Draft Guidance for Industry and Food and Drug Administration Staff - Class II Special Controls Guidance Document: Nucleic Acid-Based In Vitro Diagnostic Devices for the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

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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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Draft Guidance for Industry and Food and Drug Administration Staff - Class II Special Controls Guidance Document: Nucleic Acid-Based *In Vitro* Diagnostic Devices for the Detection of *Mycobacterium tuberculosis* Complex in Respiratory Specimens

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

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