

Fake01: Biomarkers

NSCLC - Enterprise Data Research Solution

If a portion of a date is unknown:

- Impute **15** for an unknown day
- Impute **JUN** for an unknown month
- Indicate the imputed part(s) of the date

Reference Range

Study Period: 01 Jan 2020 - Current kick off date

Initial NSCLC diagnosis date: 2022-09-06

Interviewer Name:	Interview Date:	Data Entry Start Time	Data Entry Stop Time
<i>First Last</i> Doe, Jane	2022-11-09	<i>format (hh:mm [0-23] hrs [0-59] min)</i> 09:09	<i>format (hh:mm [0-23] hrs [0-59] min)</i> 09:09

TISSUE BIOMARKER

^ Was a tissue biomarker ordered at any time prior to the end of the study observation period?

- ☒ Yes
- ☐ No

ORDER INFORMATION

^ Order Date	Order Date - Provider	Order Date - Source
2022-10-05	<input checked="" type="radio"/> MedOnc <input type="radio"/> Radiation Oncologist <input type="radio"/> Surgeon <input type="radio"/> Other <input type="radio"/> Not Documented	<input type="radio"/> Lab Report <input checked="" type="radio"/> Order Requisition <input type="radio"/> Pathology Report <input type="radio"/> Progress Note <input type="radio"/> Other

BIOMARKER RESULTS

Were tissue biomarker results available?

