# Clinical Decision Support (CDS) Content and Health Level 7 (HL7)Compliant Knowledge Artifacts (KNARTs)

# Women's Health: Diagnostic Breast Imaging Clinical Content White Paper

**Department of Veterans Affairs (VA)** 



Knowledge Based Systems (KBS)
Office of Informatics and Information Governance (OIIG)
Clinical Decision Support (CDS)

# Clinical Decision Support (CDS) Content and Health Level 7 (HL7)-Compliant Knowledge Artifacts (KNARTs): Women's Health: Diagnostic Breast Imaging Clinical Content White Paper

by Department of Veterans Affairs (VA)

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Contract: VA118-16-D-1008, Task Order (TO): VA-118-16-F-1008-0007

# Table 1. Relevant KNART Information: Women's Health: Diagnostic Breast Imaging KNARTs

Women's Health KNART	Associated CLIN
Diagnostic Breast Imaging – Event-Condition-Action (ECA) Rule	CLIN0007CA
Diagnostic Breast Imaging – Documentation Template	CLIN0009CA
Diagnostic Breast Imaging – Documentation Template/Consult Request	CLIN0005AB
Diagnostic Breast Imaging – Order Set	CLIN0004AA
Diagnostic Breast Imaging – Composite/Consult Request	N/A

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# **VA Subject Matter Expert (SME) Panel**

**Table 2. VA Subject Matter Expert (SME) Panel** 

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## Introduction

The VA is committed to improving the ability of clinicians to provide care for patients while increasing quality, safety, and efficiency. Recognizing the importance of standardizing clinical knowledge in support of this goal, VA is implementing the Health Level 7 (HL7) Knowledge Artifact Specification for a wide range of VA clinical use cases. Knowledge Artifacts, referred to as (KNARTs), enable the structuring and encoding of clinical knowledge so the knowledge can be integrated with electronic health records to enable clinical decision support.

The purpose of this Clinical Content White Paper (CCWP) is to capture the clinical context and intent of KNART use cases in sufficient detail to provide the KNART authoring team with the clinical source material to construct the corresponding knowledge artifacts using the HL7 Knowledge Artifact Specification. This paper has been developed using material from a variety of sources: VA artifacts, clinical practice guidelines, evidence in the body of medical literature, and clinical expertise. After reviewing these sources, the material has been synthesized and harmonized under the guidance of VA subject matter experts to reflect clinical intent for this use case.

Unless otherwise noted, items within this white paper (e.g., documentation template fields, orderable items, etc.) are chosen to reflect the clinical intent at the time of creation. To provide an exhaustive list of all possible items and their variations is beyond the scope of this work.

## **Conventions Used**

Conventions used within the knowledge artifact descriptions include:

<obtain>: Indicates a prompt to obtain the information listed

- If possible, the requested information should be obtained from the underlying system(s). Otherwise, prompting the user for information may be required
- The technical and clinical notes associated with a section should be consulted for specific constraints on the information (e.g., time-frame, patient interview, etc.)
- Default Values: Unless otherwise noted, <obtain> indicates to obtain the most recent observation. It is recognized that this default time-frame value may be altered by future implementations

[...]: Square brackets enclose explanatory text that indicates some action on the part of the clinical user, or general guidance to the clinical or technical teams. Examples include, but are not limited to:

[Begin ...], [End ...]: Indicates the start and end of specific areas to clearly delineate them for technical purposes.

[Activate ...]: Initiates another knowledge artifact or knowledge artifact section.

[Section Prompt: ...]: If this section is applicable, then the following prompt should be displayed to the user.

[Section Selection Behavior: ...]: Indicates technical constraints or considerations for the selection of items within the section.

[Attach: ...]: Indicates that the specified item should be attached to the documentation template if available.

[Link: ...]: Indicates that rather than attaching an item, a link should be included in the documentation template.

[Clinical Comment: ...]: Indicates clinical rationale or guidance.

[Technical Note: ...]: Indicates technical considerations or notes.

[If ...]: Indicates the beginning of a conditional section.

[Else, ...]: Indicates the beginning of the alternative branch of a conditional section.

[End if ...]: Indicates the end of a conditional section.

 $\square$ : Indicates items that should be selected based upon the section selection behavior.

# Chapter 1. Women's Health: Diagnostic Breast Imaging

#### 1. Clinical Context

[Begin Clinical Context.]

Breast cancer is the most common malignancy in women, affecting approximately one in eight women in the United States (American Cancer Society, 2017). Diagnostic imaging for breast cancer, therefore, is a topic of importance to all women and is a public health priority for the nation. Controversy has arisen around the appropriate balance between diagnostic vigilance and over-detection, with increasing attention being placed on the adverse effects of surgery, radiation, and chemotherapy for tumors that would be unlikely to develop into life-threatening cancers. Striking the right balance between these competing concerns will be achieved through evidence-based recommendations curated by authoritative professional societies such as the National Comprehensive Cancer Network (https://www.nccn.org/).

The Diagnostic Breast Imaging KNART set is intended to be used to initiate next steps in the follow-up of abnormal breast cancer screening, and management of women with breast abnormalities or complaints.

It is targeted to primary care providers, including designated women's health providers and gynecologists, their proxies (other providers, mammography coordinators, other coordinators), surgeons, and oncologists. The patient cohort includes adult women with abnormal breast imaging results or with breast abnormalities or complaints who do not have an active diagnosis of malignancy.

**Table 1.1. Clinical Context Domains** 

Target User	The target users are primary care providers and gynecologists. These providers may refer the patients to specialists and request specialist review of outside findings as appropriate. Surgeons and oncologists are not among the target users, but may be recipients of referrals/consult requests.
Patient	Adult females
Priority	Routine unless otherwise specified
Specialty	Primary Care, Gynecology, Interventional Radiology, Pathology, Oncology, Surgery
Location	Outpatient

[End Clinical Context.]

#### 2. Knowledge Artifacts

[Begin Knowledge Artifacts.]

This section describes the CDS knowledge artifacts that are intended to ensure a minimum workup is initiated prior to a diagnostic breast imaging consultation. Specific constraints for these artifacts are:

- They apply to female adult outpatients with abnormal breast cancer screening, breast abnormalities, or breast complaints.
- All imaging studies and treatment modalities are documented, and appropriate results are accessible for consultation.

