** is Primary Key.
* is required field.

Breast Reference Set Participant (Form ID: 697)
Baseline
Standard Specimen Reference Set: Breast
EDRN Validation Study and Reference Set

** 1063 Site Participant ID (Go To: **422**)

** 422 EDRN Site ID (Go To: **423**)

* 423 EDRN Protocol ID (Go To: **929**)

* 929 EDRN Staff ID of person who collected the data: (Go To: **1288**)

* 1288 Date participant signed consent form (Go To: **1219**) Month Day Year

* 1219 Date form filled out: (Go To: **1291**) Month Day Year

* 1291 Date of birth: (Go To: **1289**) Month Day Year

* 1289 Gender: (Go To: **2594**)

☐ 2 Female

* 2594 Are you currently pregnant? (Go To: **End of Form**)

☐ 0 No (Go To: **2588)** ☐ 1 Yes
☐ 9 Unknown/refused

* 2588 Are you currently breast-feeding? (Go To: **End of Form**)

☐ 0 No (Go To: **1307)** ☐ 1 Yes
☐ 9 Unknown/refused

* 1307 Have you ever had cancer (other than DCIS breast cancer or basal/squamous cell skin cancer) confirmed by a doctor? (Go To: **End of Form**)

☐ 0 No (Go To: **2636)** ☐ 1 Yes
☐ 9 Unknown/refused

* 2636 Have you been diagnosed with DCIS breast cancer? (Go To: **2587**)

☐ 0 No ☐ 1 Yes
☐ 9 Unknown/refused

* 2587 Have you been diagnosed with benign breast disease? (Go To: **1292**)

☐ 0 No ☐ 1 Yes
☐ 9 Unknown/refused

1292 What is your total current height (in inches)? (Go To: **1295**)

1295 What is your current weight (in pounds) (Go To: **1293**)

* 1293 Are you Hispanic or Latino? (Go To: **1315**)

☐ 0 No ☐ 1 Yes
☐ 9 Unknown/refused

* 1315 What is your race? Check all that apply. (Go To: **1600**)

- ☐ 1 White
- ☐ 2 Black or African-American
- ☐ 3 American Indian or Alaska Native
- ☐ 4 Asian
- ☐ 7 Native Hawaiian or other Pacific Islander
- ☐ 97 Other, specify: (Go To: **1294)**
- ☐ 99 Unknown/refused

* 1294 Race (Other, specify) (Go To: **1600**) _____

1600 Is your biological mother or father of Ashkenazi (Eastern European) Jewish decent? (Go To: **1347**)

- ☐ 0 No
- ☐ 1 Yes
- ☐ 9 Unknown/refused

1347 How old were you when you first started having menstrual periods? (Go To: **1316**) ___ Age

1316 Have your menstrual periods stopped due to natural menopause, hysterectomy, the removal of both ovaries, or radiation or chemotherapy treatment? (Go To: **1601**)

