

## Lung Screening Study

### Specifications for Completion of the Chest X-ray Screening Examination Form (XRY2)

This form is to be completed by a SC staff member and the Examiners (technologist and radiologist). The SC staff member will complete the top administrative section, the technologist will complete Part A, and the radiologist will complete Parts B and C of the form.

Although this form is designed to be scanned by an Optical Mark Reader, it will be sent to the CC to be keyed. Therefore, bubbles for items which are also written do not need to be completed (e.g., dates and staff ID numbers).

#### Administrative Section:

**Participant ID:** Affix a PID label to the space provided in the upper right corner of the form. The barcode should be aligned directly over the shaded box, with the eye-readable number toward the inside of the form. The barcode should be toward the outer edge of the form.

1. **Date of Examination:** Enter the date of the examination. Month and day should be zero filled (e.g., 02/07). For the year, all four (4) digits need to be filled.
2. **Satellite Center:** This field will not be used in the Lung Screening Study.
3. **Study Year:** This field will not be used in the Lung Screening Study.
4. **Visit Number:** Darken the circle corresponding to the number of times the participant visited the SC to complete this examination. There should be no more than three visits to the SC to complete the chest X-ray examination.
5. **Reason for Repeat Visit:** If this is a repeat visit (visit number 2 or 3), record the reason for the repeat visit. The purpose of this item is to provide important information to the Examiner regarding why the participant is returning for a repeat visit. Some example reasons:

*"Prior film was of poor quality."*

This might be entered if the participant's prior film was of poor quality during the previous visit, but s/he was willing to return to the SC for a repeat film. This information will alert the Examiner to explore the reasons for this problem.

*"Participant out of time. Unable to complete X-ray exam."*

This might be entered if the participant's schedule did not allow him to remain at the SC to complete the X-ray screening examination during a previous visit, and the examination was rescheduled.

**Form Processing:** These are the steps that should be completed in order to process the examination form. The items that will be used in the Lung Screening Study SC will be Manual Review Completed, Data Retrieval, and Final Disposition. All others should be left blank.

**Manual Review Completed:** Darken this circle after the form has been reviewed by SC staff to make sure that the information is complete, legible and consistent. (Refer to Chapter 9 for instructions on performing a manual review of forms.)

**Data Retrieval:** Complete this item to indicate the status of data retrieval. If data retrieval was attempted, regardless of whether or not additional information was collected, darken the circle next to "Attempted." If no data retrieval was required, darken the circle next to "None Required."

**Final Disposition:** The SC is required to assign a final disposition to each form. There are two final dispositions:

- Final Complete (FCM): This disposition is assigned when all sections of the XRY2 have been completed and edited by the SC.
- Final Incomplete (FIC): This disposition is assigned when information is missing from the XRY2, which cannot be corrected. This includes errors that cannot be corrected because data retrieval is not required for the item, or because the information could not be obtained, even with data retrieval.

### **Part A: Chest X-Ray Examination Findings (Completed by Technologist):**

Part A is to be completed by the X-ray technologist.

1. **Number of Attempts:** Darken the circle corresponding to the number of attempts made to take the chest X-ray. No more than two attempts are permitted at one visit. Responses are explained below:

**None:** There is no attempt to take the chest X-ray. This might occur if the participant entered the dressing room to prepare for the exam, but for some reason there was no attempt to take the X-ray (participant became ill, could not wait, etc.). (Go to Item 2.)

If the participant never prepared for the exam in any way, the exam is considered "Not Done." The XRY2 would not be filled out in such cases.

**One:** The chest X-ray is attempted once, regardless of whether or not it is successfully completed.

**Two:** The chest X-ray is attempted twice, regardless of whether or not it is successfully completed.

2. **Adequate Films Obtained:** Before the participant leaves the SC, the technologist will evaluate the X-ray for quality. Films judged to be adequate by the technologist are then sent to the study radiologist who will also judge their adequacy. A film will be considered adequate if the lung vessels are clearly visible, and the mediastinal structures are sufficiently penetrated to allow for adequate visualization. Responses are explained below:

**No:** The film is judged to be inadequate. (Go to Item 3 and complete Parts A and C of the examination form.) **Note: The XRY2 form is printed with an instruction to complete Part A only but the technologist should also complete Part C to document the Inadequate exam.)**

**Yes:** The film is judged to be adequate. (Go to Item 4).

3. **Reason for Inadequate Films:** This item is completed only if the answer to Item 2 is "No." Darken one or more circles to indicate the reason(s) for the inadequate films. An explanation of each reason for inadequate films is given below:

Participant Refusal: The participant is unwilling to cooperate, i.e., stand in the proper position, hold breath, etc.

