oncosentia™
MINIMAL RESIDUAL DISEASE

AFFIX
BARCODE LABEL – SIF
HERE

SAMPLE INFORMATION FORM

Please complete sections below in English. Please complete one Sample Information Form for each submitted sample.

PATIENT INFORMATION

FIRST NAME		LAST NAME	
DATE OF BIRTH	PATIENT GENETIC SEX		ETHNICITY
PHONE NUMBER		EMAIL	
ADDRESS	POST CODE	CITY	COUNTRY

ORDERING HEALTHCARE PROVIDER INFORMATION

CLINIC NAME		CLINIC ID	
REFERRING HEALTHCARE PROVIDER			
PHONE NUMBER	FAX		EMAIL
ADDRESS	POST CODE	CITY	COUNTRY

TEST SELECTION (REQUIRED)

☐ First OncoSentia MRD test order ☐ Subsequent OncoSentia MRD test order

** For recommended test time points refer to page 4 of the Sample Information Form.*

PATIENT HISTORY (REQUIRED)

PRIMARY DIAGNOSIS: *Only patients diagnosed with NSCLC are eligible for the test*

ICD-10 CODE: *Select one option*

- ☐ C34.0 Malignant neoplasm of main bronchus
- ☐ C34.10 Malignant neoplasm of upper lobe, unspecified bronchus or lung
- ☐ C34.11 Malignant neoplasm of upper lobe, right bronchus or lung
- ☐ C34.12 Malignant neoplasm of upper lobe, left bronchus or lung
- ☐ C34.2 Malignant neoplasm of middle lobe, bronchus or lung
- ☐ C34.31 Malignant neoplasm of lower lobe, right bronchus or lung
- ☐ C34.32 Malignant neoplasm of lower lobe, left bronchus or lung
- ☐ C34.80 Malignant neoplasm of overlapping sites of unspecified bronchus and lung
- ☐ C34.81 Malignant neoplasm of overlapping sites of right bronchus and lung
- ☐ C34.82 Malignant neoplasm of overlapping sites of left bronchus and lung
- ☐ C34.90 Malignant neoplasm of unspecified part of unspecified bronchus or lung
- ☐ C34.91 Malignant neoplasm of unspecified part of right bronchus or lung
- ☐ C34.92 Malignant neoplasm of unspecified part of left bronchus or lung

Additional ICD-10: _____

HISTOLOGY

☐ Adenocarcinoma ☐ Squamous cell carcinoma ☐ Other/NOS

DISEASE STAGE: *Samples from patients with resectable disease are **NOT** currently accepted*

☐ Stage II NSCLC ☐ Stage III NSCLC

CURRENT DISEASE STATUS: *Select all that apply*

☐ No evidence of disease ☐ Active disease with no evidence of disease progression

☐ Active disease with evidence of disease progression

☐ Other, please specify: _____

PRIOR TREATMENT HISTORY

Prior history of definitive treatment. Please specify the type of definitive treatment received:

☐ Chemotherapy ☐ Radiotherapy ☐ Chemoradiotherapy ☐ Other

Drug name: _____

SAMPLE INFORMATION

DATE OF COLLECTION (DD/MM/YY): _____

TREATMENT STATUS AT SAMPLING

Please specify treatment phase:
*For samples collected during treatment, **collect prior to the next treatment cycle***

☐ **On consolidation therapy**

Please specify: ____ weeks after treatment, cycle number ____

Type of consolidation therapy:

☐ Immunotherapy ☐ Targeted Therapy ☐ Other

Drug name: _____

☐ **Surveillance**

Please specify: ____ weeks after end of therapy

☐ **Other**

Please specify: _____

PREVIOUS GENETIC TESTING

Has the patient previously undergone any other liquid biopsy test?

