**MolDX: Non-Next Generation Sequencing Targeted Molecular Panel Tests for Predictive Testing in Cancer**

**Proposed LCD ID: DL40210**

*Submitted 12/17/2025*

LUNGevity Foundation appreciates the chance to submit remarks on DL40210, as MolDx considers revisions for a final version. We recognize that our remarks fall outside the autumn comment period, and we will keep them brief and general.

We are supportive of the overall intention of the LCD, which will clarify that rapid non-NGS tests are sometimes medically necessary to ensure rapid access to important targeted treatments. At the same time, it is a standard of care to provide comprehensive genomic profiling, considering the full spectrum of mutations (single nucleotide, small indel, copy number, and rearrangements) as well as less-common genes that are critical routes to therapy (e.g. Ros-1). Many patients also benefit from larger panels that include tumor mutational burden, MSI (Microsatellite Instability) and HRD (Homologous Recombination Deficiency), and larger-scale sequencing that allows creation of bespoke panels for minimal residual disease detection.

We urge MolDx to be sure that any final wording is clear about the complementary, non-overlapping roles of very rapid limited testing and comprehensive testing, especially in lung cancer patients. Clarity is even more important because MolDx LCDs may be templates for LCDs in non-MolDx MACs, and must be interpreted by Medicare Advantage plans as well as commercial and Medicaid plans in the states with state biomarker laws based on Medicare coverage.

Thank you for the ongoing hard work of MolDx staff to ensure prompt and medically necessary access to molecular testing.