



Advancing Transfusion and  
Cellular Therapies Worldwide

# AABB Zika Virus Biovigilance Network

## DATA ENTRY TRAINING GUIDE

The screenshot displays the Zika Virus Biovigilance Data Collection interface. At the top, there are filters for Start Date (10/30/2018) and End Date (11/29/2018), along with buttons for 'LAST 30 DAYS' and 'LAST 90 DAYS'. Below the filters is a map of the United States with 'Map' and 'Satellite' view options. A small box on the map indicates 'Zika Virus Test Results' with 'Reactive Donations: 80'. The main part of the interface is a data entry form titled 'Zika Virus Biovigilance Data Collection'. The form includes a disclaimer: 'This report is intended to assist you in complying with FDA's expectation that blood establishments communicate such ZIKV-reactive results with other blood establishments in that same geographic area and public health jurisdictions within 24 hours.' The form fields include: Reporting Organization \* (with a dropdown arrow), Unit Identifier \* (with a dropdown arrow), Date of Collection \* (with a calendar icon), Residential Zip Code \* (with a dropdown arrow), City/State Address (with a dropdown arrow), Pool size of origination of reactive donation (if originated from individual test, please choose a pool size of 1) \* (with a dropdown arrow), NAT Manufacturer \* (with a dropdown arrow), Was this donation identified during a period of time and in a geographic area declared active for Zika Virus? \* (with a dropdown arrow), Have you completed the Alternate Exposure Investigation? \* (with a dropdown arrow), Gender (with a dropdown arrow), Age At Donation (with a dropdown arrow), Did the donor experience symptoms consistent with Zika Virus infection? (with a dropdown arrow), and Final Test Interpretation (with a dropdown arrow). A note states: 'Final Test Interpretation will be used for research purposes only. Triggering and de-triggering should be based on initial test according to the EDL guideline.' At the bottom of the form are 'SUBMIT' and 'CANCEL' buttons.

For support or questions contact  
AABB Hemovigilance  
[hemovigilance@aabb.org](mailto:hemovigilance@aabb.org) or [+1.301.215.6588](tel:+13012156588)  
[www.aabb.org/hemovigilance](http://www.aabb.org/hemovigilance)

**AABB Zika Virus Biovigilance Network**  
**Data Entry Training Guide**

**Table of Contents**

Background .....	2
Log In.....	3
Add a new submission .....	5
Data Collection Form .....	6
Zika Virus Blood Donor Data Reports .....	9
Email Alerts .....	11
Helpful Resources .....	12

## Background

The Zika Virus Biovigilance Network, a collaboration between AABB and U.S. blood collection establishments, was initiated in 2016. The Network contains collection and reporting data for donors with suspected ZIKV infection and maps this data to geographical locations.

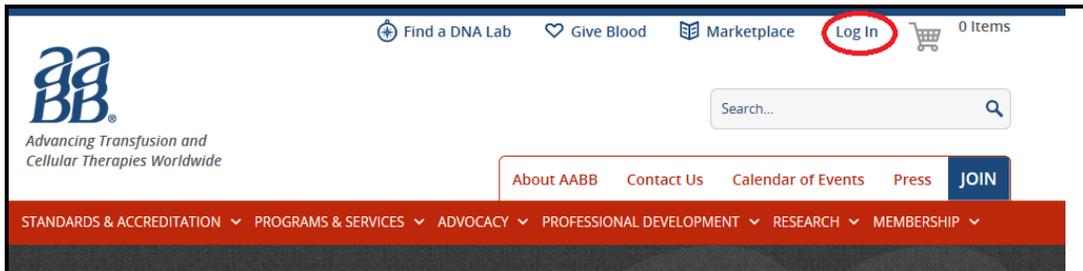
The revised Zika Virus Biovigilance Network was deployed in December 2018 to support recommendations made in the July 2018 [FDA Guidance](#).

