

Introduction and Consent

Record Number

Facility/Institution

- AKU
 KAIC
 ACC

Study ID

(This is the study ID such as AKU001)

Date of Interview

(DDMMYYYY)

Hello my name is I am here on behalf of As you know, you have been asked to participate in a study, and your doctor/nurse has explained the study to you. This study involves your breast tissue which will be used for testing and research. You were given the opportunity to sign the INFORMED CONSENT, and you willingly signed the INFORMED CONSENT and agreed to participate in the study. Today, I would like to invite you to participate in filling out this important questionnaire which is related to the study. I will be asking you questions on your socio-demographics, medical history, reproductive history and other health behaviours. I will also ask you which ethnicity you belong to. This will not in any way affect the management and treatment of your condition. In addition to these questions, we will also collect some blood, saliva and tissue samples for further testing in our laboratory. No HIV testing will be performed as part of this study. Your participation is voluntary, and if you choose not to participate, you will not be treated with prejudice. Please note that if at any point you feel uncomfortable, you can stop the interview at any time if you do not want to continue. Your answers to the questions asked will be completely confidential and will be used for research purposes only. Your responses and those of others who agree to participate in the study will be used by researchers for this study, and other partner organisations to understand the problem of breast cancer in Kenyan women and how this may differ among the three major ethnic groupings.

Do you have any questions about the survey?

- Yes
 No

Do I have agreement to proceed?

- Yes
 No

Completed Consent Document

Does the respondent agree to be interviewed?

- Yes
 No

Interviewer's Signature

Patient Identification

Full Name

Patient's Outpatient Number

Patient's Inpatient Number

Birth Date (year)

(YYYY)

Age

Patient's Telephone Number

Lead Surgeon's Name

Who else can we contact if we cannot reach you?

Spouse

- Yes
- No

Contact Details

Can we discuss your personal condition with this person?

- Yes
- No

Friend

- Yes
- No

Contact Details

Can we discuss your personal condition with this person?

- Yes
- No

Other (Specify)

- Yes
- No

Other (Please Specify)

Contact Details

Can we discuss your personal condition with this person?

- Yes
- No

Socio-Demographic

What is your father's ethnicity ?

- KIKUYU
- LUHYA
- LUO
- MERU
- KAMBA
- KALENJIN
- EMBU
- KISII
- MIJIKENDA
- SWAHILI
- SOMALI
- TAITA
- REFUSED
- DON'T KNOW
- OTHERS

If Fathers Ethnicity is Others, Please Specify.

What is your mother's ethnicity ?

- KIKUYU
- LUHYA
- LUO
- MERU
- KAMBA
- KALENJIN
- EMBU
- KISII
- MIJIKENDA
- SWAHILI
- SOMALI
- TAITA
- REFUSED
- DON'T KNOW
- OTHERS

If Mothers Ethnicity is Others, Please Specify.

What is your paternal grandfather's ethnicity ?

- KIKUYU
- LUHYA
- LUO
- MERU
- KAMBA
- KALENJIN
- EMBU
- KISII
- MIJIKENDA
- SWAHILI
- SOMALI
- TAITA
- REFUSED
- DON'T KNOW
- OTHERS

If Paternal Grandfathers Ethnicity is Others, Please Specify.

What is your maternal grandfather's ethnicity ?

- KIKUYU
- LUHYA
- LUO
- MERU
- KAMBA
- KALENJIN
- EMBU
- KISII
- MIJIKENDA
- SWAHILI
- SOMALI
- TAITA
- REFUSED
- DON'T KNOW
- OTHERS

If Maternal Grandfathers Ethnicity is Others, Please Specify.

What is your paternal grandmother's ethnicity ?

- KIKUYU
- LUHYA
- LUO
- MERU
- KAMBA
- KALENJIN
- EMBU
- KISII
- MIJIKENDA
- SWAHILI
- SOMALI
- TAITA
- REFUSED
- DON'T KNOW
- OTHERS

If Paternal Grandmothers Ethnicity is Others, Please Specify.

