



# VITEK QC ORGANISM: ATCC BAA 3144 PERMIT GUIDE

**Disclaimer:** This guide is provided for informational purposes only and serves as a general suggestion on how to apply for the relevant permit. It is not intended as legal advice or a substitute for professional consultation. All legal and regulatory responsibilities, including compliance with applicable laws and regulations, remain solely with the institution or individual applying for the permit.

## Purpose:

### Complexity around FDA requirement for QC strains with Imipenem/ Relebactam (IPR)-

The calling range of IPR is 0.25-16 for the VITEK® 2 test. BioMérieux has 2 routine QC strains in the package insert for IPR:

- BAA 1705 QC range would be off scale low at  $\leq 0.25$  (its CLSI range is 0.03-0.25)
- BAA 2814 QC range would be potentially off scale at  $\leq 0.25-0.5$  (its CLSI range is 0.06-0.5). So results could be off scale as well.
- The FDA requires a completely on-scale strain to receive clearance. The selected strain meeting this requirement during development of the cards was BAA 3144.

### Specific need of Vet permit as per USDA-

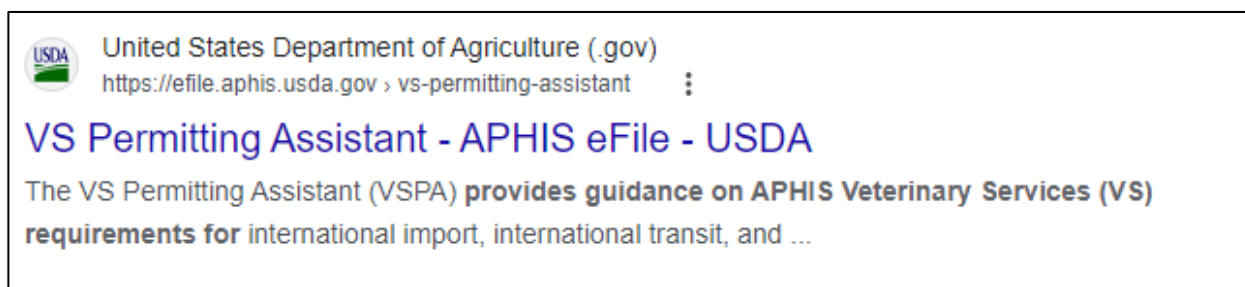
Per USDA and ATCC requirements, customers must obtain a Vet permit (VS-06) to receive BAA 3144. Although sites wanting the ATCC strain are clinical sites, the strain, *P. aeruginosa*, is a human **and** animal pathogen, hence the reason for the USDA permit.

### Obtaining a USDA VET Permit:

Visit the USDA.gov website's Veterinary Services Permitting Assistant:

[https://efile.aphis.usda.gov/s/vs-permitting-assistant?\\_gl=1\\*cwshqb\\*\\_ga\\*MjEwNTMxNzU3Mi4xNjg0MTU1Nzg0\\*\\_ga\\_NRK0CEY9GC\\*MTY5MDkyMDC5NS4yMDIuMS4xNjkwOTI1MTU2LjAuMC4w](https://efile.aphis.usda.gov/s/vs-permitting-assistant?_gl=1*cwshqb*_ga*MjEwNTMxNzU3Mi4xNjg0MTU1Nzg0*_ga_NRK0CEY9GC*MTY5MDkyMDC5NS4yMDIuMS4xNjkwOTI1MTU2LjAuMC4w)

Or search for USDA Veterinary Services Permitting Assistant in your search engine. The webpage should look like this:



- 1.) Select the following options in the Step 1 Menu: **(Make sure you select Organisms & Vectors)** Click **“Search”** when you have filled out all of the fields

**Step 1: Select a Category Tab to Enter a Commodity's Details**

Animal Products & Byproducts | Live Animals | **Organisms & Vectors**

Organisms, their derivatives, or vectors which may contain or be exposed to livestock, aquatic, and poultry pathogens.

Movement Type: Interstate Transport

Category: Livestock or Poultry Pathogen

Organism or Vector: Pseudomonas aeruginosa Live Isolate

Exposed to, Isolated from Animals/Animal Products: Ruminant Equine or Porcine

**Search**

- 2.) Add the material in step 3 of the Menu (Interstate Travel does not require step 2)

**Step 2: Select Attributes**

0 filters applied | Clear All

Your search does not require any attribute filters. Please proceed to Step 3.

