Florida Department of Health

Contaminated Steroid Product from New England Compounding Center (NECC) Guidance	Focus Area: Reporting

Guidance document number 2012-6

Fungal Meningitis and Stroke Associated with Potentially Contaminated Steroid Product from NECC

Version 1.1 October 30, 2012

Note: This document may become outdated as situations change. Documents on this topic dated after October 30, 2012 supersede this one. This document will be posted on the Bureau of Epidemiology website http://www.doh.state.fl.us/Disease_ctrl/epi/index.html.

Summary

The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) are coordinating a multistate investigation associated with epidural, paraspinal, and peripheral joint injections with preservative-free (PF) methylprednisolone acetate (80mg/ml) (MPA) (see I.7 below) prepared by New England Compounding Center (NECC), Framingham, Massachusetts. Fungal meningitis is not transmitted from person to person.

A. Patients have presented with fungal meningitis, stroke or septic arthritis.

B. As of October 29, 2012, 354 cases and 25 deaths have been reported from 19 states; 23 cases, including three deaths, have been identified in Florida.

C. All cases identified thus far have received PF MPA (80mg/ml) from among three identified lots (see I.7 below).

D. On October 6, NECC recalled all products.

E. This outbreak is rapidly evolving and information is changing on a daily basis.

F. Further information on this quickly evolving outbreak can be found at:
   1. Florida Department of Health website http://www.doh.state.fl.us/disease_ctrl/epi/htopics/popups/meningitis.html
   2. CDC's fungal meningitis website http://www.cdc.gov/hai/outbreaks/meningitis.html

G. The product, from three implicated lots:
   1. MPA (FP) 80 mg/ml Injection, Lot #05212012@68, by use date (BUD) 11/17/2012
   2. MPA (FP) 80 mg/ml Injection, Lot #06292012@26, BUD 12/26/2012
   3. MPA (FP) 80 mg/ml Injection, Lot #08102012@51, BUD 2/6/2013

H. The three implicated lots were distributed to eight healthcare facilities in Florida: Florida
   1. Pain Clinic, Ocala, FL
   2. Interventional Rehab Center, Pensacola, FL
   3. Marion Pain Management Center, Ocala, FL
   4. North County Surgicenter, Palm Beach, FL
   5. Orlando Center for Outpatient Surgery, Orlando, FL
   6. Pain Consultants of West Florida, Pensacola, FL
   7. Surgery Center of Ocala, Ocala, FL
   8. Surgical Park Center, Miami, FL

Reporting Instructions
CDC has developed an outbreak case definition that categorizes cases based on the clinical presentation. Some cases that meet the CDC outbreak case definition may also meet the Florida case definition for meningitis (bacterial, cryptococcal, mycotic). All cases that meet the CDC outbreak case definition should be reported in Merlin Outbreak Module **#1685**; cases that also meet Florida's case definition for meningitis (bacterial, cryptococcal, mycotic) should also be reported as cases under Florida Disease Code MENINGITIS, BACTERIAL, CRYPTOCOCCAL, MYCOTIC – 32090.

I. Case definitions
   A. CDC outbreak case definition, as of October 24, 2012 (please refer to current CDC case definition)
      1. Probable case

         A person who received a methylprednisolone acetate (MPA) injection, with MPA that definitely or likely came from one of the following 3 lots produced by the New England Compounding Center (NECC) [05212012@68, 06292012@26, 08102012@51], and subsequently developed any of the following:

         - Meningitis[1] of unknown etiology following epidural or paraspinal injection2 after May 21, 2012;
         - Posterior circulation stroke without a cardioembolic source and without documentation of a normal cerebrospinal fluid (CSF) profile, following epidural or paraspinal injection[2] after May 21, 2012;[3]
         - Osteomyelitis, abscess or other infection (e.g., soft tissue infection) of unknown etiology, in the spinal or paraspinal structures at or near the site of injection following epidural or paraspinal injection[2] after May 21, 2012; or
         - Osteomyelitis or worsening inflammatory arthritis of a peripheral joint (e.g., knee, shoulder, or ankle) of unknown etiology diagnosed following joint injection after May 21, 2012.