What is your maternal grandmother's ethnicity ?

- KIKUYU
- LUHYA
- LUO
- MERU
- KAMBA
- KALENJIN
- EMBU
- KISII
- MIJIKENDA
- SWAHILI
- SOMALI
- TAITA
- REFUSED
- DON'T KNOW
- OTHERS

If Maternal grandmothers Ethnicity is Others, Please Specify.

What is your residence ?

- Rural
- Urban

Where do you work ?

- Rural
- Urban

What is your location ?

What is your county ?

What is your religion ?

- Roman Catholic
- Protestant
- Other Christian
- Muslim
- No Religion
- Refused to Say
- Others

If Religion is Others, Please Specify

Have you ever attended school ?

- Yes
- No

If attended school, what is the highest level of education achieved.

- Primary
- Secondary
- Tertiary

Specify The Tertiary Education

What is your current employment status?

- Employed Full Time
- Casual Labourer
- Part time
- Unemployed
- Retired

What is your current occupation?

Reproductive

Age at menarche?

Have you had your menopause?

- Yes
 No

At what age did you attain menopause?

Was menopause attained naturally or through other means?

- Natural (stopped by itself)
 Surgical (removal of ovaries etc)
 Hormonal (medication)
 Radiation or Chemotherapy
 Other
 Don't Know

Date of Surgical Method

Please specify which Hormonal Medication

Please specify the "other" method used

Pregnancies

Have you ever been pregnant?

- Yes
 No

How many times have you been pregnant?

Have you ever given birth ?

- Yes
 No

If Yes, how many children (dead or alive) have you ever given birth to ?

First Birth

Year of Birth

Did you Breast feed ?

- Yes
 No

How long?

((months))

Second Birth

Year of Birth

Did you Breast feed ?

- Yes
- No

How long?

((months))

Third Birth

Year of Birth

Did you Breast feed ?

- Yes
- No

How long?

((months))

Fourth Birth

Year of Birth

Did you Breast feed ?

- Yes
- No

How long?

((months))

Fifth Birth

Year of Birth

Did you Breast feed ?

- Yes
- No

How long?

((months))

Sixth Birth

Year of Birth

Did you Breast feed ?

- Yes
- No

How long?

((months))

Seventh Birth

Year of Birth

Did you Breast feed ?

- Yes
- No

How long?

((months))

Eight Birth

Year of Birth

Did you Breast feed ?

- Yes
 No

How long?

((months))

Nineth Birth

Year of Birth

Did you Breast feed ?

- Yes
 No

How long?

((months))

Tenth Birth

Year of Birth

Did you Breast feed ?

- Yes
 No

How long?

((months))

If over the age of 50, have you used hormone replacement therapy?

- Yes
 No

Contraception Use:

Have you ever used any modern family planning methods?

- Yes
 No

Are you a current user of family planning methods?

- Yes
 No

**If you have used family planning methods:
Have you ever used the following methods and for how long ?**

Injectables

- Yes
 No

At what age did you start using?

How long did you use?

((months))

What type of injectables have you used ?

Implant

- Yes
 No

At what age did you start using?

How long did you use?

((months))

What type of implant have you used ?

Daily Pill

- Yes
 No

At what age did you start using?

How long did you use?

((months))

What type of daily pill have you used ?

Emergency Pill

- Yes
 No

At what age did you start using?

How many times have you used?

Other Health Behaviors

Weight

((kg))

Height

((cm))

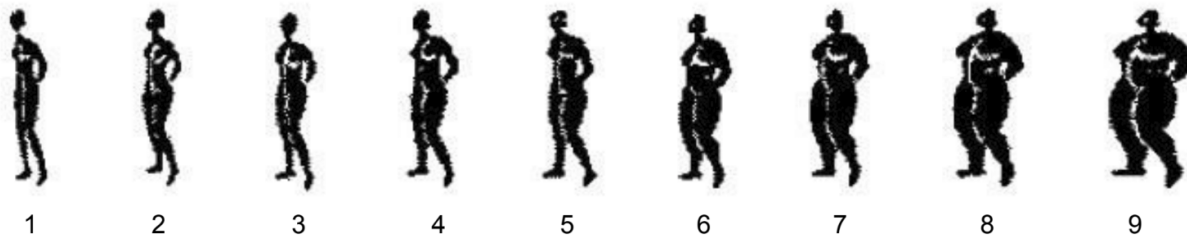
BMI

How much did you weigh 5 years ago?