### **Revised Version Salient Features**

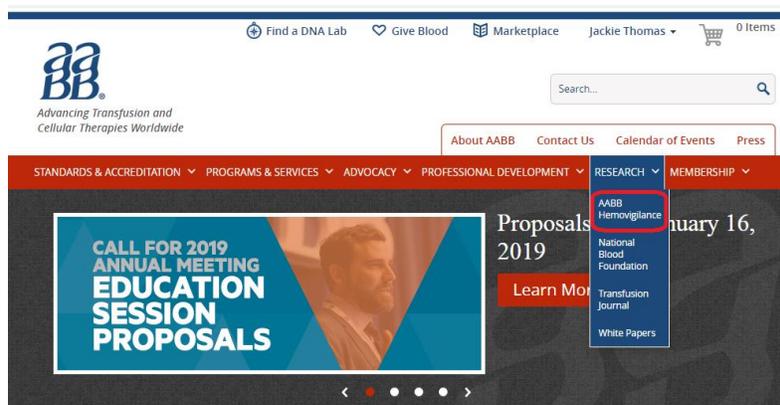
- Each reported reactive case will be identified by a unique AABB Case #.
- Blood centers and test labs that use MP NAT tests can report a reactive case once a reactive MP is resolved using ID NAT to identify the unit(s) that led to the reactivity of the MP sample.
- NAT Manufacturer options: Roche IND, Roche Licensed, Grifols IND, and Grifols Licensed.
- Presence or absence of alternate exposure (travel or sexual contact) can be reported.
- Users have the capability to update the alternate exposure status once the investigation is complete.
- Once the pertinent data is entered into the network, a Zika Virus email alert is simultaneously emailed to blood centers and testing laboratories in the Network.
- When a case is updated to indicate an alternate exposure, an updated email alert is sent to Network users. Each case can be identified by a unique AABB case #number.

## Log In

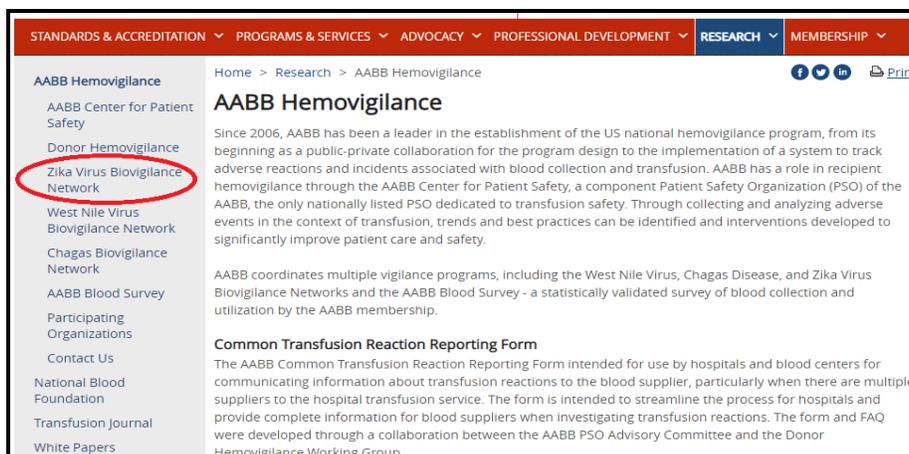
Go to [www.aabb.org](http://www.aabb.org) and click on the **Log In** link on the top of the page. Login using your AABB user ID and password. If you are unsure of your user ID or need your password reset, please email [hemovigilance@aabb.org](mailto:hemovigilance@aabb.org).



After logging in, hover over the **Research** tab and a dropdown menu will appear. Select **AABB Hemovigilance**.



Once you have reached the AABB Hemovigilance page, select **Zika Virus Biovigilance Network** by clicking the link as shown below.



When you have reached the Zika Virus Biovigilance Network page, you will find a map of current ZIKA activity and links for data collection and reports. The Zika activity map allows you to filter cases by a date range. When you filter for a certain date range, the map may take a short time to recalculate and show the reactive donations for that date range. The legend will provide you the summary of total reactive donations and cases with alternate exposure.

Home > Research > AABB Hemovigilance > Zika Virus Biovigilance Network f t in Print

## Zika Virus Biovigilance Network

The Zika Virus (ZIKV) Biovigilance Network collects and reports data on the number of blood donors in the United States with suspected ZIKV infection and maps this to geographical locations. Data are collected from those blood collection organizations in the United States that are screening some or all of their blood donors for Zika virus infection using one of two available investigational nucleic acid tests (NAT) approved for this use by the FDA. Reporting these data to the AABB is a voluntary activity.

This section includes a map showing locations where ZIKV-reactive donors have been identified and reported; background on the development of this electronic surveillance system; and a password-protected area for reporting of test results.

### U.S. Map: ZIKV-Reactive Blood Donors by Postal Code

Start Date: 11/3/2018 End Date: 12/3/2018 LAST 30 DAYS LAST 90 DAYS

Map
Satellite

**Zika Virus Test Results**  
 Total Reported: 66  
 Alternate Exposures: 51

**Zip Code Markers:**  
● Reactive Donations  
● Alternate Exposures  
● Both

Map data ©2018 Google, INEGI, ORION-ME | Terms of Use

## ZIKA Blood Donor Data Collection

The [July 2018 FDA guidance](#) recommends blood establishments to communicate ZIKV-reactive results with other blood establishments in that same geographic collection area and public health jurisdictions, within 24 hours. AABB Zika Virus Biovigilance Network can be used as a platform for such communication.

A ZIKV-reactive donation is based on:

- A donation in a reactive MP that is reactive following MP resolution testing by ID NAT, or
- A donation that is reactive by ID NAT.

To enter the data entry module, click on the link for **Zika Blood Donor Data Collection**. This will direct you to a password protected page. To receive access to the page please contact [hemovigilance@aabb.org](mailto:hemovigilance@aabb.org).



If you or someone from your facility have previously made entries for your facility, a list of them will be show on Zika Virus Biovigilance Data Collection page.

### Add a new submission

Zika Virus Biovigilance Data Collection

Find by AABB Case # Find by Unit Identifier Find by Collection Date CLEAR SEARCH < > Page 1 of 92 - Total Records: 919

AABB Case #	Unit Identifier	Organization	Collection Date	Alternate Exposure Status
1043	W2213	Anytown Hospital	2018-10-25	Travel AND Sexual Contact
1042	cdc2222	Anytown Hospital	2018-11-26	Sexual Contact
1041	ASBS	Anytown Hospital	2018-11-23	Travel
1040	w1334	Anytown Hospital	2018-12-01	No Alternate Exposure Found

+ ADD EDIT DELETE

Click + ADD.

## Data Collection Form

Click the drop-down menu to select the organization to which you are associated with. If you do not see the appropriate organization, contact [hemovigilance@aabb.org](mailto:hemovigilance@aabb.org) for assistance.

Select the date the unit was collected using the pop-up calendar that appears when you select the field.

Select the pool size of origination of the minipool from the drop-down menu. If the reactive donation originated from individual test, please choose a pool size of 1.

This is an optional section. Information on gender, age, symptoms and final (repeat) test interpretation will be used for research purpose only.

You may return to edit/update with section later, if you don't have the information at the time of submission.

To save and submit the form, press "SUBMIT".

Fields marked with (\*) are required fields.

**Zika Virus Biovigilance Data Collection**

This report is intended to assist you in complying with FDA's expectation that blood establishments communicate such ZIKV-reactive results with other blood establishments in that same geographic area and public health jurisdictions within 24 hours.

Reporting Organization \*      Unit Identifier \*

Date of Collection \*      Residential Zip Code \*      City/State Address

Pool size of origination of reactive donation (if originated from individual test, please choose a pool size of 1) \*

NAT Manufacturer \*

Was this donation identified during a period of time and in a geographic area declared active for Zika Virus? \*

Please provide information for presence or absence of Alternate Exposure for reactive donors within 24 hours or as soon as information is available. If you have not completed the investigation to determine if there was an alternate exposure, please return and update this record once you have completed your investigation.

