

1 **ADMINISTRATIVE ORDER**

2 No. 2021 - \_\_\_\_\_

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5 **SUBJECT : Amendment to the Administrative Order No. 2021-0037**  
6 **“New Rules and Regulations Governing the Regulation of**  
7 **Clinical Laboratories in the Philippines”**

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9 The Administrative Order (AO) No. 2021-0037 titled “*New Rules and Regulations*  
10 *Governing the Regulation of Clinical Laboratories in the Philippines,*” issued on June 11,  
11 2021, is hereby amended as follows:

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15 **IV. DEFINITION OF TERMS**

16 Under Section L.

17 L. Point of Care Testing (POCT) — refers to diagnostic testing done at or near the site  
18 of patient care rather than in the CL. It may be in the emergency room, operating  
19 suites, wards, and ambulances.

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21 **The aforementioned is hereby amended to read as follows:**

22 **L. Point of Care Testing (POCT) — refers to diagnostic testing, involving all the**  
23 **procedures (pre-analytical, analytical, post-analytical), done at or near the site**  
24 **of patient care rather than in the CL. It may be in the emergency room,**  
25 **operating suites, wards, ambulances, and other clinical areas within the**  
26 **premises of the DOH regulated facility where the CL is located. The official**  
27 **results shall be signed by the head of the CL or his/her associate pathologist.**

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30 Under Section M.

31 M. Satellite Clinical Laboratory (SCL) — refers to an extension of the main CL  
32 located within the facility’s compound or premises. It shall have the same  
33 service capability as the main laboratory.

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35 **The aforementioned is hereby amended to read as follows:**

36 **M. Satellite Clinical Laboratory (SCL) — refers to an extension of the main**  
37 **CL located within the DOH regulated facility’s compound or premises. The**  
38 **services to be offered may be all the services offered by the main CL or**  
39 **some of the services but shall not go beyond the service capability of the**  
40 **main CL.**

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43 Under Section N.

44 N. Referral Tests – refers to CL test that are either sent-out or outsourced to other  
45 DOH-licensed CL with the same or higher service capability

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47 **The aforementioned is hereby amended to read as follows:**

48 **N. Referral – refers to CL tests, which are mandatory to its classification but**  
49 **are sent-out to the same or higher service capability CL, only as part of the**  
50 **contingency plan such as but not limited to equipment breakdown.**

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53 **The following definition shall be inserted as Section O:**

54 **O. Outsourcing – refers when a CL sent-out a test that is beyond the required**  
55 **services for that CL category, but shall not apply to services expected from**  
56 **their level. It may be done solely for patient’s convenience.**

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60 **V. GENERAL GUIDELINES**

61 Under Section F.

62 **F. Unit/Section of health facilities performing diagnostic CL tests such as, but not**  
63 **limited to, arterial blood gas and/or Radioimmunoassay for thyroid function**  
64 **tests and Prostate Specific Antigen shall be under the DOH-licensed CL.**

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66 **The aforementioned is hereby amended to read as follows:**

67 **F. Unit/Section of health facilities performing diagnostic tests as POCT, such**  
68 **as, respiratory unit for arterial blood gas and nuclear laboratory**  
69 **performing radioimmunoassay performed on blood and other body fluids**  
70 **shall be under the DOH-licensed CL with the official results signed by the**  
71 **head of the CL or its associate pathologist.**

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74 Under Section J.

75 **J. The DOH designated NRL shall be covered by the license of the CL of the**  
76 **hospital where they are affiliated with. Independent NRLs, or those designated**  
77 **by DOH but are not affiliated with any DOH-regulated health facility, shall**  
78 **secure a DOH-LTO from HFSRB.**

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80 **The aforementioned is hereby amended to read as follows:**

81 **J. The DOH designated NRLs, and their regional or sub-regional**  
82 **counterparts, doing routine tests and complex procedures as stated in**  
83 **Republic Act 4688, shall be part of the CL’s license which is subsumed in**  
84 **the DOH-LTO of the hospital where they are affiliated with. The license of**  
85 **these NRLs shall be secured from the HFSRB/Center for Health**  
86 **Development – Regulation, Licensing and Enforcement Division (CHD-**  
87 **RLED). Independent NRLs, and their regional or sub-regional**  
88 **counterparts, or those designated by DOH but are not affiliated with any**  
89 **DOH-regulated health facility, shall secure a DOH-LTO from**  
90 **HFSRB/CHD-RLED.**

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93 Under Section O.

