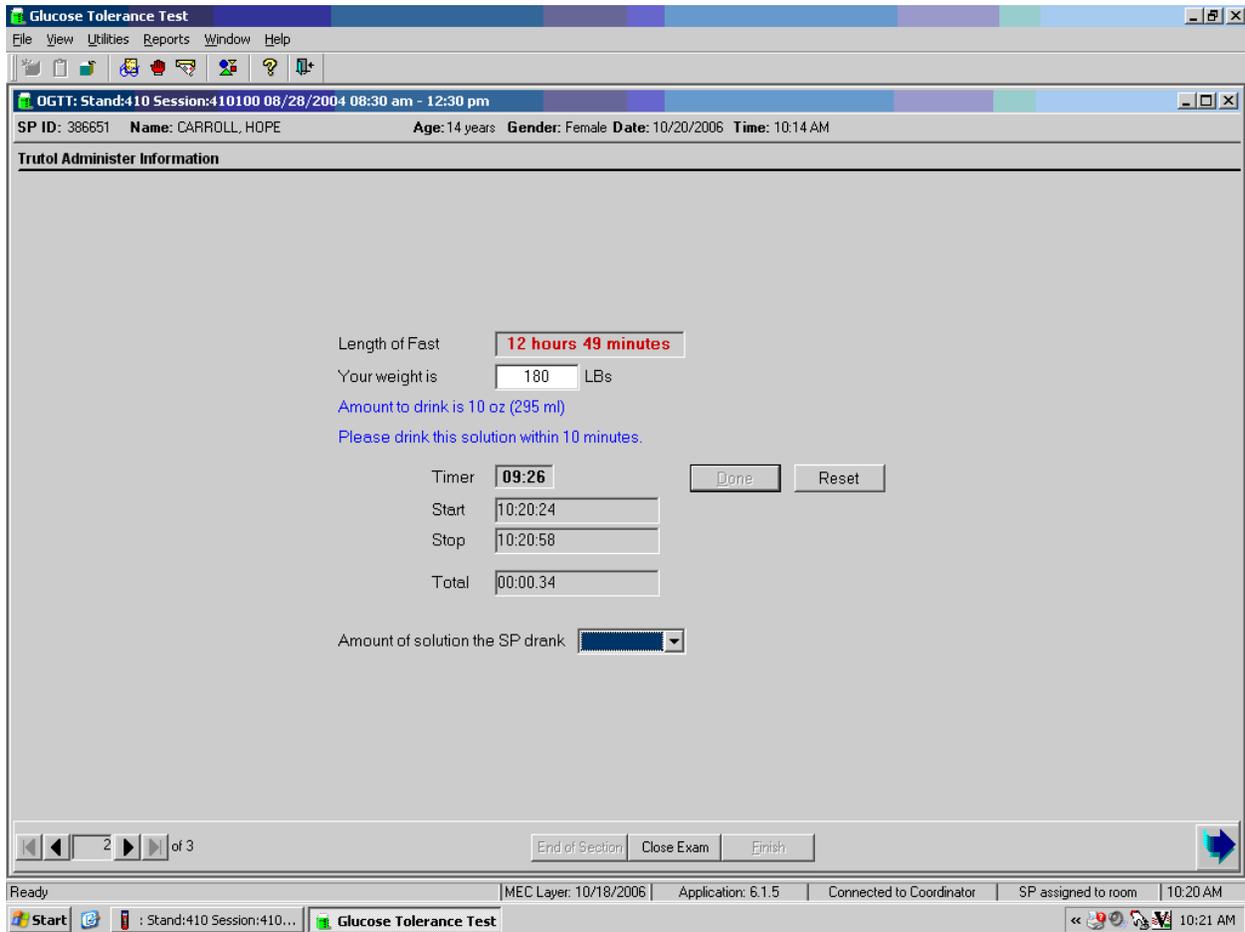
To start the timer, use the mouse to direct the mouse arrow to the start button and left click or type [Alt] [S/s].

When the SP has finished drinking the entire calibrated dose of Trutol, or cannot continue drinking the Trutol, then select the Stop button.



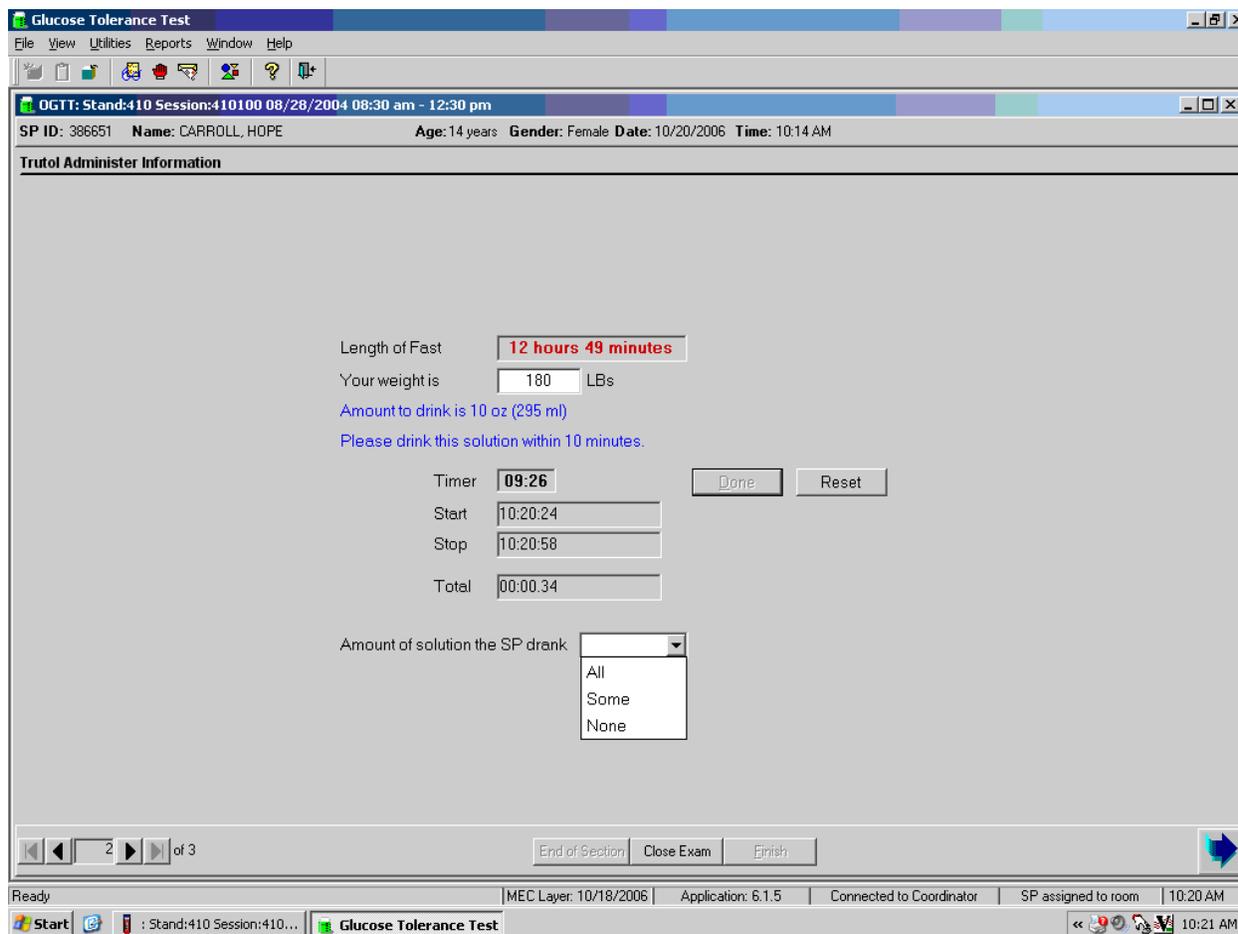
To stop the timer, use the mouse to direct the mouse arrow to the Stop button, and left click or type [Alt] [S/s].

It is possible to restart the timer.



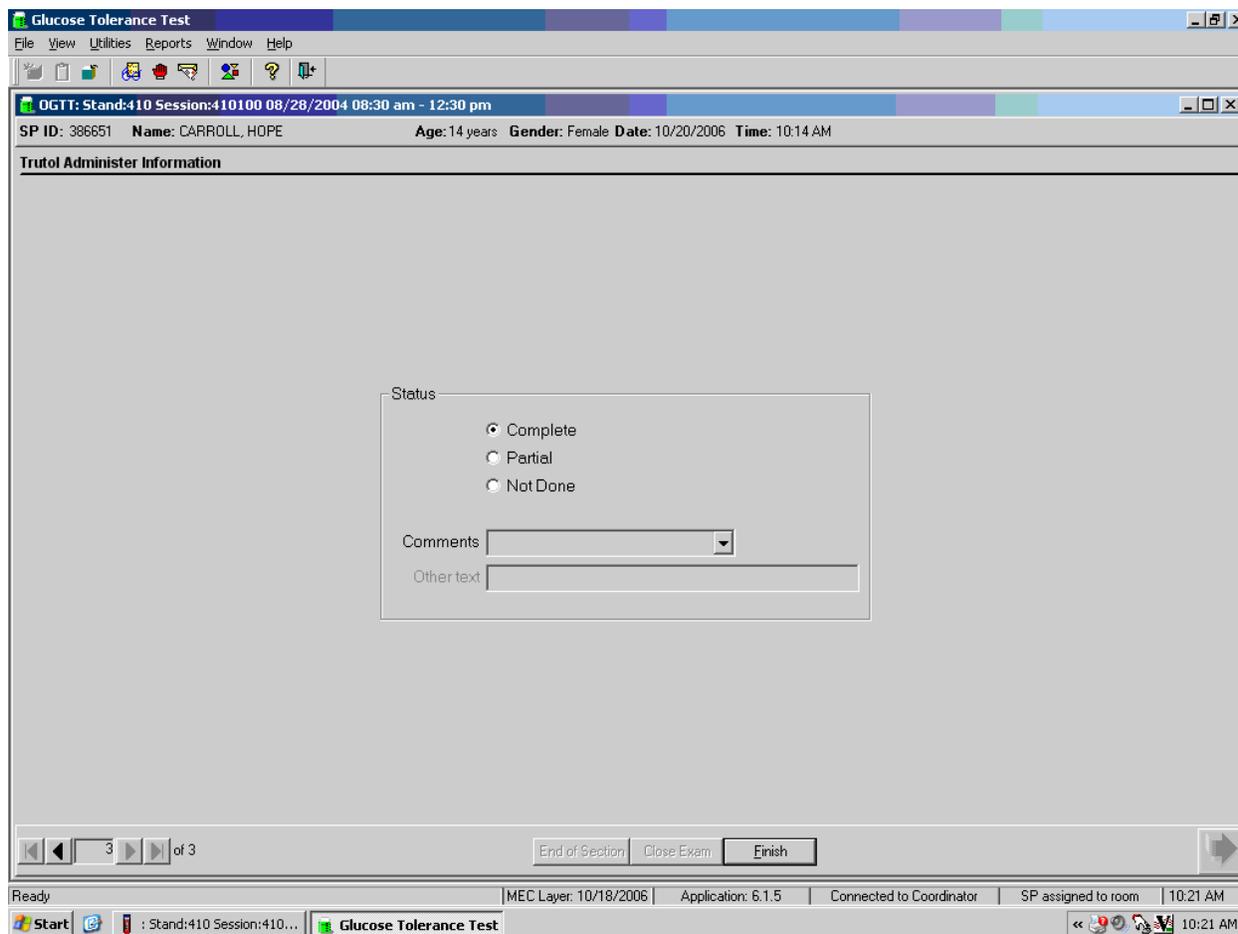
To restart the timer, use the mouse to direct the mouse arrow to the Reset button and left click. The Start, Stop, and Total fields will be cleared and the Start button will be enabled.

Record the amount of Trutol that the SP consumed.



The choices for the amount of solution that the SP consumed are “All,” “Some,” or “None.” To record the amount, use the mouse to direct the mouse arrow to the drop-down arrow on the drop-down list, left click to display the responses, and drag the mouse arrow to “All,” “Some,” or “None” and left click. To progress to the section status screen, use the mouse to direct the mouse arrow to the bright blue right arrow in the bottom right corner of the screen and left click.

Verify the Trutol Administer Information section status.

