Armune BioScience®

APIFINY®

Non-PSA blood test

USER GUIDE

401 West Morgan Road
Ann Arbor, MI 48108

www.armune.com

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INTRODUCTION

Armune BioScience, Inc. is a medical diagnostic company with corporate headquarters in Kalamazoo, MI and laboratory facilities in Ann Arbor, Michigan. Armune BioScience was founded on the mission to improve the detection of cancer. Our vision is to become a trusted and valued partner throughout the world to improve the diagnosis and prognosis of cancer. The company will accomplish this mission through the highest of ethical and professional standards and through unwavering attention to its shareholders, customers, employees and suppliers.

The company's first technology is Apifiny®, which may be used to assist in determining the risk of a man having prostate cancer. Our studies show that high Apifiny scores (at or above 59) correlate with higher risk, while lower scores (below 59) tie more closely with lower risk.

The focus of Armune BioScience is to provide quality, expedient, reliable and accurate test results. Clients include academic medical centers, community hospitals, independent hospital groups, reference laboratories and physician offices.

ARMUNE BIOSCIENCE QUALITY POLICY

Quality is the essence of the culture and work habits at Armune BioScience.

Quality is not an afterthought, a separate department, or a step in a process. It is the way we interact and think and do things.

All employees diligently focus on customers and continuous improvement in our products and services.

It is the responsibility of management and staff to implement and embrace sound quality management practices in all aspects of our business.

ACCREDITATION/LICENSURE

Armune BioScience, Inc. maintains current CLIA registration and certification with the U.S. Department of Health and Human Services Centers for Medicare & Medicaid Services (CMS). For additional information or a copy of our certificate(s), please see our website at www.armune.com.

MEDICARE COVERAGE OF LABORATORY TESTING

The patient is responsible for the charges associated with the Apifiny test performed by Armune BioScience. Armune BioScience is a participating Medicare or Medicaid provider and will bill either of these programs, and private insurance companies, for the costs associated with this test.

CONTACT INFORMATION

E-Mail address: CustomerService@armune.com

Call Center: 844-4Armune (844-427-6863)

ARMUNE BIOSCIENCE WEBSITE

www.armune.com

You can find new information from Armune BioScience on our website as well as the most current version of the Apifiny User Guide.

Also, see our website for additional information, including accreditation/licensure certificates, test request forms, and frequently asked questions.

HOLIDAY COVERAGE

Armune BioScience recognizes the following as official holidays:

New Year's Day, January 1
Memorial Day, Last Monday in May
Independence Day, July 4
Labor Day, First Monday in September
Thanksgiving, Fourth Thursday in November
Christmas, December 25

Holidays occurring on a weekend are observed on Friday or Monday.

APIFINY TECHNOLOGY

Information about the Apifiny technology can be found on our website at www.armune.com. Frequently Asked Questions and Physician's Information sections provide background information as well as detailed technology information. General instructions for specimen collection and shipment, including Apifiny specimen requirements, specimen containers, labeling, transport, specimen rejection, interpretive data, and other notes can be found in this User Guide and on the website.

APIFINY TEST REQUISITION FORMS

Instructions and requisition forms are available on our website at www.armune.com, by emailing CustomerService@armune.com, or by calling 844-4Armune (844-427-6863).

RESULTS REPORTING

Final written reports of test results are generated at the completion of the assay and sent to the ordering physician. If requested, results are reported by email or secure FAX, to the ordering physician or requesting lab. Email or secure FAX notification should be requested in writing on the original Apifiny Test Requisition Form. Information must include the name of the person or lab and specific contact information.

GENERAL INSTRUCTIONS FOR SPECIMEN COLLECTION AND SHIPMENT

General Instructions for the Physician's Office

1. Complete an ApifinyTest Requisition Form for each patient, including the Advance Beneficiary Notice (ABN) for Medicare patients.
2. Be sure to record the following:
   a. Patient name, birth date, sex, race, and address
   b. Collection time and date
   c. Number and type of blood tubes (red top, SST, or microtainer SST)
   d. Patient medical history information
3. Fill in the physician's patient I.D. number or the lab reference number in order for the patient's number to appear on the Apifiny Final Report.
4. Indicate how results should be reported, by mail, secure FAX, or e-mail.
5. Be sure the referring physician signs the Apifiny Test Requisition Form. The test CANNOT be performed without the signature of the referring physician. Refer to Apifiny User Guide section **APIFINY SPECIMEN REJECTION** for other criteria that may cause rejection or test cancellation.
6. Keep a copy of the form for your records.
7. Write patient's first and last name legibly, and spelled correctly, and date of birth on the sample tube(s). **NOTE:** Please use reagent resistant ink or pencil for any hand-written labeling.
8. Send samples overnight air delivery to:

   Armune BioScience, Inc.
   401 West Morgan Road
   Ann Arbor, MI 48108
   844-4Armune (844-427-6863)

Basic Concepts for Collection

1. Decontaminate the skin surface. Use 70-95% alcohol (ALC) to prepare the site. Allow a contact time of two minutes to maximize the antiseptic effect. Collect a sufficient quantity of material (Minimum 5mL of blood for red top or SST tubes, or 200 µL for fingerstick/microtainer SST tubes). Refer to Apifiny User Guide section **APIFINY SPECIMEN REQUIREMENTS**.

2. Use appropriate collection devices. Refer to Apifiny User Guide section **APIFINY SPECIMEN CONTAINERS**.
3. Properly label the specimen and complete the Apifiny Test Requisition Form. Refer to Apifiny User Guide section **APIFINY SPECIMEN LABELING**.
4. Minimize transport time. Maintain an appropriate environment between collection of specimens and delivery to Armune. Refer to Apifiny User Guide section **APIFINY SPECIMEN TRANSPORT.**

APIFINY SPECIMEN REQUIREMENTS

General Specimen Requirements

To produce valid results for Apifiny tests, specimen integrity is crucial and must be maintained. All specimens sent for testing must be collected and shipped in the following manner:

Blood Sample

1. Obtain venous blood by clean venipuncture. Do not use needles smaller than 23 gauge.
2. Fill red top or SST tube with a minimum of 5mL of blood, or use fingerstick lancet and fill microtainer SST tube with a minimum of 200µL of blood.
3. For red top tube, allow tube to stand for a minimum of 30 minutes at room temperature to allow clotting to occur, and then refrigerate.
4. **For SST tube or microtainer SST tube, invert tube five (5) times to ensure clot activator is adequately mixed with blood sample.** Refrigerate SST tube or microtainer SST tube, or, if you wish to spin SST tube or microtainer SST tube, follow manufacturer procedures, and then refrigerate. Do not remove serum from the SST tube or microtainer SST tube.
5. Ship samples in a Styrofoam container with a **frozen gel pack**.
6. All requests for Apifiny tests must include a completed Apifiny Test Requisition Form and, for Medicare patients only, an ABN Form. **Note:** Specimens collected in anything other than a red top or SST tube or through fingerstick in a microtainer SST tube will be rejected for Apifiny tests. Refer to Apifiny User Guide section **APIFINY SPECIMEN REJECTION.**

Minimum Acceptable Volumes

The minimum acceptable test volume is 5mL of blood in a red top or SST tube, or 200µL in a microtainer SST tube. This volume is sufficient to perform one test, and any repeat tests if necessary. If an insufficient volume is received for testing, an attempt will be made to locate any additional sample that was collected at the same time. In this case, there may be delays and the test request may be referred to the Laboratory Director for issuance of a Specimen Rejection report. Refer to Apifiny User Guide section **APIFINY SPECIMEN REJECTION.**

APIFINY SPECIMEN CONTAINERS

Armune requests that clients use the following guidelines to ensure safe handling procedures, non-compromised specimens, and fast and accurate test results.

Blood Transfer Tubes

Armune requires use of red top, SST, or microtainer SST tubes for blood collection and blood specimen submission. Specimens collected in anything else will be rejected for Apifiny tests. Refer to Apifiny User Guide section **APIFINY SPECIMEN REJECTION.**

Containers that will NOT be accepted:

1. Tubes from an automatic aliquoting system with a "pop top" type of cap. The caps may come off during air transport and do not comply with DOT regulations.
2. Leaking specimens that are not placed in a secured secondary container or that are leaking in such a way as to compromise testing.
3. Syringes.
4. Specimens received in expired transport containers or media.

APIFINY SPECIMEN LABELING

To assure positive identification and optimum integrity of patient specimens from the time of collection until testing is completed and results reported, specimens submitted to Armune BioScience for testing should be labeled with the patient's **first and last name, correctly spelled and birth date, or first and last name and a unique identifying number,** such as medical record number.

NOTE: Please use reagent resistant ink or pencil for any hand-written labeling.

Clients will be notified of inappropriately labeled specimens.