#### Women's Health: Diagnostic Breast Imaging

Five knowledge artifacts define this clinical use case. These artifacts include the Composite/Consult Request, the ECA Rule, the Documentation Template, the Documentation Template/Consult Request, and the Order Set KNART, which the following sections describe in detail.

- Composite/Consult Request: Women's Health: Diagnostic Breast Imaging KNART
  - · High level, encompassing artifact
  - · Relies upon the documentation template, documentation template/consult request, and order set artifacts
- ECA Rule: Women's Health: Diagnostic Breast Imaging KNART
  - Rule logic for results notifications, follow-up care, and activation of the Diagnostic Breast Imaging Documentation Template
- Documentation Template: Women's Health: Diagnostic Breast Imaging KNART
  - Documents information gathered from the electronic medical record and entered by the provider during patient interview and exam
  - · Includes logic for appropriate display of documentation sections
- Order Set: Women's Health: Diagnostic Breast Imaging KNART
  - Orderable items including breast imaging, consult requests, and education for patients with abnormal screening mammography, breast symptoms, or abnormal breast findings.
  - · Includes logic for appropriate display of the order set
- · Documentation Template/Consult Request: Women's Health: Diagnostic Breast Imaging KNART
  - · Documents relevant patient information for consulting specialists
  - · Includes guidance for appropriate use of documentation sections

[End Knowledge Artifacts.]

# Chapter 2. Composite/Consult Request: Diagnostic Breast Imaging

[Begin Composite/Consult Request: Diagnostic Breast Imaging.]

#### 1. Knowledge Narrative

[Begin Knowledge Narrative.]
[See Clinical Context in Chapter 1.]

[Clinical Comment: The Composite/Consult Request allows users to quickly and efficiently order follow-up care for an abnormal breast imaging results, breast symptoms, or clinical breast findings. Orders for diagnostic breast imaging incorporate requirements for fulfillment either in the community or in the VA.]

[End Knowledge Narrative.]

### 2. Consult Request

[Begin Consult Request.]

[Clinical Comment: This consult request should be made available to the provider for patients whose need for specialty consultation is identified, by screening or diagnostic breast imaging or clinical assessment, during documentation template and documentation template-consult request completion by a clinical provider.]

[Technical Note: The following list provides the basic components of the consult request. This is the high-level, encompassing artifact and must be combined with the documentation template—consult request template and order set to form a fully functional knowledge artifact.]

[Technical Note: Data should be pulled automatically from the consult request documentation template whenever possible.]

[Section Prompt: Consult orders for review of outside breast imaging [mammography, ultrasound, and magnetic resonance imaging (MRI)], for pathology, and for breast consultation services within and outside of VA.]

[Section	Prompt: Please identify consult specialty.]
[Section	Selection Behavior: Select one or more. Required.]
	□ Radiology
	☐ Pathology
	☐ Interventional Radiology
	□ Surgery
	□ Oncology
[Section	Prompt: Reason for Consult.]
[Section	Selection Behavior: Select one or more. Required.]
	☐ Breast Imaging Interpretation
	☐ Breast Biopsy Interpretation

#### Composite/Consult Request: Diagnostic Breast Imaging

☐ Evaluation of Abnormal Breast Imaging
☐ Evaluate for Breast Biopsy
☐ Other
<obtain> Details</obtain>
[Section Prompt: Relevant Clinical History.]
<obtain> Relevant Clinical History</obtain>
[Section Prompt: Goal of Consult.]
[Section Selection Behavior: Select one. Required.]
☐ Provide recommendation and return to Primary Care Provider (PCP) for therapy
☐ Start treatment and return to PCP for follow up and maintenance
☐ Start treatment, monitor for effect and when on stable therapy return to PCP
☐ Provide recommendations and treat as long as necessary (or indefinitely)
[Section Prompt: Priority.]
[Section Selection Behavior: Select one. Required.]
☐ Stat: response within 24 hours
☐ Routine
☐ Routine with Scheduling Instructions: response time-frame specified by ordering provider
[Technical Note: Obtain referring physician information from Documentation Template or input by ordering provider.]
<obtain> Referring Physician</obtain>
<obtain> Referring Physician Contact Information</obtain>
[End Consult Request.]
[End Composite/Consult Request: Diagnostic Breast Imaging.]

# Chapter 3. Event-Condition-Action (ECA) Rule: Diagnostic Breast Imaging

[Begin Event-Condition-Action (ECA) Rule: Diagnostic Breast Imaging.]

#### 1. Knowledge Narrative

[Begin Knowledge Narrative.]

[See Clinical Context in Chapter 1.]

[Clinical Comment: The ECA Rule alerts clinical providers and/or their proxies (other providers, mammography coordinators, coordinators) regarding appropriate next steps for a patient they are managing subsequent to abnormal breast imaging results, breast symptoms, or abnormal clinical breast findings.

[Clinical Comment: Clinicians will have access to the current guidelines at the point of care to guide their next steps.]

[End Knowledge Narrative.]

#### 2. Diagnostic Breast Imaging

[Begin Diagnostic Breast Imaging.]

#### **Events**

[Begin Events.]

- · A screening mammogram result is recorded; or
- · Recording of breast symptoms in the patient record; or
- · Recording of breast findings in the patient record.

[End Events.]

#### **Conditions**

[Begin Conditions.]

The population of this rule consists of adult women.

[Technical Note: Additional conditions are described in the branches below.]

[End Conditions.]

#### Actions

[Begin Actions.]

[Technical note: The actions are determined in the subbranches.]

[End Actions.]

[End Diagnostic Breast Imaging.]

### 2.1 - Follow-up to Screening Mammogram

[Begin Follow-up to Screening Mammogram.]

#### Events

[Begin Events.]

- Screening mammogram result with BI-RADS Category 0 or Category 3 or Higher is recorded; or
- Abnormal screening mammogram result without BI-RADS Category is Recorded.

[End Events.]

#### **Conditions**

[Begin Conditions.]

Women whose screening mammograms are categorized as:

- BI-RADS Category 0 (Incomplete/Needs additional imaging and/or comparison films); or
- BI-RADS Category 3 or higher; or
- Abnormal result without the BI-RAD Category recorded.

[End Conditions.]

#### Actions

[Begin Actions.]

