# Draft Guidance for Industry and Food and Drug Administration Staff - Class II Special Controls Guidance Document: Nucleic Acid-Based In Vitro Diagnostic Devices for the Detect...

U.S. Food & Drug Administration

You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov [1]. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document contact Janice Washington at 301-796-6207 or by email at janice.washington@fda.hhs.gov [2].


**U.S. Department of Health and Human Services**
**Food and Drug Administration**
**Center for Devices and Radiological Health**
**Office of *In Vitro* Diagnostic Device Evaluation and Safety**

## Preface

### Additional Copies

Additional copies are available from the Internet. You may also send an e-mail request to dsmica@fda.hhs.gov [3] to receive an electronic copy of the guidance or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number (1788) to identify the guidance you are requesting.

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1. Centers for Disease Control and Prevention Fact Sheets - *Mycobacterium bovis* (Bovine Tuberculosis) in Humans. Division of Tuberculosis Elimination. September 9, 2011.

http://www.cdc.gov/tb/publications/factsheets/general/mbovis.htm [12].
2. CR Horsburgh, Jr., Priorities for the Treatment of Latent Tuberculosis Infection in the United States. New England Journal of Medicine, 2004;350:2060-7.
3. CDC MMWR, Vol. 60, No. 11 and CDC *Reported Tuberculosis in the United States, 2010*. Atlanta, GA: US Department of Health and Human Services, CDC, October 2011.
4. Clinical and Laboratory Standards Institute. 2006 Molecular Diagnostic Methods for Infectious Disease; Proposed Guideline-Second Edition. MM3-A2. Clinical and Laboratory Standards Institute, Wayne PA.
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12. Clinical and Laboratory Standards Institute. 2008. Interpretive Criteria for Identification of Bacteria and Fungi by DNA Target Sequencing; Approved Guideline. MM18-A. Clinical and Laboratory Standards Institute, Wayne PA.
13. American Thoracic Society, CDC, and Infectious Diseases Society of America. Treatment of Tuberculosis. American Journal of Respiratory and Critical Care Medicine (2003) 167:603 - 62.

[1] *M. tuberculosis* complex includes the following species: *Mycobacterium tuberculosis, M. bovis, M. africanum, M. canetti*, *M. microti, M. caprae,* and *M. pinnipedi* . The GHTF founding members auditing systems include: the Canadian Medical Devices Conformity Assessment System; Notified Bodies designated by member states of the European Union.; Australian Therapeutics Goods Administration, Office of Manufacturing Quality; and the Japanese Ministry of Health, Labour and Welfare system for Medical Devices and In-vitro Diagnostics.

[2] CDC - Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition

[13]

[3] Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices [14]

[4] We recommend that the sponsor describe in a pre-submission the number of patients with non-sputum specimens that will be enrolled in the clinical studies. The use of non-sputum specimen types should be supported by analytical studies showing the different matrix has no effect on device performance.

[5] Throughout this special controls guidance, the term “processed” or “processing” is used to describe the digestion, decontamination, and centrifugation to pellet of respiratory specimens.

[6] These criteria are based on the Sanger di-deoxysequencing method instruments. If you propose other sequencing methods, you should specify the platform and how you will determine acceptable quality.

[7] For 200 subjects, 90% (180/200) with 95% two-sided confidence interval: 85.1% to 93.4%

[8] CDC - Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition [13]

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[14] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm
[15] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm296205.htm