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Reporting Quality of Diagnostic Accuracy Studies in Laboratory Medicine: Adherence to Standards for Reporting of Diagnostic Accuracy Studies (STARD) 2015

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Background: Poor reporting quality in diagnostic accuracy studies hampers an adequate judgment of the validity of the study. The Standards for Reporting of Diagnostic Accuracy Studies (STARD) statement was published to improve the reporting quality of diagnostic accuracy studies. This study aimed to evaluate the adherence of diagnostic accuracy studies published in Annals of Laboratory Medicine (ALM) to STARD 2015 and to identify directions for improvement in the reporting quality of these studies.

Methods: Two independent authors assessed articles published in ALM between 2012–2018 for compliance with 30 STARD 2015 checklist items to identify all eligible diagnostic accuracy studies published during this period. We included 66 diagnostic accuracy studies. A total of the fulfilled STARD items were calculated, and adherence was analyzed on an individual-item basis.

Results: The overall mean±SD number of STARD items reported for the included studies was 11.2±2.7. Only five (7.6%) studies adhered to more than 50% of the 30 items. No study satisfied more than 80% of the items. Large variability in adherence to reporting standards was detected across items, ranging from 0% to 100%.

Conclusions: Adherence to STARD 2015 is suboptimal among diagnostic accuracy studies published in ALM. Our study emphasizes the necessity of adherence to STARD to improve the reporting quality of future diagnostic accuracy studies to be published in ALM.

Key Words: Adherence, Annals of Laboratory Medicine, Diagnostic test, Laboratory, Standards for reporting of diagnostic accuracy

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INTRODUCTION

Diagnostic tests are indispensable in clinical practice as they inform clinicians about the likelihood that a patient has the suspected target disease or condition and guide subsequent decisions on further testing or treatment [1]. Accuracy is an important feature of any diagnostic testing, and diagnostic accuracy is evaluated by comparing results of the test of interest (index test) with those of a reference standard in a series of patients suspected of having a target condition. The results are typically expressed in measures, such as sensitivity and specificity, positive and negative predictive values, likelihood ratios, and area under the receiver operating characteristic (ROC) curve [2-4]. Diagnostic accuracy studies are at risk of several types of bias, which

is a systematic difference in an observed measurement from the true value [5]. Major sources of bias in diagnostic accuracy studies include methodological deficiencies in participant selection and applicability, data collection, test execution and interpretation, and data analysis [5, 6]. In addition, diagnostic accuracy studies are often not reported completely [7], which hinders a reader's ability to evaluate the risk of bias and to determine the generalizability of the study findings, and limits reproducibility.

In 2003, Standards for Reporting of Diagnostic Accuracy (STARD), composed of a list of 25 essential items that should be reported in every study report, were published to increase the transparency and completeness of reporting diagnostic accuracy studies [8, 9]. STARD are general guidelines designed to be applied to all types of diagnostic accuracy studies rather than focusing on specific issues or categories of medical tests [2-4]. This includes prognostic studies that could classify patients based on future events, monitoring studies that require testing to detect or predict an adverse event or lack of response, and studies that assess treatment selection markers [2-4]. The STARD initiative has been adopted by more than 200 journals, spanning basic research to medicine [5]. In 2015, the STARD guidelines were updated [2-4], and the essential items were increased to 30. The new standard covers the title (item 1), abstract (item 2), introduction (items 3 and 4), methods (items 5–18), results (items 19–25), and discussion (items 26 and 27), and requires additional information (items 28–30) about the study protocol and funding sources [2-4]. Since the publication of STARD, several evaluations have shown modest improvements in reporting diagnostic accuracy research [10-12].

Annals of Laboratory Medicine (ALM; ISSN 2234-3806) is the official journal of Korean Society for Laboratory Medicine and is indexed both in Medline and PubMed [13]. Since its name was changed from *Korean Journal of Laboratory Medicine* (ISSN 1598-6535) to ALM in 2012, it has consistently published numerous articles in various fields, including diagnostic hematology, clinical chemistry, clinical microbiology, diagnostic immunology, transfusion medicine, diagnostic genetics, laboratory informatics, and general laboratory medicine [13]. However, STARD have not been included in the instructions for authors by ALM.

The level of adherence of laboratory diagnostic accuracy studies to STARD 2015 is unknown in Korea. Assessing the basic status of adherence to STARD is critical and would enable us to determine and improve existing deficiencies. Thus, this study aimed to evaluate adherence of diagnostic accuracy studies published in ALM from inception in 2012 to 2018 to STARD 2015.

MATERIALS AND METHODS

Study selection

This was a cross-sectional study that evaluated all research papers published in ALM between 2012 and 2018 without distinguishing publication before or after STARD 2015 announcement. Studies for assessing the adherence to STARD 2015 were selected if they met the following inclusion criteria: (1) the diagnostic accuracy of one or more laboratory index tests was evaluated against a reference standard in human subjects and (2) at least one estimate of diagnostic accuracy, such as sensitivity, specificity, positive and negative predictive values, and ROC curve, was reported. We excluded studies, in which the index test or reference standard test was not clear, studies that compared index tests, studies that verified analytical performance, multivariable prediction model study, and letters. Two authors (M.A.J. and B.K.) independently screened the titles and abstracts of all the retrieved studies to evaluate their potential relevance. The full texts of all potentially relevant studies were assessed in duplicate. If an article was considered potentially eligible by at least one author, the full text was assessed independently by both authors against the inclusion criteria. Disagreements were discussed and resolved in consensus meetings.

