The Percepta® Registry:
A Prospective Registry to Evaluate Percepta Bronchial Genomic Classifier Patient Data

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**BACKGROUND**

Performance and decision impact following enrollment of the first 300 patients.

- Percepta on management decisions, observe outcomes of patients managed with the test who may be considered for more conservative CT scan monitoring instead of further invasive testing.
- The Percepta classifier identifies patients at low risk of malignancy following an inconclusive bronchoscopy with a negative predictive value (NPV) of bronchoscopy for lung cancer detection. The Percepta Registry is an IRB-approved multi-center prospective study, developed in accordance with the Agency for Healthcare Research and Quality (AHRQ) guidelines. It was designed to observe physician adoption of the test, evaluate the impact of Percepta on management decisions, observe outcomes of patients managed with the test and monitor test safety. This planned interim analysis reports on patient selection, usage, test performance and decision impact following enrollment of the first 300 patients.

**ELIGIBILITY AND OBJECTIVES**

Inclusion Criteria
- Patients recommended for diagnostic bronchoscopy by their physicians as part of a work-up for suspected lung cancer are eligible for participation.
- The Percepta sample is obtained by brushing the right mainstem bronchus at the beginning of the index bronchoscopy procedure and held until pathological confirmation of an inconclusive bronchoscopy is received and the Percepta test result is ordered. The post Percepta test results diagnostic plan is captured at the point of the test result reporting. Additional follow-up clinical and imaging data are collected at regular time points up to 36 months. All participating sites undergo training on the Percepta test performance, report interpretation and specimen collection techniques. Safety incidents undergo root cause analysis and review by clinical advisors.

At the time of study completion, statistical analysis will examine the difference in invasive test usage following bronchoscopy between those patients with an intermediate pre-test risk (10-60%) for lung cancer who have a Percepta positive versus negative test result. This planned interim analysis is performed primarily to assess patient selection, test usage, test performance and decision impact in comparison to the previously published modeled utility.

**METHODS**

- **Objectives**
  - Measure impact of Percepta on pulmonary lesion management in a prospective, real-world clinical setting.
  - Monitor clinical outcomes of patients managed with the test.
  - Collect data for potential future test development.

- **Inclusion Criteria**
  - Specimens for the Percepta test were obtained and shipped to Veracyte on enrollment.
  - Patients were judged to be at low risk of malignancy following an inconclusive bronchoscopy.

- **Exclusion Criteria**
  - The patient is unable to be consented into the study or unable to comply with the study requirements.

- **Results**
  - **Complete Informed Consent Forms**
  - **Bronchoscopy**
  - **Ineligible Result**
  - **Physician Orders Percepta “Wrong patient”**
  - **Post-Percepta Results**
  - **Follow-up**

- **Additional Case Actions**
  - If Malignancy Found:
    - **Low Risk**
    - **Intermediate Risk**
    - **High Risk**

- **References**

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