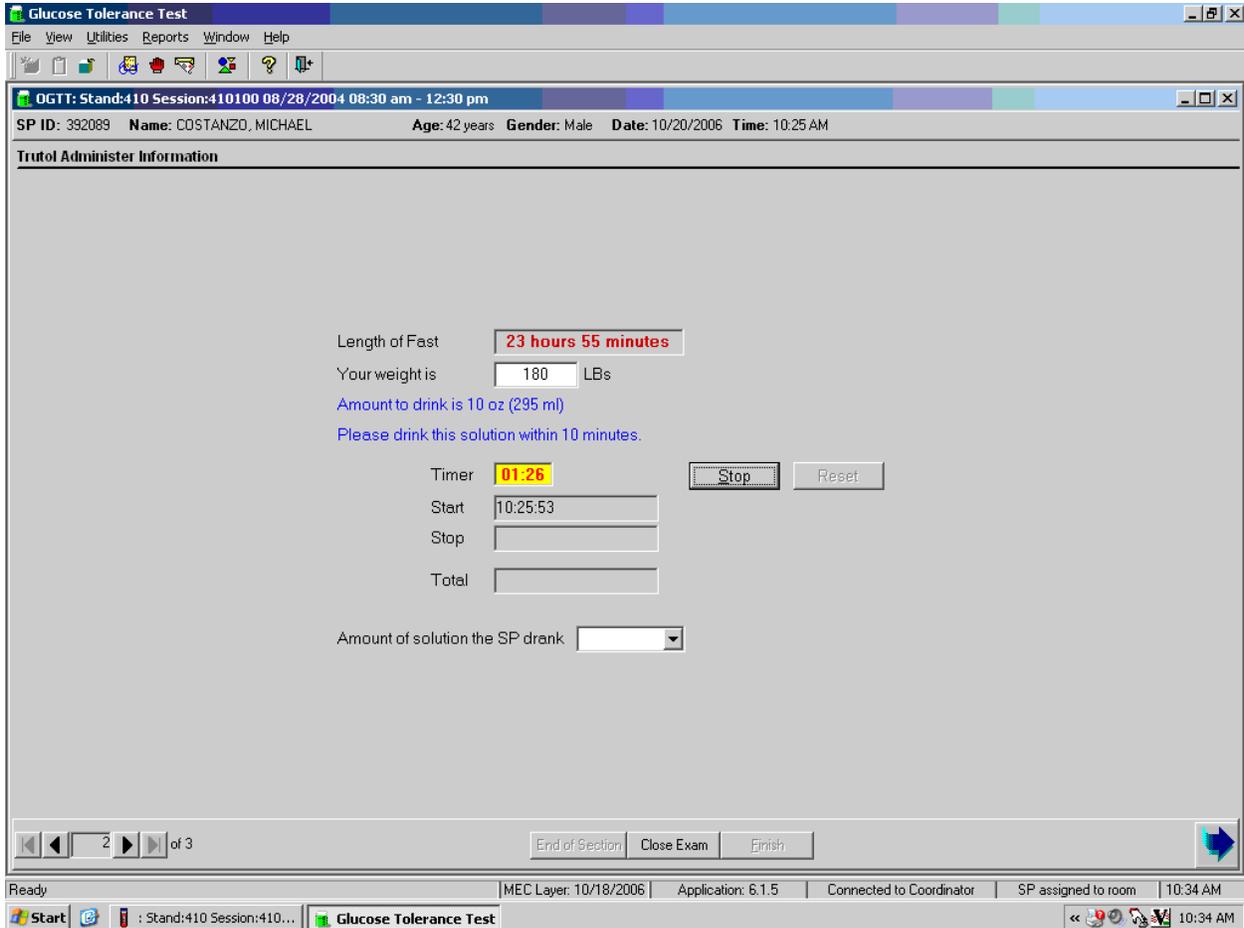


If the SP drank all of the Trutol solution, then the section status is complete. To complete the examination, use the mouse to direct the mouse arrow to the Finish button or type [Enter].

NOTE: Place the Dymo label with the return time on the outside of the SP's top.

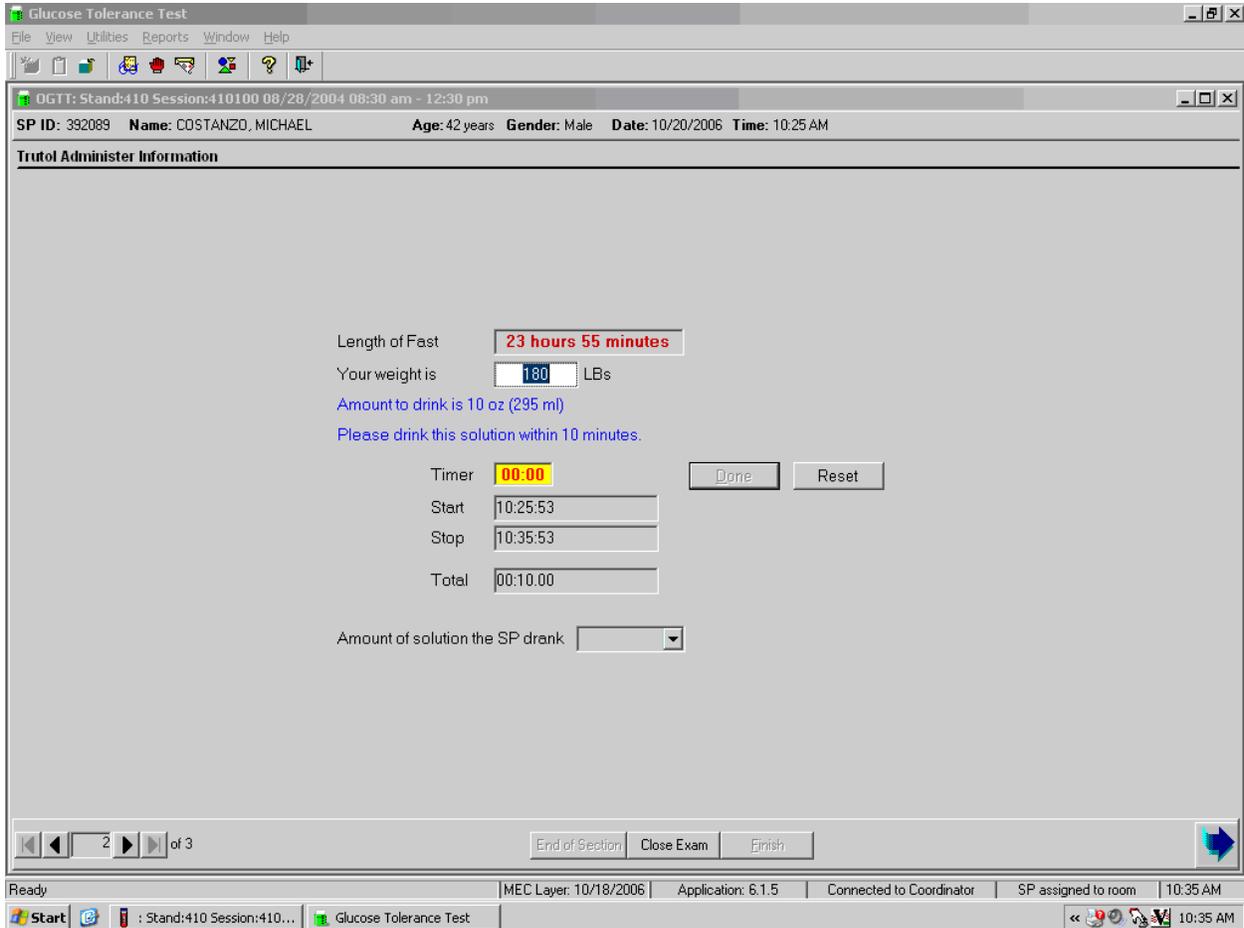
Please return this SP for
OGTT Blood Draw at
10:59 am

The timer counts down from 10:00 minutes. When the timer reaches 1:40, the background turns yellow and the numbers change to red.



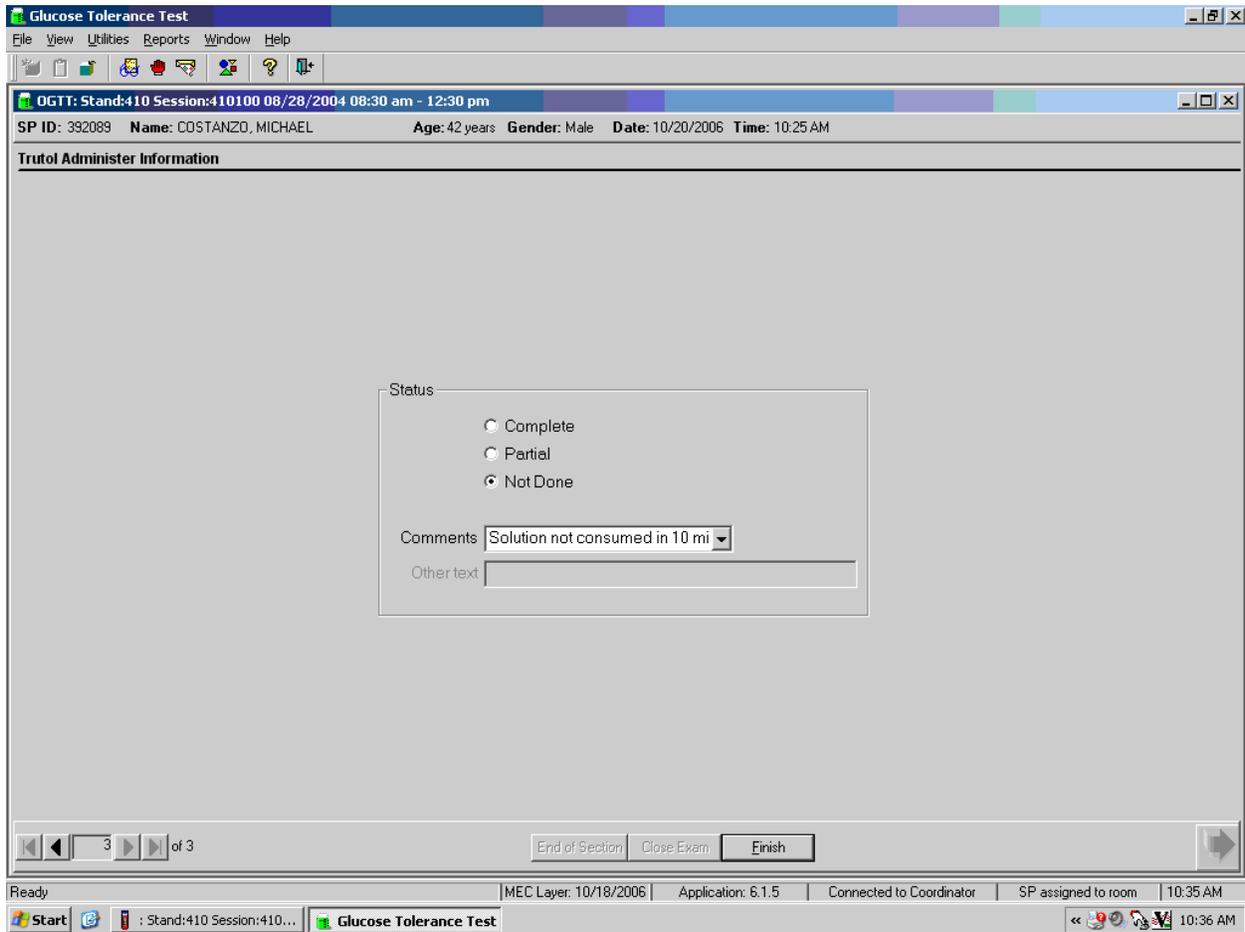
Monitor the timer display. Coach or encourage the SP to drink the solution before the 10 minutes expire.

If the total time is greater than 10 minutes, then the timer will automatically stop at 00:00 and insert 00:10:00 in the Total field.



Record the amount of solution the SP drank and proceed to the section status screen. If the SP drank “some” or “none” of the Trutol solution, then the section status is Not Done.

