GRADE criteria for rating a body of evidence for a test

Developed by the GRADE Working Group (www.gradeworkinggroup.org)

Grades and interpretations:

High: Further research is very unlikely to change our confidence in the estimate of effect.

<u>Moderate</u>: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low: Any estimate of effect is very uncertain.

Type of evidence and starting level

Direct comparison reporting sensitivity and specificity of study test compared to appropriate reference standard in clinically-relevant patient population-high

Observational study-low

Any other evidence-very low

Criteria for increasing or decreasing level

Reductions

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<u>Study quality</u><sup>†</sup> has serious (-1) or very serious (-2) problems
Important <u>inconsistency</u> in evidence (-1)
<u>Directness</u><sup>‡</sup> is somewhat (-1) or seriously (-2) uncertain
<u>Sparse or imprecise</u> data (-1)
<u>Reporting bias</u> highly probable (-1)
Increases
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All plausible confounders would reduce the effect (+1)

†-Quality considerations include potential patient selection bias, consistent performance of both tests in the same patients, and blinded interpretation of study test and reference test.

‡-Directness considerations include potential spectrum bias (patients included in study have more or less severe disease than patients seen in routine practice), test methods or interpretation different from those used in routine practice, or use of different reference standards in studies comparing different diagnostic tests.



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