Seven hundred thirty studies were published in ALM between 2012 and 2018, of which 352 were deemed potentially eligible after screening (Fig. 1). The excluded articles were letters (N=232), case reports or series (N=111), review articles (N=29), editorials (N=5), or guidelines (N=1). After reviewing the full texts, 66 (9.0%, 66/730) diagnostic accuracy studies were included in the final analysis (Supplemental Data Table S1). The selection process is illustrated in Fig. 1.

Adherence to STARD 2015

The STARD 2015 list consists of 30 essential items grouped in six sections: title and abstract, introduction, methods, results, discussion, and other information [2-4]. Several STARD 2015 items have more than one sub-item. For example, item 2 (structured abstract) is divided into 10 sub-items (2a, identification as a diagnostic accuracy study; 2b, study objectives; 2c, data collection; 2d, eligibility criteria; 2e, selection of participants; 2f, description of the index test and reference standard; 2g, numbers of participants with and without the target condition; 2h, estimates of diagnostic accuracy and precision; 2i, general interpretation of the results; and 2j, implications for practice) [14] that are scored independently. Items 10, 12, and 13 on the methods section comprise two sub-items applicable to the index test

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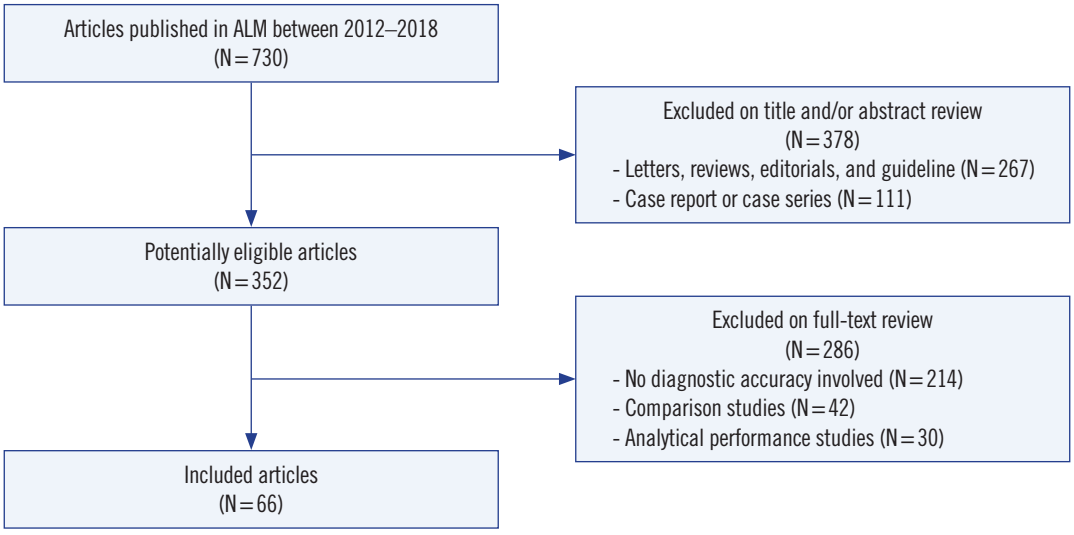

Fig. 1. Flow chart showing the selection procedure for diagnostic accuracy study reports published in Annals of Laboratory Medicine (ALM) between 2012 and 2018 in this study.

(10a, 12a, and 13a) and to the reference standard (10b, 12b, and 13b). Among them, sub-items 12a and 12b on test result cut-off or category are further subdivided into more specific items for definition and rationale (12a, definition; 12a, rationale; 12b, definition; and 12b, rationale). In addition to the above items, we identified potentially relevant contents in an item that might be helpful when analyzed in detail. For example, item 3 (scientific and clinical background in the introduction) was divided into two sub-items (3a for intended use and 3b for clinical role of index test) for more detailed analysis.

Fulfillment of an item was recorded as 1 point. Items with multiple sub-items were scored with fractional points for each sub-item, adding up to a maximum total of 1 point. For example, the 10 sub-items of item 2 were recorded as 0.1 point each. Thus, the total maximum score was 30 points (i.e. it ranged from 0 – none of the items sufficiently reported, to 30 – all items sufficiently reported). Data analysis and the scoring method largely followed practices established in similar previous studies [10, 15, 16]. Detailed descriptions of compliance with STARD 2015 are given in Supplemental Data Table S2.

Each study was evaluated by two independent authors (M.A.J. and B.K.). To ensure high agreement among authors on each item, they first received an educational session on reviewing STARD 2015 and related literature. We referred to a document providing an explanation and elaboration of STARD 2015 for a detailed rationale behind the rating of each item [17]. Before STARD scoring, we conducted pilot scoring on three diagnostic accuracy studies, and refined the description of each item and prepared a final data extraction form based on several discussions. Discrepancies between the two authors were resolved through discussions in consensus meetings and during a final review by a third expert (Y.K.L).

Statistical analysis

The overall mean number of STARD items reported were determined. The two authors' (M.A.J. and B.K.) agreement on compliance with the assessment for STARD 2015 was evaluated based on Cohen's kappa coefficient as follows: <0.00, poor; 0.00–0.20, slight; 0.21–0.40, fair; 0.41–0.60, moderate; 0.61–0.80, substantial; and 0.81–1.00, almost perfect [18]. One-way analysis of variance was used to compare fulfilled STARD items of the diagnostic accuracy studies published in ALM by year. Statistical analysis was conducted using SPSS Statistics for Windows version 25.0 (IBM Corp., Armonk, NY, USA). A two-sided $P<0.05$ was considered statistically significant.

