Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

July 11, 2016

DEPARTMENT MEMORANDUM
No: 2016- 0116-A

TO: **DOH BUREAUS, REGIONAL OFFICES, DOH RETAINED HOSPITALS AND ATTACHED AGENCIES, UNITS AND TEAMS DESIGNATED TO WORK FOR THE PREVENTION AND CONTROL OF ZIKA VIRUS IN THE COMMUNITY**

SUBJECT: **Amendment to Department Memorandum No. 2016-0116 dated February 22, 2016 entitled "Technical Guidelines, Standards and other Instructions for Reference in the Implementation of Zika Virus (ZIKV) Disease Surveillance"**

Department Memorandum No. 2016-0116 dated February 22, 2016 entitled "Technical Guidelines, Standards and other Instructions for Reference in the Implementation of Zika Virus (ZIKV) Disease Surveillance" is hereby amended to replace the attachment in the Interim Guidelines on the Zika Virus (ZIKV) Disease Surveillance.

As thus amended, all other provisions in the Department Memorandum No. 2016-0116 dated February 22, 2016 not amended shall remain in full force and effect.

By Authority of the Secretary of Health:

GERARDO V. BAYUGO, MD, MPH, CESO III
OIC- Undersecretary of Health
Office for Technical Services

INTERIM GUIDELINES NO. 2
INTERIM GUIDELINES ON THE ZIKA VIRUS (ZIKV) DISEASE SURVEILLANCE

This set of guidelines is issued as reference for all participating health agencies and their local counterparts to enable the public to cooperate and participate to strengthen Zika Virus (ZIKV) Disease Surveillance.

I. Introduction

Zika virus disease is a mosquito-borne viral infection caused by the Zika flavivirus that is transmitted to people through the bite of infected *Aedes* mosquitoes such as *Aedes aegypti*, and *Aedes albopictus*, similar vectors of Dengue and Chikungunya virus. The virus has a high potential to spread to countries where *Aedes* mosquitoes are present.

Based on WHO report on Zika in April 2016, between January 2007 and 13 April 2016, there are already 64 countries and territories that reported local transmission of Zika. Forty-two (42) countries have reported their first outbreak since 2015 with no prior evidence of virus circulation. Seventeen (17) countries have reported virus transmission before 2015, with or without ongoing transmission. Six (6) countries have reported evidence of person-to-person transmission of the virus.

The recent cluster of microcephaly cases and reports of neurological disorders in Brazil, following a similar cluster in French Polynesia in 2014, was enough to prompt the World Health Organization to declare Zika Virus (ZIKV) Disease a **Public Health Emergency of International Concern (PHEIC)** on February 1, 2016.

Based on observational, cohort and case-control studies, there is a strong scientific consensus that Zika virus causes of GBS (Guillain-Barre syndrome), microcephaly and other neurological disorders. As recommended by the Pan American Health Association (PAHO) and World Health Organization (WHO), ZIKV Disease Surveillance should be set up based on the existing surveillance system for dengue and chikungunya, while taking the differences in clinical presentation into account. Noting the epidemiological situation, surveillance should be focused to (i) determine if the Zika virus has been introduced to an area; (ii) monitor the spread of Zika virus infection once it is introduced, and (iii) monitor for neurological and autoimmune complications.

Thus, the Epidemiology Bureau (EB) of the Department of Health shall now classify Zika Virus Disease as **Category 2 classification which is weekly reportable** under the Philippine Integrated Disease Surveillance and Response (PIDSR) system.

II. General Principles

1. This surveillance aims to prevent and detect impending outbreaks caused by Zika virus which includes determining the transmission dynamics of the virus, the specific population infected, and geographic areas affected.
2. Neurological complications of ZIKV is relatively unknown, thus, the need for close monitoring.
3. Confirmation using laboratory testing is essential to rule out other etiologic agents, thus, appropriate samples from suspected cases shall be collected and sent for laboratory confirmation.
4. Collection of appropriate vector parameters to determine mosquito activity is pertinent to know the transmission dynamics of the virus.

III. Objectives

1. To monitor the introduction and spread of Zika virus in the country.
2. To describe the epidemiological, virological and clinical characteristics of Zika virus.
3. To establish mechanism for coordination among existing surveillance system in terms of case detection, confirmation, validation, investigation, reporting and feedback for ZIKV Disease Surveillance.

