

# **Table of Contents**

The purpose of this training is to assist Public Health Providers and CDC personnel in understanding the new CDC Specimen Submission form for specimens of "Human" origin. Future training will address samples from animals or food, environment, medical devices or blood products. The training is helpful to those responsible for preparing CDC Specimen Submission forms for specimens submitted to the CDC for testing.

The training is organized by the following sections and supporting topics:

#### Overview

- Webinar Objectives
- Changes to the Overall Process
- CDC Infectious Diseases Test Directory
- Benefits to PHLs
- What is the Specimen Submission Form?
- ✤ How the Form is Organized

#### **Entering Data**

- Using Pick-lists
- Entering Dates
- Entering Test Order Name
- Test Order Requirements
  - Prior Approval
  - Supplemental Form
  - Entering Submitter Data
  - Entering Email Address

#### Section on the Forms

- Origin
- Laboratory Examination Requested
- Patient Information
- Specimen Information
- CDC Use Only

#### Sections on the Form (continued)

- State PHL Submitter
- Original Submitter
- Intermediate Submitter
- Specimen Identifier
- Brief Clinical Summary
- State of Illness
- Type of Infection
- Therapeutic Agent(s) During Illness
- Extent
- Travel History
- Exposure History
- Relevant Immunization History
- Previous Laboratory Results
- Comments

#### **Expiring Template Forms**

How to Obtain a Current Template Form



#### Overview

#### **Training Objectives**

Upon completion of this material, users will be able to:

- List the overall improvements CDC ID laboratories are making to the specimen accessioning and reporting process
- Enumerate the benefits of using the new electronic Adobe specimen submission form
- Enter the necessary information on the updated submission form
- Link to the CDC Test Directory for essential information when ordering a test

#### Changes to the overall process

#### Changes to the overall process include:

- The 3<sup>rd</sup> barcode encodes page 2 of the Specimen Submission form, not the Intermediate Submitter information. Therefore the Intermediate Submitter information will be manually uploaded by CDC recipients
- Submitter information is a dropdown menu selection.
- The "State PHL...", "Original Submitter", and "Intermediate Submitter" sections now contain a direct phone number and email address for the Point of Contact, and no longer contain a phone number for the institution.
- Updated Test Directory of Services

#### Enhancements that were implemented for Form 50.34 Version 2.0:

- Federal, State, and International Submitters can now use the dropdown feature for Institution Name, allowing users to select their Institution. Institutions are listed in alphabetically and users can easily find their Institution by typing the first letter of their state.
- Selecting Institution Name from the drop-down menu causes the Address, Fax, and Institutional Email fields to be auto-populated with contact information from standardized submitter records.
- The 'Previous Laboratory Results/Comments' is now two separate fields, "Previous Laboratory Results" and "Comments"
- When a test order with additional information or pre-approval requirement is selected, an information icon *icon* or
   Additional form(s) required with alert pop-up window occurs.
- Specimen Source (Type)" is a required field and will be highlighted in red when not data is not entered.
- Version and expiration date are updated: CDC 50.34 v2.0 (Expires December 8, 2017 at 11:59pm).



#### CDC Infectious Diseases Laboratories Website

An example of the CDC Infectious Diseases Laboratories Website is below: <u>http://www.cdc.gov/laboratory/specimen-submission/index.html</u>

Infectious Diseases Laboratories	<u>CDC</u> > Infectious Diseases Laboratories	
ubmitting Specimens to CDC	<ul> <li>Submitting Specimens to CDC</li> <li>f y +</li> </ul>	
Test Directory		
Specimen Submission Form	What's New	
Help & FAQ's	Updated 12/4/2015 - We have updated our CDC 50.34 Specimen Submission Form, Online Test Directory, and supporting do	ocumentation. Review
Training	the test directory updates 🔁 (PDF - 23KB) and download the new forms prior to sending specimens to CDC for testing. Visit H additional information.	elp & FAQ's for
Shipping and Packing	additional information.	
Who May Submit Specimens	CDC accepts specimens from state public health laboratories and other federal agencies for analysis. Specimens from private he	althcare providers and
DC Drug Service	institutions must be submitted to the local state health department laboratory (state, county, city) for appropriate processing.	
	Specimen Management activities at CDC include the receipt, categorization, and distribution of specimens from public health fa Jaboratories for reference diagnostic testing and research studies. State-of-the-art technology is used to provide data and inform	
elect Agent Distribution Activity Get Email Updates	Specimen Management activities at CDC include the receipt, categorization, and distribution of specimens from public health fa	
ctivity	Specimen Management activities at CDC include the receipt, categorization, and distribution of specimens from public health fa Jaboratories for reference diagnostic testing and research studies. State-of-the-art technology is used to provide data and inform	
Cettivity Get Email Updates To receive email updates about this page, enter your	Specimen Management activities at CDC include the receipt, categorization, and distribution of specimens from public health far laboratories for reference diagnostic testing and research studies. State-of-the-art technology is used to provide data and inform crucial in the assessment of public health trends and epidemic dynamics on a national scale. Image: test provide data and information of specimens from public health frequency is used to provide data and information of specimens from public health trends and epidemic dynamics on a national scale.           Image: test provide data and select test orders, Download full         Specimen Submission	
Cet Email Updates Cet Email Updates To receive email updates about this page, enter your email address: What's this?	Specimen Management activities at CDC include the receipt, categorization, and distribution of specimens from public health far laboratories for reference diagnostic testing and research studies. State-of-the-art technology is used to provide data and inform crucial in the assessment of public health trends and epidemic dynamics on a national scale.         Image: Management activities at CDC include the receipt, categorization, and distribution of specimens from public health far laboratories for reference diagnostic testing and research studies. State-of-the-art technology is used to provide data and inform crucial in the assessment of public health trends and epidemic dynamics on a national scale.         Image: Test DIRECTORY       Search and select test orders, Download full test directory         Image: Specimen Submission form       Download the 50.34 specimen submission form         Image: HELP & FAQ'S       TRAINING         Contact information, frequently asked       TRAINING	



