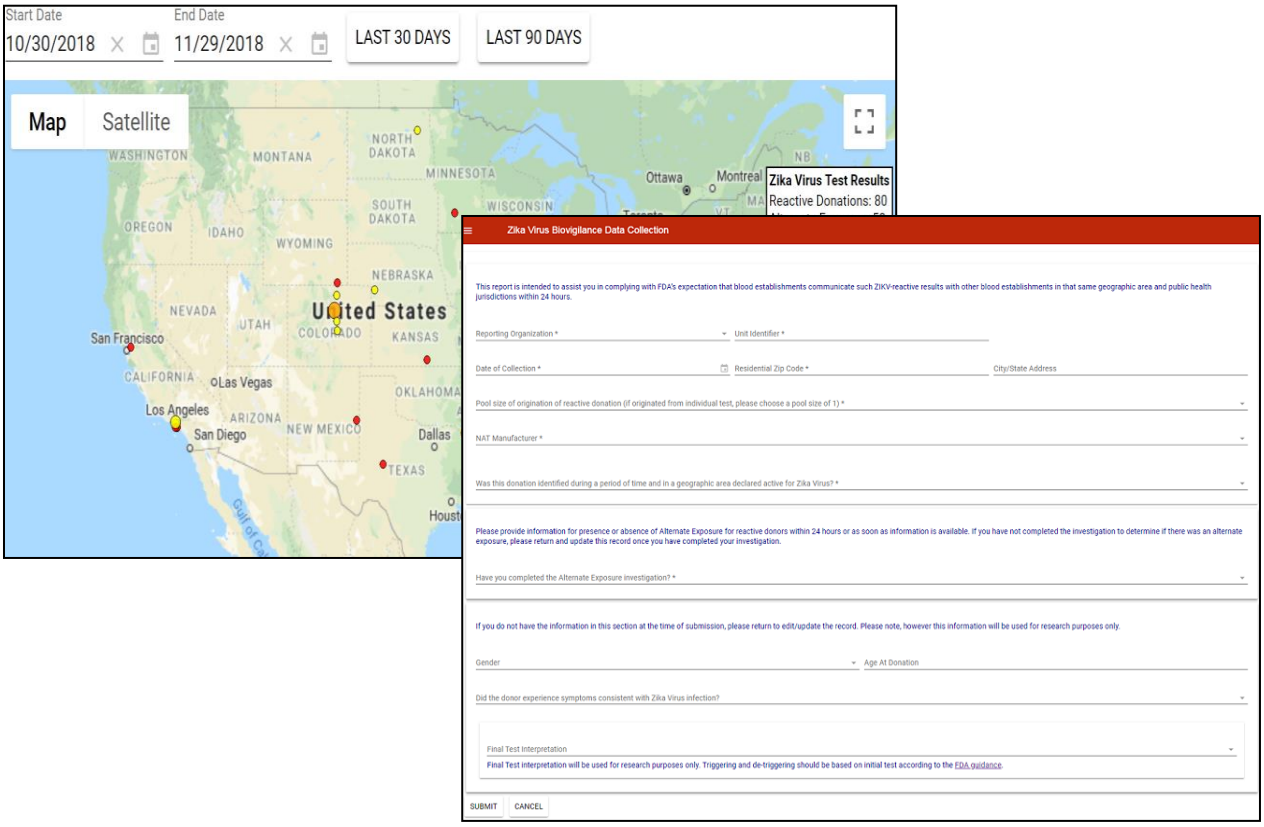
Advancing Transfusion and Cellular Therapies Worldwide

# AABB Zika Virus Biovigilance Network

## DATA ENTRY TRAINING GUIDE




For support or questions contact
AABB Hemovigilance
hemovigilance@aabb.org or +1.301.215.6588
www.aabb.org/hemovigilance

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

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## 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.

