

Published evidence and commentary on the Xpert MTB/RIF assay

On discordance in rifampicin resistance results compared to other methods

- Van Deun A et al. *Rifampin drug resistance tests for tuberculosis: challenging the gold standard*. J Clin Microbiol. 2013 Aug;51(8):2633-40. doi: 10.1128/JCM.00553-13. Epub 2013 Jun 12.
<http://jcm.asm.org/content/51/8/2633.abstract>
- Rigouts L et al. *Rifampin Resistance Missed in Automated Liquid Culture System for Mycobacterium tuberculosis Isolates with Specific rpoB Mutations*. J Clin Microbiol. 2013 Aug;51(8):2641-5. doi: 10.1128/JCM.02741-12.
<http://jcm.asm.org/content/51/8/2641.abstract>
- Somoskovi A et al. *Inconsistent Results with the Xpert-MTB/Rif Assay in Detection of Mycobacterium tuberculosis with an rpoB Mutation Associated with Low Level of Rifampin Resistance: Diagnostic Implications*. J Clin Microbiol. 2013 Jul 12.
<http://jcm.asm.org/content/early/2013/07/11/JCM.01377-13.abstract>

On impact and cost-effectiveness of the assay

- Kwak N et al. *Diagnostic Accuracy and Turnaround Time of the Xpert MTB/RIF Assay in Routine Clinical Practice*. PLoS One. 2013 Oct 29;8(10):e77456. doi: 10.1371/journal.pone.0077456.
<http://dx.plos.org/10.1371/journal.pone.0077456>
- Theron G et al. *Feasibility, accuracy, and clinical effect of point-of-care Xpert MTB/RIF testing for tuberculosis in primary-care settings in Africa: a multicentre, randomised, controlled trial*. Lancet. 2013 Oct 25. pii: S0140-6736(13)62073-5. doi: 10.1016/S0140-6736(13)62073-5.
[Epub ahead of print]
<http://www.sciencedirect.com/science/article/pii/S0140673613620735>
- Choi HW et al. *Cost-effectiveness of Xpert® MTB/RIF for diagnosing pulmonary tuberculosis in the United States*. Int J Tuberc Lung Dis. 2013 Oct;17(10):1328-35. doi: 10.5588/ijtld.13.0095.
<http://www.ingentaconnect.com/content/iuatld/ijtld/2013/00000017/00000010/art00014>
- Dowdy DW et al. *Population-Level Impact of Same-Day Microscopy and Xpert MTB/RIF for Tuberculosis Diagnosis in Africa*. PLoS One. 2013 Aug 12;8(8):e70485. doi: 10.1371/journal.pone.0070485.
<http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0070485>
- Shah M et al. *Comparison of laboratory costs of rapid molecular tests and conventional diagnostics for detection of tuberculosis and drug-resistant tuberculosis in South Africa*. BMC Infect Dis. 2013 Jul 29;13(1):352.
<http://www.ncbi.nlm.nih.gov/pubmed/23895665>

- Pantoja A et al. *Xpert MTB/RIF for the rapid diagnosis of TB and drug resistant TB: a cost and affordability analysis*. ERJ Express. Published on December 20, 2012 as doi: 10.1183/09031936.00147912.
<http://erj.ersjournals.com/content/early/2012/12/19/09031936.00147912.abstract>
- Winetsky DE et al. *Screening and rapid molecular diagnosis of tuberculosis in prisons in Russia and eastern europe: a cost-effectiveness analysis*. PLoS Med. 2012 Nov;9(11):e1001348. doi: 10.1371/journal.pmed.1001348. Epub 2012 Nov 27.
<http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1001348>
- Menzies NA et al. *Population Health Impact and Cost-Effectiveness of Tuberculosis Diagnosis with Xpert MTB/RIF: A Dynamic Simulation and Economic Evaluation*. PLoS Med. 2012 Nov;9(11):e1001347. doi: 10.1371/journal.pmed.1001347. Epub 2012 Nov 20.
<http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1001347>
- Meyer-Rath G et al. *The Impact and Cost of Scaling up GeneXpert MTB/RIF in South Africa*. PLoS ONE 7(5): e36966. Epub 2012 May 31. doi:10.1371/journal.pone.0036966.
<http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0036966>
- Schnippel K et al. *Scaling up Xpert MTB/RIF technology: the costs of laboratory- vs. clinic-based roll-out in South Africa*. Tropical Medicine & International Health, 12 Jun 2012. DOI: 10.1111/j.1365-3156.2012.03028.x.
<http://onlinelibrary.wiley.com/doi/10.1111/j.1365-3156.2012.03028.x/abstract>
- Andrews JR et al. *The cost-effectiveness of routine tuberculosis screening with Xpert MTB/RIF prior to initiation of antiretroviral therapy in South Africa: a model-based analysis*. AIDS. 2012 Feb 13. [Epub ahead of print]
http://journals.lww.com/aidsonline/Abstract/publishahead/The_cost_effectiveness_of_routine_tuberculosis.98980.aspx
- Abimbola TO. *Cost-effectiveness of Tuberculosis Diagnostic Strategies to Reduce Early Mortality among Persons with Advanced HIV Infection Initiating Antiretroviral Therapy*. JAIDS. Post acceptance, 11 January 2012. doi: 10.1097/QAI.0b013e318246538f
<http://journals.lww.com/jaids/pages/articleviewer.aspx?year=9000&issue=00000&article=98589&type=abstract>
- Vassall A et al. *Rapid Diagnosis of Tuberculosis with the Xpert MTB/RIF Assay in High Burden Countries: A Cost-Effectiveness Analysis*. PLoS Med. 2011 Nov;8(11):e1001120. Epub 2011 Nov 8.
<http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1001120>
- Dowdy DW et al. *Is Scale-Up Worth It? Challenges in Economic Analysis of Diagnostic Tests for Tuberculosis*. PLoS Med 8(7): e1001063.
<http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1001063>
- Meyer-Rath G et al. *The incremental cost of introducing Xpert® MTB/RIF into the South African national tuberculosis programme: Results of the National TB Cost Model 2011/12 - 2016/17*. Johannesburg: Health Economics and Epidemiology Research Office, 2011.
<http://www.tbonline.info/media/uploads/documents/hero-costofgenexpert.pdf>