RESULTS

Overall adherence to STARD 2015

Characteristics of the articles included for final analysis are summarized in Table 1. The overall mean (SD) number of STARD item for the 66 diagnostic accuracy studies in ALM was 11.2±2.7 (Table 1). Inter-author agreement in compliance assessment for STARD 2015 was almost perfect, with a kappa value of 0.9. Only five (7.6%) studies reported more than 50% of the 30 items (total fulfilled STARD items>15). No study satisfied more than 80%

Table 1. Characteristics of diagnostic accuracy studies published in ALM between 2012 and 2018 and adherence to STARD 2015

Characteristic	Number (%) of studies	Mean STARD items reported (±SD)
Total	66 (100.0)	11.2±2.7
Discipline category		
Clinical microbiology	37 (56.1)	10.1±2.3
Diagnostic immunology	11 (16.7)	12.2±2.2
Clinical chemistry	8 (12.1)	14.6±2.0
Diagnostic hematology	7 (10.6)	11.6±2.0
General laboratory medicine	2 (3.0)	13.0±2.1
Diagnostic genetics	1 (1.5)	NA
Publication type		
Original article	55 (83.3)	11.5±2.7
Brief communication	11 (16.7)	9.9±2.2
Publication year		
2012	8 (12.1)	10.2±2.1
2013	10 (15.2)	11.3±2.3
2014	7 (10.6)	9.9±2.3
2015	12 (18.2)	10.2±2.4
2016	7 (10.6)	11.5±3.4
2017	10 (15.2)	11.6±2.4
2018	12 (18.2)	13.1±2.9

Abbreviations: ALM, Annals of Laboratory Medicine; NA, not applicable; STARD, Standards for Reporting of Diagnostic Accuracy.

of the items (total fulfilled STARD items>24). The fulfilled number of STARD items were not significantly different from year to year.

Item-specific adherence to STARD 2015

Item-by-item adherence of the 66 diagnostic accuracy studies in ALM to the STARD 2015 is summarized in Table 2. Overall, adherence to STARD 2015 for each item varied widely, ranging from 0% to 100%. Eleven items or sub-items were reported in more than 80% of the studies: title or abstract (item 1), abstract (items 2a, 2b, 2i, and 2j), introduction (items 3a and 4a), methods (items 8b and 10a), results (item 24), and discussion (item 27a). Three of these items were reported in all studies (items 2b, 3a, and 4a).

Conversely, 23 STARD items or sub-items were adhered to <30% of the studies: abstract (items 2c, 2e, and 2h), introduction (items 3b and 4b), methods (items 6, 7, 12b, 13a, 13b, 15, 16, 17, and 18), results (items 19, 20, 21a, 21b, 22, and 25), discussion (item 27b), and other information (items 28 and 29). None of the studies showed adherence to items 13a, 16, or 25.

DISCUSSION

We investigated the adherence of diagnostic accuracy studies published in ALM between 2012 and 2018 to STARD 2015. The reporting quality of diagnostic accuracy studies was suboptimal, with an overall STARD adherence of only 37.3% (11.2/30 items) and high variability across items.

In comparison with previous assessments of adherence to STARD 2015, the average number of STARD items reported in the current study is low. In 2017, Michelessi, *et al*. [19] reported an adherence of 54.1% (16.8/31 items) in studies on glaucoma. In 2018, Hong, *et al*. [20] reported a higher adherence in their evaluation of imaging studies assessing accuracy (55.3%, 16.6/30 items) [20]. A systematic review of 90 laboratory diagnostic accuracy studies on tuberculosis, malaria, and HIV revealed an overall STARD adherence of 54.4% (13.6/25 items) [11, 21]. Another study of imaging and laboratory diagnostic accuracy studies revealed a high adherence rate of 61.2% (15.3/25 items) [10]. Choi, *et al*. [16] identified a substantially higher adherence among 63 imaging studies (74%, 20/27 items). Therefore, we believe that differences in research fields do not explain differences in adherence to STARD. Rather, we hypothesize that the fact that ALM does not require authors to adhere to STARD accounts for the low adherence observed in the current study. Previous studies have shown that the numbers of reported STARD items are higher in STARD-adopting than those in non-adopting journals [10, 20].

Several STARD items have been infrequently reported and are in need of improvement. In the introduction of a scientific study, the authors should describe the intended use and clinical role of the index test under evaluation (items 3a and 3b), and study objectives and testable hypotheses (items 4a and 4b). The clinical role of the index test refers to its anticipated position relative to other existing tests, such as a triage, add-on, or replacement [17]. Hypotheses are defined as acceptance criteria for a single test, such as the minimum level of sensitivity or specificity, which guide the calculation of the sample size required for the study [8]. Only 14% and 12% of the diagnostic accuracy studies in ALM properly reported the clinical role of the test and hypothesis, respectively (Table 2). In addition, several items related to participants, such as items 7, 9, 19, 20, 21, and 22, were poorly reported in more than two-thirds of the studies. This information is important because test performance is not fixed and may vary in different settings and among patients with different characteristics [5, 22].