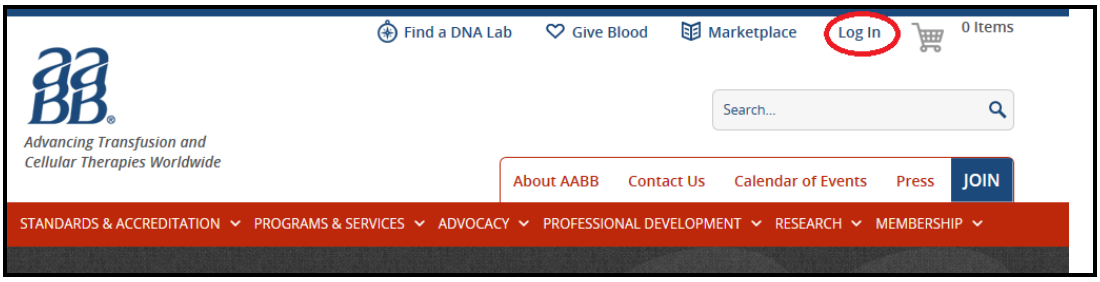
The revised Zika Virus Biovigilance Network was deployed in December 2018 to support recommendations made in the July 2018 FDA Guidance.

**Revised Version Salient Features**

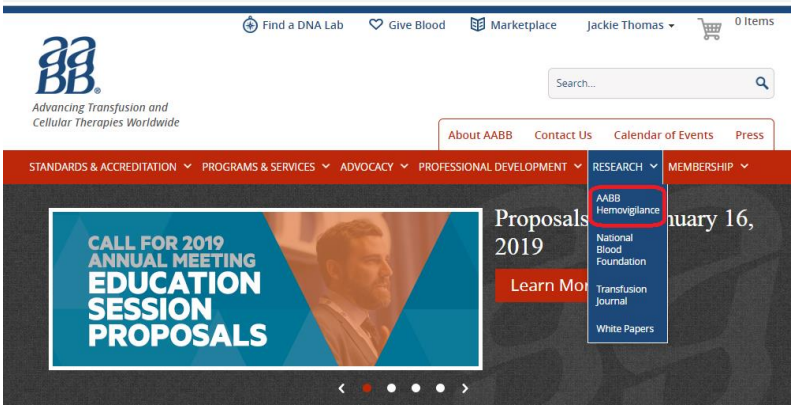
- Each reported reactive case will be identified by a unique AABB Case #.
- Blood centers and test labs that use MP NAT tests can report a reactive case once a reactive MP is resolved using ID NAT to identify the unit(s) that led to the reactivity of the MP sample.
- NAT Manufacturer options: Roche IND, 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

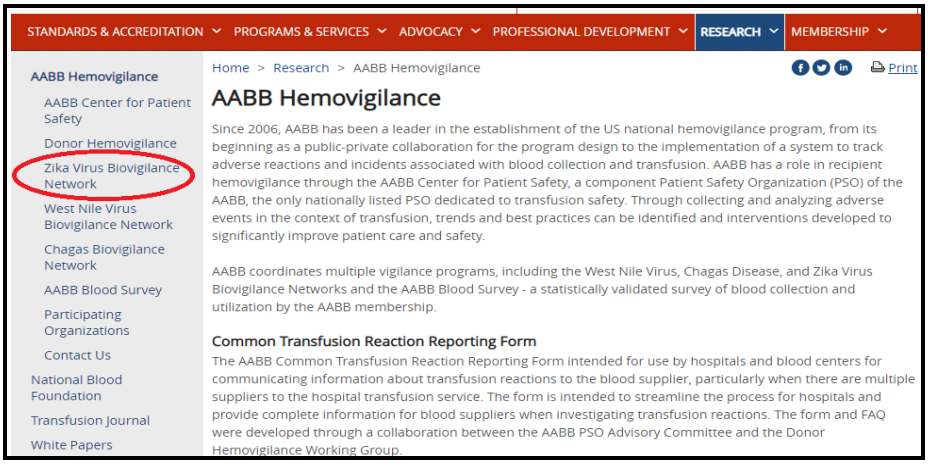
Go to www.aabb.org and click on the **Log In** link on the top of the page. Login using your AABB user ID and password. If you are unsure of your user ID or need your password reset, please email hemovigilance@aabb.org.



