

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

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Royalties: Funds are coming in to you or your institution due to your patent

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Section 1. Identifying Information

1. Given Name (First Name) Brian	2. Surname (Last Name) Kidd	3. Date 04-February-2016
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name Joel T. Dudley
5. Manuscript Title Evaluation of Direct-to-Consumer Low-Volume Lab Tests in Healthy Adults		
6. Manuscript Identifying Number (if you know it) 86318-JCI-CMED-RV-2		

Section 2. The Work Under Consideration for Publication

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1. Given Name (First Name) Samir	2. Surname (Last Name) Parekh	3. Date 05-February-2016
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name Joel Dudley
5. Manuscript Title Evaluation of Direct-to-Consumer Low-Volume Lab Tests in Healthy Adults		
6. Manuscript Identifying Number (if you know it)		

Section 2. The Work Under Consideration for Publication

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1. Given Name (First Name)
Patricia

2. Surname (Last Name)
Glowe

3. Date
04-February-2016

4. Are you the corresponding author?

Yes No

Corresponding Author's Name
Joel T Dudley

5. Manuscript Title
Evaluation of Direct-to-Consumer Low-Volume Lab Tests in Healthy Adults

6. Manuscript Identifying Number (if you know it)
86318-JCI-CMED-RV-2

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Joel T Dudley

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Nicolina

2. Surname (Last Name)
Babic

3. Date
05-February-2016

4. Are you the corresponding author?

Yes No

Corresponding Author's Name
Joel Dudley

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4. Intellectual Property.

This section asks about patents and copyrights, whether pending, issued, licensed and/or receiving royalties.

5. Relationships not covered above.

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Other: Anything not covered under the previous three boxes

Pending: The patent has been filed but not issued

Issued: The patent has been issued by the agency

Licensed: The patent has been licensed to an entity, whether earning royalties or not



ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name) Matthew	2. Surname (Last Name) Doust	3. Date 05-February-2016
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name Joel Dudley
5. Manuscript Title Evaluation of Direct-to-Consumer Low-Volume Lab Tests in Healthy Adults		
6. Manuscript Identifying Number (if you know it)		

Section 2. The Work Under Consideration for Publication

Did you or your institution **at any time** receive payment or services from a third party (government, commercial, private foundation, etc.) for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.)?

Are there any relevant conflicts of interest? Yes No

Section 3. Relevant financial activities outside the submitted work.

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Are there any relevant conflicts of interest? Yes No

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? Yes No



ICMJE Form for Disclosure of Potential Conflicts of Interest

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Are there other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work?

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Section 6. Disclosure Statement

Based on the above disclosures, this form will automatically generate a disclosure statement, which will appear in the box below.

Dr. Doust has nothing to disclose.

Evaluation and Feedback

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Royalties: Funds are coming in to you or your institution due to your patent

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Li _____

2. Surname (Last Name)

Li _____

3. Date

05-February-2016 _____

4. Are you the corresponding author?

Yes No

Corresponding Author's Name

Joel Dudley _____

5. Manuscript Title

Evaluation of Direct-to-Consumer Low-Volume Lab Tests in Healthy Adults _____

6. Manuscript Identifying Number (if you know it)

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Are there any relevant conflicts of interest? Yes No

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Are there any relevant conflicts of interest? Yes No

Section 4. Intellectual Property -- Patents & Copyrights

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Dr. Li has nothing to disclose.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)
Joseph

2. Surname (Last Name)
Morgan

3. Date
04-February-2016

4. Are you the corresponding author? Yes No
Corresponding Author's Name
Joel Dudley

5. Manuscript Title
Evaluation of Direct-to-Consumer Low-Volume Lab Tests in Healthy Adults

6. Manuscript Identifying Number (if you know it)

Section 2. The Work Under Consideration for Publication

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Are there any relevant conflicts of interest? Yes No

Section 3. Relevant financial activities outside the submitted work.

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Are there any relevant conflicts of interest? Yes No

If yes, please fill out the appropriate information below.

Name of Entity	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
The Mount Sinai School of Medicine	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Harris Center for Precision Wellness

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? Yes No

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 5. Relationships not covered above

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Dr. Morgan reports personal fees from The Mount Sinai School of Medicine, outside the submitted work; .