Compared to your current weight, would you say your weight five years ago was:

- Much Less than Now
 A Little Less than Now
 About the same as Now
 A Little More than Now
 Much More than Now

Please look at these silhouettes for the next questions.



Which silhouette best represents your body shape for most of your adult years (from the age of 18)?

Has your silhouette changed within the last five years?

- Yes
 No
 Don't Know

Which silhouette best represents your current body shape?

Waist circumference

((cm))

Hip circumference

((cm))

Blood Pressure (systolic)

(mmHg)

Blood Pressure (diastolic)

(mmHg)

Family History

Has anyone in your family ever been diagnosed with breast cancer?

- Yes
 No
 Don't Know

Please specify relationship:

- Grandmother
 Mother
 Sister
 Aunt
 Child
 Other (please specify)
 (Select all that apply)

Other:

Has anyone in your family ever been diagnosed with any other type of cancer?

- Yes
 No
 Don't Know

Please specify relationship:

What Types of Cancer did the family members have?

Personal Medical History

Have you ever been diagnosed with diabetes (high blood sugar)?

- Yes
 No

(Not including diabetes associated with pregnancy)

Have you ever been diagnosed with hypertension?

- Yes
 No

Have you received radiation therapy in the past?

- Yes
 No
 Don't Know

Notes on personal medical history

Have you ever smoked tobacco or used smokeless tobacco ?

- Yes
 No

Do you currently smoke any tobacco products, such as cigarettes, cigars or pipes ?

- Yes
 No

How old were you when you first started smoking daily?

Do you currently use tobacco products daily ?

Yes
 No

How many manufactured cigarettes do you smoke daily ?

If None put 0.

How many hand-rolled cigarettes do you smoke daily ?

If None put 0.

How many pipes full of tobacco do you smoke daily ?

If None put 0.

How many cigars, cheerots, cigarillos do you smoke daily ?

If None put 0.

Any others not above you smoke daily ?

If None put 0.

In the past, did you ever smoke daily ?

Yes
 No

How old were you when you stopped smoking daily ?

Does anyone in the house where you live/place where you work currently smoke?

Yes
 No

If Yes, How many people smoke ?

Do the people that smoke where you live or work do so in your vicinity?

Yes
 No

(where you can smell and inhale the smoke)

As an adult, how many years have you lived/worked with someone who has smoked regularly?

< 1 year or none
 1-4 years
 5-9 years
 10-19 years
 20-29 years
 30-39 years
 40+ years

Did anyone in the house where you grew up smoke ?

Yes
 No

If, YES, did the people that smoked where you grew up do so in your vicinity?

Yes
 No

As a child, how many years did you live with someone who smoked regularly?

- < 1 year or none
 1-4 years
 5-9 years
 10-19 years

Have you consumed alcohol (such as beer, wine, spirits, fermented cider or chang'a in the last 12 months?

- Yes
 No

How old were you when you first started consuming alcohol?

In the past, how frequently have you had at least one alcoholic drink ?

- DAILY
 WEEKLY
 MONTHLY
 OCCASIONALLY

How much time do you usually spend sitting or reclining on a typical day ?

How many hours do you usually spend sleeping in a typical 24 hour day?

Who do you usually seek help from when you are ill?

Please do not include visits made related to the health of friends or family members.

- DOCTOR
 NURSE
 TRADITIONAL HEALER (FETISH PRIEST, HERBALIST, FAITH HEALER)
 DO NOT SEEK HELP
 OTHER (SPECIFY)

If Others in seeking help, Please specify

In addition to the places you usually go for health care, have you ever seen a traditional healer about your health?