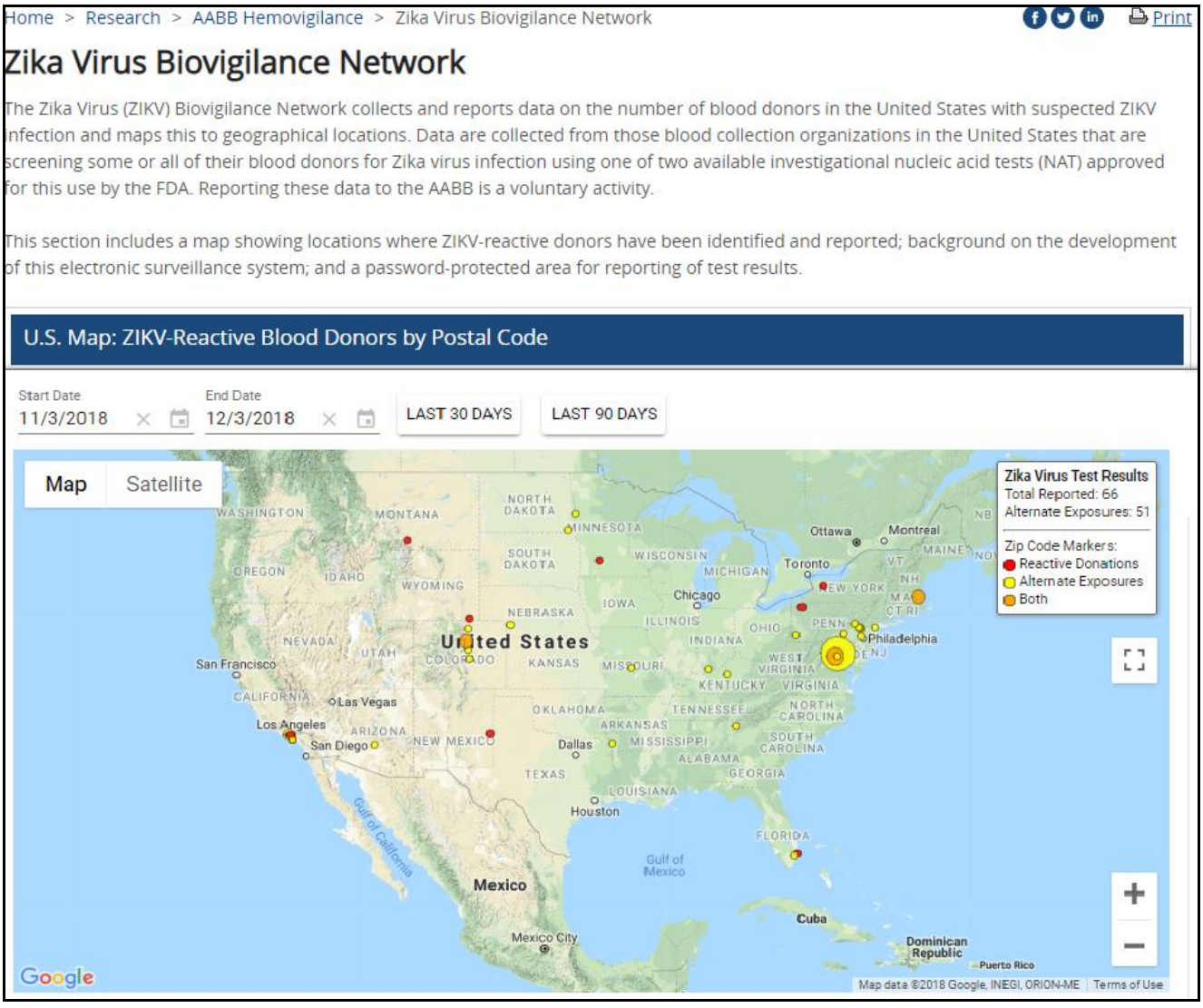

After logging in, hover over the **Research** tab and a dropdown menu will appear. Select **AABB Hemovigilance**.




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.