**Step 3: Select Your Material**

Showing 1 of 1 Materials | Show 3 results per page | Sort by: PR #

**Pseudomonas aeruginosa Live Isolate**  
Livestock or Poultry Pathogen | PR-022714

Attributes  
No attributes to be displayed.

**+ Add Material**

Please add material or to an ingredients list, to see permit requirements on the summary page. Actual conditions for this material are not determined until added to your request.

**Make sure to “Select” the Pseudomonas aeruginosa Live Isolate, the icon will turn red if you selected it correctly**

**View Summary**

- 3.) Enter your email and click send – **this will send the application to complete the permit through the USDA system.** If you already have an account, proceed **to Log-In and complete the application online.** The approval process times may vary pending the USDA.

Go Back and Add More Materials
Proceed to Log-In

Permit Applications(1)
No Permit Required but Conditions Apply
Inadmissible

### 1. VS 16-3 Interstate Transport Permit Application

Subtotals (1 Materials) Estimated processing fee: \$150.00

**Pseudomonas aeruginosa Live Isolate**

Livestock or Poultry Pathogen | PR-022714

Interstate Transport | Exposed To: Ruminant Equine or Porcine

Attributes

*No attributes to be displayed.*

✓ Permit Required

*You need a permit for this request. The recipient of the material (importer) must apply for the permit.*

✓ Documentation Required

#### Applications Summary

**Subtotal (1 Materials):**

1 Permit Applications

0 No Permit Required but Conditions Apply

0 Inadmissible

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**VS 16-3 Interstate Transport Permit Application**

- Pseudomonas aeruginosa Live Isolate **\$150.00**

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**Estimated Processing Fee** **\$150.00**

**Disclaimer**

This is a non-refundable fee and is subject to change based on further provided information entered in the application form.


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Email a Copy of the Overall Summary i

Enter your email here ...

Send

4.) Refer to the APHIS eFile Guidance for Submitting a VS 16-3 Permit Application if you have any questions regarding the application process (separate document):



**Animal and Plant Health Inspection Service**

U.S. DEPARTMENT OF AGRICULTURE

## APHIS eFile

### Guidance for Submitting a VS 16-3 Permit Application

*Application for 16-6A permit to import or transport animal products, organisms and vectors*

Version 3.0  
August 2022

PIONEERING DIAGNOSTICS

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5.) Once you are logged in, you will be able to see the permit application, it should be in “Draft”. Click on “Go to Draft” to complete more information on the application

The screenshot shows a dashboard with a 'Filter' sidebar on the left and a main content area. The sidebar includes sections for 'Filters Applied (3)', 'Activity Type', 'Document Type', 'Form Number', 'Status', 'APHIS Program', 'Team Sharing Account', and 'Applicant'. The main content area has a search bar, 'Showing 1 of 1 items', and a 'Sort by' dropdown. Below this is a 'Display recent' section with a 'View All' dropdown. The main list shows one item with a red box around the 'Program: VS | VS 16-3' and another red box around the 'Go to Draft' button. The item details include: Applicant: John Doe MD, Commodity Type: Organism & Vectors, Intended Use, Started: 09/06/2024, and Status: Draft.

6.) For the “Responsible Party” section, please fill out your institution’s responsible party. **This person will be responsible for the permit (permittee).** Please refer to your institution’s guidelines for the responsible party

The screenshot shows the 'New VS 16-3 Permit Application' form. At the top, it says 'Application Number: A-00514871' and has a 'Delete Draft' button. Below this is a progress bar with steps: 'Responsible Party' (highlighted), 'Exporter', 'Material', 'Upload Files', and 'Review and Submit'. The 'Applicant Details' section is highlighted in blue. There is a field for 'Application Reference Name'. Below that is the 'Instructions' section, which states: 'Confirm that your information is correct and answer the following question(s). The permit will be issued to the permittee declared on this page and their name, organization and business address will be listed on the permit.' The 'Responsible Party' section shows 'John Doe MD' from 'Great Hospital' with an 'Edit' button. To the right, there is a question: '\* Will you be the permittee?' with two radio button options: 'Yes' and 'No, I am applying on behalf of the permittee'. A text box below this question says 'Fill this information out according to your institution’s guidelines'. At the bottom right, there are 'Save' and 'Save and Next' buttons.

7.) For the “Exporter” section, please list the ATCC organization. You can add the ATCC organization by clicking “Create New Contact” and entering the information

**Knowledge of Exporters**

**Instructions**

Please provide information regarding the entities who will be shipping your commodity(s) to you.

Note: The information you input here will appear on your permit in the “shipper” section.

\* Do you know the identity of who is shipping the commodities to the permittee?