☐ No ☐ Yes (If yes, please specify and attach relevant report)

Comments: _____

ATTACHMENTS (REQUIRED)

- ☐ PATHOLOGY REPORT
- ☐ MOST RECENT CLINICAL REPORT
- ☐ TEST RESULTS FROM PREVIOUS MOLECULAR DIAGNOSTIC ASSAYS

FOR LABORATORY USE ONLY

F-OPR-01/33-V02-EN

ORDER NUMBER	LAB ID NUMBER	KIT LOT NUMBER
COMMENTS	DATE & TIME OF RECEIPT (DD/MM/YY HH:MM)	RECEIVED BY

CONFIDENTIAL

MEDICOVER GENETICS
Neas Engomis 31, Nicosia, 2409 Cyprus
Phone: +357 22266888 Fax: +357 22266899
Web: www.medicover-genetics.com
Email: info.genetics@medicover.com

PATIENT CONSENT (REQUIRED)

By placing my signature below I hereby:

1. Confirm that I have read, or have had read to me, the attached Patient Informed Consent and that I understand it.
2. Declare that I have had the opportunity to receive counselling from my referring healthcare provider on the OncoSentia MRD test and to discuss with the healthcare provider all aspects of the OncoSentia MRD test and this form including the benefits, risks and limitations of the OncoSentia MRD test as well as the reasons for performing the test and availability of alternative testing options to my satisfaction.
3. Authorize my referring healthcare provider to collect the necessary blood sample, and to submit this form and transport the samples to Medicover Genetics laboratories for the purposes of conducting the tests requested with this form.
4. Authorize Medicover Genetics to use any part of or the entirety of the biological sample for the purposes of conducting the tests requested with this form.
5. Authorize Medicover Genetics to communicate the results of the test to my referring healthcare provider.
6. Confirm that all the information on this form is true to the best of my knowledge.

☐ For the above scope, I consent to the inclusion of my leftover, de-identified sample in Medicover Genetics' database, the coding, storing and using of biological material for the purpose of research and development, technology advancement, validation and internal quality assurance.

PATIENT/GUARDIAN SIGNATURE (REQUIRED)	DATE

HEALTHCARE PROVIDER ATTESTATION (REQUIRED)

I hereby certify and undertake that:

1. I am the referring healthcare professional ordering this test.
2. The test results will determine my patient's medical management.
3. The patient has been informed about the nature and purpose of the testing.
4. The patient has been duly and thoroughly counseled about the test and has received all the advice necessary to provide their informed consent, including the benefits, risks, and limitations of the OncoSentia MRD test.
5. I have answered all the patient's queries about the OncoSentia MRD test.
6. This form has been completed according to the wishes and instructions of the patient.
7. I have obtained the patient's informed consent and have attested their signature.

HEALTHCARE PROVIDER SIGNATURE (REQUIRED)	DATE

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PATIENT INFORMED CONSENT

GENERAL INFORMATION

GENETIC TESTING

The purpose of this test is to provide a non-invasive method for detecting circulating tumor DNA (ctDNA) as a potential biomarker of minimal residual disease, which may be detectable prior to radiologic progression, including in situations where tumor tissue is unavailable.

MEDICOVER GENETICS MRD

OncoSentia MRD is a tumor-agnostic, plasma-informed Laboratory Developed Test (LDT) by Medicover Genetics Ltd for minimal residual disease detection and monitoring of disease progression by analysing ctDNA in patients with NSCLC following definitive non-surgical therapy. Clinical validation of this assay was conducted as part of the DART trial (NCT04392505).

SAMPLE COLLECTION

The test requires the collection of 20 mL of blood. Your healthcare provider will send the sample to Medicover Genetics laboratories for analysis by following the provided sample collection instructions. Occasionally, an additional sample may be needed if there is a shipping delay, a breakage of the sample collection device, sample degradation, sample contamination, inadequate sample quantity or if the sample has been submitted incorrectly.

RESULT INTERPRETATION

The results are communicated within 2-3 weeks directly to your healthcare provider. The healthcare provider ordering this test is responsible to understand the specific uses and limitations of the test, communicate this information to you and answer any questions you may have. Reports are issued for samples received after the initiation of definitive therapy.