Data analysis was also often poorly reported. For example,

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Table 2. Adherence to individual STARD 2015 items

Report section	Item number and description	Number (%) of studies, N = 66
Title or abstract	1. Identification as a diagnostic accuracy test	60 (91)
Abstract	2a. Identification as diagnostic accuracy test	60 (91)
	2b. Study objectives	66 (100)
	2c. Data collection	9 (14)
	2d. Eligibility criteria	27 (41)
	2e. Whether participants formed a consecutive, random, or convenience series	5 (8)
	2f. Description of the index test and reference standard	50 (76)
	2g. Numbers of participants with and without the target condition	27 (41)
	2h. Estimates of diagnostic accuracy and precision	14 (21)
	2i. General interpretation of the results	65 (98)
	2j. Implications for practice, including the intended uses of the index test	62 (94)
Introduction	3a. Intended use of the index test	66 (100)
	3b. Clinical role of the index test	9 (14)
	4a. Study objectives	66 (100)
	4b. Hypotheses	8 (12)
Methods	5. Data collection (prospective or retrospective)	25 (38)
	6. Eligibility criteria	20 (30)
	7. On what basis potentially eligible participants were identified	13 (20)
	8a. Study location	52 (79)
	8b. Study dates	59 (89)
	9. Participant sampling (consecutive, random, or convenience)	21 (32)
	10a. Details to allow replication of the index test	53 (80)
	10b. Details to allow replication of the reference standard	41 (62)
	11. Rationale for choosing the reference standard	34 (52)
	12a. Definition of test positivity cut-offs of the index test	35 (53)
	12a. Rationale for test positivity cut-offs of the index test	24 (36)
	12b. Definition of test positivity cut-offs of the reference standard	32 (48)
	12b. Rationale for test positivity cut-offs of the reference standard	20 (30)
	13a. Blind to the index test	0 (0)
	13b. Blind to the reference standard	1 (2)
	14. Methods for estimating diagnostic accuracy	50 (76)
	15. How indeterminate index test or reference standard results were handled	8 (12)
	16. How missing data were handled	0 (0)
	17. Any analyses for distinguishing pre-specified from exploratory	5 (8)
	18. Intended sample size and how it was determined	3 (5)
Results	19. Flow of participants, using a diagram	3 (5)
	20. Demographics of the participants	20 (30)
	21a. Distribution of severity of disease in those with the target condition	19 (29)
	21b. Distribution of alternative diagnoses in those without the target condition	7 (11)
	22. Time interval between index test and reference standard	6 (9)
	23. Cross tabulation of the index test results	34 (52)
	24. Estimates of diagnostic accuracy and precision	53 (80)
	25. Any adverse events	0 (0)

(*Continued to the next page*)

Table 2. Continued

Report section	Item number and description	Number (%) of studies, N = 66
Discussion	26. Study limitations	40 (61)
	27a. Intended use of the index test	65 (98)
	27b. Clinical role of the index test	15 (23)
Other information	28. Registration number and name of registry	3 (5)
	29. Where the full study protocol can be accessed	3 (5)
	30. Sources of funding and other support; role of funders	43 (65)

Revised schema from STARD 2015 statement [2-4]. The STARD 2015 is released under the Creative Commons CC BY-NC license (http://creativecommons.org/licenses/by-nc/4.0).

handling of indeterminate (item 15) or missing (item 16) data was reported in 12% and 0% of the studies, respectively. Analyses of variability in diagnostic accuracy were reported in only 8% of studies, and only 5% of the studies reported the intended sample size and how it was determined. Indeterminate or missing data are common in all types of biomedical researches [17, 23, 24]. Missing data can occur in index or reference standard testing and pose a challenge when evaluating the performance of a diagnostic test [17]. The source of funding, including the role of the funder (item 30), was reported in 65% of the studies. Frequently, authors did report the source of funding, but did not describe the role of the funder. Registration number and name of registry (item 28) as well as full study protocol details (item 29) were reported in only 5% of the studies.

Diagnostic accuracy studies are sensitive to a number of unique sources of bias [5, 25]. Bias can occur at several stages, including the study population, test protocol, reference standard and verification process, and interpretation and analysis [22, 25, 26]. We identified several common biases in the diagnostic accuracy reports in ALM. First, spectrum bias (related to STARD items 6–9), which arises from differences in demographic features or disease severity, and bias in patient selection occurred frequently [22, 25, 26]. In a study evaluating the performance of a hepatitis C virus (HCV) rapid antibody test, the authors recruited 137 patients diagnosed as having HCV infection and 300 healthy blood donors, and reported a sensitivity of 97.8% and specificity of 100% [27]. We would expect the diagnostic accuracy to be greater in this study because it was conducted in patients with confirmed rather than suspected disease, as the former are encountered more often in practice. Therefore, data obtained from studies in populations with significant differences in disease severity may not be comparable [5].

Second, partial verification bias (data for only a selected sample of patients who underwent the index test are verified by the reference standard, related to STARD items 16 and 19) was also common [22, 25]. For example, in one study, monoplex PCR was used as a reference test for some selected samples (17%, 74/426 samples) that showed discrepancies between two index multiplex PCR tests to detect 16 respiratory viruses [28], indicating partial verification bias. Such a bias might increase the probability of falsely elevated sensitivity and falsely decreased specificity [5]. Third, incorporation bias (the result of the index test is included as a criterion for the reference standard, related to STARD item 11) can be observed at the interpretation stage [5, 25]. For example, in a study on molecular detection of human papillomavirus (HPV), the authors calculated the sensitivity and specificity of each index test based on consensus HPV results between the three index tests [29]. One study reported higher sensitivity and lower specificity in the presence of incorporation bias [30]. In the era of evidence-based medicine, researchers should recognize the importance of biases and try to avoid their common sources. Furthermore, researchers should mention potential sources of bias in the discussion section (related to STARD item 26) to inform the reader of the limitations of their study and to accurately present the results and conclusions of the study [17].

