PALMETTO GBA DEX®

Technical Assessment Submission Checklist and Questionnaire (GEN-CQM-003-v2)

Please complete Section 1 and submit the following relevant information with your dossier as indicated. If you have been asked to submit additional documentation (example: tech transfer, methodology changes) complete Section 2. 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.

Not all services require additional Technical Assessment documentation.

Do not proceed unless additional documentation has been requested via email.

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

Section 1. 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.

NOTE: Only complete this form if your test **DOES NOT** fall into a category listed below

2.	○	○	Is this a Transplant Related test? If yes, please indicate the following, and proceed to **Additional Information**.

- ☐ Allograft Assessment, complete ALLO-CQ-003, ALLO-PF-009
- ☐ Chimerism by non-STR based method, complete GEN-PF-001

3.	○	○	Is this a Pharmacogenomics (PGx) panel/test? If yes, complete form PGX-PF-007, and proceed to **Additional Information**.
4.	○	○	Is this a Molecular Syndromic Infectious Disease (ID) panel test? If yes, please indicate the following, then complete form MID-PF-019, and proceed 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:

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

a. Is this test for risk stratification of cancer?

b. Indication/Organ System:

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

Questions continue on next page.

Section 1. Test Details Checklist/Questionnaire Continued:

	YES	NO	
6.	○	○	Is this test for Somatic Testing? If yes, please indicate the following, and proceed to **Additional Information**.

a. Is this test for Targeted or Comprehensive (CGP) (as defined in Definitions):

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

- ☐ Solid Tumor, complete form SOM-PF-004
- ☐ Solid Tumor, plasma-based, complete form SOM-PF-004
- ☐ Myeloid Malignancies, complete form SOM-PF-005

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

7.	○	○	Is this test for Inherited Cancer Testing? If yes, please complete form GER-PF-006, and proceed to **Additional Information**.
8.	○	○	Is this test for Inherited Germline (non-Cancer) Testing? If yes, please complete form GER-PF-008, proceed to **Additional Information**.

NOTE: Do not submit a TA for a Germline Test unless requested.

If the test is not described above, please moldx@palmettogba.com for assistance.

See the following page for Additional Information and Definitions.

Section 1. Test Details Checklist/Questionnaire Continued:

Additional Information: Please submit the following documentation 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.
7. ☐ Full-text **PDF copy of peer-reviewed publications** that demonstrate clinical validity and clinical utility for the intended use of this (or similar) tests in the intended-use population, if applicable. For example, **MID** and **Allograft** TAs both require supporting literature.

Section 2: Requests for Supplemental TA Documentation for services previously assessed by MolDX

Revisions to Existing Services: Please submit the following documentation:
Note: Substantial changes to the service may require **Section 1** to be completed.

1. ☐ **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, what has been updated and its intended use.
2. ☐ Updated sample reports.
3. ☐ Updated **Analytical and Clinical Validation** documents.

Technical Transfers: Please submit the following documentation:
Technical Transfer of same service from one physical location to another, or adding a secondary testing location under the same parent facility.

1. ☐ **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 how the test has been verified in the subsequent location.
2. ☐ Updated sample reports.
3. ☐ **Tech Transfer Documentation:** Comparator data between the two locations.

Please contact moldx@palmettogba.com with any questions.

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)** – CGP testing refers to 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 select intronic regions. CGP tests can detect multiple types of molecular alterations (i.e., SNVs, small and large INDELs, copy number variants (CNVs), 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 (MSI), total mutational load/burden (TMB) and chromosome abnormalities such as loss of heterozygosity (LOH). CGP testing may also include RNA sequencing to detect structural variations, such as translocations or large deletions, and to detect functional splicing mutations. CGP testing is not defined as a targeted panel by MolDX. CGP tests are expected to yield information of clinical relevance beyond a targeted panel, for example, to identify relevant clinical trials for patient management or identify possible therapeutic interventions for off-label use. It is expected that a CGP will identify all clinically relevant information attainable for the type of service performed.

- **Targeted Panel** – Targeted tumor panels are hereby defined as 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 panels are limited to specific variant types at defined sites, such as single nucleotide variants (SNVs), small insertions/deletions (INDELs), single site copy number variants, or gene fusions. These alterations typically represent response or lack of response to corresponding targeted cancer therapies. The hotspot test should include relevant targets required for companion diagnostic testing and/or known to be necessary for proper patient management.

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