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name)

Joel

2. Surname (Last Name)

Dudley

3. Date

04-February-2016

4. Are you the corresponding author?

Yes No

5. Manuscript Title

Evaluation of Direct-to-Consumer Low-Volume Lab Tests in Healthy Adults

6. Manuscript Identifying Number (if you know it)

86318-JCI-CMED-RV-2

Section 2. The Work Under Consideration for Publication

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Are there any relevant conflicts of interest? Yes No

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Dr. Dudley has nothing to disclose.

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ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name) Gregory 2. Surname (Last Name) Botwin 3. Date 05-February-2016

4. Are you the corresponding author? Yes No Corresponding Author's Name
Joel Dudley and Eric Schadt

5. Manuscript Title
Evaluation of Direct-to-Consumer Low-Volume Lab Tests in Healthy Adults

6. Manuscript Identifying Number (if you know it)

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Are there any relevant conflicts of interest? Yes No

If yes, please fill out the appropriate information below. If you have more than one entity press the "ADD" button to add a row. Excess rows can be removed by pressing the "X" button.

Name of Institution/Company	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments
Harris Family Charitable Foundation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Gift
National Institutes of Health	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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Mr. Botwin reports other from Harris Family Charitable Foundation, grants from National Institutes of Health , during the conduct of the study; .

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Licensed: The patent has been licensed to an entity, whether earning royalties or not

ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information

1. Given Name (First Name) Gabriel	2. Surname (Last Name) Hoffman	3. Date 04-February-2016
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name Joel T Dudley
5. Manuscript Title Evaluation of Direct-to-Consumer Low-Volume Lab Tests in Healthy Adults		
6. Manuscript Identifying Number (if you know it) 86318-JCI-CMED-RV-2		

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Are there any relevant conflicts of interest? Yes No

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Are there any relevant conflicts of interest? Yes No

Section 4. Intellectual Property -- Patents & Copyrights

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Dr. Hoffman has nothing to disclose.

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3. Relevant financial activities outside the submitted work.

This section asks about your financial relationships with entities in the bio-medical arena that could be perceived to influence, or that give the appearance of potentially influencing, what you wrote in the submitted work. You should disclose interactions with ANY entity that could be considered broadly relevant to the work. For example, if your article is about testing an epidermal growth factor receptor (EGFR) antagonist in lung cancer, you should report all associations with entities pursuing diagnostic or therapeutic strategies in cancer in general, not just in the area of EGFR or lung cancer.

Report all sources of revenue paid (or promised to be paid) directly to you or your institution on your behalf over the 36 months prior to submission of the work. This should include all monies from sources with relevance to the submitted work, not just monies from the entity that sponsored the research. Please note that your interactions with the work's sponsor that are outside the submitted work should also be listed here. If there is any question, it is usually better to disclose a relationship than not to do so.

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Definitions.

Entity: government agency, foundation, commercial sponsor, academic institution, etc.

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Personal Fees: Monies paid to you for services rendered, generally honoraria, royalties, or fees for consulting, lectures, speakers bureaus, expert testimony, employment, or other affiliations

Non-Financial Support: Examples include drugs/equipment supplied by the entity, travel paid by the entity, writing assistance, administrative support, etc.

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Section 1. Identifying Information

1. Given Name (First Name) Gregory	2. Surname (Last Name) Stock	3. Date 05-February-2016
4. Are you the corresponding author?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Corresponding Author's Name Joel Dudley
5. Manuscript Title Evaluation of Direct-to-Consumer Low-Volume Lab Tests in Healthy Adults		
6. Manuscript Identifying Number (if you know it)		

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Are there any relevant conflicts of interest? Yes No

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Are there any relevant conflicts of interest? Yes No

Section 4. Intellectual Property -- Patents & Copyrights

Do you have any patents, whether planned, pending or issued, broadly relevant to the work? Yes No



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Licensed: The patent has been licensed to an entity, whether earning royalties or not

Royalties: Funds are coming in to you or your institution due to your patent



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Section 1. Identifying Information

1. Given Name (First Name)
Eric

2. Surname (Last Name)
Schadt

3. Date
04-February-2016

4. Are you the corresponding author? Yes No

5. Manuscript Title
Evaluation of Direct-to-Consumer Low-Volume Lab Tests in Healthy Adults

6. Manuscript Identifying Number (if you know it)
86318-JCI-CMED-RV-2

Section 2. The Work Under Consideration for Publication

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