

Publicly Available "Higher Order" <sup>1</sup> Reference Materials for Inherited Genetic Diseases			
Organization	FDA-Approved <sup>2</sup>	CE Marked <sup>2</sup>	Certified & Standardized Reference Materials
<a href="#">National Institute for Biological Standards and Controls (NIBSC)</a>			04/224: WHO Reference Reagent Factor V Leiden, Human gDNA
			05/130: WHO Reference Reagent Prothrombin Mutation G20210A, Human gDNA
			08/158: WHO Reference Reagent Fragile X Syndrome gDNA Genetic Reference Panel
<a href="#">Institute for Reference Materials and Measurements (IRMM)</a>			IRMM/IFCC-491: CRM Plasmid DNA carrying human prothrombin gene mutation (homozygous G20210A)
			IRMM/IFCC-490: CRM Plasmid DNA carrying human prothrombin gene (Wildtype)
			IRMM/IFCC-492: CRM Plasmid DNA carrying human prothrombin gene mutation (heterozygous G20210A)
<a href="#">National Institute of Standards and Technology (NIST)</a>			SRM 2392-I: Mitochondrial DNA Sequencing (Human HL-60 DNA)
			SRM 2392: Mitochondrial DNA Sequencing (Human DNA)
			SRM 2399: Fragile X Human DNA Triplet Repeat Standard
			SRM 2394: Heteroplasmic Mitochondrial DNA Mutation Detection Standard
<a href="#">ParagonDx</a>	CYP2D6 *4a/*2AXN		
	CYP2D6 *2M/*17		
	CYP2D6 *29/*2AXN		
	CYP2D6 *6B/*41		
	CYP2D6 *1/*5		
	CYP2D6 *3A/*4A		
<a href="#">Maine Molecular Quality Controls</a>	INTROL™ CF Panel I		

Updated: 12/29/2008

<sup>1</sup>The term "higher order" is not a technical definition and is used by the GeT-RM program in this case to signify Standardized Reference Materials, Certified Reference Materials, FDA-cleared reference materials, and CE-marked reference materials. CE marking (conformity mark) is a mandatory European marking for certain product groups to indicate conformity with the essential health and safety requirements set out in European Directives.

<sup>2</sup>Information provided by manufacturer