Equipment Malfunction: There is a problem with the radiographic equipment, which prevents the successful completion of the X-ray.

Poor Film Quality: A film was obtained, but was not adequate for interpretation. Poor film quality may be due to excessive rotation, inadequate inspiration, motion or processing artifact, over or under penetration, or exclusion of parts of the lung and mediastinal structures from the film.

Other (SPECIFY): Describe any other situation in which adequate films could not be obtained in the space provided.

4. **Comments:** The comments box may be used to record information that may help clarify a situation, provide further information for an item in another part of the form, and to record additional "Other (SPECIFY)" information, if needed.

If more than one chest X-ray system (e.g., Thoravision, CR or conventional) is used at an SC, record the type of system used for the specific X-ray examination here.

If there are no additional comments, darken the circle next to "No." If there are additional comments, darken the circle next to "Yes." Enter the item number indicating the item to which the comments are related. The item number should include a letter indicating the section of the form, and a number indicating the item within that section (e.g., A.3). If the comment is not related to a specific item in Part A of the form, use the item number for the comments section itself (A.4). Then enter the comments in the space provided to the right of the item number. If more space is needed, darken the circle next to "Continued" and record additional comments on a Comments Continuation Form (CCF).

5. **Technologist Identification:** Sign the form in the space provided, enter your 4 digit staff ID number.

**Part B: Chest X-Ray Examination Findings (Completed by Radiologist):**

Part B is to be completed by the interpreting radiologist. At some SCs, the SC staff will complete this section using the interpreting radiologist's written report. If the result of the examination (Item C.1) is "Inadequate" Part B should be left blank.

**1. Abnormality Noted:**

**No:** No abnormality was seen. (Go to Part C.)

**Yes:** An abnormality (either suspicious for lung cancer or abnormal for any other reason) was seen.

**2. Record Information for Each Abnormality:** Complete this item for up to five radiographic abnormalities. Complete the chart by darkening the circle corresponding to the correct response in each column and row. Enter information about the first abnormality in the row labeled "1", the second abnormality in the row labeled "2", etc.

**Location:** If an abnormality is seen in both the right and left hemithorax or in more than one section of a hemithorax (e.g., a nodule or mass seen in more than one hemithorax) darken the circles for all locations that apply. In the case of abnormalities which may be widespread (e.g., fibrosis or chronic obstructive pulmonary disease (COPD)) the location "diffuse" may be applicable. If an abnormality is seen in only one hemithorax, darken the circle for NA for the other hemithorax.

Right Hemithorax:

Upper 1/3: The abnormality was found in the upper 1/3 of the right hemithorax.

Middle 1/3: The abnormality was found in the middle 1/3 of the right hemithorax.

Lower 1/3: The abnormality was found in the lower 1/3 of the right hemithorax.

Diffuse: The abnormality was spread throughout the right hemithorax. If diffuse is marked, no other location in the right hemithorax should be marked.

NA: The abnormality was not in the right hemithorax.

Left Hemithorax:

Upper 1/3: The abnormality was found in the upper 1/3 of the left hemithorax.

Middle 1/3: The abnormality was found in the middle 1/3 of the left hemithorax.

Lower 1/3: The abnormality was found in the lower 1/3 of the left hemithorax.

Diffuse: The abnormality was spread throughout the left hemithorax. If diffuse is marked, no other location in the left hemithorax should be marked.

NA: The abnormality was not in the left hemithorax.

The only instances where it is appropriate for the examiner to code NA for both the left and the right hemithorax is for the following abnormalities:

- #20: Bone/soft tissue lesion;
- #21: Cardiac abnormality/cardiomegaly/congestive heart failure; and
- #88: Other

**Description of Abnormality:** Darken one circle corresponding to the description of the abnormality. Please note that codes 01, 02, 07, and codes 13 through 16 (in bold) are considered to be a positive screen for lung cancer (i.e., for these abnormalities, the examination result in Part C.1. must be coded "Positive Screen - Referral Required"). The abnormalities are listed below:

- 01 = Nodule (1 - 30 mm)**
- 02 = Mass (> 30 mm)**
- 07 = Pleural mass**
- 08 = Granuloma
- 13 = Right hilar/mediastinal lymph nodes (exclude calcified nodes)**
- 14 = Left hilar mediastinal lymph nodes (exclude calcified nodes)**
- 15 = Major atelectasis/collapse**
- 16 = Infiltrate (consolidation/alveolar opacity)**
- 17 = Scarring/pulmonary fibrosis/honeycombing
- 18 = Pleural fibrosis/pleural plaque
- 19 = Pleural fluid
- 20 = Bone/soft tissue lesion
- 21 = Cardiac abnormality/cardiomegaly/congestive heart failure
- 22 = COPD/emphysema/bullae
- 88 = Other (SPECIFY): The abnormality is other than those listed above. Specify the abnormality on the line provided in the "Description of Abnormality" column.