- Yes
 No
 Don't Know

This is someone who is not a doctor or nurse. Traditional healers include fetish priests, herbalists, and faith healers.

Please do not count visits you made related to the health of other friends or family members.

How long does it usually take you to travel from your home to the place where you are most likely to seek health care?

Please specify in Minutes, Hours or Days explicitly (IF UNKNOWN, ENTER 999)

Interviewers Observations

INTERVIEWER'S OBSERVATIONS - TO BE FILLED IN AFTER
COMPLETING THE INTERVIEW

COMMENTS ON SPECIFIC QUESTIONS:

ANY OTHER COMMENTS ?

NAME OF DATA COLLECTOR

DATE

Tracking

Date _____

Age _____

District of Residence _____

Source of Case _____

Eligible Yes
 No

Consent Full Consent
 Partial Consent

Questionnaire Yes
 No

Study ID _____
(This is the study ID such as AKU001)

Saliva Yes
 No

Saliva ID _____
(This is the unique code on the sample saliva)

Blood Yes
 No

Comments _____

Blood Collection

Site ID AKU
 KAIC
 ACC

Study ID

(This is the study ID such as AKU001)

Did the participant agree to collect a blood sample? Yes
 No

SECTION 1:

Do you have hemophilia? Yes
 No

Are you currently taking blood-thinning medication other than aspirin? Yes
 No

If the answer to any question in SECTION 1 is "Yes", then DO NOT COLLECT BLOOD.

After administering the questions in Section 1, is the participant able to provide a blood sample? Yes
 No

SECTION 2

Have you received chemotherapy, had a blood transfusion, platelets, plasma or other blood product in the past four weeks? Yes
 No

Have you ever had your blood drawn before? Yes
 No

Have you ever had problems when your blood was drawn? Yes
 No

What types of problems have you had? (RECORD ALL) Bruising
 Felt Faint or Dizzy
 Problems with Veins
 Others

What Other Problems. Please Specify _____

When was the last time you had anything to eat or drink other than water?
DATE _____

When was the last time you had anything to eat or drink other than water?
TIME _____

Date Blood Collected

Time Blood Collected

(Use the 24 hour format)

Yellow Tube (SST Tube)

- Full
- Partial
- Not Collected

Big Blue Tube (PAXGene ccfDNA 10mL Tube)

- Full
- Partial
- Not Collected

Small Blue Tube (PAXGene DNA 2.5mL Tube)

- Full
- Partial
- Not Collected

Red Tube (PAXGene RNA 2.5mL Tube)

- Full
- Partial
- Not Collected

Lab Technician Initials

Lab Technician Employee Number

SAMPLE PROCESSING

RECORD IF ALIQUOT WAS MADE:

Lab Technician Initials

Lab Technician Employee Number

Date Processed

Time Processed

PAXGene ccfDNA 10mL Tube
Plasma
Seq # 0011

- Yes
- No

Volume Plasma Seq #0011

PAXGene ccfDNA 10mL Tube
Plasma
Seq # 0012

- Yes
- No

Volume Plasma Seq #0012

PAXGene ccfDNA 10mL Tube
Plasma
Seq # 0013

- Yes
 No

Volume Plasma Seq #0013

PAXGene ccfDNA 10mL Tube
Plasma
Seq # 0014

- Yes
 No

Volume Plasma Seq #0014

PAXGene ccfDNA 10mL Tube
Plasma
Seq # 0015

- Yes
 No

Volume Plasma Seq #0015

PAXGene ccfDNA 10mL Tube
Plasma
Seq # 0016

- Yes
 No

Volume Plasma Seq #0016

PAXGene ccfDNA 10mL Tube
Buffy coat
Seq # 0021

- Yes
 No

Volume Buffy Coat Seq #0021

PAXGene ccfDNA 10mL Tube
RBC
Seq # 0031

- Yes
 No

Volume RBC Seq #0031

PAXGene ccfDNA 10mL Tube
RBC
Seq # 0032

- Yes
 No

Volume RBC Seq #0032

PAXGene ccfDNA 10mL Tube
RBC
Seq # 0033

- Yes
 No

Volume RBC Seq #0033

PAXGene ccfDNA 10mL Tube
RBC
Seq # 0034

Yes
 No

Volume RBC Seq #0034

PAXGene ccfDNA 10mL Tube
RBC
Seq # 0035

Yes
 No

Volume RBC Seq #0035

PAXGene ccfDNA 10mL Tube
RBC
Seq # 0036

Yes
 No

Volume RBC Seq #0036

SST Yellow Top Tube
Serum
Seq # 0041

Yes
 No

Volume Serum Seq #0041

SST Yellow Top Tube
Serum
Seq # 0042

Yes
 No

Volume Serum Seq #0042

SST Yellow Top Tube
Serum
Seq # 0043

Yes
 No

Volume Serum Seq #0043

SST Yellow Top Tube
Serum
Seq # 0044

Yes
 No

Volume Serum Seq #0044

SST Yellow Top Tube
Serum
Seq # 0045

Yes
 No

Volume Serum Seq #0045

SST Yellow Top Tube
Serum
Seq # 0046

Yes
 No

Volume Serum Seq #0046

SST Yellow Top Tube
Blood Clot
Seq # 0051

Yes
 No

Volume Blood Clot Seq #0051

SST Yellow Top Tube
Blood Clot
Seq # 0052

Yes
 No

Volume Blood Clot Seq #0052

SST Yellow Top Tube
Blood Clot
Seq # 0053

Yes
 No

Volume Blood Clot Seq #0053

Time Aliquots were placed in -80 Freezer

Blood Collection Document

(Saving the hard copies of the blood collection form)

Freezer Code

Saliva Collection

Site ID

- AKU
 KAIC
 ACC

Study ID

_____ (This is the study ID such as AKU001)

Did the participant agree to collect a saliva sample?

- Yes
 No

Has it been at least 20 minutes since you have had anything to eat or drink (including water or chewing gum)?

- Yes
 No

Has it been at least 20 minutes since you have smoked?

- Yes
 No

WAIT UNTIL 20 MINUTES HAVE PASSED BEFORE COLLECTING SAMPLE

Date Collected

Time Collected

_____ (Use the 24 hour format)

Was enough saliva collected to reach the fill line ?

- Yes
 No

Lab Technician Initials

Lab Technician Employee Number

Saliva Collection Document

(Saving the hard copies of the saliva collection form)

Tissue Collection

Site ID

- AKU
 KAIC
 ACC

Study ID

(This is the study ID such as AKU001)

Histology Number

Doctor Name

Surgery Type

Date Specimen Removed

Time Specimen Removed

Date Specimen Received in Lab

Time Specimen Received in Lab

Date Specimen Put In Formalin

Time Specimen Put In Formalin

Date of Specimen Processing

Time of Specimen Processing

Tumor Size (mm)

FROZEN TISSUE

Tumor Periphery

- FT11
 FT12
 FT13

Tumor Towards Centre

- FT21
 FT22
 FT23

Near Normal (Within 2 cm of Tumor)

- FN11
 FN12
 FN13

Distant Normal (>2 cm of Tumor)

- FN21
 FN22
 FN23

FFPE TISSUE

Tumor Periphery

- T11
 T12
 T13
 T14
 T15

Tumor Towards Centre

- T21
 T22
 T23
 T24
 T25

Near Normal (Within 2 cm of Tumor)

- N11
 N12
 N13
 N14
 N15

Distant Normal (>2 cm of Tumor)

- N21
 N22
 N23
 N24
 N25

Technologist Name

Pathologist

Breast Examination

Breast Examination

Nodal Basin Results: Axillary nodes palpable

- Yes
 No

Nodal Basin Results: Mobile ipsilateral nodes

- Yes
 No

Nodal Basin Results: fixed ipsilateral nodes

- Yes
 No

Nodal Basin Results: Supraclavicular nodes palpable

- Yes
 No

Fine needle aspiration (FNA) cytology done?