Have you completed the Alternate Exposure investigation? \*

If you do not have the information in this section at the time of submission, please return to edit/update the record. Please note, however this information will be used for research purposes only.

Gender      Age At Donation

Did the donor experience symptoms consistent with Zika Virus infection?

Final Test Interpretation

Final Test interpretation will be used for research purposes only. Triggering and de-triggering should be based on initial test according to the [EDA guidance](#).

SUBMIT      CANCEL

Enter a unique identifier to identify the entry. This can be the Donor Identification Number (DIN) or another tracking number to assist your identification of the record. This number will appear on some of the reports.

**Note:** The use of letters in the Unit Identifier field are case sensitive.

Enter the zip code of the donor's residence. The system will auto-populate the state.

Select the NAT test Manufacturer:  
-Roche IND  
-Roche Licensed  
-Grifols IND  
-Grifols Licensed  
You will have the opportunity to enter S/CO value(s) on Grifols tests.

Yes,  
No, or  
Unsure

If you have completed the alternative exposure investigation then select "Yes", otherwise select "No".

If you select "No" your alternative exposure status will be shown as "Pending" in the list of reported cases and in the alert emails.

An email alert will be sent to Network users, once you submit a form with required fields.

Once you return to the form to update the alternate exposure status, the system will send an updated email alert along with AABB case # for tracking.

## **Alternate Exposure investigation**

Select Yes or No, based on whether you have completed the investigation to determine the existence of alternate exposure.

Please provide information for presence or absence of Alternate Exposure for reactive donors within 24 hours or as soon as information is available. If you have not completed the investigation to determine if there was an alternate exposure, please return and update this record once you have completed your investigation.

Have you completed the Alternate Exposure investigation? \*

Yes X ▾

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Zika Virus Exposure

Pick one or more from the list below:

INVESTIGATION FOUND NO ALTERNATE EXPOSURE

TRAVEL - WITHIN LAST 30 DAYS  
Travel outside the collection area to an area at risk for ZIKV transmission as defined on the [CDC website](#).

SEXUAL CONTACT – WITHIN LAST 30 DAYS  
Sexual contact with a partner with a travel-related ZIKV diagnosis OR with a partner with a history of travel to or residence in an [area at risk for local mosquito-borne ZIKV transmission](#) in the 3 months prior to the last sexual contact.

If you have not completed the investigation to determine an alternate exposure, you can select “No”. Please return within 24-hours to update this record once you have completed your investigation.

## **No Alternate Exposure**

No relevant history of travel or sexual contact (defined below).  
and/or

CDC or other public health authority announced that there is an increased risk for ZIKV transmission in a county, based on symptomatic disease cases, the presence of competent vectors, the likelihood of local mosquito-borne transmission, and other epidemiological information (refer to the CDC’s webpage dedicated to providing [information for blood and tissue collection centers](#)).

## **Alternate Exposure**

- a. Travel – within last 30 days. Travel outside the collection area to an area at risk for ZIKV transmission as defined on the [CDC website](#).
  - Enter the location of travel (City, State, Country as known)
- b. Sexual contact in the last 30 days with a partner with travel-related ZIKV diagnosis OR with a partner with a history of travel to or residence in an [area at risk for local mosquito-borne ZIKV transmission](#) in the 3 months prior to the last sexual contact.
  - Enter the date of last contact from the drop down calendar

## Optional Fields

- a) Gender: Select Male or Female.
- b) Age at Donation: Enter the age of the donor on the date of donation.
- c) Did the donor experience symptoms consistent with Zika virus infection?
  - Enter Yes or No
  - If yes, enter dates of symptom onset and end

d) Final Test Interpretation

This information will be used for research purposes only. Triggering and de-triggering should be based on initial test according to the FDA guidance.