## 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.

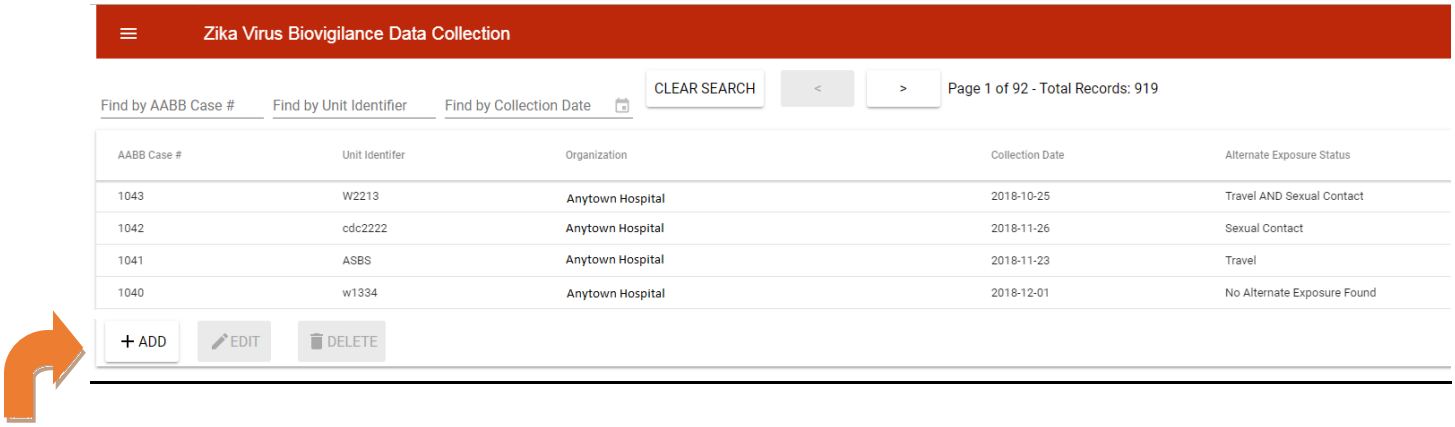
A ZIKV-reactive donation is based on:

- 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.


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.