☒ Yes

☐ No

COLLECTION INFORMATION

^ Collection Date

2022-10-20

Collection - Biopsy Type

☐ Pleural Fluid

☒ Tissue

☐ Other

☐ Not Documented

^ Collection - Lab

☐ Accupath Diagnostic Lab

☒ Albany Medical Center

☐ ARUP

☐ Bon Secours

☐ Carilion Lab

☐ Clariant Diagnostics

☐ Dominion Pathology

☐ Foundation Medicine

☐ GenPath/BioReference Labs

☐ Johns Hopkins

☐ Legacy Central Lab

☐ Medfusion

☐ Parkview Medical Center

☐ Providence/PSJH

☐ Strata Oncology

☐ Not documented

☐ ACL Laboratories

☐ Allina Health Lab

☐ Aurora Diagnostics

☐ Brigham and Womens Hospital

☐ Caris

☐ Compass Diagnostic Laboratory

☐ Esoterix Genetic Lab

☐ Gene Path Diagnostics

☐ Inova

☐ Knight Diagnostic Laboratories

☐ Mayo Clinic

☐ NeoGenomics

☐ PathGroup

☐ Quest

☐ Tempus

☐ Advocate Health Care

☐ AmeriPath

☐ Banner

☐ Cancer Genetics Inc

☐ City of Hope

☐ Destiny Health

☐ Fairview

☐ Genoptix

☐ Integrated Oncology

☐ LabCorp

☐ MD Anderson

☐ Oregon Regional Laboratory

☐ Prince William Medical Center

☐ Sentara

☐ Other

RESULT INFORMATION

<p>^ Result Date</p> <p>2022-10-30</p>	<p>Result Date - Source</p> <p><input checked="" type="radio"/> Genetic Report</p> <p><input type="radio"/> Lab Report</p> <p><input type="radio"/> Pathology Report</p> <p><input type="radio"/> Progress Note</p> <p><input type="radio"/> Other</p>																																																
<p>^ Resulting - Lab</p> <table style="width: 100%; border: none;"> <tr> <td><input type="radio"/> Accupath Diagnostic Lab</td> <td><input type="radio"/> ACL Laboratories</td> <td><input type="radio"/> Advocate Health Care</td> </tr> <tr> <td><input type="radio"/> Albany Medical Center</td> <td><input checked="" type="radio"/> Allina Health Lab</td> <td><input type="radio"/> AmeriPath</td> </tr> <tr> <td><input type="radio"/> ARUP</td> <td><input type="radio"/> Aurora Diagnostics</td> <td><input type="radio"/> Banner</td> </tr> <tr> <td><input type="radio"/> Bon Secours</td> <td><input type="radio"/> Brigham and Womens Hospital</td> <td><input type="radio"/> Cancer Genetics Inc</td> </tr> <tr> <td><input type="radio"/> Carilion Lab</td> <td><input type="radio"/> Caris</td> <td><input type="radio"/> City of Hope</td> </tr> <tr> <td><input type="radio"/> Clariant Diagnostics</td> <td><input type="radio"/> Compass Diagnostic Laboratory</td> <td><input type="radio"/> Destiny Health</td> </tr> <tr> <td><input type="radio"/> Dominion Pathology</td> <td><input type="radio"/> Esoterix Genetic Lab</td> <td><input type="radio"/> Fairview</td> </tr> <tr> <td><input type="radio"/> Foundation Medicine</td> <td><input type="radio"/> Gene Path Diagnostics</td> <td><input type="radio"/> Genoptix</td> </tr> <tr> <td><input type="radio"/> GenPath/BioReference Labs</td> <td><input type="radio"/> Inova</td> <td><input type="radio"/> Integrated Oncology</td> </tr> <tr> <td><input type="radio"/> Johns Hopkins</td> <td><input type="radio"/> Knight Diagnostic Laboratories</td> <td><input type="radio"/> LabCorp</td> </tr> <tr> <td><input type="radio"/> Legacy Central Lab</td> <td><input type="radio"/> Mayo Clinic</td> <td><input type="radio"/> MD Anderson</td> </tr> <tr> <td><input type="radio"/> Medfusion</td> <td><input type="radio"/> NeoGenomics</td> <td><input type="radio"/> Oregon Regional Laboratory</td> </tr> <tr> <td><input type="radio"/> Parkview Medical Center</td> <td><input type="radio"/> PathGroup</td> <td><input type="radio"/> Prince William Medical Center</td> </tr> <tr> <td><input type="radio"/> Providence/PSJH</td> <td><input type="radio"/> Quest</td> <td><input type="radio"/> Sentara</td> </tr> <tr> <td><input type="radio"/> Strata Oncology</td> <td><input type="radio"/> Tempus</td> <td><input type="radio"/> Other</td> </tr> <tr> <td><input type="radio"/> Not documented</td> <td></td> <td></td> </tr> </table>		<input type="radio"/> Accupath Diagnostic Lab	<input type="radio"/> ACL Laboratories	<input type="radio"/> Advocate Health Care	<input type="radio"/> Albany Medical Center	<input checked="" type="radio"/> Allina Health Lab	<input type="radio"/> AmeriPath	<input type="radio"/> ARUP	<input type="radio"/> Aurora Diagnostics	<input type="radio"/> Banner	<input type="radio"/> Bon Secours	<input type="radio"/> Brigham and Womens Hospital	<input type="radio"/> Cancer Genetics Inc	<input type="radio"/> Carilion Lab	<input type="radio"/> Caris	<input type="radio"/> City of Hope	<input type="radio"/> Clariant Diagnostics	<input type="radio"/> Compass Diagnostic Laboratory	<input type="radio"/> Destiny Health	<input type="radio"/> Dominion Pathology	<input type="radio"/> Esoterix Genetic Lab	<input type="radio"/> Fairview	<input type="radio"/> Foundation Medicine	<input type="radio"/> Gene Path Diagnostics	<input type="radio"/> Genoptix	<input type="radio"/> GenPath/BioReference Labs	<input type="radio"/> Inova	<input type="radio"/> Integrated Oncology	<input type="radio"/> Johns Hopkins	<input type="radio"/> Knight Diagnostic Laboratories	<input type="radio"/> LabCorp	<input type="radio"/> Legacy Central Lab	<input type="radio"/> Mayo Clinic	<input type="radio"/> MD Anderson	<input type="radio"/> Medfusion	<input type="radio"/> NeoGenomics	<input type="radio"/> Oregon Regional Laboratory	<input type="radio"/> Parkview Medical Center	<input type="radio"/> PathGroup	<input type="radio"/> Prince William Medical Center	<input type="radio"/> Providence/PSJH	<input type="radio"/> Quest	<input type="radio"/> Sentara	<input type="radio"/> Strata Oncology	<input type="radio"/> Tempus	<input type="radio"/> Other	<input type="radio"/> Not documented		
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<p>Were results available for any of the biomarkers listed below?</p> <p style="color: blue;">If results were available, please collect both positive and negative results for the biomarkers selected.</p> <p><i>Please select all that apply.</i></p> <table style="width: 100%; border: none;"> <tr> <td><input checked="" type="checkbox"/> ALK</td> <td><input checked="" type="checkbox"/> BRAF</td> <td><input checked="" type="checkbox"/> EGFR</td> <td><input checked="" type="checkbox"/> HER2/ERBB2</td> </tr> <tr> <td><input checked="" type="checkbox"/> KRAS</td> <td><input checked="" type="checkbox"/> MET</td> <td><input checked="" type="checkbox"/> MSI</td> <td><input checked="" type="checkbox"/> NTRK</td> </tr> <tr> <td><input checked="" type="checkbox"/> PD-L1</td> <td><input checked="" type="checkbox"/> RET</td> <td><input checked="" type="checkbox"/> ROS1</td> <td><input checked="" type="checkbox"/> TMB</td> </tr> <tr> <td><input type="checkbox"/> None</td> <td></td> <td></td> <td></td> </tr> </table>		<input checked="" type="checkbox"/> ALK	<input checked="" type="checkbox"/> BRAF	<input checked="" type="checkbox"/> EGFR	<input checked="" type="checkbox"/> HER2/ERBB2	<input checked="" type="checkbox"/> KRAS	<input checked="" type="checkbox"/> MET	<input checked="" type="checkbox"/> MSI	<input checked="" type="checkbox"/> NTRK	<input checked="" type="checkbox"/> PD-L1	<input checked="" type="checkbox"/> RET	<input checked="" type="checkbox"/> ROS1	<input checked="" type="checkbox"/> TMB	<input type="checkbox"/> None																																			
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^ Were additional positive results detected for any of the biomarkers listed below?

