401 W. Morgan Road
Ann Arbor MI 48108
844-4Armune (844-427-6863)
www.armune.com

# Apifiny® 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.**

Hospital/Clinic Name: _____

Physicians/Approved Providers at this location:

| NAME | NPI | NAME | NPI |
|---|---|---|---|
| ❑ | | ❑ | |
| ❑ | | ❑ | |
| ❑ | | ❑ | |
| ❑ | | ❑ | |

Physician/Approved Provider Signature _____ Date _____

Address _____

City _____ State _____ ZIP _____ Country _____

Phone/Ext _____Secure FAX 1_____ Secure FAX 2_____

E-Mail _____ Report Final Results by: ❑ Mail ❑ Secure FAX ❑ E-Mail

**PLEASE ATTACH COPY OF OFFICE NOTES**

**ICD-10:** **Please check all that apply**

- ❑ **D29.1** Benign neoplasm of prostate
- ❑ **D49.5** Neoplasm of unspecified behavior of other genetourinary organs
- ❑ **N40.0** Enlarged prostate without lower urinary tract symptoms
- ❑ **N40.1** Enlarged prostate with lower urinary tract symptoms
- ❑ **Z12.5** Encounter for screening for malignant neoplasm of the prostate
- ❑ **Z00.01** Encounter for general adult medical exam with abnormal findings
- ❑ **D07.5** Carcinoma in situ of prostate
- ❑ **N41.9** Inflammatory disease of prostate, unspecified
- ❑ **N42.9** Disorder of prostate, unspecified
- ❑ **R97.20** Elevated prostate specific antigen (PSA)
- ❑ **R97.21** Rising PSA following treatment for malignant neoplasm of prostate
- ❑ **Z80.42** Family history of malignant neoplasm of prostate
- ❑ **C61** Malignant neoplasm of prostate
- ❑ **N41.1** Chronic prostatitis ❑ **Other** Please specify: _____

## 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 ___ Microtainer SST ___

Date and Time of Blood Draw _____ Sample Ship Date _____

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.**

## 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, or call 844-4Armune (844-427-6863).

1. Follow standard blood-borne pathogen safety precautions.

2. Collect at least 5 mL of blood in an SST tube. (Samples collected in other tubes may be rejected.) Be sure to label tube with patient's full name and date of birth.

   OR

   Collect at least 200 µL 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.

   **GENTLY invert SST 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 may be rejected.

4. **Store tube at room temperature for at least 30 minutes after collection and multiple inversions to allow the blood to clot**, and then refrigerate. If you wish to spin the SST tube or microtainer SST tube, follow manufacturer procedures, and then refrigerate or freeze.

   **DO NOT FREEZE WHOLE BLOOD.**

   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 8ºC in a Styrofoam container with at least one **frozen gel pack** along with the completed 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 account numbers for submitting samples for testing are:

   **2F6074 for UPS** shipments
   Call 1-800-PICKUPS to schedule a UPS pick up

   **6410-6930-2 for FedEx** shipments
   Call 1-800-GOFEDEX to schedule a FedEx pick up

## Most Common Causes for Order Delay or Rejection

**Please read carefully**

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

For additional sample collection and preparation information, or for more information about Armune's laboratory, please refer to the Apifiny / Apifiny PRO User Guide. The guide is available on-line at www.armune.com, through Armune Customer Service at 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. Apifiny®** 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 **D. Apifiny** below.

| D. Apifiny® | E. Reason Medicare May Not Pay: | F. Estimated Cost |
|---|---|---|
| Apifiny is a blood test that measures the immune system's response to prostate cancer. Apifiny 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 the Apifiny test as it is new and may be considered to be experimental and research use tests. | $705.00 |

**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. Apifiny Test*** 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 Apifiny Test 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 Apifiny Test 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 Apifiny Test 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 the Apifiny technology, 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.** For 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: |
|---|---|



Form CMS-R-131 (03/11) Form Approved OMB No. 0938-0566

FOR MEDICARE PATIENTS ONLY