The current study has several limitations: (1) we evaluated only 66 diagnostic accuracy studies, (2) since the articles evaluated were published in a single journal, findings cannot be generalized to reports in other journals, (3) no further analysis was performed on specific features such as study purpose, test areas, markers, instruments, or target conditions, and (4) several STARD 2015 items are open to interpretation and are rather subjective. We tried to minimize this limitation by defining each item in detail, performing pilot exercises, and conducting thorough discussions during consensus meetings. On the other hand, this study has the following strengths: (1) this is the first study to estimate the adherence of laboratory diagnostic accuracy studies published in ALM to STARD 2015 and (2) we analyzed STARD 2015 items in as much detail as possible. For ex-

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ample, STARD for abstract (item 2) encompass a list of 11 essential sub-items [14]. Except for the last sub-item on study registration, the remaining 10 sub-items were analyzed individually, allowing detailed evaluation of which sub-items were aptly adhered to (Table 2).

Taken together, our results show that adherence of diagnostic accuracy studies published in ALM to STARD 2015 is low, and more work and effort are needed to improve the reporting quality of such studies. Our data emphasize the necessity of adopting STARD to enhance the value of future diagnostic accuracy studies to be published in ALM.

AUTHOR CONTRIBUTIONS

Conceptualization: Mi-Ae Jang, Bohyun Kim, and You Kyoung Lee. Data curation & formal analysis: Mi-Ae Jang and Bohyun Kim. Project administration & supervision: You Kyoung Lee. Validation: Mi-Ae Jang, Bohyun Kim, and You Kyoung Lee. Writing–original draft preparation: Mi-Ae Jang and Bohyun Kim. Writing–review & editing: Mi-Ae Jang, Bohyun Kim, You Kyoung Lee. All authors read and approved the final manuscript.

CONFLICTS OF INTEREST

No potential conflicts of interest relevant to this article are reported.

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Supplemental Data Table S1. Complete list of studies included in the current study and their overall STARD adherence

Year	Volume	Page	Type	Specific area	Study title	STARD items
2012	32	23–30	OA	CC	Diagnostic utility of osteocalcin, undercarboxylated osteocalcin, and alkaline phosphatase for osteoporosis in premenopausal and postmenopausal women.	12.0
2012	32	79–81	BC	CM	Evaluation of a new immunochromatographic assay kit for the rapid detection of norovirus in fecal specimens.	10.4
2012	32	133–138	OA	CM	Comparison of sputum and nasopharyngeal swab specimens for molecular diagnosis of *Mycoplasma pneumoniae, Chlamydophila pneumoniae*, and *Legionella pneumophila.*	9.3
2012	32	201–205	OA	CM	Comparison of the AdvanSure human papillomavirus screening real-time PCR, the Abbott RealTime High Risk human papillomavirus test, and the Hybrid Capture human papillomavirus DNA test for the detection of human papillomavirus.	8.1
2012	32	257–263	OA	CM	Evaluation of peptide nucleic acid probe-based real-time PCR for detection of *Mycobacterium tuberculosis* complex and nontuberculous mycobacteria in respiratory specimens.	8.4
2012	32	331–338	OA	DI	Clinical usefulness of cell-based indirect immunofluorescence assay for the detection of aquaporin-4 antibodies in neuromyelitis optica spectrum disorder.	14.3
2012	32	355–358	BC	CM	Evaluation of the Xpert *Clostridium difficile* assay for the diagnosis of *Clostridium difficile* infection.	9.0
2012	32	407–412	OA	CM	Methicillin-resistant *Staphylococcus aureus* in nasal surveillance swabs at an intensive care unit: an evaluation of the LightCycler MRSA advanced test.	10.1
2013	33	34–38	OA	CC	Point of care D-dimer testing in the emergency department: a bioequivalence study.	13.3
2013	33	39–44	OA	CM	Usefulness of a rapid real-time PCR assay in prenatal screening for group B streptococcus colonization.	9.8
2013	33	45–51	OA	DI	Association between elevated pleural interleukin-33 levels and tuberculous pleurisy.	12.8
2013	33	105–110	OA	DH	Role of the neutrophil-lymphocyte count ratio in the differential diagnosis between pulmonary tuberculosis and bacterial community-acquired pneumonia.	14.0
2013	33	174–183	OA	DI	Flow cytometric human leukocyte antigen-B27 typing with stored samples for batch testing.	8.5
2013	33	184–189	OA	DI	Performance evaluation of the OraQuick hepatitis C virus rapid antibody test.	8.6
2013	33	255–260	OA	CM	Comparative evaluation of three chromogenic media combined with broth enrichment and the real-time PCR-based Xpert MRSA assay for screening of methicillin-resistant *Staphylococcus aureus* in nasal swabs.	11.3
2013	33	326–330	OA	CM	Evaluation of vancomycin resistance 3 multiplexed PCR assay for detection of vancomycin-resistant enterococci from rectal swabs.	8.6
2013	33	420–425	OA	DI	Reduction of the HIV seroconversion window period and false positive rate by using ADVIA Centaur HIV antigen/antibody combo assay.	11.5
2013	33	449–454	OA	GLM	Procalcitonin and C-reactive protein in the diagnosis and prediction of spontaneous bacterial peritonitis associated with chronic severe hepatitis B.	14.5
2014	34	51–55	BC	CM	Assessment of the quantitative ability of AdvanSure TB/NTM real-time PCR in respiratory specimens by comparison with phenotypic methods.	7.6
2014	34	85–91	OA	DH	Changes in plasma levels of natural anticoagulants in disseminated intravascular coagulation: high prognostic value of antithrombin and protein C in patients with underlying sepsis or severe infection.	11.0
2014	34	127–133	OA	DG	Clinical validation of AdvanSure GenoBlot assay as primary screening and test of cure for human papillomavirus infection.	7.1
2014	34	203–209	OA	CM	Evaluation of propidium monoazide real-time PCR for early detection of viable *Mycobacterium tuberculosis* in clinical respiratory specimens.	12.1
2014	34	235–239	BC	CM	Evaluation of a rapid membrane enzyme immunoassay for the simultaneous detection of glutamate dehydrogenase and toxin for the diagnosis of *Clostridium difficile* infection.	10.2
2014	34	354–359	OA	CM	Evaluation of the optimal neutrophil gelatinase-associated lipocalin value as a screening biomarker for urinary tract infections in children.	8.5
2014	34	376–379	BC	CM	Performance of chromID *Clostridium difficile* agar compared with BBL *C. difficile* selective agar for detection of *C. difficile* in stool specimens.	13.1
2015	35	28–34	OA	DH	Flow cytometric white blood cell differential using CytoDiff is excellent for counting blasts.	8.6