IV. Implementing Guidelines

1. All suspected cases of Zika virus disease shall be **reported weekly** and all confirmed cases of Zika virus disease shall be reported within **24 hours** to the Epidemiology Bureau.
2. All Disease Reporting Units (DRUs) shall collect appropriate specimens for laboratory confirmation and send them to the Research Institute for Tropical Medicine (RITM) and subnational laboratories (SNL) using the transport and packaging arrangements described in Annex C.

V. Core Surveillance Activities

1. Case Detection, Notification, and Reporting

   1.1. Disease Surveillance Coordinators (DSCs), Disease Surveillance Officers (DSOs) and Disease Reporting Advocates (DRAs) shall report suspected Zika virus disease using the usual means of reporting. (Annex B).

   1.2. Reporting of Zika virus disease shall follow the described flow of notification for weekly reporting of notifiable disease in PIDSR (Annex A)

2. Case Definition for Zika Virus Disease

All cases of Zika Virus Infection shall be reported and investigated using the standard case definition for Zika Virus Disease such as:

2.1 Suspected case

A. A patient with skin rash and one of the following:
- Fever (measured (<38.5°C) or reported history of fever within the past 5 days prior to consultation)
- Arthralgia
- Arthritis
- Conjunctivitis

B. A mother whose fetus, newborn or infant has any neurological condition listed below that cannot be explained by other etiologies:
- Head circumference less than the -3 Standard Deviation (<-3SD) or occipitofrontal circumference less than the 3rd percentile on standard growth charts OR
- Disproportionately small head compared to infant's length, OR
- Intra-cranial calcifications

C. A fetus, newborn or infant whose mother had confirmed or presumed infection with Zika virus during pregnancy.

D. All newly diagnosed Guillain-Barre syndrome (GBS)

2.2 Probable case

A suspected case with Zika virus who tested positive for IgM serology for Zika virus.

2.3 Confirmed case

A suspected or probable case of ZIKV virus (ZIKV) who tested positive in:
- Real-time PCR (Polymerase Chain Reaction) or
- Virus isolation in any body fluid

3. Laboratory Testing

3.1. All DRUs shall facilitate the collection, storage, and transport of specimen from suspected cases in coordination with the respective RESUs.

3.2. Real-time PCR assay for ZIKV shall be used for testing. However, antibody assay may also be performed once it is available. (Annex C for types of samples to be collected for ZIKV testing.)

3.3. Only samples with accompanying Case Investigation Form shall be processed. (Annex B)

4. Feedback

4.1. Disease surveillance coordinators shall implement and exercise zero case reporting and submit it to the next higher level even if there is no case found in their respective DRUs.
4.2. Research Institute for Tropical Medicine (RITM) shall provide the laboratory results electronically to the Epidemiology Bureau (EB), Disease Prevention and Control Bureau (DPCB), and respective RESU in a form of a transmittal within 48 hours after the receipt of the sample or as indicated by the Secretary of Health.
4.3. SNLs shall report to RITM and EB simultaneously using the prescribed reporting system.

VI. Roles and Responsibilities of the Concerened Offices

Concerned Offices, bureaus, and units have the following roles and responsibilities:

A. Epidemiology Bureau

1. Assess all reported epidemics within 48 hours.
2. Provide support through provision of specialized technical staff and logistics assistance during epidemic investigation and response.
3. Ensure effective networking with other relevant government agencies at the national and local levels.
4. Ensure direct operational link with senior health and other officials at the national and local levels to rapidly approve and implement containment and control measures.
5. Provide guidelines and training on case detection, confirmation, validation, investigation, reporting, and feedback on ZIKV Disease Surveillance.

B. Disease Control and Prevention Bureau

1. Provide updates, technical advice, and recommendations on the recognition, prevention, and control of Zika Virus Disease.
2. Develop and implement the integrated national epidemic preparedness and response plan.
3. Organize the DOH Management Committee for the Prevention and Control of Emerging and Re-emerging Infectious Diseases.
4. Determine rapidly the control measures required to prevent domestic and international spread of disease.

C. *Research Institute for Tropical Medicine (RITM)*

C.1 As the National Reference Laboratory for Dengue and other arboviruses:

1. Provide guidelines and training on the proper collection, handling, transport and storage of specimens.
2. Provide laboratory results to EB, DPCB, and RESU within 48 hours upon receipt of the samples or as directed by the Secretary of Health.
3. Provide technical assistance to the SNLs for ZIKV testing.
4. Oversee quality assurance of SNLs and other laboratories doing ZKV testing.

C. 2 As National Referral Center for Emerging and Re-emerging Diseases:

1. Provide assistance on formulation of clinical management guidelines on Zika Virus Infection.
2. Provide technical assistance to EB, DPCB and RESU on surveillance and outbreak response, prevention and control measures.

D. *DOH Regional Offices*

1. Provide assistance (e.g., technical, logistics, and laboratory analysis of samples) to supplement local epidemic investigations and control.
2. Establish, operate, and maintain a regional epidemic preparedness and response plan, including the creation of multidisciplinary teams to respond to events that may constitute a public health emergency of local and international concern.
3. Assess reported epidemics immediately and report all essential information to DOH Central Office.
4. Ensure networking with other regional government agencies.
5. Provide technical and logistical assistance in the establishment of ESUs at the provincial/city/municipal health offices.
6. Ensure the functionality of the Regional Disease Surveillance and Response System.

E. *Other Laboratory Facilities doing Zika Testing*

1. Report all positive cases to EB for investigation of cases using standard case report form.
2. Coordinate with RITM using the referral mechanism for samples
   2.1. First 50-100 samples regardless of result shall be sent to RITM for confirmatory testing
   2.2. Send samples to RITM composed of the following: 100% of Zika-positive and 10% of Zika-negative samples per month thereafter, until expected concordance rate has been met as deemed by RITM National Reference Laboratory following the approved guidelines on transport and packaging system. (Annex C)

F. Local Government Units

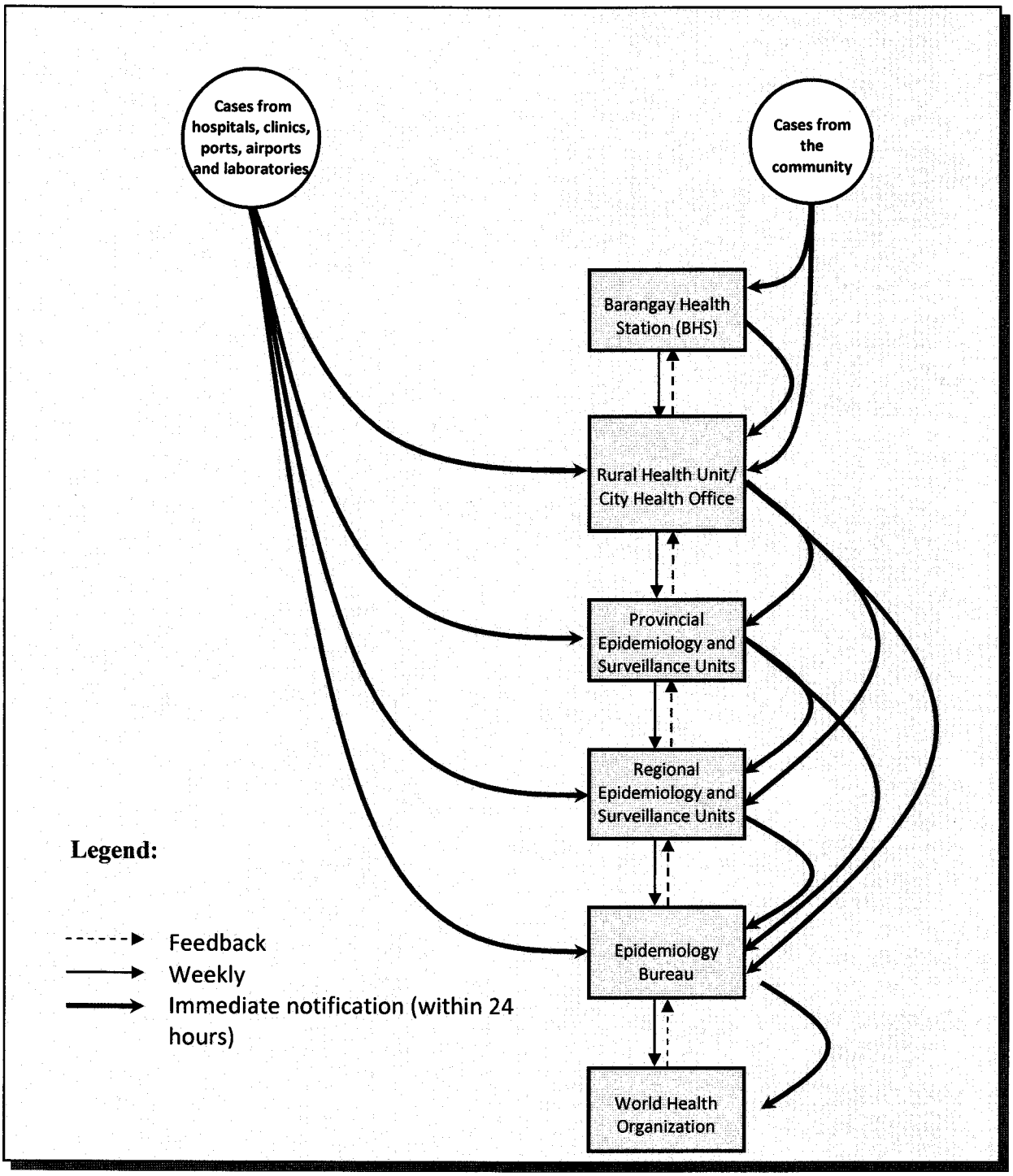
F.1 Provincial Health Office

1. Collect, organize, analyze and interpret surveillance data in their respective areas through their respective ESUs.
2. Report all available essential information (e.g., clinical description, laboratory results, numbers of human cases and deaths, sources and type of risk) immediately to RO and EB.
3. Verify and investigate reported Zika Virus Disease cases, clustering or epidemics immediately and report all essential information to their respective Regional Offices and DOH central office.
4. Provide assistance (e.g., technical, logistics, and laboratory analysis of samples) as requested to supplement local epidemic investigations and control.

F.2 Municipal/City Health Office

1. Collect, organize, analyze and interpret surveillance data in their respective areas.
2. Report all available essential information (e.g., clinical description, laboratory results, numbers of human cases and deaths, sources and type of risk) immediately to PHO, RO, and EB.
3. Implement appropriate epidemic control measures immediately.
4. Establish, operate and maintain a municipal/city epidemic preparedness and response plan, including the creation of multidisciplinary teams to respond to events that may constitute a public health emergency.
5. Facilitate submission of immediately/weekly notifiable disease surveillance reports from public and private hospitals.

Annex A. Flow of Notification for Notifiable Diseases, Syndromes, and Events



Philippine Integrated Disease Surveillance and Response

Annex B. Case Investigation Form
Zika Virus Disease
(ICD 10 Code: U06.9)

Version 2016

Region/Province/Municipality	Type: ☐ Public Hospital ☐Private Hospital
Name of Disease Reporting Unit:	Patient No. _____

Date Admission:	MM	DD	YY	Name of the Investigator	
Date of Investigation:	MM	DD	YY	Email Address:	Contact Nos.:

I. PATIENT INFORMATION

Last Name _____ First Name _____ Middle Name _____

Address: _____

Occupation: _____

Name of Workplace/School: _____

Date of Birth: ___/___/___ MM/DD/YYYY

Age: _____ Sex:

☐ Days ☐ Female
☐ Months ☐ Male
☐ Years

Contact Number: _____

II. CLINICAL DATA

Clinical Features	Y	N	Date of Onset MM / DD/ YYYY	Clinical features	Y	N	Date of Onset MM / DD/ YYYY
Fever*	☐	☐	___/___/___	Tingling sensations in the legs*	☐	☐	___/___/___
Skin Rash	☐	☐	___/___/___	Paralysis*	☐	☐	___/___/___
Myalgia*	☐	☐	___/___/___	Seizures	☐	☐	___/___/___
Asthenia (generalized weakness)*	☐	☐	___/___/___	Back Pain	☐	☐	___/___/___
Arthralgia*	☐	☐	___/___/___	Non-purulent Conjunctivitis	☐	☐	___/___/___
Arthralgia (joint pain) – Circle/list joints involved: Hand: R | L Wrist R | L Foot: R | L Ankle: R | L				Retro-orbital Pain			
Lower Limb Edema	☐	☐	___/___/___	Abdominal Pain	☐	☐	___/___/___
Periarticular Edema	☐	☐	___/___/___	Diarrhea*	☐	☐	___/___/___
Headache	☐	☐	___/___/___	Others (specify)			

Check the patient for signs and symptoms of Acute Flaccid Paralysis and Guillain-Barré Syndrome

III. EXPOSURE AND TRAVEL HISTORY

	Y	N	Date MM / DD/ YYYY	Details
1. Has the patient travelled to a Zika fever endemic/epidemic area* within the past 2 weeks?	☐	☐	___/___/___	
2. Has the mother travelled to a Zika fever endemic/epidemic area during pregnancy?	☐	☐	___/___/___	
3. Has the patient had sexual contact with a Zika fever case within the past 2 weeks?	☐	☐	___/___/___	
4. Has the patient received blood or blood products within the previous 30 days prior to symptom onset?	☐	☐	___/___/___	
5. Does the patient have a history of Guillain-Barre syndrome (GBS) ?	☐	☐	___/___/___	

Places Visited:	Any Fever? Y/N		Arrival MM / DD/ YYYY	Departure MM / DD/ YYYY	Received Treatment? Y/N		Specify:
1.	☐	☐	___/___/___	___/___/___	☐	☐	
2.	☐	☐	___/___/___	___/___/___	☐	☐	

Countries and Territories with reported confirmed autochthonous cases of Zika Virus infection in the past nine months

American Samoa, Aruba, Barbados, Bolivia, Bonaire, Brazil, Cape Verde, Colombia, Costa Rica, Curacao, Dominican Republic, Ecuador, El Salvador, Fiji, French Guiana, Guadeloupe, Guatemala, Guyana, Haiti, Honduras, Jamaica, Maldives, Marshall Islands, Martinique, Mexico, New Caledonia (France), Nicaragua, Panama, Paraguay, Puerto Rico, Philippines, Saint Martin, Saint Vincent and the Grenadines, Samoa, Saint Maarten, Solomon Islands, Suriname, Thailand, Tonga, Trinidad and Tobago, Vanuatu, Venezuela ,US Virgin Islands

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Annex B. Case Investigation Form
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Version 2016

IV. INFANT/FETAL INFORMATION (For Microcephaly and Pregnant Mothers)

Anthropometric Measurement		Y	N	Remarks
Type of birth ☐ Livebirth ☐ Stillbirth ☐ Fetus less than 20 weeks gestation	**Neonate/infant abnormalities (specify)**			
	a. Head circumference at birth (in centimeters)			
	b. Head circumference at birth < third percentile	☐	☐	
Length:	c. Head circumference 24 hours after birth: (in centimeters, to one decimal point)			
Birth weight:				
Chest Circumference:				
Apgar Score:	d. Head circumference 24 hours after birth < third percentile	☐	☐	
Ballard Score:				
Age of Gestation (AOG):	e. Result of neuroimaging study (brain echography; MRI; CT): (with/without findings)	☐	☐	
Birth Complications ☐ Respiratory Distress ☐ Sepsis ☐ Meningitis ☐ Others_____ Contact number: _____	f. Does the newborn present any other congenital abnormality?	☐	☐	
	g. In the case of a stillbirth or live newborn that dies within the first hours after birth: Was an autopsy performed?	☐	☐	

Maternal Information

_____
Last Name First Name Middle Name

Address: _____

Attending Physician's/health Care Provider's Name: _____

Contact number: _____

Age: _____

Date of Birth: ___/___/___ MM/DD/YYYY

Date of last menstrual period: ___/___/___MM/DD/YYYY

Estimated Date of Delivery: ___/___/___MM/DD/YYYY

Health History

Gravidity:_____ Parity:_____

☐ Smoking
No. of sticks/packs per day_____
☐ Heart Disease
☐ Stroke
☐ Obesity
☐ Malnutrition
☐ Drug Abuse
☐ Alcohol
No. of bottles consumed per day_____
☐ Medications_____
☐ Exposure to mercury
If Yes, give details_____