See above: Theron G et al. (Eur Respir J. 2011 Nov 10), Schnippel K et al. (S Afr Med J. 2013 Jan 14), Van Rie A et al. (Int J Tuberc Lung Dis. 2013 Mar)

On evaluation of the assay

- Walusimbi S et al. Meta-analysis to compare the accuracy of GeneXpert, MODS and the WHO 2007 algorithm for diagnosis of smear-negative pulmonary tuberculosis. *BMC Infect Dis.* 2013 Oct 30;13(1):507. [Epub ahead of print]
<http://www.biomedcentral.com/1471-2334/13/507/abstract>
- Lawn SD et al. HIV-associated tuberculosis: relationship between disease severity and the sensitivity of new sputum-based and urine-based diagnostic assays. *BMC Med.* 2013 Oct 29;11(1):231. [Epub ahead of print]
<http://www.biomedcentral.com/1741-7015/11/231>
- Centers for Disease Control and Prevention (CDC). *Availability of an Assay for Detecting Mycobacterium tuberculosis, Including Rifampin-Resistant Strains, and Considerations for Its Use - United States, 2013.* *MMWR Morb Mortal Wkly Rep.* 2013 Oct 18;62(41):821-4.
<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6241a1.htm>
- Al-Darraj HA et al. *The Diagnostic Performance of a Single GeneXpert MTB/RIF Assay in an Intensified Tuberculosis Case Finding Survey among HIV-Infected Prisoners in Malaysia.* *PLoS One.* 2013 Sep 9;8(9):e73717. doi: 10.1371/journal.pone.0073717.
<http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0073717>
- Park KS et al. *Comparison of the Xpert MTB/RIF and COBAS TaqMan MTB assays for the detection of Mycobacterium tuberculosis in respiratory specimens.* *J Clin Microbiol.* 2013 Jul 17.
<http://jcm.asm.org/content/early/2013/07/15/JCM.01335-13.abstract>
- Bates M et al. *Use of the Xpert® MTB/RIF assay for diagnosing pulmonary tuberculosis comorbidity and multidrug-resistant TB in obstetrics and gynaecology inpatient wards at the University Teaching Hospital, Lusaka, Zambia.* *Trop Med Int Health.* 2013 Jul 3. doi: 10.1111/tmi.12145.
<http://onlinelibrary.wiley.com/doi/10.1111/tmi.12145/abstract>
- Theron G et al. *Accuracy and impact of Xpert MTB/RIF for the diagnosis of smear-negative or sputum-scarce tuberculosis using bronchoalveolar lavage fluid.* *Thorax.* 2013 Jun 29. doi: 10.1136/thoraxjnl-2013-203485.
<http://thorax.bmj.com/content/early/2013/06/28/thoraxjnl-2013-203485.long>
- Antonenka U et al. *Comparison of Xpert MTB/RIF with ProbeTec ET DTB and COBAS TaqMan MTB for direct detection of M. tuberculosis complex in respiratory specimens.* *BMC Infect Dis.* 2013 Jun 20;13:280. doi: 10.1186/1471-2334-13-280.
<http://www.biomedcentral.com/1471-2334/13/280>
- Hanrahan CF et al. *Time to Treatment and Patient Outcomes among TB Suspects Screened by a Single Point-of-Care Xpert MTB/RIF at a Primary Care Clinic in Johannesburg, South Africa.* *PLoS One.* 2013 Jun 6;8(6):e65421. doi: 10.1371/journal.pone.0065421. Print 2013.
<http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0065421>

- Lessells RJ et al. *Impact of a novel molecular TB diagnostic system in patients at high risk of TB mortality in rural South Africa (Uchwepheshe): study protocol for a cluster randomised trial.* *Trials.* 2013 Jun 12;14:170. doi: 10.1186/1745-6215-14-170.
<http://www.trialsjournal.com/content/14/1/170>
- Lee HY et al. *Diagnostic accuracy of Xpert® MTB/RIF on bronchoscopy specimens in patients with suspected pulmonary tuberculosis.* *Int J Tuberc Lung Dis.* 2013 Apr 23. [Epub ahead of print]
<http://www.ingentaconnect.com/content/iuatld/ijtld/pre-prints/ijtld120885>
- Kayigire XA et al. *Direct Comparison of Xpert MTB/RIF Assay with Liquid and Solid Mycobacterial Culture for Quantification of Early Bactericidal Activity.* *J Clin Microbiol.* 2013 Jun;51(6):1894-8. doi: 10.1128/JCM.03290-12. Epub 2013 Apr 17
<http://jcm.asm.org/content/51/6/1894.abstract>
- Muñoz L et al. *GeneXpert® for smear-negative pulmonary tuberculosis: does it play a role in low-burden countries?* *Diagn Microbiol Infect Dis.* 2012 Dec 28. pii: S0732-8893(12)00494-4. doi: 10.1016/j.diagmicrobio.2012.11.011. [Epub ahead of print]
<http://www.sciencedirect.com/science/article/pii/S0732889312004944>
- Kurbatova EV, DA Kaminski et al. *Performance of Cepheid® Xpert MTB/RIF® and TB-Biochip® MDR in two regions of Russia with a high prevalence of drug-resistant tuberculosis.* *Eur J Clin Microbiol Infect Dis.* 2012 Dec 22. [Epub ahead of print].
<http://link.springer.com/article/10.1007%2Fs10096-012-1798-0>
- Yoon C. *Impact of Xpert MTB/RIF Testing on Tuberculosis Management and Outcomes in Hospitalized Patients in Uganda.* *PloS One* 2012;7(11):e48599. doi: 10.1371/journal.pone.0048599. Epub 2012 Nov 6.
<http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0048599>
- Al-Ateah SM et al. *Evaluation of direct detection of Mycobacterium tuberculosis complex in respiratory and non-respiratory clinical specimens using the Cepheid Gene Xpert system.* *Saudi Med J.* 2012 Oct; 33(19): 1100-5.
<http://www.ncbi.nlm.nih.gov/pubmed/23047207>
- Clouse K et al. *Implementation of Xpert MTB/RIF for routine point-of-care diagnosis of tuberculosis at the primary care level.* *S Afr Med J.* 2012 Sept 7; 102(10):805-7.
<http://www.ncbi.nlm.nih.gov/pubmed/23034211>
- Kim SY et al. *The Xpert® MTB/RIF assay evaluation in South Korea, a country with an intermediate tuberculosis burden.* *IJTLD* 2012 Nov; 16(11):1471-6. doi: 10.5588/ijtld.11.0602. Epub 2012 Sep 12.
<http://dx.doi.org/10.5588/ijtld.11.0602>
- Barnard M et al. *Diagnostic performance of Genotype(R) MTBDRplus Version 2 line probe assay is equivalent to the Xpert(R)MTB/RIF assay.* *J Clin Microbiol.* 2012 Nov; 50(11): 3712-6. doi: 10.1128/JCM.01958-12. Epub 2012 Sep 12.
<http://jcm.asm.org/content/early/2012/09/06/JCM.01958-12.abstract>