- 1. Send mammography results to the clinical provider; and
- 2. Notify the patient of need for follow up; and
- 3. Schedule patient for follow-up appointment with clinical provider; and
- 4. Make sure guideline recommendations are available to clinical provider; and
- 5. Open Diagnostic Breast Imaging Documentation Template when patient record is opened during a patient encounter

[End Actions.]

[End Follow-up to Screening Mammogram.]

### 2.2 - Breast Symptoms

[Begin Breast Symptoms.]

#### Events

[Begin Events.]

• Opening of female patient electronic health record during visit with clinical provider for the evaluation of breast symptoms.

[End Events.]

#### **Conditions**

[Begin Conditions.]

• This subgroup consists of women who have scheduled an appointment for evaluation of breast symptoms.

[End Conditions.]

#### Actions

[Begin Actions.]

- 1. Make sure guideline recommendations are available to clinical provider; and
- 2. Open the Diagnostic Breast Imaging Documentation Template

[End Actions.]

[End Breast Symptoms.]

### 2.3 - Clinical Breast Findings

[Begin Clinical Breast Findings.]

#### Events

[Begin Events.]

· Visit with clinical provider in which breast symptoms and/or abnormal clinical breast findings are recorded.

[End Events.]

#### **Conditions**

[Begin Conditions.]

• This subgroup consists of women whose clinicians record breast symptoms and/or abnormal clinical breast findings during an exam.

[End Conditions.]

#### Actions

[Begin Actions.]

- 1. Make sure guideline recommendations are available to clinical provider; and
- 2. Open the Diagnostic Breast Imaging Documentation Template

[End Actions.]

[End Clinical Breast Findings.]

[End Event-Condition-Action (ECA) Rule: Diagnostic Breast Imaging.]

# **Chapter 4. Documentation Template: Diagnostic Breast Imaging**

[Begin Documentation Template: Diagnostic Breast Imaging.]

#### 1. Knowledge Narrative

```
[Begin Knowledge Narrative.]
[See Clinical Context in Chapter 1.]
[End Knowledge Narrative.]
```

#### 2. Reason for Visit

```
[Begin Reason for Visit.]
```

[Technical Note: Data housed in the electronic health record will populate the fields below if available.]

```
<obtain> Patient age in years
<obtain> Reason for visit
```

[End Reason for Visit.]

#### 3. Breast Imaging History

[Begin Breast Imaging History.]

[Technical Note: Data housed in the electronic health record will populate the fields below if available.]

[Technical Note: "Screening Mammography Results" and its subordinate questions should be made available only for patients with abnormal imaging results.]

[Technical Note: Image links to be available for image viewing along with the text transcription for all imaging results when possible.]

[Section Prompt: Most Recent Screening Mammography Results.]

```
<obtain> Date
<obtain> BI-RADS Category
<obtain> General breast composition
<obtain> Important findings
<obtain> Mammography comparison to prior imaging
<obtain> Management recommendations
[Section Prompt: Patient or Proxy notification completed?]
□ Yes
<obtain> Date
<obtain> Method
```

<obtain> Notification recipient</obtain>
$\square$ No
[Section Prompt: Prior Breast Imaging?]
□ Yes
[Technical Note: Display section below if "Yes" is selected for "Prior Breast Imaging".]
[Section Prompt: Is a written report available?]
□Yes
[Section Prompt: Please send a copy of the report to the radiology department to record result in electronic health record and to document result.]
[Section Selection Behavior: Select one. Optional.]
☐ Normal image (no evidence of malignancy)
☐ Abnormal image
☐ Incomplete image needing additional image
[Section Prompt: Additional Details?]
<obtain> BI-RADS Categories</obtain>
<obtain> Dates</obtain>
<obtain> Locations</obtain>
<obtain> Results</obtain>
[Technical Note: Enable recording of multiple prior imaging results.]
□ No
☐ No Prior Imaging
[End Breast Imaging History.]
4. Focused History
[Begin Focused History.]
[Technical Note: Data housed in the electronic health record will populate the fields below if available.]
[Section Prompt: Patient Breast Symptoms?]
[Section Selection Behavior: Select one or more. Optional.]
☐ Distinct breast mass
<obtain> Location</obtain>
<obtain> Details</obtain>
☐ Indistinct breast tissue thickening or nodularity
<obtain> Location</obtain>

<obtain> Details</obtain>	
☐ Nipple discharge	
□Normal lactation	
□Nonspontaneous	
□Suspicious	
<obtain> Details</obtain>	
☐ Skin Changes	
<obtain> Location</obtain>	
<obtain> Details</obtain>	
☐ Breast Pain	
□ Focal	
<obtain> Location</obtain>	
<obtain> Details</obtain>	
☐ Other breast symptoms	
<obtain> Details</obtain>	
☐ No breast symptoms	
[Section Prompt: Breast Cancer Risk Factors?]	
[Section Selection Behavior: Select one or more. Optional.]	
☐ Dense breast tissue	
☐ Radiation therapy to chest before age of 30 years	
☐ BRCA mutation carrier	
☐ First degree relative is a BRCA mutation carrier	
☐ Prior proliferative breast disease on biopsy	
☐ Personal history of breast cancer	
☐ Family history of breast cancer	
☐ Significant family history of other cancers	
☐ Other	
<obtain> Details</obtain>	
[Section Prompt: Overall Breast Cancer Risk?]	
<obtain> Details of overall breast cancer risk</obtain>	

