### Project/Topic of your Clinical Question:

**Reviewer:**

**Today’s Date:**

**Final Evidence Level:**

**Article Title:**

**Year:**

**First Author:**

**Journal:**

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### Do the study aim/purpose/objectives and inclusion/exclusion criteria assist in answering your clinical question?

- **Study Aim/Purpose/Objectives:**
  - **Inclusion Criteria:**
  - **Exclusion Criteria:**

**Is a CCT or cohort study congruent with the author’s study aim/purpose/objectives above?**

- **Comments:**

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### VALIDITY: ARE THE RESULTS OF THE CLINICAL TRIAL OR COHORT STUDY VALID OR CREDIBLE?

1. **Were data collected prospectively?**
   - **Comments:**

2. **Did the sample include an appropriate variety of patients to whom the index test (e.g., diagnostic test being studied) will be applied in clinical practice?**
   - **Were the selection criteria clearly described?**
   - **Was the reference standard (e.g., gold standard or currently used test) likely to correctly identify the diagnosis in question?**
   - **Did the cohort include both diseased and non-diseased participants?**
   - **Were the clinicians blinded to the participant diagnosis prior to reviewing any test results (i.e., diagnostic uncertainty)?**
   - **Comments:**

3. **Were the patients similar at the start of the trial, with respect to known prognostic factors (i.e., demographic and clinical variables)?**
   - **Comments:**

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[LEGEND: Evidence Appraisal of a Single Study](http://groups/ce/NewEBC/EBCFiles/GLOSSARY-EBDM.pdf)

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[April 9, 2012](http://www.cincinnatichildrens.org/evidence)

[CCHMC Evidence Collaboration: James M. Anderson Center for Health Systems Excellence | Center for Professional Excellence | Edward L. Pratt Research Library](http://www.cincinnatichildrens.org/evidence)
4. Did patients receive the same reference standard, regardless of the index test? □ Yes □ No □ Unknown
   Comments:

5. Was the execution of the index test and the reference standard described? □ Yes □ No □ Unknown
   • Was the time period between reference standard and index test short enough to be reasonably sure that the target condition did not change between tests?
   Comments:

6. Were all patients accounted for at the conclusion of the study? □ Yes □ No □ Unknown
   • Were withdrawals from the study explained?
   • Was the rate of attrition acceptable?
   Comments:

7. Was there freedom from conflict of interest? □ Yes □ No □ Unknown
   • Sponsor/Funding Agency or Investigators
   Comments:

**RELIABILITY: ARE THE VALID STUDY RESULTS IMPORTANT?**

8. Did the study have a sufficiently large sample size? □ Yes □ No □ Unknown
   • Was a power analysis described?
   • Did the sample size achieve or exceed that resulting from the power analysis?
   • Did each subgroup also have sufficient sample size *(e.g., at least 6 to 12 participants)*?
   Comments:

9. What are the main results of the study? *(e.g., Helpful data: Page #, Table #, Figures, Graphs)*
   • What was the effect size?
     *(e.g., Diagnostic Accuracy – Sensitivity/Specificity, Likelihood Ratios, Limits of Agreement, Patient data to calculate these)*
   • What were the measures of statistical uncertainty *(e.g., precision)*?
     *(Were the results presented with Confidence Intervals or Standard Deviations?)*

10. Were the index test results and the reference standard results interpreted independently *(without knowledge of the results of the other test, blinded)*? □ Yes □ No □ Unknown
    Comments:
11. Were the same clinical data available when test results were interpreted as
   would be available when the test is used in practice?
   - Yes
   - No
   - Unknown

12. Were all test results reported, including uninterpretable or intermediate test
   results?
   - Yes
   - No
   - Unknown

APPLICABILITY: CAN I APPLY THESE VALID, IMPORTANT STUDY RESULTS TO TREATING MY PATIENTS?

13. Can the results be applied to my population of interest?
   - Yes
   - No
   - Unknown

   - Is the diagnostic test feasible in my care setting?
   - Is the setting of the study applicable to my population of interest?
   - Are the likely benefits worth the potential harm and costs?
   - Were the patients in this study similar to my population of interest?

   Comments:

14. Are my patient’s and family’s values and preferences satisfied by the use of the
diagnostic test?
   - Yes
   - No
   - Unknown

   Comments:

15. Would you include this study/article in development of a care recommendation?
   - Yes
   - No
   - Unknown

   Comments:

ADDITIONAL COMMENTS OR CONCLUSIONS (“TAKE-HOME POINTS”):
**QUALITY LEVEL / EVIDENCE LEVEL**

- Consider each “No” answer and the degree to which this limitation is a threat to the validity of the results, then check the appropriate box to assign the level of quality for this study/article.
- Consider an “Unknown” answer to one or more questions as a similar limitation to answering “No,” if the information is not available in the article.

**THE EVIDENCE LEVEL IS:**

- [ ] Good Quality CCT  [2a]
- [ ] Lesser Quality CCT  [2b]
- [ ] Good Quality Cohort-Prospective  [3a]
- [ ] Lesser Quality Cohort-Prospective  [3b]
- [ ] Good Quality Cohort-Retrospective  [4a]
- [ ] Lesser Quality Cohort-Retrospective  [4b]
- [ ] Not Valid, Reliable, or Applicable

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<td><strong>TYPE OF STUDY / STUDY DESIGN</strong></td>
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<td><strong>Diagnosis / Assessment</strong></td>
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*CCT = Controlled Clinical Trial*

Development for this appraisal form is based on: