



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

DEC 21 2016

ADMINISTRATIVE ORDER

No. 2016 - 0043

SUBJECT: Guidelines for the Nationwide Implementation of Dengue Rapid Diagnostic Test (RDT)

I. RATIONALE

The Philippines ranked first in the Western Pacific Region among countries with most number of dengue cases from 2013 to 2015. A total of 200,415 suspected dengue cases and 598 deaths were reported nationwide in 2015. There is no specific medicine against dengue and treatment for dengue involves supportive measures such as fluid management and monitoring of warning signs. Early detection and prompt management are very critical. Mortality rate is reduced to <1% as compared to 20% death rate if proper management is initiated early (WHO, 2016).

The introduction of the Rapid Diagnostic Test (RDT) for Dengue Non-Structural protein 1 (NS1) antigen, complements the overarching 4S Strategy of the National Dengue Prevention and Control Program specifically in seeking early consultation. The 4S Strategy includes: Search and Destroy, Seek Early Consultation, Self-Protection Measures and Saying Yes to fogging when there is an impending outbreak. Through the Dengue NS1 RDT, test results are produced within the day making early detection, prompt treatment and timely referral possible.

The early recognition of dengue through clinical examination, complemented with a simple and rapid diagnostic tool is the cornerstone of its early diagnosis. Hence, the introduction and adoption of Dengue NS1 RDT by the National Dengue Prevention and Control Program shall upgrade our existing facilities at the point-of-care and strengthen the diagnosis and management capabilities of our Rural Health Units.

II. OBJECTIVE

This issuance shall provide technical and procedural guidelines on the nationwide implementation of Rapid Diagnostic Test at the Rural Health Units (RHUs) and other point of care.

III. SCOPE

This issuance shall apply to the DOH - Central Office, Regional Offices, DOH – ARMM, Philippine Health Insurance Corporation and Rural Health Units.

IV. DEFINITION OF TERMS:

1. **Rapid Diagnostic Test (RDT)** – a collection of reagents and other materials for in-vitro diagnostics, intended to be used for the detection of either antigen or antibody from clinical samples, usually blood, within a shorter period.
2. **Dengue Non-Structural protein 1 (NS1) RDT**- is an immuno-chromatography based test used to detect the Dengue virus non-structural protein 1 antigen in human serum, plasma, or whole blood to suggest acute Dengue infection.

3. **Suspected Dengue Case-** a person with an acute febrile illness of 2-7 days duration with 2 or more of the following: headache, body malaise, retro-orbital pain, myalgia, arthralgia, anorexia, nausea, vomiting, diarrhea, flushed skin, rash (petechial, Hermann's sign). (*Refer to PIDSAR Manual of Procedures, 3rd Edition 2014*).
4. **Probable Dengue Case-** a suspected case and with a laboratory test result of at least CBC with leucopenia with or without thrombocytopenia and/or a positive Dengue NS1 antigen test or dengue IgM antibody test. (*Refer to PIDSAR Manual of Procedures, 3rd Edition 2014*).
5. **Confirmed Dengue Case-** a suspected case with positive result for viral culture isolation, and/or Polymerase Chain Reaction (PCR). (*Refer to PIDSAR Manual of Procedures, 3rd Edition 2014*).

V. GENERAL GUIDELINES

1. Aligned with the Dengue Program 4S strategy of "Seeking Early Consultation", a suspected dengue case shall be eligible for Dengue NS1 RDT test if the signs and/or symptoms manifest between day one and day five of the illness. THE DENGUE NS1 RDT SHALL NOT BE USED TO A PATIENT BEYOND FIVE DAYS OF ILLNESS.
2. Dengue NS1 RDT shall be used in support for the clinical diagnosis of suspected dengue. However, it shall not be the sole basis for the final diagnosis of dengue. (RT-PCR, Hemagglutination Inhibition test and virus isolation remain to be the "confirmatory test" for the detection of dengue virus in human blood.)
3. Dengue NS1 RDT shall be performed by a health care worker, such as medical technologist, nurse, midwife, barangay health worker (BHW), and other health professional who has undergone appropriate training on its use.
4. The performance of Dengue NS1 RDT shall be supported by a quality assurance system.

