** is Primary Key.
* is required field.

Breast Reference Set Baseline Case Clinical (Form ID: 704)
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: **2603**)

* 2603 Proposed study group: (Go To: **End of Form**)

- ☐ 3 Case: DCIS (Go To: **1288)**
- ☐ 4 Case: Invasive (Go To: **1288)**
- ☐ 5 Case: LCIS (Go To: **1288)**
- ☐ 6 Case: Pagets (Go To: **1288)**
- ☐ 98 Excluded
- ☐ 99 Unknown/refused

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

* 1219 Date of chart abstraction: (Go To: **1054**) Month Day Year

* 1054 Specimen collection date: (Go To: **2596**) Month Day Year

* 2596 Date of biopsy (MM/DD/YYYY): (Go To: **844**) Month Day Year

* 844 Date pathology report completed: (Go To: **1636**) Month Day Year

* 1636 What was the mode of breast cancer detection? (check all that apply) (Go To: **1700**)

- ☐ 1 Ultrasound
- ☐ 2 Mammography
- ☐ 3 Palpation
- ☐ 4 MRI
- ☐ 97 Other, specify: (Go To: **1637)**

* 1637 Mode of breast cancer detection, other specify: (Go To: **1700**)

1700 If a mammogram was the mode of detection, was it incident (first ever screen) or prevalent (prior mammogram)? Leave blank if mammography was not the mode of detection. (Go To: **2597**)

- ☐ 1 Incident
- ☐ 2 Prevalent

* 2597 Is this the definitive diagnostic biopsy for the current presentation of disease? (Go To: **End of Form**)

- ☐ 0 No
- ☐ 1 Yes (Go To: **2638)**
- ☐ 9 Unknown/refused

* 2638 Is the current presentation a recurrence of a previous cancer? (Go To: **End of Form**)

- ☐ 0 No (Go To: **2646)**
- ☐ 1 Yes
- ☐ 9 Unknown/refused

2646 Neoadjuvant therapy(s) administered: (Select all that apply) (Go To: **1120**)

- ☐ 1 Chemotherapy
- ☐ 2 Radiation therapy
- ☐ 3 Surgery
- ☐ 4 Hormone therapy
- ☐ 44 None
- ☐ 95 Other
- ☐ 99 Unknown

* 1120 Breast T-Stage, Pathologic (Go To: **1706**)

- ☐ 1 pTX
- ☐ 2 pT0
- ☐ 4 pTis
- ☐ 5 pTis (DCIS)
- ☐ 6 pTis (LCIS)
- ☐ 7 pTis (Paget's)
- ☐ 8 pT1
- ☐ 9 pT1mic
- ☐ 10 pT1a
- ☐ 11 pT1b
- ☐ 12 pT1c
- ☐ 13 pT2
- ☐ 16 pT3
- ☐ 19 pT4
- ☐ 20 pT4a
- ☐ 21 pT4b
- ☐ 22 pT4c
- ☐ 23 pT4d

* 1706 Breast N Stage, Pathologic : (Go To: **1707**)

- ☐ 1 pNX
- ☐ 2 pN0
- ☐ 3 pN0(i+)
- ☐ 4 pN0(i-)
- ☐ 5 pN0(mol-)
- ☐ 6 pN0(mol+)
- ☐ 7 pN1
- ☐ 8 pN1mi
- ☐ 9 pN1a
- ☐ 10 pN1b
- ☐ 11 pN1c
- ☐ 12 pN2
- ☐ 13 pN2a
- ☐ 14 pN2b
- ☐ 15 pN3
- ☐ 16 pN3a
- ☐ 17 pN3b
- ☐ 18 pN3c

* 1707 Breast M Stage, Pathologic: (Go To: **1708**)

- ☐ 1 pMX
- ☐ 2 pM0
- ☐ 3 pM1

1708 Stage Grouping, Pathologic (Breast) (Go To: **1639**)

- ☐ 1 0
- ☐ 2 I
- ☐ 3 IIA
- ☐ 4 IIB
- ☐ 6 IIIA
- ☐ 7 IIIB
- ☐ 8 IIIC
- ☐ 10 IV
- ☐ 99 Not reported