Select test interpretation from the drop-down menu.

a. **Confirmed Positive:**

One or more of the following is true:

- The sample's initial NAT reactivity repeats in one or more replicates using the primary or alternate NAT assay performed on samples from the index donation or a donor follow up sample.
- The demonstration of NAT repeat reactivity can be obtained from a sample from the plasma unit or from an EDTA plasma tube sample.
- If red cell testing is performed and reactive results are obtained, these may also be used to support sample confirmation.
- The donor demonstrates anti-Zika IgM reactivity at index and/or donor follow-up.

b. **False Positive:**

ALL the following are true:

- The index donation was nonreactive by all repeat NAT performed using the primary or alternate NAT.
- The index donation was negative for anti-Zika IgM.
- If the donor completed follow-up, the results for NAT and anti-Zika IgM should be non-reactive/negative.

c. **Cannot Conclude/Pending:**

- The donor does not meet the definition of confirmed positive or false positive.
- Cannot conclude includes:
  - further testing is pending, no sample is available for further testing, or
  - results to date do not meet the definition of confirmed positive or false positive.

d. **Cannot Conclude/No Additional Testing Planned:**

- There is no plan of conducting repeat test on the sample.

## Zika Virus Blood Donor Data Reports

*Please note – The available reports in this area reflect the report formats from the previous release of the platform.*

Members can access reports in one of two ways:

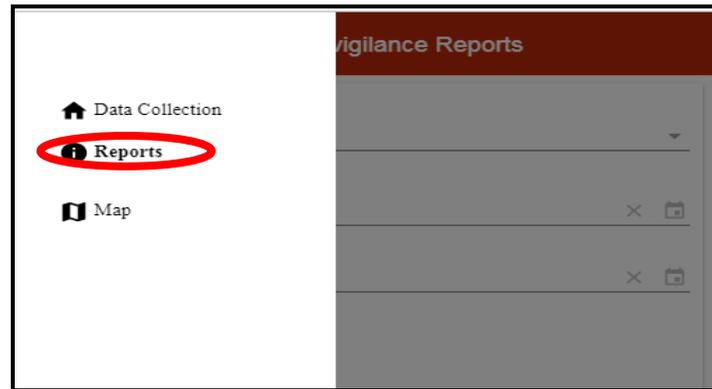
1. To enter the reports feature, click on **Zika Blood Donor Data Reports**.

### ZIKV Blood Donor Data Collection and Reports

[ZIKV Blood Donor Data Collection](#) (password-protected)

[ZIKV Blood Donor Data Report](#) (password-protected)

2. Pick **“Reports”** from the left menu (three bars) when you are already in the data entry area.



Both (steps 1 and 2) will direct you to the reports page with several options. Click on the report to generate a report of the current data in the system. Users have the ability to change the start and the end dates. If there is no data existing for the time period, the page will return blank.



- **Reactive Donor Information:** This report provides a list of details about donors testing reactive. Reports can be tracked through the unique AABB case number.

Date of Collection	State	Zip Code	Final Test Interpretation	Gender	Age	Alternate Exposure	Zika Virus Symptoms	AABB Case Number
02/04/2019	Kansas	66085				PENDING		898
01/05/2019	Illinois	60084	False Positive	Male	34	No Alternate Exposure Found	No	897
01/04/2019	Florida	32934	False Positive	Male	62	Travel Travel Location: New York City, NY	No	896
12/30/2018	Illinois	60440	Cannot Conclude/Pending	Female	32	No Alternate Exposure Found	No	895

- **Test Results by State:** This report allows you to review ZIKV results by state.

State	Donation Tracking Number	Collection Date	Zip Code	Pool Size	First S/CO Value	Region Active for	Alternate Exposure	AABB Case Number
<b>Alabama</b>								
	W204118885510	11/26/2018	35242	1	28.50	No	Travel Travel Location: Mississippi	309
	W041618026623	12/05/2018	36518	1	4.96	Unsure	No Alternate Exposure Found	868
<b>Arizona</b>								
	W041018153908	11/03/2018	85139	1	3.50	N/A	No Alternate Exposure Found	241

For technical support or for more information, please call 1-800-793-9376 (weekdays between 8:30 am and 5:00 pm ET).

## Email Alerts

Email alerts are sent to members with subscription to the zika email alert listserv. To subscribe, contact us at [hemovigilance@aabb.org](mailto:hemovigilance@aabb.org).