If positive results were detected, please select all that apply. No other additional results are required for the biomarkers selected.

Please select all that apply.



FGFR1



KRAS



KEAP1



MAP2K1



NRAS



NRF2



PIK3CA



STK11



TP53



Other



None

ALK - RESULT

^ ALK - Type of Assay



FISH



IHC



NGS



Not documented

^ ALK - Result



Negative



Positive fusion/rearrangement



Equivocal



Inconclusive



Indeterminate



QNS



Test not performed



Other



Not documented

BRAF - RESULT

^ BRAF - Type of Assay

- ☐ IHC
- ☒ NGS
- ☐ PCR
- ☐ Pyrosequencing
- ☐ Sanger
- ☐ SNaPshot
- ☐ Not documented

^ BRAF - Result

- ☐ Negative
- ☐ 601N
- ☐ V600E
- ☒ V600 (not specified)
- ☐ Inconclusive
- ☐ Indeterminate
- ☐ QNS
- ☐ Test not performed
- ☐ Other
- ☐ Not documented

EGFR - RESULT

^ EGFR - Type of Assay

- ☐ IHC
☒ NGS
☐ PCR
☐ Pyrosequencing
☐ Sanger
☐ SNaPshot
☐ Not documented

^ EGFR - Result

Please select all that apply.

