PALMETTO GBA
DEX™

Technical Assessment Submission Checklist and Questionnaire (GEN-CQM-003-v1)

Please complete the questionnaire below and submit the following relevant information with your dossier as indicated. Include this form with your submission. Please note that **all relevant** materials must be submitted for a dossier to be considered complete. If you believe that any requested items do not or should not apply, please indicate this and briefly explain why.

Applicant/Lab | Test Name | DEX Z-Code™

Test Details Checklist/Questionnaire:

	YES	NO	
1.	○	○	Is this test based on novel/proprietary technology or algorithms, and/or provides a result based on such technology or algorithms? If checked, Clinical Validity and Clinical Utility must be described. Complete form GEN-PF-001, Technical Assessment Summary Form.
2.	○	○	Does this test include NGS Methodology?
3.	○	○	Is this an Allograft Assessment test? If yes, complete forms ALLO-CQ-003, ALLO-PF-009 and skip to **Additional Information**.
4.	○	○	Is this a Pharmacogenomics (PGx) panel/test? If yes, complete form PGX-PF-007 and skip to **Additional Information**.
5.	○	○	Is this a Molecular Syndromic Infectious Disease (ID) panel test? If yes, please indicate the following, then complete form MID-PF-019 and skip to **Additional Information**.

a. Type of panel test: Select the type of panel. If Other, please specify:

b. Methodology: Select methodology. If Other, please specify:

6.	○	○	Is this a Molecular Risk Stratification test? If yes, please indicate the following, then complete forms MRS-PF-020, GEN-PF-001 and skip to **Additional Information**.

a. Is this test for risk stratification of cancer?

b. Indication/Organ System:

c. Methodology: Select methodology. If Other, please specify:

7.	○	○	Is this test for Somatic Testing? If yes, please indicate the following and proceed to **Additional Information**.

Note: Question continues on next page

a. Check if this is for Solid Tumor or Hematopoietic Malignancies:

- ☐ Solid Tumor
- ☐ Solid Tumor, plasma-based
- ☐ Hematopoietic Malignancies

Questions continue on next page

Test Details Checklist/Questionnaire Continued:

YES NO

7. (continued) b. Check if this application is an NGS "Targeted" or "Comprehensive Genomic Profile" (CGP) (as defined in **Definitions**):

- ☐ Targeted
  - ➢ Solid Tumor and Solid Tumor, plasma-based, complete form NGS-PF-004
  - ➢ Hematopoietic Malignancies, complete form NGS-PF-005
- ☐ CGP
  - ➢ Solid Tumor and Solid Tumor, plasma-based, complete forms NGS-PF-004 and NGS-PF-002
  - ➢ Hematopoietic Malignancies, complete forms NGS-PF-005 and NGS-PF-002

c. ☐ Check if this test is to detect Minimal Residual Disease (MRD), complete form MRD-PF-016

- ☐ Check if test includes tumor profiling prior to MRD testing, in addition to MRD-PF-016, complete form NGS-PF-002

8. ◯ ◯ Is this test for Germline Testing?
If yes, please indicate the following, and proceed to **Additional Information**.

- ☐ Inherited Cancer, complete form NGS-PF-006
- ☐ Whole Exome Sequencing (WES), complete form NGS-PF-002
- ☐ Whole Genome Sequencing (WGS), complete form NGS-PF-002

If the test is not described above, please email for assistance.

Additional Information: The following documentation is required along with forms described above.

1. ☐ A list or table of contents of all materials submitted as part of the dossier.
2. ☐ **Executive Summary:** Include name of test, Z-Code assigned, test description including platform, lab providing the test (or manufacturer), NPI, and a brief description of the clinical validity of the test. Provide a summary on the background of the test and its intended use. This includes who should be tested, when, and why. Additionally, any professional society or other clinical guidelines addressing the use of this test or similar tests, if no such guidelines have been published, please indicate this. For example, how does the test change physician behavior and/or improve patient outcomes? Please limit summary to one page.
3. ☐ Sample reports.
4. ☐ Complete **Analytical and Clinical Validation** documents.
5. ☐ A copy of your **test requisition form (TRF)**.
6. ☐ Documentation of final test approval by **New York State Department (NYSDOH)** and/or the **US Food and Drug Administration (FDA)**, as well as any written questions from NYSDOH and/or the FDA and your written response(s), if applicable.

See the following page for Definitions.

Definitions:

- **Algorithm** – An algorithm may be considered a meaningful and independent component of a laboratory process when ALL the following conditions are met:
  - It is an unambiguous problem-solving operation that includes deploying a set of rules or calculations requiring computer processing;
  - The test result (or a component of the result) is the calculated output of this process, and not an intermediary process;
  - The same or similar test result could not be obtained without the use of this process;
  - The input for the computation is derived from biological samples using analytical processes, and must include data from the sample submitted for the test;
  - The process must:
    - Either be required for the analytical result, OR
    - If adjunct to the analytical result as a post-analytical process, the calculation itself must be independently found to be reasonable and necessary apart from the other components of the test.
- **Comprehensive Genomic Profile (CGP)** – NGS based molecular assays that provide additional insight beyond individual gene hotspots; these assays seek to describe the genomic makeup of a tumor and can help identify underlying mechanisms of disease to guide clinical decision making. These tests include not only mutations in individual relevant genes, but also patterns of mutations across related genes in established cancer pathways and often include an assessment of overall mutational burden. These tests typically involve sequencing of entire exonic regions of genes of interest (within a comprehensive gene panel or whole exome sequencing), and may also include selected intronic regions. CGP can detect multiple types of molecular alterations (i.e., SNVs, small and large INDELs, copy number alterations (CNAs), structural variants (SVs), and splice-site variants) in a single assay. Patterns of mutations seen across multiple genes may be used to infer clinically relevant etiologies, such as DNA mismatch repair deficiency and microsatellite instability, and total mutational load/burden (TMB) may be determined. CGP testing may also include RNA sequencing to detect structural variations, such as translocations or large deletions, and to detect functional splicing mutations.

- **Targeted Panel –** Tests that identify somatic alterations known to occur in certain regions (i.e., 'hotspots') within specific genes of interest for cancer management (i.e., diagnosis, selection of molecularly targeted therapies, prognosis in a context where prognostic classification is essential for treatment selection). Generally, these NGS panels can detect single nucleotide variants (SNVs) and small insertions or deletions (INDELs) within these regions.

- **Sample Level Data** – Expected versus observed results for each unique sample tested. For an example of how this data can be displayed, refer to Table 2 of Technical Assessment Summary Form (GEN-PF-001).