#### Documentation Template: Diagnostic Breast Imaging

[Technical Note: In (https://www.cancer.	nclude link to the National Cancer Institute's Breast Cancer Risk Assessment Too gov/bcrisktool/).]
[Section Prompt: Bre	east Implants?]
[Section Selection Be	ehavior: Select one. Required.]
☐ Yes	
<ol> <li><ol> </ol> </li></ol> </li> </ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol>	btain> Details
□ No	
[Section Prompt: Prior	or Breast Surgeries or Biopsies Not Addressed Above?]
[Section Selection Be	ehavior: Select one. Required.]
□ Yes	
<ol><li><ol< li=""></ol<></li></ol>	btain> Surgical procedure(s)
<ol> <li><ol> </ol> </li></ol> </li> </ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol>	btain> Date(s)
□ No	
[Section Prompt: Cur	rrent Therapy for Breast Conditions?]
[Section Selection Be	ehavior: Select one. Required.]
☐ Yes	
<ol><li><ol< li=""></ol<></li></ol>	btain> Diagnosis of breast condition
<ol> <li><ol> </ol> </li></ol> </li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol>	btain> Current therapy for breast condition description(s)
[Section Prompt: Ent	ter additional condition?]
<ol> <li><ol> </ol> </li></ol> </li> </ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol></li></ol>	btain> Details
□ No	
[Section Prompt: Rep	
	ehavior: Select one or more. Optional.]
□ Postmeno	opausal
☐ Pregnant	
☐ Premenop	pausal, Not pregnant
[Section Prompt: Con	ntraceptive Status?]
[Section Sel	lection Behavior: Select one. Required.]
☐ Not appli	cable
<ol><li><ol< li=""></ol<></li></ol>	btain> Details
☐ Tubal liga	ation or permanent implanted birth control
☐ Using co	ntraceptives

<obtain> Details

☐ Attempting to conceive

☐ Not attempting to conceive, not using contraception

[End Focused History.]

#### 5. Problem List

[Begin Problem List.]

[Technical Note: Data housed in the electronic health record will populate the fields below if available.]

[Section Prompt: Problem List.]

<obtain> Problem List

<obtain> Relevant comorbidities to breast cancer risk

[End Problem List.]

### 6. Surgical History

[Begin Surgical History.]

[Technical Note: Data housed in the electronic health record will populate the fields below if available.]

[Section Prompt: Surgical History.]

<obtain> Relevant Surgical History Not Addressed Above

[End Surgical History.]

#### 7. Medication List

[Begin Medical List.]

[Technical Note: Data housed in the electronic health record will populate the fields below if available.]

[Section Prompt: Medication List.]

<obtain> Current Medication List

[End Medication List.]

#### 8. Clinical Breast Exam

[Begin Clinical Breast Exam.]

[Section Prompt: Breast Exam Findings?]

[Section Prompt: Include Location and Distance from Nipple for Positive Findings.]

<obtain> Appearance

<obtain> Findings on breast palpation

<obtain> Lymph node findings

<obtain> Other findings

[End Clinical Breast Exam.]

# 9. Patient/Proxy Discussion

[Begin Pa	atient/Proxy Discussion.]
[Section I	Prompt: Imaging results reviewed, and next steps/plan of care discussed with:]
[Section S	Selection Behavior: Select one. Required.]
[	□ Patient
[	□ Proxy
[	Section Prompt: Relationship]
[	Section Selection Behavior: Select one. Required.]
[	□ Spouse
[	☐ Significant other
[	☐ Medical power of attorney
[	□ Other
	<obtain> Details</obtain>
	<obtain> Legal status, if applicable</obtain>
	<obtain> Details</obtain>
[Section I	Prompt: Patient aware of need for extended follow-up?]
[Section S	Selection Behavior: Select one. Optional.]
[	☐ Potential need for extended follow-up addressed
	al Note: If checkbox "Potential need for extended follow up addressed" is selected, then display the questions.]
[Section I	Prompt: Is patient likely to be available for extended follow up?]
[Section S	Selection Behavior: Select one. Required.]
[	□Yes
[	□ No
<	<obtain> Details</obtain>
[Section I	Prompt: Patient/Proxy Preferences Discussed?]
[Section S	Selection Behavior: Select one. Required.]
[	□Yes
[	Section Prompt: Patient Preferences:]
[Section S	Selection Behavior: Select one. Required.]
[	☐ Active pursuit of diagnosis

#### Documentation Template: Diagnostic Breast Imaging

☐ Monit	oring only
☐ Aggre	ssive treatment
☐ Palliat	ion only
☐ Other	
	<obtain> Details</obtain>
□ No	
[Section Prompt: ]	Patient Contact Preference?]
[Section Selection	Behavior: Select one or more. Required.]
☐ Phone	call
☐ In pers	son
□ Non-re	egistered letter
☐ Secure	e messaging
☐ Other	
	<obtain> Details</obtain>
[End Patient/Prox	y Discussion.]
10. Plan	of Care
[Begin Plan of Ca	re.]
[Section Prompt: ]	Plan of Care]
[Section Selection	Behavior: Select one or more. Optional.]
☐ Contir	nue Standard Screening Mammography
[Section Prompt: ]	Recommended for BI-RADS Category 1 or 2 Screening Mammography result.]
	<obtain> Date next mammogram due</obtain>
	☐ Diagnostic Mammography in 6 months from today
[Section Prompt: ]	Recommended for evaluation of BI-RADS Category 3 Screening Mammography result.]
	<obtain> Date next mammogram due</obtain>
	☐ Diagnostic Mammography Now
or Nodularity, Per	Recommended for Patients Age 30 Years or Older with a Breast Mass, Asymmetric Thickening sistent Focal Breast Pain, Skin Changes, or Suspicious Nipple Discharge; an Option for Patients e 30 Years with Asymmetric Thickening or Nodularity, Skin Changes, or Suspicious Nipple
	<obtain> Details</obtain>
	☐ Breast Ultrasound Imaging Now

# Documentation Template: Diagnostic Breast Imaging

[Section Prompt: Recommended for Patients Younger Than Age 30 Years with a Breast Mass, Asymmetric Thickening or Nodularity, Persistent Focal Breast Pain, Skin Changes, or Suspicious Nipple Discharge; Recommended in Conjunction with Diagnostic Mammography for Patients Age 30 Years or Older with Asymmetric Thickening or Nodularity, Skin Changes, or Suspicious Nipple Discharge; an Option in Conjunction with Diagnostic Mammography for Patients Age 30 Years or Older with Persistent Focal Breast Pain; an Option as the Initial Diagnostic Evaluation for Patients Age 30 to 39 Years Old with a Suspected Cyst or a Breast Mass or Asymmetric Thickening or Nodularity Where the Clinical Suspicion is Low.]