         [1] Clinically diagnosed meningitis with one or more of the following symptoms: headache, fever, stiff neck, or photophobia, in addition to a CSF profile showing pleocytosis (>5 white blood cells, adjusting for presence of red blood cells by subtracting 1 white blood cell for every 500 red blood cells present) regardless of glucose or protein levels.

         [2] Paraspinal injections include, but are not limited to, spinal facet joint injection, sacroiliac joint injection, or spinal or paraspinal nerve root/ganglion block.

         [3] Patients in this category who do not have any documented CSF results should have a lumbar puncture performed if possible, using a different site than was used for the epidural injection when possible.

   B. Florida case definition for meningitis (bacterial, cryptococcal, mycotic)
      1. Clinical description: meningitis manifests most commonly with fever, headache, and a stiff neck; the disease may progress rapidly to shock and death. However, other manifestations may be observed.
      2. Laboratory criteria for diagnosis

         Isolation of a bacterial, cryptococcal, or fungal species from the cerebrospinal fluid (CSF) OR

Positive blood culture for a bacterial, cryptococcal, or fungal species

3. Case classification

   Confirmed: a clinically compatible case that is laboratory confirmed

C. **CDC will be counting outbreak cases according to the state of exposure; as such, Florida will also be counting outbreak cases based on the county of EXPOSURE, not residence**

1. Case investigations can be conducted by the state or county where the patient resided, but official outbreak case counts will reflect the county and state of exposure
2. When entering cases in Merlin, please use the person's residential address, regardless of where he/she was exposed; the location of exposure for official outbreak case counts will be determined by the Related to Setting field in the Outbreak Module

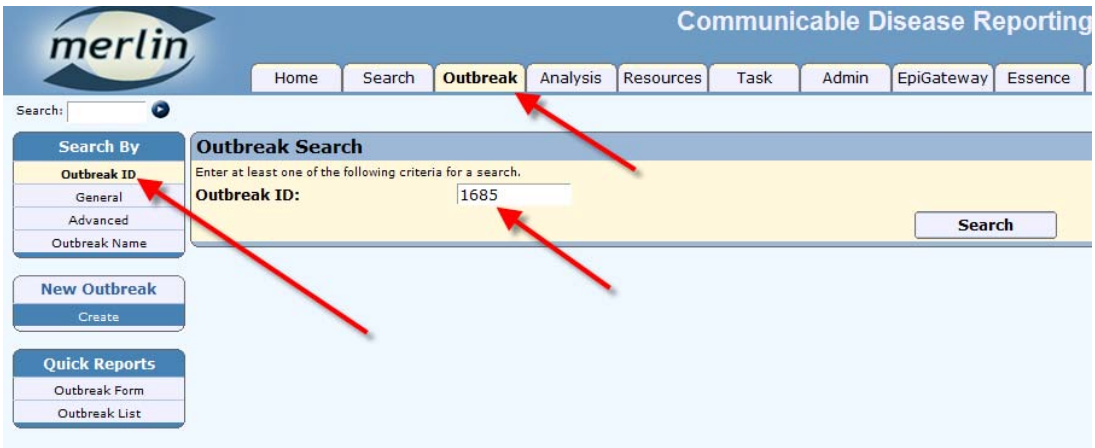
II. Please use the Meningitis Outbreak Following Epidural Steroid Injection Case Report Form (CRF) for all identified cases

A. This form can be accessed on the Bureau of Epidemiology's website under Hot Topics (Multi-state Fungal Meningitis Outbreak): http://www.doh.state.fl.us/disease_ctrl/epi/htopics/popups/meningitis.html or on the Bureau's Disease/Condition Specific Case Report Forms website: http://www.doh.state.fl.us/disease_ctrl/epi/topics/crforms.html

B. When the CRF is complete scan the document and attach to Merlin Outbreak Module #1685 (additional instruction below in IIIE)