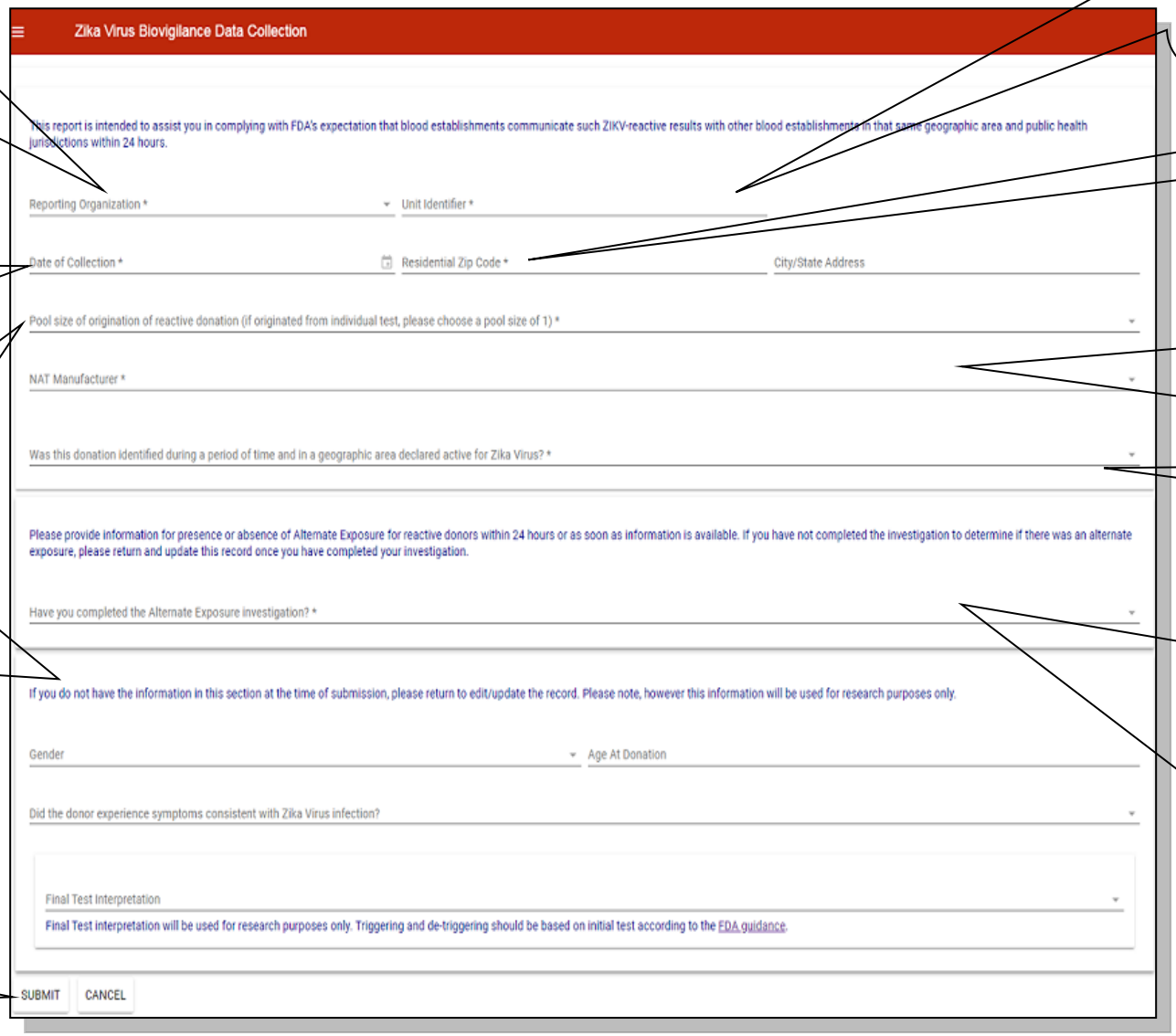
## Add a new submission




**Click + ADD**.

## Data Collection Form

Fields marked with (*) are required fields.




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 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".

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".

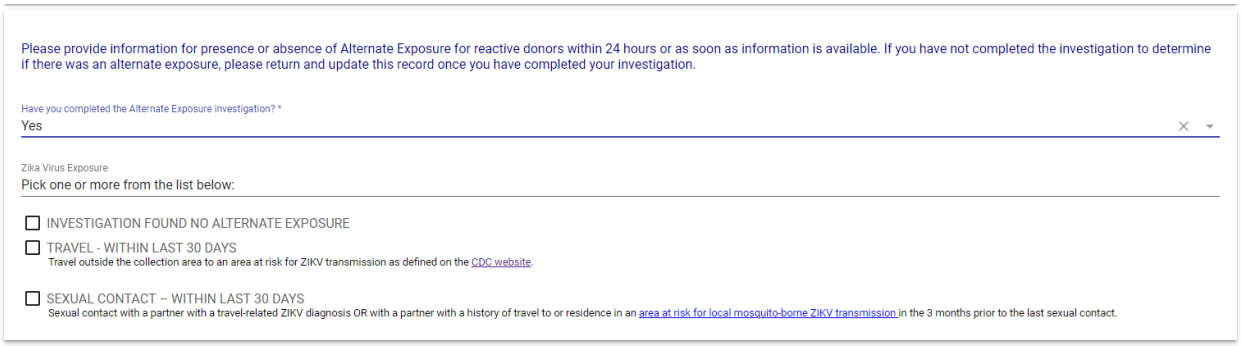
If you select "No" your alternative exposure status will be shown as "Pending" in the list of reported cases and in the alert emails.

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.




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.