- Carriquiry G et al. *A Diagnostic Accuracy Study of Xpert® MTB/RIF in HIV-Positive Patients with High Clinical Suspicion of Pulmonary Tuberculosis in Lima, Peru*. PLoS One. 2012;7(9):e44626. Epub 2012 Sep 7.
<http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0044626>
- Alvarez-Uria G et al. *Rapid Diagnosis of Pulmonary and Extrapulmonary Tuberculosis in HIV-Infected Patients. Comparison of LED Fluorescent Microscopy and the GeneXpert MTB/RIF Assay in a District Hospital in India*. Tuberculosis Research and Treatment 2012 (2012): 932862. Epub 2012 Aug 26.
<http://www.hindawi.com/journals/trt/2012/932862/abs/>
- Ntinginya EN et al. *Performance of the Xpert® MTB/RIF assay in an active case-finding strategy: a pilot study from Tanzania [Short communication]*. IJTLD 2012 Nov; 16(11): 1468-70. doi: 10.5588/ijtld.12.0127. Epub 2012 Sep 7.
<http://dx.doi.org/10.5588/ijtld.12.0127>
- Yin QQ and AD Shen. *Diagnostic value of Xpert MTB/RIF assay for tuberculosis* (in Chinese). Chinese Journal of Tuberculosis and Respiratory Diseases (Zhonghua Jie He He Hu Xi Za Zhi): 2012 May; 35(5): 363-5.
<http://www.ncbi.nlm.nih.gov/pubmed/22883998>
- Balcells ME et al. *Rapid molecular detection of pulmonary tuberculosis in HIV-infected patients in Santiago, Chile*. IJTLD 1 October 2012, 16(10): 1349-1353(5).
<http://www.ingentaconnect.com/content/iatld/ijtld/2012/00000016/00000010/art00013>
- O'Grady J et al. *Evaluation of the Xpert(R) MTB/RIF assay at a tertiary referral hospital in a high TB/HIV endemic setting*. Clin Infect Dis. 2012 Nov; 55(9): 1171-8. doi: 10.1093/cid/cis631. Epub 2012 Jul 17.
<http://cid.oxfordjournals.org/content/early/2012/07/13/cid.cis631.abstract>
- Peter JG et al. *The Diagnostic Accuracy of Urine-Based Xpert MTB/RIF in HIV-Infected Hospitalized Patients Who Are Smear-Negative or Sputum Scarce*. PLoS One. 2012; 7(7):e39966. Epub 2012 Jul 9.
<http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0039966>
- Williamson DA et al. *An evaluation of the Xpert MTB/RIF assay and detection of false-positive rifampicin resistance in Mycobacterium tuberculosis*. Diagn Microbiol Infect Dis. 2012 Oct;74(2):207-9. doi: 10.1016/j.diagmicrobio.2012.06.013. Epub 2012 Jul 20.
<http://www.sciencedirect.com/science/article/pii/S0732889312002623>
- Miotto P et al. *Early tuberculosis treatment monitoring by Xpert® MTB/RIF*. ERJ May 1, 2012; 39(5): 1269-1271: doi: 10.1183/09031936.00124711.
<http://erj.ersjournals.com/content/39/5/1269.extract>
- Lawn SD et al. *Characteristics and Early Outcomes of Patients With Xpert MTB/RIF-Negative Pulmonary Tuberculosis Diagnosed During Screening Before Antiretroviral Therapy*. Clin Infect Dis. (2012) doi: 10.1093/cid/cir1039. First published online: February 7, 2012.
<http://cid.oxfordjournals.org/content/early/2012/02/06/cid.cir1039.abstract>

(and related correspondence in reply: Theron G et al. *Characteristics of Xpert MTB/RIF-Negative Patients With Pulmonary Tuberculosis*. *Clin Infect Dis*. (2012) doi: 10.1093/cid/cis465. First published online : May 9, 2012.
<http://cid.oxfordjournals.org/content/early/2012/06/05/cid.cis465.extract>)