#### CDC Infectious Diseases Laboratories Website Test Directory

An example of the Infectious Diseases Laboratories Test Directory is below: <u>http://www.cdc.gov/laboratory/specimen-submission/list.html</u>

Infectious Diseases I	aboratories	
Infectious Diseases Laboratories	<u>CDC</u> > Infectious Diseases Laboratories > Submitting Specimens to CDC	
Submitting Specimens to CDC	Test Directory       Submitting Specimens to CDC	
Test Directory	f 😏 🕂	
Specimen Submission Form		
Help & FAQ's	CDC's Infectious Diseases Laboratories provides an online Test Directory that allows you to identify the right test Directory features an up-to-date list of orderable tests and provides information on specimen requirements, con	e service and a service service
Training	and other supplemental information. Access the directory here or while completing a Specimen Submission Form	
Shipping and Packing	You may also download a copy 🛃 [381 pgs, 3.06 MB] of the entire Test Directory.	
Who May Submit Specimens	Effective December 4 <sup>th</sup> 2015, an updated test directory is available. View the major list of changes here 🐔 [PDF	23 KB].
CDC Drug Service	Search	
Select Agent Distribution Activity	Narrow the results with a keyword, test title, test synonym, or point of contact:	
Get Email Updates	Go	
To receive email updates about this page, enter your email address:	A B C D E E G H I J K L M N O P R S I V Y Showing 357 of 357 tests.	
	Test Name	Test Code
What's this? Submit	Acanthamoeba Molecular Detection	CDC-10471
	Actinomyces - Anaerobic ID	CDC-10483
Related Links	Actinomycetes-Aerobic -ID	CDC-10148



#### Benefits to PHLs

The benefits to the PHLs are included below:

- Select a test offered by CDC via dropdown menu
- Select their Institution Name via dropdown menu and have contact information auto-populated with standardized record information
- ✤ Ability to electronically enter data into the form and save it
- Control the distribution of the new form with their clinical labs
- Increase accuracy of information entered into the CDC Laboratory Information Management System (LIMS)
- Delivery of results faster as encrypted PDFs sent by secure email
- Prepare for electronic messaging
- Links automatically to supplemental forms, additional information, and CDC contacts for pre-approval and consultation.

#### What is the Specimen Submission Form?

Public Health Providers and other Submitters must complete a Specimen Submission form for each specimen they submit to the Centers for Disease Control and Prevention (CDC) Infectious Diseases Laboratories for testing. The new CDC 50.34 Specimen Submission form provides the most effective way to record the necessary information required to identify the specimen, patient, and submitter.

The Specimen Submission form provides the following benefits:

- The form is downloadable and the data you enter can be saved to the form at any time.
- The form can be filled out on your computer, printed, and then sent to the CDC with the specimen. This ensures the content is legible which reduces the possibility of erroneous data.
- Printing is prevented until all required data fields are filled appropriately to prevent missing information being sent to CDC.
- Pick-lists are provided to allow for the selection of valid field values which ensures the integrity of the data.
- Some pick-lists auto-populate fields which saves submitters time
- Barcodes expedite the process of transferring data from the form into the CDC Laboratory Information Management System (LIMS), which eliminates the need for manual entry and reduces the amount of human error.

This document will provide training by introducing you to the CDC Specimen Submission form and provide instructions on how to fill out the form.



#### How the Form is Organized

The Human Specimen Submission form is a two-sided document that is divided into 22 sections.

#### Notes:

- The section numbers in the list below correspond to the section numbers on the sample form in figures 1 and 2.
- The barcodes on both sides of the form will not appear until the form is validated and printed successfully.



# Front of the Form (Figure 1)

- 1. Origin
- 2. Laboratory Examination Requested
- 3. Patient Information
- 4. Specimen Information
- 5. CDC Use Only
- 6. Barcode 1
- 7. State PHL Submitter
- 8. Original Submitter
- 9. Intermediate Submitter

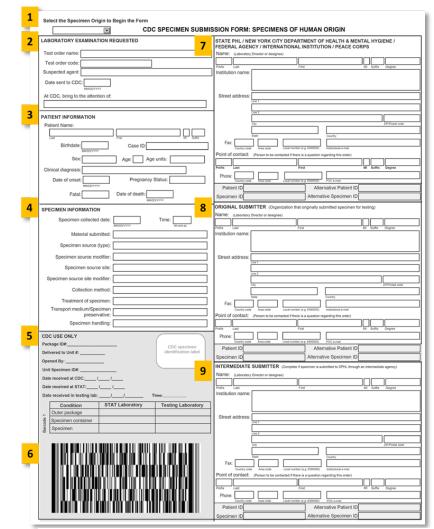


Figure 1: Human Specimen Submission Form (Front)



#### Back of the Form (Figure 2)

- 10. Specimen Identifier
- 11. Brief Clinical Summary
- 12. State of Illness
- 13. Type of Infection
- 14. Therapeutic Agent(s) During Illness
- 15. Extent
- 16. Travel History
- 17. Exposure History
- 18. Relevant Immunization History
- 19. Previous Laboratory Results
- 20. Comments
- 21. Barcode 2
- 22. Barcode 3

