Aspyre® Clinical Test for Lung

Test requisition

Attach Label Here

Aspyre® Clinical Test

Patient Information (Required)

LAST NAME	FIRST NAME	MI	SUFFIX	DOB (MM/DD/YYYY)	BIOLOGICAL SEX ☐ M ☐ F

MEDICAL RECORD NUMBER	ASSOCIATED TEST ORDER NUMBER (OPTIONAL)

STREET	APT/SUITE	CITY	STATE	ZIP CODE

EMAIL	PHONE

RACE
☐ Asian ☐ Black or African American ☐ Native American ☐ White ☐ Other: _____

ETHNICITY
☐ Hispanic/Latino ☐ Not Hispanic/Latino ☐ Unknown

Ordering Physician Information (Required)

INSTITUTION			
LAST NAME	FIRST NAME	MI	
NPI	EMAIL		
PHONE	FAX		
STREET	CITY	STATE	ZIP CODE

Additional Provider (Send copy of reports)

INSTITUTION	
NAME	EMAIL
PHONE	FAX

Pathologist Information (Required for tissue specimen)

INSTITUTION			
LAST NAME	FIRST NAME	MI	
EMAIL	PHONE	FAX	
STREET	CITY	STATE	ZIP CODE

Test(s) Requested (Required)

☐ ASPYRE CLINICAL TEST FOR LUNG

11 genes, 114 targets (*BRAF, EGFR, ERBB2, KRAS, RET, ROS, ALK, MET* Exon 14 skipping, *NTRK* 1, 2, & 3)

☐ Optional PD-L1 IHC Testing*

(Tissue ONLY; requires 4 additional slides) Please select ONE:

- ☐ Dako 22C3 (cemiplimab-rwlc, pembrolizumab)
- ☐ Ventana SP142 (atezolizumab)
- ☐ Ventana SP263 (atezolizumab)
- ☐ Dako 28-8 (nivolumab)

☐ Optional HER2 IHC Testing*

(Tissue ONLY; requires 3 additional slides)

* PD-L1 and HER2 IHC performed and reported by Pathline LLC, NJ, CLIA #31D2050001

Specimen Information (Required)

SPECIMEN TYPE

☐ FFPE Tissue Block

Block ID: _____

☐ FFPE Tissue Slides (5 µm) Unstained*

* Minimum 10 for Aspyre Clinical Test for Lung + 4 for PD-L1 *OR* + 3 for HER2 *OR* + 5 for PD-L1 and HER2

☐ Peripheral Whole Blood (2 PAXgene Tubes)

SPECIMEN SITE	COLLECTION DATE (MM/DD/YYYY)
RETURN BLOCK REQUESTED? ☐ No ☐ Yes (See reverse)	COLLECTION TIME

Patient Clinical History (Required)

DIAGNOSIS
☐ NSCLC ☐ Other: _____

DISEASE STAGE

ATTACHMENTS
☐ Recent Pathology/Cytology Reports ☐ Test Results From Other Molecular Assays ☐ Other Clinical Notes

Billing Information (Required; attach copy of front and back of patient's insurance card)

ICD-10 CODES _____ _____ _____

PAYMENT TYPE
☐ Insurance ☐ Medicare ☐ Hospital/Institution ☐ Self-Pay

PATIENT STATUS
☐ Hospital Inpatient ☐ Hospital Outpatient ☐ Non-Hospital Patient

SUBSCRIBER LAST NAME	SUBSCRIBER FIRST NAME	MI	DOB (MM/DD/YYY)

PHONE	RELATIONSHIP TO INSURED ☐ Self ☐ Spouse ☐ Child ☐ Other: _____

PRIMARY INSURANCE	POLICY #	GROUP #	PRIOR AUTHORIZATION #
SECONDARY INSURANCE	POLICY #	GROUP #	PRIOR AUTHORIZATION #

Treating Physician Consent/Certification of Medical Necessity (Required)

My signature certifies that I have determined that the test(s) being ordered is medically necessary for the patient, certifies that the results of this test will inform the patient's ongoing treatment plan, and certifies that I am the patient's treating physician. I have explained to the patient the nature and purpose of the test(s) to be performed and have obtained the patient's informed consent and authorization, to the extent required under applicable federal and state law, to permit Biofidelity, or any laboratory with which Biofidelity has contracted, to (**a**) perform the test(s) specified herein, (**b**) analyze and report on other genomic information generated during the testing process or conduct additional analyses of the patient's sample for future diagnostic or monitoring use, (**c**) use results from test(s) specified herein for verification of test accuracy, (**d**) retain the test results and any biospecimens for an indefinite period for internal quality assurance/operations purposes, (**e**) de-identify any biospecimens and data in accordance with the HIPAA Privacy Rule and use and/or disclose such de-identified information and materials for future unspecified research, or other purposes, and (**f**) release the test results and related patient information to the patient's third-party payer as needed for reimbursement purposes.

TREATING PHYSICIAN SIGNATURE: _____ NAME (PRINT): _____ DATE (MM/DD/YYYY): _____

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CLIA: 34D2236526
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BFI-REQ.003 | MKTCLIN-14

Aspyre®
Clinical Test

FFPE Block Return Information (Required if return block requested)			
OFFICE/PRACTICE		ATTN	
STREET	APT/SUITE	CITY	
STATE	ZIP CODE	EMAIL	PHONE

Relevant Clinical History (FOR BLOOD ONLY - All required for medical coverage determination)

- ☐ Yes ☐ No Is a tissue specimen from a recent procedure available?
- ☐ Yes ☐ No Is the tissue specimen insufficient for testing or tissue testing resulted as a Quantity Not Sufficient (QNS)?
- ☐ Yes ☐ No Is the patient medically unfit for invasive sampling?

Tumor Confirmation Testing

Tumor cellularity will be confirmed prior to running Aspyre Clinical Test for Lung for tissue specimens. Tumor confirmation consists of determination of specimen adequacy for testing and annotation of tumor section.

For Medicare Beneficiaries Only

A Medicare Advance Beneficiary Notice (ABN) may be provided to a Medicare patient if Medicare will likely not cover the testing service. This requisition form does not constitute an ABN.

About the Test

Aspyre Clinical Test for Lung evaluates comprehensive cancer care guideline-recommended DNA and RNA variants known to be actionable in non-small cell lung cancer (NSCLC). Targets include *BRAF* V600E (missense), *EGFR* exon 18 (missense), *EGFR* exon 19 (indels), *EGFR* exon 20 (missense, insertions & duplications), *EGFR* exon 21 (missense), *ERBB2* exon 17 (missense) and *ERBB2* exon 20 (insertions), *KRAS* exon 2 and *KRAS* exon 3 (missense), *ALK* (fusions), *ROS1* (fusions), *RET* (fusions), *MET* exon 14 skipping, and *NTRK* 1/2/3 (fusions). DNA and RNA are extracted from formalin fixed paraffin embedded (FFPE) tissue or peripheral whole blood. Targets are amplified by multiplex (RT) PCR, and variants are detected using ASPYRE (Allele-Specific PYrophosphorolysis REaction) detection chemistry with read out on a real-time PCR instrument. For more information, visit: **www.biofidelity.com**.

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