- Theron G et al. *The Use of an Automated Quantitative Polymerase Chain Reaction (Xpert MTB/RIF) to Predict the Sputum Smear Status of Tuberculosis Patients*. *Clin Infect Dis*. 2012 Feb; 54(3):384-8. Epub 2011 Dec 1.
<http://cid.oxfordjournals.org/content/54/3/384.abstract>
- Van Rie A et al. *False-positive rifampicin resistance on Xpert® MTB/RIF: case report and clinical implications [Technical note]*. *Int J Tuberc Lung Dis*. 2012 Feb; 16(2): pp. 206-208(3).
<http://www.ingentaconnect.com/content/iatld/ijtld/2012/00000016/00000002/art00013>
- Zeka AN et al. *Evaluation of the GeneXpert MTB/RIF Assay for the Rapid Diagnosis of Tuberculosis and detection of RIF-resistance in Pulmonary and Extrapulmonary Specimens*. *J Clin Microbiol*. 2011 Sep 28. [Epub ahead of print]
<http://jcm.asm.org/cgi/content/abstract/JCM.05434-11v1>
- Hanif SN et al. *GeneXpert® MTB/RIF for rapid detection of Mycobacterium tuberculosis in pulmonary and extra-pulmonary samples*. *Int J Tuberc Lung Dis*. 2011 Sep;15(9):1274-5.
<http://www.ingentaconnect.com/content/iatld/ijtld/2011/00000015/00000009>
- Ioannidis P et al. *Cepheid GeneXpert MTB/RIF Assay for Mycobacterium tuberculosis Detection and Rifampin Resistance Identification in Patients with Substantial Clinical Indications of Tuberculosis and Smear-Negative Microscopy Results*. *J Clin Microbiol*. 2011 Aug;49(8): 3068-3070.
<http://jcm.asm.org/cgi/content/abstract/49/8/3068>
- Teo J et al. *Comparison of two nucleic acid amplification assays, the Xpert MTB/RIF and the Amplified Mycobacterium Tuberculosis Direct (MTD) assay, for the detection of Mycobacterium tuberculosis in respiratory and non-respiratory specimens*. *J Clin Microbiol*. 2011 Oct;49(10):3659-62. Epub 2011 Aug 24.
<http://jcm.asm.org/cgi/content/abstract/JCM.00211-11v1?maxtoshow=&hits=10&RESULTFORMAT=&fulltext=mtb%2Frif&searchid=1&FIRSTINDEX=10&resourcetype=HWCIT>
- Miller MB et al. *Performance of Xpert MTB/RIF RUO Assay and IS6110 Real-Time PCR for Mycobacterium tuberculosis Detection in Clinical Samples*. *J Clin Microbiol*. 2011 Oct;49(10):3458-62. Epub 2011 Aug 17.
<http://jcm.asm.org/cgi/content/abstract/49/10/3458>
- Blakemore R et al. *A Multi-Site Assessment of the Quantitative Capabilities of the Xpert(R) MTB/RIF Assay*. *Am J Respir Crit Care Med*. 2011 Aug 11. [Epub ahead of print]
<http://ajrccm.atsjournals.org/cgi/content/abstract/201103-0536OCv1>
- Scott LE et al. *2011 Comparison of Xpert MTB/RIF with Other Nucleic Acid Technologies for Diagnosing Pulmonary Tuberculosis in a High HIV Prevalence Setting: A Prospective Study*. *PLoS Med* 8(7): e1001061.
<http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1001061>
- Theron G et al. *Evaluation of the Xpert MTB/RIF assay for the diagnosis of pulmonary tuberculosis in a high HIV prevalence setting*. *Am J Respir Crit Care Med*. 2011 Jul

1;184(1):132-40. Epub 2011 Apr 14.

<http://ajrccm.atsjournals.org/cgi/content/abstract/184/1/132>

- Lawn S et al. *Screening for HIV-Associated Tuberculosis and Rifampicin Resistance before Antiretroviral Therapy Using the Xpert MTB/RIF Assay: A Prospective Study.* PLoS Med 8(7): e1001067.
<http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1001067>
- Bowles EC et al. *Xpert MTB/RIF[®], a novel automated polymerase chain reaction-based tool for the diagnosis of tuberculosis.* Int J Tuberc Lung Dis. 2011 Jul;15(7):988-9.
<http://www.ingentaconnect.com/content/iuatld/ijtld/2011/00000015/00000007>
- Rachow A et al. *Rapid and accurate detection of Mycobacterium tuberculosis in sputum samples by Cepheid Xpert MTB/RIF assay--a clinical validation study.* PLoS One. 2011;6(6):e20458. Epub 2011 Jun 29.
<http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0020458>
- Armand S et al. *Comparison of the Xpert MTB/RIF test with an IS6110-TaqMan real-time PCR assay for direct detection of Mycobacterium tuberculosis in respiratory and nonrespiratory specimens.* J Clin Microbiol. 2011 May;49(5):1772-6. Epub 2011 Mar 16.
<http://jcm.asm.org/cgi/content/abstract/49/5/1772>
- Malbruny B et al. *Rapid and efficient detection of Mycobacterium tuberculosis in respiratory and non-respiratory samples.* Int J Tuberc Lung Dis. 2011 Apr;15(4):553-5.
<http://www.ingentaconnect.com/content/iuatld/ijtld/2011/00000015/00000004>
- Boehme C et al. *Feasibility, diagnostic accuracy, and effectiveness of decentralised use of the Xpert MTB/RIF test for diagnosis of tuberculosis and multidrug resistance: a multicentre implementation study.* Lancet. 2011 Apr 30;377(9776):1495-505.
<http://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2811%2960438-8/abstract>
- Marlowe EM et al. *Evaluation of the Cepheid Xpert MTB/RIF assay for direct detection of Mycobacterium tuberculosis complex in respiratory specimens.* J Clin Microbiol. 2011 Apr;49(4):1621-3. Epub 2011 Feb 2.
<http://jcm.asm.org/cgi/content/abstract/49/4/1621>
- Moure R et al. *Rapid detection of Mycobacterium tuberculosis complex and rifampin resistance in smear-negative clinical samples by use of an integrated real-time PCR method.* J Clin Microbiol. 2011 Mar;49(3):1137-9. Epub 2010 Dec 29.
<http://jcm.asm.org/cgi/content/abstract/49/3/1137>
- Boehme C et al. *Rapid Molecular Detection of Tuberculosis and Rifampin Resistance.* N Engl J Med 2010 Sep 9; 363(11):1005-1015.
<http://www.nejm.org/doi/full/10.1056/NEJMoa0907847>
- Blakemore R et al. *Evaluation of the analytical performance of the Xpert MTB/RIF assay.* J Clin Microbiol. 2010 Jul;48(7):2495-501. Epub 2010 May 26.
<http://jcm.asm.org/cgi/content/abstract/48/7/2495>