- | | |
|---|--|
| <input type="checkbox"/> Negative | <input checked="" type="checkbox"/> A750 |
| <input checked="" type="checkbox"/> A767 | <input checked="" type="checkbox"/> D770 |
| <input checked="" type="checkbox"/> E709 | <input checked="" type="checkbox"/> E746 |
| <input checked="" type="checkbox"/> E749K | <input checked="" type="checkbox"/> Exon 18 mutation |
| <input checked="" type="checkbox"/> Exon 19 deletion | <input checked="" type="checkbox"/> Exon 19 mutation |
| <input checked="" type="checkbox"/> Exon 20 insertion | <input checked="" type="checkbox"/> Exon 20 mutation |
| <input checked="" type="checkbox"/> Exon 21 deletion | <input checked="" type="checkbox"/> Exon 21 mutation |
| <input checked="" type="checkbox"/> G719 | <input checked="" type="checkbox"/> G719A |
| <input checked="" type="checkbox"/> G719C | <input checked="" type="checkbox"/> G719S |
| <input checked="" type="checkbox"/> G719T | <input checked="" type="checkbox"/> G719X |
| <input checked="" type="checkbox"/> G724S | <input checked="" type="checkbox"/> H773 |
| <input checked="" type="checkbox"/> H835L | <input checked="" type="checkbox"/> K728R |
| <input checked="" type="checkbox"/> K745 | <input checked="" type="checkbox"/> L747 |
| <input checked="" type="checkbox"/> L833V | <input checked="" type="checkbox"/> L858R |
| <input checked="" type="checkbox"/> L861Q | <input checked="" type="checkbox"/> M766 |
| <input checked="" type="checkbox"/> N771 | <input checked="" type="checkbox"/> P772 |
| <input checked="" type="checkbox"/> P848L | <input checked="" type="checkbox"/> R776H |
| <input checked="" type="checkbox"/> S768 | <input checked="" type="checkbox"/> S768I |
| <input checked="" type="checkbox"/> T751 | <input checked="" type="checkbox"/> T790M |
| <input checked="" type="checkbox"/> V769 | <input checked="" type="checkbox"/> V774L |
| <input checked="" type="checkbox"/> V774M | <input checked="" type="checkbox"/> Y869 |
| <input type="checkbox"/> Inconclusive | <input type="checkbox"/> Indeterminate |
| <input type="checkbox"/> QNS | <input type="checkbox"/> Test not performed |
| <input type="checkbox"/> Other | <input type="checkbox"/> Not documented |

HER2/ERBB2 - RESULT**^ HER2/ERBB2 - Type of Assay**

- ☐ CISH
- ☒ FISH
- ☐ IHC
- ☐ ISH
- ☐ Dual-ISH
- ☐ NGS
- ☐ Not documented

^ HER2/ERBB2 - Result

Please select all that apply.

- ☐ Negative
- ☐ Positive
- ☒ A775_G776insYVMA
- ☒ D769Y
- ☒ G776
- ☒ G776D
- ☒ G778
- ☐ G882V
- ☐ S310
- ☒ Y772
- ☐ Y772_A775
- ☐ 0
- ☐ 1+
- ☐ 2+
- ☐ 3+
- ☐ Amplification
- ☐ Equivocal
- ☐ Inconclusive
- ☐ Indeterminate
- ☐ QNS
- ☐ Test not performed
- ☐ Other
- ☐ Not documented

KRAS - RESULT

^ KRAS - Type of Assay

- ☐ NGS
- ☐ PCR
- ☒ Pyrosequencing
- ☐ Sanger
- ☐ SNaPshot
- ☐ Not documented

^ KRAS- Result

Please select all that apply.

- ☐ Negative
- ☒ G12A
- ☒ G12C
- ☒ G12D
- ☒ G12R
- ☒ G12S
- ☒ G12V
- ☒ G13A
- ☒ G13C
- ☒ G13D
- ☒ G13R
- ☒ G13V
- ☒ Q61H
- ☒ Q61L
- ☐ Other Codon 12
- ☐ Other Codon 13
- ☐ Other Codon 61
- ☐ Amplification
- ☐ Inconclusive
- ☐ Indeterminate
- ☐ QNS
- ☐ Test not performed
- ☐ Other
- ☐ Not documented

MET - RESULT

^ MET - Type of Assay

- ☐ FISH
- ☒ NGS
- ☐ Not documented

^ MET- Result

Please select all that apply.

