


Family/Last name Date of birth Given name(s) Patient identifiers Date of request Accession/Laboratory number Elements in **black text** are CORE. Elements in **grey text** are NON-CORE.  indicates multi-select values  indicates single select valuesSCOPE OF THIS DATASET **CLINICAL INFORMATION**  Information not provided**Presentation mode**

- Information not provided  
 Screening  
 Symptomatic

**Current clinical findings for which this surgery is performed** (select all that apply)

- Information not provided  Paget disease of the nipple  
 Nipple discharge  Palpable mass  
 Other, *specify*

**Prior presurgical therapy for this diagnosis of invasive breast carcinoma**

- Information not provided  No  
 Yes (a separate dataset is to be used in the setting of neoadjuvant therapy)

**Prior history of breast cancer**

- Information not provided  No  
 Yes, *specify laterality, site(s), diagnosis, and prior treatment(s)*

**Imaging modality** (select all that apply)

- Information not provided  None  
 Mammography  Ultrasound  
 Magnetic resonance imaging (MRI)  
 Other, *specify*

**Radiological findings** (select all that apply)

- Information not provided  None  
 Single lesion  Multiple lesions  
 Calcifications  Architectural distortion  
 Mass  
 Other, *specify*

Extent by imaging, if available Clip inserted  Yes  No  Not known**Known genetic predisposition** Information not provided  None Gene predisposition, *specify***Other clinical information, specify****OPERATIVE PROCEDURE<sup>a</sup>** 

- Not specified  
 Excision (less than total mastectomy)  
 Diagnostic excision/excision biopsy/localisation biopsy  
 Therapeutic wide local excision  
 Duct excision/microdochectomy  
 Re-excision  
 Total mastectomy  
 Simple mastectomy  
 Nipple-sparing mastectomy  
 Skin-sparing mastectomy  
 Modified radical mastectomy  
 Radical mastectomy  
 Additional specimens, *specify*

<sup>a</sup> If a *lymph node staging specimen* is submitted, then a separate dataset is used to record the information.**SPECIMEN LATERALITY**  Left  Right  Not specified**SPECIMEN DIMENSIONS** x  x **SPECIMEN WEIGHT**

**SPECIMEN DETAILS**

**Depth of tissue excised**

Skin to deep fascia  Yes  No

**Specimen includes** (select all that apply)

- Skin
- Nipple
- Skeletal muscle

**TUMOUR SITE** (select all that apply)

Not specified

Distance from nipple  mm

AND

Position, specify  o'clock

OR

- Upper outer quadrant
- Lower outer quadrant
- Upper inner quadrant
- Lower inner quadrant
- Central
- Nipple
- Other, specify

**TUMOUR FOCALITY**

- Cannot be assessed
- Single focus of invasive carcinoma
- Multiple foci of invasive carcinoma

**Number of foci**

Cannot be assessed

is at least

**Sizes of individual foci<sup>b</sup>**

<sup>b</sup> Record the largest measurement of individual foci in millimetres. If there are many foci a range may be included.

**TUMOUR DIMENSIONS**

- No residual invasive carcinoma
- Only microinvasion present ( $\leq 1$  mm)<sup>c</sup>

Maximum dimension of largest invasive focus >1 mm (specify exact measurement rounded to nearest mm)<sup>d</sup>  mm

Additional dimensions of largest invasive focus  mm x  mm

Maximum dimension of whole tumour field (invasive + DCIS)/total extent of disease  mm

Cannot be assessed, specify

<sup>c</sup> For microinvasive disease refer to the DCIS, variants of LCIS and low grade lesions dataset.

<sup>d</sup> Based on a combination of macroscopic and microscopic assessment.

