



# Apifyn<sup>®</sup> Test Requisition Form

Make a copy of completed form for your records

## PHYSICIAN AND DIAGNOSIS INFORMATION

This Test **CANNOT** be performed without the signature of the referring physician or other approved health care provider. Signature confirms your certification of medical necessity and that you have obtained patient's permission for Armune BioScience to release test results to the patient's third-party payer as necessary when submitting for reimbursement.

Physician/Approved Provider Signature \_\_\_\_\_ Date \_\_\_\_\_

Physician/Approved Provider Name (Print) \_\_\_\_\_ NPI \_\_\_\_\_

Hospital/Clinic Name \_\_\_\_\_

Address \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ ZIP \_\_\_\_\_ Country \_\_\_\_\_

Phone \_\_\_\_\_ Ext \_\_\_\_\_ Secure FAX \_\_\_\_\_

E-Mail \_\_\_\_\_ Report Final Results by:  Mail  Secure FAX  E-Mail

Please state why test is needed (Diagnosis/Signs/Symptoms) \_\_\_\_\_

- |   |   |
|---|---|
| <b>ICD-10:</b> <input type="checkbox"/> <b>D29.1</b> Benign neoplasm of prostate  | <input type="checkbox"/> <b>N41.9</b> Inflammatory disease of prostate, unspecified |
| <input type="checkbox"/> <b>D49.5</b> Neoplasm of unspecified behavior of other genitourinary organs                            | <input type="checkbox"/> <b>N42.9</b> Disorder of prostate, unspecified             |
| <b>Please check all that apply</b> <input type="checkbox"/> <b>N40.0</b> Enlarged prostate without lower urinary tract symptoms | <input type="checkbox"/> <b>R97.2</b> Elevated prostate specific antigen (PSA)      |
| <input type="checkbox"/> <b>N40.1</b> Enlarged prostate with lower urinary tract symptoms                                       | <input type="checkbox"/> <b>N41.1</b> Chronic prostatitis                           |
| <input type="checkbox"/> <b>Z12.5</b> Encounter for screening for malignant neoplasm of the prostate                            | <input type="checkbox"/> <b>C61</b> Malignant neoplasm of prostate                  |
| <input type="checkbox"/> <b>Z00.01</b> Encounter for general adult medical exam with abnormal findings                          | <input type="checkbox"/> <b>Other</b> Please specify: _____                         |
| <input type="checkbox"/> <b>D07.5</b> Carcinoma in situ of prostate   |   |

## PATIENT INFORMATION

Patient Name \_\_\_\_\_ Date of Birth \_\_\_\_\_

Patient ID # \_\_\_\_\_ Race \_\_\_\_\_

Address \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ ZIP \_\_\_\_\_ Country \_\_\_\_\_ Phone \_\_\_\_\_

## MEDICAL HISTORY

Date(s)/Result(s) of Last PSA Test(s) \_\_\_\_\_

Date of Last DRE \_\_\_\_\_ Result  Normal  Abnormal Prostate Biopsy?  No  Yes Pathology Result \_\_\_\_\_

Family History of Prostate Cancer  No  Yes Relationship \_\_\_\_\_ Age at Diagnosis \_\_\_\_\_

**Would patient like to be contacted for advanced genetic screening for inherited cancer?**  Yes  No

## SAMPLE INFORMATION

**Sample Type:** SST \_\_\_ Red Top \_\_\_

Date and Time of Blood Draw \_\_\_\_\_ Sample Ship Date \_\_\_\_\_ Microtainer SST \_\_\_

Number of Tubes/Vials \_\_\_\_\_ Time Sample at 15-30°C \_\_\_\_\_ Draw Lab Name \_\_\_\_\_

## PAYMENT INFORMATION

**Patient Self-Pay** (Invoice will be sent to patient when results are reported to physician.)

**Primary Private Insurance Carrier** \_\_\_\_\_ **Attach front/back copy of insurance card**

Subscriber Name & Date of Birth \_\_\_\_\_ Subscriber's relation to patient \_\_\_\_\_