APIFINY SPECIMEN TRANSPORT

It is critical that all specimens are transported as quickly as possible. Prompt processing minimizes loss in signal and ensures a more accurate appraisal of the specimen.

To ensure optimum testing conditions for a specimen that is sent to Armune BioScience, the shipper must determine two things.

1. The infectious nature of the specimen to be sent, using the definitions below.
2. The temperature at which the specimen must be maintained during transit, using instructions in section **APIFINY SPECIMEN REQUIREMENTS.**

Definitions of "Diagnostic" and "Infectious" Specimens

Diagnostic Specimens: Any human or animal material, including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluids, ***being shipped for purposes of diagnosis***, but excluding live, infected animals. Diagnostic specimens not known or thought likely to be infectious are excluded from following procedures for shipping Infectious Substances.

Infectious Substances: Specimens known to contain, or thought likely to contain, pathogens. These specimens are capable of spreading disease when an individual is exposed to them. Transport authority requires the shipping laboratory to identify specimens as to their shipping description. Specimens not identified as infectious by this definition should be shipped as "Diagnostic Specimens."

Samples for the Apifiny assay are considered "non-infectious diagnostic specimens."

Transport of Diagnostic Specimens

All specimens must be in leak-resistant primary receptacles (tubes), and must be placed in leak-resistant secondary packaging (plastic bags). There must be sufficient absorbent material included in the bag to absorb the entire contents of the primary receptacle. Couriers are not allowed to pick up specimens that are leaking or are not in secondary packaging.

Shipping Containers

If you are using an Armune prepaid mailer, follow the packaging instructions that accompany the mailer.

Important Notes
Packing should always be done in a manner that ensures that at least one frozen gel pack can be placed in the Styrofoam container with the specimen bag(s).

Inner Packaging
As defined by International Air Transport Association Packing Instruction 602, inner packaging is comprised of:

1. Waterproof primary receptacle (tube)
2. Waterproof secondary packaging (plastic bag)
3. Absorbent material placed between the primary receptacle and secondary packaging

Outer Packaging

1. Rigid outer packaging (Styrofoam container). Include at least one gel pack in the Styrofoam container as described above.
2. Seal the shipping container securely.
3. Complete the form for the Air bill (see instructions below).

When Shipping Specimen

1. Fill in the shipper information on the Air bill, including the name and phone number of the person sending the shipment. If you are not using an Armune preprinted Air bill, fill in the delivery details shown in step 5 below and bill to recipient using one of the following account numbers:

   For UPS shipments, 2F6074
   For FedEx shipments, 6410-6930-2

2. Follow shipper requirements and any other controlling regulations for packaging blood/serum for shipment.

Note: Apifiny orders should only be shipped Monday through Thursday. **Do not ship on Friday**. **Samples are accepted Tuesday through Friday only. Samples must be shipped for standard overnight air delivery.**

3. If the Air bill asks "Does this shipment contain dangerous goods?", check "No". Samples for the Apifiny assay are considered "non-infectious diagnostic specimens."
4. Send samples in an acceptable container as described above with a completed Apifiny Test Order Form for each sample.
5. Send samples standard overnight air delivery to:

   Armune BioScience, Inc.
   401 West Morgan Road
   Ann Arbor, MI 48108
   844-4Armune (844-427-6863)

APIFINY SPECIMEN REJECTION

Specimens to which the following conditions apply may be rejected and returned to the originating site.

1. Specimen is submitted without an ApifinyTest Requisition Form.
2. Specimen is not labeled with the patient name.
3. Patient name (or other identifying information) on the specimen and order form do not correspond.
4. Specimen is labeled appropriately but the Apifiny Test Requisition Form is not complete.
5. Specimen container is irreparably broken or damaged.
6. Specimen is submitted from an unauthorized source.
7. Referring physician has not signed the Apifiny Test Requisition Form.

All specimens must be collected, labeled, transported and processed according to procedure. Selecting the container type, volume and special handling requirements needed for analysis before the specimen is collected is essential. If the criteria for these processes are not met, the specimen may be rejected or the test may be canceled. The following represent some reasons for specimen rejection or test cancellation:

1. Inappropriate specimen type
2. Insufficient volume for analysis
3. Improperly labeled specimen
4. Inappropriate specimen container
5. Improper specimen transport
6. Specimen that has been damaged in transit
7. Specimen that has been sent in expired transport media
8. Incomplete or incorrect test order form
9. Test request without a specimen
10. Specimen without a test order form

QUESTIONS

Email CustomerService@armune.com or call 844-4Armune (844-427-6863).