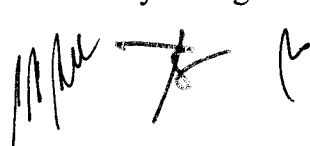


VI. SPECIFIC GUIDELINES

A. Screening and Early Diagnosis of Patient

1. An initial assessment of a suspected dengue case based on history of illness and physical examination shall be guided by AO 2012-0006: Revised Dengue Clinical Case Management Guidelines 2011 prior to using dengue NS1 RDT. (*Refer to Annex 1: Guide in the Initial Assessment of Suspected Dengue Case.*) The Dengue NS1 RDT shall only be performed to a patient who fits the criteria of a SUSPECTED DENGUE CASE.
2. Serum, plasma or whole blood specimen shall be used for Dengue NS1 RDT. Capillary blood shall be used if the health facility has limited laboratory equipment or there is no medical technologist available to perform the venipuncture.
3. A positive result shall be defined as probable dengue case. However, a negative result does not rule out Dengue infection and therefore shall be correlated with the clinical information of the patient. The health provider shall rule out a window or convalescence period, wherein the virus may no longer be detected and antibody titer starts to rise. In this case, other laboratory tests may be performed.

B. Performing the Test

1. Specimen from the capillary blood may be obtained from a finger prick. (*Refer to Annex 2: Methods for Collecting Specimen.*)
2. The dengue NS1 RDT shall be performed and the result shall be made available during the time of consultation. It shall observe the same day testing and releasing of result.

C. Recording and Reporting

1. All positive results shall be recorded as PROBABLE DENGUE CASE, while negative cases shall be recorded as SUSPECTED DENGUE CASE and shall be reported using the PIDS Case Report Form (CRF) (Refer to Annex 4). Those with invalid interpretation after the second test shall still be recorded as SUSPECTED DENGUE CASE.
2. For interpretation of invalid results, the test shall be repeated on the same day when the first test is done. The result of the second test shall be used as basis of the final interpretation. Two invalid results shall still be classified as SUSPECTED DENGUE CASE and shall be managed accordingly.
3. The frequency for reporting shall follow the PIDS reporting system.

D. Quality Assurance Program

1. Lot Testing
 - a. Pre-shipment lot testing:
RITM shall subject fifteen percent (15%) of RDT kits to evaluation prior to shipment to health facilities.
 - b. Post-shipment lot testing:
RITM shall evaluate the RDT kits sent to three selected health facilities and then returned to RITM.
 - c. Report of the pre-shipment and post shipment testing shall be available after 2 weeks of receipt of the RDT kits.
2. External Quality Assurance
 - a. RITM shall conduct a proficiency testing to health facilities at least every two years.
 - b. Health facility passing the EQA shall receive a certificate valid for 2 years.
 - c. Health facility that will not pass the EQA shall subject to onsite assessment, retraining, and close monitoring of performance until all recommendations are satisfactorily met.
3. Validation
 - a. RITM and DPCB shall select 50 health facilities to send samples for validation.
 - b. Selected health facility shall store one sample per week collected from the agreed day and shall be sent to RITM on a quarterly basis.
 - c. RITM shall perform testing of these samples.

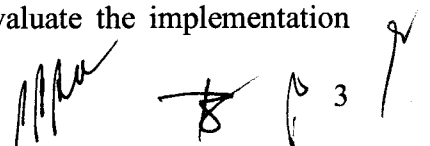
VII. ROLES AND RESPONSIBILITIES

A. Department of Health (DOH)

1. Disease Prevention and Control Bureau (DPCB)

The DOH-DPCB shall be responsible for the overall execution of the policy and guidelines on the introduction of Dengue Rapid Diagnostic Test (RDT) for the early diagnosis of dengue infection at the point of care level. The DPCB shall undertake the following tasks:

- a) Lead in the formulation and dissemination of policy and guidelines for the use of dengue RDT;
- b) Facilitate the orientation and/or training of concerned Regional Offices;
- c) Oversee the procurement and distribution of dengue RDT supplies from the central to the peripheral health units. Ensure that the supplies are stored at room temperature not exceeding 30°C;
- d) Provide funds and coordinate with RITM for the quality assurance system of the dengue RDT kits; and
- e) Coordinate with EB for the data about dengue cases specifically on the PROBABLE DENGUE CASES. Monitor and evaluate the implementation

 3

jointly with the region and provincial/city/municipal health offices and concerned technical partners.

2. Research Institute for Tropical Medicine (RITM)

- a) Provide technical assistance for the implementation of the RDT testing in the following areas: training on proper collection, handling, transport and storage of specimens and kits; testing; and reporting of results.
- b) Perform lot testing of RDTs pre and post shipment.
- c) Provide proficiency panel to serve as EQAS to health facilities.
- d) Provide feedback and recommendations on the performance of RDT and health facilities to DPCB.

3. Epidemiology Bureau (EB)

- a) Provide accurate, timely and complete data as basis for program use such as policy decisions, strategic directions and prioritization of resources;
- b) Enhance the current PIDSIR dengue case definition to include reporting of PROBABLE DENGUE CASE based on the result of the dengue RDT and reporting form; and
- c) Strengthen reporting of dengue cases at the RHU level using the PIDSIR reporting system.

4. PhilHealth

- a) Review as necessary the dengue benefit package to include dengue RDT result as one of the basis of claim both in public and in private sectors.

5. Department of Health Regional Offices (DOH-RO)

- a) Ensure the dissemination, orientation and/or training of the Regional Office staff on the dengue RDT implementation policy and guidelines for its adoption and implementation in different localities within their respective regions;
- b) Integrate the monitoring of dengue RDT implementation in their existing monitoring teams;
- c) Ensure the availability and continuous supply of dengue RDT kits at the RHUs for their regular provision of dengue services;
- d) Strengthen existing communication/advocacy plans to continuously promote the 4S Laban sa Dengue Strategy alongside with the use of dengue RDT;
- e) Support and ensure the implementation of the quality assurance system for dengue RDT; and
- f) Ensure timely submission of dengue report using PIDSIR reporting system including dengue RDT data.

B. Local Government Units

1. Provincial/City/Municipal Health Office (P/C/MHO)

- a) Strengthen existing communication/advocacy plans to continuously promote the 4S Laban sa Dengue Strategy alongside with the use of dengue RDT;
- b) Conduct orientation/training of concerned staff on the use of dengue RDT;
- c) Advocate with municipalities/cities to adopt and support the use of dengue RDT;
- d) Support the quality assurance system of dengue RDT; and
- e) Provide weekly report to the region using the PIDSIR reporting system.

2. Rural Health Units (RHUs)

- a) Strengthen existing communication/advocacy plans to continuously promote the 4S Laban sa Dengue Strategy alongside with the use of dengue RDT;

- b) Implement the use of dengue RDT for screening and early diagnosis of dengue cases;
- c) Ensure proper storage of dengue RDT kits to ensure longer shelf life; and
- d) Ensure timely submission of dengue report using PIDSR reporting system including dengue RDT data.

VIII. REPEALING CLAUSE

No previous Orders inconsistent in part or in whole to this Administrative Order are being rescinded or amended.

IX. EFFECTIVITY

This Order shall take effect immediately.


PAULYN JEAN B. ROSELL-UBIAL, MD, MPH, CESO II
Secretary of Health

ANNEXES

Annex 1. Guide in the Initial Assessment of a Suspected Dengue Case (Please refer to Administrative Order No. 2012-0006)

Include both with warning and without warning signs as per AO No. 2012-0006

Patient history should include:	<ul style="list-style-type: none">• Date of onset of fever/illness• Quantity of oral intake• Assessment of dengue “warning signs”• Diarrhea• Seizures, impaired consciousness, behavioral changes• Urine output (frequency, volume and time of last voiding)• Other important relevant histories:<ul style="list-style-type: none">○ Family member/s or neighbors with dengue, or travel to dengue-endemic areas○ Co-existing conditions such as infancy, pregnancy, obesity, diabetes mellitus, hypertension, etc.○ Jungle trekking and swimming in waterfall (consider leptospirosis, typhus, malaria)○ Recent unprotected sexual or drug use behavior (consider acute HIV seroconversion illness)
-------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Annex 2: Methods for Collecting Specimen

1. Serum samples
 - a. Collect 3 to 5ml of whole blood using red or yellow top tubes following the usual guidelines for venipuncture. Allow blood to clot at room temperature for 30 minutes.
 - b. Process into serum.
 - c. Aliquot at least 1ml of serum for validation testing in RITM.
2. Capillary blood samples
 - a. Collect at least 3 drops of capillary blood following the usual guidelines for capillary blood collection.
 - b. The puncture should be one quick, continuous and deliberate stroke, to achieve a good flow of blood and to prevent the need to repeat the puncture.
 - c. Wipe away the first drop of blood because it may be contaminated with tissue fluid or debris.
 - d. Avoid squeezing the finger or heel too tightly because this dilutes the specimen with tissue fluid (plasma) and increases the probability of haemolysis
 - e. Place 3 drops of blood directly onto the Dengue NS1-Ag RDT sample well.

