

## Worksheet for Structured Review of Physical Exam or Diagnostic Test Study

Title of Manuscript: \_\_\_\_\_

Authors of Manuscript: \_\_\_\_\_

Journal and Citation: \_\_\_\_\_

**Identify and State the Hypothesis**

Primary Hypothesis: \_\_\_\_\_

Secondary Hypothesis: \_\_\_\_\_

**Methods Questions:**

- 1.) Does this Diagnostic Study use a Cross Sectional Study Design?  Yes,  No. If not what study design used? \_\_\_\_\_
- 2.) What is the Diagnostic Test? \_\_\_\_\_
- 3.) What is the Gold-Standard?
  - 3a.) Appropriate Gold Standard Used?  Yes,  No
  - 3b.) Alternative Gold Standards \_\_\_\_\_
- 4.) What is the Target Disorder the Test is Trying to Diagnose? \_\_\_\_\_
- 5.) What is the Patient Population in whom the Test is Applied?
  - 5a.) Appropriate Patient Population Studied?  Yes,  No
  - 5b.) If No, What is the Appropriate Patient Population? \_\_\_\_\_

**Evaluation of Bias:**

Were Examiners Blinded (Independent Examiner Used)?  Yes,  No

Are there sources of Selection Bias:

- Filter Bias?  Yes,  No Explain \_\_\_\_\_  
Spectrum Bias?  Yes,  No Explain \_\_\_\_\_  
Subgroup Bias?  Yes,  No Explain \_\_\_\_\_  
Verification Bias?  Yes,  No Explain \_\_\_\_\_  
Incorporation Bias?  Yes,  No Explain \_\_\_\_\_

Are there sources of Observer Bias:

- Absence of a Reference Test?  Yes,  No Explain \_\_\_\_\_  
Review or Interpretation Bias?  Yes,  No Explain \_\_\_\_\_  
Context Bias?  Yes,  No Explain \_\_\_\_\_

Are there Miscellaneous Sources of Bias:

- Could the test be graded as indeterminate?  Yes,  No  
Is the test result reader dependent?  Yes,  No  
Has continuous test data been converted to discrete data to determine a significant threshold value?  Yes,  No  
Is the test reported subject to future improvements (i.e. in technology)?  Yes,  No  
Is the study sponsored by the technology company?  Yes,  No

**Statistical Analysis:**

Were appropriate statistical methods used (e.g. type of test, estimator or confidence interval; choice of paired vs unpaired assessment; adjustment for baseline variables)?

- Yes, and methods required minimal assumptions.
- Yes, distributional (normal or non-normal) and other assumptions were justified.
- Probably, methods are appropriate in general for the type of response variable, but assumptions were not justified.
- No, but the test used is unlikely to affect the conclusions.
- No, and there is a good possibility that the inappropriate statistical methods used have affected the conclusions.

Is Statistical Consultation Requested?  Yes,  No Who should do it? \_\_\_\_\_