☐ Others *(please specify)*: _____

Chronic and Acute Conditions During Pregnancy

☐ Diabetes
☐ Type 1 ☐ Type 2

☐ Epilepsy
Years_____ Medications:_____

☐ Infections *(please specify)*: _____
Year acquired:_____

Others *(please specify)*: _____

Pregnancy Complications:

☐ Placental Abruption
☐ Ectopic Pregnancy
☐ Preterm Labor
☐ Gestational Diabetes:

Prenatal Testing

	Date Tested MM / DD/ YYYY	Results Received MM / DD/ YYYY	Findings:
1. Ultrasound	___/___/___	___/___/___	
2. Amniocentesis	___/___/___	___/___/___	
3. Glucose Tolerance Test	___/___/___	___/___/___	
4. Hepatitis	___/___/___	___/___/___	
5. Others	___/___/___	___/___/___	

Philippine Integrated Disease Surveillance and Response

Annex B Case Investigation Form
Zika Virus Disease
(ICD 10 Code: U06.9)

Version 2016

V. LABORATORY INFORMATION

Sample Type	Date Collected MM / DD/ YYYY	Date sent to testing lab MM / DD/ YYYY	Date received in Lab MM / DD/ YYYY	Test Done	Results
Blood (Acute phase)	__/__/__	__/__/__	__/__/__		
Blood (Convalescent phase)	__/__/__	__/__/__	__/__/__		
CSF	__/__/__	__/__/__	__/__/__		
Amniotic Fluid samples (For pregnant women with fetal microcephaly)	__/__/__	__/__/__	__/__/__		
Cord Blood	__/__/__	__/__/__	__/__/__		
Placenta	__/__/__	__/__/__	__/__/__		
Urine	__/__/__	__/__/__	__/__/__		
NPS/OPS					

VI. DIAGNOSTIC INFORMATION

Neuro-imaging study	Date Performed MM / DD/ YYYY	Date Received MM / DD/ YYYY	Result
1. Cranial Ultrasound	__/__/__	__/__/__	
2. CT Scan	__/__/__	__/__/__	
3. MRI Scan	__/__/__	__/__/__	
4. Others _____			

VII. OUTCOME

☐ Alive	☐ Died
Date Discharged: __/__/__ MM/DD/YYYY	*Date Died:* __/__/__ MM/DD/YYYY

VIII. FINAL CASE CLASSIFICATION:

Suspected Case	Confirmed Case	Discarded Case
☐ Imported	☐ Imported	☐ Yes
☐ Autochthonous	☐ Autochthonous	☐ No

Annex C. Guidelines in Specimen Collection, Storage, Handling and Transport

I. Routine Surveillance

A. Types of Samples for ZIKV Testing (See Table 1 for summary):

1. Paired blood samples- acute phase and convalescent phase
2. Amniotic fluid
3. Cord Blood
4. Fresh frozen and formalin-fixed paraffin-embedded tissue blocks from placenta, which includes umbilical cord, placenta, and placental membrane
5. Urine
6. Cerebrospinal Fluid (CSF)
7. Nasopharyngeal Swab/ Oropharyngeal swab (NPS/OPS)

B. Storage and Transport

1. Label the sample container with patient's name, EPIID, age, type of specimen, and date of collection
2. Store the samples in 2 to 8°C or in refrigerator temperature until shipment
3. Place the sample container into a sealable plastic bag or pouches containing absorbent materials such as cotton to soak up any leakage that may occur
4. Seal the CIF in a separate plastic bag and enclose within the shipping box
5. Place the specimens in the transport box with frozen ice packs no less than 6 pieces fitted around the specimens

II. Outbreak Investigation

A. Specimen Type and Timing of Collection

1. Serum-Acute Phase: Collect samples from **50-100** of the suspected cases with onset of symptoms of not more than 5 days from date of collection. This is to ensure that the virus is detectable.
2. Serum-Convalescent Phase: Collect samples from **50-100** of suspected cases with onset of symptoms of more than 7 days from date of collection. This is to be used for antibody testing once it becomes available.
3. NPS/OPS: Collect if highly suspicious of measles or rubella or collect from cases with onset of symptoms of not more than 5 days (less than 5 days) from date of collection. This is to ensure that the virus is detectable

