



**Appendix A. ACCE Model List of 44 Targeted Questions Aimed at a Comprehensive Review of Genetic Testing (CDC, 2013)**

Element	Component	Specific Question
<p><b>Disorder/Setting</b></p>		<p>What is the specific clinical disorder to be studied?            What are the clinical findings defining this disorder?            What is the clinical setting in which the test is to be performed?            What DNA test(s) are associated with this disorder?            Are preliminary screening questions employed?            Is it a stand-alone test or is it one of a series of tests?            If it is part of a series of screening tests, are all tests performed in all instances (parallel) or are only some tests performed on the basis of other results (series)?</p>
<p><b>Analytic Validity</b></p>		<p>Is the test qualitative or quantitative?</p>
	<p>Sensitivity</p>	<p>How often is the test positive when a mutation is present?</p>
	<p>Specificity</p>	<p>How often is the test negative when a mutation is not present?</p>
		<p>Is an internal QC program defined and externally monitored?            Have repeated measurements been made on specimens?            What is the within- and between-laboratory precision?            If appropriate, how is confirmatory testing performed to resolve false positive results in a timely manner?            What range of patient specimens have been tested?            How often does the test fail to give a useable result?            How similar are results obtained in multiple laboratories using the same, or different technology?</p>



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<b>Clinical Validity</b>	Sensitivity	How often is the test positive when the disorder is present?
	Specificity	How often is the test negative when a disorder is not present?
		Are there methods to resolve clinical false positive results in a timely manner?
	Prevalence	What is the prevalence of the disorder in this setting?
		Has the test been adequately validated on all populations to which it may be offered? What are the positive and negative predictive values? What are the genotype/phenotype relationships? What are the genetic, environmental or other modifiers?
<b>Clinical Utility</b>	Intervention	What is the natural history of the disorder?
	Intervention	What is the impact of a positive (or negative) test on patient care?
	Intervention	If applicable, are diagnostic tests available?
	Intervention	Is there an effective remedy, acceptable action, or other measurable benefit?
	Intervention	Is there general access to that remedy or action?
		Is the test being offered to a socially vulnerable population?
	Quality Assurance	What quality assurance measures are in place?
	Pilot Trials	What are the results of pilot trials?



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	Health Risks	What health risks can be identified for follow-up testing and/or intervention?
		What are the financial costs associated with testing?
	Economic	What are the economic benefits associated with actions resulting from testing?
	Facilities	What facilities/personnel are available or easily put in place?
	Education	What educational materials have been developed and validated and which of these are available?
		Are there informed consent requirements?
	Monitoring	What methods exist for long term monitoring?
		What guidelines have been developed for evaluating program performance?
<b>ELSI</b>	Impediments	What is known about stigmatization, discrimination, privacy/confidentiality and personal/family social issues?
		Are there legal issues regarding consent, ownership of data and/or samples, patents, licensing, proprietary testing, obligation to disclose, or reporting requirements?
	Safeguards	What safeguards have been described and are these safeguards in place and effective?