* 1639 Breast Imaging Reporting and Data System (BIRADS) category for right breast: (Go To: **2600**)

- ☐ 1 Category 1
- ☐ 2 Category 2
- ☐ 3 Category 3
- ☐ 4 Category 4
- ☐ 5 Category 5
- ☐ 6 Category 6
- ☐ 7 Category 0
- ☐ 99 Not reported (Go To: **1640)**

2600 Mode of detection for right BIRADS score: (Go To: **1640**)

- ☐ 1 Ultrasound
- ☐ 2 Mammography
- ☐ 4 MRI
- ☐ 95 Other

* 1640 Breast Imaging Reporting and Data System (BIRADS) category for left breast: (Go To: **2598**)

- ☐ 1 Category 1
- ☐ 2 Category 2
- ☐ 3 Category 3
- ☐ 4 Category 4
- ☐ 5 Category 5
- ☐ 6 Category 6
- ☐ 7 Category 0
- ☐ 99 Not reported (Go To: **1641)**

2598 Mode of detection for left BIRADS score: (Go To: **1641**)

- ☐ 1 Ultrasound
- ☐ 2 Mammography
- ☐ 4 MRI
- ☐ 95 Other

1641 Breast Density Score (BDS) for right breast: (Go To: **2601**)

- ☐ 1 Category 1
- ☐ 2 Category 2
- ☐ 3 Category 3
- ☐ 4 Category 4

2601 Mode of detection for right breast density score: (Go To: **1642**)

- ☐ 1 Ultrasound
- ☐ 2 Mammography
- ☐ 4 MRI
- ☐ 95 Other

1642 Breast Density Score (BDS) for left breast: (Go To: **2599**)

- ☐ 1 Category 1
- ☐ 2 Category 2
- ☐ 3 Category 3
- ☐ 4 Category 4

2599 Mode of detection for left breast density score: (Go To: **1635**)

- ☐ 1 Ultrasound
- ☐ 2 Mammography
- ☐ 4 MRI
- ☐ 95 Other

* 1635 Estimated size of largest tumor by clinical exam (cm) (Go To: **1638**) ☐☐☐

* 1638 Estimated tumor size by imaging (cm) (Go To: **1703**) ☐☐☐

1703 Pathologic primary invasive tumor size (cm): (Go To: **2646**) ☐☐☐

1701 Pathological tissue site: (Go To: **1643**)

- ☐ 1 Primary
- ☐ 2 Regional nodal
- ☐ 3 Distant metastasis
- ☐ 97 Other, specify: (Go To: **1702)**

1702 Pathological tissue site (Other, specify): (Go To: **1643**) _____

1643 Histological type (breast): (Go To: **1646**)

- ☐ 1 Adenoid Cystic
- ☐ 4 Ductal
- ☐ 5 Lobular
- ☐ 6 Papillary
- ☐ 7 Micropapillary
- ☐ 8 Metaplastic
- ☐ 9 Metastatic to breast
- ☐ 10 Medullary
- ☐ 11 Mucinous (colloid)
- ☐ 12 Malignant phyllodes tumor
- ☐ 13 Tubular
- ☐ 97 Other, specify: (Go To: **1644)**
- ☐ 99 Unknown/refused

1644 Histological type, other specify (breast): (Go To: **1646**) _____

1646 Nuclear Grade (Go To: **1647**)

- ☐ 1 1 pt
- ☐ 2 2 pts
- ☐ 3 3 pts
- ☐ 7 Indeterminate

1648 Architecture (Go To: **1704**)

- ☐ 1 1 pt
- ☐ 2 2 pts
- ☐ 3 3 pts
- ☐ 7 Indeterminate

1647 Mitotic Count (Go To: **1648**)

- ☐ 1 1 pt
- ☐ 2 2 pts
- ☐ 3 3 pts
- ☐ 7 Indeterminate

1704 SBR Score: (Go To: **1705**)

1704 SBR Score: (Go To: **1705**)

- ☐ 3 3
- ☐ 4 4
- ☐ 5 5
- ☐ 6 6
- ☐ 7 7
- ☐ 8 8
- ☐ 9 9

1705 Histologic grade (Nottingham): (Go To: **1649**)

- ☐ 1 Grade I (low)
- ☐ 2 Grade II (intermediate)
- ☐ 3 Grade III (high)
- ☐ 7 Indeterminate