- Yes
 No

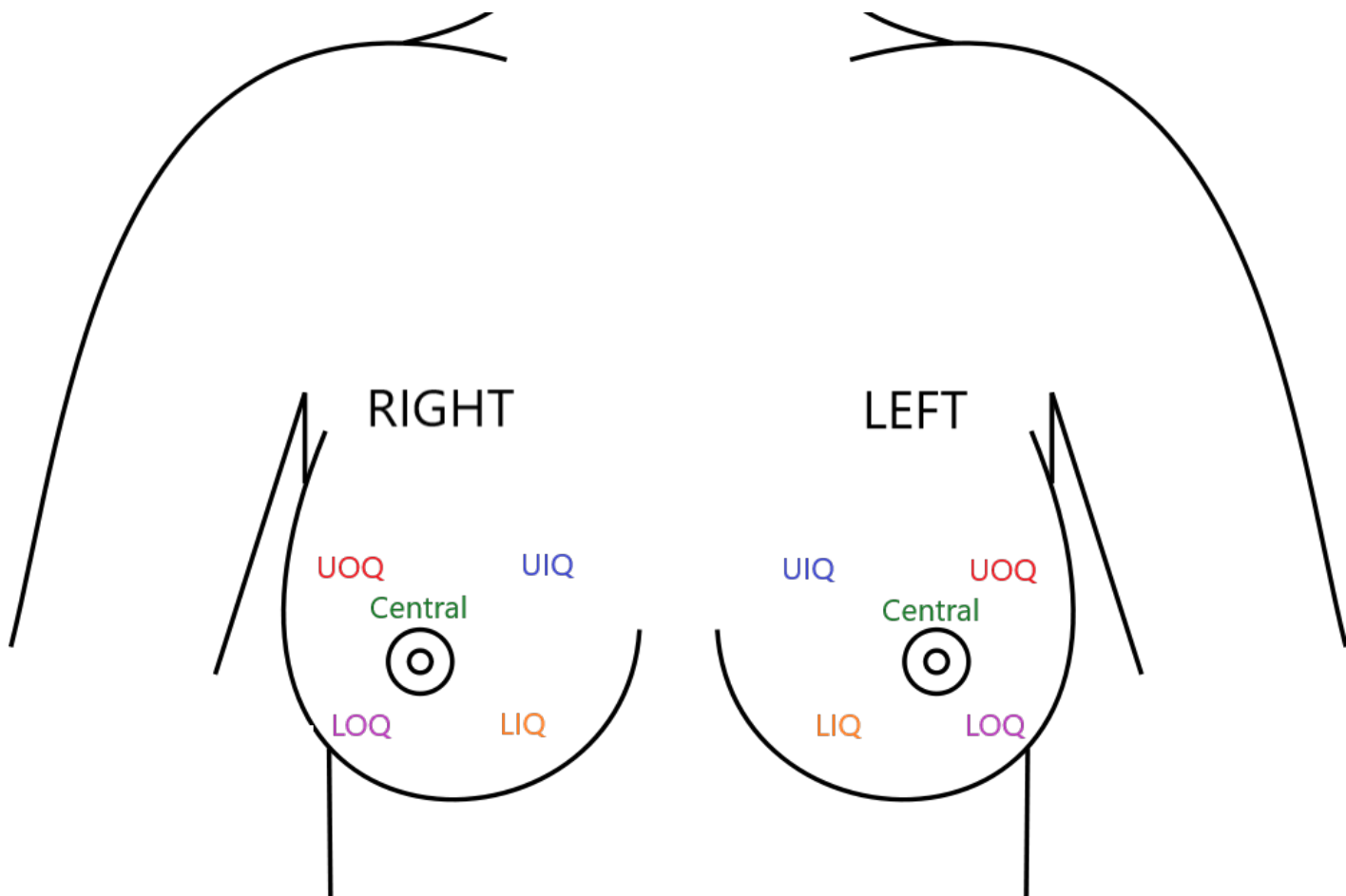
FNA Result

- Inadequate
 Benign
 Atypical, Probably Benign
 Suspicious for Malignancy
 Malignant

Breast Tumors

How many tumors are present?

