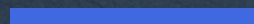




OncoSure Testing

Oncosure Rapid Cancer Screening Test Protocol

Standard Operating Procedures for Effective Screening



Purpose of the Protocol

The Oncosure Test is designed to detect all types of cancer using a single blood draw as early as stage -1, enabling early diagnosis and timely intervention.

- **A standardized protocol ensures consistency and reliability, improving the accuracy of test results and providing clear guidelines for healthcare providers.**
- **By following this protocol, we aim to enhance patient outcomes and support healthcare professionals in the early detection and management of cancer.**



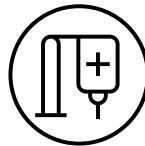
Importance of Early Cancer Detection

Maximizing Survival Rates and Improving Patient Outcomes through Early Detection



Early Detection Saves Lives:

- Detecting cancer at an early stage significantly increases the chances of successful treatment and survival.
- Early detection allows for less aggressive treatments and better quality of life for patients.



Improved Prognosis:

- Patients diagnosed early often have a better prognosis and higher survival rates.
- Early-stage cancers are typically less advanced and easier to treat effectively.



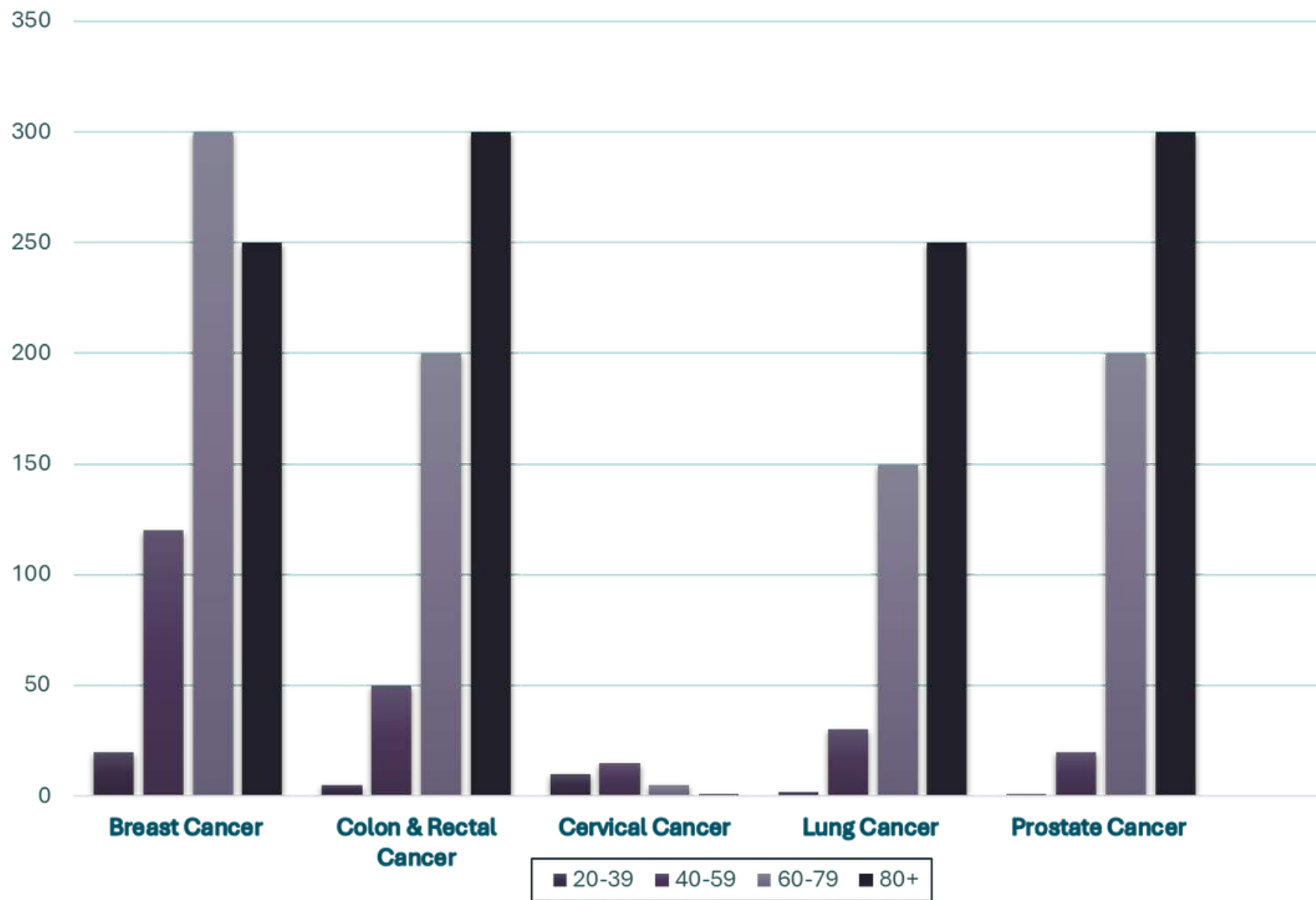
Cost-Effective:

- Early detection can reduce healthcare costs by avoiding more extensive and expensive treatments required for advanced-stage cancers.
- Early intervention can minimize the economic burden on patients and healthcare systems.