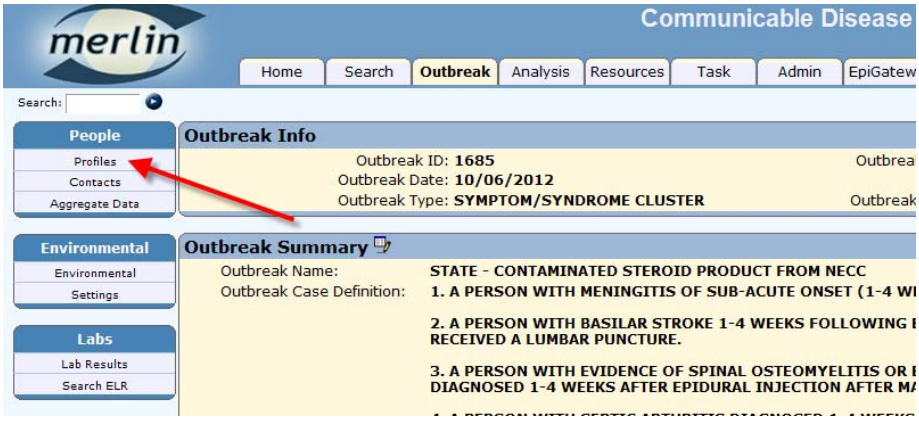
III. Merlin reporting: for all cases under investigation, create a case in Merlin Outbreak Module #1685 and complete survey questions **within 24**

A. To find this outbreak, go to the Outbreak tab in Merlin, click on Outbreak ID under Search By on the left side menu, then enter the number 1685 and click on the Search button

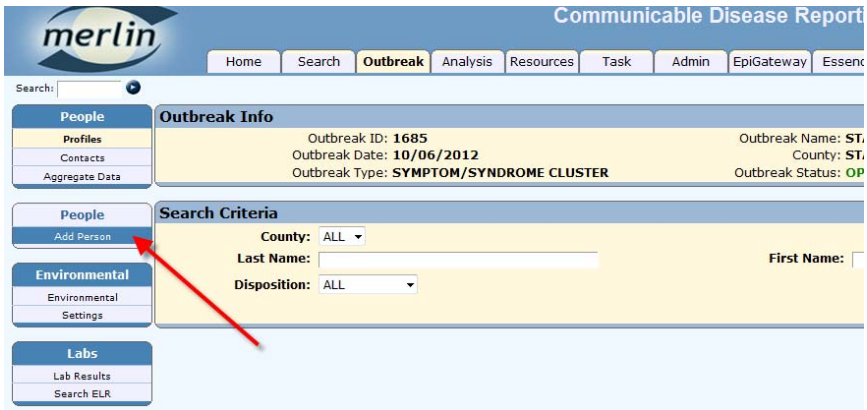


B. The Outbreak Summary includes the case definition, information on dates, type of outbreak, summary case counts, and a list of people associated with the outbreak

C. To enter a new case, click on Profiles under People on the left side menu



D. Click on Add Person under People on the left side menu



E. Enter as much demographic and clinical information as is available, but please be sure to complete the following fields (bold fields are required to save):

1. **Reason included (PATIENT/RESIDENT)**
2. **Last name,** first name
3. Gender
4. Date of birth
5. Race
6. Ethnicity
7. Street Name **(USE THE PATIENT'S ACTUAL RESIDENCE,**
8. Zip **REGARDLESS OF WHERE HE/SHE WAS EXPOSED)**
9. **County or State**
10. Dx status **(THIS SHOULD REFLECT CDC OUTBREAK DEFINITION)**
11. Date Onset
12. Investigated and Date Investigated
13. Interviewed and Date Interviewed (if investigated)

14. Symptomatic at Interview (if interviewed)
15. Final Known Outcome
16. Emergency Department Visit
17. Inpatient Hospitalization
18. **Related to Setting**
19. **This should be the clinic where the person received injection, and will be used to determine official outbreak case counts**
20. If the clinic is out of state and not listed in the dropdown, please choose “OTHER (CONTACT MERLIN_HELPDESK@DOH.STATE.FL.US) and contact the Merlin Helpdesk so that the clinic can be added to the menu
21. Symptoms
22. All Survey Questions (subset of questions from the CRF; questions on the CRF that correlate to survey questions are bolded in blue font)

merlin

Communicable Disease Reporting

Home | Search | Outbreak | Analysis | Resources | Task | Admin | EpiGateway | Essence | FDENS | Food Recalls | Help | Log Off

Search:

The record was saved successfully.