POSSIBLE RESULTS

The following describes the possible results of the test analysis:

ctDNA detected: The presence of ctDNA has been detected at the evaluated timepoint. The presence of ctDNA during or after consolidation therapy has been associated with a higher risk of disease progression for patients with unresectable NSCLC (based on data from the DART trial with patients undergoing consolidative immunotherapy). Correlation with clinical findings and re-testing at clinically relevant intervals is recommended.

ctDNA not detected: ctDNA was not detected at the evaluated timepoint. The absence of ctDNA during and after consolidation therapy has been associated with a lower risk of disease progression for patients with unresectable NSCLC (based on data from the DART trial with patients undergoing consolidative immunotherapy). ctDNA not detected does not rule out cancer. Correlation with clinical findings and re-testing at clinically relevant intervals is recommended.

Inconclusive: Test analysis could not be completed since the sample has failed to pass quality check criteria. A redraw sample may be requested if available, before the initiation of the next treatment cycle.

Result interpretation is based on currently available information in the medical literature, research and scientific databases. Because the literature, medical and scientific knowledge are constantly changing, new information that becomes available in the future may change the interpretation of your test results.

DISCLOSURE

The test has been validated for patients diagnosed with unresectable NSCLC. The test is not indicated for patients who are pregnant or had a blood transfusion within the last 3 months, or have a history of allogeneic bone marrow or organ transplantation or have multiple primary malignancies. Although this test is highly accurate, there is still a possibility for false positive or false negative results. This may be caused by technical and/or biological limitations, including but not limited to poor sample quality, treatment, tumor histology, tumor location, tumor growth dynamics, ctDNA release dynamics and number of somatic alterations in the tumor. Other reasons for false positive or false negative results include, but are not limited to: mislabelled samples, inaccurate reporting of clinical/medical information and rare technical errors. Genetic testing is an important part of the diagnostic process. However, genetic tests may not always give a definitive answer. This may be due to limitations in current medical knowledge or testing technology. A negative result should not be taken as definitive evidence of absence of malignancy. Correlation with clinicopathological data and other tests is recommended. Results should always be considered in context with other clinical criteria. The analysis is specific only for the test ordered. The referral clinician is responsible for counselling before and after the test; including the provision of advice regarding the need for additional genetic testing. Other diagnostic tests may still be necessary.

BENEFITS

Your genetic test results may help you and your doctor make informed choices about your healthcare and management. It is recommended that you receive genetic counselling before and after having this genetic test.

QUALITY IMPROVEMENT

Please choose the relevant option on the consent form to grant us permission to anonymously use your remaining sample to improve the quality, accuracy and effectiveness of OncoSentia MRD.

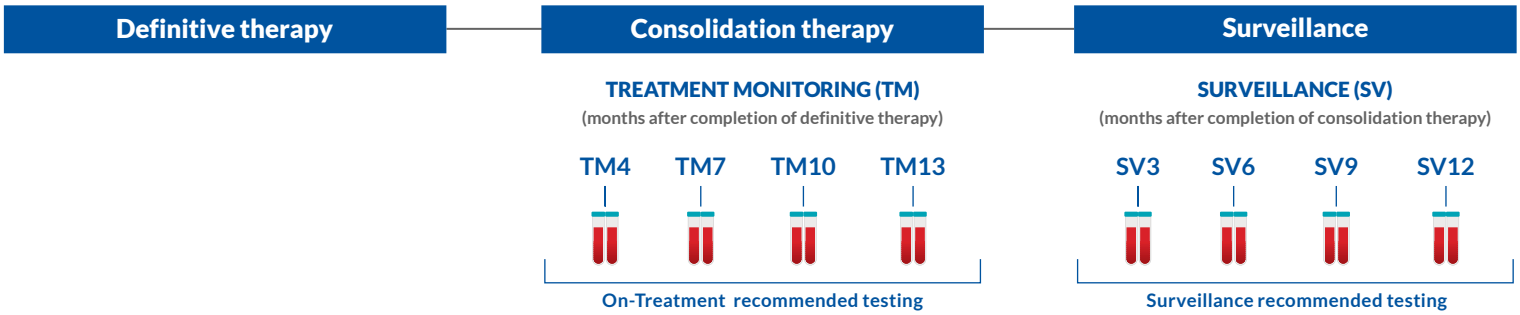
Please make sure you read and understand the information on this document before signing and complete all relevant information accurately as incorrect information can lead to inaccurate test results. Please discuss any questions you may have with your healthcare provider. For additional information please visit our website at ***www.medicover-genetics.com****.*

