

## The STARD 2015 list

Section & Topic	No.	Item
<b>TITLE OR ABSTRACT</b>		
	<b>1</b>	Identification as a study of diagnostic accuracy using at least one measure of accuracy (such as sensitivity, specificity, predictive values, or AUC)
<b>ABSTRACT</b>		
	<b>2</b>	Structured summary of study design, methods, results, and conclusions (for specific guidance, see STARD for Abstracts)
<b>INTRODUCTION</b>		
	<b>3</b>	Scientific and clinical background, including the intended use and clinical role of the index test
	<b>4</b>	Study objectives and hypotheses
<b>METHODS</b>		
<i>Study design</i>	<b>5</b>	Whether data collection was planned before the index test and reference standard were performed (prospective study) or after (retrospective study)
<i>Participants</i>	<b>6</b>	Eligibility criteria
	<b>7</b>	On what basis potentially eligible participants were identified (such as symptoms, results from previous tests, inclusion in registry)
	<b>8</b>	Where and when potentially eligible participants were identified (setting, location and dates)
	<b>9</b>	Whether participants formed a consecutive, random or convenience series
<i>Test methods</i>	<b>10a</b>	Index test, in sufficient detail to allow replication
	<b>10b</b>	Reference standard, in sufficient detail to allow replication
	<b>11</b>	Rationale for choosing the reference standard (if alternatives exist)
	<b>12a</b>	Definition of and rationale for test positivity cut-offs or result categories of the index test, distinguishing pre-specified from exploratory
	<b>12b</b>	Definition of and rationale for test positivity cut-offs or result categories of the reference standard, distinguishing pre-specified from exploratory
	<b>13a</b>	Whether clinical information and reference standard results were available to the performers/readers of the index test
	<b>13b</b>	Whether clinical information and index test results were available to the assessors of the reference standard
<i>Analysis</i>	<b>14</b>	Methods for estimating or comparing measures of diagnostic accuracy
	<b>15</b>	How indeterminate index test or reference standard results were handled
	<b>16</b>	How missing data on the index test and reference standard were handled
	<b>17</b>	Any analyses of variability in diagnostic accuracy, distinguishing pre-specified from exploratory
	<b>18</b>	Intended sample size and how it was determined
<b>RESULTS</b>		
<i>Participants</i>	<b>19</b>	Flow of participants, using a diagram
	<b>20</b>	Baseline demographic and clinical characteristics of participants
	<b>21a</b>	Distribution of severity of disease in those with the target condition
	<b>21b</b>	Distribution of alternative diagnoses in those without the target condition
	<b>22</b>	Time interval and any clinical interventions between index test and reference standard
<i>Test results</i>	<b>23</b>	Cross tabulation of the index test results (or their distribution) by the results of the reference standard
	<b>24</b>	Estimates of diagnostic accuracy and their precision (such as 95% confidence intervals)
	<b>25</b>	Any adverse events from performing the index test or the reference standard
<b>DISCUSSION</b>		
	<b>26</b>	Study limitations, including sources of potential bias, statistical uncertainty, and generalisability
	<b>27</b>	Implications for practice, including the intended use and clinical role of the index test
<b>OTHER INFORMATION</b>		
	<b>28</b>	Registration number and name of registry
	<b>29</b>	Where the full study protocol can be accessed
	<b>30</b>	Sources of funding and other support; role of funders