People
- Profiles
- Contacts
- Aggregate Data

People Detail
- Profile Detail
- Notes
- Print OB Form

Environmental
- Environmental
- Settings

Labs
- Lab Results
- Search ELR

Analysis
- Summary
- Reports
- Statistics
- Export

Admin
- Closure
- Definition
- Event Log
- Survey
- Documents

Link to Case
- Link by Case #
- Link by Name
- Create Case

Outbreak Info

Outbreak ID: **1673**
Outbreak Date: **10/08/2012**
Outbreak Type: **SYMPTOM/SYNDROME CLUSTER**
Outbreak Name: **STATE - MENINGITIS**
County: **STATE**
Outbreak Status: **OPEN**

These fields are required to save

Outbreak People Detail

ID: **29419**
Disposition: **CASE**
Outcome: **RECOVERED**

Reason Included: PATIENT/RESIDENT
Date Added: **10/08/2012**
Last Name: QUE
First Name: SUSIE

Gender: FEMALE
Date of Birth: 04/03/1979
Age: 33 YEARS
Race: BLACK
Ethnicity: NON HISPANIC
US Address: Yes No
Street Name 1: 1515 MAIN STREET
Street Name 2:
Zip: 32311
City: TALLAHASSEE
County: LEON
OR State: FL
Home Phone:
Phone Work:

Clinical

Investigation Status:
FL Disease Code: MENINGITIS, BACTERIAL, CRYPTOCOCCAL, MYCOTIC - 32090
Investigator: EISENSTEIN, LEAH (LEAHE)
Disposition: CASE
Date Disposition: 10/08/2012
DX Status: CONFIRMED
Date Onset: 09/25/2012
Investigated: Yes
Date Investigated: 10/08/2012
Interviewed: No
Date Interviewed:
Symptomatic At Interview:
Final Known Outcome: RECOVERED
Date Outcome:
Emergency Department Visit: Yes
Inpatient Hospitalization: Yes
Prophylaxed: NOT APPLICABLE
Day Care: NO
Occupation: HEALTH CARE WORKER

Duration of Illness: In:
Related to Setting: INTERVENTIONAL REHAB CENTER, PENSACOLA, FL
Primary Case (Zero):

CHD First Notified via ELR: No
How First Notified:

Symptoms

Symptoms:

BACK PAIN
FEVER
HEADACHE
INCONTINENCE
LIGHT SENSITIVITY
NAUSEA

Add >>
<< Remove

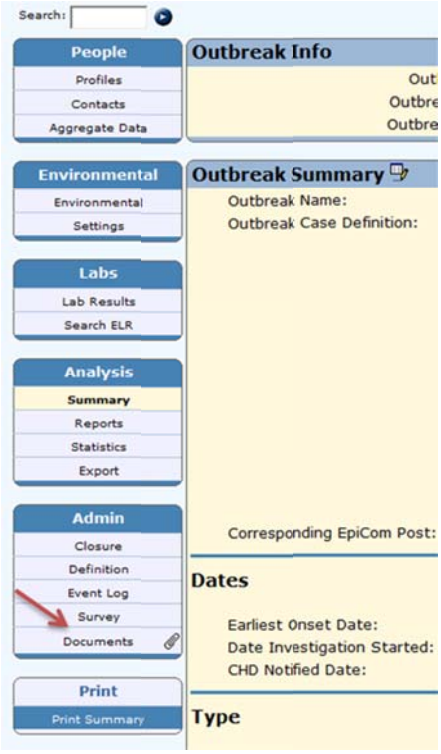
CONFUSION
DECREASED VISION
DIFFICULTY MOVING LIMBS
FALLING DOWN

Survey Questions

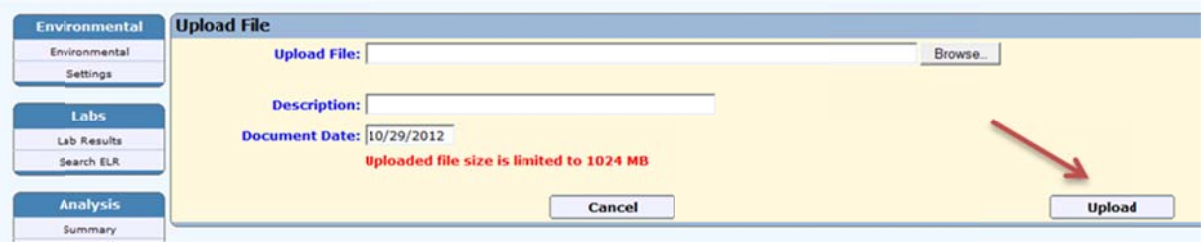
Order #	Survey Question	Answer
1	**FLORIDA INVESTIGATION ID# (FL + COUNTY + SEQUENCE#; EX. FLMARION1):**	FLESCA
2	**CDC INVESTIGATION ID# (ASSIGNED BY CDC):**	FL-13
3	**IS THE CASE UNDER MEDICAL REVIEW AND THUS HAS NOT BEEN RELEASED TO THE PUBLIC?**	○ Yes
4	**HOSPITAL (AT THE TIME THE CASE REPORTED):**	ST THC
5	**DID THIS PERSON HAVE MENINGITIS OF UNKNOWN ETIOLOGY FOLLOWING EPIDURAL INJECTION OF METHYLPREDNISOLONE ACETATE PRODUCED BY NECC AFTER MAY 21, 2012?**	○ Yes
6	**DID THIS PERSON HAVE A STROKE FOLLOWING EPIDURAL INJECTION WITH METHYLPREDNISOLONE ACETATE PRODUCED BY NECC AFTER MAY 21, 2012, WITH NO DIAGNOSTIC LUMBAR PUNCTURE?**	○ Yes
7	**DID THIS PERSON HAVE SPINAL OSTEOMYELITIS OR EPIDURAL ABSCESS OF UNKNOWN ETIOLOGY AT THE SITE OF AN EPIDURAL OR SACROILIAC INJECTION WITH METHYLPREDNISOLONE ACETATE PRODUCED BY NECC AFTER MAY 21, 2012?**	○ Yes
8	**DID THIS PERSON HAVE OSTEOMYELITIS OR WORSENING INFLAMMATORY ARTHRITIS OF A PERIPHERAL JOINT (E.G., KNEE) OF UNKNOWN ETIOLOGY DIAGNOSED FOLLOWING JOINT INJECTION WITH METHYLPREDNISOLONE ACETATE PRODUCED BY NECC AFTER MAY 21, 2012?**	○ Yes
9	**DID THIS PERSON DEVELOP AN INFECTION OF A NORMALLY STERILE SITE (E.G., BLOOD, CSF, PLEURAL FLUID, PERITONEAL FLUID, PERICARDIAL FLUID, SURGICAL ASPIRATE, BONE, JOINT FLUID, OR INTERNAL BODY SITE [E.G., LYMPH NODE, BRAIN]) FOLLOWING USE OF A PRODUCT LABELED AS STERILE PREPARED BY THE NECC?**	○ Yes
10	**DID THIS PERSON HAVE UNDERLYING MEDICAL CONDITIONS (SEE PATIENT MEDICAL HISTORY ON CASE ABSTRACTION FORM)?**	◉ Yes
11	**IF YES, SPECIFY MEDICAL CONDITIONS:	RHEUM.
12	**DID THIS PERSON RECEIVE ONE OR MORE STEROID INJECTIONS FROM A CLINIC THAT RECEIVED NECC PRODUCTS IN THE 2 MONTHS PRIOR TO ILLNESS ONSET? IF YES, PLEASE PROVIDE THE FOLLOWING INFORMATION FOR THE MOST RECENT INJECTION.**	◉ Yes
13	**IF YES, SPECIFY CLINIC:	PAIN C
14	**IF YES, PROCEDURE DATE (MM/DD/YY):	08/30/
15	**IF YES, SPECIFY THE INJECTION SITE (EPIDURAL, JOINT, OR OTHER):	EPIDUR
16	*******IF JOINT INJECTION, SPECIFY JOINT; IF OTHER TYPE OF INJECTION, SPECIFY TYPE:	
17	**IF YES, LOT NUMBER:	
18	**DID THE PATIENT RECEIVE MORE THAN ONE PROCEDURE? IF YES, PLEASE PROVIDE THE FOLLOWING INFORMATION FOR THE 2ND MOST RECENT INJECTION.**	◉ Yes
19	**IF YES, NUMBER OF **OTHER** INJECTIONS:	1
20	**IF YES, SPECIFY CLINIC	PAIN C
21	**IF YES, PROCEDURE DATE (MM/DD/YY)	08/01/
22	**IF YES, SPECIFY THE INJECTION SITE (EPIDURAL, JOINT, OR OTHER)	EPIDUR
23	*******IF JOINT INJECTION, SPECIFY JOINT; IF OTHER TYPE OF INJECTION, SPECIFY TYPE:	
24	**IF YES, LOT NUMBER	
25	**WAS A DIAGNOSTIC LUMBAR PUNCTURE PERFORMED ON THIS PERSON? IF YES, SPECIFY THE INFORMATION BELOW FOR THE 1ST LUMBAR PUNCTURE.**	◉ Yes