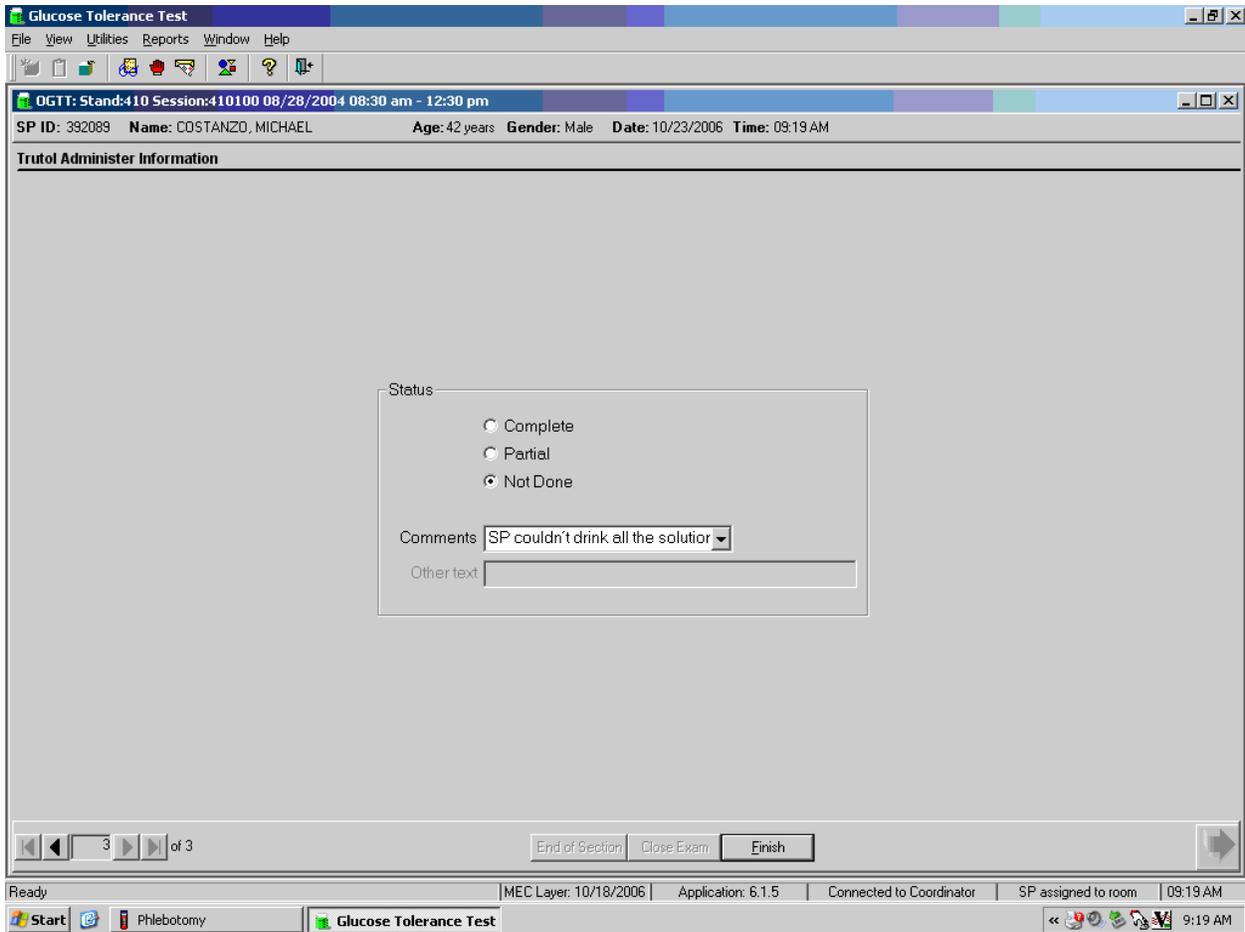
Review the comment in the section status screen.



If the total time is 00:10:00, then the comment will default to “Solution not consumed in 10 minutes.”

3.6.3 Section Status

If the SP drank “some” or “none” of the Trutol solution, then the section status is Not Done. Choose and enter the appropriate comment code when the Trutol Administer Information section status is Not Done.



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. To complete the examination, use the mouse to direct the mouse arrow to the Finish button or type [Enter].

Comment code	Use when:
Safety exclusion	Not applicable This is reserved for positive responses to the insulin, oral diabetic medications, hemophilia and chemotherapy exclusion questions, and positive pregnancy tests. It is automatically coded by the application. The coordinator may code exams using this comment.
SP refusal	The SP refuses to drink the Trutol. This is SP initiated nonresponse due to refusal. The SP refuses the component for any reason other than an illness or emergency. If the SP refuses in the reception area, the coordinator codes the exam. If the SP refuses after starting the exam, the examiner codes the exam.
No time	Not applicable
Physical limitation	Not applicable
Communication problem	Not applicable
Equipment failure	Not applicable
SP ill/emergency	Use this comment to code not done or partial when the SP faints or is about to faint or the SP becomes ill or an emergency occurs and the test cannot be performed on the SP.
Interrupted	Not applicable
SP couldn't drink all the solution	Use this code when the SP cannot consume the entire calibrated dose of the Trutol.
Solution not consumed in 10 minutes	Use this code when the timer expires before the SP has consumed the entire calibrated dose of the Trutol.
SP regurgitated the solution	Use this code when the SP becomes ill and regurgitates the Trutol.
SP broke fast	Use this code if the SP eats anything or drinks anything other than plain water after consuming the Trutol but before completing the second blood draw.
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.

4. BLOOD DRAW OGTT APPLICATION

4.1 OGTT Application – Section Two (Blood Draw)

If an SP consumed the entire calibrated dose of the Trutol solution in 10 minutes, and 1 hour and 40 minutes has elapsed, then he or she is eligible to return to phlebotomy to have (1) one additional 2-mL gray top drawn and (2) any tubes that were not drawn during the initial venipuncture examination drawn.

A pop-up message window will alert the coordinator and the phlebotomist when an SP is eligible to return to phlebotomy for the second blood draw.

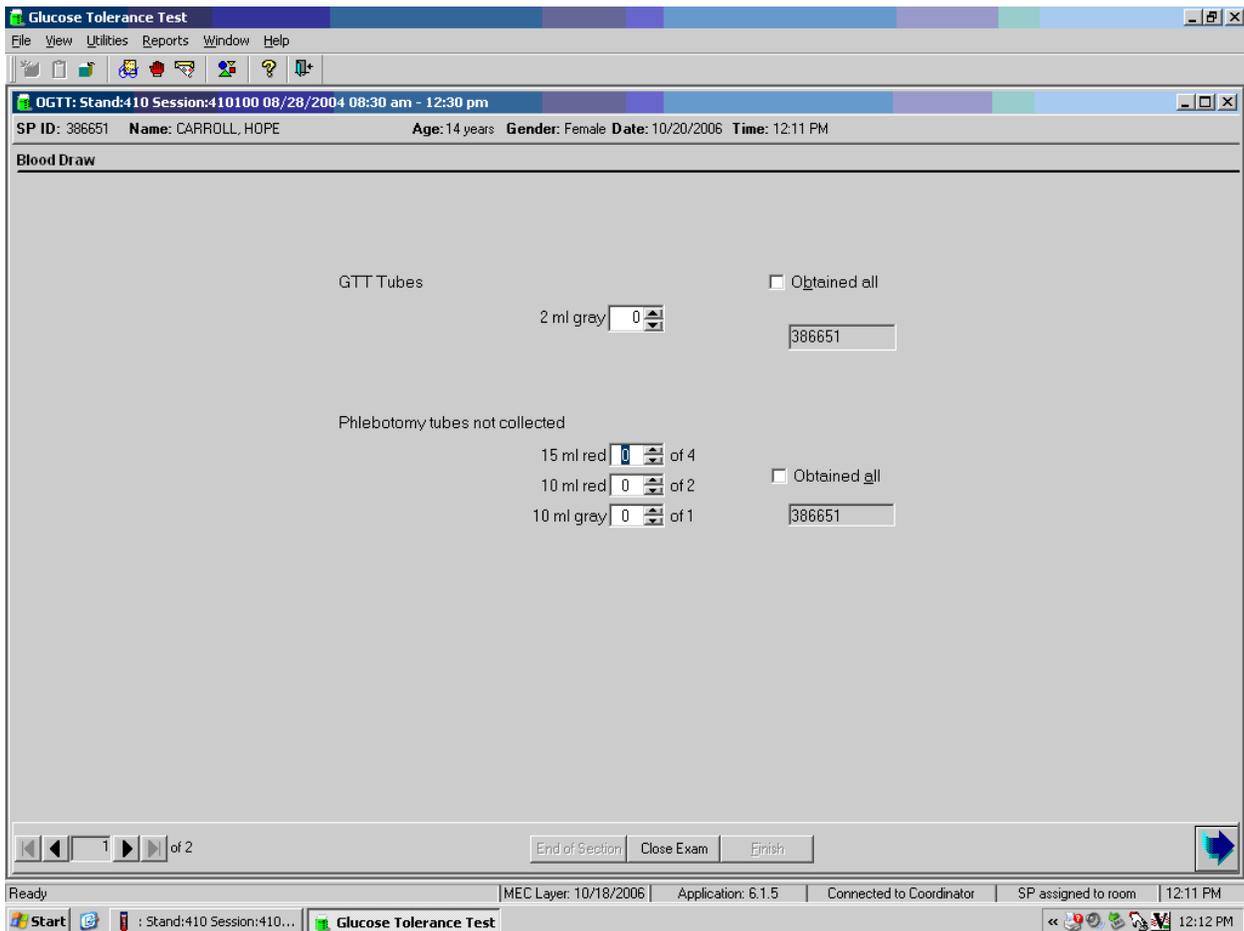
The screenshot displays the 'Coordinator Console' application window. At the top, a menu bar includes 'File', 'Reports', 'Utilities', 'Window', and 'Help'. The main window title is 'Coordinator Console Stand:410 Session:410100 28-Aug-2004 08:30 am - 12:30 pm'. Below the title bar is a grid of service status indicators for various departments, including Audiology, Oral Health, Body Composition, Laboratory, Phleb, OGTT, Lbl/Shp, Staff Area, Ophthalmology, Dietary 2, Dietary 1, MEC Int 2, OGTT, MEC Int 1, OGTT, Physician, Broncho, Body Measures, Vision, Coordinator, and Puckett T. A 'Message Center' pop-up window is open in the center, displaying a message from 'Reception Coordinator' to 'MARGARET BECKER (SPID: 866665)' stating she is eligible to continue to OGTT. The message was received at 10:49:01. The message center also shows a 'Total: 1 Unread: 1' and a '1:56' timer. On the right side of the interface, there is a 'Technician Skill' table listing various technicians and their skills.

Technician	Skill
✓ Matthew G. E.	Dietary Interviewer
✓ Grunby D. M.	Health Tech
✓ Louise R. O.	Health Tech
✓ Macnamara J. W.	Health Tech
✓ Mossey S. F.	Health Tech
✓ Spedaro O. J.	Health Tech
✓ Cheney J. M.	Lab Tech
✓ Lacey S.	Lab Tech
✓ Nesbitt R. F.	Lab Tech
✓ Vitner M.	Lab Tech
✓ Gonzales M.	MEC Interviewer
✓ Neves E.	MEC Interviewer
✓ Brown F. K.	Phlebotomist
✓ Carolyn S.	Physician

To close or remove the Message Center box, use the mouse to direct the mouse arrow to the Close button and left click, or use the mouse to direct the mouse arrow to the upper right hand corner to the x and left click.