- Helb D et al. *Rapid detection of Mycobacterium tuberculosis and rifampin resistance by use of on-demand, near-patient technology*. J Clin Microbiol. 2010 Jan;48(1):229-37. Epub 2009 Oct 28.
<http://jcm.asm.org/cgi/content/abstract/48/1/229>

On development of the assay

- Banada P et al. *Containment of Bioaerosol Infection Risk by the Xpert MTB/RIF Assay and Its Applicability to Point-of-Care Settings*. J Clin Microbiol. 2010 Oct;48(10): 3551-3557.
<http://jcm.asm.org/cgi/content/abstract/48/10/3551?maxtoshow=&hits=10&RESULTFORM AT=&fulltext=mtb%2Frif&searchid=1&FIRSTINDEX=0&resourcetype=HWCIT>
- El-Hajj HH et al. *Detection of rifampin resistance in mycobacterium tuberculosis in a single tube with molecular beacons*. J. Clin. Microbiol. 39, 4131–4137 (2001).
<http://jcm.asm.org/cgi/content/abstract/39/11/4131>
- Piatek AS et al. *Genotypic analysis of mycobacterium tuberculosis in two distinct populations using molecular beacons: implications for rapid susceptibility testing*. Antimicrob. Agents Chemother. 44, 103–110 (2000).
<http://aac.asm.org/cgi/content/abstract/44/1/103>
- Piatek AS et al. *Molecular beacon sequence analysis for detecting drug resistance in mycobacterium tuberculosis*. Nat. Biotechnol. 16, 359–363 (1998).
<http://www.nature.com/nbt/journal/v16/n4/full/nbt0498-359.html>

On detection of extrapulmonary TB

- Nhu NT et al. *Evaluation of Xpert MTB/RIF for the diagnosis of tuberculous meningitis*. J Clin Microbiol. 2013 Nov 6. [Epub ahead of print]
<http://jcm.asm.org/content/early/2013/10/31/JCM.01834-13.long>
- Patel VB et al. *Diagnostic Accuracy of Quantitative PCR (Xpert MTB/RIF) for Tuberculous Meningitis in a High Burden Setting: A Prospective Study*. PLoS Med. 2013 Oct;10(10):e1001536. doi: 10.1371/journal.pmed.1001536. Epub 2013 Oct 22.
<http://dx.plos.org/10.1371/journal.pmed.1001536>
and commentary:
<http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1001537>
- Ablanedo-Terrazas Y et al. *Xpert MTB/RIF for diagnosis of tuberculous cervical lymphadenitis in HIV-infected patients*. Laryngoscope. 2013 Oct 25. doi: 10.1002/lary.24478. [Epub ahead of print]
<http://onlinelibrary.wiley.com/doi/10.1002/lary.24478/abstract;jsessionid=3C7174997EC2ED8E6AE5FA94B73CB666.f01t03>
- Shenai S et al. *Exploring alternative biomaterials for diagnosis of pulmonary tuberculosis in HIV negative patients using the Xpert MTB/RIF assay*. J Clin Microbiol. 2013 Oct 9. [Epub ahead of print]
<http://jcm.asm.org/content/early/2013/10/03/JCM.01743-13.abstract>

- Dhana AV et al. Identification of Mycobacterium tuberculosis from pericardial fluid using the new Xpert MTB/RIF assay. *BMJ Case Rep.* 2013 Aug 28;2013. pii: bcr2013200615. doi: 10.1136/bcr-2013-200615.
<http://casereports.bmj.com/content/2013/bcr-2013-200615.abstract>
- Christopher DJ et al. Performance of Xpert(R) MTB/RIF on pleural tissue for the diagnosis of pleural tuberculosis. *Eur Respir J.* 2013 Jul 30. [Epub ahead of print]
<http://erj.ersjournals.com/content/early/2013/07/30/09031936.00103213.long>
- Porcel JM et al. *Xpert® MTB/RIF in pleural fluid for the diagnosis of tuberculosis [Short communication]* *Int J Tuberc Lung Dis.* 2013 Jul 3
<http://www.ingentaconnect.com/content/iatld/ijtld/pre-prints/ijtld130178>
- Banada P et al. *Detection of Mycobacterium tuberculosis in blood using the Xpert(R) MTB/RIF assay.* *J Clin Microbiol.* 2013 May 15. [Epub ahead of print]
<http://jcm.asm.org/content/early/2013/05/10/JCM.00332-13.abstract>
- Feasey N et al. *Evaluation of Xpert MTB/RIF for the detection of TB from blood of HIV-infected adults confirms MTB-bacteremia as indicator of poor prognosis.* *J Clin Microbiol.* 2013 May 15. [Epub ahead of print]
<http://jcm.asm.org/content/early/2013/05/10/JCM.00330-13.abstract>
- Van Rie A et al. *Diagnostic accuracy and effectiveness of the Xpert MTB/RIF assay for the diagnosis of HIV-associated lymph node tuberculosis.* *Eur J Clin Microbiol Infect Dis.* 2013 May 10. [Epub ahead of print]
<http://link.springer.com/article/10.1007%2Fs10096-013-1890-0>
- Hella JJ et al. *Paraspinal abscess secondary to tuberculous spondylitis diagnosed by Xpert MTB/RIF assay in rural Tanzania.* *BMJ Case Reports* 2013 Apr 10; doi:10.1136/bcr-2013-009156.
<http://casereports.bmj.com/content/2013/bcr-2013-009156.abstract>
- Walters E et al. *Rapid Diagnosis of Pediatric Intrathoracic Tuberculosis From Stool Samples Using the Xpert MTB/RIF Assay: A Pilot Study.* *Pediatr Infect Dis J.* 2012 Dec;31(12):1316. doi: 10.1097/INF.0b013e318266c21c.
http://journals.lww.com/pidj/Citation/2012/12000/Rapid_Diagnosis_of_Pediatric_Intrathoracic.29.aspx
- Lawn SD and Al Zumla AI. *Diagnosis of extrapulmonary tuberculosis using the Xpert® MTB/RIF assay.* *Expert Rev Anti Infect Ther.* 2012 Jun;10(6):631-5.
<http://www.ncbi.nlm.nih.gov/pubmed/22734954>
- Taylor N et al. *Can a simple flotation method lower the limit of detection of M. tuberculosis in extrapulmonary samples by the GeneXpert MTB/RIF assay?* *J Clin Microbiol.* 2012 May 2. doi: 10.1128/JCM.01012-12.
<http://jcm.asm.org/content/early/2012/04/26/JCM.01012-12.abstract>