<obtain> Details</obtain>
☐ Referral for Breast Biopsy Now
[Section Prompt: Recommended for Evaluation of BI-RADS Category 4 or 5 Screening Mammography Result: Recommended for Evaluation of BI-RADS Category 3 Screening Mammography Result in Patients Unlikely to Return for Follow-Up; an Option for Evaluation of BI-RADS Category 3 Screening Mammography Result in Patients with a Strong Preference for More Immediate Evaluation.]
<obtain> Details</obtain>
☐ Reassurance and Patient Education with or without Symptomatic Therapy
[Section Prompt: Recommended for Patients with Cyclic, Diffuse Pain, Whose Clinical Breast Exams Are Otherwise Normal and Whose Mammograms Are Up-to-Date and Normal.]
<obtain> Details</obtain>
☐ Observation and Patient Education
[Section Prompt: Recommended for Patients with Bilateral or Multiple-Duct Nonspontaneous Nipple Discharge Whose Clinical Breast Exams Are Otherwise Normal and Whose Screening Mammograms, If Recommended, Are Up-to-Date and Normal.]
☐ Observation and Patient Education
[Section Prompt: Recommended for Patients Younger Than Age 30 Years with a Palpable Breast Mass of Asymmetric Thickening or Nodularity Where the Clinical Suspicion Is Low.]
☐ Evaluate Medications for Potential Causes of Galactorrhea
<obtain> Details</obtain>
☐ Obtain Prior External Breast Imaging Results and/or Films
<obtain> Details</obtain>
☐ Plan Reviewed with and Agreed to by Patient/Proxy
□ Other
<obtain>Details</obtain>
[End Plan of Care.]
[Technical Note: Completion of the Diagnostic Breast Imaging Documentation template results in activation of the Diagnostic Breast Imaging Order set.]
[End Documentation Template: Diagnostic Breast Imaging.]

# **Chapter 5. Order Set: Diagnostic Breast Imaging**

[Begin Order Set: Diagnostic Breast Imaging.]

[Technical Note: This order set is activated by completion of the diagnostic breast imaging documentation template or by provider request.]

[Technical Note: This order set should be completed automatically to the extent possible by pulling data entered in the plan section of the diagnostic breast imaging documentation template.]

### 1. Knowledge Narrative

[Begin Knowledge Narrative.]

[See Clinical Context in Chapter 1.]

[Clinical Comment: The order set allows users to quickly address the issues revealed by abnormal breast imaging and to efficiently aide in the management of breast abnormalities and complaints.]

[End Knowledge Narrative.]

#### 2. Obtain Prior Films

[Begin Obtain Prior Films.]

[Section Prompt: Obtain Prior Films]

☐ Request prior films

<obtain> Location of prior films

<obtain> Consent from patient to obtain

[End Obtain Prior Films.]

### 3. Obtain Prior Pathology Specimens

[Begin Obtain Prior Pathology Specimens.]

[Section Prompt: Obtain Prior Pathology Specimens.]

☐ Request prior pathology specimens

<obtain> Location of pathology specimens

<obtain> Consent from patient to obtain

[End Obtain Prior Pathology Specimens.]

### 4. Imaging

[Begin Imaging.]

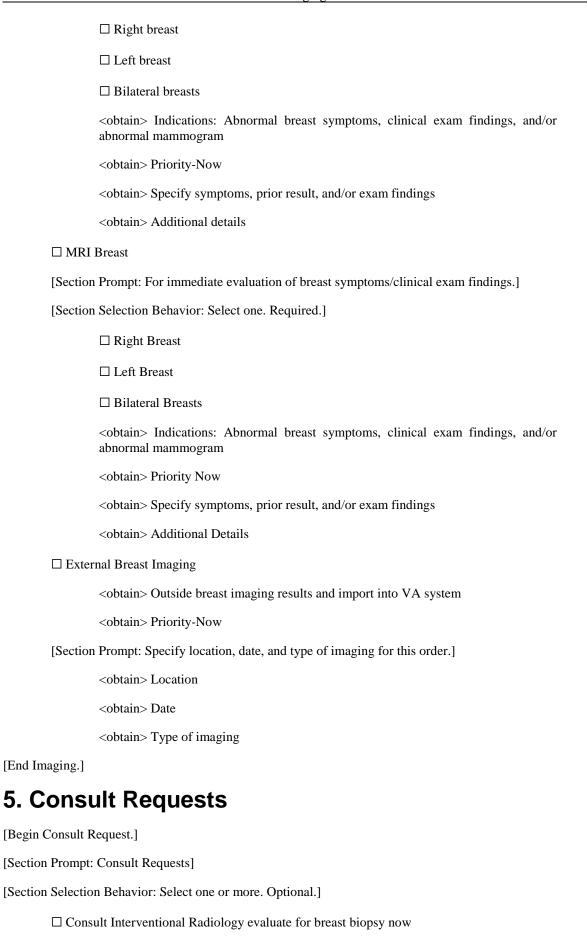
[Section Prompt: Imaging.]

[Section Selection Behavior: Select one or more. Optional.]

#### Order Set: Diagnostic Breast Imaging

☐ Screening Mammography
[Section Prompt: Screening mammogram to be scheduled when next due if no criteria for diagnostic imaging are met.]
[Section Selection Behavior: Select one. Required.]
☐ Right breast
☐ Left breast
☐ Bilateral breasts
<obtain> Indications: Screening mammogram</obtain>
<obtain> Priority –Routine</obtain>
<obtain> Additional details</obtain>
☐ Diagnostic Mammography in six months from today
[Section Prompt: For evaluation of BI-RADS Category 3 screening mammography in 6 months.]
[Section Selection Behavior: Select one. Required.]
☐ Right breast
☐ Left breast
☐ Bilateral breasts
<obtain> Indications: Follow up BI-RADS Category 3 screening mammography</obtain>
<obtain> Priority-Routine</obtain>
<obtain> Additional details</obtain>
☐ Diagnostic Mammography
[Section Prompt: For immediate evaluation of breast symptoms/clinical exam findings.]
[Section Selection Behavior: Select one. Required.]
☐ Right breast
☐ Left breast
☐ Bilateral breasts
<obtain> Indications: Evaluate breast symptoms/clinical exam findings</obtain>
<obtain> Priority-Now</obtain>
<obtain> Specify symptoms, prior result, and/or exam findings</obtain>
<obtain> Additional details</obtain>
☐ Ultrasound Breast
[Section Prompt: For immediate evaluation of breast symptoms/clinical exam findings.]
[Section Selection Behavior: Select one. Required.]

