Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

May 29, 2018

DEPARTMENT CIRCULAR
No. 2018- 0223

TO : **REGIONAL DIRECTORS, BUREAU DIRECTORS, HOSPITAL CHIEFS, LABORATORY OWNERS, HEAD OF LABORATORIES, REGIONAL OFFICE – REGULATION, LICENSING AND ENFORCEMENT DIVISION (RO-RLED) CHIEFS, REGULATORY OFFICERS AND OTHERS CONCERNED**

SUBJECT : **Guidelines in Securing Remote Collection Permit for Clinical Laboratories**

Section VI.B.2.i of Administrative Order (A.O.) No. 2007-0027 dated August 22, 2007, titled "Revised Rules and Regulations Governing the Licensure and Regulation of Clinical Laboratories in the Philippines", states that "Mobile clinical laboratories shall be licensed as part of the main clinical laboratory and shall be permitted to collect specimens only. It shall be allowed to operate only within one hundred (100) km radius from its main laboratory."

It has come to our attention that diagnostic procedures are being performed in non-clinical laboratory settings and conducted by unlicensed medical technologist. Since laboratory procedures are important in diagnostic decision making, it is imperative to ensure the reliability, accuracy and precision of every laboratory tests. Thus, to have quality examination reports, pre-analytical procedures such as collection, handling, and transport of specimens must be performed properly.

In view of the above, clinical laboratories conducting mobile collection shall now be required to secure a Remote Collection Permit for Clinical Laboratory (RCP-CL) from the Department of Health (DOH) through Health Facilities and Services Regulatory Bureau (HFSRB) or through the Regional Office – Regulation, Licensing, and Enforcement Division (RO-RLED) based on the following:

GUIDELINES:

1. Only DOH licensed clinical laboratories shall be allowed to apply for RCP-CL.
2. Mobile or remote collection can only be done in the following non-clinical laboratory settings such as but not limited to:
   - 2.1 Schools;
   - 2.2 Offices;
   - 2.3 Churches; and
   - 2.4 Other areas used for community based activities
3. Remote collection facility should have a proper area for specimen collection. (e.g. clean toilet for urine and stool collection)
4. Only employed Registered Medical Technologists (RMTs) of the applicant's clinical laboratory shall be allowed to collect blood samples/specimens.

5. No testing or processing of specimens shall be done in the temporary collection facility.
6. The activity at the remote facility shall only last for four (4) to six (6) hours.
7. Specimens should be properly handled and transported,
    7.1 Samples for routine urinalysis and routine fecalysis shall be stored at refrigerated temperature within one (1) hour from the time of collection.
    7.2 The serum from blood samples for chemistry must be separated within four (4) hours from the time collection.
8. The collection site shall be located within the same region, at a maximum of (100) kilometre radius, from the address of DOH licensed clinical laboratory.
9. RCP-CL shall be secured from the DOH at least seven (7) working days prior to the scheduled remote collection activity.
10. RCP-CL shall be secured from:
    10.1 HFSRB – for institution-based clinical laboratories under the one-stop shop, this includes Level 2, 3, Specialty, Medical Facilities for Overseas Workers and Seafarers (MFOWS), Ambulatory Surgical Clinic (ASC), Dialysis Clinics.
    10.2 RO-RLEDs – for Level 1 hospitals, Infirmaries, Birthing Homes, and Free-standing clinical laboratories.
11. RCP-CL shall be signed by the Director IV of HFSRB or Regional Office, or his designate.
12. The following are the documentary requirements:
    12.1 Letter of request, signed by the Head of Clinical Laboratory, to conduct remote collection with the following information:
        12.1.1 Name of facility with DOH-LTO number
        12.1.2 Address of facility
        12.1.3 Date of collection
        12.1.4 Time of collection
        12.1.5 Venue
        12.1.6 Estimated number of clients
        12.1.7 Specimen to be collected
    12.2 Notarized Memorandum of Agreement or contract between the contracting parties.
    12.3 Technical or operational procedures for remote collection including specimen handling and transportation.
    12.4 List of laboratory supplies/equipment to be used during remote collection including the transport materials.
13. A remote collection permit fee of Php500.00 for each site shall be collected from the clinical laboratory.
14. The RCP-CL shall be valid only for two (2) weeks from the date of issuance.
15. A copy of the RCP-CL shall be posted in conspicuous area of the remote collection facility.
16. The clinical laboratory shall maintain records of all remote collection performed.
17. The HFSRB or RO-RLED may inspect the remote collection site prior to the issuance of the permit or monitor during the actual collection.
18. In case of failure to conduct the collection at the specified date, the laboratory shall inform the HFSRB or RO-RLED in writing, at least within 48 hours before the scheduled date of remote collection, and shall be informed of the

new schedule which should be within the validity period. Otherwise, another RCP-CL shall be secured.

19. Home service blood collection shall be exempted from securing RCP-CL provided, that it is upon the patient's doctor request, and the area of collection must be within (1) hour travel time, under normal circumstances, from the licensed clinical laboratory. To ensure proper specimen collection and handling, provision nos. 4, 5, 7.1, and 8 of this guidelines should be followed.
20. Violations of the guidelines stated herein, and related policies or laws shall be the basis for suspension/revocation of the RCP-CL and the LTO of the main clinical laboratory.

For strict implementation.

By Authority of the Secretary of Health

ROLANDO ENRIQUE D. DOMINGO, MD, DPBO
Undersecretary of Health
Health Regulations Cluster