**Laboratory Quality Checklist for BRCA Genetic Testing**

[Practice Name]

All laboratories that perform health-related testing, including genetic testing, are subject to federal regulatory standards called the Clinical Laboratory Improvement Amendments (CLIA). Some states have even stricter requirements than the federal guidelines. Check your state specific requirements prior to performing genetic testing.

CLIA standards cover how tests are performed, the qualifications of laboratory personnel, quality control, and testing procedures for each laboratory. CLIA standards do not address the clinical validity or clinical utility of genetics. The Federal Drug Administration (FDA) is considering a regulatory structure that would standardize genetic testing. Until the FDA standardizes genetic testing−consider the following minimum criteria when evaluating laboratories that will receive genetic test laboratory specimens from your patients.

**Laboratory Quality Checklist: BRCA Genetic Testing**

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| * Number of BRCA genetic specimens evaluated |
| * Percentage of the gene evaluated |
| * Depth of the intron sequenced |
| * Database and algorithms used to interpret variants |
| * Analytical sensitivity and specificity |
| * Operating history, supporting data, and quality control measures |
| * Commitment to variant reclassification when new information is discovered |
| * Communication of both the initial result and any follow-up results |

**Resources:**

U.S. National Library of Medicine, National Institutes of Health: <https://ghr.nlm.nih.gov/primer/testing/validtest>

Physician Insurance of America Association (PIAA) Failure to Recommend Genetic Testing: *The Next Wave of Medical Professional Liability Lawsuits?* Second Quarter, 2017.