Validation Element and Relevant Guidance Document(s)[1]	Validation Element Detail		Test-specific Information • For each cell below, please provide the following information (or indicate "N/A" and briefly explain why): • Brief description of experimental design (e.g., number and type of samples, etc.) • Final results including any associated statistical analyses. (For any point estimates, please provide 95% confidence intervals.) • Page and/or section number(s) in dossier where detailed information can be found.
Reagent Stability (EP-25A)	**Closed/Shelf Life** **Open/In-use** **Shipping (only appliesto manufacturers)** **Freeze thaw**	● Provide brief description of experimental design with final results for each applicable measure based on how reagents are stored prior to testing. ● Reagents should be in primary end-use container.	
Reference Intervals (normal values) (C28-A3C)	**Specimens from healthy subjects in intended-use population** ● Not applicable if test only for use in affected population		
Sample Stability (MM-01) (MM-05) (MM-06) (MM-19) (MM-13A)	**Shipping** **Primary Sample** **Intermediate Samples (e.g., extracted DNA or RNA)** **Freeze thaw**	● Provide brief description of experimental design with final results for each applicable measure based on how samples are stored prior to testing. ● May not be needed depending on nature of primary sample stability testing.	

Validation Element and Relevant Guidance Document(s)[1]	Validation Element Detail	Test-specific Information • For each cell below, please provide the following information (or indicate "N/A" and explain why): • Brief description of experimental design (e.g., number and type of samples, etc.) • Final results including any associated statistical analyses • Page/section number in dossier where detailed information can be found
Clinical Validity Evaluation of Genomic Applications in Practice and Prevention (EGAPP) Working Group recommendations	Include the following: ● Indication(s) for use ● Intended use population(s) ● Summaries of the studies supporting the clinical validity of the test. Include elements of the study design, all primary and secondary endpoints, and any associated statistical analyses. Please limit to 2-3 sentences per study.	
	● Inclusion and exclusion criteria from studies should be consistent with the indication(s) for use and intended use population(s).	
Clinical Utility Evaluation of Genomic Applications in Practice and Prevention (EGAPP) Working Group recommendations	Include the following: ● 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, and any associated statistical analyses. Please limit to 2-3 sentences per study.	

[1] Relevant guidance documents referenced in column 1 above are provided as suggestions for best practices. The list is neither exhaustive nor binding. Unless indicated otherwise, these documents are published by the Clinical Laboratory Standards Institute® (CLSI).

Table 2. Validation Sample Master List[1]

Sample ID	Format (e.g., FFPE, cell line, extracted DNA, etc.)	Source	Tissue (e.g., Lung)	Tumor Type (e.g., NSCLC)	Tumor subtype (e.g., Adenocarcinoma)	Expected Result(s)	Expected Result(s) Methodology	Applicable Validation Element (e.g., accuracy, precision, etc.)

[1] If submitters believe a particular element does not apply to their specific test, please indicate "N/A".