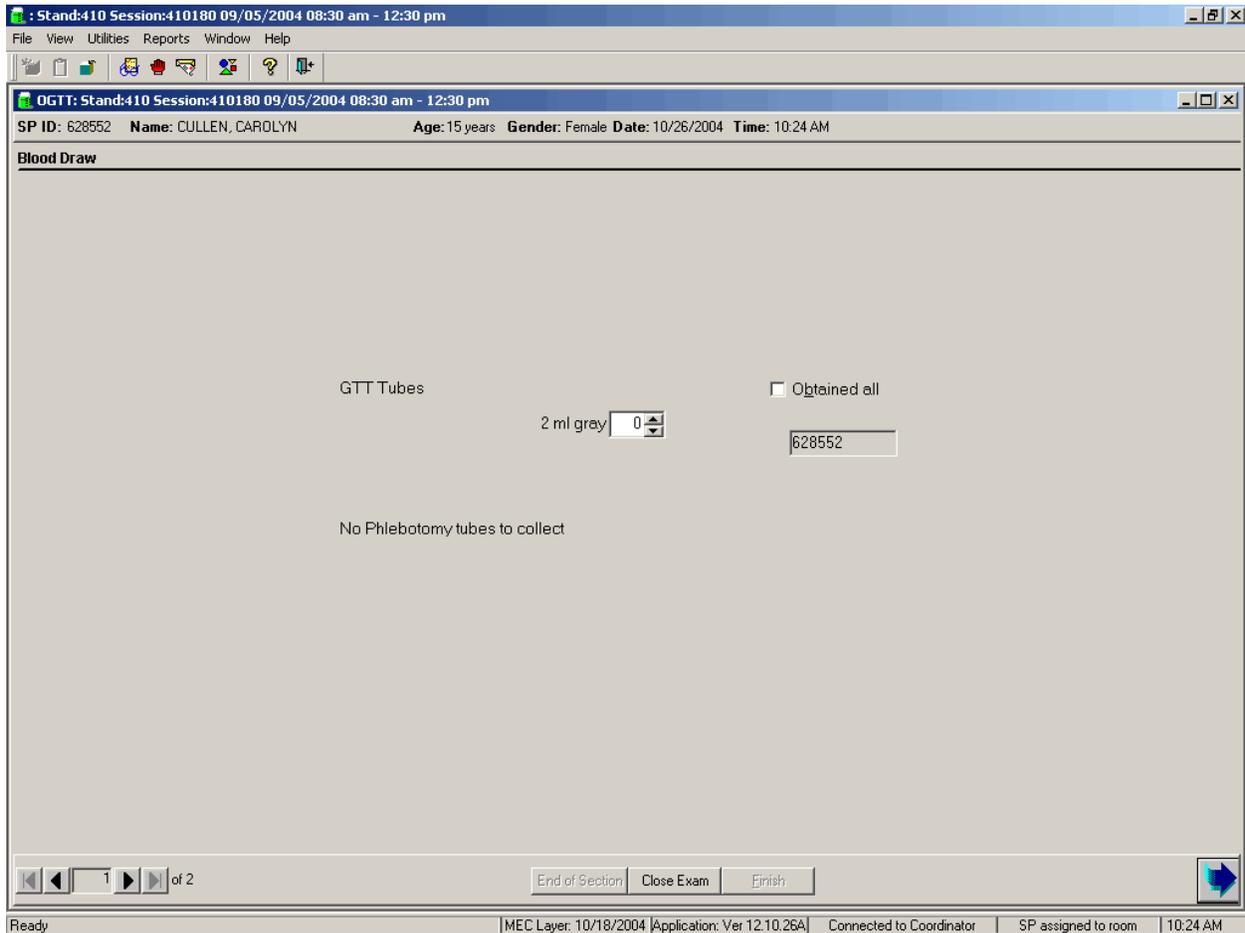
Logon to the OGTT application and log the SP into the component.

The blood draw screen is divided into two sections.



The upper section is identical to the venipuncture screen in the phlebotomy examination except that it contains only one 2-mL gray top tube. The bottom half of the screen lists any tubes that were not drawn during the initial venipuncture examination. The sections function exactly like the venipuncture screen in the phlebotomy examination.

If all of the blood tubes were drawn during the phlebotomy examination, then only the first half of the blood draw screen will contain the 2-mL gray top tube. The lower section of the blood draw screen will indicate that there are “No phlebotomy tubes to collect.”



Draw the additional 2-mL gray top tube and then any tubes that were missed during the phlebotomy examination first. Draw all tubes according to the protocol described in Chapter 4 of the *Laboratory Procedures Manual*.

Labels will print for all the tubes marked as collected, including the second 2-mL gray top tube. The label for the second 2-mL gray top tube contains a bar code with the SP ID concatenated with the vessel ID (# 98) and includes the test name “OGTT.”

Immediately after completing the venipuncture, enter the results of the blood draw and any comments about the venipuncture.

The screenshot displays the 'Glucose Tolerance Test' software window. The title bar reads 'OGTT: Stand:410 Session:410100 08/28/2004 08:30 am - 12:30 pm'. The patient information bar shows 'SP ID: 386651 Name: CARROLL, HOPE Age: 14 years Gender: Female Date: 10/20/2006 Time: 12:11 PM'. The main area is titled 'Blood Draw' and contains the following data:

Tube Type	Quantity	Status	SP ID
GTT Tubes	2 ml gray	<input checked="" type="checkbox"/> Obtained all	386651
Phlebotomy tubes not collected	15 ml red	<input type="checkbox"/> Obtained all	
	10 ml red	<input checked="" type="checkbox"/> Obtained all	
	10 ml gray	<input type="checkbox"/> Obtained all	386651

At the bottom of the window, there are navigation buttons: 'End of Section', 'Close Exam', and 'Finish'. The status bar at the very bottom shows 'Ready', 'MEC Layer: 10/18/2006', 'Application: 6.1.5', 'Connected to Coordinator', 'SP assigned to room', and '12:12 PM'.

To record all tubes as filled or obtained, use the mouse to direct the mouse arrow to the “Obtained all” check box and left click, or type [Alt] [B/b]. This records a check mark in the box and marks all tubes as obtained. To mark individual tubes as filled or obtained, use the mouse to direct the mouse arrow to the up-down controls on the spin box and toggle the number of each tube up or down or type the correct number using the numeric keys.

Verify the Blood Draw section status.

: Stand:410 Session:410180 09/05/2004 08:30 am - 12:30 pm

File View Utilities Reports Window Help

OGTT: Stand:410 Session:410180 09/05/2004 08:30 am - 12:30 pm

SP ID: 628552 Name: CULLEN, CAROLYN Age: 15 years Gender: Female Date: 10/26/2004 Time: 10:24 AM

Blood Draw Section Status

Status

Complete
 Partial
 Not Done

Comments

Other text

2 of 2

End of Section Close Exam Finish

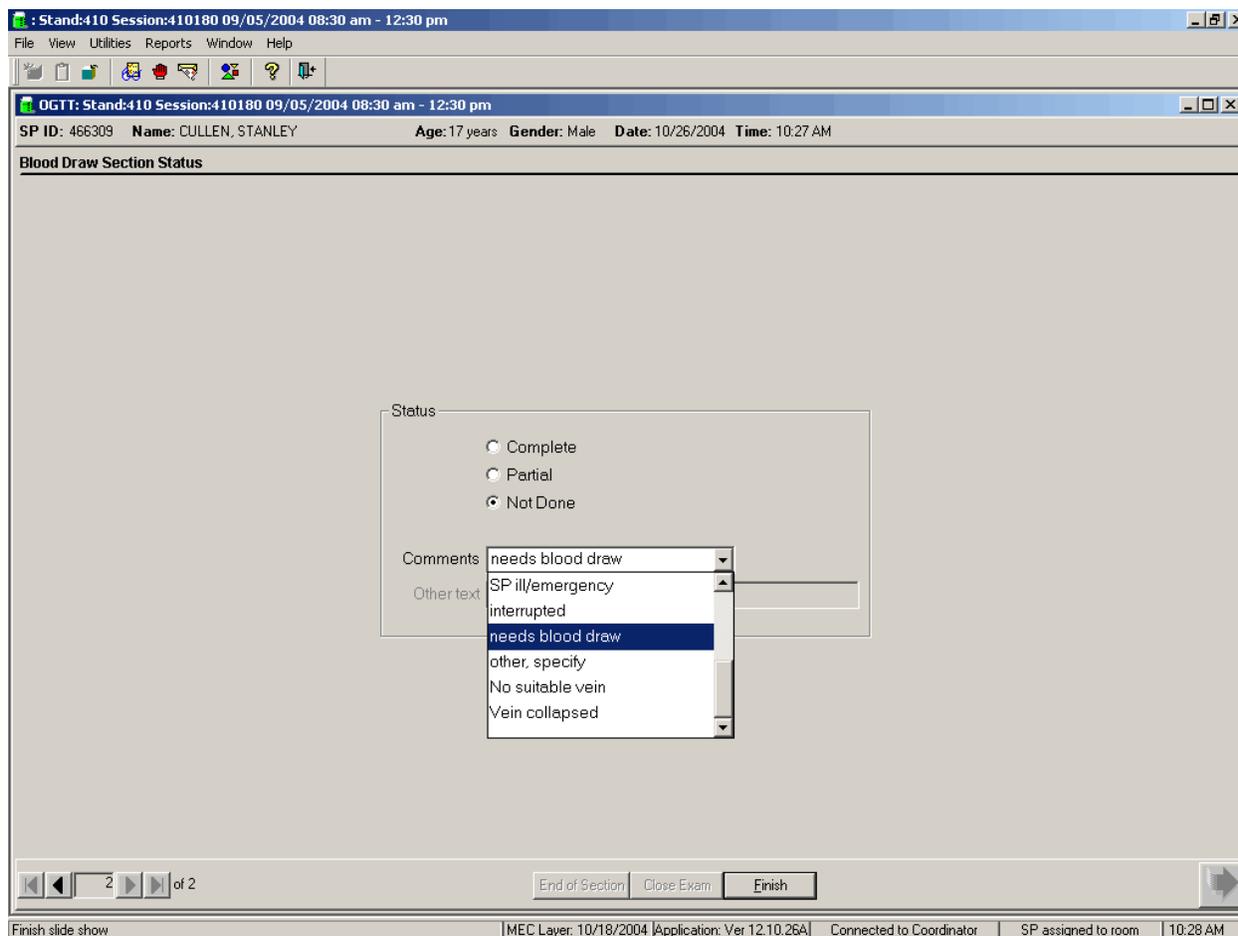
Ready | MEC Layer: 10/18/2004 | Application: Ver 12.10.26A | Connected to Coordinator | SP assigned to room | 10:25 AM

The blood draw section status is complete if the second 2-mL gray top tube is collected.

If any blood tubes were not drawn during the initial phlebotomy examination and they were drawn during the blood draw section of the OGTT examination, then the phlebotomy section status will automatically update to reflect the additional tubes drawn during the OGTT examination.

Remove the Dymo label from the SP's gown and ask the SP if he or she is allergic to peanuts. If not, then offer the SP peanut butter crackers and juice. If the SP is allergic to peanuts or does not know, then offer the standard crackers and juice.

Use comment codes to explain Not Done status codes.



The blood draw section status is Not Done if the second 2-mL gray top tube is not collected. **Once the tube is marked as not obtained, the comment will default to “needs blood draw.”** Correct the comment by selecting the most appropriate comment code. 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.

Comment code	Use when:
Safety exclusion	Not applicable This is reserved for positive responses to the hemophilia and chemotherapy exclusion questions and it is automatically coded by the application. The coordinator may code exams using this comment.
SP refusal	The SP refuses to have his or her blood collected. This is an SP-initiated nonresponse due to refusal. The SP refuses the component for any reason other than an illness or emergency. If the SP refuses in the reception area, the coordinator codes the exam. If the SP refuses after starting the exam, the examiner codes the exam. Use this comment to code partial exams when the SP refuses after one tube has been drawn, or the blood flow stops after one tube but before all tubes have been successfully drawn.
No time	Not applicable
Physical limitation	Not applicable
Communication problem	Not applicable
Equipment failure	Not applicable
SP ill/emergency	Use this comment to code not done or partial when the SP faints or is about to faint or the SP becomes ill or an emergency occurs and the test cannot be performed on the SP.
Interrupted	Not applicable
Error (technician/software/supply)	Use this comment to code partial and not done exams when there are phlebotomist errors, or software or supply issues.
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.
No suitable vein	Use this comment to code exams as not done (no tubes drawn) when the SP does not have an accessible vein, any arms available, casts on both arms, there is a rash over the entire area, or the blood draw was started but there was no blood in the tubing.
Vein collapsed	Use this comment to code exams as partial when one or more tubes are successfully drawn but blood flow stops before all tubes are drawn or when the veins collapse.

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

5. LABORATORY PROCESSING

5.1 Laboratory Overview

The vessel for OGTT is #98 (Exhibit 5-1). Use the gtt processing module to record the blood processing results. Labels for the OGTT vessel print for all SPs after the last blood processing set of labels. Keep the OGTT labels together and place them in the lab with the blood processing racks. Do not label the vessels in advance; label each vessel as it is processed.

Exhibit 5-1. Primary SP's OGTT processing protocol

ID	Test name	Ages	Sample (mL)	Sample type	Collection type	Vessel type	Remarks
98	OGTT	12+	0.5	Plasma	Gray	2-mL	Morning SPs only

5.2 Process the 2-mL Gray Top Tube for OGTT

Centrifuge and separate the plasma from the 2-mL gray top tube as soon as possible. Process the specimen even if the contents of the gray tube clot.

- Place the tube in the centrifuge carrier of either tabletop centrifuge. Balance the tube in the centrifuge by using water-filled tubes if necessary. Centrifuge the 2-mL gray tube at 17-25°C or 4-8°C and 2,900 rpm for 10 minutes to yield plasma for vessel 98 (OGTT.)