94 **O. The CL shall be compliant with the prescribed standards and requirements**  
95 **(Annex A), Assessment Tool for Licensing Clinical Laboratories (Annex B1**  
96 **and B2) and other relevant laws and issuances. These standards shall also apply**  
97 **to MCL and SCL.**

The aforementioned is hereby amended to read as follows:

O. The CL shall be compliant with the revised prescribed standards and requirements (Revised Annex A), Assessment Tool for Licensing Clinical Laboratories (Annex B1 Revision 01 and B2 Revision 01) and other relevant laws and issuances. These standards shall also apply to MCL and SCL.

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The following provision shall be inserted as Section Q:

Q. The minimum required services for clinical laboratories of Medical Facility for Overseas Worker and Seafarers (MFOWS) shall be based on the required services indicated in ANNEX A of AO No. 2013-006 titled: "Guidelines to" Rules XI: Role of DOH in the Omnibus Rules and regulations Implementing the Migrant Workers and Overseas Filipino Act of 1995, as Amended by Republic Act No. 10022," issued on February 7, 2013.

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The following provision shall be inserted as Section R:

R. A valid Memorandum of Agreement (MOA) shall be required for all referred or outsourced test/s and all the official results shall be issued by the DOH licensed CL which performed the test/s.

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The following provision shall be inserted as Section S:

S. All CL shall also follow the guidelines specified in Department Circular No 2021-0511, titled "Clarifications on the Roles and Functions of Registered Respiratory Therapists, Registered Medical Technologists and Head of Clinical Laboratory," dated October 29, 2021 (ANNEX G).

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**VI. SPECIFIC GUIDELINES**

Under Section 4. Classification by Service Capability

a. Clinical Laboratory for Clinical and Anatomic Pathology

Section	Category			
	i. Primary	ii. Secondary	iii. Tertiary	iv. Limited
	<i>Provides the following minimum service capabilities:</i>	<i>Provides the minimum service capabilities of a primary category, plus the following:</i>	<i>Provides the minimum service capabilities of a secondary category, plus the following:</i>	<i>Provides one (1) or two (2) specialized tests that are not classified under Anatomic or Molecular Pathology, as exemplified below:</i>
Clinical Microscopy	- Urinalysis - Fecalalysis - Fecal Occult Blood Test - Pregnancy Test (Rapid Test Kits – Lateral Flow) - Wet Smear for Trichomonas			- Hormones - Trace Metals
Clinical Chemistry	- Fasting and Random Blood Sugar - Oral Glucose Tolerance Test - Lipid Profile	- Serum Electrolytes (Sodium, Potassium, Chloride)	- Other Clinical Chemistry Examinations  Hospital-based:	- Tumor markers - Allergy Panel

	(Total Cholesterol, HDL, LDL, Triglycerides) - Creatinine - Blood Urea Nitrogen - Blood Uric Acid	- ALT - AST	Arterial Blood Gases	- This classification shall also apply to facilities offering DOH-program related tests, e.g., Kato Katz for Schistosomiasis, Malarial Smear, Filaria Smear, Slit-skin Smear, Rapid Plasma Reagin for Syphilis
Hematology	- Complete Blood Count (Hemoglobin, Hematocrit, Red Blood Cell Count, White Blood Cell Count with Differential Count, Quantitative Platelet Count) - Forward and reverse ABO grouping and Rh (D) typing (tube method)	For Hospital-based - Coagulation studies (PT, aPTT)		
Serology/ Immunology	- Dengue - Syphilis - Hepatitis B (Screening) - HIV (Screening) Using Rapid Test Kits		- Any machine-based serological and immunological testing such as, but not limited to: tumor markers, thyroid function tests and hepatitis profile	
Microbiology	- TB (DSSM) or Nucleic Acid Amplification Test – for government facilities	- Gram Stain - KOH	- Culture and sensitivity (aerobic and anaerobic)	
Anatomic Pathology		- Pap smear	For Hospital-based: - Cytology and Histopathology	