TYPES OF CANCER STATISTICS

This chart can be used as a guideline to determine which age range should be screened more often than others.

Age Group (years) | Incidence Rate per 100,000



WHO SHOULD TEST?

What qualifies someone as a good candidate for this test?

- **UNDERGOING CANCER TREATMENT**

We monitor changes in oncosome levels to assess treatment effectiveness and guide decision-making on treatment plans.

- **EXPERIENCING SYMPTOMS**

Individuals experiencing symptoms suggestive of cancer, such as unexplained weight loss or persistent pain, qualify for the Oncosure test to aid in diagnosis.

- **OLDER AGE**

As age increases, the risk of developing cancer also rises.

- **HIGH RISK**

Individuals with a high risk of cancer, such as those with a family history of cancer or in remission, qualify for the Oncosure test. Early detection through the test can significantly impact treatment outcomes and survival rates.

- **SMOKERS**

Individuals who smoke or have a history of smoking are at an elevated risk for developing various types of cancer, particularly lung cancer.



Different types of cancer screening test that are available on the market today:

Here are some other screening tests that are available that have been shown to not be the most effective, but are still offered.

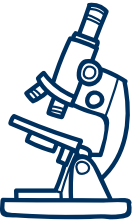
- **Alpha-fetoprotein blood test**
- **Breast MRI**
- **CA-125 Test**
- **Clinical Breast exams and regular breast self-exams**
- **Multi-cancer detection tests**
- **PSA Test (prostate-specific antigen)**
- **Skin Exams**
- **Transvaginal ultrasound**
- **Virtual colonoscopy**

Innovative Approach:



Oncosure employs a pioneering approach in cancer screening. Our methodology focuses on detecting oncosomes, the extracellular vesicles that mimic parental tumor cells, present in all cancers.

Advanced Technology:



We utilize state-of-the-art fluorescent microscopy technology. This enables precise identification and quantification of oncosomes, ensuring high sensitivity and accuracy in cancer detection.

Clinical Validation:



Our methodology is backed by extensive clinical validation studies. Studies have demonstrated the reliability and robustness of our test in diverse patient populations.

Oncosure Methodology and Excellence



Oncosure offers rapid results, providing definitive yes or no answers for cancer screening, as well as cancer treatment monitoring. Our streamlined process ensures timely decision-making and patient care.



Quality Assurance:

Stringent quality control measures are integral to our methodology. We adhere to rigorous standards to maintain the highest level of accuracy and reproducibility.



Patient Impact:

Our methodology contributes to early cancer detection, improving patient outcomes. By detecting cancer at its earliest stages, we empower healthcare providers to initiate timely interventions.

QUALITY CONTROL MEASURES

Ensuring Accuracy and Reliability in Cancer Screening



Stringent Protocols:

Adherence to stringent protocols ensures consistency and reliability in our testing process. Every step, from sample collection to analysis, follows standardized guidelines.



Regular Calibration:

Regular calibration of fluorescent microscopy equipment guarantees precision in oncosome detection. Ensuring that all instruments are operating at optimal performance is a top priority.



Validation and Verification:

Each test undergoes rigorous validation and verification procedures. Regular cross-checks and reviews confirm the accuracy of results.



Training and Competency:

Continuous training programs for laboratory personnel ensure high competency levels. Regular proficiency assessments maintain the highest standards of testing.



External Quality Assurance:

Participation in external quality assurance programs benchmarks our performance against industry standards. These programs provide additional layers of oversight and validation.

PATIENT PREPARATION GUIDELINES

Informing the Patient:

- Explain the purpose and procedure of the Oncosure Test clearly to the patient.
- Provide written and verbal instructions to ensure the patient understands the test process.

No Special Preparation Required:

- Patients can eat and drink normally before the test. There is no need for fasting or special preparation prior to blood draw.

Medical History and Consent:

- Collect comprehensive health and medical history, including current medications and allergies.
- Ensure the patient completes and signs the necessary consent forms.



SAFETY AND HYGIENE PROTOCOL

Ensuring Safe and Sterile Procedures

01



Personal Protective Equipment:

- Wear disposable gloves and a lab coat during the entire procedure.
- Use a face mask and eye protection as needed to protect against splashes or aerosols.

02



Hand Hygiene:

- Perform hand hygiene before and after patient contact and between procedures.
- Use alcohol-based hand sanitizer or wash hands with soap and water for at least 20 seconds.

03



Patient Preparation:

- Ensure the patient is comfortably positioned and informed about the procedure.
- Maintain patient privacy and dignity throughout the blood draw process.

04



Equipment Sterilization:

- Use sterile, single-use needles and dispose of sharps in designated puncture-proof containers.
- Clean and disinfect reusable equipment according to medical standards after each use.

05



Environmental Safety:

- Maintain a clean and organized workspace to prevent cross-contamination.
- Dispose of biohazardous materials, such as used gloves and blood collection supplies, in designated containers.

Step-by-Step Instructions

Preparation:

- Gather all necessary materials: sterile needle, collection tubes, and labels.
- Ensure the workspace is clean and sanitized according to medical standards

Patient Identification:

- Verify patient identity using two unique identifiers (e.g., name and date of birth).
- Match the patient's information with the requisition form.

Blood Collection Process:

- Explain the procedure to the patient and address any questions or concerns.
- Perform venipuncture using a sterile technique to collect the blood sample.

Sample Handling:

- Label the collection tubes accurately with patient information and sample details.
- Store the cold sample at 40°-45° F as per specified storage guidelines to maintain sample integrity.

Documentation:

- Complete all required documentation, including patient information and procedure details.
- Ensure all entries are legible, accurate, and compliant with regulatory standards.

STORAGE AND TRANSPORT GUIDELINES

Ensuring Sample Integrity from Collection to Laboratory

01

Sample Storage Requirements:

- Store blood samples in labeled, leak-proof containers.
- Maintain cold samples at the recommended temperature range (40°-45° F) to preserve sample integrity.



03

Transport Conditions:

- Transport samples promptly to the laboratory to minimize delays in processing.
- Follow established transport protocols to ensure samples arrive safely and maintain stability.



02

Transport Containers

- Use insulated containers with temperature monitoring devices for sample transport.
- Ensure containers are secure and labeled with patient information and handling instructions.



04

Documentation:

- Complete transport documentation accurately, including sample identification, transport conditions, and any special handling instructions.
- Keep records of sample transport times and conditions for traceability and quality assurance.

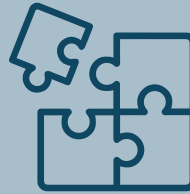


Time Frame for Sample Processing and Laboratory Analysis



Sample Processing Timeline:

- Samples are processed immediately upon receipt in the laboratory to ensure timely analysis.
- Results are typically communicated to the doctor the day after sample receipt, providing rapid insights for patient management.



Laboratory Analysis Techniques:

- The Oncosure Test detects oncosomes, extracellular vesicles indicative of tumor presence.
- Analysis involves using fluorescent microscopy to accurately identify and quantify oncosomes, ensuring reliable results.



Reporting and Communication:

- Abnormal findings are communicated promptly through a clear yes or no report, detailing the presence of oncosomes.
- Efforts are made to ensure effective communication of results to healthcare providers for informed patient management.



Reading and Interpreting Results

The Oncosure Rapid Cancer Screening Test provides clear yes or no results for cancer screening based on the detection of oncosomes in the blood sample. Preliminary results are typically available within 2 hours of sample receipt, typically communicated to the doctor the next day. The report includes a definitive yes or no result along with the number of oncosomes detected, which can also be used to monitor cancer treatment. Positive results indicate the presence of cancer and the need for further diagnostic evaluation by healthcare providers.



Further Diagnostic Recommendations

Once a patient receives a positive result from the Oncosure Test, it is recommended to undergo further diagnostic testing. This next phase involves identifying the specific type of cancer and determining the most appropriate treatment plan. Follow-up diagnostics may include imaging studies, biopsies, and consultations with oncology specialists. Early and accurate diagnosis is essential for effective treatment and better patient outcomes. Once treatment begins, this test can also be used to monitor cancer treatment by closely monitoring the change in oncosome counts.

QUESTIONS TO ASK YOUR DOCTOR ABOUT CANCER SCREENING

Navigating when to start, how often, and when to stop cancer screening tests can be perplexing. Talking with your doctor can help determine the best screening schedule for you.

- What type of cancer screening tests do you recommend for me based on my age and health history?
- How can this test benefit me during cancer treatment?
- How often should I undergo cancer screening?
- What should I do if my screening test results are positive?
- Are there any lifestyle changes I can make to reduce my risk of developing cancer?
- Are there any specific preparations I need to make before undergoing a cancer screening test?
- How will you communicate the results of my screening tests, and what do I do if I have questions afterward?
- If I'm in remission, how often should I test?



TAKE CONTROL OF YOUR HEALTH, AND HELP REDUCE YOUR RISK OF GETTING CANCER.



Strategies That Can Be Done In Health

HEALTH

- Stay away from all forms of tobacco.
- Get to and maintain a healthy weight.
- Get moving with regular physical activity.
- Eat healthy with plenty of fruits and vegetables.
- It's best not to drink alcohol. If you do drink, have no more than 1 drink per day for women or 2 per day for men.
- Protect your skin.
- Know yourself, your family history, and your risks.
- Get regular check-ups and cancer screening tests.



CONTACT INFORMATION FOR SUPPORT



-  +1 888-925-4816
-  info@oncosuretesting.com
-  www.oncosuretesting.com
-  1550 N Andrews Ave Ext
Pompano Beach, FL 33069