Vessel 98

- Use a calibrated plastic transfer pipette to transfer all plasma from this tube but at least 0.5-mL plasma for vessel 98 (OGTT) on primary into a 2-mL vessel.
- Determine if the plasma is hemolyzed, turbid, lipemic, or icteric. If so, enter a comment to describe the plasma when entering the processing results.
- Close all vessels secured to prevent leakage and evaporation.
- Record results using the gtt module as described in Section 8.7.3 of the *Laboratory Procedures Manual*.
- Store all specimens immediately as outlined in Section 8.10 of the *Laboratory Procedures Manual*.

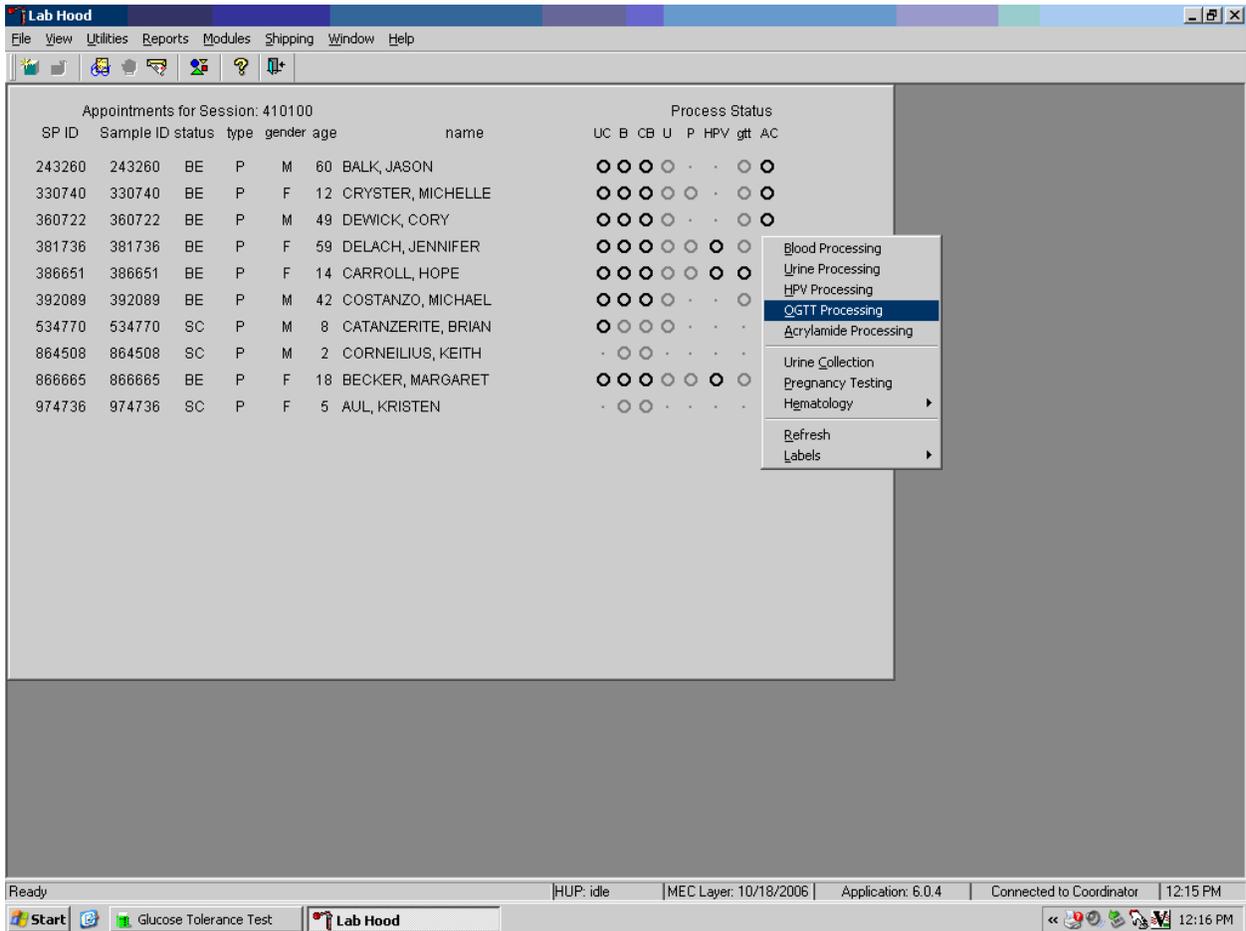
5.3 Record the Results of Specimen Processing

Open and log onto the Laboratory application. Use the heads-up display to view the SPs, the modules for which they are eligible, and their current process status. Record blood processing results for vessel 98 using the ‘gtt’ module.

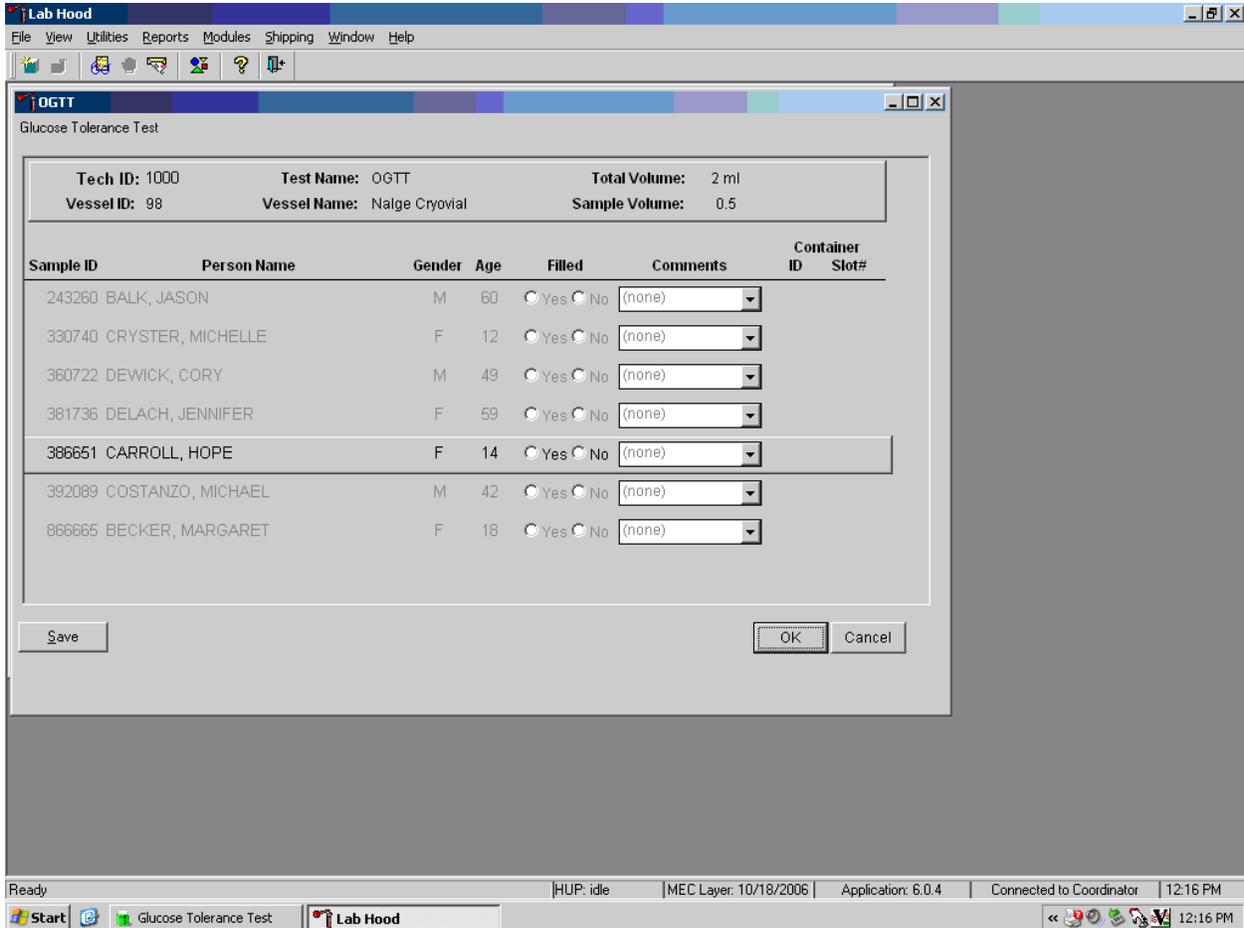


The ‘gtt’ module is grayed out until at least one SP has the second 2-mL gray top tube drawn. Once one SP has the second 2-mL gray top tube drawn, the processing circle for that SP turns black.

Select the correct SP and access the OGTT processing module. To access the OGTT module, use the mouse to direct the mouse arrow to the SP on the heads-up display, left click, drag the mouse arrow to OGTT Processing, and right click.

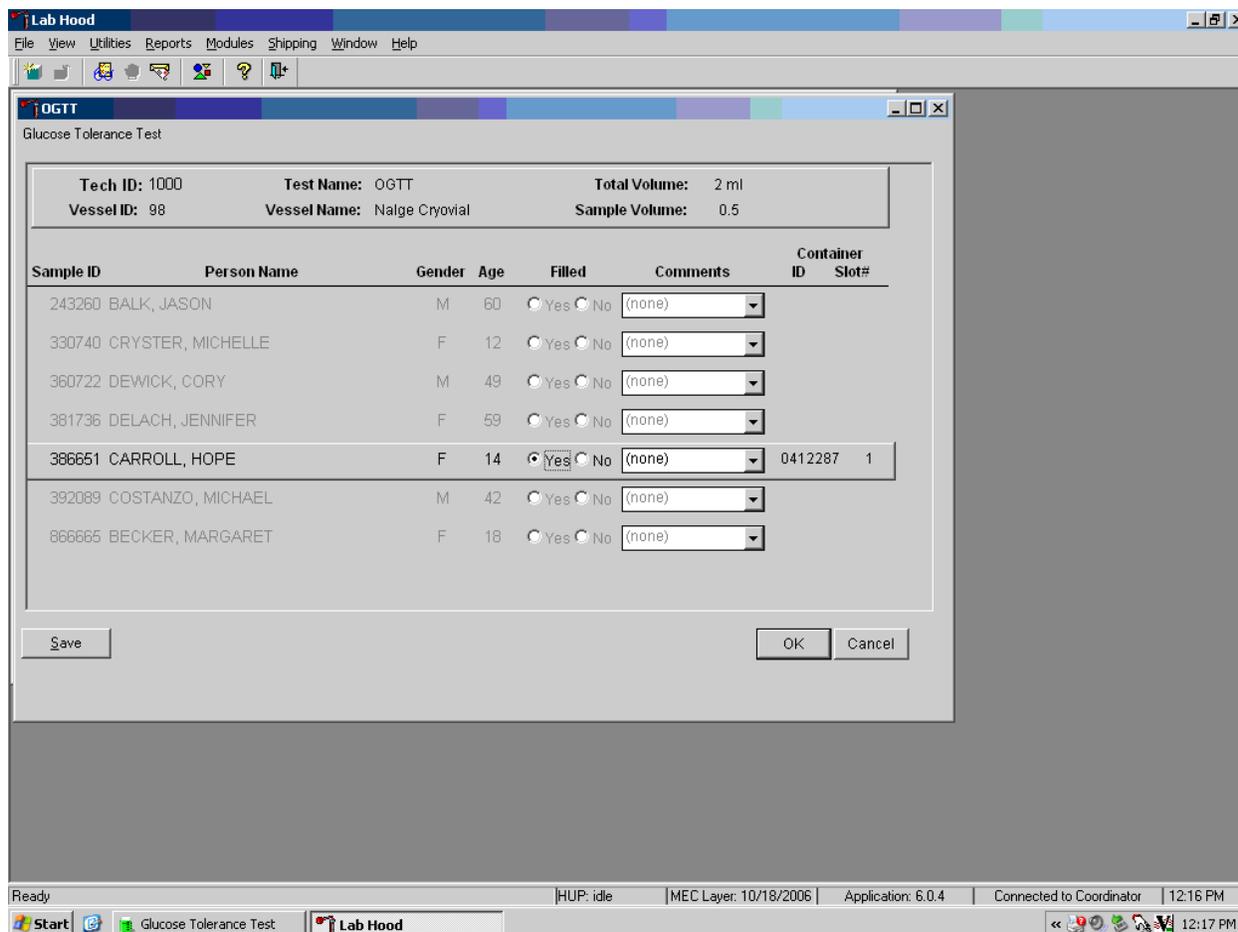


Record the vessel 98 processing results in the OGTT processing window. All SPs are included in the same window but are listed separately by rows.