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**The aforementioned is hereby amended to read as follows:**

**a. Clinical Laboratory for Clinical and Anatomic Pathology**

Section	Category			
	i. Primary	ii. Secondary	iii. Tertiary	iv. Limited
	<i>Provides the following minimum service capabilities:</i>	<i>Provides the minimum service capabilities of a primary category, plus the following:</i>	<i>Provides the minimum service capabilities of a secondary category, plus the following:</i>	<i>Provides one (1) or two (2) specialized tests that are not classified under the minimum requirements for CL for Clinical and Anatomic Pathology or Anatomic or Molecular Pathology, as exemplified below:</i>
Clinical Microscopy	- Urinalysis - Fecalalysis - Pregnancy Test (Rapid Test Kits – Lateral Flow) - Fecal Occult Blood Test - Wet Smear for Trichomonas			- Hormones - Trace Metals - Tumor markers - Allergy Panel
Clinical Chemistry	- Fasting and Random Blood Sugar - Total Cholesterol - Oral Glucose Tolerance Test - Lipid Profile (Total Cholesterol, HDL, LDL, Triglycerides)			- This classification shall also apply to facilities offering

	- Creatinine - Blood Urea Nitrogen - Blood Uric Acid			<i>DOH-program related tests, such as but not limited to:</i> - Kato Katz for Schistosomiasis, Malarial Smear, Filarial Smear, Slit-skin Smear, Rapid Plasma Reagin for Syphilis, DSSM/AFB smear for Tuberculosis, <b>Human Immunodeficiency Virus test</b>
Hematology	- Complete Blood Count (Hemoglobin, Hematocrit, Red Blood Cell Count, White Blood Cell Count with Differential Count, Quantitative Platelet Count) - Forward and reverse ABO grouping and Rh (D) typing (tube method)			
Serology/ Immunology		- Any rapid lateral flow serological or immunological diagnostic test	- Any machine-based serological or immunological diagnostic test such as, but not limited to: tumor markers, thyroid function tests and hepatitis profile	
Microbiology		- Gram Stain - KOH Smear	- Culture and sensitivity (aerobic or anaerobic)	
Anatomic Pathology			- Pan Cervico-Vaginal Cytology (Papsmear)	

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**The following provision shall be inserted:**

**Additional minimum service capability for hospital-based CL**

Section	Category		
	i. Primary	ii. Secondary	iii. Tertiary
Clinical Chemistry		- Serum Electrolytes	
Hematology		- Coagulation Studies	
Microbiology			- Culture and sensitivity (aerobic and anaerobic)
Anatomic Pathology		- Pan Cervico-Vaginal Cytology (Papsmear)	- Cytology and Histopathology

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**VII. PROCEDURAL GUIDELINES**

Under Section C. Certificate of Registration (COR)

C. Certificate of Registration (COR)

1. COR is required for research and teaching laboratories.

**The aforementioned is hereby amended to read as follows:**

**C. Certificate of Registration (COR)**

- 151 1. **COR is required for research and teaching laboratories and shall not issue**  
152 **an official result for diagnostic purposes.**  
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156 **IX. VIOLATIONS, SANCTIONS AND APPEAL**

157 **The following provision shall be inserted as Section J:**

- 158 **A. Refusal or non-participation in an EQAP provided by a designated NRL**  
159 **or other local and international EQAP approved by the DOH, shall be**  
160 **subjected to the following penalties:**