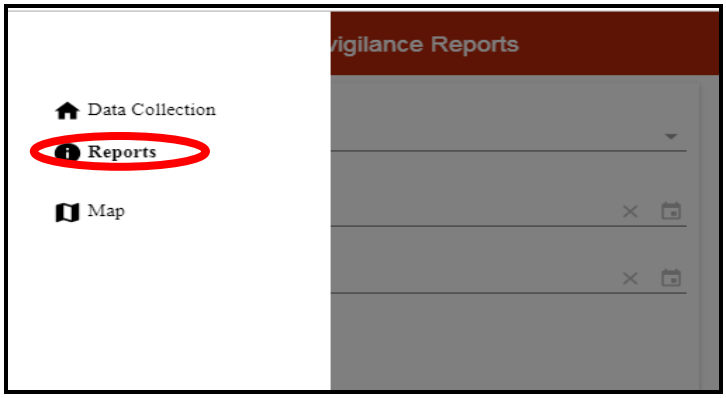
## Zika Virus Blood Donor Data Reports

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

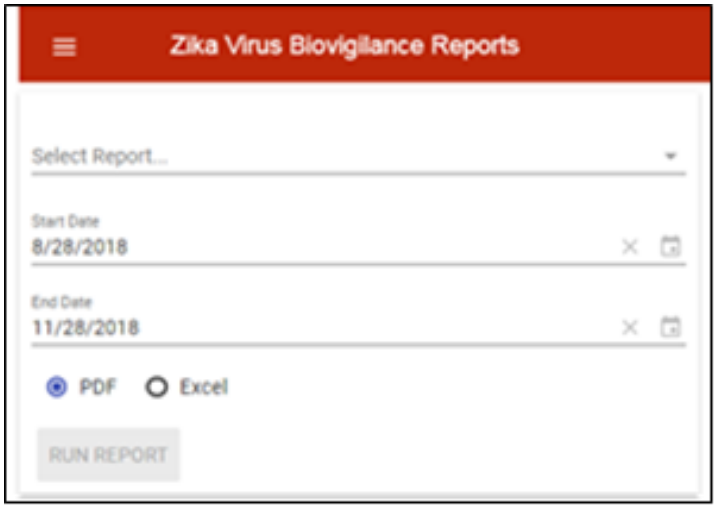
Members can access reports in one of two ways:

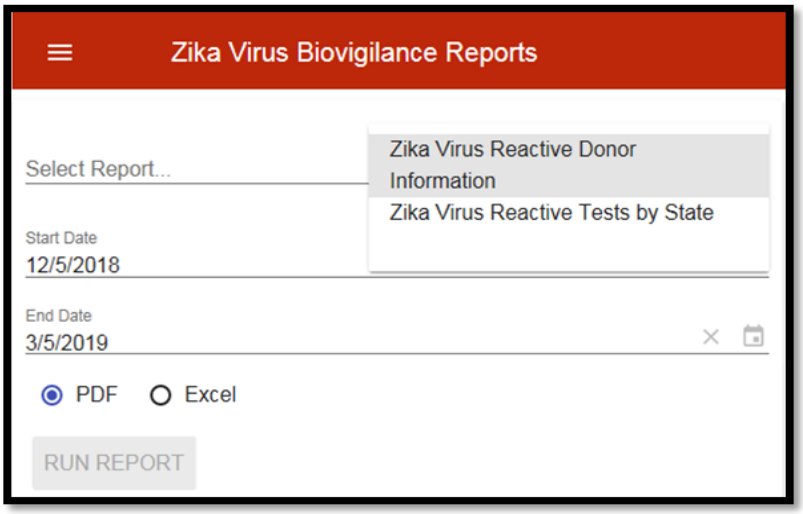
1. To enter the reports feature, click on **Zika Blood Donor Data Reports**.


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

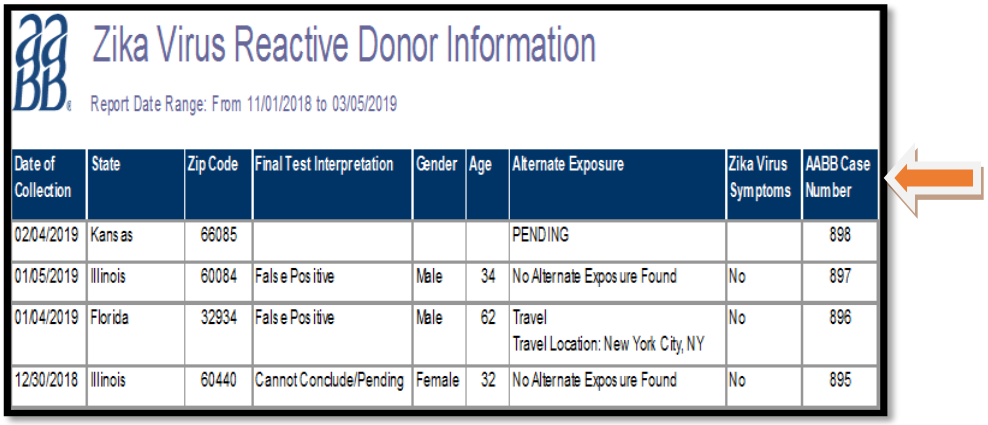



Both (steps 1 and 2) will direct you to the reports page with several options. Click on the report to generate a report of the current data in the system. Users have the ability to change the start and the end dates. If there is no data existing for the time period, the page will return blank.