**HISTOLOGICAL TUMOUR TYPE<sup>c</sup>**

(Value list based on the World Health Organization Classification of Breast Tumours (2019))

- No residual invasive carcinoma
- Invasive breast carcinoma of no special type (invasive ductal carcinoma, not otherwise specified)<sup>e</sup>
- Invasive lobular carcinoma
- Tubular carcinoma
- Cribriform carcinoma
- Mucinous carcinoma
- Invasive micropapillary carcinoma
- Carcinoma with apocrine differentiation
- Metaplastic carcinoma
- Mixed, specify subtypes present<sup>f</sup>

Other, specify

<sup>e</sup> Refer to Note for details of variants including medullary carcinoma.

<sup>f</sup> Tumour exhibiting more than one tumour type should be designated mixed and the types present stated.

**HISTOLOGICAL TUMOUR GRADE**

- No residual invasive carcinoma
- Grade 1 (scores of 3, 4, or 5)
- Grade 2 (scores of 6 or 7)
- Grade 3 (scores of 8 or 9)

Tubule score 1,2,3

Nuclear pleomorphism 1,2,3

Mitotic count  per mm<sup>2</sup>

OR

per 10 HPF (field diameter \_\_\_\_ mm)

Score 1,2,3

Total score

- Only microinvasion present (not graded)<sup>c</sup>
- Score cannot be determined, specify

**CARCINOMA IN SITU**

- Not identified
- Present (select all that apply)
  - Ductal carcinoma in situ (DCIS)
    - Negative for extensive intraductal component (EIC)
    - Positive for EIC
  - Paget disease of the nipple
  - Encapsulated papillary carcinoma
  - Solid papillary carcinoma in situ
  - Lobular carcinoma in situ (LCIS)

**CLASSIFICATION OF CARCINOMA IN SITU** (if present) **Histological nuclear grade***(Applicable to DCIS, encapsulated papillary carcinoma and solid papillary carcinoma in situ)*

- Grade 1 (Low)
- Grade 2 (Intermediate)
- Grade 3 (High)

**Histological architectural pattern** (select all that apply)*(Applicable to DCIS only)*

- Cribriform
- Micropapillary
- Papillary
- Solid
- Other (e.g., clinging/flat<sup>9</sup>), specify

<sup>9</sup> Applies to high nuclear grade DCIS only.**Necrosis**

- Not identified
- Present
  - Central (Comedo) necrosis
  - Focal (Punctate) necrosis (<10% duct diameter)

**Classification of LCIS** (select all that apply)*(Applicable if LCIS is present in specimen)*

- Classical LCIS
- Pleomorphic LCIS
- Florid LCIS
- Other, specify

**TUMOUR EXTENSION<sup>h</sup>** **Skin**

- Skin is not present
- Skin is present and uninvolved
- Invasive carcinoma directly invades into the dermis or epidermis without skin ulceration
- Invasive carcinoma directly invades into the dermis or epidermis with skin ulceration (classified as pT4b)
- Satellite skin foci of invasive carcinoma are present (i.e., not contiguous with the invasive carcinoma in the breast) (classified as pT4b)

**Nipple (including areola complex)**

- Nipple tissue is not present
- DCIS does not involve the nipple epidermis
- DCIS involves nipple epidermis (Paget disease of the nipple)

**Skeletal muscle**

- Skeletal muscle is not present
- Skeletal muscle is free of carcinoma
- Tumour involves skeletal muscle
- Tumour involves both skeletal muscle and chest wall (classified as pT4a)

<sup>h</sup> Where there is disease extension to involve skin, nipple or skeletal muscle, disease extent classification is a core element; in all other cases it is non-core.**MARGIN STATUS<sup>i</sup>** *(For wide local excision specimens and similar non-complete mastectomy specimens)*

- Cannot be assessed, specify

**Invasive carcinoma**

- Involved (select all that apply)

- Anterior (superficial)

Specify extent

- Posterior (deep)

Specify extent

- Superior

Specify extent

- Inferior

Specify extent

- Medial

Specify extent

- Lateral

Specify extent

- Other margin, specify

Specify extent

- Not involved

Specify closest margin, if possible

Distance of invasive carcinoma to closest margin

 mm (< or > may be used)

- Cannot be determined, specify

Distance of invasive carcinoma to other margins (&lt; or &gt; may be used)

Anterior (superficial)  mmPosterior (deep)  mmSuperior  mmInferior  mmMedial  mmLateral  mmOther margin, specify  mm<sup>i</sup> Core for all wide local excision specimens, similar non-complete mastectomy and some (refer to Note) complete mastectomy specimens.