- Lawn SD et al. *High diagnostic yield of tuberculosis from screening urine samples from HIV-infected patients with advanced immunodeficiency using the Xpert MTB/RIF assay.* JAIDS 23 April 2012; doi: 10.1097/QAI.0b013e318258c6af.
<http://journals.lww.com/jaids/pages/articleviewer.aspx?year=9000&issue=00000&article=98518&type=abstract>
- Moure R et al. *Effectiveness of an Integrated Real-Time PCR Method for Detection of the Mycobacterium tuberculosis Complex in Smear-Negative Extrapulmonary Samples in an Area of Low Tuberculosis Prevalence.* J. Clin. Microbiol. February 2012 50:2 513-515; published ahead of print 7 December 2011.
<http://jcm.asm.org/content/50/2/513.abstract>
- Tortoli E et al. *Clinical validation of Xpert MTB/RIF for the diagnosis of extrapulmonary tuberculosis.* ERJ. Published online before print January 12, 2012 erj01763-2011.
<http://erj.ersjournals.com/content/early/2012/01/12/09031936.00176311.abstract>
- van Zyl-Smit RN. *Comparison of Quantitative Techniques including Xpert MTB/RIF to Evaluate Mycobacterial Burden.* PLoS One. 2011;6(12):e28815. Epub 2011 Dec 22.
<http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0028815>
- Friedrich SO et al. *Xpert MTB/RIF assay for the diagnosis of pleural tuberculosis.* J Clin Microbiol. 2011 Oct 12. [Epub ahead of print]. doi: 10.1128/JCM.05454-11.
<http://jcm.asm.org/content/early/2011/10/12/JCM.05454-11.abstract>
- Causse M et al. *Comparison of Two Molecular Methods for Rapid Diagnosis of Extrapulmonary Tuberculosis.* J Clin Microbiol. 2011 Aug;49(8): 3065-3067.
<http://jcm.asm.org/cgi/content/abstract/49/8/3065>
- Ligthelm LJ et al. *Xpert® MTB/RIF for the rapid diagnosis of tuberculous lymphadenitis from Fine Needle Aspiration biopsy specimens.* J Clin Microbiol. 2011 Nov;49(11):3967-70. Epub 2011 Aug 31.
<http://jcm.asm.org/cgi/content/abstract/JCM.01310-11v1?maxtohide=&hits=10&RESULTFORMAT=&fulltext=mtb%2Frif&searchid=1&FIRSTINDEX=0&resourcetype=HWCIT>
- Vadwai V et al. *Xpert MTB/RIF: a New Pillar in Diagnosis of Extrapulmonary Tuberculosis?* J Clin Microbiol. 2011 Jul;49(7):2540-5.
<http://jcm.asm.org/cgi/content/abstract/49/7/2540>
- Hillemann D et al. *Rapid molecular detection of extrapulmonary tuberculosis by the automated GeneXpert MTB/RIF system.* J Clin Microbiol. 2011 Apr;49(4):1202-5.
<http://jcm.asm.org/cgi/content/abstract/49/4/1202>
- See also above under "On evaluation of the assay": Lawn et al., Al-Ateah et al., Alvarez-Uria G et al., Zeka AN et al.; Ioannidis P et al.; Teo J et al.; Hanif et al.; Miller et al. ; Armand S et al. ; Malbruny B et al. ; Moure R et al.

On detection of paediatric TB

- Nicol MP et al. *Xpert MTB/RIF Testing of Stool Samples for the Diagnosis of Pulmonary Tuberculosis in Children.* Clin Infect Dis. 2013 Apr 26. [Epub ahead of print]
<http://cid.oxfordjournals.org/content/early/2013/04/25/cid.cit230.abstract>

