Pre-submission Guidance Form

Please complete this form and attach to pre-submission email request.

Validation Element	Validation Element Detail	Comments	Test-specific Information (Please respond to all criteria below or indicate "N/A".)
Accuracy	Method Comparison(s)	Provide a brief description of experimental design (including reference method) with final results and 95% CI.	
Analytical Sensitivity	Limit of Detection	Provide results if applicable.	
	Limits of Quantitation (Upper and Lower)	Provide results if applicable.	
	Minimum Input Quantity and Quality	Provide results if applicable.	
	Minimum Tumor Content	Provide results if applicable.	
Analytical Specificity	Interfering Substances	Indicate, if performed.	

Validation Element	Validation Element Detail	Comments	Test-Specific Information (Please respond to all criteria below or indicate N/A".)
Precision	Intermediate Precision (i.e., inter-assay, "inter-run", between runs, "intra- lab", within lab)	Provide brief description of experimental design with final results and 95% CI.	
	Reproducibility (i.e., "inter-lab", "inter-site", between labs/sites)	Are there multiple lab sites (i.e., CLIA licenses) at which the test is performed?	
	Lot-to-lot Reproducibility	Indicate, if performed.	
Reagent Stability		Indicate, if performed.	
Sample Stability		Indicate, if performed	

Validation Element	Validation Element Detail	Comments	Test-specific Information (Please respond to all criteria below or indicate "N/A".)
Clinical Validity	Indication(s) for use		
	Intended use population		
	Summaries of the studies supporting the clinical validity of the test. Include, for example, elements of the study design, such as the sample size, all primary and secondary endpoints, final results, and any associated statistical analyses.*		
Clinical Utility	Summaries of the studies supporting the clinical utility of the test. Include, for example, elements of the study design, such as the sample size, all primary and secondary endpoints, final results, and any associated statistical analyses. Also provide the MolDX clinical trial designation (mCTD) for each study.*		

* Please provide full citation and copy of published material where available.