	CDC SPECIMEN SUBMISSION FORM: SPECIMENS OF HUMAN ORIGIN
LO Patient	name: AND/OR Original Patient ID: AND/OR SPHL Specimen ID:
	11
ATIENT HISTORY	UMMARY (include signs, symptoms, and underlying illnesses if known)
BREF CERECKE B	versioner (include signs, symptoms, and underlying intesses in more)
STATE OF ILLNES	13
<ul> <li>Sympton</li> <li>Asympto</li> </ul>	
Asympto	Cardovasoular Skinisot tissue 1.
Chronic	Gastrointestinal Ocular 2
Convaler Recover	icent Gental Jointbone
Hecover	ed Urinary tract Disseminated 3.
EPIDEMIOLOGICAL	
EXTENT	15 TRAVEL HISTORY Travel: 16 Dates of Travel: 16
Isolated case	
Carrier	Travel: Foreign (Countries) Travel: United States (States)
Contact	
Cutbreak	
Famil	
	hunity Foreign Residence (Country) United States Residence (Inve)
Epide	hcare-associated
EXPOSURE HISTOR	nome reactions states or outperfer or raises should be entired in the ball outperfer
Animal	Interview         Interview <t< th=""></t<>
Common Scientific	name: 3
Arthrop	bd Type of Exposure:
Common	name:
Scientific	name:
PREVIOUS LABORA	TORY RESULTS (Or attach copy of test results or worksheet) COMMENTS
	19 20
5	
CDC DE OWLY	
Public Health Service Act, S control programs, and come State or local public health d circumstances to conduct fur	troit and Prevention (SSC), an agency of the Department of Health and Human Stanicas, is authorized to colled this information, including the Social Security mustles (if applicable), under provisions action 321 (U.S.C. 201), Suppring the Information is volcimating and them as a parallely for of providing 1. The site and to increase understanding of Selesse parallely and the provisions action 2010 (U.S.C. 201), Suppring the Information is volcimating and them as a parallely for of providing 1. The site and the under the site and the understanding of Selesse parallely the Selesse parallely the Selesse parallely the Selesse parallely of Selesse parallely and the selesses and the seless and the Selesses and the

Figure 2: Human Specimen Submission Form (Back)



# **Entering Data**

Before we take a look at the individual sections in detail, we will show you how to enter and correct data on the form

**Using Picklists** 

Overview	<ul> <li>Pick-lists are available for many fields to provide you with a convenient way to select field values. Click the downarrow and the pick-list appears, or type the first letter of the value you want to jump to the selection.</li> <li>If your information is not in the pick-list, select the blank field and hand-write your information after you print the form. Some fields with pick-lists e.g. sex, may not have a blank row at the top. In these instances, you must select from a value in that pick-list; values may not be hand-entered.</li> </ul>	Material submitted:	Data_Sequence DNA-Deoxyribonucleic acid Grid (Electron Microscopy) Image Isolate Original material Protein Slide
Action	<ul> <li>Follow these steps to select a value from a pick-list:</li> <li>Click the down-arrow for the field. The pick-list for the field appears.</li> <li>Click the value on the pick-list which best represents your selection.</li> </ul>	Material submitted:	Data_Sequence DNA-Deoxyribonucleic acid Grid (Electron Microscopy) Image Isolate Original material Protein Slide
Result	The value that you selected appears in the field.	Material submitted:	Data_Sequence



# **Entering Dates**

Overview	Dates may be entered in one of two ways, you may enter the date in "MM/DD/YYYY" format, or you may select the date from the calendar.	Date of death:
	When you enter an invalid date, or the date you enter does not meet the rules established for that date, you will receive an error message. Some examples include:	
	<ul> <li>Date of death cannot be after today's date.</li> <li>Start Date cannot be after End Date.</li> <li>Invalid date format. Please enter date as "MM/DD/YYYY".</li> </ul>	
Action	<ol> <li>You may enter a date using the format: MM/DD/YYYY, or follow these steps to select the date from the calendar:</li> <li>Click inside the date field. The drop-down arrow appears.</li> <li>Click the drop-down arrow. The calendar appears.</li> <li>Select a specific day using the calendar format, or click the blue-lined box at the bottom of the calendar to select today's date.</li> <li>Note: Make sure you are in the correct calendar month and year.</li> </ol>	Sun Mon Tue Wed Thu       Fri       Sat         24       25       26       27       28       29       30         1       2       3       4       5       6       7         8       9       10       11       12       13       14         15       16       17       18       19       20       21         22       23       24       25       26       27       28         29       30       31       1       2       3       4
Result	The date you entered or selected appears in the date field.	Date of death: 05/13/2016



Entering Test Order Name



Overview	<ul> <li>The test order name is mandatory in order to submit specimens to the CDC for testing. The test order code will auto-populate based on the test order name selected. Alternatively, if you know the test order code, select it, and the test order name will auto-populate.</li> <li>If the test order code and name are left blank and you try to print the form, you will receive the following error message:</li> <li><i>"The following required fields are empty: Required field – Test order name"</i></li> <li>Follow these steps to select the test order name:</li> <li>Click the Test Order Name drop-down arrow. The pick-list appears.</li> <li>Select the Test Order Name from the pick-list.</li> </ul>	Test order code:       Image: Content in the image: Conten in the imag
Result	The Test Order Name you selected appears, and the Test Order Code auto-populates based on your selection. The <b>Information</b> icon appears next to the Test Order Code. Click this icon to find additional information for the specific test order.	Test order code: CDC-10148  Test order name: Actinomycetes - Aerobic - ID