- ☐ Negative
- ☐ Copy Number amplification (CNA)
- ☒ Exon 14 Pathogenic
- ☒ Exon 14 Skipping Detected
- ☐ Inconclusive
- ☐ Indeterminate
- ☐ QNS
- ☐ Test not performed
- ☐ Other
- ☐ Not documented

MSI - RESULT

MSI - Type of Assay

- ☐ NGS
- ☒ PCR
- ☐ Pyrosequencing
- ☐ Sanger
- ☐ Not documented

MSI - Result

- ☐ Low
- ☐ Stable
- ☒ High
- ☐ Inconclusive
- ☐ Indeterminate
- ☐ QNS
- ☐ Test not performed
- ☐ Other
- ☐ Not documented

NTRK - RESULT

NTRK - Type of Assay

- ☐ FISH
- ☒ IHC
- ☐ NGS
- ☐ Not documented

NTRK - Result

- ☐ Negative
- ☐ Positive NTRK1 fusion/rearrangement
- ☐ Positive NTRK2 fusion/rearrangement
- ☒ Positive NTRK3 fusion/rearrangement
- ☐ Inconclusive
- ☐ Indeterminate
- ☐ Test not performed
- ☐ QNS
- ☐ Other
- ☐ Not documented

PD-L1 - RESULT

^ PD-L1 Antibody used for testing

Please select all that apply.

- ☒ 22C3 (Pembro)
- ☒ 28-8 (Nivo)
- ☒ SP142 (Atezo)
- ☒ SP263 (Durva)
- ☐ Not documented

^ PD-L1 Expression

(%)

90

^ PD-L1 Score Type

- ☐ CPS
- ☒ TPS
- ☐ Not documented

RET - RESULT**RET - Type of Assay**

- ☐ FISH
- ☒ NGS
- ☐ Not documented

RET- Result

- ☐ Negative
- ☐ Positive fusion/rearrangement
- ☒ Inconclusive
- ☐ Indeterminate
- ☐ QNS
- ☐ Test not performed
- ☐ Other
- ☐ Not documented

ROS1 - RESULT**ROS1 - Type of Assay**

- ☒ FISH
- ☐ IHC
- ☐ NGS
- ☐ Not documented

ROS1 - Result

- ☐ Negative
- ☐ Positive fusion/rearrangement
- ☒ Equivocal
- ☐ Inconclusive
- ☐ Indeterminate
- ☐ QNS
- ☐ Test not performed
- ☐ Other
- ☐ Not documented

TMB - RESULT**TMB - Result***(mutations/Mb)*

7

Additional Comments

Only use the *Additional Comments* field to record necessary additional information found during chart review

Generally, this field will not have a response

History for - Interviewer Name: (interv_name)

Sandra DiLullo Value changed from "" to "Doe, Jane"
09-Nov-2022 21:29:56 UTC-00:00

History for - Interview Date: (interv_dt)

Sandra DiLullo Value changed from "" to "2022-11-09"
09-Nov-2022 21:29:52 UTC-00:00

History for - Data Entry Start Time (bio_st_tm)

Sandra DiLullo Value changed from "" to "09:09"
09-Nov-2022 21:29:59 UTC-00:00

History for - Data Entry Stop Time (bio_en_tm)

Sandra DiLullo Value changed from "" to "09:09"
09-Nov-2022 21:30:02 UTC-00:00

History for - ^ Was a tissue biomarker ordered at any time prior to the end of the study observation period? (bio_ord_yn)

Sandra DiLullo Value changed from "" to "Yes (1)"
09-Nov-2022 21:30:03 UTC-00:00

History for - ^ Order Date (bio_ord_dt)

Sandra DiLullo Value changed from "" to "2022-10-05"
09-Nov-2022 21:30:07 UTC-00:00

History for - Order Date - Provider (bio_ord_dr)

Sandra DiLullo Value changed from "" to "MedOnc (1)"
09-Nov-2022 21:30:08 UTC-00:00

History for - Order Date - Source (bio_ord_dt_src)

Sandra DiLullo Value changed from "" to "Order Requisition (2)"
09-Nov-2022 21:30:10 UTC-00:00

History for - Were tissue biomarker results available? (bio_resu_yn)

Sandra DiLullo Value changed from "" to "Yes (1)"
09-Nov-2022 21:30:11 UTC-00:00