

CAP laboratory-developed test oversight model

Classification	Determining factors	Oversight	Examples
Low risk	<p>The test result is often used in conjunction with other findings to establish a diagnosis.</p> <p>No claim that the test result indicates prognosis or direction of therapy.</p> <p>The test presents low risk to patients.</p>	<p>The laboratory performs and reviews validation internally prior to offering the test clinically.</p> <p>The accreditor will verify, during the normally scheduled inspections, that the laboratory performed appropriate validation studies.</p>	Cytokeratin Fragile X
Moderate risk	<p>The test result is often used for predicting disease progression or identifying whether a patient is eligible for a specific therapy.</p> <p>The laboratory may make claims about clinical accuracy or clinical utility.</p> <p>The test poses a moderate level of risk to patients.</p>	<p>The laboratory must submit validation studies to the accreditor for external review prior to offering the test clinically.</p>	KRAS HER2
High risk	<p>The test result predicts risk, progression, patient eligibility for a specific therapy.</p> <p>The test uses proprietary algorithms or computations such that the test result cannot be tied to the methods used or inter-laboratory comparisons cannot be performed.</p> <p>The test poses potentially significant risk to patients.</p>	<p>The laboratory must submit the test to the FDA for review prior to offering it clinically.</p>	Oncotype DX