Test Order Name Requirements – Prior Approval and Supplemental Forms

Overview	The test order name is mandatory. The test order code will auto-populate based on the test order name selected. Alternatively, if you know the test order code, select it, and the test order name will auto-populate. If you select a test order code, please verify that the test order name matches the test order you wish to order. For some test orders, you will be required to provide supplemental information. For instance, in this example, you are required to fill out an additional form for test order code, 'CDC-10274'. After selecting the test order code, you will receive the following message: <i>"Specimen submissions for this test order require supplemental information and/or prior approval in addition to completing this form. Please click on the link that appears above the test order code that links to the CDC Test Order web page for specific instructions.</i>	Warning: JavaScript Window - CDC Specimen Submission Form         Image: Specimen submissions for this test order require supplemental information and/or prior approval in addition to completing this form. Please click on the link that appears above the test order code that links to the CDC Test Order web page for specific instructions.         Image: OK       OK         Image: OK       OK         Image: OK       Image: OK
Action	<ul> <li>Follow these steps to locate the additional required form:</li> <li>1. Click OK to acknowledge the warning message. The Help icon next to the test order code disappears and is replaced by the "Additional form(s) required" button: Additional form(s) required</li> <li>2. Click the "Additional form(s) required" button to access prior approval or supplemental form instructions.</li> </ul>	Additional form(s) required Test order code: CDC-10274 Test order name: Alkhurma Identification
Result	The CDC Test Order web page appears with specific instructions for prior approval or supplemental forms.	



# Entering Submitter Data

Overview	You must enter data in the State PHL Submitter section, including a standard address and valid email address. If you leave the submitter data blank, the following message appears: <i>"Submitter information is required including a</i> <i>valid email address"</i> .	Warning: JavaScript Window -  The following validation error must be fixed before the form can be printed: Submitter information is required including a valid email address.  OK	
Action	<ol> <li>Follow these steps to add submitter data:</li> <li>Click OK to acknowledge the warning message.</li> <li>Under the "State PHL" section, select your institution from the "Institution Name" dropdown menu. You can also type the first letter of your state to find your institution name more quickly. Contact information from standardized records will appear.</li> <li>If the institutional information that appears is not correct, erase the Institution Name and enter all data fields manually.</li> </ol>	Institution name: Alabama Department of Public Health Bureau of Clinical Laboratories Alaska State Public Health Laboratory, State Health Department Arizona State Public Health Laboratory, Arizona Department of Health Services Arkansas Dept. of Health-Public Health Lab, Clinical Micro Lab Arkansas Dept. of Health-Public Health Lab, Molecular Diagnostics Arkansas Dept. of Health-Public Health Lab, TB/Mycology Lab Arkansas Dept. of Health-Public Health Lab, Zoonotic Disease Section Arkansas Dept. of Health-Public Health Lab, Zoonotic Disease Section Arkansas Dept. of Health-Public Health Lab.	
Result	The submitter data and email address appears.	institutionalemail@state.gov	



# Entering Email Address

Overview	If you do not enter an email address, the following warning message appears: <i>"The following required fields are empty: Required field – SPHL approved laboratory email address".</i> If the institution does not have an approved laboratory email address, then enter the Lab Director's email address.	Warning: JavaScript Window -         Image: Second
Action	<ul> <li>Follow these steps to correct the email address:</li> <li>4. Click OK to acknowledge the warning message. The erroneous email address field appears highlighted in red.</li> <li>5. Enter the email address in the following format: name@somewhere.com.</li> </ul>	Institutional e-mail
Result	The corrected email address appears.	institutionalemail@state.gov



# Sections of the Form

#### Origin

The Origin section appears below:

#### Select the Specimen Origin to Begin the Form

HUMAN	
ANIMAL	
FOOD	
ENVIRONMENTAL	
MEDICAL DEVICE	
BIOLOGIC	

This section is used to specify the origin for the material you are submitting. The fields on the form will change based on the origin selected.

There will be three distinctly different forms in this form. Fields on the Human form are different from those on the Animal form and these are different from a single form that is used for submitting specimens of Food, Environmental, Medical Device, or Biologic origin.

# Field Name Field Instructions

Origin	Select the origin for the material you are submitting from the pick-list.
	Valid options are:
	✤ Human
	station Animal
	✤ Food
	<ul> <li>Environmental</li> </ul>
	<ul> <li>Medical Device</li> </ul>
	✤ Biologic



#### Laboratory Examination Requested

The Laboratory Examination Requested section appears below:

Test order code:	•	
Test order name:		
Suspected agent:		
Date sent to CDC:		
At CDC, bring to the attention of:		

This section is used to specify the test order name and code assigned to the specimen, the suspected agent, the date the specimen was sent to the CDC, and to whom the specimen was sent. Valid field values may be selected from the pick-lists, where available.



Field Name	Field Instructions		
Test Order Code and Test Order Name	The test order name is mandatory. The test order code will auto-populate based on the test order name selected. Alternatively, if you know the test order code, select it, and the test order name will auto-populate.		
	In some cases, you may receive the following message:		
	"Specimen submissions for this test order require supplemental information and/or prior approval in addition to completing this form. Please click on the link that appears above the test order code that links to the CDC Test Order web page for specific instructions."		
	In this case, click the link that appears and follow the instructions.		
Suspected Agent	Select the suspected agent from the list of bacteria, viruses, fungi, and parasites.		
Date Sent to CDC	Enter/select the date the specimen was shipped to the CDC. This date is important because it lets us know if the specimen is delayed in transit and whether the delay affects its suitability for testing.		
At CDC, bring to attention of:	If you have prior approval or have talked with someone in the CDC laboratory about this specimen/order, enter the name of that person to facilitate the testing. This space may be left blank if prior approval for testing is not required.		