**Secondary Private Insurance Carrier** \_\_\_\_\_ **Attach front/back copy of insurance card**

Subscriber Name & Date of Birth \_\_\_\_\_ Subscriber's relation to patient \_\_\_\_\_

**MEDICARE** **Attach front/back copy of insurance card**  **MEDICAID** **Attach front/back copy of insurance card**

- Hospital Inpatient (more than 24-hr stay)  
 Hospital Outpatient  Non-hospital patient

**NOTE: For questions about insurance coverage, please call 877-436-3894.**

## Apifiny Blood Sample Collection and Handling Procedures

### Please read carefully

**NOTE:** A free prepaid Sample Mailer is available from Armune BioScience. To order, please contact [CustomerService@Armune.com](mailto:CustomerService@Armune.com), or call 844-4Armune (844-427-6863).

1. Follow standard blood-borne pathogen safety precautions.
2. Collect at least 5 mL of blood in a red top or SST tube. (Samples collected in other tubes are not acceptable and will be rejected.) Be sure to label tube with patient's full name and date of birth.

OR

Collect at least 200  $\mu$ L of blood in a microtainer SST tube using the included manufacturer fingerstick collection instructions. Be sure to label tube with patient's full name and date of birth.

**NOTE: If using an SST tube or microtainer SST tube, invert the tube five (5) times to ensure clot activator is adequately mixed with blood sample.**

3. **IMPORTANT: Tube(s) must be labeled with the patient's full name and date of birth.** Patient ID, date and time of collection, and the Physician's/Clinic's name are also recommended. Please use reagent resistant ink or pencil for any hand-written labeling. Tube(s) without at least patient's full name and date of birth will be rejected.
4. **Store tube at room temperature for at least 30 minutes after collection to allow the blood to clot,** and then refrigerate. Refrigerate SST or microtainer SST tube, or, if you wish to spin the SST tube or microtainer SST tube, follow manufacturer procedures, and then refrigerate. Do not remove serum from the SST or microtainer SST tube.

Ship promptly. **Ship samples Monday through Thursday by standard overnight air delivery. Samples are accepted Tuesday through Friday only.**

5. Send samples at 2° to 8°C in a Styrofoam container with at least one **frozen gel pack** along with the completed Apifiny Test Requisition Form for each sample. Use shipper's appropriate packaging and follow shipper's requirements and any other controlling regulations for packaging blood/serum for shipment.

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

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

6. Send samples by standard overnight air delivery to:

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

For your reference, Armune's UPS account number for submitting samples for Apifiny testing is 2F6074.

If your mailer has FedEx shipping materials, or you prefer to use FedEx, Armune's FedEx account number is 6410-6930-2.

For additional sample collection and preparation information, or for more information about Armune's laboratory, please refer to the Apifiny User Guide. The guide is available on-line at [www.armune.com](http://www.armune.com), through Armune Customer Support at [CustomerService@Armune.com](mailto:CustomerService@Armune.com) or by calling 844-4Armune (844-427-6863).

# FOR MEDICARE PATIENTS ONLY

A. Notifier: Armune BioScience, Inc. (877) 436-3894

B. Patient Name:

C. Identification Number:

## Advance Beneficiary Notice of Noncoverage (ABN)

**NOTE:** If Medicare doesn't pay for **D. Apifyny<sup>®</sup>** below, you may have to pay.

Medicare does not pay for everything, even some care that you or your health care provider have good reason to think you need. We expect Medicare may not pay for the **D. Apifyny** below.

D. Apifyny <sup>®</sup>	E. Reason Medicare May Not Pay:	F. Estimated Cost
Apifyny is a blood test measuring the immune system's response to prostate cancer. Apifyny is the only cancer specific, non-PSA blood test that may aid clinicians in the assessment of risk for the presence of prostate cancer.	Medicare may not pay for Apifyny as it is a new test with a limited amount of clinical data supporting its use.	<b>\$705.00</b>

### WHAT YOU NEED TO DO NOW:

- Read this notice, so you can make an informed decision about your care.
  - Ask us any questions that you may have after you finish reading.
  - Choose an option below about whether to receive the **D. Apifyny** listed above.
- Note:** If you choose Option 1 or 2, we may help you to use any other insurance that you might have, but Medicare cannot require us to do this.