- ☐ 0 No
- ☐ 1 Yes (Go To: **1348)**
- ☐ 9 Unknown/refused

1348 How old were you when your menstrual periods stopped? (Go To: **1601**) ___ Age

1601 Have you ever used hormonal birth control (such as birth control pills)? (Go To: **1605**)

- ☐ 0 No
- ☐ 1 Yes (Go To: **1602)**
- ☐ 9 Unknown/refused

1602 How old were you when you first started taking hormonal birth control? (Go To: **1603**) ___ Age

1603 Are you currently taking hormonal birth control? (Go To: **1604**)

- ☐ 0 No
- ☐ 1 Yes
- ☐ 9 Unknown/refused

1604 How many years total have you taken hormonal birth control? (Go To: **1605**) ___

1605 Do you have any biological children? (Go To: **1608**)

- ☐ 0 No
- ☐ 1 Yes (Go To: **1606)**
- ☐ 9 Unknown/refused

1606 What was your age at the birth of your first child? (Go To: **1607**) ___ Age

1607 Have you ever breast fed? (Go To: **1608**)

- ☐ 0 No
- ☐ 1 Yes (Go To: **1714)**
- ☐ 9 Unknown/refused

1714 Did you experience a breast infection (mastitis) while nursing? (Go To: **1608**)

- ☐ 0 No
- ☐ 1 Yes
- ☐ 9 Unknown/refused

1608 Have you ever taken Hormone Replacement Therapy (HRT)? (Go To: **1614**)

- ☐ 0 No
- ☐ 1 Yes (Go To: **1609)**
- ☐ 9 Unknown/refused

1609 How old were you when you started taking Hormone Replacement Therapy (HRT) (Go To: **1610**) ___ Age

1610 Are you currently taking Hormone Replacement Therapy (HRT)? (Go To: **1611**)

- ☐ 0 No
- ☐ 1 Yes
- ☐ 9 Unknown/refused

1611 For how long have you been taking Hormone Replacement Therapy (HRT)? (value) (Go To: **1612**) ☐☐☐

1612 For how long have you been taking Hormone Replacement Therapy (HRT)? (unit) (Go To: **1613**)

- ☐ 3 Days
- ☐ 4 Months
- ☐ 5 Years
- ☐ 9 Unknown/refused

1613 Type of Hormone Replacement Therapy (HRT) taken: (Check all that apply.) (Go To: **1614**)

- ☐ 1 Estrogen only
- ☐ 2 Progestin only (Provera)
- ☐ 3 Estrogen and Progestin (Prempro)
- ☐ 4 Estrogen and Testosterone (Estratest)
- ☐ 5 Natural hormone therapy (Herbal supplements)
- ☐ 95 Other
- ☐ 99 Unknown/refused

1614 Have you ever had a breast biopsy? (Go To: **1617**)

- ☐ 0 No
- ☐ 1 Yes (Go To: **1615)**
- ☐ 9 Unknown/refused

1615 How many breast biopsies have you had? (Go To: **1616**) ☐☐

1616 Have any of your breast biopsies revealed atypical hyperplasia? (Go To: **1617**)

- ☐ 0 No
- ☐ 1 Yes
- ☐ 9 Unknown/refused

1617 Have you ever had a heart attack? (Go To: **1618**)

- ☐ 0 No
- ☐ 1 Yes
- ☐ 9 Unknown/refused

1618 Have you ever been treated for heart failure? (Go To: **1619**)

- ☐ 0 No
- ☐ 1 Yes
- ☐ 9 Unknown/refused

1619 Have you had an operation to unclog or bypass the arteries in your heart? (Go To: **1620**)

- ☐ 0 No
- ☐ 1 Yes
- ☐ 9 Unknown/refused

1620 Have you had a stroke, cerebrovascular accident, blood clot or bleeding in the brain, or a transient ischemic attack (TIA)? (Go To: **1622**)

- ☐ 0 No
- ☐ 1 Yes (Go To: **1621)**
- ☐ 9 Unknown/refused

1621 Do you have difficulty moving an arm or leg as a result of the stroke or cerebrovascular accident? (Go To: **1623**)

- ☐ 0 No
- ☐ 1 Yes
- ☐ 9 Unknown/refused

1622 Do you have asthma? (Go To: **1623**)

- ☐ 0 No
- ☐ 1 Yes

☐ 2 Only flare-ups ☐ 9 Unknown/refused

1623 Do you have stomach ulcers, or peptic ulcer disease? (Go To: **1625**)

☐ 0 No ☐ 1 Yes (Go To: **1624)**
☐ 9 Unknown/refused

1624 Has your stomach ulcers or peptic ulcer disease been diagnosed by endoscopy or an upper GI or barium swallow study? (Go To: **1625**)

☐ 0 No ☐ 1 Yes
☐ 9 Unknown/refused

1625 Do you have diabetes (high blood sugar)? (Go To: **1627**)

☐ 0 No ☐ 1 Yes, treated by modifying my diet (Go To: **1626)**
☐ 2 Yes, treated by medications taken by mouth (Go To: **1626)** ☐ 3 Yes, treated by insulin injections (Go To: **1626)**
☐ 9 Unknown/refused

