TEMPLATE INSTRUCTIONS: The template black text and tables would appear as written and/or displayed. The blue text describes the intended report content, provides recommendations on, or includes clarifications regarding the intended report content.

ANYLAB, INC. MRN: _____ Report Status: _____

MOLECULAR BIOMARKER REPORT

Patient Name: _____	Test: _____	Collection date: _____
Medical record number (MRN): _____	Tumor Type: _____	Received date: _____
	Specimen Type: _____	Report date: _____
Date of birth (DOB): _____	Specimen No.: _____	Report status: _____
Sex: *Assigned at birth* Gender: *Optional, self-identified*	Percentage neoplastic cells: _____%	

MOLECULAR BIOMARKER RESULT SUMMARY

Tier*	Variant Detected	Alteration Type	Allele Frequency (VAF)† / Copy Number‡	Level of Evidence	Targeted Therapy
I	*Genomic alteration using HUGO gene name, transcript and HGVS nomenclature (c., p.) and colloquial name (if applicable) reported per AMP/ASCO/CAP Standards and Guidelines for the Interpretation and Reporting of Sequence Variants in Cancer (PMID: 27993330).*	*Single nucleotide variants, indels, splice site, exon skipping, copy number variant, missense, gene fusion, etc.*	*If there are multiple genomic alterations, list in matching numbered rows. If not applicable, state "Not applicable."*	*Level of Evidence*: Therapeutic, Diagnosis, and/or Prognosis; Levels A–D.*	*Targeted therapies relevant for the specific practice area provided here (e.g., FDA in the US); Use drug classes if there are too many options.*
II	*If there are multiple genomic alterations detected, they should appear in separate numbered rows based on disease relevance. If none are detected, state "None detected at the time of the report."*	*If there are multiple genomic alterations, list in matching numbered rows. If none are detected, state "Not applicable."*	*Allele Frequency (VAF) / Copy Number; If there are multiple genomic alterations, list in matching numbered rows. If not applicable, state "Not applicable."*	*If there are multiple genomic alterations, list in matching numbered rows. If none are detected, state "Not applicable."*	*If there are multiple genomic alterations, list in matching numbered rows. If none are detected, state "Not applicable."*
III					
IV					

*Tier and Level of Evidence based on *AMP/ASCO/CAP Standards and Guidelines for the Interpretation and Reporting of Sequence Variants in Cancer* (PMID: 27993330)
†VAF = Variant Allele Frequency or Variant Allele Fraction. VAF is defined in Test Description section below. ‡More information available in the Interpretative Summary.
Define VAF in Test Description section below. State the ratio, then state gain or loss with an asterisk, with more information in the Interpretative Summary. If the ratio is stated, incorporate a disclosure or description.

GENOMIC SIGNATURES RESULT SUMMARY*

Biomarker	Sample	Result
Microsatellite instability (MSI)	*Sample type; Tumor only or Tumor / Germline Pair*	*High / Low with ranges/cutoffs as defined by laboratory OR Assay not performed*
Tumor Mutational Burden (TMB)	*Sample type; Tumor only or Tumor / Germline Pair*	*High / Low with ranges/cutoffs as defined by laboratory OR Assay not performed*
Homologous recombination deficiency (HRD) status	*Sample type; Tumor only or Tumor / Germline Pair*	*High / Low with ranges/cutoffs as defined by laboratory OR Assay not performed*

*Inclusion of genomic signatures results will depend upon the test(s) being ordered / assay(s) being performed.

INTERPRETATIVE SUMMARY

HISTOLOGICAL DIAGNOSIS

Include histological diagnosis, but not immunohistochemistry (IHC) results unless directly relevant (optional inclusion). Alternatively, provide comments to check the IHC results if they appear elsewhere. If there were concerns with the sample (e.g., quality) that may impact result interpretation indicate here. Histological diagnosis verbatim from surgical pathology report.

TEST RESULT INTERPRETATION

Summarily describe clinically relevant molecular biomarkers detected and any methodological information that could impact the clinician's understanding of the results or subsequent decision making here. Refer clinician to Detailed Interpretation for additional details. Include biomarker-related therapeutic information and PMIDs as appropriate. Include a similar summary of genomic signature test information here when available.

PERTINENT NEGATIVES

State specifically if these assays did not identify any other clinically relevant molecular alterations. Call out specific pertinent negatives for the diagnosis / condition.

CLINICAL CORRELATION

Include a prominent statement that clinical correlation of these results in the patient is required and findings are a snapshot based on currently available information, therefore subject to change.

CLINICAL TRIALS *(Optional section)*

State if biomarker results qualify patient for clinical trials. Optional location to list the trials; lab may choose to place information in a dedicated section further in the report or an Appendix.