#### Order Set: Diagnostic Breast Imaging



#### Order Set: Diagnostic Breast Imaging

☐ Consult Surgery evaluate for breast biopsy now
☐ Consult Oncology evaluate for breast biopsy now
☐ Consult Radiology for review of outside breast imaging study or studies
☐ Consult Pathology for review of outside specimen(s)
[Technical Note: Launch Diagnostic Breast Imaging Documentation Template Consult Request when any consult box selected.]
[End Consult Request.]
6. Patient and Caregiver Education
[Begin Patient and Caregiver Education.]
[Section Prompt: Patient and Caregiver Education.]
[Section Selection Behavior: Select one or more. Optional]
[Technical Note: All orders below are to be executed with "Priority Now."]
☐ Abnormal mammogram education (patient-appropriate materials)
☐ Breast symptom education (patient-appropriate materials)
☐ Clinical breast exam finding education (patient-appropriate materials)
☐ Diagnostic breast imaging education (patient-appropriate materials)
☐ Breast biopsy education (patient-appropriate materials)
[End Patient and Caregiver Education.]
[End Order Set: Diagnostic Breast Imaging.]

# Chapter 6. Documentation Template Consult Request: Diagnostic Breast Imaging

[Begin Documentation Template Consult Request: Diagnostic Breast Imaging.]

#### 1. Knowledge Narrative

[Begin Knowledge Narrative.]

[See Clinical Context in Chapter 1.]

[Clinical Comment: This documentation template-consult request should be made available to clinical providers following the work-up ordered within the Diagnostic Breast Imaging Order set.]

The proposed use of the Documentation Template--Consult Request is for follow-up on Diagnostic Breast imaging orders. Follow-up includes:

- · Review of prior films
- Review of additional imaging, unilateral and bilateral (mammography, ultrasound, and MRI
- · Review of prior pathology
- Review of additional breast biopsies
- · Consult request for evaluation and management, to surgeon, interventional radiologist, or oncologist
- Schedule follow up.

[End Knowledge Narrative.]

### 2. Consult Request: Radiology

Begin Consult Request: Radiology.]
Section Prompt: For review of outside breast imaging study or studies please provide the following information.]
Section Selection Behavior: Select one. Optional.]
☐ Consult: Radiology
[Section Selection Behavior: Select one. Optional.]
☐ Screening mammogram interpretation
☐ Diagnostic mammogram interpretation
☐ Breast ultrasound interpretation
☐ Other breast imaging interpretation
[Technical Note: Display questions below for each of the options selected.]
[Technical Note: Links should be attached automatically if text is provided for the Radiology Interpretation fields.]

```
Priority: Routine
                 <obtain> Full report
                 link> Images
                 <obtain> Date
                 <obtain> BI-RADS category
                 <obtain> General breast composition
                 <obtain> Important findings
                 <obtain> Comparison to prior imaging
                 <obtain> Management recommendations
[End Consult Request: Radiology.]
3. Consult Request: Pathology
[Begin Consult Request: Pathology.]
[Section Prompt: For review of outside specimen(s) please provide the following information.]
[Section Selection Behavior: Select one. Optional.]
        ☐ Consult: Pathology
        [Section Selection Behavior: Select one. Optional.]
                 ☐ Breast biopsy interpretation
                 <obtain> Full pathology report: Breast biopsy
                 Pathology images: Breast biopsy
        [Technical Note: Links should be attached automatically if text is provided for the Breast Biopsy
        Interpretation field.]
                Priority: Routine
                 <obtain> Date
                 <obtain> Biopsy type
                 <obtain> Gross description
                 <obtain> Microscopic description
        [Section Prompt: Concordant with imaging?]
        [Section Selection Behavior: Select one. Required.]
                ☐ Yes
                 <obtain> Details
                \square No
                 <obtain> Additional Details
```

[Section Prompt: Additional Breast Biopsies?]

<obtain> Type of biopsy

<obtain> Location, date

<obtain> Key findings

<obtain> Concordance with Imaging

<obtain> Additional detail as appropriate

[End Consult Request: Pathology.]

# 4. Consult Request: Evaluation of Abnormal Breast Imaging

[Begin Consult Request: Evaluation of Abnormal Breast Imaging.]

[Section Prompt: For abnormal imaging result BI-RADS Category 4 or 5, or abnormal result with symptoms or exam finding requiring urgent evaluation].

exam fii	nding req	uiring urgent evaluation].
[Section	Prompt:	Consult Specialty.]
[Section	Selectio	n Behavior: Select one or more. Optional.]
	□ Onco	logy
	□ Surge	ery
	☐ Interv	ventional Radiology
		<obtain> Reason for Consult: Evaluate for abnormal breast imaging</obtain>
	[Section	Prompt: Goal of Consult.]
	[Section	Selection Behavior: Select one. Required.]
		$\hfill\square$ Provide recommendation and return to primary care provider (PCP) for the rapy
		$\square$ Start treatment and return to PCP for follow up and maintenance
		$\hfill\Box$ Start treatment, monitor for effect and when on stable therapy return to PCP
		☐ Provide recommendations and treat as long as necessary (or indefinitely)
	Priority	Urgent
	<obtain:< td=""><td>&gt; Date desired</td></obtain:<>	> Date desired
	<obtain:< td=""><td>&gt; Referring physician</td></obtain:<>	> Referring physician
	<obtain:< td=""><td>&gt; Referring physician contact information</td></obtain:<>	> Referring physician contact information
	<obtain:< td=""><td>&gt; Most recent breast imaging abnormal result</td></obtain:<>	> Most recent breast imaging abnormal result
	<obtain:< td=""><td>&gt; Prior breast imaging results</td></obtain:<>	> Prior breast imaging results
	Section	Prompt: Clinical History.]

# Documentation Template Consult Request: Diagnostic Breast Imaging

#### <obtain> Relevant clinical history

[Technical Note: Auto filled via Documentation Template or input by ordering provider.]

[End Consult Request: Evaluation of Abnormal Breast Imaging.]

[End Documentation Template Consult Request: Diagnostic Breast Imaging.]

