MolDX Technical Assessment Submission Checklist and Questionnaire for Tests seeking coverage under *MolDX: Molecular Testing for Solid Organ Allograft Rejection (L38568)*
form M00159v1

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*_____

*Z-identifier:*_____

Does your test demonstrate similar indicated uses and similar performance to any if the tests currently covered by MolDx identified in the following Billing and Coding Article - MolDX: Molecular Testing for Solid Organ Allograft Rejection (A58019) ? ☐ **Yes** ☐ **No**

If Yes, please list the most similar tests here _____

If you have questions, contact MolDx at moldx@palmettogba.com

Test Details Checklist/Questionnaire:

1. Is this an FDA approved or cleared test? ☐ **Yes** ☐ **No**
2. For which of the following allograft types is this test used (mark all that apply)?

   ☐ **Kidney** ☐ **Heart** ☐ **Other**

If Other, list the types here : _____and submit form M00116, ***Technical Assessment (TA) Summary Form.***

3. The test provides information about *at least one* of the two following clinical status determinations:
   - Acute Rejection (AR) status ☐ **Yes** ☐ **No**
   - Cellular or Antibody-mediated rejection (ACR or AMR) status ☐ **Yes** ☐ **No**
4. 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 M00116) ☐ **Yes** ☐ **No**
   - 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 ☐ **Yes** ☐ **No**
   - For further evaluation of allograft status for the probability of allograft rejection after a physician-assessed pretest ☐ **Yes** ☐ **No**
   - 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 M00116) ☐ **Yes** ☐ **No**
5. 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 M00116). ☐ **Yes** ☐ **No**

6. In the following table, please list the 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

7. What is the specimen source?
   ___ Blood or Plasma
   ___ Other (if other, describe here and submit form M00116: _____)

8. What are the measured analytes (check all that apply)?
   ___ Allograft cfDNA
   ___ Other (if other, describe here and submit form M00116: _____)

9. Is this a test based on novel/proprietary technology or algorithms, and/or provides a result based on such technology or algorithms (as defined in A58650 MolDX: Algorithm definition as a component of a laboratory test)? (Y/N) ***If Yes, Clinical Validity and Clinical Utility must be described. Complete form M00116.***

10. Does this test include NGS Methodology? ☐ **Yes** ☐ **No**

11. Does this test include Microarray gene expression analysis? ☐ **Yes** ☐ **No**
    If Yes to #11, submit form M00116.

Please submit the following additional documentation (IF a section is not applicable for your test, please write N/A next to that specific item)

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 ***M00160, Allograft Rejection Performance Tables*** *(complete each applicable worksheet in the workbook).*
6. **If submitting form M00116, 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 State 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 response(s).

d. ☐ Results from the last cycle of **proficiency (PT) testing as well as the SOP for performing PT**.

e. ☐ A copy of your **test requisition 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.**