



HCHS/SOL V3 Biospecimen Collection and Processing (BIO) QxQ

02/06/2023

General Instructions

The Biospecimen Collection form is completed during the participant's field center visit to record information on the collection and processing of blood and urine samples. Technicians performing venipuncture and processing blood and urine samples must be certified and should have a working knowledge of the relevant Manuals of Operations for Biospecimen Collection and Processing (MOP #7), Visit 3 Examination (MOP #2), and Data Management (MOP #13).

Place bar code Lab ID# labels in the appropriate spot at the top of the form that matches the collection vials being used for a participant's specimens. The correct pairing of the specimen ID# with the HCHS/SOL ID# is *critical* for routine results reporting and safety monitoring of clinical laboratory measurements.

QxQ Instructions

Note: Use the language preferred by the participant when asking all five of the safety screening questions.

A. Safety Questions

1. If the participant has had a radical mastectomy or other surgery where lymph nodes were removed from their armpits, Notelog which arm, specify the issue in Q12, and do not perform venipuncture on that arm. If lymph nodes were removed from both armpits, venipuncture cannot be performed on this participant.

If needed, English and Spanish information sheets from the Susan G. Komen foundation are found at the end of this document, and describe different types of mastectomies to assist participants in indicating the correct procedure they may have had.

2. If participant has a bleeding disorder, Notelog the type, specify in Q12, and consult with the field center physician, physician assistant, or nurse practitioner before proceeding with the venipuncture. If the participant does not know whether he/she has a bleeding disorder, offer the explanation: "If you have a bleeding disorder you would have symptoms like excessive nose bleeds, or very easy bruising, or problems with bleeding after tooth extractions, or any type of surgery." If the participant is still unsure, consult with field center medical personnel before continuing.
3. If a participant has a graft or shunt for kidney dialysis, Notelog which arm, specify in Q12 and do not perform venipuncture from the arm with the graft or shunt. If the participant has a graft or shunt in both arms, venipuncture cannot be performed on this participant.

B. Fasting Blood Collection Information



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4. Select the answer that best indicates the last day the participant ate or drank anything (other than water).
5. Enter the time that the participant ate or drank anything (other than water). If the participant has not fasted for at least 8 hours, exclude them from the blood draw. Tell them "Because you have not fasted for 8 hours, it is not useful for you to participate in this part of the study."

C. Blood Collection

6. Enter the date of the blood collection.
7. Enter the time of the blood collection using 24-hour format (i.e. 13:00 = 1:00pm).
8. Confirm if the fasting blood was collected before a snack was given.
9. Enter the number of venipuncture attempts. Include all venipuncture attempts by all phlebotomists. The same technician should not attempt a venipuncture more than twice.
10. Indicate if there were any problems with the blood collection. If Yes, specify in Q11 and/or in Q12.

Any **difficult draws** should always have Q10 answered as Yes. This includes when an alternative sequence of collection tubes is collected, or in any incidences where not all tubes could be collected, or were not completely filled, due to a difficult draw.

SUPPLY CHAIN ISSUES

Due to supply chain issues, substitutions in the blood collection tubes may sometimes be necessary. **These should not be considered as incidents or problems and Q10 should still be answered as No. Instead, a notelog should be listed in Q10.**

Notelog: All that is necessary is to state the issue number. There is no need to give specifics such as which tube was a substitute or expired. For example:

Issue #1

Issue #2

Or Issue #3

Interpretation of notelogs:

Issue #1: A substitute tube(s) needed to be used, but it did not affect sample volume.
Example: Two (6 mL) EDTA plasma tubes are substituted for one (10 mL) EDTA plasma tube. Note that the extra sample that does not fit in the aliquot vials can be discarded.



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Issue #2: A substitute tube(s) needed to be used, and it did affect sample volume.

Example: A (7mL) serum tube is substituted for the (8.5 mL) serum tube.

Issue #3: It is necessary to use a tube that has expired. Example: The (2.7 mL) sodium citrate tube used was past its expiration date.

11. Note any blood drawing incidents or problems, and document in the table provided. Place an "X" in box(es) corresponding to the tubes in which the blood drawing problem(s) occurred. If a specific incident or problem is not listed in the table, document it on Q12. If there were no incidents or problems, skip to Q13.
12. Enter any comments, incidents or blood drawing problems that were not listed in Q11, and include items identified in the safety questions.
13. Enter the ID code for the technician who collected the blood. If more than one technician attempted to draw the blood, enter the code of the first technician.