1626 Has the diabetes caused problems with any of the following? (Go To: **1627**)

☐ 1 Problems with your kidneys ☐ 2 Problems with your eyes, treated by an opthalmologist
☐ 4 None ☐ 9 Unknown/refused

1627 Have you ever had any of the following problems with your kidneys? (Go To: **1628**)

☐ 1 Poor kidney function (blood tests show high creatine) ☐ 2 Have used hemodialysis or peritoneal dialysis
☐ 3 Have received kidney transplantation ☐ 4 None
☐ 9 Unknown/refused

1628 Do you have rheumatoid arthritis? (Go To: **1629**)

☐ 0 No ☐ 1 Yes
☐ 9 Unknown/refused

1629 Do you have any of the following medical conditions? (Go To: **1630**)

☐ 1 Alzheimers disease or another form of dementia ☐ 2 Lupus
☐ 3 Cirrhosis or serious liver damage ☐ 4 Mixed connective tissue disease
☐ 5 Polymalgia rheumatica ☐ 6 Scleroderma polymyositis
☐ 7 Uveitis ☐ 9 Degenerative Joint Disease (osteoarthritis)
☐ 10 Persistent high blood pressure (hypertension) ☐ 11 Bleeding from the stomach, intestines, bowel, (gastrointestinal bleeding)
☐ 12 Heavy or squeezing chest pain (angina) ☐ 16 AIDS
☐ 44 None ☐ 99 Unknown/refused

1630 Do you have any of the following thyroid diseases? (Go To: **1631**)

☐ 1 Goiter ☐ 2 Graves disease
☐ 3 Hashimotos disease ☐ 4 Hyperthyroid
☐ 5 Hypothyroid ☐ 9 Unknown/refused
☐ 44 None ☐ 95 Other

1631 Have you ever had exposure to theraputic radiation, including for cancer treatment? (Go To: **1633**)

☐ 0 No ☐ 1 Yes
☐ 9 Unknown/refused

1633 Have you ever been exposed to diethylstilbestrol (DES)? (Go To: **1300**)

- ☐ 0 No
- ☐ 1 Yes
- ☐ 9 Unknown/refused

1300 Have you ever smoked cigarettes regularly, at least one a day for a year or more? (Go To: **1634**)

- ☐ 0 No
- ☐ 1 Yes (Go To: **1299)**
- ☐ 9 Unknown/refused

1299 Do you currently smoke cigarettes regularly, at least one a day? (Go To: **1297**)

- ☐ 0 No (Go To: **1298)**
- ☐ 1 Yes
- ☐ 9 Unknown/refused

1298 How old were you when you permanently quit smoking cigarettes? (Go To: **1297**) ___ Age

1297 How old were you when you began smoking cigarettes regularly, at least one a day? (Go To: **1301**) ___ Age

1301 How many years total have you smoked? (Go To: **1325**) ___

1325 During the time you have smoked, on average, how many cigarettes did you smoke per day? (Go To: **1634**)
___ Cigarettes

1634 What are the medications or supplements (prescribed or over-the-counter) you are currently taking? (Go To: **1329**)

1329 On average, how many glasses of wine do you drink? Count a four-ounce glass of wine as one drink. (Go To: **1330**)

- ☐ 4 None
- ☐ 5 <1 per week
- ☐ 6 1-6 per week
- ☐ 7 1-2 per day
- ☐ 8 3-5 per day
- ☐ 9 6+ per day

1330 On average, how many glasses/cans of beer do you drink? Count a twelve-ounce can as one beer. (Go To: **1331**)

- ☐ 4 None
- ☐ 5 <1 per week
- ☐ 6 1-6 per week
- ☐ 7 1-2 per day
- ☐ 8 3-5 per day
- ☐ 9 6+ per day

1331 On average, how many shots of hard liquor or mixed drinks do you drink? Count one shot (1 1/2 ounces) or one mixed drink as one drink. (Go To: **1379**)