#### Patient Information

The Patient Information section appears below:

Last	First	MI Suffix
Birthdate:	Case ID:	
Sex:	Age: Age units:	
Clinical diagnosis:		•
Date of onset:	Pregnancy Status:	•
Fatal:	Date of death:	

CLIA requires that two identifiers be provided to ensure that the results of testing uniquely identify the correct patient.



Field Name	Field Instructions
Patient Name	Enter the name of the patient. Make sure to enter the complete patient name; these are particularly important
(Last, First, MI, Suffix)	for patients with common first and last names.
Birthdate	Enter the patient's birthdate.
Case ID	Enter a pre-existing Case ID, if applicable
Sex	Select the appropriate gender for the patient. You must select a value from the pick-list; you cannot hand-write a value in this field.
Age	If you don't know the birthdate of the patient but know the age, enter the age in this field. The age must be a whole number, for example 30 months to indicate 2 years and 6 months. Decimal points are not allowed.
Age units	Select the appropriate unit for the age entered (e.g., day, month, and year). You must select a value from the pick-list; you cannot hand-write a value in this field.
Clinical diagnosis	If you know the patient's disease, syndrome, or condition (for example, gonorrhea), then select it from the pick- list. If the value you require is not in the pick-list, select the blank entry, and then hand-write the value on the printed form.
Date of onset	If you know the date of onset identified by the healthcare provider who originally submitted the specimen for testing, enter it here.
Pregnancy Status	Enter patient's pregnancy status, if known
Fatal	Was the patient deceased at the time the specimen was submitted? Select 'Yes', 'No', or 'Unknown'.
Date of death	If the person is deceased, enter the date of death, if known.



#### Specimen Information

The Specimen Information section appears below:

SPECIMEN INFORMATION	
Specimen collected date:	Time: hhmm:ss
Material submitted:	V
Specimen source (type):	
Specimen source modifier:	
Specimen source site:	
Specimen source site modifier:	
Collection method:	
Treatment of specimen:	
Transport medium/Specimen preservative:	
Specimen handling:	

This section is used to enter pertinent information about the specimen that will allow the testing laboratory to determine the suitability for testing.

**Note:** Valid values for all fields are available in the pick-lists. If the value you require is not in a pick-list, select the blank entry, and then handwrite the value on the printed form.



Field Name	Field Instructions
Specimen collected (Date, Time)	Enter the date the specimen was collected as MM/DD/YYYY. Enter the time as HH:MM:SS. If a date is entered and the time is left blank, the default time is 01:00:00. Blank minutes or seconds default to 00.
Material submitted	Select the original specimen or a specimen derivative such as an isolate or nucleic acid that has been extracted from the original specimen.
Specimen Source (Type)	Select the type of specimen that was collected, or the specimen where the isolate was recovered.
Specimen Source Modifier	Used to indicate the status of a serum specimen, i.e., whether it was collected from a patient during the 'acute' or 'convalescent' phase of an infection. Other values such as S1 are intended for specimens being collected for studies.
Anatomic (body) site	Select the anatomic (body) site from which the original specimen was taken (e.g., arm, leg, liver). In most cases, this field will not be filled for specimens such as blood.
Anatomic (body) site modifier	Provides more information about the anatomic (body) site from which the specimen was taken such as 'right' (arm), if applicable. Not required for blood or serum.
Collection method	Provides information about how the specimen was collected. This is critical information about the adequacy of the specimen collected, and includes values such as 'Aspiration' and 'Biopsy'.
Treatment of specimen	Select what treatment the specimen has received (e.g., Centrifugation).
Transport medium/Specimen preservative	Select the medium in which the specimen was submitted, or the substance that has been added to the specimen, to ensure its suitability for testing (e.g., Campy-BAP agar).
Specimen handling	Select the temperature or other conditions under which you are submitting the specimen (e.g., dry ice, ambient temperature).



#### CDC Use Only

The CDC Use Only section appears below:

Packa	USE ONLY ge ID#: red to Unit #:		CDC specimen identification label
Unit S	pecimen ID#:		
Date r	eceived at CDC:/	/	
Date r	eceived at STAT:/	I	
Date r	eceived in testing lab: _		Time:
	Condition	STAT Laboratory	Testing Laboratory
-	Outer package		
arcode	Specimen container		
Bar	Specimen		

This section is reserved for CDC use only. The CDC personnel responsible for processing the specimen package will use this section to record the package identifiers, dates of receipt, and the condition of the package and contents.

**Note:** The fields in this section are protected. The information must be hand written directly on the paper form by the appropriate CDC personnel.

Field Instructions	
CDC use only	



#### State PHL Submitter

The State PHL Submitter section appears below:

	y Director or designee)				
refix Last	-1	First			egree
nstitution name					
Street address	Line 1				
	Line 2 City			ZIP	/Postal code
	State	•	Country		
Fax:			institutionalemail	Dstate.gov	
Country coo		al number (e.g. 6390000) d if there is a question	Institutional e-mail		
fix Last		First		MI Suffix De	egree
Phone:	e Area code Loc	al number (e.g. 6390000)	POC e-mail		
Patient ID		Alte	ernative Patient ID		

This section includes the submitter information for the State PHL, New York City HD laboratory, Federal Agency, International Institution, and Peace Corps that submitted the specimen for examination.



