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PGDx elio™ tissue complete test verification

Requirements and Example

PGDx elio™ tissue complete is an FDA-cleared IVD test that only requires a verification to allow for rapid deployment into the clinical laboratory.

Verification should be conducted in a certified high-complexity CLIA laboratory under the direction of the laboratory director in accordance with 42 CFR 493.

The laboratory director is responsible for ensuring that verification procedures are adequate to determine the accuracy, precision and other pertinent performance characteristics of the method (42 CFR 293.1445(e)(3)(ii)).

CAP IVD verification requirements from the CAP All Common checklist:

- ACCURACY, COM.40300 – The laboratory verifies or establishes analytical accuracy for each test using a sufficient number of characterized samples
- PRECISION, COM.40310 – The laboratory verifies or establishes analytical precision for each test using a sufficient number of characterized samples with repeated analysis
- REPORTABLE RANGE, COM.40600 – The reportable range is verified or established for each analytical procedure before implementation

For laboratories processing samples from New York state, additional information can be found here:
New York State Department of Health Clinical Laboratory Standards of Practice
Note: Verify the manufacturer's reference interval is appropriate for the laboratory's population.

Example of Verification

The following tables provide two examples of laboratory verifications that were performed using the PGDx elio tissue complete test:

Laboratory 1 (Comprehensive)

Specification	Sample Type	Number of Samples	Description
Accuracy	Clinical FFPE	75	20 tumor types characterized with an orthogonal assay
Precision	Clinical FFPE	13	Previously characterized material across 2 operators, 2 instruments and 3 days
Reportable Range	FFPE / Cell lines	75 (same as accuracy)	Verified TMB scores of the accuracy cases throughout the reportable range

Laboratory 2 (Standard)

Specification	Sample Type	Number of Samples	Description
Accuracy	Clinical FFPE	15	9 clinical samples, 1 standard, 5 cell lines
Precision	Clinical FFPE	9	Previously characterized material across 2 operators, 1 instrument, 2 days
Reportable Range	FFPE / Cell lines	15	9 clinical samples, 1 standard, 5 cell lines

The following reference standards contain a variety of clinically relevant variants that may be used to assess detection of SNVs, indels, amplifications and fusions. Please see vendor pages for detailed variant information.

Vendor	Product Name	Catalog ID	Variants confirmed
Horizon Diagnostics	Structural Multiplex Reference Standard (FFPE)	HD789	SNV, indel, amplification, fusion
Seracare	Seraseq® Tumor Mutation DNA Mix v2 AF 7 HC	Material Number 0710-0095	SNV, amplification, fusion

The references and examples presented here, are not all inclusive of studies that may need to be performed depending on the patient population, the laboratory certification or the laboratory environment. PGDx does not make any recommendations with respect to verification.

Learn more about PGDx at PersonalGenome.com
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