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OncoSentia MRD REFERENCE INFORMATION

OncoSentia MRD recommended testing intervals:

Recommended for stage II or stage III unresectable NSCLC patients that are treated with consolidation therapy following curative-intent definitive therapy.



ON-TREATMENT RECOMMENDED TESTING

TM4, TM7 & TM10: Blood draws at 4, 7 and 10 months (±2 weeks) after the end of definitive therapy and during consolidation therapy (prior to the initiation of 4th, 7th or 10th treatment cycle).

TM13: Blood draw at 13 months after the end of definitive therapy or 1 month after the end of consolidation therapy, whichever event occurs first.

SURVEILLANCE RECOMMENDED TESTING

SV3-SV12: Blood draw every 3 months for 1 year after the end of consolidation therapy.

Testing intervals for OncoSentia MRD are determined at the clinician's discretion. The recommended intervals are informed by the sampling schedule and findings from the DART trial (NCT04392505), conducted in patients with unresectable stage III non-small cell lung cancer (NSCLC) receiving definitive chemoradiotherapy followed by consolidation durvalumab. Plasma samples were collected during treatment and surveillance and were analysed using OncoSentia MRD[1,2].

References:

1. *Horndalsveen, H. et al. ctDNA-Based MRD Detection in Stage III NSCLC Treated With Chemoradiotherapy and Durvalumab. Journal of Thoracic Oncology 21, (2026).*
2. *Horndalsveen H. et al. Serial ctDNA-based MRD Detection During Surveillance After Chemoradiotherapy and Durvalumab in Unresectable Stage III NSCLC. 2565P. ESMO Congress (2026).*

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PATIENT PRIVACY SUMMARY

This privacy notice provides a summary of how Medicover Genetics Limited collects and processes your personal data with this form. It is important that you read this privacy notice together with our full privacy policy which contains more detailed information about our data processing. A copy is available online at www.medicover-genetics.com.

1. Important information and who we are

Medicover Genetics is responsible for processing the personal data collected on this form.

We have appointed a data protection officer (DPO). If you have any questions about this privacy notice or our data protection practices, please contact the DPO.

CONTACT DETAILS

Full name of legal entity: Medicover Genetics Limited (HE 418406)
Email address: dpo.cy@medicover.com
Postal address: 31 Neas Engomis Street, 2409 Engomi, Nicosia, Cyprus
Telephone number: + (357) 22266888

2. The data we collect about you

We collect, use, store and transfer different kinds of personal data about you as follows:

- Identity Data.
- Contact Data.
- Sensitive data (ethnicity, patient genetic sex, medical/clinical data).

3. How we use your personal data

We will only use your personal data for the purpose for which we collected it which includes the following:

- To register you as a new customer.
- To conduct the selected test and to process and deliver your results.
- To manage your relationship with us.
- To contact you regarding your results or for consultation purposes.
- To invoice the referring healthcare provider.

4. How we share your personal data

We share your personal data with your referring healthcare provider, so we can notify the results of your test to them.

We may also share your personal data with cloud service providers, as we store certain information online.

5. International transfers

We do not transfer, store or process your personal data outside the European Economic Area (EEA) unless you or your referring healthcare provider are located outside the EEA.

6. Your legal rights

Under certain circumstances, you have rights under data protection laws in relation to your personal data including the right to receive a copy of the personal data we hold about you, the right to erasure ('right to be forgotten'), the right to restriction of processing and the right to make a complaint at any time to the Office of the Commissioner for Personal Data Protection.

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