PALMETTO GBA
DEX®

Technical Assessment Submission Checklist and Questionnaire for:
Molecular Testing for Solid Organ Allograft Rejection (ALLO-CQ-003-v3)

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.	◯	◯	Does your test demonstrate *similar indicated uses and similar performance* to any other commercially available test on the market? If Yes, please list the most similar test:
2.	◯	◯	Is this an FDA approved or cleared test?

3. For which of the following allograft types is this test used (mark all that apply)?

- ☐ Kidney
- ☐ Heart
- ☐ Other, list:

If Other, GEN-PF-001, Technical Assessment (TA) Summary Form must be submitted.

4. The test provides information about at least one of the two following clinical determinations:

- ☐ *Acute Rejection (AR) status*
- ☐ *Cellular or Antibody-mediated rejection (ACR or AMR) status*

5. What is the intended use of the test (check all that apply)?

- ☐ *To assist in the evaluation of adequacy of immunosuppression, wherein a non-invasive or minimally invasive test can be used in lieu of a tissue biopsy in a patient for whom information from a tissue biopsy would be used to make a management decision regarding immunosuppression* (if yes, submit form GEN-PF-001)
- ☐ *As a rule-out test for AR in validated populations of patients with clinical suspicion of rejection with a non-invasive or minimally invasive test to make a clinical decision regarding obtaining a biopsy*
- ☐ *For further evaluation of allograft status for the probability of allograft rejection after a physician-assessed pretest*
- ☐ *To assess rejection status in patients that have received a biopsy, but the biopsy results are inconclusive or limited by insufficient material* (if yes, submit form GEN-PF-001)

YES NO

6. ◯ ◯ Has assay performance been assessed separately relative to protocol as well as for- cause biopsies?
(If performance has been assessed only relative to protocol biopsies, complete form GEN-PF-001)

7. In the following table, please list ALL intended uses of this test, and include defined characteristics of the intended use population, such as: time post-transplant for eligibility, patient age, or other demographic criteria for use. Add more rows to the table if necessary.

Intended Use	Eligibility criteria

8. What is the specimen source?
- ☐ Blood or Plasma
- ☐ Other (if other, describe here and submit form GEN-PF-001):

9. What are the measured analytes (check all that apply)?
- ☐ Allograft cfDNA
- ☐ Other (if other, describe here and submit form GEN-PF-001):

10. ◯ ◯ Is this test based on novel/proprietary technology or algorithms, and/or provides a result based on such technology or algorithms (as defined in **Definitions** below)?
If Yes, Clinical Validity and Clinical Utility must be described. Complete form GEN-PF-001.

11. ◯ ◯ Does this test include NGS Methodology?

12. ◯ ◯ Does this test include Microarray gene expression analysis?
If Yes, submit form GEN-PF-001.

See the following page for additional documentation that may be required.

Please submit the following information:
IF a section is not applicable for your test, do not check the box.

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); and NPI. Provide a summary on the background of the test and its intended use. This includes who should be tested, when, and why.
3. ☐ Sample reports.
4. ☐ Most recent inspection results (including recommendations) from CLIA, CAP, and NYSDOH, as applicable).
5. ☐ Form ALLO-PF-009, Allograft Rejection Performance (complete each applicable worksheet in the workbook).
6. ☐ **If submitting form GEN-PF-001, also submit the following:**
    a. ☐ Complete Analytical and Clinical Validation documents.
    b. ☐ Complete Algorithm Validation documents, if relevant.
    c. ☐ Documentation of final test approval by **New York Stat Department of Health (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 responses(s).
    d. ☐ Results from the last cycle of **proficiency testing (PT) as well as the SOP for performing PT.**
    e. ☐ A copy of your **test requestion form (TRF).**
    f. ☐ Any **technology assessments** (e.g., Evidence Street, AHRQ, Hayes, ECRI, etc.) and/or medical policy decisions for this test or similar tests. If none have been performed or published, please indicate this.
    g. ☐ **Any professional society or other clinical guidelines** addressing use of this test or similar tests. If no such guidelines have been published, please indicate this.
    h. ☐ **Educational and/or marketing materials** for providers and/or patients (including web-based materials).
    i. ☐ **Full-text PDF copies of the peer-reviewed literature, as well as an outline or Table highlighting the most noteworthy points relevant to your test.**

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.

  Examples:
    - A gene expression profile test wherein sequencing data must be compared in a calculation to an existing and validated set of profiles to bin it in one of several possible risk stratification groups would require the use of an algorithm as defined above.
    - A next generation sequencing (NGS) test that uses computation to identify variants in a sample is not considered as using an algorithm in this context. The calculation in this scenario is seen as an intermediary process.
    - Calculations using only clinical information not derived from analytical services on biological samples are not considered algorithms in this context. Examples would include using the clinical information from the patient in a calculation to assess their risk stratification or using a similar process to identify relevant clinical annotations derived from literature as associations with sequencing variants.
    - A test that inputs resultant analytical processes that are reasonable and necessary (such as gene variants or protein markers) that are post processed by computation, but wherein that subsequent computation is not independently established as reasonable and necessary above and beyond the other lab components, shall not be considered an algorithm as a valid component of a laboratory test.