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

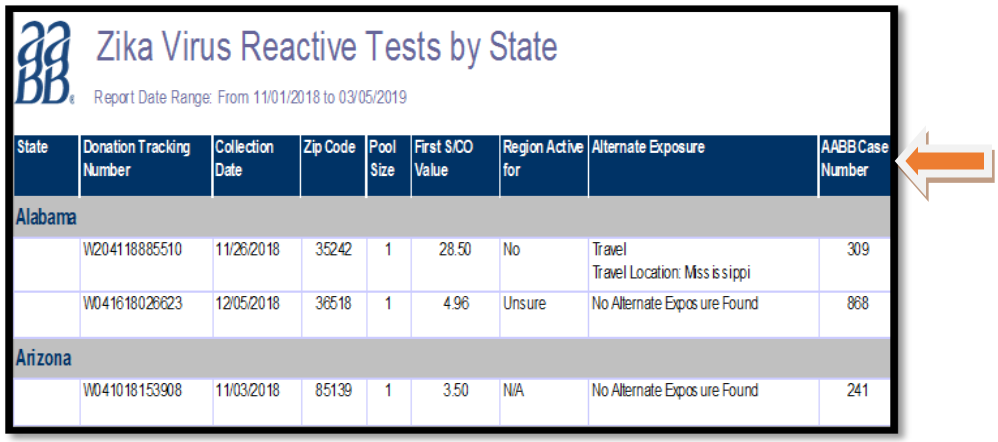


Zika Virus Reactive Donor Information

Report Date Range: From 11/01/2018 to 03/05/2019

| 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<br>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.



Zika Virus Reactive Tests by State

Report Date Range: From 11/01/2018 to 03/05/2019

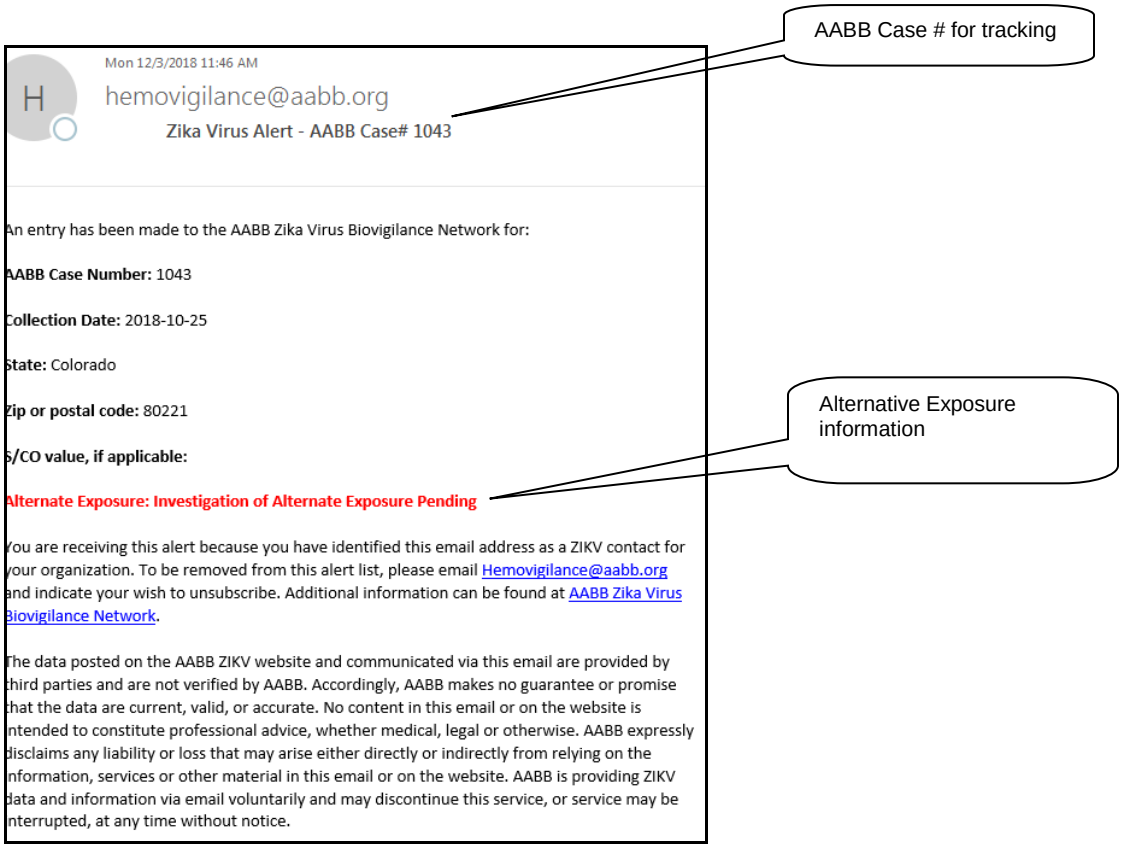
| State | Donation Tracking Number | Collection Date | Zip Code | Pool Size | First S/CO Value | Region Active for | Alternate Exposure | AABB Case Number |
|---|---|---|---|---|---|---|---|---|
| **Alabama** | | | | | | | | |
| | W204118885510 | 11/26/2018 | 35242 | 1 | 28.50 | No | Travel<br>Travel Location: Mississippi | 309 |
| | W041618026623 | 12/05/2018 | 36518 | 1 | 4.96 | Unsure | No Alternate Exposure Found | 868 |
| **Arizona** | | | | | | | | |
| | 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).

