

INTRODUCTION

This checklist is used in conjunction with the All Common and Laboratory General Checklists to inspect a clinical biochemical genetics laboratory section or department.

The Clinical Biochemical Genetics Checklist covers aspects of clinical biochemical genetic testing performed for the diagnosis of inborn errors of metabolism (IEM), including, but not limited to, the analysis of amino acids, organic acids, enzymes involved in intermediary metabolism, carnitine and acylcarnitines, acylglycines, CSF neurotransmitters, sugars, glycosaminoglycans and glycoproteins. Biochemical tests for the identification of heterozygotes of IEMs and newborn screening for IEMs are also covered.



Policy/Procedure icon - The placement of this icon next to a checklist requirement indicates that a written policy or procedure is required to demonstrate compliance with the requirement. The icon is not intended to imply that a separate policy or procedure is required to address individual requirements. A single policy or procedure may cover multiple checklist requirements.

Laboratories not subject to US regulations: Checklist requirements apply to all laboratories unless a specific disclaimer of exclusion is stated in the checklist. When the phrase "FDA-cleared/approved test (or assay)" is used within the checklist, it also applies to tests approved by an internationally recognized regulatory authority (eg, CE-marking).

CLINICAL BIOCHEMICAL GENETICS GENERAL ISSUES

QUALITY MANAGEMENT

GENERAL ISSUES

Inspector Instructions:

	<ul style="list-style-type: none">Sampling of patient results with review by the laboratory director or qualified designee within the turnaround time specified
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CBG.10900 Result Review

Phase I



The laboratory director or qualified designee reviews test results within the turnaround time specified by the laboratory's written procedure.

NOTE: In the case of clinically significant abnormal results, there must be a procedure for rapid communication to and receipt by the laboratory director or qualified designee.