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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Clinical Laboratory Improvement Advisory Committee

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: Clinical Laboratory Improvement Advisory Committee (CLIAC).

Times and Dates:

8:30 a.m.-5 p.m., February 16, 2005.
8:30 a.m.-3 p.m., February 17, 2005.

Place: Doubletree Hotel (Atlanta/Buckhead), 3342 Peachtree Rd. NE., Atlanta, Georgia 30326, Telephone: (404) 231-1234.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 100 people.

Purpose: This committee is charged with providing scientific and technical advice and guidance to the Secretary of Health and Human Services, the Assistant Secretary for Health, and the Director, CDC, regarding the need for, and the nature of, revisions to the standards under which clinical laboratories are regulated; the impact on medical and laboratory practice of proposed revisions to the standards; and the modification of the standards to accommodate technological advances.

Matters To Be Discussed: The agenda will include updates from the Food and Drug Administration, the Centers for Medicare & Medicaid Services, and the Centers for Disease Control and Prevention; implementation of cytology proficiency testing for individuals; a report from the CLIAC Workgroup on Good Laboratory Practices for Waived Testing, and discussion of the Workgroup's proposals related to such; and an introduction to appropriate quality control for diverse and evolving test systems, including microbiology identification systems. Agenda items are subject to change as priorities dictate.

Providing Oral or Written Comments: It is the policy of CLIAC to accept written public comments and provide a brief period for oral public comments whenever possible. Oral Comments: In general, each individual or group requesting to make an oral presentation will be limited to a total time of five minutes (unless otherwise indicated). Speakers must also submit their comments in writing for inclusion in the meeting's Summary Report. To assure adequate time is scheduled for public comments, individuals or groups planning to make an oral presentation should, when possible, notify the contact person below at least one week prior to the meeting date. Written Comments: For individuals or groups unable to attend the meeting, CLIAC accepts written comments until the date of the meeting (unless otherwise stated). However, the comments should be received at least one week prior to the meeting date so that the comments may be made available to the Committee for their consideration and public

distribution. Written comments, one hard copy with original signature, should be provided to the contact person below. Written comments will be included in the meeting's Summary Report.

Contact Person for Additional Information: Rhonda Whalen, Chief, Laboratory Practice Standards Branch, Division of Laboratory Systems, Office of Public Health Partnerships, CDC, 4770 Buford Highway, NE, Mailstop F-11, Atlanta, Georgia 30341-3717; telephone (770) 488-8042; fax (770) 488-8279; or via e-mail at RWhalen@cdc.gov.

The Director, Management Analysis and Services Office, has been delegated the authority to sign Federal Register Notices pertaining to announcements of meetings and other committee management activities, for CDC and the Agency for Toxic Substances and Disease Registry.

Dated: January 20, 2005.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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