- Sekadde MP et al. *Evaluation of the Xpert MTB/RIF test for the diagnosis of childhood pulmonary tuberculosis in Uganda: a cross-sectional diagnostic study*. BMC Infect Dis. 2013 Mar 12;13:133. doi: 10.1186/1471-2334-13-133.
<http://www.biomedcentral.com/1471-2334/13/133>
- Nguyen TQ et al. *Evaluation of Xpert MTB/RIF and MODS assay for the diagnosis of pediatric tuberculosis*. BMC Infect Dis. 2013; 13: 31.
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3562258/>
- Walters E et al. *Rapid Diagnosis of Pediatric Intrathoracic Tuberculosis From Stool Samples Using the Xpert MTB/RIF Assay: A Pilot Study*. Pediatr Infect Dis J. 2012 Dec;31(12):1316. doi: 10.1097/INF.0b013e318266c21c.
http://journals.lww.com/pidj/Citation/2012/12000/Rapid_Diagnosis_of_Pediatric_Intrathoracic.29.aspx
- Bates M et al. *Assessment of the Xpert MTB/RIF assay for diagnosis of tuberculosis with gastric lavage aspirates in children in sub-Saharan Africa: a prospective descriptive study*. Lancet Infect Dis. 2012 Nov 2. pii: S1473-3099(12)70245-1. [Epub ahead of print]
[http://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(12\)70245-1/abstract](http://www.thelancet.com/journals/laninf/article/PIIS1473-3099(12)70245-1/abstract)
- Whittaker E and HJ Zar. *Promising directions in the diagnosis of childhood tuberculosis*. Expert Rev Respir Med. 2012 Aug; 6(4): 385-95.
<http://www.expert-reviews.com/doi/abs/10.1586/ers.12.36>
- Zar HJ et al. *Rapid molecular diagnosis of pulmonary tuberculosis in children using nasopharyngeal specimens*. Clin Infect Dis. 2012 Jul 2. [Epub ahead of print]
<http://cid.oxfordjournals.org/content/early/2012/06/28/cid.cis598.abstract>
- Rachow A et al. *Increased and Expedited Case Detection by Xpert MTB/RIF Assay in Childhood Tuberculosis: A Prospective Cohort Study*. Clin Infect Dis. 2012 Apr 3. [Epub ahead of print]
<http://cid.oxfordjournals.org/content/early/2012/03/29/cid.cis190.abstract>
- Nicol M et al. *Accuracy of the Xpert MTB/RIF test for the diagnosis of pulmonary tuberculosis in children admitted to hospital in Cape Town, South Africa: a descriptive study*. Lancet Infect Dis. 2011 Nov;11(11):819-24. Epub 2011 Jul 19.
[http://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(11\)70167-0/fulltext](http://www.thelancet.com/journals/laninf/article/PIIS1473-3099(11)70167-0/fulltext)

On diagnostic algorithms

- Yaesoubi R and T Cohen. *Identifying dynamic tuberculosis case-finding policies for HIV/TB coepidemics*. Proc Natl Acad Sci U S A. 2013 May 20. [Epub ahead of print]
<http://www.ncbi.nlm.nih.gov/pubmed/23690585>
- Veggim D. et al. *Integrating the Xpert MTB/RIF assay in a diagnostic work flow for rapid detection of Mycobacterium tuberculosis in a low prevalence area*. J Clin Microbiol. 2013 Apr 24. [Epub ahead of print]
<http://jcm.asm.org/content/early/2013/04/18/JCM.00151-13.abstract>

- Van Rie A et al. *Point-of-care Xpert® MTB/RIF for smear-negative tuberculosis suspects at a primary care clinic in South Africa*. Int J Tuberc Lung Dis. 2013 Mar;17(3):368-72. doi: 10.5588/ijtld.12.0392.
<http://www.ingentaconnect.com/content/iuatld/ijtld/2013/00000017/00000003/art00019>
- Schnippel K et al. *Diagnosing Xpert MTB/RIF negative TB: Impact and cost of alternative algorithms for South Africa*. S Afr Med J. 2013 Jan 14;103(2):101-6. doi: 10.7196/samj.6182.
<http://www.ncbi.nlm.nih.gov/pubmed/23374320>
- Theron G et al. *Do adjunct TB tests, when combined with Xpert MTB/RIF, improve accuracy and the cost of diagnosis in a resource-poor setting?* Eur Respir J. 2011 Nov 10. [Epub ahead of print].
<http://erj.ersjournals.com/content/early/2011/11/09/09031936.00145511.abstract>
- Turnbull E et al. *A Model of Tuberculosis Screening for Pregnant Women in Resource-Limited Settings Using Xpert MTB/RIF*. J Pregnancy. 2012; 2012: 565049. Published online 2011 October 5. doi: 10.1155/2012/565049.
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3189576/?report=abstract>

For use in prevalence surveys

- Dorman SE et al. *Performance Characteristics of the Cepheid Xpert MTB/RIF Test in a Tuberculosis Prevalence Survey*. PLoS One. 2012; 7(8): e43307. Epub 2012 Aug 15.
<http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0043307>

On quality assurance

- Gous N et al. *Performance monitoring of Mycobacterium tuberculosis Dried Culture Spots for use on the GeneXpert within a National Program in South Africa*. J Clin Microbiol. 2013 Sep 25. [Epub ahead of print].
<http://jcm.asm.org/content/early/2013/09/20/JCM.01715-13.abstract>
- Scott LE et al. *Dried Culture Spots for Xpert MTB/RIF External Quality Assessment: Results of phase 1 pilot study from South Africa*. Journal of Clinical Microbiology. First published October 2011, doi: 10.1128/JCM.05167-11.
<http://jcm.asm.org/content/early/2011/10/05/JCM.05167-11.abstract>

Commentary and review

- Pinto LM and ZF Udawadia. *Xpert MTB/RIF and pulmonary tuberculosis: time to delve deeper?* Thorax. 2013 Jul 4. doi: 10.1136/thoraxjnl-2013-203885.
<http://thorax.bmj.com/content/early/2013/07/03/thoraxjnl-2013-203885.long>
- Singh JA et al. *Diagnosis of drug-resistant TB and provision of second-line TB treatment in India: some ethical considerations*. Indian J Med Ethics. 2013 Apr-Jun;10(2):110-4.
<http://www.ncbi.nlm.nih.gov/pubmed/23697491>

