<table>
<thead>
<tr>
<th>Section &amp; Topic</th>
<th>No</th>
<th>Item</th>
<th>Reported on page #</th>
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</thead>
<tbody>
<tr>
<td><strong>TITLE OR ABSTRACT</strong></td>
<td></td>
<td>Identification as a study of diagnostic accuracy using at least one measure of accuracy (such as sensitivity, specificity, predictive values, or AUC)</td>
<td>1</td>
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<tr>
<td><strong>ABSTRACT</strong></td>
<td></td>
<td>Structured summary of study design, methods, results, and conclusions (for specific guidance, see STARD for Abstracts)</td>
<td>4</td>
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<tr>
<td><strong>INTRODUCTION</strong></td>
<td></td>
<td>Scientific and clinical background, including the intended use and clinical role of the index test</td>
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<td></td>
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<td>Study objectives and hypotheses</td>
<td>7</td>
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<tr>
<td><strong>METHODS</strong></td>
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<td><strong>Study design</strong></td>
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<td>5</td>
<td>Whether data collection was planned before the index test and reference standard were performed (prospective study) or after (retrospective study)</td>
<td>8</td>
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<td></td>
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<td><strong>Participants</strong></td>
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<td>6</td>
<td>Eligibility criteria</td>
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<td>On what basis potentially eligible participants were identified (such as symptoms, results from previous tests, inclusion in registry)</td>
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<td>8</td>
<td>Where and when potentially eligible participants were identified (setting, location and dates)</td>
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<td>9</td>
<td>Whether participants formed a consecutive, random or convenience series</td>
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<td><strong>Test methods</strong></td>
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<tr>
<td></td>
<td>10a</td>
<td>Index test, in sufficient detail to allow replication</td>
<td>8-9</td>
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<tr>
<td></td>
<td>10b</td>
<td>Reference standard, in sufficient detail to allow replication</td>
<td>8-9</td>
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<td>11</td>
<td>Rationale for choosing the reference standard (if alternatives exist)</td>
<td>8-9</td>
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<tr>
<td></td>
<td>12a</td>
<td>Definition of and rationale for test positivity cut-offs or result categories of the index test, distinguishing pre-specified from exploratory</td>
<td>9</td>
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<tr>
<td></td>
<td>12b</td>
<td>Definition of and rationale for test positivity cut-offs or result categories of the reference standard, distinguishing pre-specified from exploratory</td>
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<tr>
<td></td>
<td>13a</td>
<td>Whether clinical information and reference standard results were available to the performers/readers of the index test</td>
<td>9-11</td>
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<tr>
<td></td>
<td>13b</td>
<td>Whether clinical information and index test results were available to the assessors of the reference standard</td>
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<td><strong>Analysis</strong></td>
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<td>14</td>
<td>Methods for estimating or comparing measures of diagnostic accuracy</td>
<td>12</td>
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<td>15</td>
<td>How indeterminate index test or reference standard results were handled</td>
<td>N/A</td>
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<td>16</td>
<td>How missing data on the index test and reference standard were handled</td>
<td>11-13</td>
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<td>17</td>
<td>Any analyses of variability in diagnostic accuracy, distinguishing pre-specified from exploratory</td>
<td>11-13</td>
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<td>18</td>
<td>Intended sample size and how it was determined</td>
<td>11-12</td>
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<tr>
<td><strong>RESULTS</strong></td>
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<td><strong>Participants</strong></td>
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<td>19</td>
<td>Flow of participants, using a diagram</td>
<td>14-15 Fig 1-3</td>
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<td>20</td>
<td>Baseline demographic and clinical characteristics of participants</td>
<td>14 Table 2</td>
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<td>21a</td>
<td>Distribution of severity of disease in those with the target condition</td>
<td>14 Table 3</td>
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<td>21b</td>
<td>Distribution of alternative diagnoses in those without the target condition</td>
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<td>22</td>
<td>Time interval and any clinical interventions between index test and reference standard</td>
<td>N/A</td>
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<td><strong>Test results</strong></td>
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<td>23</td>
<td>Cross tabulation of the index test results (or their distribution) by the results of the reference standard</td>
<td>15 Table 4</td>
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<td>24</td>
<td>Estimates of diagnostic accuracy and their precision (such as 95% confidence intervals)</td>
<td>14-15</td>
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<td>25</td>
<td>Any adverse events from performing the index test or the reference standard</td>
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<tr>
<td><strong>DISCUSSION</strong></td>
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<td>Study limitations, including sources of potential bias, statistical uncertainty, and generalisability</td>
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<td>27</td>
<td>Implications for practice, including the intended use and clinical role of the index test</td>
<td>22</td>
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<tr>
<td><strong>OTHER INFORMATION</strong></td>
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<td>Registration number and name of registry</td>
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<td>29</td>
<td>Where the full study protocol can be accessed</td>
<td>3</td>
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<td>30</td>
<td>Sources of funding and other support; role of funders</td>
<td>2</td>
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