D. Blood Processing

14. Record the time at which the centrifuge containing tubes 5, 6, and 7 began to spin, using 24-hour format.
15. Record the time at which the centrifuge containing tubes 1, 2 and 3 began to spin, using 24-hour format.
16. Record the time at which samples from aliquot tray 1 vials were placed in the freezer in 24-hour format.
17. Enter the code number of the technician who began processing blood tubes.
18. Indicate if there were any incidents or problems with the blood processing OR **URINE COLLECTION/PROCESSING**. If Yes, specify in Q19 and/or in Q25.

Note that Q18 in the Biospecimen Collection Form does not list Urine Collection/Processing incidents or problems. However, any urine collection or processing issues should also result in answering Q18 as Yes as well as putting a comment in Q25.

For any aliquot volume issues or empty vials that were not caused by blood collection tube substitutions, Q18=Yes, and a comment is placed in Q25. However, if the phlebotomist already answered Q10 as a Yes, and noted a tube not drawn, or a partial sample drawn, in Q11, there is no need to record it again here. This is only for samples where the low



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volume wasn't noticed by the phlebotomist, but was noticed during the processing procedure while preparing the aliquots. These lower volumes are likely due to the intrinsic nature of the blood sample.

SUPPLY CHAIN ISSUES

For any aliquot volume issues or empty vials caused by blood collection tube substitutions due to **laboratory supply shortages**, Q18=No. Instead, this is recorded as issue #2 in a notelog for Q10. This should have already been recorded by the phlebotomist, so check if it is there. If Issue #2 was recorded, Q18=No.

Issue #2 interpretation: A substitute tube(s) needed to be used, and it did affect sample volume. Example: A (7mL) serum tube is substituted for the (8.5 mL) serum tube.

19. Note any blood processing incidents or problems and document in the table provided. Place an "X" in box(es) corresponding to the tubes in which the blood processing problem(s) occurred. If an incident or problem is not listed below, document it on Q25. If there were no incidents or problems, go to Q20.

E. Urine Sample

20. Indicate if a urine sample was collected. If No, enter any incidents or comments for blood processing and/or urine sample collection in Q25.
21. Record the date the urine sample was collected.
22. Record the time the urine sample was collected in 24-hour format.
23. Record the time the urine sample was processed in 24-hour format.
24. Enter the code number of the technician who processed the urine sample.
25. Enter any comments, incidents or problems in processing blood or collecting and processing urine.

F. V3 Ancillary Studies

26. Has the participant consented to participate in SOL VIDA? Answer No or Yes.

References - Breast surgery/mastectomy information sheets:



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DATOS PARA LA VIDA Cirugía de cáncer de seno

El propósito de la cirugía de cáncer de seno es extraer el tumor completo del seno. Algunos de los ganglios linfáticos del área de la axila (ganglios linfáticos axilares) posiblemente también se extirpan para ver si hay células cancerosas.

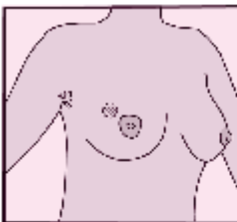
Además de la cirugía, el tratamiento también puede incluir radioterapia, quimioterapia, terapia hormonal y/o terapia dirigida. Estos tratamientos ayudan a destruir células cancerosas que puedan quedar en el cuerpo.

Tipos de cirugía de cáncer de seno

Hay dos tipos de cirugía de cáncer de seno: lumpectomía (cirugía de conservación de seno) y mastectomía. La supervivencia bajo el tratamiento de lumpectomía más radioterapia es la misma que con la mastectomía.

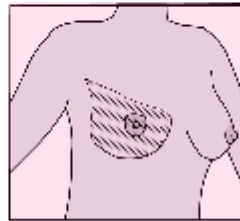
Lumpectomía (casi siempre va seguida de la radioterapia):

En la lumpectomía, el cirujano extrae el tumor y un pequeño borde del tejido normal alrededor de éste. El resto del seno permanece intacto. La lumpectomía casi siempre va seguida de la radioterapia.