F. Scan and attach the CRF to outbreak #1685 in the Merlin Outbreak Module

1. Click on Documents under the Admin tab on the left side of the outbreak summary screen



2. Click Upload
3. Browse for CRF file, name file in the following format and click Upload: CDC ID#, FL ID#, Profile initials – CASE REPORT FORM.



G. Be sure to click the Save button at the bottom of the screen

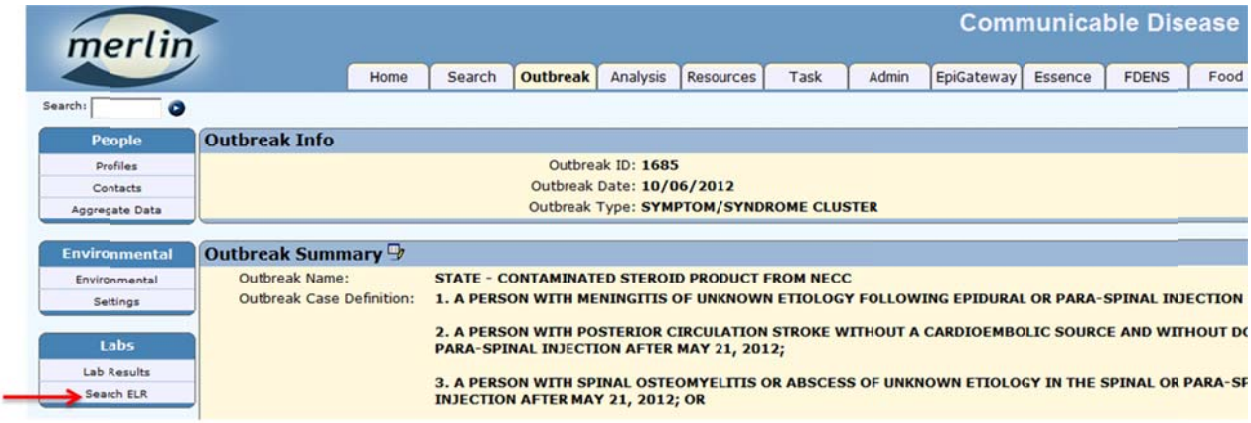
IV. Laboratory results

All specimens (including post-mortem specimens) from all individuals who are determined to be a case associated with this outbreak should be submitted to the Bureau of Public Health Laboratories (BPHL) who will forward specimens to Centers of Disease Control and Prevention (CDC) for fungal PCR and other testing. See "County Health Department Specimen Submission Instructions for Cases Associated with Contaminated Injectable Product" guidance document for submission instructions (http://www.doh.state.fl.us/disease_ctrl/epi/htopics/popups/meningitis.html).