B. Storage and Transport

1. Label the cryovial or UTM with patient's name, EPIID, age, type of specimen, and date of collection
2. Store the samples in 2 to 8°C or in refrigerator temperature until shipment
3. Place the cryovial or the UTM into a sealable plastic bag or pouches containing absorbent materials such as cotton to soak up any leakage that may occur.
4. The CIF shall be sealed in a separate plastic bag and enclosed within the shipping box
5. Place the specimens in the transport box with frozen ice packs no less than 6 pieces fitted around the specimens

Address the shipment to:

AMADO O. TANDOC, MD
Head of Virology Department
Research Institute for Tropical Medicine
9002 Research Drive, Filinvest Corporate City Compound
Alabang, Muntinlupa City, 1781
Telefax Number: (02) 809-7120

Table 1. Summary of Specimen Collection, Storage, and Transport

Sample Type	Timing of Collection	Conditions	Quantity	Storage	Transport
*Blood- Acute Phase	Within 5 days after onset of symptoms	For general population	5 ml	Refrigerator, 2 to 8°C	Transport within 48 hours/ 2 days after collection
*Blood- Convalescent Phase	After 7 days from onset of symptoms	For general population	5 ml	Refrigerator, 2 to 8°C	Transport within 48 hours/ 2 days after collection
*Urine	5 to 10 days after onset of symptoms	If blood collection is not feasible	5 ml	Refrigerator, 2 to 8°C	Transport within 48 hours/ 2 days after collection
Amniotic Fluid	≥ 15 gestational weeks	For pregnant suspected case	1 ml	Refrigerator, 2 to 8°C	Transport within 48 hours/ 2 days after collection
Placenta (include umbilical cord, placenta, and placental membrane)	Immediately after birth	For new born infant of suspected mother	2 Fresh Frozen Paraffin Embedded cassette blocks AND 2 Formalin-fixed Paraffin Embedded cassette blocks	Room temperature	Transport within 3 days after collection
Cord Blood	Immediately after birth	For new born infant of suspected mother	5 ml	Refrigerator, 2 to 8°C	Transport within 48 hours/ 2 days after collection
CSF	Upon first contact or when possible	If with CNS manifestations	1 ml	Refrigerator, 2 to 8°C	Transport within 48 hours/ 2 days after collection
NPS/OPS	Collect within 5 days after onset when suspecting for Measles or Rubella	If suspected for Measles or Rubella	1 VTM or UTM	Refrigerator, 2 to 8°C	Transport within 3 days after collection

*** Primary sample of choice and should be paired**

Annex D. Glossary

1. Cluster - refers to the aggregation of relatively uncommon events or diseases in space and/or time in magnitude that is believed or perceived to be greater than could be expected by chance

2. Epidemiology and Surveillance Unit - refers to the unit established in the DOH Regional Offices, Provincial Health Offices (PHO), City Health Offices (CHO) and Rural Health Units (RHU) that provides services on public health surveillance and epidemiology

3. Disease Reporting Unit (DRU) - refers to any health facility where cases of notifiable diseases are identified and reported (e.g., hospitals, clinics, MHOs, CHOs, Barangay Health Stations [BHS], community, Quarantine Stations)

4. Disease Surveillance Officer (DSO) - refers to a fulltime staff of the Epidemiology and Surveillance Unit (ESU) of the CHOs (chartered cities), MHOs, PHOs and ROs who has received training on basic epidemiology, public health surveillance and PIDSR with an official designation as disease surveillance officer by the head of office. Ideally, a DSO should either be a physician or a nurse

5. Disease Surveillance Coordinator (DSC) – refers to staff of government and non-government health facilities (e.g. hospitals, clinic, RHUs) who have received training on PIDSR with an official designation as disease surveillance coordinator by the head of the facility

6. Disease Reporting Advocate (DRA) – refers to health workers and other individuals (e.g. community leaders, private practitioners) who have attended orientation on PIDSR and are committed to actively participate in reporting cases

7. Endemic - infection is maintained in the population without the need for external inputs

8. Epidemic - refers to the occurrence in a community or region of cases of an illness, specific health-related behavior, or other health-related events clearly in excess of normal expectancy

9. Risk Assessment - the process to identify potential hazards and analyze what could happen if a hazard occurs