1649 Dermal lymphatics invasion (Go To: **1650**)

- ☐ 0 No
- ☐ 1 Yes
- ☐ 3 Suspicious
- ☐ 99 Not specified

1650 Lymphovascular invasion (Go To: **1653**)

- ☐ 0 No
- ☐ 1 Yes
- ☐ 3 Suspicious
- ☐ 99 Not specified

1653 Presence of necrosis (Go To: **1655**)

- ☐ 0 No
- ☐ 1 Yes (Go To: **1654)**
- ☐ 99 Not specified

1654 Extent of necrosis (Go To: **1655**)

- ☐ 1 Scant
- ☐ 2 Moderate
- ☐ 3 Extensive
- ☐ 7 Indeterminate
- ☐ 9 Unknown/refused

1655 Is DCIS present? (Go To: **1663**)

- ☐ 0 No
- ☐ 1 Yes (Go To: **1656)**
- ☐ 99 Not specified

1656 DCIS histological type: (Go To: **2639**)

- ☐ 1 Clinging
- ☐ 2 Comedo
- ☐ 3 Cribriform
- ☐ 4 Intra-cystic (encysted papillary)
- ☐ 6 Papillary
- ☐ 7 Micropapillary
- ☐ 8 Solid
- ☐ 9 Solid and papillary
- ☐ 97 Other, specify: (Go To: **1657)**
- ☐ 99 Not specified (Go To: **1658)**

1657 DCIS histological type, other specify: (Go To: **2639**) _____

2639 Characterization of DCIS tumor: (Go To: **1658**)

- ☐ 1 Contiguous sections
- ☐ 2 Scattered microscopic foci
- ☐ 95 Other
- ☐ 99 Not reported

1658 Pathologic primary DCIS tumor size (cm): (Go To: **1659**) ☐☐☐

1659 DCIS nuclear grade: (Go To: **1660**)

- ☐ 1 Grade I (low)
- ☐ 2 Grade II (intermediate)
- ☐ 3 Grade III (high)
- ☐ 7 Indeterminate

1660 Is necrosis present for DCIS? (Go To: **1663**)

☐ 0 No ☐ 1 Yes (Go To: **1661)**
☐ 99 Not specified

1661 Type of necrosis (DCIS) (Go To: **1663**)

☐ 1 Comedonecrosis ☐ 2 Punctate
☐ 97 Other, specify: (Go To: **1662)** ☐ 99 Not specified

1662 Type of necrosis, other specify (DCIS): (Go To: **1663**) _____

1663 Is LCIS present? (Go To: **1669**)

☐ 0 No ☐ 1 Yes (Go To: **1664)**
☐ 99 Not specified

1664 Extent of LCIS (Go To: **1665**)

☐ 1 Focal ☐ 3 Extensive
☐ 99 Not specified

1665 Nuclear type/size of LCIS (Go To: **1666**)

☐ 1 Classic small cell type ☐ 2 Large cell pleomorphic type
☐ 99 Not specified

1666 Is necrosis present for LCIS? (Go To: **1709**)

☐ 0 No ☐ 1 Yes (Go To: **1667)**
☐ 99 Not specified

1667 Type of necrosis: (LCIS) (Go To: **1709**)

☐ 1 Comedonecrosis ☐ 2 Punctate
☐ 97 Other, specify: (Go To: **1668)** ☐ 99 Not specified

1668 Type of necrosis, other specify (LCIS): (Go To: **1709**) _____

1709 Number of lobules involved (LCIS): (Go To: **1669**)

☐ 1 Few (less than 10) ☐ 2 Many (10 or more)
☐ 99 Not specified

1669 Were pathological microcalcifications present? (Go To: **1671**)

☐ 0 No ☐ 1 Yes (Go To: **1670)**
☐ 99 Not specified

1670 In what kind of tissue were microcalcifications present? (Go To: **1671**)

☐ 1 Involving benign tissue ☐ 2 Involving DCIS
☐ 3 Involving LCIS ☐ 4 Involving invasive cancer