The OGTT processing window lists the vessel requirements across the top. SPs are listed separately in rows. The upper section of the Glucose Tolerance Test window contains the following information: Tech ID, Vessel ID (98), Test Name (OGTT), Total Volume (2 ml), Vessel Name (Nalge cryovial), and Sample Volume (0.5.) The lower section of the window contains columns for Sample ID, Person Name (Last, First), Gender, Age, Filled Yes and No radio buttons, Comments text box, and a Container ID/Slot # column N. Use the Phlebotomy button to view the SP's original venipuncture protocol and updated results. Use the Save button to save the results to the database. Use the OK button to save the results to the database and close the module. Use the Cancel button to close the window without saving any data to the database.

Record blood processing results for each SP. Individually mark each vessel as Filled–“Yes.”

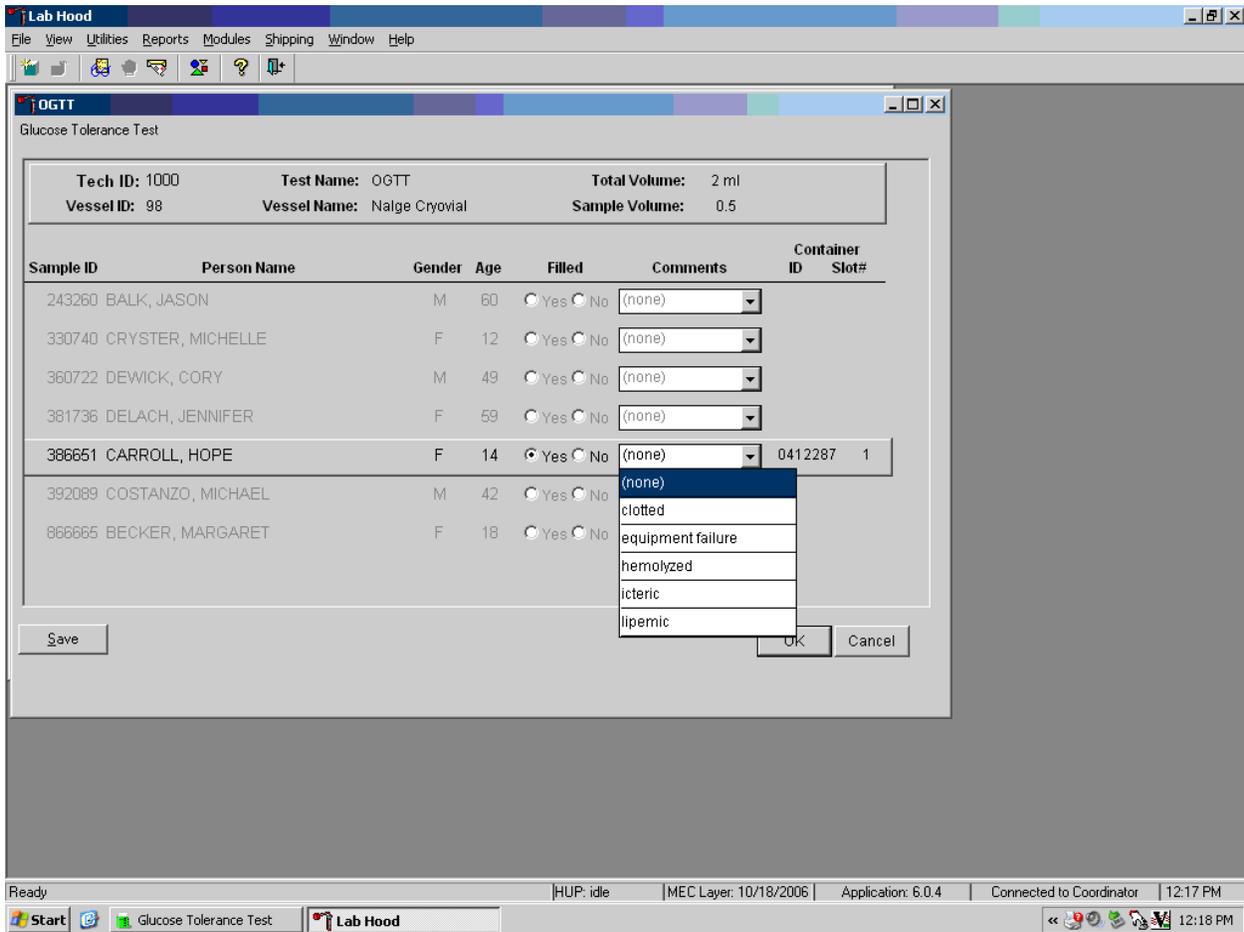


Only SPs who have had the second 2-mL gray top tubes marked as collected in the OGTT application are eligible to be processed. Once the tube is collected, the row changes from gray to black, indicating that the SP is ready to be marked as processed. To mark an individual vessel as collected or Filled–“Yes” use the mouse to direct the mouse arrow to the center of the “Yes” radio button and left click. As each vessel is marked as Filled–“Yes,” it is automatically assigned to a slot in an existing (open) container.

Quality comment codes are available to describe the quality of the specimen.

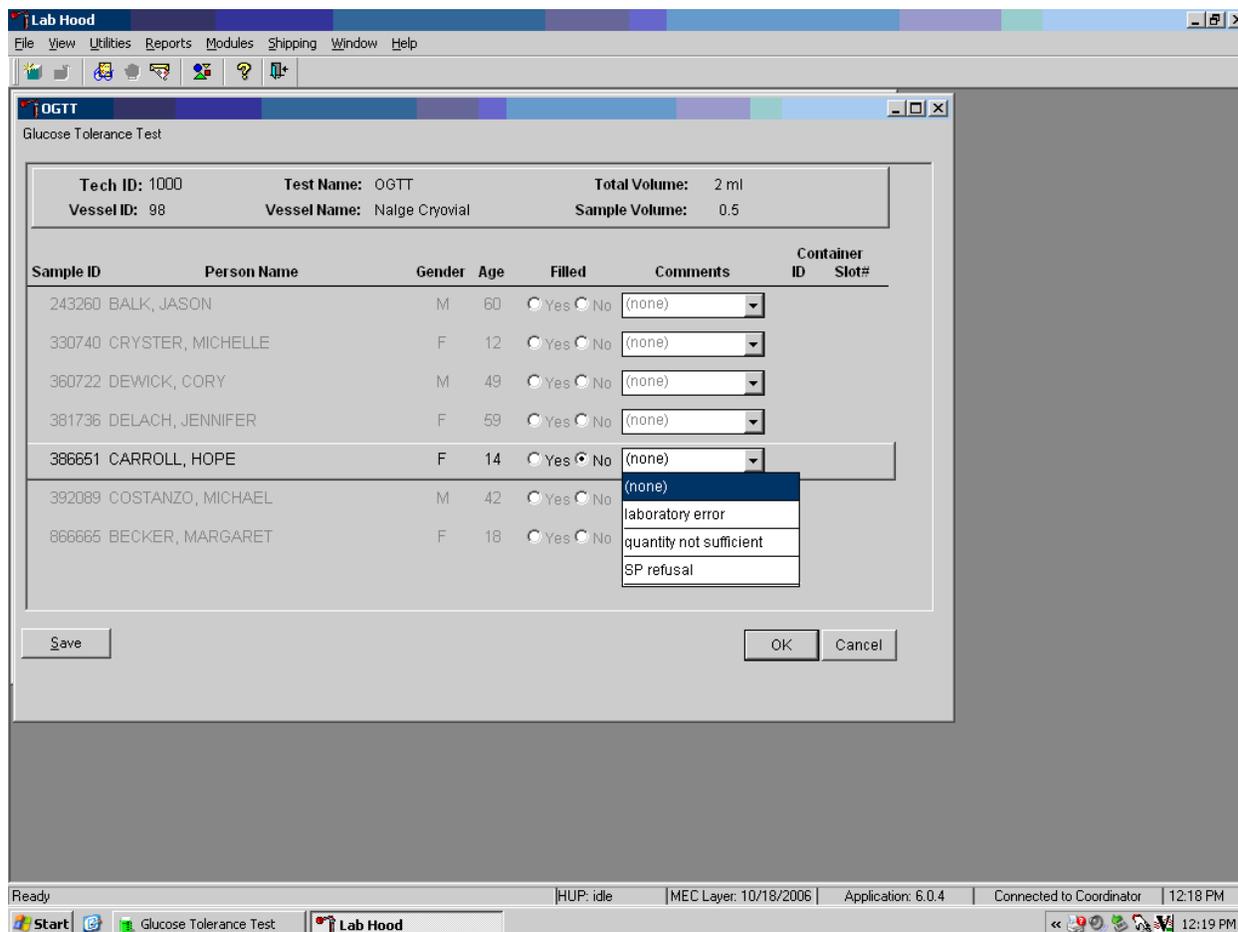
Comment for filled vessels	Use when:
clotted	The whole blood sample contains a fibrin formation. This is due to inadequate mixing or inadequate clotting.
equipment failure	Pipettes are malfunctioning.
hemolyzed	There is red appearance to the serum or plasma. Hemolysis refers to the abnormal lysis of erythrocytes. Hemolysis can occur before venipuncture (<i>in vivo</i> hemolysis) or during the analytic procedure (<i>in vitro</i> hemolysis). If <i>in vivo</i> , hemolysis will give plasma a red color. Use when describing visible hemolysis, which occurs when the concentration of hemoglobin exceeds 200 mg/L.
icteric	There is visible orange color to the serum or plasma. Icteric refers to orange color imparted to a sample because of the presence of bilirubin. Bilirubin present in serum results in visible “jaundice” color when the concentration of bilirubin is above 430 $\mu\text{mol/L}$.
lipemic	There is turbid appearance to the serum or plasma. Lipemia refers to the presence of lipid particles (usually very low-density lipoprotein) in a sample, which gives the sample a turbid appearance. Plasma appears visibly lactescent or lipemic when the concentration of triglycerides exceeds 4.6 mmol/L.

Attach a comment to an individual filled vessel.



To attach a quality control comment to a filled vessel, use the mouse to direct the mouse arrow to the drop-down list under the Comments button to display the choices, drag the arrow to the correct choice, and left click or highlight the Comment text box and type the first letter of the desired choice (c, e, h, i, l).

Record blood processing results for each SP. Individually mark each vessel as Filled–“No.”