DETAILED INTERPRETATION

SPECIFIC VARIANT IDENTIFIED *If there are multiple genomic alterations detected, they should appear in separate numbered rows based on disease relevance. If none are detected, state "None detected at the time of the report."*	**BACKGROUND** *Succinct background on variant and known role in oncogenesis for disease with PMIDs. Hyperlinks could provide additional information. Content should be written for expert use with sufficient detail to provide report portability but with the understanding that there are multiple consumers of the report (e.g., non-oncologist clinicians, community practice providers, patients). Consider having a subsection for non-oncologists, community practice providers, and patients if needed.* **VARIANT PREVALENCE** *If prevalence is unknown, then state that it is unknown, with clarification when necessary. If prevalence in patient's demographic is unknown, state known prevalence(s) with comment that prevalence in patient's demographic is currently unknown.* **VARIANT EFFECT** *Succinct description with PMIDs. Content should be written with sufficient detail to provide report portability but with the understanding that there are multiple consumers of the report (e.g., non-oncologist clinicians, community practice providers, patients).* **PRACTICE GUIDELINES** *Citation of relevant practice guidelines; include both evidence-based and consensus-based peer-reviewed guidelines as appropriate.* **THERAPEUTIC IMPLICATIONS** *(incorporates predictive)* TUMOR TYPE: *If none are available at the time of the report, state "none available at the time of the report."* NON-TUMOR TYPE: *Include if applicable and available at the time of the report.* **PROGNOSTIC IMPLICATIONS** *If unknown, then state that it is unknown, with clarification when necessary.*

VARIANTS OF UNKNOWN CLINICAL SIGNIFICANCE (VUS)

Define VUS and provide a brief explanation of why they are included in the report. Content should be written with sufficient detail to provide report portability for a molecular laboratory professional but with the understanding that there are multiple consumers of the report (e.g., non-oncologist clinicians, community practice providers, patients).

Sample language: The variant(s) below were detected in this sample. The significance of these variant(s) has not been adequately characterized in the scientific literature at the time of this report and/or the context makes the significance of these variant(s) unclear. They are included here in the event that they become clinically meaningful in the future.

VUS DETECTED:

Provide list of VUS detected. If no VUS detected, report "none detected."

TEST DESCRIPTION

Assay performance characteristics should be listed here. This should include, but is not limited to, relevant pre-analytical, analytical, clinical, demographic, interpretive, and reporting components that can affect result interpretation by molecular laboratory professionals, pathologists, and clinicians. Definitions and/or calculations should be provided as appropriate, including Variant Allele Frequency or Variant Allele Fraction. Content should be written with sufficient detail to provide report portability for a molecular laboratory professional but with the understanding that there are multiple consumers of the report (e.g., non-oncologist clinicians, community practice providers, patients).

Information on areas of genomic coverage can be listed or provided either as hyperlink or upon request.

TEST LIMITATIONS

Assay limitations that can affect result interpretation should be listed here.

CPT CODING

Optional section.

TESTING LABORATORY

Contact information for the testing laboratory. Specific content may be subject to accreditation and/or regulatory requirements.

CLINICAL TRIALS *(Section is optional or could be included as an appendix)*

VARIANT *Specific variant that qualifies the patient for the trial*	**CLINICAL TRIALS MATCHED FOR VARIANT AND DISEASE** *If provided, favor providing open trials and/or trials that patient has a reasonable expectation of being able to take part in (e.g., geographic location, etc.).*
	CLINICAL TRIALS MATCHED FOR VARIANT ONLY *If provided, favor providing open trials and/or trials that patient has a reasonable expectation of being able to take part in (e.g., geographic location, etc.).*

VARIANT *Specific variant that qualifies the patient for the trial*	**CLINICAL TRIALS MATCHED FOR VARIANT AND DISEASE** *If provided, favor providing open trials and/or trials that patient has a reasonable expectation of being able to take part in (e.g., geographic location, etc.).*
	CLINICAL TRIALS MATCHED FOR VARIANT ONLY *If provided, favor providing open trials and/or trials that patient has a reasonable expectation of being able to take part in (e.g., geographic location, etc.).*

VARIANT *Specific variant that qualifies the patient for the trial*	**CLINICAL TRIALS MATCHED FOR VARIANT AND DISEASE** *If provided, favor providing open trials and/or trials that patient has a reasonable expectation of being able to take part in (e.g., geographic location, etc.).*
	CLINICAL TRIALS MATCHED FOR VARIANT ONLY *If provided, favor providing open trials and/or trials that patient has a reasonable expectation of being able to take part in (e.g., geographic location, etc.).*

DISCLAIMER

Include a Clinical Trials Disclaimer Sample language: Availability of clinical trials depends on many factors. Whether any specific trial is appropriate for an individual patient should be discussed with the care team.