Field Name	Field Instructions
Name (last, first, MI, suffix, degree)	Name of person authorizing reference testing from the CDC. This person is usually the
	laboratory director or their designee.
Institution Name	Use the dropdown menu to select the institution name and specific department, if available.
Street address 1	Will autofill if dropdown is used or enter the street address, including the specific floor/room
	number.
Street address 2	Will autofill if dropdown is used or enter the post office box or mailstop.
City, State, Zipcode, Country	Will autofill if dropdown is used or enter the city, state or province, zip or postal code, and
	country.
Phone (country code, area code, local	Will autofill if drop down is used or enter local phone number for the laboratory, including
number, extension)	country code and area code (numbers only; no spaces or special characters).
Fax (country, area code, local number)	Will autofill if dropdown is used or enter country code, area code, and local number in the
	appropriate fields (numbers only; no spaces or special characters).
Institutional e-mail	Will autofill if dropdown is used or enter a standardized institution or lab email address that is
	approved for the CDC form.
Point of Contact (prefix, last, first, middle	Enter the primary or alternative person in the laboratory who can answer questions regarding
initial, suffix, degree)	the specimen submission.
Phone (country, area code, local number)	Enter the Point of Contact's direct phone number
POC e-mail	Enter the Point of Contact's direct email address
Patient ID	Enter the primary patient ID if assigned by the State PHL. The number might be used for
	surveillance or study purposes.
Specimen ID	Enter the primary specimen ID if assigned by the State PHL. The number might be used for
	surveillance or study purposes.
Alternative Patient ID	Alternative patient ID if assigned by the State PHL.
Alternative Specimen ID	Alternative specimen ID if assigned by the State PHL.



#### **Original Submitter**

The Original Submitter section appears below:

ORIGINAL SUBMITTER (Organization that originally submitted specimen for testing)				
Name: (Laboratory	/ Director or designee)			
Prefix Last	First	MI Suffix Degree		
Institution name:				
Street address:				
	Line 1			
	Line 2			
	City	ZIP/Postal code		
	State	Country		
Fax:				
Country cod		.g. 6390000) Institutional e-mail		
Point of contact:	(Person to be contacted if there is	a question regarding this order)		
Prefix Last	First	MI Suffix Degree		
Phone:				
Country cod	le Area code Local number (e.g	g. 6390000) POC e-mail		
Patient ID		Alternative Patient ID		
Specimen ID		Alternative Specimen ID		

This section includes the submitter information for the laboratory, hospital, or clinic that originally submitted the specimen for examination.



Field Name	Field Instructions		
Name (last, first, MI, suffix, degree)	Name of person authorizing reference testing to be performed. This person is usually the		
	laboratory director or their designee.		
Institution Name	Enter the institution name and specific department		
Street address 1	Enter the street address, including the specific floor/room		
Street address 2	Enter the post office box or mailstop.		
City, State, Zipcode, Country	Enter the city, state or province, zip or postal code, and country.		
Phone (country code, area code, local	Enter local phone number for the laboratory, including country code and area code (numbers		
number, extension)	only; no spaces or special characters).		
Fax (country code, area code, local number)	Enter country code, area code, and local number in the appropriate fields (numbers only; no		
	spaces or special characters).		
Institutional e-mail	Enter an email address for the institution or lab director.		
Point of Contact (prefix, last, first, middle	Enter the primary person in the laboratory who can answer questions regarding the specimen		
initial, suffix, degree)	submission.		
Phone (country, area code, local number)	Enter the Point of Contact's direct phone number		
POC e-mail	Enter the Point of Contact's direct email address		
Patient ID	Enter the primary patient ID if assigned by the lab. The number might be used for surveillance		
	or study purposes.		
Specimen ID	Enter the primary specimen ID if assigned by the lab. The number might be used for surveillance		
	or study purposes.		
Alternative Patient ID	Alternative patient ID if assigned by the lab.		
Alternative Specimen ID	Alternative specimen ID if assigned by the lab.		



#### Intermediate Submitter

The Intermediate Submitter section appears below:

INTERMEDIATE SUBMITTER (Complete if specimen is submitted to SPHL through an intermediate agency)					
Name: (Laborator	y Director or designee)				
				-	
Prefix Last	Firs	t	MI	Suffix	Degree
Institution name:					
Street address:					
	Line 1				
	Line 2				
	01				71010-1-1
	City				ZIP/Postal code
					▼
	State	Country			
Fax:					
Country cod		.g. 6390000) Institutional e-mail			
Point of contact:	(Person to be contacted if there is	a question regarding this order)			
				•	
Prefix Last	Firs	t	MI	Suffix	Degree
Phone:					
Country cod	e Area code Local number (e.	1			
Patient ID		Alternative Patient ID			
Specimen ID		Alternative Specimen ID			

This section is used to enter the name, address, and contact information for the intermediate laboratory, which is usually the reference laboratory that handled the sample (e.g., Quest, Lab Corp, ARUP, Mayo Clinic, and so on).



Field Name	Field Instructions
Name (last, first, MI, suffix, degree)	Name of person authorizing reference testing to be performed. This person is usually the
	laboratory director or their designee.
Institution Name	Enter the institution name and specific department, if appropriate.
Street address 1	Enter the street address, including the specific floor/room number.
Street address 2	Enter the post office box or mailstop.
City, State, Zipcode, Country	Enter the city, state or province, zip or postal code, and country.
Phone (country code, area code, local	Enter local phone number for the laboratory, including country code and area code (numbers
number, extension)	only; no spaces or special characters).
Fax (country code, area code, local number)	Enter country code, area code, and local number in the appropriate fields (numbers only; no
	spaces or special characters).
Institutional e-mail	Enter an email address for the institution or lab director.
Point of Contact (prefix, last, first, middle	Enter the primary or alternative person in the laboratory who can answer questions regarding
initial, suffix, degree)	the specimen submission.
Phone (country, area code, local number)	Enter the Point of Contact's direct phone number
POC e-mail	Enter the Point of Contact's direct email address
Patient ID	Enter the primary patient ID if assigned by the lab. The number might be used for surveillance
	or study purposes.
Specimen ID	Enter the primary specimen ID if assigned by the lab. The number might be used for
	surveillance or study purposes.
Alternative Patient ID	Alternative patient ID if assigned by the lab.
Alternative Specimen ID	Alternative specimen ID if assigned by the lab.