NOTE: Lab results will not show up in the task list. The Bureau of Epidemiology will alert the counties when CDC results are available. Lab specimen logs will be emailed to CHDs with updates regarding pending or resulted lab statuses.

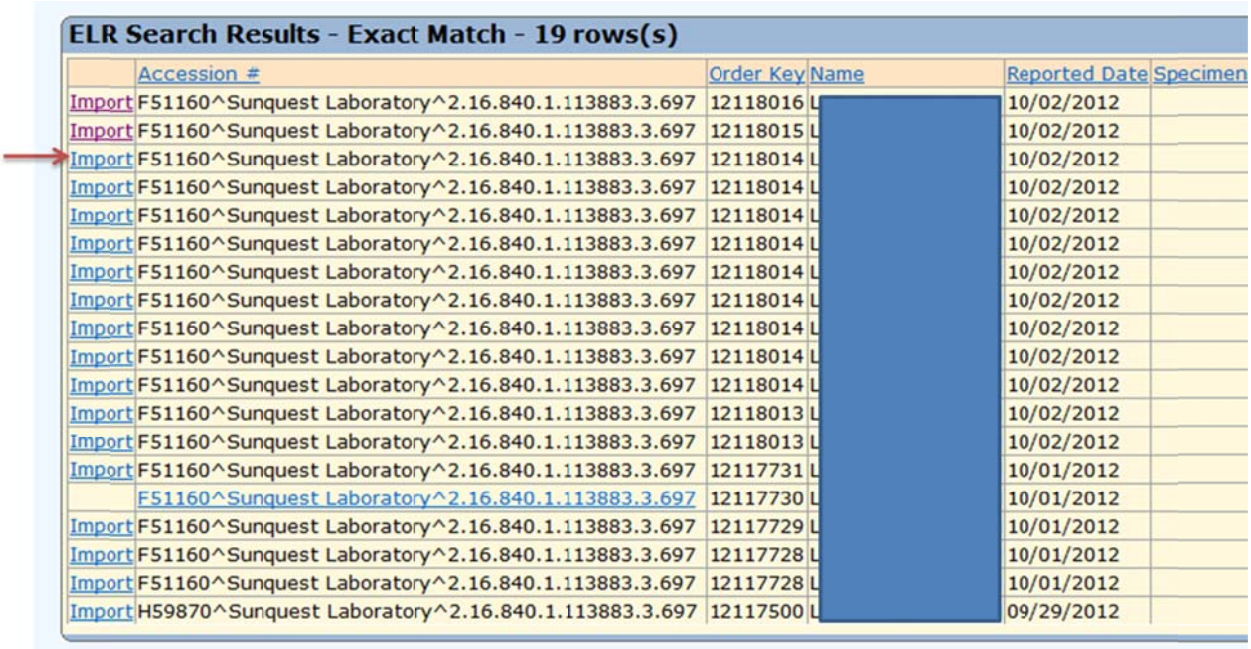
A. To link ELR lab results to cases in the outbreak, search for the lab result within the outbreak module

B. Click on Search ELR under Labs on the left side menu



C. Enter search criteria (Last Name, First Name, Lab Result Date Range) and click Search

D. All labs meeting search criteria will appear in ELR Search Results box; click on Import (far left column) next to the result of interest



