Technical Assessment (TA) Summary Form (M00116 v2)

Please complete the following table summarization of the dossier.

Not all sections are relevant to all test types

Table 1. Summary of Evidence

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"): • Brief description of experimental design (e.g., number and type of samples, etc.). Please limit to 2-3 sentences. • Final results including confidence intervals and statistics (e.g., p-values). • Page and/or section number(s) in dossier where detailed information is found.
Accuracy (EP-9A2)	**Method Comparison(s)** ● Indicate orthogonal reference method ● Estimate method bias	
	Specimen Types ● Indicate all validated specimen types (e.g., FFPE, fresh frozen, core biopsy, cytology, etc.) and briefly describe how validated.	
(EP-14A2)	**Matrix Comparison(s)** ● Indicate all validated sample matrices (e.g., serum, plasma, etc.) and briefly describe how validated.	
Analytical Sensitivity (EP-17A2)	**Limit of Blank**	
	Limit of Detection	
	Limits of Quantitation (Upper and Lower) ● Include description of analytically measurable range and clinically reportable range.	

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Analytical Sensitivity (con't) (EP-06A)	**Linearity and Reportable Range** ● Sample should be free of known interfering substances	
(MM-09A2)	**Minimum Input Quantity and Quality**	
	Minimum Tumor Content	
Analytical Specificity (EP-07A2)	**Primer and Probe Specificity** ● If applicable, provide lists of primers and probes and briefly describe how specificity was determined.	
	Interfering Substances ● Endogenous and exogenous ● Include cross-reactivity if applicable.	

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Precision (EP-05A2) (Quantitative) (EP-12A2) (Qualitative)	**Repeatability** **(i.e., intra-assay, "intra-run", within run)** ● Single operator, instrument, lot, day and run ● "Near" clinical decision points	
	Intermediate Precision **(i.e., inter-assay, "inter-run", between runs, "intra-lab", within lab)** ● Multiple operators, instruments, days and runs (as applicable) within a lab ● "Near" clinical decision points if possible	
	Reproducibility **(i.e., "inter-lab", "inter-site", between labs/sites)** ● Multiple labs/sites (if applicable) ● "Near" clinical decision points if possible	
	Lot-to-lot Reproducibility ● Multiple reagent, calibrator and control lots (as applicable; at least 2 manufacturing lots) ● "Near" clinical decision points if possible	

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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.	

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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. ● Include the MolDX clinical trial designation (mCTD) for each 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".