Methods for Testing Specimen

1. PRE-ANALYTIC

- a. Bring out the Dengue NS1-Ag RDT kit from the refrigerator and equilibrate at room temperature for 30 minutes. Do not perform the test unless the kit is at room temperature (20-25 °C).
- b. Mix by vortex mixer and spin down the samples for around 10-20 seconds.
- c. Prepare the working area: place the absorbent liner with biohazard bags on top of the bench.

- d. Prepare test protocol by filling up all information and arrange samples in the same order as reflected in the testing protocol.

2. ANALYTIC

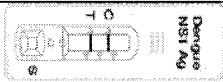

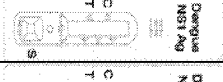

- a. Remove the cassette from the foil pouch and place it on a table just prior to use.
- b. Label the cassette with the corresponding Laboratory ID.
- c. Place 3 drops of serum or whole blood into the sample well. If using a micropipette, add 100ul of serum or whole blood.
- d. Incubate at room temperature for 20 minutes.
- e. Read the results by grading the intensity of the band as follows:

-	Absence of pink band
+/-	Faint/shadow band
+	Faint full band
++	Light pink band
+++	Pink band
++++	Dark pink band

- f. Record the reading into the protocol.
- g. A second reader is to validate the results.

3. POST ANALYTIC

- a. Results are to be interpreted as follows:

Result	Appearance	Interpretation	Recommendation
Two purple band at C and T zones		Positive	Report as Dengue NS1-Ag Positive
One purple band at C zone		Negative	Report as Dengue NS1-Ag Negative
No visible band		Invalid	Review and repeat the test. The procedures may not follow correctly or the kit has deteriorated.
One purple band at T zone		Invalid	

Specimen Handling, Transport and Storage

A. Handling and Storage of Dengue NS1-Ag RDT

1. The Dengue NS1-Ag RDT kits shall be transported at temperatures between 2-25°C.
2. The Dengue NS1-Ag RDT kits shall be stored inside a refrigerator between 2-8°C until expiration date.
3. A single pouch of RDT corresponds to the number of samples to be tested. The RDTs shall not be repeatedly taken in and out of the refrigerator to maintain its stability.

B. Storage and Transport of Serum Samples for Validation

1. Aliquots of samples stored for validation testing shall be sent to RITM following usual system of sample referral.
2. The vials shall be placed inside a resealable plastic bag and sent together with the information sheet.
3. Place the bag into the transport box with 4 to 6 frozen ice packs.

Annex 3: Dengue RDT Laboratory Request Form

To be filled out by Health Worker

Case Number: _____

Name of Collection Unit: _____ Date of Request: _____

Name of Requesting Physician: _____ Contact #: _____

Name of Patient: _____ Age: _____ Sex: ☐ M ☐ F

Address: _____ Contact #: _____

Signs and Symptoms: ☐ fever: number of days: _____ ☐ body malaise
☐ headache ☐ retro-orbital pain
☐ muscle pain ☐ anorexia
☐ joint pain ☐ vomiting
☐ diarrhea ☐ flushed skin
☐ rash ☐ others: _____

Duration of Signs & Symptoms: _____ days

Reason for Examination: ☐ Diagnosis
☐ Follow up

Type of Specimen: ☐ Venous blood, ml _____
☐ Capillary blood, ml _____

Repeat Collection? ☐ No ☐ Yes Reason: _____

Test Requested: Dengue NS1 RDT

Specimen Date Collection: _____

Name of Specimen Collector: _____ Designation: _____
Signature over Printed Name

Cut here -----

Dengue RDT Laboratory Result Form

Name of Patient: _____

Case Number: _____

Age: _____ Sex: ☐ M ☐ F

Date Received: _____

Laboratory Result:

