## STARD checklist for reporting of studies of diagnostic accuracy (Version January 2003) 08PLME-RA-2461

Section and Topic	Item #		On page #
TITLE/ABSTRACT/	1	Identify the article as a study of diagnostic accuracy (recommend MeSH	1;3
INTRODUCTION	2	heading 'sensitivity and specificity').  State the research questions or study aims, such as estimating diagnostic accuracy or comparing accuracy between tests or across participant	6;7
METHODS		groups.	
	3	The study population: The inclusion and exclusion criteria, setting and	8
Participants	3	locations where data were collected.	0
	4	Participant recruitment: Was recruitment based on presenting symptoms, results from previous tests, or the fact that the participants had received the index tests or the reference standard?	8
	5	Participant sampling: Was the study population a consecutive series of participants defined by the selection criteria in item 3 and 4? If not, specify how participants were further selected.	8
	6	Data collection: Was data collection planned before the index test and reference standard were performed (prospective study) or after (retrospective study)?	8;9
Test methods	7	The reference standard and its rationale.	9;18
	8	Technical specifications of material and methods involved including how and when measurements were taken, and/or cite references for index tests and reference standard.	9; Supplement al Material
	9	Definition of and rationale for the units, cut-offs and/or categories of the results of the index tests and the reference standard.	13-14; Supplement al Material
	10	The number, training and expertise of the persons executing and reading the index tests and the reference standard.	8-9
	11	Whether or not the readers of the index tests and reference standard were blind (masked) to the results of the other test and describe any other clinical information available to the readers.	8-9
Statistical methods	12	Methods for calculating or comparing measures of diagnostic accuracy, and the statistical methods used to quantify uncertainty (e.g. 95%	9-10; Supplement
	13	confidence intervals).  Methods for calculating test reproducibility, if done.	al Material 14; Supplement al Material
RESULTS			ai wateriai
Participants	14	When study was performed, including beginning and end dates of recruitment.	8
	15	Clinical and demographic characteristics of the study population (at least information on age, gender, spectrum of presenting symptoms).	Not applicable
	16	The number of participants satisfying the criteria for inclusion who did or did not undergo the index tests and/or the reference standard; describe why participants failed to undergo either test (a flow diagram is strongly recommended).	See STARD diagram included
Test results	17	Time-interval between the index tests and the reference standard, and any treatment administered in between.	8
	18	Distribution of severity of disease (define criteria) in those with the target condition; other diagnoses in participants without the target condition.	Not applicable
	19	A cross tabulation of the results of the index tests (including indeterminate and missing results) by the results of the reference standard; for continuous results, the distribution of the test results by the results of the reference standard.	25 (Table 2)
	20	Any adverse events from performing the index tests or the reference standard.	Not applicable
Estimates	21	Estimates of diagnostic accuracy and measures of statistical uncertainty (e.g. 95% confidence intervals).	14-15; Supplement al Material
	22	How indeterminate results, missing data and outliers of the index tests were handled.	15

	23	Estimates of variability of diagnostic accuracy between subgroups of	14-15
		participants, readers or centers, if done.	
	24	Estimates of test reproducibility, if done.	14;
			Supplement
			al Material
DISCUSSION	25	Discuss the clinical applicability of the study findings.	19-20