Yes

No, but they are various exporter(s) within the United States

**Exporter Details**

**Instructions**

Select the U.S. based exporters who are shipping the commodities to the permittee OR create a new contact to use instead.

\* **Exporter**

Find an Exporter

or

Create New Contact

Responsible Party
Exporter
Material
Upload Files
Review and Submit
✕

You have 1 Error

Add or Edit Contact

If your exporter is a company, you do not need to list a person's name. Instead, list the company's name split across the First Name and Last Name fields and do not list the company name in the organization field.

Salutation	* First Name	Middle Name	* Last Name	Suffix
<input type="text" value="--None--"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
* Email			Additional Email	
<input type="text"/>			<input type="text"/>	
* Phone			Additional Phone	
<input type="text"/>			<input type="text"/>	
Organization			Doing Business As?	
<input type="text"/>			<input type="text"/>	

**Address Information**

* Business Street	* Business Country
<input type="text"/>	<input type="text"/>

This is the information you can use for the ATCC when creating a contact:  
(Please adhere to your institution's guidelines for permit application and creating the ATCC contact information)

American Type Culture Collection (ATCC)

ATCC

<p><b>Business Address</b></p> <p>10801 University Boulevard Manassas, Virginia 20110 United States <a href="tel:+17035206806">+17035206806</a> <a href="mailto:sales@atcc.org">sales@atcc.org</a></p>	<p><b>Mailing Address</b></p> <p>10801 University Boulevard Manassas, Virginia 20110 United States</p>
--	--

Responsible Party

✓ Exporter

Material

Upload Files

Review and Submit

## Knowledge of Exporters

### Instructions

Please provide information regarding the entities who will be shipping your commodity(s) to you.

Note: The information you input here will appear on your permit in the "shipper" section.

\*Do you know the identity of who is shipping the commodities to the permittee?

- Yes  
 No, but they are various exporter(s) within the United States

## Exporter Details

### Instructions

Select the U.S. based exporters who are shipping the commodities to the permittee OR create a new contact to use instead.

Exporter 1

 **American Type Culture Collection (ATCC)**  
ATCC Edit

<b>Business Address</b>	<b>Mailing Address</b>
10801 University Boulevard	10801 University Boulevard
Manassas, Virginia 20110	Manassas, Virginia 20110
United States	United States
+17035206806	
sales@atcc.org	

Remove Exporter

+ Add Another Exporter

Back

Save

Save and Next

- 8.) For the “Material” Section, if you are using this organism for the QC of VITEK 2 Cards, please fill out the sections as follows. **If the organism will be used for other purposes, please fill out the sections according to your institution’s guideline and procedures:**

**Material(s) Details**

**Instructions**

Fill out the following information for all of your materials and/or products.

[+ Add Another Material](#)

Material: [Pseudomonas aeruginosa Live Isolate](#)

**Material: Pseudomonas aeruginosa Live Isolate**

Copy Pseudomonas aeruginosa Live Isolate's Information to Other Materials

Copy Information From

--None--

✓ VS Permitting Assistant Selections

**Pseudomonas aeruginosa Live Isolate**

Livestock or Poultry Pathogen | PR-022714

Interstate Transport | Exposed To: Ruminant Equine or Porcine

Attributes

*No attributes to be displayed.*

✓ Permit Required

*You need a permit for this request. The recipient of the material (importer) must apply for the permit.*

✓ [Documentation Required](#)

Movement Type	Category	Organism or Vector	Exposed To
Interstate Transport	Livestock or Poultry Path...	Pseudomonas aeruginos...	Ruminant Equine or Porci...

**Intended Use**

\* Intended Use

In Vitro Studies

\* Intended Use Sub-Category

Other

\* Brief Description of Proposed Use of Material and Derivatives

This isolate will be used to verify the quality control of Imipenem Relebactam on the VITEK 2 Gram Negative AST Cards

\* Describe the Material to be Transported

Sealed and Frozen Vial of ATCC BA3144 Pseudomonas aeruginosa live isolate in Tryptic Soy Broth medium.

**Suggested wording only, please fill out according to your institution’s guidelines and protocols**

9.) The following portions of the application will need to be filled out according to your institution:

Ruminant Equine or Porcine

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**Facilities**

\* Will material be sent to a laboratory with a designated biosafety level?

Yes

No

N/A

**Use in Animals**

\* Will animals be exposed to the transported material?