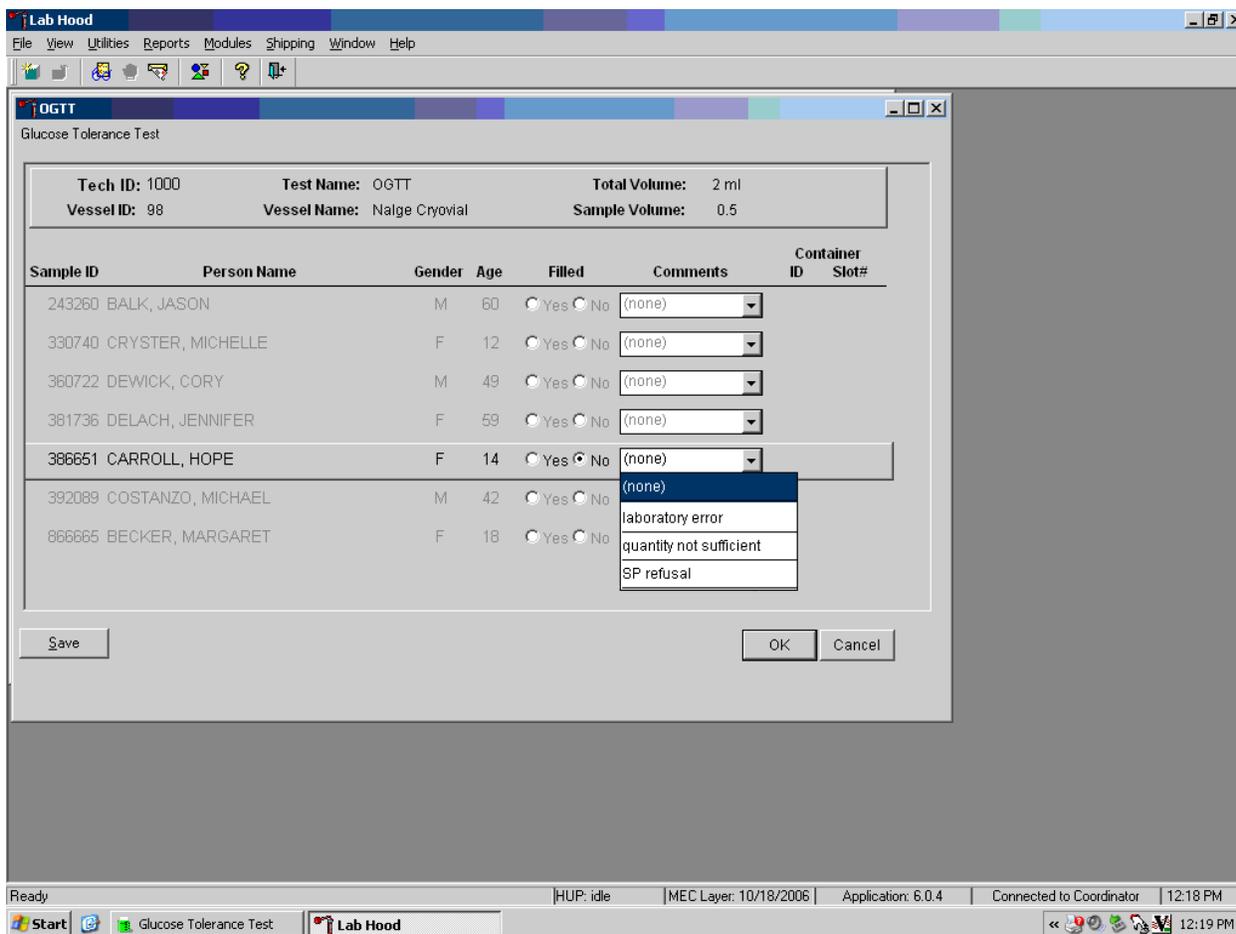


To mark vessel 98 as not collected or Filled–“No,” use the mouse to direct the mouse arrow to the center of the “No” radio button and left click. Vessels marked as “No” require a comment.

Enter comment codes to describe the reasons why a vessel is marked as Filled–“No,” or why the protocol is incomplete.

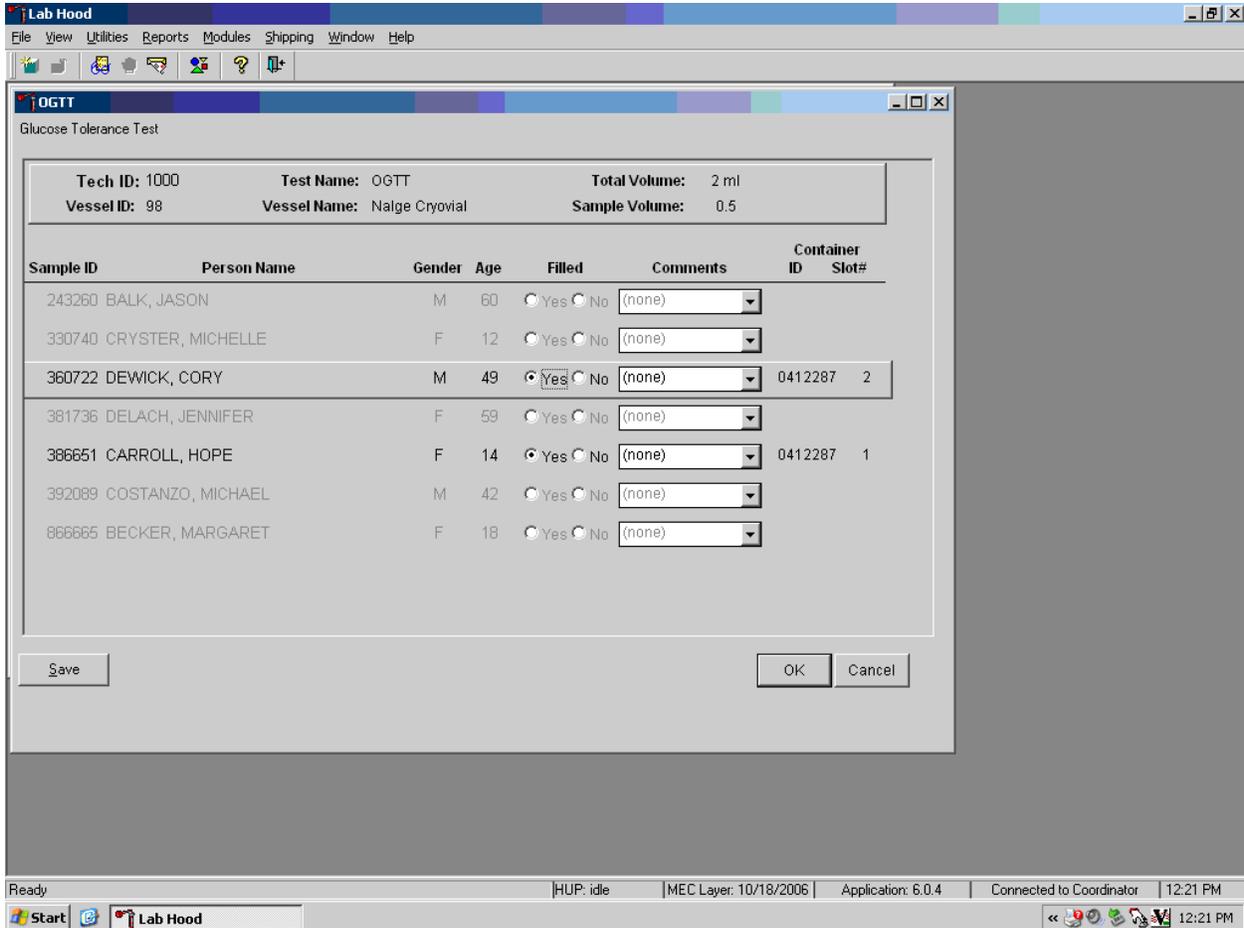
Comment for not filled vessels	Use when:
laboratory error	A tube breaks in the centrifuge, contents spill, or other technologist error.
quantity not sufficient	Quantity of blood is not sufficient to complete the protocol.
SP refusal	The SP refused the blood draw.

Attach a comment to an individual Filled–“No” vessel.



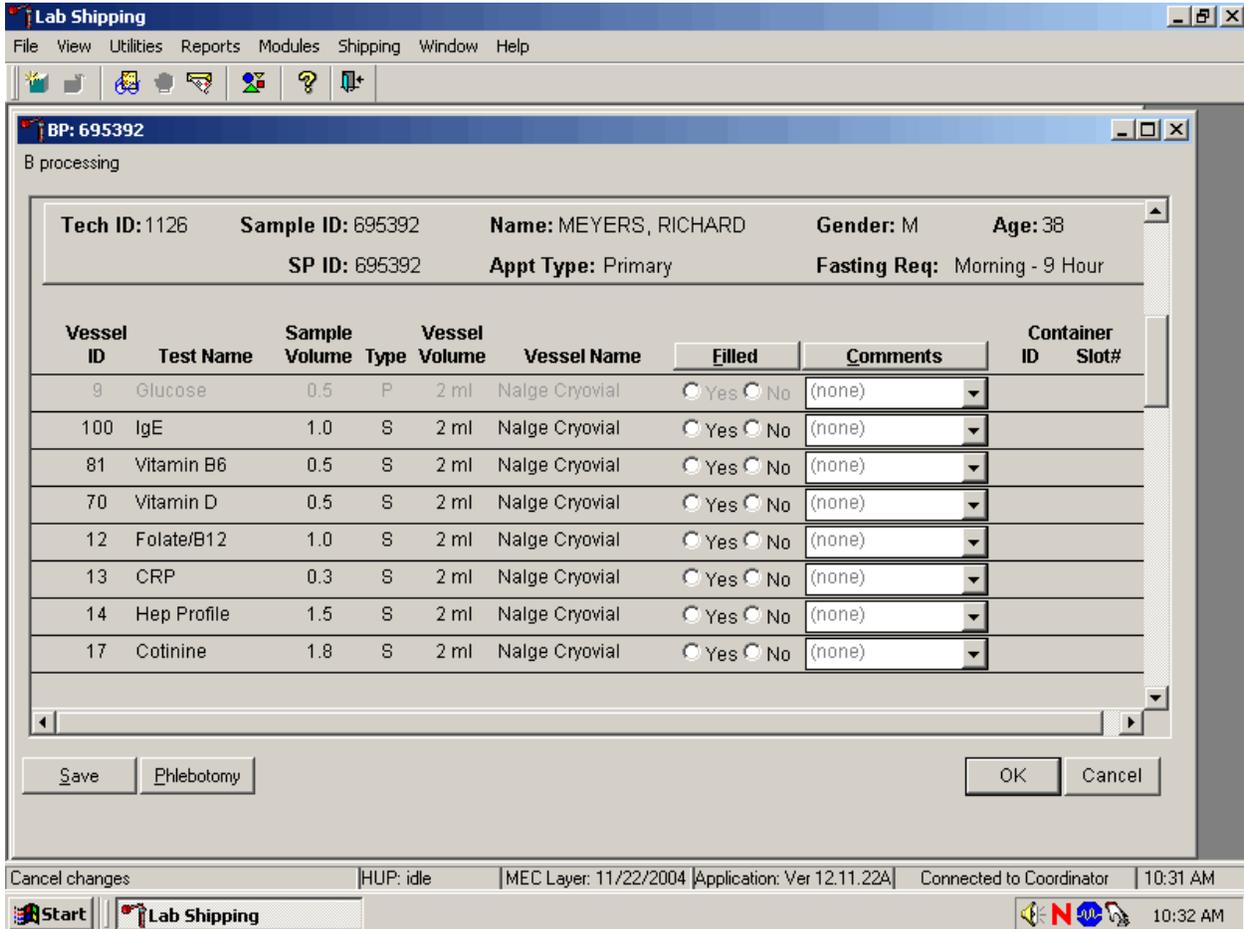
To attach a Filled–“No” comment to a vessel, use the mouse to direct the mouse arrow to the drop-down list under the Comments button to display the choices, drag the arrow to the correct choice, and left click. Alternatively, highlight the Comment text box and type the first letter of the desired choice.

Continue to enter results as vessels are processed. Review the information in the OGTT processing window and save the data to the database.



Store each filled vessel in the assigned slot in the assigned container. To record this action or to save this data to the database, use the mouse to direct the mouse arrow to the Save button and left click. To record this action or to save this data to the database and to exit the module, use the mouse to direct the mouse arrow to the OK button, and left click. To close the window without saving any data in the database, use the mouse to direct the mouse arrow to the Cancel button, and left click.

It is not possible to mark vessels 9 (glucose) and 23 (insulin) in the blood processing module after the second 2-mL gray top tube has been marked as collected in phlebotomy. They are grayed out on the blood processing window.



Process the blood from the first venipuncture as soon as possible. Contact the system programmer if the blood tubes for vessels 9 and 23 were drawn before the second 2-mL gray top tube was marked as collected in phlebotomy.

During the OGTT blood draw (2 hours after the initial venipuncture and after the SP has consumed the Trutol), the phlebotomist will draw any tubes that were missed during the first venipuncture. Add the “Post OGTT draw” comment to any blood vessel processed or filled from blood collected during the OGTT blood draw.

The screenshot shows the 'Lab Shipping' application window. The main window title is 'BP: 695392'. Below the title bar, it says 'B processing'. The patient information section includes:

- Tech ID: 1126
- Sample ID: 695392
- Name: MEYERS, RICHARD
- Gender: M
- Age: 38
- SP ID: 695392
- Appt Type: Primary
- Fasting Req: Morning - 9 Hour

Below this is a table of vessels with the following columns: Vessel ID, Test Name, Sample Volume, Sample Type, Vessel Volume, Vessel Name, Filled (Yes/No), Comments, Container ID, and Slot#.

Vessel ID	Test Name	Sample Volume	Sample Type	Vessel Volume	Vessel Name	Filled	Comments	Container ID	Slot#
94	PTH 2	1.0	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	Post OGTT draw	0410442	4
77	HPV Serum	0.5	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	Post OGTT draw	0410432	3
79	Vitamin C	0.1	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	Post OGTT draw	0410434	4
18	Biochem	0.8	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	Post OGTT draw	0410409	4
23	Insulin	1.0	S	2 ml	Nalge Cryovial	<input type="radio"/> Yes <input checked="" type="radio"/> No	(none)		
22	HIV	0.5	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	Post OGTT draw	0410411	1
24	HSV	0.2	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	Post OGTT draw	0410413	2
15	Vit A/E/Car	0.5	S	2 ml	Nalge Cryovial	<input checked="" type="radio"/> Yes <input type="radio"/> No	Post OGTT draw	0410407	3

At the bottom of the window, there are buttons for 'Save', 'Phlebotomy', 'OK', and 'Cancel'. The status bar at the very bottom shows 'Ready', 'HUP: idle', 'MEC Layer: 11/22/2004', 'Application: Ver 12.11.22A', 'Connected to Coordinator', and the time '10:33 AM'.