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Supplemental Data Table S1. Continued

Year	Volume	Page	Type	Specific area	Study title	STARD items
2015	35	35–40	OA	DH	A novel marker for screening paroxysmal nocturnal hemoglobinuria using routine complete blood count and cell population data.	9.9
2015	35	50–56	OA	CM	Highly sensitive and novel point-of-care system, aQcare Chlamydia TRF kit for detecting *Chlamydia trachomatis* by using europium (Eu) (III) chelated nanoparticles.	10.6
2015	35	62–68	OA	CM	Evaluation of matrix-assisted laser desorption ionization-time of flight mass spectrometry-based VITEK MS system for the identification of *Acinetobacter* species from blood cultures: comparison with VITEK 2 and MicroScan systems.	7.7
2015	35	76–81	OA	CM	Evaluation of the iNtRON VRE *vanA/vanB* real-time PCR assay for detection of vancomycin-resistant enterococci.	14.2
2015	35	212–219	OA	CM	Combined use of the modified Hodge test and carbapenemase inhibition test for detection of carbapenemase-producing *Enterobacteriaceae* and metallo-β-lactamase-producing *Pseudomonas* spp.	7.4
2015	35	298–305	OA	CM	Further modification of the modified Hodge test for detecting metallo-β-Lactamase-producing carbapenem-resistant *Enterobacteriaceae*.	11.5
2015	35	306–313	OA	CM	Multiplex teal-time PCR method for simultaneous identification and toxigenic type characterization of *Clostridium difficile* from stool samples.	13.7
2015	35	356–361	BC	CM	Comparison of AdvanSure TB/NTM PCR and COBAS TaqMan MTB PCR for detection of *Mycobacterium tuberculosis* complex in routine clinical practice.	9.2
2015	35	454–457	BC	CM	Direct identification of *Staphylococcus aureus* and determination of methicillin susceptibility from positive blood-culture bottles in a Bact/ALERT system using Binax Now *S. aureus* and PBP2a tests.	13.1
2015	35	487–493	OA	CM	Detection of first-line anti-tuberculosis drug resistance mutations by allele-specific primer extension on a microsphere-based platform.	7.6
2015	35	500–505	OA	CM	Evaluation of dual-color fluorescence in situ hybridization with peptide nucleic acid probes for the detection of *Mycobacterium tuberculosis* and non-tuberculous mycobacteria in clinical specimens.	9.6
2016	36	1–8	OA	DH	Immature platelet fraction in septic patients: clinical relevance of immature platelet fraction is limited to the sensitive and accurate discrimination of septic patients from non-septic patients, not to the discrimination of sepsis severity.	13.5
2016	36	131–137	OA	CM	Evaluation of Xpert *C. difficile*, BD MAX Cdiff, IMDx *C. difficile* for Abbott m2000, and Illumigene *C. difficile* assays for direct detection of toxigenic *Clostridium difficile* in stool specimens.	9.9
2016	36	291–299	OA	DH	Screening PCR versus Sanger sequencing: detection of *CALR* mutations in patients with thrombocytosis.	13.4
2016	36	405–412	OA	CC	Can a point-of-care troponin I assay be as good as a central laboratory assay? A MIDAS investigation	16.8
2016	36	434–440	OA	CM	Disk carbapenemase test for the rapid detection of KPC-, NDM-, and other metallo-β-lactamase-producing gram-negative bacilli	6.8
2016	36	441–449	OA	CM	Analysis of the vaginal microbiome by next-generation sequencing and evaluation of its performance as a clinical diagnostic tool in vaginitis	8.5
2016	36	542–549	OA	DI	Soluble ST2 levels and left ventricular structure and function in patients with metabolic syndrome	12.0
2017	37	28–33	OA	CC	Comparison of urine albumin-to-creatinine ratio (ACR) between ACR strip test and quantitative test in prediabetes and diabetes	14.7
2017	37	39–44	OA	CM	Evaluation of BD MAX Staph SR assay for differentiating between *Staphylococcus aureus* and coagulase-negative Staphylococci and determining methicillin resistance directly from positive blood cultures	10.1
2017	37	53–57	BC	CM	Fecal calprotectin level reflects the severity of *Clostridium difficile* infection	12.0
2017	37	240–247	OA	DI	Performance of an automated fluorescence antinuclear antibody image analyzer	11.9
2017	37	267–271	BC	CM	Comparison of luminex NxTAG respiratory pathogen panel and xTAG respiratory viral panel FAST version 2 for the detection of respiratory viruses	7.2
2017	37	305–312	OA	CM	Evaluation of six phenotypic methods for the detection of carbapenemases in gram-negative bacteria with characterized resistance mechanisms	9.1