--None--

**Treatment of Material Prior to Transportation**

\* Please describe processing and purification methods for this material including time at specific temperatures, pH, other treatments, disease safeguards, etc. If you wish to provide supporting documentation, please use the Attachments section at the end of this page.

Processed and purified according to ATCC quality practices. Please see attachment for details on BAA 3144 Pseudomonas aeruginosa provided by the ATCC organization

**Method of Disposition of Transported Material and Derivatives**

\* Method of Disposition Description

Select your Method(s) of Disposition

\* Are you planning to store the material for future use after completion of the current study?

Yes

No

N/A-will not be conducting a study

**Additional Information**

If there is any additional information you would like us to know, please describe below.

**Attachments**

Please upload any supporting documentation for this material, such as an ingredient list, processing flow charts, purification method description, product label, government certificates, instructions for use, journal references, etc.

[Add New File](#)

File Name	File Type	Description	Created Date	
BAA-3144 Produc....pdf	pdf	ATCC Overview Sheet	09/06/2024, 11:31 AM	

Show: 10

Page 1 of 1

Total records: 1

The attachment will be the information provided by ATCC for BA3144 (product Sheet) – See next page

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## *Pseudomonas aeruginosa* (Schroeter) Migula

BAA-3144™

[DOWNLOAD GENOME](#)

[LEARN ABOUT THE ATCC GENOME PORTAL >](#)

*Pseudomonas aeruginosa* strain 105617 is a whole-genome sequenced strain that was isolated from a human.

This product requires a VS 16-6A permit, which can be downloaded at the [USDA website here](#). Please submit the completed permit form to [SalesPermits@atcc.org](mailto:SalesPermits@atcc.org) with your ATCC sales order number and/or your purchase number noted in the subject line and body of the email.

**Buy Now**

Price: **\$460.00 ea**

Discounts may be available for our fellow nonprofit organizations. [Login](#) to see your price.

Generally ships within 1-3 business days

Quantity  [ADD TO CART](#)

[ADD TO LIST](#)

**Documentation**

[Product sheet](#) [Certificate of analysis](#) [Safety data sheet](#)

Product category	Bacteria
Strain designation	105617
Type strain	No

This is the ATCC website for BAA 3144

- 10.) Upload any materials your institution requires, or that you feel would help USDA understand the permit you are applying for. This may include the package inserts for the VITEK 2 GN AST Cards you plan on using that require the organism, the SDS from ATCC, and any protocols your hospital has regarding the QC Testing of VITEK 2 Cards requiring the proper organism.

**New VS 16-3 Permit Application**

Application Number: A-00514871 Delete Draft

Status: Draft  
Type: New Application

Responsible Party ✓ Exporter Material Upload Files Review and Submit

### Supporting Documentation

**Instructions**

Upload supporting documentation you feel would be beneficial to your application.

I don't have any files to upload

[Add New File](#)

No records to display

[Back](#) [Save](#) [Save and Next](#)

11.) Once you are done, you can review and submit your application after processing the payment.

Status: Draft  
 Type: New Application

✓ Responsible Party > ✓ Exporter > ✓ Material > ✓ Upload Files > Review and Submit

### Responsible Party

**Instructions** Edit

Confirm that the following information is correct. Click on "Edit" if you need to edit the information.

**Applicant & Permittee**

**John Doe MD**  
Great Hospital

Business Address	Mailing Address
123 Road Ave St New York, New York 12345 United States 123-456-7890 john.doe@emailaddress.com	123 Road Ave St New York, New York 12345 United States

### Exporter

**Instructions** Edit

Confirm that the following information is correct. Click on "Edit" if you need to edit the information.

Do you know the identity of who is shipping the commodities to the permittee? Yes

**Exporter 1**

**American Type Culture Collection (ATCC)**  
ATCC

Business Address	Mailing Address
10801 University Boulevard Manassas, Virginia 20110 United States +17035206806	10801 University Boulevard Manassas, Virginia 20110 United States

### Confirm Information & Submit

Check the box below to confirm that you agree that the information you have entered is accurate. Then proceed to the next step of submitting your application.

I CERTIFY, AS AUTHORIZED BY THE COMPANY/INSTITUTION THAT I REPRESENT, THAT THIS MATERIAL WILL BE USED IN ACCORDANCE WITH ALL RESTRICTIONS AND PRECAUTIONS AS MAY BE SPECIFIED IN THE PERMIT.

Back
Save and Exit
Proceed to Payment

12.) After completing payment, wait for the permit to be approved. Once it has been approved, you can use it to purchase the ATCC BA 3144 organism from the ATCC (Refer to ATCC instructions when ordering the organism)