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- American Cancer Society. Lifetime Probability of Developing and Dying from Cancer, 2011-2013. American Cancer Society, Surveillance Research, 2017. Cancer Facts & Figures 2017 website. https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2017/lifetime-probability-of-developing-and-dying-from-cancer-2011-2013.pdf
- American College of Radiology, Quality and Safety Resources Breast Imaging Reporting and Data Systems (BI-RADS) Atlas. https://www.acr.org/Quality-Safety/Resources/BIRADS.
- Radiopedia 5-tier ACR system of radiologic breast findings. <a href="https://radiopaedia.org/articles/5-tier-acr-system-of-radiologic-breast-findings">https://radiopaedia.org/articles/5-tier-acr-system-of-radiologic-breast-findings</a>.
- Radiology Assistant BI-RADS Final Assessment. <a href="http://www.radiologyassistant.nl/en/p53b4082c92130/bi-rads-for-mammography-and-ultrasound-2013.html">http://www.radiologyassistant.nl/en/p53b4082c92130/bi-rads-for-mammography-and-ultrasound-2013.html</a> in53b4389d91374.
- American College of Radiology. *ACR BI-RADS Atlas 5th Edition Mammography: Reporting System. American College of Radiology website*. <a href="https://www.acr.org/~/media/ACR/Documents/PDF/QualitySafety/Resources/BIRADS/01-Mammography/02--BIRADS-Mammography-Reporting.pdf?la=en">https://www.acr.org/~/media/ACR/Documents/PDF/QualitySafety/Resources/BIRADS/01-Mammography/02--BIRADS-Mammography-Reporting.pdf?la=en</a>. Published 2013.
- American College of Radiology. *ACR BI-RADS Atlas 5th Edition Ultrasound: Reporting System. American College of Radiology website*. <a href="https://www.acr.org/~/media/ACR/Documents/PDF/QualitySafety/Resources/BIRADS/02-Ultrasound/05--BIRADS-US-Reporting.pdf?la=en">https://www.acr.org/~/media/ACR/Documents/PDF/QualitySafety/Resources/BIRADS/02-Ultrasound/05--BIRADS-US-Reporting.pdf?la=en</a>. Published 2013.
- National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines):

  Breast Cancer Screening and Diagnosis, Version 1.2017. National Comprehensive Cancer Network
  Guidelines website. <a href="https://www.nccn.org/professionals/physician\_gls/pdf/breast-screening.pdf">https://www.nccn.org/professionals/physician\_gls/pdf/breast-screening.pdf</a>.

  Revised June 2017.
- [Oeffinger, 2015] KC Oeffinger, ETH Fontham, R Etzioni, and et al. "Breast Cancer Screening for Women at Average Risk: 2015 Guideline Update From the American Cancer Society". *JAMA*. 2015. 314. 15. 1599-1614.

# **Appendix A. Existing VA Artifacts**

Figure A.1. Non-VA Care Mammogram Consult (completed in conjunction with the imaging order set)

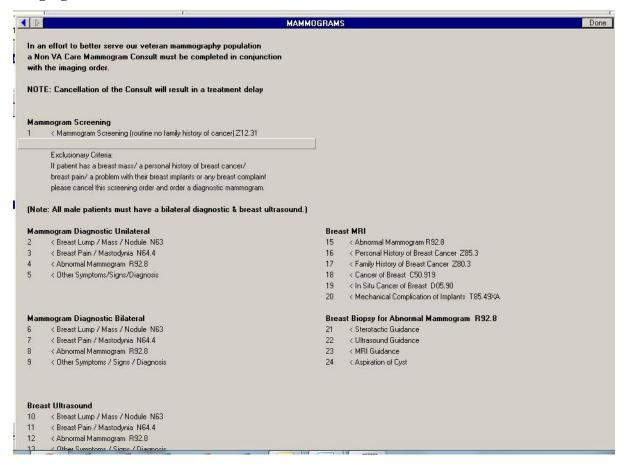


Figure A.2. Reason for Consult Request

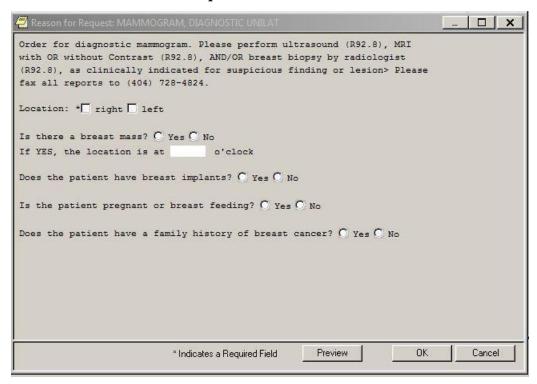
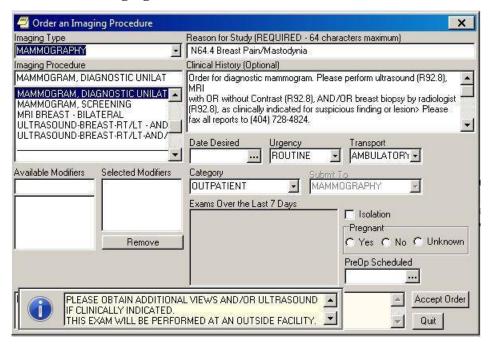


Figure A.3. Order an Imaging Procedure



 $\begin{tabular}{ll} Figure A.4. Breast Imaging - Reporting and Data Systems (BI-RAD) Category 0 SMART \\ Template \end{tabular}$ 

F	☑ Document/order follow up actions and patient notification:		
	▼ BI-RAD 0: Incomplete, further imaging or information is required, e.g. compression, magnification, special mammographic views, ultrasound		
	Obtain Prior Films		
	Additional Imaging		
	☐ Referrals/Consults		
	Currently under treatment		
	Biopsy Previously Obtained		

Figure A.5. Breast Imaging – Reporting and Data Systems (BI-RAD) Category 3 SMART Template

<b></b> ■	I-RAD 3: Probably Benign, short interval follow-up suggested		
	□ Obtain Prior Films		
	☐ Additional Imaging		
	☐ Referrals/Consults		
	☐ Currently under treatment		
	☐ Biopsy Previously Obtained		

Figure A.6. Breast Imaging – Reporting and Data Systems (BI-RAD) Category 4 SMART Template

wh:	RAD 4: Suspicious Abnormality: there is a mammographic appearance ich is suspicious for malignancy, biopsy should be considered for ch a lesion
	Obtain Prior Films
	☐ Additional Imaging ☐ Referrals/Consults
	☐ Currently under treatment ☐ Biopsy Previously Obtained