### **Part C: Chest X-Ray Interpretation Results**

Part C is to be completed by the interpreting radiologist. At some SCs, the SC staff will complete this section using the interpreting radiologist's written report. In cases where an adequate film was not obtained (A.2 = No), Part C should be completed by the technologist to document the result of the examination as "Inadequate."

1. **Examination Results:** Darken the circle corresponding to the result of the examination. Definitions of examination results are given below:

Positive Screen - Referral Required: Evaluation reveals any of the following pulmonary abnormalities:

- nodule (a circular opacity less than or equal to 3.0 cm in diameter)
- mass (any discrete opacity greater than 3.0 in diameter without regard to contour, homogeneity or border characteristics)

- hilar or mediastinal lymph node enlargement (exclude calcified nodes)
- major atelectasis/lobar collapse
- infiltrate/consolidation/alveolar opacity
- pleural mass

Negative Screen - No Abnormalities :

Evaluation reveals no abnormalities.

Negative Screen, Other Abnormalities (Referral Required):

Evaluation reveals, but is not limited to, any of the following pulmonary abnormalities:

- scarring, pulmonary fibrosis, honeycombing;
- pleural fluid;
- bone or soft tissue lesion;
- cardiac abnormality, cardiomegaly, congestive heart failure.

Negative Screen, Other Abnormalities (Referral Optional):

Evaluation reveals, but is not limited to, any of the following pulmonary abnormalities:

- granuloma(s);
- pleural fibrosis, pleural plaque;
- COPD/emphysema/bullae.

Inadequate: The X-Ray films were inadequate and sufficient information could not be obtained. Record the reason(s) for an inadequate examination in Item C.2 below.

If there is an abnormality which is indicative of a positive screen and one which is indicative of a negative screen - other abnormalities, only "Positive Screen - Referral Required" should be marked.

2. **Reason for Inadequate Exam:** Darken one or more circles to indicate the reason for an inadequate exam. If the exam was inadequate for reasons other than or in addition to poor film quality and/or films lost, darken the circle for "Other" and specify the reason(s) on the lines provided.
3. **Level of Referral:** Darken the circle corresponding to the level of referral.
  - 1 - Significant Abnormality, Referral: The examination result was "Positive Screen - Referral Required," or the result was "Negative Screen - Other Abnormalities" or "Inadequate" and an abnormality considered to be significant and requiring referral was found.

- 2 - Moderate Abnormality, Referral: The examination result was "Negative Screen - Other Abnormalities" or "Inadequate," and an abnormality considered to be moderate and requiring referral was found.
- 3 - Slight Variation from Normal, No Referral: The examination result was "Negative Screen - Other Abnormalities" or "Inadequate," and an abnormality considered to be a slight variation from normal, not requiring referral, was found.
- 4 - Normal/Result Not Available, No Referral: The examination result was "Negative Screen - No Abnormalities" or "Inadequate," and no abnormalities were seen or the result of the examination is not available.

4. **Comments:** The comments box should be used to record information that may help clarify a situation, provide further information for an item in another part of the form, and to record additional "Other (Specify)" information, if needed.

If there are no additional comments, darken the circle next to "No." If there are additional comments, darken the circle next to "Yes." Enter the item number indicating the item to which the comments are related. The item number should include a letter indicating the section of the form, and a number indicating the item within that section (e.g., B.2.1). If the comment is not related to a specific item in parts B or C of the form, use the item number for the comments section itself (C.4). Then enter the comments in the space provided to the right of the item number. If more space is needed, darken the circle next to "Continued," and record additional comments on a Comments Continuation Form (CCF) (Appendix 9-11).

Note that if a dictated report is not provided, the Comments section should be used to describe significant and minor abnormalities occurring with a negative screen.

5. **Radiologist Identification:** *(This item should be completed by the radiologist. In the case where an adequate film was not obtained, the technologist will complete this item.)*

Sign the form in the space provided, enter your 4-digit ID number. If this section was completed by a member of the SC staff using the radiologist's written report, the SC staff member should enter the radiologist's name and staff ID, then sign his/her own name below the name of the radiologist. If adequate films were not obtained and the technologist assigned the examination result of "Inadequate," the technologist should record his/her name and ID in the space provided.