MolDX Technical Assessment Submission Checklist and Questionnaire (M00151, V5)

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 _____

Test Details Checklist/Questionnaire

1. Does this test result in a report/information that is *limited to* providing patient genetic/genomic information and ancillary data that are not proprietary, utilizing methodologies for which Clinical Validity (CV) and Clinical Utility (CV) are well-established in the literature? If yes, skip to question #3. ◯ Yes ◯ No
2. Is this a test based on novel/proprietary technology or algorithms, and/or provides a result based on such technology or algorithms? If yes, Clinical Validity and Clinical Utility must be described. Complete form M00116**,** Technical Assessment Summary Form. ◯ Yes ◯ No
3. Does this test include NGS Methodology? ◯ Yes ◯ No
   a. If no, and if #2 above does not apply, a TA submission is not required at this time. We will inform you if other forms are needed for your submission. If #2 above does apply, see the next page.
   b. If yes, specify if the test is for somatic or germline testing: ◯ Somatic ◯ Germline
   c. Somatic testing - Select the following that apply:

      ☐ Is a Targeted Panel test (see definition in Article A54795)

      ☐ Includes full exonic coverage of a majority of genes

      ☐ Allows comprehensive assessment of cancer pathway activation

      ☐ Reliably detects INDELs >40bp

      ☐ Reliably detects amplifications at a single locus

      ☐ Reliably detects copy number alterations at the single allele level (gain/loss)

      ☐ Reliably detects splice site variants

      ☐ Reliably detects gene fusions from DNA (including intronic regions)

      ☐ Reliably detects fusions/translocations from RNA-based libraries

      ☐ Calculates Tumor Mutational Burden (TMB)

      ☐ Identifies microsatellite instability (MSI) status

   d. Select the following that apply to this test (germline):

      ☐ Disease-specific panel (specify disease(s)): _____

      ☐ Hereditary cancer panel (specify cancers or identify as “pan cancer”): _____

      ☐ Whole Exome Sequencing (WES) (submit form M00119)

      ☐ Whole Genome Sequencing (WGS) (submit form M00119)

      For germline tests, please complete form M00155

4. ☐ Check if this application is for an NGS “Targeted Panel” test described by CPT codes 81445 or 81450 (defined in A54795):
   a. If performing a solid tumor test, complete form M00153
   b. If performing panel for hematopoietic malignancies, complete form M00154
5. ☐ Check if this test is an NGS “Comprehensive Genomic Profile” (CGP) as defined in Article A54795. Complete form M00119 in addition to M00153 for a solid tumor test and M00154 for a hematopoietic malignancy test.
6. ☐ Check if this test is a cell-free DNA (ctDNA) test.
7. If the test includes NGS methodology but is not described by numbers 3, 4, 5, or 6, please email us at moldx@palmettogba.com.

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

If you are submitting an application for a test that fulfills *any* of the following criteria:

a. Answered "yes" to question #2 above
b. Is a CGP, WES or WGS test
c. Test not otherwise described in any of the sections above

Please submit the following information:

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. Also include a brief description of the clinical validity and utility of the test. 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 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), if applicable.
7. ☐ **Most recent inspection results** (including recommendations) from CLIA, CAP, and NYSDOH, as applicable).
8. ☐ **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.
9. ☐ **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.
10. ☐ **Educational and/or marketing materials** for providers and/or patients (including web-based materials).
11. ☐ **Results** from the last cycle of **proficiency (PT) testing**, as well as the SOP describing PT for the test (if applicable).