- ☐ 4 None
- ☐ 5 <1 per week
- ☐ 6 1-6 per week
- ☐ 7 1-2 per day
- ☐ 8 3-5 per day
- ☐ 9 6+ per day

1379 How many living and deceased blood-related daughters do you have? (Not including adopted, foster, or step-daughters) (Go To: **1378**) ___

1378 How many living and deceased blood-related sons do you have? (Not including adopted, foster, or step-sons) (Go To: **1380**) ___

1380 How many living and deceased blood-related brothers do you have? (Not including adopted, foster, half-brothers or step-brothers) (Go To: **1381**) ___

1381 How many living and deceased blood-related sisters do you have? (Not including adopted, foster, half-sisters or step-sisters) (Go To: **1349**) ___

* 1349 Have any of your living and deceased first degree blood relatives (biological parents, siblings, children) been diagnosed with cancer (other than basal/squamous cell skin cancer?) Do not include half- or step- relatives. (Go To: **1007**)

To: **1097**)

- ☐ 0 No
- ☐ 1 Yes (Go To: **1350)**
- ☐ 9 Unknown/refused

✱ 1350 How many of your living and deceased first degree blood relatives (biological parents, siblings, children) have been diagnosed with cancer (other than basal/squamous cell skin cancer)? Do not include half- or step- relatives. (Go To: **1351**) ☐☐☐

✱ 1351 Relative type (mother, brother, etc): Answer questions 1351, 1311, 1430, 1317 for each relative with cancer. (Go To: **1311**)

- ☐ 1 Brother
- ☐ 2 Sister
- ☐ 3 Son
- ☐ 4 Daughter
- ☐ 5 Father
- ☐ 6 Mother
- ☐ 9 Unknown/refused

✱ 1311 First primary cancer: (Go To: **1430**)

- ☐ 1 Bladder
- ☐ 2 Bone
- ☐ 3 Brain
- ☐ 4 Breast
- ☐ 5 Cervix
- ☐ 6 Colon
- ☐ 7 Esophagus
- ☐ 8 Head & neck (mouth, nose, and throat)
- ☐ 9 Kidney
- ☐ 10 Liver
- ☐ 11 Leukemia
- ☐ 12 Lung
- ☐ 13 Lymphoma, including Hodgkins
- ☐ 14 Ovary
- ☐ 15 Pancreas
- ☐ 16 Prostate
- ☐ 17 Rectum
- ☐ 18 Skin (melanoma, no basal or squamous)
- ☐ 19 Stomach
- ☐ 20 Thyroid
- ☐ 21 Uterus
- ☐ 24 Testis
- ☐ 26 Vagina
- ☐ 95 Other
- ☐ 99 Unknown/refused

✱ 1430 Age when diagnosed:(If unknown, enter an estimate. If unavailable, enter 999) (Go To: **1317**) ☐☐☐

1317 Subsequent primary cancer(s): (Go To: **1097**)

- ☐ 1 Bladder
- ☐ 2 Bone
- ☐ 3 Brain
- ☐ 4 Breast
- ☐ 5 Cervix
- ☐ 6 Colon
- ☐ 7 Esophagus
- ☐ 8 Head & neck (mouth, nose, and throat)
- ☐ 9 Kidney
- ☐ 10 Liver
- ☐ 11 Leukemia
- ☐ 12 Lung
- ☐ 13 Lymphoma, including Hodgkins
- ☐ 14 Ovary
- ☐ 15 Pancreas
- ☐ 16 Prostate
- ☐ 17 Rectum
- ☐ 18 Skin (melanoma, no basal or squamous)
- ☐ 19 Stomach
- ☐ 20 Thyroid
- ☐ 21 Uterus
- ☐ 24 Testis
- ☐ 26 Vagina
- ☐ 44 None
- ☐ 95 Other
- ☐ 99 Unknown/refused

1097 Comments: (Go To: **End of Form**)

Shaded areas indicated questions to be completed by research staff.

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