#### Specimen Identifier (Auto Populated)

The Specimen Identifier section appears below:

Patient name:		AND/OR Original Patient ID	:	AND/OR SPHL Specimen ID:
Last	Fint			

This section is found at the top-most area on the second page of the form. The purpose of this section is to carry forward the patient and specimen identifiers that were entered on the front of the form. This is helpful in the event that the form is printed on two separate pieces of paper.

**Caution:** If you are not filling out the form using your computer, the Patient Identifier section will not auto populate. For printed forms, be sure to hand-write the patient name, original patient ID, and the SPHL specimen ID in the Patient Identifier section.

Field Name	Field Instructions
Patient Name (first, last)	Auto-populated from the Patient Name in the Patient Information section.
AND/OR Orig Patient ID	Auto-populated from the Patient ID in the Original Submitter section.
AND/OR SPHL Specimen ID	Auto-populated from the Specimen ID in the State PHL section



#### **Brief Clinical Summary**

The Brief Clinical Summary section appears below:

BRIEF CLINICAL SUMMARY (Include signs, symptoms, and underlying illnesses if known)

This section is used to enter a brief clinical summary for the patient which may include signs, symptoms, and underlying illnesses, if known.

**Note:** When attaching additional documentation to the form, please indicate that you are attaching additional information and note the name of the attached document.

#### Field Name Field Instructions

Brief	Enter a brief clinical history for the patient (250
Clinical	character limit). If you need to include more
Summary	information, enter test results under "Previous Laboratory Results", attach additional documentation
	Laboratory Results", attach additional documentation
	(e.g., worksheet) to the form, and/or add additional
	(e.g., worksheet) to the form, and/or add additional information under "Comments".



#### State of Illness

The State of Illness section appears below:

# STATE OF ILLNESS Symptomatic Asymptomatic Acute

Acute
Chronic
Convalescent
Recovered

This section is used to select one or more characteristics to describe the patient's state of illness.

Field Name	Field Instructions
Symptomatic	Select, if applicable.
Asymptomatic	Select, if applicable.
Acute	Select, if applicable.
Chronic	Select, if applicable.
Convalescent	Select, if applicable.
Recovered	Select, if applicable.



#### Type of Infection

# The Type of Infection section appears below: TYPE OF INFECTION



This section is used to select one or more types of infection the patient may have.

Field Name	Field Instructions
Upper	Select, if applicable.
respiratory	
Lower	Select, if applicable.
respiratory	
Cardiovascular	Select, if applicable.
Gastrointestinal	Select, if applicable.
Genital	Select, if applicable.
Urinary tract	Select, if applicable.
Sepsis	Select, if applicable.
Central nervous	Select, if applicable.
system	
Skin/soft tissue	Select, if applicable.
Ocular	Select, if applicable.
Joint/Bone	Select, if applicable.
Disseminated	Select, if applicable.
Other, specify	If you do not see the type of
	infection listed, then type the
	infection you desire in the space
	provided.



#### Therapeutic Agent(s) During Illness

The Therapeutic Agent(s) During Illness section appears below:

THERAPEUTIC AGENT(S) D	RING ILLNESS
Agent	Start date End date
1.	
2.	
3.	
	MM/DD/YYYY MM/DD/YYYY

This section is used to specify one or more relevant therapeutic agents that the patient has received.

#### Field Name Field Instructions

Agent	Select the treatment.
Start Date	Enter/select the date treatment started.
End Date	Enter/select the date treatment ended.



#### Extent

The Extent section appears below:

EXTENT	
	Isolated case
	Carrier
	Contact
	Outbreak
	E Family
	Community
	Healthcare-associated
	Epidemic

This section is used to establish the extent of the patient's illness. Is the illness an isolated case or part of an outbreak? Indicate the extent of the outbreak.

Field Name	Field Instructions
Isolated Case	Select, if applicable.
Carrier	Select, if applicable.
Contact	Select, if applicable.
Outbreak	If the extent of the outbreak is not listed, enter it in the Outbreak field (e.g., cruise ship).
Family	Select, if applicable.
Community	Select, if applicable.
Healthcare-associated	Select, if applicable.
Epidemic	Select, if applicable.



#### **Travel History**

The Travel History section appears below:

TRAVEL HISTORY Travel:	Dates of Travel: to
Travel: Foreign (Countries)	Travel: United States (States)
V	V
Foreign Residence (Country)	United States Residence (State)
▼	
Note: Additional states or countries of residence or travel shou	ld be entered in the Brief Clinical Summary field.

This section is used to indicate the patients travel history, during the period of illness, including the dates of travel and travel destinations. The patient's state or country of residence may also be entered.



