

1 **ONLINE SUPPLEMENT**

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3 Sensitivity of C-Tb – a Novel RD-1-Specific Skin Test for the Diagnosis of TB Infection

4 Authors

5 Soren T. Hoff², Jonathan G. Peter¹, Grant Theron¹, Mellissa Pascoe¹, Pernille N. Tingskov³,
6 Henrik Aggerbeck³, Daniel Kolbus³, Morten Ruhwald², Peter Andersen^{2*} Keertan Dheda^{1*}

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8 Author affiliations

9 ¹Lung Infection and Immunity Unit, Division of Pulmonology & UCT Lung Institute, Department
10 of Medicine, University of Cape Town, Cape Town, South Africa.

11 ² Statens Serum Institut, Department of Infectious Diseases immunology, Copenhagen,
12 Denmark

13 ³Statens Serum Institut, Department of Vaccine Development, Copenhagen, Denmark

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15 *Corresponding authors. For questions regarding this trial specifically, please contact Professor
16 Keertan Dheda. For questions regarding C-Tb in general, please contact Professor Peter
17 Andersen.

18 Professor Keertan Dheda, H47 Old Main Building, Groote Schuur Hospital, Observatory, 7925,
19 South Africa. Phone: +27214046509; Fax: +27214047651; E-mail: keertan.dheda@uct.ac.za.

20 Professor Peter Andersen, Statens Serum Institut, Artillerivej 5, 2300 Copenhagen S, Denmark.

21 Phone: +45 3268 3462, E-mail: PA@ssi.dk

| All, N=241 | | | | HIV-uninfected, N=146 | | | | HIV-infected, N=95 | | | |
|------------|-----------|--------|------------|-----------------------|-----------|--------|-----------|--------------------|------------|--------|-----------|
| C-Tb * | TST ** | QFT-GI | N (%) | C-Tb * | TST ** | QFT-GI | N (%) | C-Tb * | TST *** | QFT-GI | N (%) |
| + | + | + | 144 (59.8) | + | + | + | 87 (59.6) | + | + | + | 57 (60.0) |
| + | + | - | 16 (6.6) | + | + | - | 12 (8.2) | + | + | - | 4 (4.2) |
| + | + | ind | 13 (5.4) | + | + | ind | 9 (6.2) | + | + | ind | 4 (4.2) |
| + | - | + | 5 (2.1) | + | - | + | 4 (2.7) | + | - | + | 1 (1.1) |
| + | - | - | 0 (0.0) | + | - | - | 0 (0.0) | + | - | - | 0 (0.0) |
| + | - | ind | 0 (0.0) | + | - | ind | 0 (0.0) | + | - | ind | 0 (0.0) |
| - | + | + | 19 (7.9) | - | + | + | 14 (9.6) | - | + | + | 5 (5.3) |
| - | + | - | 16 (6.6) | - | + | - | 8 (5.5) | - | + | - | 8 (8.4) |
| - | + | ind | 4 (1.7) | - | + | ind | 3 (2.1) | - | + | ind | 1 (1.1) |
| - | - | + | 13 (5.4) | - | - | + | 7 (4.8) | - | - | + | 6 (6.3) |
| - | - | - | 9 (3.7) | - | - | - | 1 (0.7) | - | - | - | 8 (8.4) |
| - | - | ind | 2 (0.8) | - | - | ind | 1 (0.7) | - | - | ind | 1 (1.1) |

*C-Tb cut-point ≥ 5 mm in all participants, ** TST cut-point ≥ 15 mm in HIV-uninfected participants,
*** TST cut-point ≥ 5 mm in HIV-infected participants.
ind: indeterminate QFT-GIT result

23 **TABLE S5 (online supplement).** Number of patients that were positive by C-Tb and/or TST

24 and/or QFT-GIT.

| All, N=241 | | | HIV-uninfected, N=146 | | | HIV-infected, N=95 | | | | | |
|--|--------|--------|--|----------|--------|---|--------|----------|----|----|----|
| | TST pc | TST ne | | TST pc | TST ne | | TST pc | TST ne | | | |
| C-Tb pos | 173 | 5 | 178 | C-Tb pos | 108 | 4 | 112 | C-Tb pos | 65 | 1 | 66 |
| C-Tb neg | 39 | 24 | 63 | C-Tb neg | 25 | 9 | 34 | C-Tb neg | 14 | 15 | 29 |
| | 212 | 29 | 241 | | 133 | 13 | 146 | | 79 | 16 | 95 |
| McNemar's test: p< 0.0001 Agreement: 0.82 | | | McNemar's test: p= 0.0002 Agreement: 0.80 | | | McNemar's test: p= 0.002 Agreement: 0.84 | | | | | |