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Supplemental Data Table S1. Continued

Year	Volume	Page	Type	Specific area	Study title	STARD items
2017	37	388–397	OA	CC	Proenkephalin, neutrophil gelatinase-associated lipocalin, and estimated glomerular filtration rates in patients with sepsis	14.9
2017	37	484–493	OA	DH	Benefits of thromboelastography and thrombin generation assay for bleeding prediction in patients with thrombocytopenia or hematologic malignancies	11.1
2017	37	494–498	OA	CM	Performance evaluation of the PowerChek MERS (upE & ORF1a) real-time PCR kit for the detection of Middle East respiratory syndrome coronavirus RNA	11.5
2017	37	499–504	OA	CM	Multicenter evaluation of an image analysis device (APAS): comparison between digital image and traditional plate reading using urine cultures	13.5
2018	38	39–45	OA	GLM	Urinary YKL-40 as a candidate biomarker for febrile urinary tract infection in young children	11.5
2018	38	46–50	BC	CM	Evaluation of Allplex respiratory panel 1/2/3 multiplex real-time PCR assays for the detection of respiratory viruses with influenza A virus subtyping	6.8
2018	38	95–101	OA	CC	Evaluation of sFlt-1/PlGF ratio for predicting and improving clinical management of preeclampsia: experience in a specialized perinatal care center	15.4
2018	38	119–124	OA	CM	Comparative evaluation of the loop-mediated isothermal amplification assay for detecting pulmonary tuberculosis	13.6
2018	38	155–159	BC	CM	Prevalence of *blaZ* gene and performance of phenotypic tests to detect penicillinase in *Staphylococcus aureus* isolates from Japan	10.0
2018	38	306–315	OA	CC	Galectin-3 reflects the echocardiographic grades of left ventricular diastolic dysfunction	17.6
2018	38	331–337	OA	DI	Usefulness of enhanced liver fibrosis, glycosylation isomer of Mac-2 binding protein, galectin-3, and soluble suppression of tumorigenicity 2 for assessing liver fibrosis in chronic liver diseases	15.5
2018	38	348–354	OA	DI	Diagnosis of liver fibrosis with *Wisteria floribunda* agglutinin-positive Mac-2 binding protein (WFA-M2BP) among chronic hepatitis B patients	12.3
2018	38	425–430	OA	CC	Plasma neutrophil gelatinase-associated lipocalin as a predictor of renal parenchymal involvement in infants with febrile urinary tract infection: A preliminary study	12.3
2018	38	466–472	OA	DI	The role of the signal-to-cutoff ratio in automated anti-HCV chemiluminescent immunoassays by referring to the nucleic acid amplification test and the recombinant immunoblot assay	14.0
2018	38	569–577	OA	CM	Detection of rifampicin- and isoniazid-resistant *Mycobacterium tuberculosis* using the quantamatrix multiplexed assay platform system	15.6
2018	38	578–584	OA	DI	Development of a rapid automated fluorescent lateral flow immunoassay to detect hepatitis B surface antigen (HBsAg), antibody to HBsAg, and antibody to Hepatitis C	13.0

Abbreviations: BC, Brief Communication; CC, Clinical Chemistry; CM, Clinical Microbiology; DG, Diagnostic Genetics; DH, Diagnostic Hematology; DI, Diagnostic Immunology; GLM, General Laboratory Medicine; HCV, hepatitis C virus; MERS, Middle East respiratory syndrome coronavirus; MRSA, methicillin-resistant *Staphylococcus aureus*; MTB, *Mycobacterium tuberculosis*; OA, Original Article; sFlt-1/PlGF, soluble fms-like tyrosine kinase 1/placental growth factor; STARD, Standards for Reporting of Diagnostic Accuracy; TB/NTM, tuberculosis/non-tuberculous mycobacterium; TRF, time-resolved fluorescence; VRE, vancomycin-resistant enterococci.

Supplemental Data Table S2. Lists of STARD 2015 items with associated criteria for determining adherence

Section	Item	Criteria for yes/no
Title or abstract	1. Identification as a study of diagnostic accuracy using at least one measure of accuracy (such as sensitivity, specificity, predictive values, or AUC).	Yes: accuracy, sensitivity, specificity, predictive values, or AUC is mentioned in the title or abstract No: not reported
Abstract	2a. Identification as diagnostic accuracy test	Yes: accuracy, sensitivity, specificity, predictive values or AUC is mentioned in the abstract. No: not reported
	2b. Study objectives	Yes: as explained No: not reported
	2c. Data collection whether this was a prospective or retrospective study	Yes: prospective or retrospective is mentioned No: not reported
	2d. Eligibility criteria for participants and settings where the data were collected	Yes: inclusion criteria for participants and the place where the study was conducted are reported No: not reported
	2e. Whether participants formed a consecutive, random, or convenience series	Yes: consecutive, random, or convenience series is mentioned No: not reported
	2f. Description of the index test and reference standard	Yes: as explained No: not reported
	2g. Numbers of participants with and without the target condition	Yes: as explained No: not reported
	2h. Estimates of diagnostic accuracy and their precision (such as 95% confidence intervals)	Yes: 95% confidence intervals are reported No: not reported
	2i. General interpretation of the results	Yes: as explained No: not reported
	2j. Implications for practice, including the intended uses of the index test	Yes: as explained No: not reported
	2k. Registration number and name of registry	Not considered in this study
Introduction	3a. Scientific and clinical background - intended use of index test	Yes: diagnosis, screening, staging, monitoring, surveillance, prognosis, treatment selection, or other purpose is reported No: not reported
	3b. Scientific and clinical background - clinical role of index test	Yes: replacement, triage, or add-on or other clinical role is reported No: not reported
	4a. Study objectives	Yes: as explained No: not reported
	4b. Study hypotheses	Yes: statistical acceptability criteria reported quantitatively or the statistical equality or non-inferiority among two or more index tests is mentioned No: not reported