### G. OPTIONS: Check only one box. We cannot choose a box for you.

- OPTION 1.** I want the **D. Apifyny** listed above. You may ask to be paid now, but I also want Medicare billed for an official decision on payment, which is sent to me on a Medicare Summary Notice (MSN). I understand that if Medicare doesn't pay, I am responsible for payment, but **I can appeal to Medicare** by following the directions on the MSN. If Medicare does pay, you will refund any payments I made to you, less co-pays or deductibles.
- OPTION 2.** I want the **D. Apifyny** listed above, but do not bill Medicare. You may ask to be paid now as I am responsible for payment. **I cannot appeal if Medicare is not billed.**
- OPTION 3.** I don't want the **D. Apifyny** listed above. I understand with this choice I am **not** responsible for payment, and **I cannot appeal to see if Medicare would pay.**

**H. Additional Information:** Armune BioScience, the makers of Apifyny, are committed to providing access for every patient, regardless of insurance coverage and created a process to support individual patient financial situations. After processing insurance reimbursement, if a patient is responsible for any portion of the payment, Armune provides options for patient out of pocket costs, including: (1) Convenient payment using check or debit/credit card and (2) Individualized billing process to support various patient financial situations. If you have questions, please call the billing department at (877) 436-3894. We are available from 8 AM – 5 PM ET, Mon-Fri.

**This notice gives our opinion, not an official Medicare decision.** If you have other questions on this notice or Medicare billing, call **1-800-MEDICARE** (1-800-633-4227/TTY: 1-877-486-2048).

Signing below means that you have received and understand this notice.

I. Signature:

J. Date:

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0566. The time required to complete this information collection is estimated to average 7 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.



**The Five Most Common Causes for Apifyny Order Delay or Rejection**

*Please read carefully*

	<b>Cause</b>	<b>Result</b>
<b>1</b>	<p><b>Sample tube has no identification</b></p> <p>Tube <b>MUST BE</b> labeled with the patient's <b>FULL NAME AND DATE OF BIRTH</b>, or <b>FULL NAME AND OTHER UNIQUE IDENTIFIER</b>, such as patient ID. The identifiers on the tube <b>MUST MATCH THE TEST REQUISITION FORM</b>.</p>	Order Rejection
<b>2*</b>	<p><b>Sample tube has only one identifier</b></p> <p>Tube <b>MUST HAVE</b> at least <b>TWO UNIQUE IDENTIFIERS</b> (full name and date of birth, or full name and other identifier, such as patient ID) that match the test requisition form to assure sample/patient correlation.</p>	Processing and Reporting Delay. Possible Order Rejection
<b>3</b>	<p><b>Order shipped without frozen gel pack or without Styrofoam box</b></p> <p>Sample <b>MUST BE</b> packaged inside a <b>STYROFOAM BOX WITH A FROZEN GEL PACK</b> to ensure proper sample temperature is maintained.</p>	Order Rejection
<b>4</b>	<p><b>Sample fails to clot</b></p> <p>Sample <b>MUST BE</b> stored at <b>ROOM TEMPERATURE</b> for at least <b>30 MINUTES</b> after collection to allow the blood to clot, and <b>then REFRIGERATED</b> until it is shipped. <b>DO NOT STORE IN FREEZER. SST and microtainer SST tubes MUST BE INVERTED 5 TIMES</b> to ensure clot activator is adequately mixed with sample, then stored at room temperature for at least 30 minutes before refrigeration. <b>DO NOT STORE IN FREEZER.</b></p>	Order Rejection
<b>5*</b>	<p><b>No physician (or ordering professional) signature</b></p> <p>Order <b>MUST HAVE</b> an <b>AUTHORIZING SIGNATURE</b></p>	Processing and Reporting Delay. Possible Order Rejection

\* In the case of only one identifier on a sample tube or no authorizing signature, Armune may send a Sample ID Confirmation Form or a Physician Order Confirmation Form, respectively, to allow the ordering physician to complete the order and prevent order rejection.