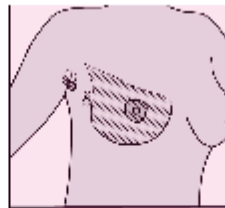
Mastectomía

En la mastectomía se quita todo el seno por completo. En algunos casos, la radioterapia puede suministrarse después de la mastectomía.



Mastectomía total:

El cirujano extrae todo el seno y el recubrimiento de los músculos del tórax, pero ningún otro tejido.



Mastectomía radical modificada:

El cirujano extrae el seno por completo, el recubrimiento de los músculos del tórax y algunos ganglios linfáticos axilares.

Mastectomía de salvamento de la piel y mastectomía de salvamento del pezón

Si le van a hacer cirugía de reconstrucción al mismo tiempo que mastectomía, es posible que el cirujano aplique una técnica de salvamento de la piel o técnica de salvamento del pezón.

Una mastectomía de salvamento de la piel preserva tanta parte de la piel como sea posible. El cirujano plástico puede usar esa piel para ayudar a formar el seno reconstruido. Una mastectomía de salvamento del pezón es una mastectomía de salvamento de la piel que también conserva intacto el pezón y la areola (el círculo de piel sombreada alrededor del pezón).

Para obtener más información, visite komen.org o bien, llame a la línea de Susan G. Komen para el cuidado de los senos al 1-877-465-6636 (1-877 GO KOMEN) de lunes a viernes, de 9 a.m. a 10 p.m., hora del Este.



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BREAST CANCER SURGERY

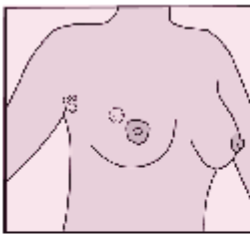
The goal of breast cancer surgery is to remove the entire tumor from the breast. Some lymph nodes from the underarm area (axillary lymph nodes) may also be removed to check for cancer cells.

Besides surgery, treatment may also include radiation therapy, chemotherapy, hormone therapy and/or targeted therapy. These treatments help kill any cancer that might still be in the body.

Types of breast cancer surgery

There are 2 types of breast cancer surgery: lumpectomy (breast conserving surgery) and mastectomy. Survival with lumpectomy plus radiation therapy is the same as with mastectomy.

Lumpectomy:



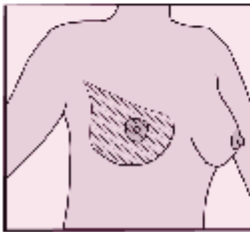
With a lumpectomy, the surgeon removes the tumor and a small amount of normal tissue around it. The rest of the breast remains intact. Most often, the general shape of the breast and nipple area are retained.

A lumpectomy is also sometimes called breast conserving surgery, partial mastectomy or wide excision.

Radiation therapy is usually given after a lumpectomy to get rid of any cancer cells that might be left in or around the breast.

Mastectomy:

With a mastectomy, the whole breast is removed. In some cases, radiation therapy may be given after mastectomy.



Total (simple) mastectomy:

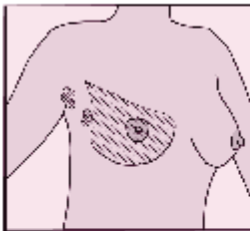
The surgeon removes the whole breast and the lining of the chest muscle, but no other tissue.

Skin-sparing mastectomy and nipple-sparing mastectomy

If you are having breast reconstruction at the same time as a mastectomy, the surgeon may be able to use a skin-sparing or a nipple-sparing technique.

A skin-sparing mastectomy saves as much of the skin of the breast as possible. The plastic surgeon can use this skin to help form the reconstructed breast. A nipple-sparing mastectomy is a skin-sparing mastectomy that also keeps the nipple and areola (the darkly shaded circle of skin around the nipple) intact.

Also, the choice of surgery does not affect whether you will need chemotherapy, hormone therapy and/or targeted therapy. Drug therapies are given based on the characteristics of the tumor, not the type of surgery you have.



Modified radical mastectomy:

The surgeon removes the whole breast, the lining of the chest muscle and some of the axillary lymph nodes.

For more information, visit komen.org or call Susan G. Komen's breast care helpline at 1-877 GO KOMEN (1-877-465-6636) Monday through Friday, 9 AM to 10 PM ET.

FACTS FOR LIFE