Field Name	Field Instructions
Travel	Select (yes, no, or unknown) to indicate if the patient traveled during the period in which the infection was acquired.
Dates of Travel (begin	Enter the date travel begun.
date)	
Date of Travel (end	Enter the date travel was completed.
date)	
Travel Foreign	If the patient traveled outside the U.S., select the country where they traveled. If there were more than three
(country)	countries, enter the additional countries in the Brief Clinical Summary section.
Travel United States	If the patient traveled within the U.S., please list the states where they traveled. If there were more than three
	states, enter the additional states in the Brief Clinical Summary section.
Foreign Residence	If the patient lives outside the U.S., please enter the country of residence. A patient may have both a foreign and
(country)	United States residence
United States	If the patient has a United States residence, enter the state of residence. A patient may have both a foreign and
Residence (states)	United States residence



#### **Exposure History**

The Exposure History section appears below:

EXPOSURE HISTORY	Exposure: Date of Exposure:		-
Animal	Type of Exposure:	V	Not
Common name:		•	com
Scientific name:		T	pick
Arthropod	Type of Exposure:	•	top
Common name:		•	the
Scientific name:		•	

**Note:** If the value you require for the common or scientific name is not in the bick-list, select the blank entry at the cop of the pick-list, and then handwrite the value on the printed form.

This section is used to indicate whether or not the patient came in contact with an animal or arthropod. The name of the animal or arthropod and the type of exposure such as a bite or scratch may also be selected.

Field Name	Field Instructions	
Exposure	Select (yes, no, or unknown) to Indicate if the patient was exposed to any animal or arthropod that may have been associated with their infection.	
Date of Exposure	Enter date of exposure, if known.	
Animal	Select, if the patient was exposed to an animal as a possible source of infection.	
Type of Exposure	Select the type of exposure (e.g., bite, scratch).	
Common name	Select a common name. The corresponding scientific name (if there is one) will auto-populate in the Scientific Name field.	
Scientific name	Select a scientific name. The corresponding common name (if there is one) will auto-populate in the Common Name field.	
Arthropod	Select, if the patient was exposed to an arthropod as a possible source of infection	
Type of Exposure	Select the type of exposure (e.g., bite, scratch).	
Common name	Select a common name. The corresponding scientific name (if there is one) will auto-populate in the Scientific Name field.	
Scientific name	Select a scientific name. The corresponding common name (if there is one) will auto-populate in the Common Name field.	



#### Relevant Immunization History

#### The Relevant Immunization History section appears below:

#### RELEVANT IMMUNIZATION HISTORY

Immu	nization(s)	Date received
1.		
2.		
3.		
4.		
		MM/DD/YYYY

This section is used to specify the patient's relevant immunization history, indicating the date and type of vaccination(s) that were administered.

# Field Name Field Instructions Immunization(s) Select the immunization given to the patient.

	<u></u>
Date Received	Enter the date the patient received the immunization.



#### **Previous Laboratory Results**

The Previous Laboratory Results section appears below:

heet)

**Note:** When attaching additional documentation to the form, please indicate that you are attaching additional information and note the name of the attached document in the Previous Laboratory Results section.

This section is used to document any previous laboratory results associated with this specimen. Additional documentation such as test results may be attached to the form. Any additional information about the submitted specimen can be captured in "Comments"

Field Name	Field Instructions	
Previous Laboratory Results	esults Enter the patient's previous laboratory results (250 character limit). If more space is needed, attach addition	
	documentation (e.g., test results, worksheet) to the form and/or continue under "Comments".	

#### Comments

The Comments section appears below:

COMMENTS		

This section is used to document any additional information about the submitted specimen or when more space is required for other data fields.

Field Name	Field Instructions	
Comments	Enter additional information related to the specimen (250 character limit). Note: This field is also used to	
	record data for fields where more space is required.	



#### CDC Use Only Barcodes

The image below depicts a CDC Use Only Barcode.



Information that is entered into the form is recorded and saved in one of three barcode sections that only appear when the form prints successfully. When a specimen is received at the CDC, the data from its corresponding Specimen Submission form is scanned via the barcodes directly into the CDC Enterprise LIMS. This eliminates the need for data entry and reduces the amount of human error.

**Caution:** The form must be filled out on your computer, printed and then sent to the CDC with the specimen in order to take full advantage of the barcode functionality. Information that is hand-written on the form will not be recorded in the barcodes.

#### Field Name Field Instructions

Barcode 1	Encodes information on page 1, left column
Barcode 2	Encodes information on page 1, right column
Barcode 3	Encodes information on page 2



Expiring Template Forms How to Obtain a Current Template Form



Overview	The Specimen Submission form contains a version number and expiration in the footer, on the bottom right side of both sides of the form. You will not be able to fill out the form or print the form after the expiration date. You will receive the following warning message each time you open the form, beginning two weeks prior to the expiration date: <i>"This form will expire on 'Month 99, 9999'. The form will no longer be fillable/printable after this date. Effective 'Month 99, 9999' you will have to download a new version of the form at: http://www.cdc.gov/laboratory/specimen- submission/form.html" If you open the form after the expiration date, you will receive the following message: <i>"This form expired on 'Month 99, 9999'. Effective 'Month 99, 9999', please use the new version of the form available at: http://www.cdc.gov/laboratory/specimen-</i></i>	Warning: JavaScript Window -         Image: Solution of the form available after this date. Effective December 10, 2016, you will have to use a new version of the form available at: http://www.cdc.gov/laboratory/specimen-submission/form.html.         OK
Action		Version 2.0, Expiration Date: 12/08/2017
	<ol> <li>Discard all blank paper template forms, and blank template forms stored on your computer that reflect the expiration date.</li> <li>Download a new version of the template form at: http://www.cdc.gov/laboratory/specimen-submission/form.html</li> </ol>	
Result	The downloaded form should reflect the new expiration date in the footer on the front and back of the form.	Version 2.0, Expiration Date: 12/08/2017