**DCIS<sup>j</sup>**

Involved (select all that apply)

Anterior (superficial)  
Specify extent

Posterior (deep)  
Specify extent

Superior  
Specify extent

Inferior  
Specify extent

Medial  
Specify extent

Lateral  
Specify extent

Other margin, specify   
Specify extent

Not involved

Specify closest margin, if possible

Distance of DCIS to closest margin

mm

Cannot be determined, specify

Distance of DCIS to other margins (< or > may be used)

Anterior (superficial)  mm

Posterior (deep)  mm

Superior  mm

Inferior  mm

Medial  mm

Lateral  mm

Other margin, specify  mm

<sup>j</sup> Required only if DCIS or florid LCIS or pleomorphic LCIS is also present in specimen.

**MARGIN STATUS<sup>i</sup>** 

(For complete mastectomy specimens)

Cannot be assessed, specify

**Invasive carcinoma**

Involved, specify margin/sites of involvement

Not involved

Specify closest margin, if possible

Distance of invasive carcinoma to closest margin

mm (< or > may be used)

Cannot be determined, specify

**DCIS<sup>j</sup>**

Involved, specify margin/sites of involvement

Not involved

Specify closest margin, if possible

Distance of DCIS to closest margin

mm (< or > may be used)

Cannot be determined, specify

<sup>i</sup> Core for all wide local excision specimens, similar non-complete mastectomy and some (refer to Note) complete mastectomy specimens.

**LYMPHOVASCULAR INVASION IN PRIMARY BREAST CARCINOMA** 

Not identified

Present

Specify extent

Indeterminate

Lymphovascular invasion identified elsewhere, specify

**COEXISTENT PATHOLOGY** 

- None identified
- Present, *specify*

**MICROCALCIFICATIONS** (select all that apply) (Note 14)

- Not identified
- Present in DCIS
- Present in invasive carcinoma
- Present in non-neoplastic tissue
- Other, *specify*

**ESTROGEN RECEPTOR (ER)** 

Antibody clone, *specify*

**Testing performed on**  Core biopsy  Current specimen

- Positive
- Low positive

For both options above specify percentage of cells with nuclear positivity<sup>k</sup>

%	OR	Range	
			<input type="radio"/> 1-10% <sup>l</sup>
			<input type="radio"/> 11-20%
			<input type="radio"/> 21-30%
			<input type="radio"/> 31-40%
			<input type="radio"/> 41-50%
			<input type="radio"/> 51-60%
			<input type="radio"/> 61-70%
			<input type="radio"/> 71-80%
			<input type="radio"/> 81-90%
			<input type="radio"/> 91-100%

AND

Average intensity of staining

- Weak
- Moderate
- Strong
- Negative (less than 1% nuclear positivity)
  - Internal control cells present and stain as expected
  - Internal control cells absent
  - Other, *specify*
- Cannot be determined
  - Internal control cells present but no immunoreactivity of either tumour cells or internal controls
  - Other, *specify*

**PROGESTERONE RECEPTOR (PR)** 

Antibody clone, *specify*

**Testing performed on**  Core biopsy  Current specimen

- Positive
- Percentage of cells with nuclear positivity<sup>k</sup>

%	OR	Range	
			<input type="radio"/> 1-10%
			<input type="radio"/> 11-20%
			<input type="radio"/> 21-30%
			<input type="radio"/> 31-40%
			<input type="radio"/> 41-50%
			<input type="radio"/> 51-60%
			<input type="radio"/> 61-70%
			<input type="radio"/> 71-80%
			<input type="radio"/> 81-90%
			<input type="radio"/> 91-100%