1671 Estrogen receptor marker test method: (Go To: **1673**)

☐ 1 Immunohistochemistry (IHC) ☐ 97 Other, specify: (Go To: **1672)**

1672 Estrogen receptor marker test method, other specify: (Go To: **1673**) _____

1673 Percentage of tumor cells with nuclear staining for estrogen: (Go To: **1674**) ___

1674 Intensity of estrogen staining: (Go To: **1675**)

☐ 1 Weak (1+) ☐ 2 Moderate (2+)

☐ 1 Weak (1+) ☐ 2 Moderate (2+)
☐ 3 Not reported ☐ 4 Strong (3+)

1675 Final estrogen receptor status diagnosis: (Go To: **1676**)

☐ 1 Positive ☐ 2 Negative
☐ 7 Indeterminate

1676 Progesterone receptor marker test method: (Go To: **1678**)

☐ 1 Immunohistochemistry (IHC) ☐ 97 Other, specify: (Go To: **1677)**

1677 Progesterone receptor marker test method, other specify: (Go To: **1678**) _____

1678 Percentage of tumor cells with nuclear staining for progesterone: (Go To: **1679**) ☐☐☐

1679 Intensity of progesterone staining: (Go To: **1680**)

☐ 1 Weak (1+) ☐ 2 Moderate (2+)
☐ 3 Not reported ☐ 4 Strong (3+)

1680 Final progesterone receptor status diagnosis: (Go To: **1681**)

☐ 1 Positive ☐ 2 Negative
☐ 7 Indeterminate

1681 Was HER-2/neu assessed? (Go To: **1686**)

☐ 0 No ☐ 1 Yes (Go To: **1682)**

1682 Breast marker test method: (Select all that apply) (Go To: **1683**)

☐ 1 Immunohistochemistry (IHC) ☐ 2 Fluorescence in situ hybridization (FISH) (Go To: **1684)**
☐ 95 Other

1684 FISH result: (Go To: **1683**)

☐ 1 Not amplified ☐ 2 Amplified
☐ 33 Not done

1683 HER-2/neu score (Go To: **1685**)

☐ 1 0 ☐ 2 1+
☐ 3 2+ ☐ 4 3+

1685 Final diagnosis with HER2/neu: (Go To: **1686**)

☐ 1 Positive ☐ 2 Negative
☐ 3 Equivocal ☐ 99 Not specified

1686 Total number of lymph nodes with metastasis (>0.02 cm) (Go To: **1687**) ☐☐☐

1687 Total number of lymph nodes examined : (Go To: **1688**) ☐☐☐

1688 Size of largest metastasis (cm) (Go To: **1689**) ☐☐☐

1689 Extracapsular/extranodal extension (Go To: **1690**)

☐ 0 No ☐ 1 Yes
☐ 99 Not specified

1690 Benign histologic types: (check all that apply) (Go To: **1997**)

1690 Benign histologic types: (check all that apply) (Go To: **1097**)

- ☐ 1 Atypical ductal hyperplasia (ADH)
- ☐ 2 Atypical lobular hyperplasia (ALH)
- ☐ 5 Cysts
- ☐ 6 Fat necrosis
- ☐ 7 Lactational change
- ☐ 8 Mastitis
- ☐ 10 Nipple adenoma
- ☐ 12 Papilloma/papillomatosis
- ☐ 13 Sclerosing adenosis
- ☐ 15 Unspecified non-proliferative findings
- ☐ 16 Unspecified proliferative fibrostic changes with atypia
- ☐ 17 Unspecified proliferative fibrostic changes without atypia
- ☐ 20 Complex sclerosing lesion
- ☐ 21 Fibroadenoma
- ☐ 22 Radial scar
- ☐ 23 Usual ductal hyperplasia
- ☐ 24 Apocrine metaplasia
- ☐ 99 Not reported

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

Shaded areas indicated questions to be completed by research staff.

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