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Supplemental Data Table S2. Continued

Section	Item	Criteria for yes/no
Methods	5. Whether data collection was planned before the index test and reference standard were performed (prospective study) or after (retrospective study)	Yes: prospective or retrospective is mentioned No: not reported
	6. Eligibility criteria	Yes: detailed diagnostic criteria of target disease or condition for, including participants, setting, and location of data collection, are reported No: neither or either reported
	7. On what basis potentially eligible participants were identified (such as symptoms, results from previous tests, inclusion in registry).	Yes: methods for identifying eligible participants, such as clinical examination, results from previous tests, or inclusion in registry of hospital database, are reported No: not reported
	8a. Where potentially eligible participants were identified	Yes: as explained No: not reported
	8b. When potentially eligible participants were identified	Yes: as explained No: not reported
	9. Whether participants formed a consecutive, random or convenience series	Yes: as explained No: not reported
	10a. Index test, in sufficient detail to allow replication	Yes: detailed methods for index and reference tests, including pre-analytical, analytical and post-analytical phase, are reported No: not reported
	10b. Reference standard, in sufficient detail to allow replication	
	11. Rationale for choosing the reference standard	Yes: reason or reference for choosing the reference standard is reported No: not reported
	12a. Definition of test positivity cut-offs or result categories of the index test	Yes: as explained No: not reported
	12a. Rationale for test positivity cut-offs or result categories of the index test	Yes: rationale, such as previous studies, cut-offs used in clinical practice, thresholds recommended by clinical practice guidelines or thresholds recommended by manufacturer, is reported No: not reported
	12b. Definition of test positivity cut-offs or result categories of the reference standard	Yes: as explained No: not reported
	12b. Rationale for test positivity cut-offs or result categories of the reference standard	Yes: rationale, such as previous studies, cut-offs used in clinical practice, thresholds recommended by clinical practice guidelines or thresholds recommended by manufacturer, is reported No: not reported
	13a. Whether clinical information and reference standard results were available to the performers or readers of the index test	Yes: information about blinding or masking is reported No: not reported
	13b. Whether clinical information and index test results were available to the assessors of the reference standard	
	14. Methods for estimating or comparing measures of diagnostic accuracy	Yes: as explained No: not reported
	15. How indeterminate index test or reference standard results were handled	Yes: as explained No: not reported

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Supplemental Data Table S2. Continued

Section	Item	Criteria for yes/no
	16. How missing data on the index test and reference standard were handled	Yes: as explained No: not reported
	17. Any analyses of variability in diagnostic accuracy distinguishing prespecified from exploratory	Yes: differences in accuracy across subgroups of participants, readers or centers are reported No: not reported
	18. Intended sample size and how it was determined	Yes: as explained No: not reported
Results	19. Flow of participants, using a diagram	Yes: as explained No: not reported
	20. Baseline demographic and clinical characteristics of participants	Yes: as explained No: not reported
	21a. Distribution of severity of disease in those with the target condition	Yes: severity of target disease or condition based on any classification system is reported No: not reported
	21b. Distribution of alternative diagnoses in those without the target condition	Yes: type, spectrum, and frequency of alternative diagnoses in those without the target condition are reported No: not reported
	22. Time interval and any clinical interventions between index test and reference standard	Yes: as explained No: not reported
	23. Cross tabulation of the index test results (or their distribution) by the results of the reference standard	Yes: cross tabulation is reported No: not reported
	24. Estimates of diagnostic accuracy and their precision (such as 95% CIs)	Yes: 95% confidence intervals are reported No: not reported
	25. Any adverse events from performing the index test or the reference standard	Yes: as explained No: not reported
Discussion	26. Study limitations, including sources of potential bias, statistical uncertainty and generalizability	Yes: one or more limitations are reported No: not reported
	27a. Implications for practice - intended use of the index test	Yes: diagnostic purposes, for susceptibility, screening, risk stratification, staging, prediction, prognosis, treatment selection, monitoring, surveillance or other purpose is mentioned. No: not reported
	27b. Implications for practice - clinical role of the index test	Yes: index test's positioning relative to existing tests for the same purpose, within the same clinical setting (triage, add-on, or replacement) is mentioned No: not reported
Other information	28. Registration number and name of registry	Yes: as explained No: not reported
	29. Where the full study protocol can be accessed	Yes: as explained No: not reported
	30. Sources of funding and other support; role of funders	Yes: acknowledgement is present No: not reported

Revised schema from STARD 2015 statement [2-4]. The STARD 2015 is released under the Creative Commons CC BY-NC license (http://creativecommons.org/licenses/by-nc/4.0).
Abbreviation: AUC, area under the receiver operating characteristic curve.