- Lawn SD et al. *Advances in tuberculosis diagnostics: the Xpert MTB/RIF assay and future prospects for a point-of-care test*. Lancet Infect Dis. 2013 Apr;13(4):349-61. doi: 10.1016/S1473-3099(13)70008-2. Epub 2013 Mar 24.
<http://www.sciencedirect.com/science/article/pii/S1473309913700082>
- Lawn SD. *Diagnosis of pulmonary tuberculosis*. Curr Opin Pulm Med. 2013 May;19(3):280-8. doi: 10.1097/MCP.0b013e32835f1b70.
<http://www.ncbi.nlm.nih.gov/pubmed/23528956>
- Steingart KR et al. *Xpert® MTB/RIF assay for pulmonary tuberculosis and rifampicin resistance in adults*. Cochrane Database Syst Rev. 2013 Jan 31;1:CD009593. doi: 10.1002/14651858.CD009593.pub2.
<http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD009593.pub2/pdf>
- Auld S and E Pevzner. *Reaching beyond our Xpert potential: reflections on the 43rd Union World Conference [Correspondence]*. Int J Tuberc Lung Dis, Volume 17, Number 3, 1 March 2013, pp. 423-424(2).
<http://www.ingentaconnect.com/content/iatld/ijtld/2013/00000017/00000003/art00028>
- Weyer K et al. *Rapid molecular TB diagnosis: evidence, policy-making and global implementation of Xpert® MTB/RIF*. Eur Respir J. 2012 Nov 22. doi:10.1183/09031936.00157212 [Epub ahead of print]
<http://erj.ersjournals.com/content/early/2012/11/22/09031936.00157212.abstract>
- Dheda K et al. *Point-of-Care Diagnosis of Tuberculosis – Past, Present and Future*. Respiriology. 2012 Nov 27. doi: 10.1111/resp.12022. [Epub ahead of print]
<http://onlinelibrary.wiley.com/doi/10.1111/resp.12022/abstract>
- Kirwan DE et al. *Rapid Implementation of New TB Diagnostic Tests: Is It Too Soon for a Global Roll-Out of Xpert MTB/RIF?* Am J Trop Med Hyg 2012 87(2): 197-201. doi: 10.4269/ajtmh.2012.12-0107.
<http://www.ajtmh.org/content/87/2/197.abstract>
[in response] Talbot EA et al. *Transforming TB Diagnosis: Can Patients and Control Programs Afford to Wait?* Am J Trop Med Hyg 2012 87: 202-204. doi:10.4269/ajtmh.2012.12-0247.
- Peters D et al. *Should Xpert® MTB/RIF be rolled out in low-income countries? [correspondence]* Int J Tuberc Lung Dis 2012; 16 (5): 702-703.
<http://www.ingentaconnect.com/content/iatld/ijtld/2012/00000016/00000005/art00029>
- Trébuq A et al. *In reply to 'Should Xpert® MTB/RIF be rolled out in low-income countries?' [correspondence]* Int J Tuberc Lung Dis 2012; 16 (5): 703-704.
<http://www.ingentaconnect.com/content/iatld/ijtld/2012/00000016/00000005/art00030>
- Lawn SD et al. *Location of Xpert® MTB/RIF in centralised laboratories in South Africa undermines potential impact [correspondence]* Int J Tuberc Lung Dis 2012; 16 (5): 701.
<http://www.ingentaconnect.com/content/iatld/ijtld/2012/00000016/00000005/art00027>
- Trébuq A and A Harries. *In reply to 'Location of Xpert® MTB/RIF in centralised laboratories in South Africa undermines potential impact' [Correspondence]* Int J Tuberc Lung Dis 2012; 16 (5): 702.
<http://www.ingentaconnect.com/content/iatld/ijtld/2012/00000016/00000005/art00028>

- Bodmer T and A Ströhle. *Diagnosing Pulmonary Tuberculosis with the Xpert MTB/RIF Test*. Journal of Visualized Experiments 2012; 62, e3547, DOI: 10.3791/3547.
<http://www.jove.com/video/3547/diagnosing-pulmonary-tuberculosis-with-the-xpert-mtbrif-test>
- Chang K et al. *Rapid and effective diagnosis of tuberculosis and rifampicin resistance with Xpert MTB/RIF assay: A meta-analysis*, J Infect, 2012, doi:10.1016/j.jinf.2012.02.012
<http://www.sciencedirect.com/science/article/pii/S0163445312000424>
- Trébuq A et al. *Xpert® MTB/RIF for national tuberculosis programmes in low-income countries: when, where and how?* Int J Tuberc Lung Dis. 15(12), December 2011, pp. 1567-1572(6).
<http://www.ingentaconnect.com/content/iatld/ijtld/2011/00000015/00000012/art00005>
- Singh JA and A Bhan. *The ethics of national tuberculosis programmes in low-income countries not rolling out Xpert® MTB/RIF*. Int J Tuberc Lung Dis. 15 (12), December 2011: 1563-1563(1).
<http://www.ingentaconnect.com/content/iatld/ijtld/2011/00000015/00000012/art00001>
- Lawn SD and MP Nicol. *Xpert® MTB/RIF assay: development, evaluation and implementation of a new rapid molecular diagnostic for tuberculosis and rifampicin resistance*. Future Microbiol. 2011 Sep;6:1067-82.
http://www.futuremedicine.com/doi/abs/10.2217/fmb.11.84?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%3dpubmed
- Evans CA. *GeneXpert—A Game-Changer for Tuberculosis Control?* PLoS Med 8(7): e1001064.
<http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1001064>
- Van Rie A et al. *Xpert® MTB/RIF for point-of-care diagnosis of TB in high-HIV burden, resource-limited countries: hype or hope?* Expert Rev Mol Diagn. 2010 Oct;10(7):937-46.
<http://www.expert-reviews.com/doi/abs/10.1586/erm.10.67>
- Small P and M Pai. *Tuberculosis Diagnosis - Time for a Game Change*. N Engl J Med 2010; 363:1070-1071.
<http://www.nejm.org/doi/full/10.1056/NEJMe1008496>

For information on the roll-out of Xpert MTB/RIF, visit:

<http://www.who.int/tb/laboratory/mtbrifrollout/en/index.html>