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CDC Recommendations: Good Laboratory Practices for Biochemical Genetic Testing and Newborn Screening for Inherited Metabolic Disorders

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On April 6, 2012, the Centers for Disease Control and Prevention (CDC) published recommendations for good laboratory practices that address the quality-management needs of biochemical genetic testing and newborn screening (1). The CDC recommendations were developed on the basis of the recommendations and input of 3 federal advisory committees (the Clinical Laboratory Improvement Advisory Committee; the Secretary's Advisory Committee on Genetics, Health, and Society; and the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children), as well as stakeholders and organizations representing newborn-screening laboratories. The specific areas covered in these recommendations include quality-management systems; planning and preparing for the introduction of new tests; establishing and verifying test performance; preanalytical (e.g., provision of test information, informed consent, test requests, specimen submission), analytical (e.g., quality control, proficiency testing, and alternative performance assessment), and postanalytical (e.g., test result reporting, result record retention, quality assessment) aspects; confidentiality of patient information and test results; and personnel qualifications and responsibilities. These recommendations provide a comprehensive guide for all those involved in laboratory testing for the screening, detection, diagnosis, monitoring, and clinical management of inherited metabolic diseases.

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Reference

1. CDC. Good laboratory practices for biochemical genetic testing and newborn screening for inherited metabolic disorders. MMWR Recomm Rep 2012;61:1–44. http://www.cdc.gov/mmwr/pdf/rr/rr6102.pdf (Accessed October 2012).