From:	MOLDX
To:	MOLDX.POLICY
Subject:	[EXTERNAL] New LCD Request — [Multi-gene PCR based testing in Oncology]
Date:	Friday, May 16, 2025 1:50:56 PM

From: Anjana Bhattacharya <a.bhattacharya@biofidelity.com>
Sent: Tuesday, June 11, 2024 12:18 AM
To: MOLDX.POLICY <MOLDX.POLICY@palmettogba.com>
Subject: [EXTERNAL] New LCD Request — [Multi-gene PCR based testing in Oncology]

Dear MolDX team,

As per your earlier advice, please find attached our LCD request for coverage of multi-gene PCR based testing in oncology along with supporting evidence.

Incomplete molecular testing, limited clinical sample availability, complex testing workflows coupled with report interpretation and racial disparities are barriers to the routine delivery of precision oncology despite ample evidence showing that clinical outcomes in cancer patients improve with appropriate targeted therapies. Our LCD request submission is supported by key validation publication(s) (in the attached zip folder) of several multi-gene PCR-based methodologies for genomic biomarker detection across multiple solid tumor indications that can address these gaps.

We especially highlight the need for low overall specimen and nucleic acid input testing in diverse clinical specimens that is enabled by these newer methodologies as emerging biomarkers are added to clinical practice and increasing strain is being put on clinical specimen triage. The analytical success rate is higher with PCR-based tests, likely due to the simpler testing process compared with NGS-based methods. These newer PCR-based testing methodologies also benefit patient care by simplifying genomic analysis/interpretation and reducing turnaround time, especially when the test results are needed in parallel with other types of testing such as PD-L1 immunohistochemistry (IHC) to inform the appropriate first-line treatment plan.

Lastly, racial, and ethnic disparities in biomarker testing is an ongoing challenge and PCR-

based methods show the potential for addressing some of the current gaps and providing access to clinical guideline mandated biomarker testing to diverse patient populations.

We thank you for your kind consideration in advance. Please let us know if you have any further questions or concerns.

Anjana Bhattacharya, PhD
Vice President, Strategic Marketing

email: a.bhattacharya@biofidelity.com
phone: 1-608-695-5696