

## Baseline Screening Protocol, results and workup recommendations

**Negative:** No nodules, **RETURN FOR ANNUAL REPEAT** **IELCAP = 1**

**Semi-Positive: RETURN FOR ANNUAL REPEAT** **IELCAP = 2**

- a. Only nonsolid nodules, regardless of size, or
- b. Largest solid, part-solid (solid component) < 6.0 mm,
- c. Peri-fissural nodules < 10.0 mm in diameter with smooth margin and lentiform, oval, or triangular shape;
- d. Costal pleural nodules < 10.0 mm in diameter with smooth margin and any shape (lenticular, oval, semi-circular, triangular, polygonal, or round shape); other than irregular.

**Indeterminate: RETURN FOR LDCT IN 3 MONTHS** **IELCAP = 3**

- e. Largest solid, part-solid (solid component) 6.0-14.9 mm when follow-up CT scan *in 3 months after baseline shows growth at a nonmalignant rate, RETURN 9 MONTHS LATER FOR FIRST ANNUAL REPEAT.*

**Positive:** **IELCAP = 4**

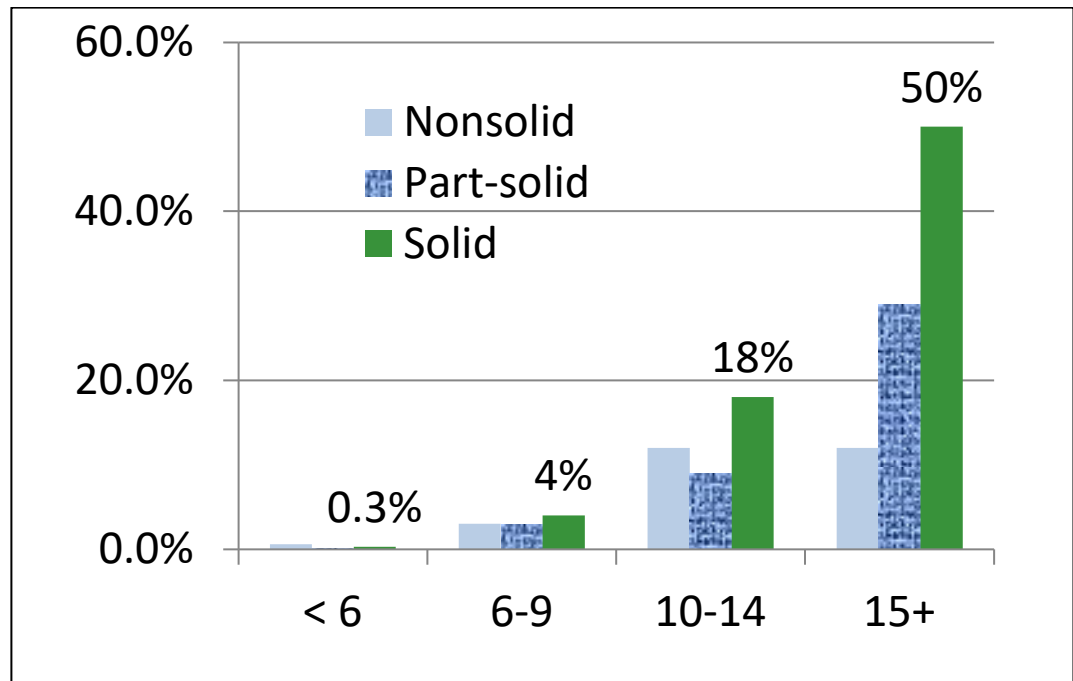
- a. Largest solid, part-solid (solid component) 6.0-14.9 mm in size *after a follow-up CT scan in 3 months shows growth at a malignant rate;*
- b. Largest solid or part-solid nodule 15.0 mm or larger;
- c. Solid endobronchial nodule.

### WORKUP OPTIONS FOR POSITIVE RESULTS:

- A) If the nodule appearance is highly suggestive of lung cancer, immediate biopsy is recommended.
- B) Another option is to perform PET scan, particularly if the solid component of the nodule is 10.0 or more mm in diameter. If the PET result is positive, biopsy is recommended, but if negative or indeterminate a low-dose CT 1-3 months later is performed. If there is growth, biopsy is recommended, but if there is partial or complete resolution on CT, the workup stops.
- C) When multiple nodules are present and occult infection or inflammation is a possibility, an added option is a course of a broad spectrum antibiotic with anaerobic coverage followed by low-dose CT 1-3 months later (72). The result is acted on as specified in option B.
- D) If an endobronchial nodule is identified at the time of the initial CT, the participant is asked to cough vigorously several times and the region of interest is reimaged at that time. If the endobronchial nodule is not recognized at the time of the baseline CT scan, the participant is recalled for a follow-up low-dose CT within one month. At the time of the follow-up CT scan, the participant is asked to cough vigorously several times. If the nodule is still present, the participant is referred for pulmonary consultation, and if necessary, bronchoscopy. If classic features of retained secretions are identified such as low attenuation, air bubbles, stranding and multiplicity, call back is not necessary [also see NCCN Guidelines 2016 (92)].

**NOTE: All participants in whom diagnostic work-up was stopped or the biopsy, if adequate, did not lead to a diagnosis of lung cancer, REPEAT CT 12 months is to be performed.**

**Baseline Round. Probability of malignancy based on nodule size and consistency**



**Baseline Round: Change needed in nodule diameter to identify growth at a malignant rate for volume doubling times of 180 days or faster**

BASELINE ROUND		
Original diameter (mm)	Diameter (mm) in 3 months without measurement error VDT: 180 days	Diameter (mm) in 3 months with measurement error VDT: 180 days
6.0	6.7	7.1
7.0	7.9	8.3
8.0	9.0	9.4
9.0	10.1	10.5
10.0	11.2	11.6
11.0	12.3	12.7
12.0	13.5	13.9
13.0	14.6	15.0
14.0	15.7	16.1