To attach a quality control comment to an individually filled vessel, use the mouse to direct the mouse arrow to the drop-down list under the Comments button to display the choices, drag the arrow to the correct choice, and left click or highlight the Comment text box and type the first letter of the desired choice (c, e, h, I, l, p).

To collectively assign the same comment to all vessels, use the mouse to direct the mouse arrow to the Comments button on the top of the radio buttons, left click, drag the arrow to {Filled Comments}, drag the mouse arrow to the correct choice, and left click. Alternatively, to assign the same comment to all filled vessels type [Shift] [C/c], and the first letter of the correct choice (i, l, e, c, h, p).

5.4 Vessel 98 Storage Protocol

Fill the vessels, enter the OGTT processing results, and prepare to store the vessels. Store vessels in numbered storage boxes according to test as indicated in Exhibit 5-2.

Exhibit 5-2. Storage protocol for GTT

Shipping location	Vessels	Conditions	Vessel storage
NHANES Diabetes Laboratory	98 OGT	Frozen	9 x 9 two inch box

5.5 Vessel 98 Shipping Protocol

Ship the OGTT container weekly on dry ice to the NHANES Diabetes Laboratory. Exhibit 5.3 describes the shipping protocol.

Exhibit 5-3. GTT shipping protocol

Location	Vessels	Conditions	Vessel storage	Shipping frequency
Blood				
NHANES Diabetes Laboratory Vessel 98	OGTT	Frozen	9 x 9 two inch box	Weekly

Pack the container in the same shipper as vessels 9, 23, and 21. Close the container using procedures described in Section 9.9 of the *Laboratory Procedures Manual*. Assign the closed container(s) to the same airbill that was created for the frozen shipper being sent to the NHANES Diabetes Lab. Exhibit 5-4 includes the contract laboratory address. Use procedures described in Section 9.10 of the *Laboratory Procedures Manual*. Follow the steps listed in Section 9.11 to create the shipping manifest and to send the electronic file. Pack and label the shipper using procedures described in Section 9.13 of the *Laboratory Procedures Manual*.

Exhibit 5-4. Contract laboratory addresses

Laboratory/destination specimen shipment address	Vessels/assays	Conditions	Contact name telephone number
NHANES Diabetes Laboratory Jean Bucksa Fairview-University Medical Center 420 Delaware St SE Mayo L275 Minneapolis, MN 55455	9/Glucose 23/Insul 98/OGTT 21/Lipids	Frozen	Jean Bucksa (612) 273-3645

6. SPANISH SPEAKING SPs

6.1 Performing the OGTT on SPs Who Do Not Speak English

When the MEC staff must conduct the OGTT procedure with an SP who does not speak English and the staff member does not speak the language of the SP, a translator who does speak the language of the SP assists the phlebotomist.

The translator stays with the phlebotomist and the SP **for the entire procedure**. It is very important that the phlebotomist be able to communicate with the SP if the SP becomes ill during the examination.

6.2 Convert Screen Text to English or Spanish

Convert exam screen text from English to Spanish or from Spanish to English at any time before, during, or after an exam.

To view the exam screen text in Spanish, use the mouse to direct the mouse arrow to {Utilities} in the menu bar, left click, drag the arrow to {Spanish}, and left click, or type [Ctrl] [S/s]. To return exam screen text to English, use the mouse to direct the mouse arrow to {Utilities} in the menu bar, left click, drag the arrow to {English}, and left click, or type [Ctrl] [E/e].

English <i>Ctrl+E</i>	Toggle option to set exam language to English.
Spanish <i>Ctrl+S</i>	Toggle option to set exam language to Spanish.

The following eight screenshots document the English and official Spanish translations for the phlebotomy and OGTT components:

- Phlebotomy Interview English;
- Phlebotomy Interview Spanish;
- Fasting Questionnaire English;
- Fasting Questionnaire Spanish;
- Exclusion Questions English;
- Exclusion Questions Spanish;
- Trutol Administration English; and
- Trutol Administration Spanish.

Phlebotomy Interview English

Phlebotomy

File View Utilities Reports Window Help

Phlebotomy: Stand:410 Session:410100 08/28/2004 08:30 am - 12:30 pm

SP ID: 381736 Name: DELACH, JENNIFER Age: 59 years Gender: Female Date: 10/23/2006 Time: 09:25 AM

Phlebotomy Interview

Are you currently pregnant?

Do you have hemophilia?

Have you received cancer chemotherapy in the past four weeks?

<< < 1 > >> of 4 End of Section Close Exam Finish

Ready MEC Layer: 10/18/2006 Application: 6.0.3 Connected to Coordinator SP assigned to room 09:24 AM

Start Phlebotomy Glucose Tolerance Test 9:25 AM

Phlebotomy Interview Spanish

Phlebotomy

File View Utilities Reports Window Help

Phlebotomy: Stand:410 Session:410100 08/28/2004 08:30 am - 12:30 pm

SP ID: 381736 Name: DELACH, JENNIFER Age: 59 years Gender: Female Date: 10/23/2006 Time: 09:25 AM

Phlebotomy Interview

¿Está usted actualmente embarazada? No

¿Tiene hemofilia? No

¿Ha recibido tratamiento de quimioterapia para el cáncer en las cuatro semanas pasadas? No

1 of 4

End of Section Close Exam Finish

Ready MEC Layer: 10/18/2006 Application: 6.0.3 Connected to Coordinator SP assigned to room 09:25 AM

Start Phlebotomy Glucose Tolerance Test 9:25 AM

Fasting Questionnaire English

Phlebotomy [Window Title]

File View Utilities Reports Window Help

Phlebotomy: Stand:410 Session:410100 08/28/2004 08:30 am - 12:30 pm

SP ID: 381736 Name: DELACH, JENNIFER Age: 59 years Gender: Female Date: 10/23/2006 Time: 09:25 AM

Fasting Questionnaire

When was the last time you ate or drank anything other than plain water? [Do not include diet soda, black coffee or tea with saccharine or Equal.] [: [] [] //

Have you had any of the following since

Coffee or tea with cream or sugar? [Include milk or non-dairy creamers.] [] [] [] [] //

Alcohol, such as beer, wine, or liquor? [] [] [] [] //

Gum, breath mints, lozenges or cough drops, or other cough or cold remedies? [] [] [] [] //

Antacids, laxatives, or anti-diarrheals? [] [] [] [] //

Dietary supplements such as vitamins and minerals? [Include multivitamins and single nutrient supplements.] [] [] [] [] //

Fasting Hours Minutes

[Navigation icons] 2 of 4 [End of Section] [Close Exam] [Finish]

Ready | MEC Layer: 10/18/2006 | Application: 6.0.3 | Connected to Coordinator | SP assigned to room | 09:26 AM

Start [Phlebotomy] [Glucose Tolerance Test] [System tray icons] 9:26 AM

Fasting Questionnaire Spanish

Phlebotomy [Window Icon] [Close Icon]

File View Utilities Reports Window Help

Phlebotomy: Stand:410 Session:410100 08/28/2004 08:30 am - 12:30 pm [Window Icon] [Close Icon]

SP ID: 381736 Name: DELACH, JENNIFER Age: 59 years Gender: Female Date: 10/23/2006 Time: 09:25 AM

Fasting Questionnaire

¿Cuándo fue la última vez que comió o bebió algo que no haya sido agua sola? [No incluya soda de dieta, café sin azúcar ni leche o té con sacarina o 'Equal'] [] : [] [//]

Ha tomado o comido algo de lo siguiente ¿desde

¿Café o té con crema o azúcar? [Incluya leche o cremas que no sean productos lácteos.] [] : [] [//]

¿Alcohol, tal como cerveza, vino o licor? [] : [] [//]

¿Chicle, mentas para el aliento, tabletas o pastillas para la tos, u otra medicina para la tos o el resfriado? [] : [] [//]

¿Antiácidos, laxantes, o antidiarreicos? [] : [] [//]

¿Suplementos para la dieta tales como vitaminas y minerales? [Incluya multivitaminas y suplementos nutritivos individuales.] [] : [] [//]

Fasting Hours Minutes

[] [] [] of 4 End of Section Close Exam Finish [Blue Arrow]

Ready MEC Layer: 10/18/2006 Application: 6.0.3 Connected to Coordinator SP assigned to room 09:26 AM

Start Phlebotomy Glucose Tolerance Test 9:27 AM

Exclusion Questions English

The screenshot shows a software application window titled "Glucose Tolerance Test". The window has a menu bar with "File", "View", "Utilities", "Reports", "Window", and "Help". Below the menu bar is a toolbar with various icons. The main content area is titled "OGTT: Stand:410 Session:410100 08/28/2004 08:30 am - 12:30 pm" and displays patient information: "SP ID: 381736 Name: DELACH, JENNIFER Age: 59 years Gender: Female Date: 10/23/2006 Time: 09:29 AM". The section is labeled "Exclusion Question".

Are you now taking insulin? (Insulin: A chemical used in the treatment of diabetes. Typically, insulin is administered with a syringe by the patient.)

Are you now taking diabetic pills to lower your blood sugar? (These are sometimes called oral agents or oral hypoglycemic agents.)

Length of Fast

At the bottom of the window, there are navigation buttons: "End of Section", "Close Exam", and "Finish". A status bar at the very bottom shows "Ready", "MEC Layer: 10/18/2006", "Application: 6.1.5", "Connected to Coordinator", "SP assigned to room", and "09:29 AM". The Windows taskbar at the bottom shows the Start button, "Phlebotomy", and "Glucose Tolerance Test" taskbar icons, with the system clock showing "9:29 AM".

Exclusion Questions Spanish

Glucose Tolerance Test

File View Utilities Reports Window Help

OGTT: Stand:410 Session:410100 08/28/2004 08:30 am - 12:30 pm

SP ID: 381736 Name: DELACH, JENNIFER Age: 59 years Gender: Female Date: 10/23/2006 Time: 09:29 AM

Exclusion Question

¿Está usted ahora tomando insulina? (Insulina: Producto químico que se usa para el tratamiento de la diabetes. Típicamente, el paciente mismo se administra la insulina con una jeringa.)

¿Está usted ahora tomando píldoras para la diabetes para reducir el nivel de azúcar en la sangre? (A veces estos son llamados agentes orales o agentes orales hipoglucémicos.)

Length of Fast **11 hours 59 minutes**

1 of 3

End of Section Close Exam Finish

Ready MEC Layer: 10/18/2006 Application: 6.1.5 Connected to Coordinator SP assigned to room 09:29 AM

Start Phlebotomy Glucose Tolerance Test 9:29 AM

Trutol Administration English

Glucose Tolerance Test

File View Utilities Reports Window Help

OGTT: Stand:410 Session:410100 08/28/2004 08:30 am - 12:30 pm

SP ID: 381736 Name: DELACH, JENNIFER Age: 59 years Gender: Female Date: 10/23/2006 Time: 09:29 AM

Trutol Administer Information

Length of Fast

Your weight is LBs

Amount to drink is

Please drink this solution within 10 minutes.

Timer

Start

Stop

Total

Amount of solution the SP drank

Ready MEC Layer: 10/18/2006 Application: 6.1.5 Connected to Coordinator SP assigned to room 09:29 AM

Start Phlebotomy Glucose Tolerance Test 9:30 AM

TruTol Administration Spanish

Glucose Tolerance Test

File View Utilities Reports Window Help

OGTT: Stand:410 Session:410100 08/28/2004 08:30 am - 12:30 pm

SP ID: 381736 Name: DELACH, JENNIFER Age: 59 years Gender: Female Date: 10/23/2006 Time: 09:29 AM

TruTol Administer Information

Length of Fast

Your weight is LBs

Amount to drink is

Por favor tómese esta solución dentro de 10 minutos.

Timer

Start

Stop

Total

Amount of solution the SP drank

Ready MEC Layer: 10/18/2006 Application: 6.1.5 Connected to Coordinator SP assigned to room 09:30 AM

Start Phlebotomy Glucose Tolerance Test 9:30 AM