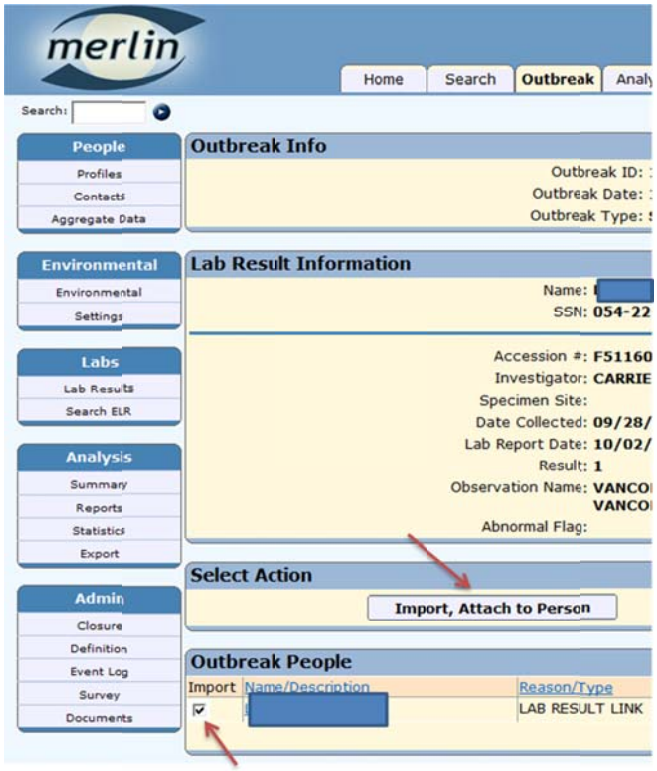
ELR Search Results - Exact Match - 19 rows(s)

	Accession #	Order Key	Name	Reported Date	Specimen
Import	F51160^Sunquest Laboratory^2.16.840.1.113883.3.697	12118016	L [redacted]	10/02/2012	
Import	F51160^Sunquest Laboratory^2.16.840.1.113883.3.697	12118015	L [redacted]	10/02/2012	
Import	F51160^Sunquest Laboratory^2.16.840.1.113883.3.697	12118014	L [redacted]	10/02/2012	
Import	F51160^Sunquest Laboratory^2.16.840.1.113883.3.697	12118014	L [redacted]	10/02/2012	
Import	F51160^Sunquest Laboratory^2.16.840.1.113883.3.697	12118014	L [redacted]	10/02/2012	
Import	F51160^Sunquest Laboratory^2.16.840.1.113883.3.697	12118014	L [redacted]	10/02/2012	
Import	F51160^Sunquest Laboratory^2.16.840.1.113883.3.697	12118014	L [redacted]	10/02/2012	
Import	F51160^Sunquest Laboratory^2.16.840.1.113883.3.697	12118014	L [redacted]	10/02/2012	
Import	F51160^Sunquest Laboratory^2.16.840.1.113883.3.697	12118014	L [redacted]	10/02/2012	
Import	F51160^Sunquest Laboratory^2.16.840.1.113883.3.697	12118014	L [redacted]	10/02/2012	
Import	F51160^Sunquest Laboratory^2.16.840.1.113883.3.697	12118014	L [redacted]	10/02/2012	
Import	F51160^Sunquest Laboratory^2.16.840.1.113883.3.697	12118013	L [redacted]	10/02/2012	
Import	F51160^Sunquest Laboratory^2.16.840.1.113883.3.697	12118013	L [redacted]	10/02/2012	
Import	F51160^Sunquest Laboratory^2.16.840.1.113883.3.697	12117731	L [redacted]	10/01/2012	
	F51160^Sunquest Laboratory^2.16.840.1.113883.3.697	12117730	L [redacted]	10/01/2012	
Import	F51160^Sunquest Laboratory^2.16.840.1.113883.3.697	12117729	L [redacted]	10/01/2012	
Import	F51160^Sunquest Laboratory^2.16.840.1.113883.3.697	12117728	L [redacted]	10/01/2012	
Import	F51160^Sunquest Laboratory^2.16.840.1.113883.3.697	12117728	L [redacted]	10/01/2012	
Import	H59870^Sunquest Laboratory^2.16.840.1.113883.3.697	12117500	L [redacted]	09/29/2012	

E. Import Order box will contain all results associated with an order

1. To import entire order containing all results associated with an order, click on To Outbreak within the Import Order box
2. To import only the selected result, click on To Outbreak within the Import Individual Observation from the Order Shown Above box

F. In the Outbreak People box, check the box in the Import column next to the desired name. In the Select Action box, click on Import, Attach to Person to attach lab results (pending or final) to an existing person in the outbreak.



G. Ensure all **blue** fields are complete and then click Save at the bottom of the screen.

H. Please remember to update results in the profile detail survey questions.