Tumor Location Diagram



Tumor 1 Location (side)

- Left
- Right

Location (quadrant)

- UOQ
- LOQ
- UIQ
- LIQ
- Central
- Multicentric

Size

((cm))

Palpable?

- Yes
- No

Location (O'clock from nipple)

Location (Distance from nipple)

If unknown enter 9999

((cm))

Local Extension

- Yes
- No

Is there skin involvement? Yes
 No

Is there peau d'orange? Yes
 No

Is this an inflammatory cancer? Yes
 No

Is there a chest wall fixation? Yes
 No

Tumor 2 Location (side) Left
 Right

Location (quadrant) UOQ
 LOQ
 UIQ
 LIQ
 Central
 Multicentric

Size _____
((cm))

Palpable? Yes
 No

Location (O'clock from nipple) _____

Location (Distance from nipple) _____
If unknown enter 9999 ((cm))

Local Extension Yes
 No

Is there skin involvement? Yes
 No

Is there peau d'orange? Yes
 No

Is this an inflammatory cancer? Yes
 No

Is there a chest wall fixation? Yes
 No

Tumor 3 Location (side) Left
 Right

Location (quadrant)

UOQ
 LOQ
 UIQ
 LIQ
 Central
 Multicentric

Size

((cm))

Palpable?

Yes
 No

Location (O'clock from nipple)

Location (Distance from nipple)

If unknown enter 9999

((cm))

Local Extension

Yes
 No

Is there skin involvement?

Yes
 No

Is there peau d'orange?

Yes
 No

Is this an inflammatory cancer?

Yes
 No

Is there a chest wall fixation?

Yes
 No

Tumor 4 Location (side)

Left
 Right

Location (quadrant)

UOQ
 LOQ
 UIQ
 LIQ
 Central
 Multicentric

Size

((cm))

Palpable?

Yes
 No

Location (O'clock from nipple)

Location (Distance from nipple)

If unknown enter 9999

((cm))

Local Extension

- Yes
 No
-

Is there skin involvement?

- Yes
 No
-

Is there peau d'orange?

- Yes
 No
-

Is this an inflammatory cancer?

- Yes
 No
-

Is there a chest wall fixation?

- Yes
 No
-

Tumor 5 Location (side)

- Left
 Right
-

Location (quadrant)

- UOQ
 LOQ
 UIQ
 LIQ
 Central
 Multicentric
-

Size

((cm))

Palpable?

- Yes
 No
-

Location (O'clock from nipple)

Location (Distance from nipple)

If unknown enter 9999

((cm))

Local Extension

- Yes
 No
-

Is there skin involvement?

- Yes
 No
-

Is there peau d'orange?

- Yes
 No
-

Is this an inflammatory cancer?

- Yes
 No

Is there a chest wall fixation? Yes
 No

Notes on breast examination

Radiology

Was a mammogram done? Yes
 No

Mammography Results: Birads Classification

((1, 2, 3, 4, 5 or 6))

Was a breast ultrasound done ? Yes
 No

Breast ultrasound results Normal
 Abnormal

If Abnormal, What was present ? Fluid Filled sac (Simple cyst)
 Cyst with particles (Complex cyst)
 Solid Lump
 Others

If Others, Please specify

Was a Chest X-ray done ? Yes
 No

If Yes, Result was ? Normal
 Possible Metastases Present
 Metastases Present

Was a liver ultrasound done ? Yes
 No

If Yes, Result was ? Normal
 Possible Metastases Present
 Metastases Present

Was a bone scan done ? Yes
 No

If Yes, Result was ? Normal
 Possible Metastases Present
 Metastases Present

Was a MRI done ? Yes
 No

If Yes, Result was ?

- Normal
- Possible Metastases Present
- Metastases Present

Was a PET Scan done ?

- Yes
- No

If Yes, Result was ?

- Normal
- Possible Metastases Present
- Metastases Present

Other notes