Date of Examination: _____ Examined by: _____
Signature over Printed Name

Municipality/City: _____

Type: ☐ RU ☐ CHO ☐ Govt Hospital ☐ Private Hospital ☐ Clinic

☐ Private Laboratory ☐ Public Laboratory ☐ Seaport/Airport

9

Annex 5. Dengue NS1 RDT Registry

DENGUE NS1 RDT REGISTRY

Region: _____

Province: _____

Municipality: _____

Name of Trained Health Worker: _____

Contact Number: _____

Year: _____ Quarter: _____

No	Date of Collection/ Examination (mm-dd-yy)	Care No. (mm-dd-yy)	Dengue Suspect (Last Name, First Name, MI)	Age	Sex (M/F)	Address & Contact Number (street, barangay, municipality)	Duration of Signs & Symptoms (No. of days)	Result of NS1 RDT Positive (P) Negative (N) Indeterminate (I)	Examined by Examiner (Signature)	Case Classification Suspect (S) Probable (P) Non-dengue (ND)	Decision of Health Worker	Remarks
1.												
2.												
3.												
4.												
5.												
6.												
7.												
8.												
9.												
10.												
Total No. Positive										Total No. Dengue (suspect)		
Total No. Negative										Total No. Dengue (probable)		
Total No. Repeat Exam										Total No. Non-Dengue		

Instruction on How to Use the Dengue NS1 RDT Registry

This Dengue NS1 RDT Registry is to be filled-out properly using blue or black pen by the Medical Technologist or trained worker assigned in the facility to perform the Dengue NS1 Rapid Diagnostic Test (RDT). Positive examination result should be written in the Registry using red pen for easier identification.

1. Write down the name of region, province and municipality where the facility is located.
2. Write down the name of the person who is filling-out the form and his/her contact number.
3. Write down the quarter and year the Dengue NS1 RDT was performed. It is advisable to use a new sheet of the Registry for a different quarter.
4. Fill in columns as follows:

- Column 1:* Date of Collection/ Examination –date the specimen is collected and examined. Write date in mm/dd/yy format.
- Column 2:* Case Number- consecutive number assigned to a person as s/he comes in the facility. One person shall receive one case number only regardless of how many times he/she submitted specimens for testing. Write Case Number using the following format: year-xxxx. (ie.2016-0001, 2016-0002, and so on)
- Column 3:* Write family name first, all in capital letters, then the first name and middle initial of the patient.
- Column 4:* Age-write age in complete years as of the last birthday or months if less than one (1) year old.
- Column 5:* Sex-write F for female, write M for male.
- Column 6:* Address- write complete address of the person and his/her contact number.
- Column 7:* Duration of Signs and Symptoms- number of interval days since the first signs and symptoms appear and before the blood specimen is drawn.
- Column 8:* Result of Dengue NS1 RDT- write P for positive result, N for negative result and I for indeterminate result. Repeat test if the result is indeterminate and follow the same instructions above in writing result.
- Column 9:* Examined by-write name of the Medical Technologist or health worker who performed the test. Do not affix signature only.
- Column 10:* Case Classification-identify patient as follows:
- a. Dengue without Warning Signs
 - Suspect case- person with acute febrile illness of 2-7 days duration plus two of the following: headache, body malaise, myalgia, arthralgia, retro-orbital pain, anorexia, nausea, vomiting, diarrhea, flushed skin, rash (petechial, Herman's sign). Write S for suspect case.
 - Probable case-a suspect case with a laboratory test result positive with Dengue NS1 RDT. Write P for probable dengue case.
 - b. Non-Dengue case- a suspect case ruled out for dengue disease and becomes suspect for other diseases upon result of Dengue NS1 RDT. Write ND for Non-Dengue case.
- Column 11:* Decision of Health Worker- health worker decides on the intervention to be provided to the person after laboratory test that may include the following:

- Home Care/ Home Management. Write HC or HM.
- Refer to physician or hospital. Write Refer.
- Consider other diseases or other tests. Write other disease or other test.

Column 12: Remarks- write any remarks including but not limited to what happened to the specimen or patient (ie. repeat collection, repeat examination, rejected specimen, etc.)

**DENGUE NSI RDI
MONTHLY CONSOLIDATION REPORT FORM**

☐ Region: _____

☐ Municipality: _____

☐ Date:

Noted by: _____ Name & Signature: _____
Position: _____