## First Email Alert

Mon 12/3/2018 11:46 AM  
H hemovigilance@aabb.org  
Zika Virus Alert - AABB Case# 1043

An entry has been made to the AABB Zika Virus Biovigilance Network for:

**AABB Case Number:** 1043  
**Collection Date:** 2018-10-25  
**State:** Colorado  
**Zip or postal code:** 80221  
**City/CO value, if applicable:**

**Alternate Exposure: Investigation of Alternate Exposure Pending**

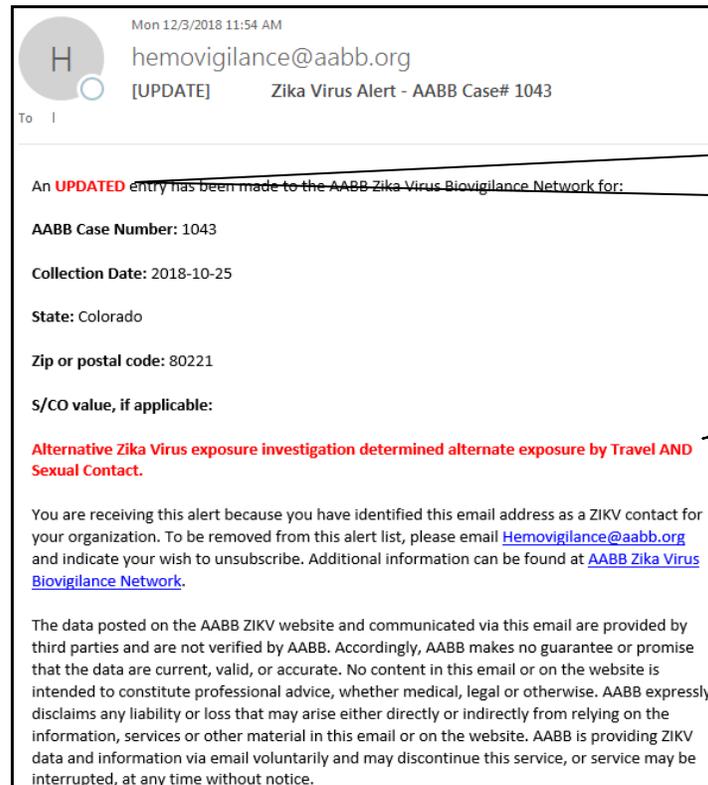
You are receiving this alert because you have identified this email address as a ZIKV contact for your organization. To be removed from this alert list, please email [Hemovigilance@aabb.org](mailto:Hemovigilance@aabb.org) and indicate your wish to unsubscribe. Additional information can be found at [AABB Zika Virus Biovigilance Network](#).

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Callout 1: AABB Case # for tracking (points to 'AABB Case Number: 1043')

Callout 2: Alternative Exposure information (points to 'Alternate Exposure: Investigation of Alternate Exposure Pending')

## Updated Email Alert



UPDATED indicates that Alternate Exposure has been updated on a previously reported case.

Updated Alternative Exposure information

## Helpful Resources

1. FDA Guidance for Industry. Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components. July 2018: <https://www.fda.gov/downloads/biologicsbloodvaccines/guidancecomplianceregulatoryinformation/guidances/blood/ucm518213.pdf>
2. AABB flowcharts to reflect understanding of the FDA recommendations :  
[Flowchart 1 - Conversion to ZIKV ID NAT](#)  
[Flowchart 2 - Return to ZIKV MP NAT](#)  
[Flowchart 3 - Product Management](#)
3. World Map of Areas with Risk of Zika: <https://wwwnc.cdc.gov/travel/page/world-map-areas-with-zika>
4. Blood & Tissue Safety: Geographic areas at increased risk for Zika virus transmission through blood or tissue donation: <https://www.cdc.gov/zika/areasatrisk.html>
5. Facility Identification Number Information Search: <https://www.iccbbba.org/lookup-tools/find-facility-information>