AND

Average intensity of staining

- Weak
- Moderate
- Strong
- Negative (less than 1% nuclear positivity)
  - Internal control cells present and stain as expected
  - Internal control cells absent
  - Other, *specify*
- Cannot be determined
  - Internal control cells present; no immunoreactivity of either tumour cells or internal controls
  - Other, *specify*

**HER2** 

Antibody clone, *specify*

**Testing performed on**  Core biopsy  Current specimen

**By immunohistochemistry**

- Not performed
- Negative (Score 0)
- Negative (Score 1+)
- Equivocal (Score 2+)
- Positive (Score 3+)
  - Percentage of cells with uniform, intense, complete membrane staining  %
- Cannot be determined, *specify*

<sup>k</sup> Percentage of cells with nuclear positivity may be reported as a specific number or a range if more than 10%.

<sup>l</sup> Classified as low ER positive.

## HER2 continued

### By in situ hybridization

- Not performed  
 Negative (not amplified)  
 Positive (amplified)  
 Pending  
 Cannot be determined, *specify*

Number of observers

Number of invasive tumour cells counted

Dual probe assay

Average number of HER2 signals per cell

Average number of CEP17 signals per cell

HER2/CEP17 ratio

Single probe assay

Average number of HER2 signals per cell

Aneusomy

- Not identified  
 Present

Heterogeneous signals

- Not identified  
 Present

Percentage of cells with amplified HER2 signals

## ANCILLARY STUDIES

- Not performed  
 Performed

Ki-67 proliferation index

Other, *specify test(s) and result(s)*

**Representative blocks for ancillary studies, specify those blocks best representing tumour and/or normal tissue for further study**

## PATHOLOGICAL STAGING (UICC TNM 8<sup>th</sup> edition)<sup>m</sup>

**TNM Descriptors** (only if applicable) (select all that apply)

- m - multiple foci of invasive carcinoma  
 r - recurrent

### Primary tumour (pT)<sup>n</sup>

- TX Primary tumour cannot be assessed  
 T0 No evidence of primary tumour  
 T1 Tumour 2 cm or less in greatest dimension  
 T1a More than 0.1 cm but not more than 0.5 cm in greatest dimension  
 T1b More than 0.5 cm but not more than 1 cm in greatest dimension  
 T1c More than 1 cm but not more than 2 cm in greatest dimension  
 T2 Tumour more than 2 cm but not more than 5 cm in greatest dimension  
 T3 Tumour more than 5 cm in greatest dimension  
 T4 Tumour of any size with direct extension to chest wall and/or to skin (ulceration or skin nodules)<sup>o</sup>  
 T4a Extension to chest wall (does not include pectoralis muscle invasion only)  
 T4b Ulceration, ipsilateral satellite skin nodules, or skin oedema (including peau d'orange)  
 T4c Both 4a and 4b  
 T4d Inflammatory carcinoma<sup>p</sup>

<sup>m</sup> Reproduced with permission. Source: UICC TNM Classification of Malignant Tumours, 8<sup>th</sup> Edition, eds by James D. Brierley, Mary K. Gospodarowicz, Christian Wittekind. 2016, Publisher Wiley (incorporating any errata published up until 6<sup>th</sup> October 2020).

<sup>n</sup> Note that the results of *surgically removed lymph nodes* are derived from a separate dataset.

<sup>o</sup> Invasion of the dermis alone does not qualify as T4. Chest wall includes ribs, intercostal muscles, and serratus anterior muscle but not pectoral muscle.

<sup>p</sup> Inflammatory carcinoma of the breast is characterised by diffuse, brawny induration of the skin with an erysipeloid edge, usually with no underlying mass. If the skin biopsy is negative and there is no localised measurable primary cancer, the T category is pTX when pathologically staging a clinical inflammatory carcinoma (T4d). Dimpling of the skin, nipple retraction, or other skin changes, except those in T4b and T4d, may occur in T1, T2, or T3 without affecting the classification.