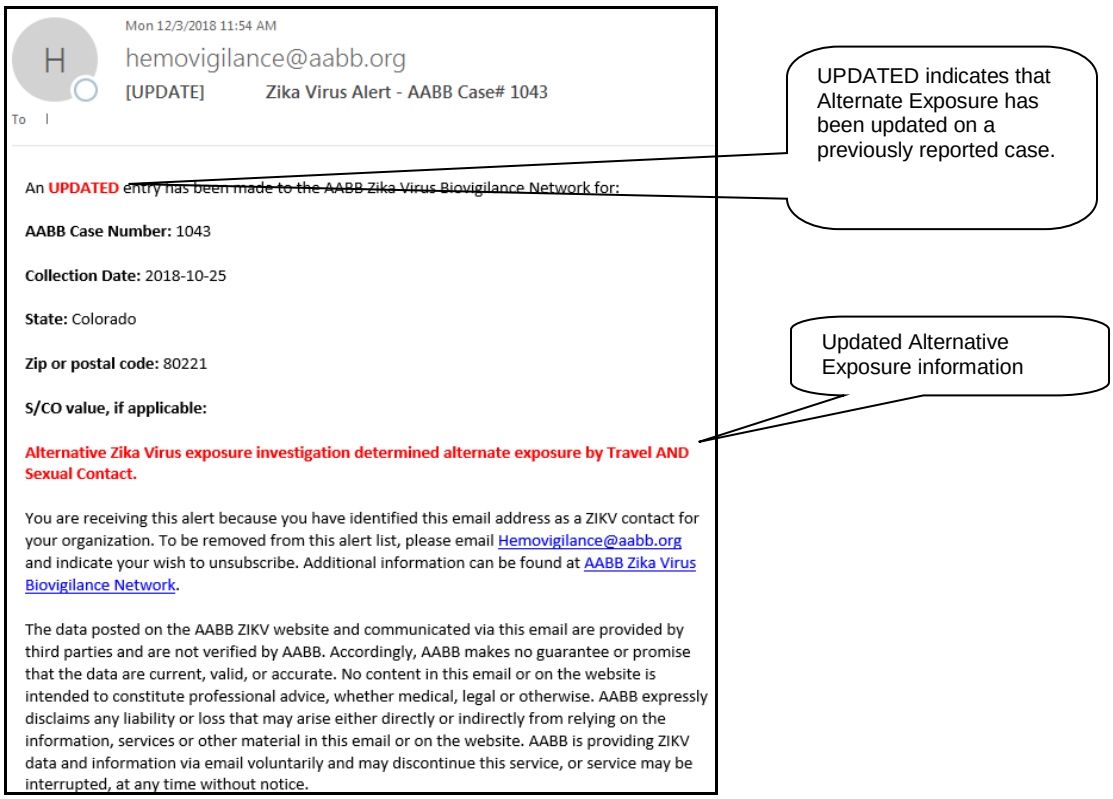
## Email Alerts

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

## First Email Alert



## Updated Email Alert




## 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.iccbba.org/lookup-tools/find-facility-information