25 **TABLE S6A (Online supplement).** C-Tb versus TST (TST cut-points: HIV- ≥ 15 mm, HIV+ 5 mm)

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| All, N=241 | | | HIV-uninfected, N=146 | | | HIV-infected, N=95 | | | | | |
|--|--------|--------|--|----------|--------|---|--------|----------|----|----|----|
| | TST pc | TST ne | | TST pc | TST ne | | TST pc | TST ne | | | |
| C-Tb pos | 174 | 4 | 178 | C-Tb pos | 110 | 2 | 112 | C-Tb pos | 64 | 2 | 66 |
| C-Tb neg | 41 | 22 | 63 | C-Tb neg | 27 | 7 | 34 | C-Tb neg | 14 | 15 | 29 |
| | 215 | 26 | 241 | | 137 | 9 | 146 | | 78 | 17 | 95 |
| McNemar's test: p< 0.0001 Agreement: 0.81 | | | McNemar's test: p< 0.0001 Agreement: 0.80 | | | McNemar's test: p= 0.006 Agreement: 0.83 | | | | | |

28 **TABLE S6B (Online supplement).** C-Tb versus TST (TST cut-point ≥ 10 mm for all)

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| All, N=241 | | | | HIV-uninfected, N=146 | | | | HIV-uninfected, N=146 | | | | | | |
|---|-------|-------|--------|---|-------|-------|--------|---|-------|-------|--------|----|---|----|
| | QFT + | QFT - | QFT in | | QFT + | QFT - | QFT in | | QFT + | QFT - | QFT in | | | |
| C-Tb+ | 149 | 16 | 13 | 178 | C-Tb+ | 91 | 12 | 9 | 112 | C-Tb+ | 58 | 4 | 4 | 66 |
| C-Tb- | 32 | 25 | 6 | 63 | C-Tb- | 21 | 9 | 4 | 34 | C-Tb- | 11 | 16 | 2 | 29 |
| | 181 | 41 | 19 | 241 | | 112 | 21 | 13 | 146 | | 69 | 20 | 6 | 95 |
| McNemar's test: p= 0.030 Agreement: 0.78 | | | | McNemar's test: p= 0.164 Agreement: 0.75 | | | | McNemar's test: p= 0.121 Agreement: 0.83 | | | | | | |

30 **TABLE S6C (Online supplement).** C-Tb versus QFT-GIT

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| | N | | Mild N (%) E | Moderate N (%) E | Severe N (%) E | Total N (%) E | p-value* |
|----------------|-----|------|-----------------|---------------------|-------------------|------------------|----------|
| All | 253 | C-Tb | 98 (38.7) 184 | 18 (1.6) 34 | 4 (1.6) 10 | 120 (47.4) 228 | 0.0003 |
| | | TST | 127 (50.2) 228 | 19 (7.5) 40 | 4 (1.6) 8 | 150 (59.3) 276 | |
| HIV-uninfected | 153 | C-Tb | 63 (41.2) 115 | 11 (7.2) 22 | 2 (1.3) 4 | 76 (49.7) 141 | 0.0014 |
| | | TST | 86 (56.2) 151 | 9 (5.9) 20 | 2 (1.3) 4 | 97 (63.4) 175 | |
| HIV-infected | 100 | C-Tb | 35 (35.0) 69 | 7 (7.0) 22 | 2 (2.0) 6 | 44 (44.0) 87 | 0.1096 |
| | | TST | 41 (41.0) 77 | 10 (10.0) 20 | 2 (2.0) 4 | 53 (53.0) 101 | |

N= Number of participants experiencing at least one injection site adverse reaction.
E= total number of reported injection site adverse reactions.
*McNemars's test comparing total number of participants experiencing at least one event between C-Tb and TST

32 **Table S7 (Online supplement).** Injection site adverse reactions

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