ICF - Informed Consent Form

Molecular classification test for indeterminate thyroid nodule | **mir-THYpe full**

*Mandatory information

The test will only be performed upon receipt of this completed and signed form. This document must not be altered, must be in complete accordance with the patient's/legal representative's document, and any missing information may be requested or consulted by Onkos. Delays in sending the form, or sending it with inconsistent information, may lead to a rescheduling of your result deadline.

Patient Data

Full name (as per ID document)*

Patient's E-mail*

Date of birth* / /

Biological sex*

ID*

Mother's full name*

Legal Representative Data *(for minors under 18 or incapacitated patients)*

Legal Representative's Name

Legal Representative's ID

I, ☐ **PATIENT** or ☐ **LEGAL REPRESENTATIVE**, specified above, authorize Onkos Diagnósticos Moleculares LTDA (CNPJ No. 22.203.791/0002-70) to perform the **mir-THYpe full**, using the genetic material extracted from cells collected in a Fine Needle Aspiration (FNA), to determine the potential malignancy of indeterminate nodule(s) as "Negative" or "Positive", according to the clinical indication of the requesting physician.

Information about the test

The **mir-THYpe full,** test, developed by Onkos Diagnósticos Moleculares Laboratory in partnership with Hospital de Amor, is the only molecular test for indeterminate thyroid nodules validated exclusively with samples from Brazilian patients. It analyzes cells collected during a previously performed Fine Needle Aspiration (FNA), without the need for a new collection, provided that the material sent is sufficient and meets the minimum criteria defined by Onkos.

The test evaluates the expression of microRNAs and uses an algorithm to compare the sample's expression profile with known patterns of benign or malignant nodules. Additionally, it analyzes the expression of microRNAs: miR-146b (associated with papillary carcinoma) and miR-375 (associated with medullary thyroid carcinoma), as well as mutations in the nodule's DNA. The final report classifies the nodule as "negative" or "positive" and estimates the risk of malignancy. **The result is made available on the Onkos Portal for the patient and the requesting physician, with restricted, non-transferable, and personal access.**

Test Results and Performance *(For more information, access the detailed Technical Document at www.onkos.com.br/mir-thype-full/tcle)*

- **Negative Predictive Value (NPV): 96%** (meaning the probability of a "negative" result being wrong is only 4%).
- **Positive Predictive Value (PPV): 76%** (meaning the probability of a "positive" result being wrong is only 24%).

Sample Requirements

Acceptable samples for the **mir-THYpe full** test include:

- ✓ FNA Cytology Slides containing:
  - ✓ At least 6 clusters of 10 cells each - totaling 60 cells;
  - ✓ Stained with Papanicolaou, Diff-Quick, Panótico, HE, or Giemsa protocols;
  - ✓ Covered with a coverslip or varnish.

Unacceptable samples for the **mir-THYpe full** test include:

- ✗ Punctures performed with anticoagulants, especially heparin;
- ✗ Slides stained with Shorr stain;
- ✗ Broken slides;
- ✗ Liquid material and/or in liquid medium;
- ✗ Cell Block, Core Biopsy/TruCut collected more than 1 year ago;
- ✗ Materials collected more than 5 years ago.

Sample Disposal and Use

- Samples stored at Onkos for more than 5 years may be discarded according to current legislation if the patient does not request their return within this period.
- Onkos does not store liquid punctures or fresh materials; if received, they will be returned to the patient, who will bear the shipping costs, or discarded with the patient's prior authorization.
- If there is no response from the patient within 15 days of the first contact, the material will be discarded without further notice.
- Surplus materials may be used for research unless the patient requests their return within 30 days after the report is released.
- If the test is canceled, the material will be returned to the patient, with shipping costs covered by them or by personal pickup at the Onkos headquarters.
- If the material is not returned or picked up within 3 months, it may be used for research by Onkos's own R&D team or discarded.

Consent, Acknowledgment, and Signature

By signing this document, I am aware that:

- I agree that the data generated by the analysis of my material may be included, anonymously, in a database and used for medical research and scientific publications in specialized medical literature, in an aggregated form and without the possibility of individual identification, in order to obtain useful information and/or generate new knowledge relevant to the advancement of medicine and the test. Onkos commits to maintaining the confidentiality, privacy, and secure storage of the data, also respecting the General Data Protection Law (LGPD). Information will not be passed on to third parties not involved in the research.
- Although the current legislation is clear and establishes that the biological sample stored in the laboratory of origin/preparation belongs to me and that I have an unrestricted right to request it or authorize third parties to request it, some laboratories create bureaucracies and processes that may make it impossible to retrieve my sample, and this can lead to significant delays in my result deadline.
- If the sample sent does not meet the eligibility requirements or has any rejection criteria that, at Onkos's discretion, could compromise the quality of the analysis, the test may not be performed (pre-test). In this case, my doctor may request that I undergo a new FNA. This procedure will not be performed, covered, or be the responsibility of Onkos.
- In the absence of any documentation or information requested by Onkos that makes it unfeasible to perform the test with quality and safety, the test will not be carried out until the documentation and/or information is provided/sent/validated by the patient, and this may cause delays in my test result deadline.
- Even if the sent sample is considered eligible (pre-test = visual inspection + documentation and information), the data generated from the analysis of my genetic material may not meet the minimum technical quality control parameters established in the test's development (post-test). In this case, the result may be considered inconclusive.
- If the test is performed on the initially eligible sample, but the results obtained are not within the minimum technical quality control parameters established in the test's development (post-test) due to the quality of the material, Onkos offers to perform a new test for the patient at no additional cost. For this, the patient must send a new FNA with a cytological report of the same nodule already analyzed, preferably performed at a new laboratory. The patient has up to 6 months to send the new sample, counting from the moment the patient is informed about the sample quality. The new FNA will not be covered, performed, or be the responsibility of Onkos, which is only responsible for repeating the molecular test.
- The time for issuing the test result (sending the report) is 15 business days and **starts counting from the validation of the sample by the Onkos technical team within up to 2 business days.**
- The biological material sent may be exhausted, according to the needs of the test, i.e., used in its entirety. In this case, there will be no biological material stored or available for future retrieval.
- Onkos has no responsibility if the biological material suffers any damage or is lost during the transport and shipping process carried out by the Post Office or any logistics agent used for sending the material.

I attest, under my civil and criminal liability, that I am aware of and agree with all the provisions of this document, as well as the truthfulness of the information described and specified in this form.

Location: _____

Date: _____

Signature of the patient or legal representative
(As it appears on the ID document)

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