Figure A.7. Breast Imaging – Reporting and Data Systems (BI-RAD) Category 5 SMART Template

hig	NAD 5: Action needed: there is a mammographic appearance which Whily suggestive of malignancy
	Obtain Prior Films
	Additional Imaging
	Referrals/Consults
	Currently under treatment
	Biopsy Previously Obtained

Figure A.8. Breast Imaging – Reporting and Data Systems (BI-RAD) Category 6 SMART Template

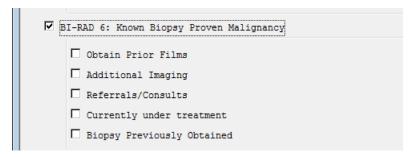


Figure A.9. Additional Imaging SMART Template

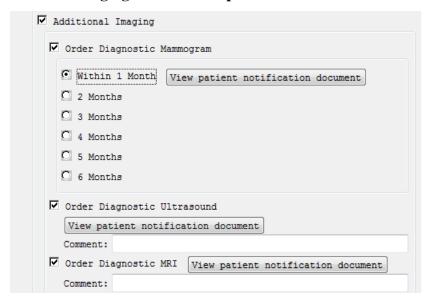


Figure A.10. Biopsy SMART Template



Figure A.11. Referrals/Consults SMART Template



Figure A.12. Breast Imaging – Reporting and Data Systems (BI-RAD) Definitions

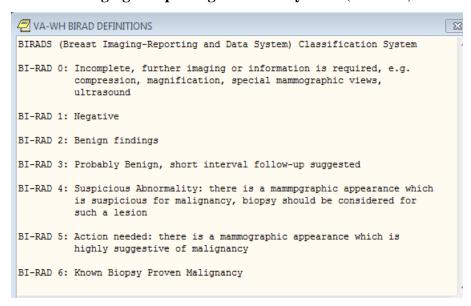


Figure A.13. Patient Notification SMART Template

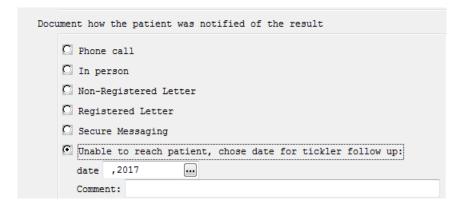


Figure A.14. Patient Notification Details SMART Template

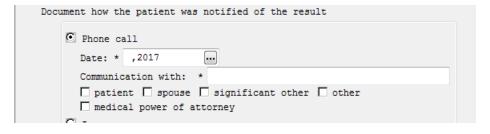


Figure A.15. Non-Registered Letter Details SMART Template

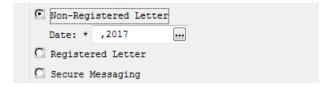


Figure A.16. Report Written Outside Report SMART Template

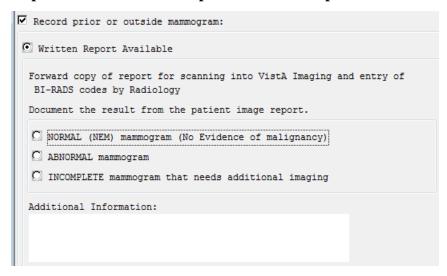


Figure A.17. Verbal Outside Report SMART Template

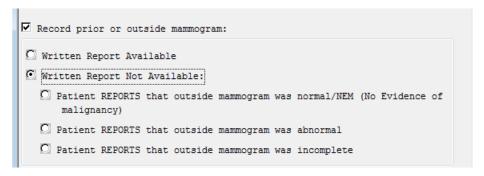


Figure A.18. Abnormal Mammogram SMART Template



Figure A.19. Incomplete Mammogram SMART Template

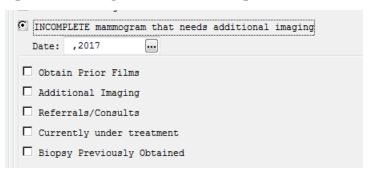


Figure A.20. Verbal Outside Report Normal SMART Template

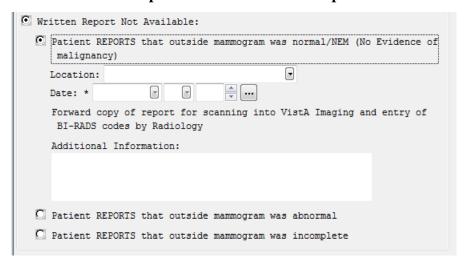
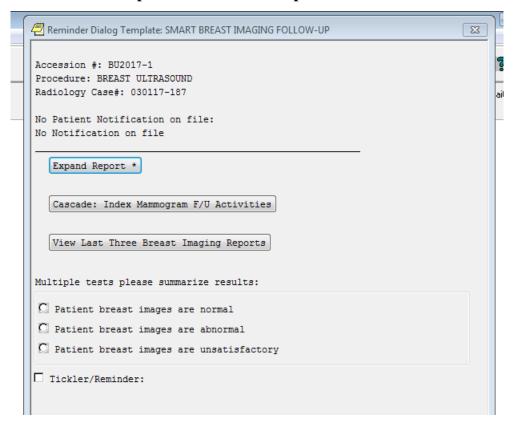


Figure A.21. Record Multiple Tests SMART Template



# **Appendix B. Basic Laboratory Panel Definition**

- Blood Urea Nitrogen
- Calcium
- Chloride
- CO2 (Carbon Dioxide, Bicarbonate)
- Creatinine
- Glucose
- Potassium
- Sodium

# **Appendix C. Acronyms**

Acronym	Definition
ACR	American College of Radiology
BI-RADS	Breast Imaging-Reporting and Data Systems
BRCA	Either of two genes (BRCA1 or BRCA2) that, if inherited in a mutated form, may predispose some carriers to develop breast or ovarian cancer
CCWP	Clinical Content White Paper
CDS	Clinical Decision Support
CO2	Carbon dioxide
ECA	Event-Condition-Action
HL7	Health Level 7
KBS	Knowledge Based Systems
KNART	Knowledge Artifact
MRI	Magnetic Resonance Imaging
NCCN	National Comprehensive Cancer Network
OIIG	Office of Informatics and Information Governance
PCP	Primary Care Provider
SME	Subject Matter Expert
ТО	Task Order
VA	Department of Veterans Affairs