- 161 i. **1<sup>st</sup> offense: Warning**  
162 ii. **2<sup>nd</sup> offense: Thirty thousand pesos (Php 30,000.00)**  
163 iii. **3<sup>rd</sup> offense: Fifty thousand pesos (Php 50,000.00)**  
164 iv. **4<sup>th</sup> offense: Suspension/Revocation of DOH-LTO**  
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168 **X. TRANSITORY PROVISIONS**

169 Under Section D.

- 170 **D. For CL currently headed by Anatomic Pathologists with an associate Clinical**  
171 **Pathologist or Clinical Pathologists heading tertiary CL with Anatomic Pathology**  
172 **services, such headships shall be retained until his/her eventual retirement,**  
173 **resignation or replacement. Thereafter, all CL shall be headed by a pathologist**  
174 **certified in Clinical Pathology by the Board of Pathology of the Philippine Society**  
175 **of Pathologists except for tertiary CL with anatomic pathology service which shall**  
176 **be headed by a pathologist certified in both Anatomic and Clinical Pathology.**  
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178 **The aforementioned is hereby amended to read as follows:**

- 179 **D. For CL currently headed by Anatomic Pathologists with an associate Clinical**  
180 **Pathologist, such headships shall be retained until his/her eventual retirement,**  
181 **resignation or replacement. Thereafter, all CL shall be headed by a pathologist**  
182 **certified in Clinical Pathology by the Board of Pathology of the Philippine**  
183 **Society of Pathologists (PSP). For CL with Anatomic (Surgical) Pathology**  
184 **section, an Anatomic Pathologists certified in Anatomic Pathology by the**  
185 **Board of Pathology of the PSP as an associate, shall be allowed for a period of**  
186 **five (5) years. Thereafter, all CL with Anatomic (Surgical) Pathology Section**  
187 **shall be headed by a pathologist certified both in Clinical Pathology and**  
188 **Anatomic Pathology by the Board of Pathology of the PSP.**  
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191 **The following provision shall be inserted as Section E:**

- 192 **E. Registered Special Clinical Laboratories prior to the issuance of this Order**  
193 **shall be reclassified accordingly (e.g., CL with Limited Service, CL for**  
194 **Anatomic Pathology, CL for Molecular Pathology, Stem Cell Facility), and**  
195 **shall follow the standards set for them.**  
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198 **The following provision shall be inserted as Section F:**

- 199 **F. The secondary clinical laboratory of MFOWS shall be an equivalent to the**  
200 **services of a primary clinical laboratory as provided in this AO until such time**  
201 **that the AO of MFOWS shall be revised.**

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The following provision shall be inserted as Section G:  
**G. Registration of digital signature to Department of Information and Communications Technology-Philippine National Public Key Infrastructure (DICT-PNPKI) of the pathologist/s and the Registered Medical Technologist (RMT) shall be given one (1) year from the effectivity of this amendment. Thereafter, official results shall be signed either digital (DICT-PNPKI authenticated) or original/physically affixed both the analyst who performed the test and the head of CL or his/her associate pathologist.**

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The following provision shall be inserted as Section H:  
**H. DOH-program based CL shall be given two (2) years to fully comply with the requirements, provided that the CL is identified or recognized as such by the DOH with a proof of certification.**

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Likewise, clarifications were made in the following Annexes:

1. **Revised Annex E for Guidelines in Securing for Remote Collection Permit for Clinical Laboratories.**
2. **Annex F Revision 01 for Application Form for Certificate of Registration for Research and Teaching Clinical Laboratories.**

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#### **XI. REPEALING CLAUSE**

All other provisions of Administrative Order No. 2021-0037 shall remain in effect and provisions/issuances inconsistent or contrary to this Order are hereby rescinded or modified accordingly.

#### **XII. SEPARABILITY**

In the event that any provision or part of this issuance is declared unconstitutional or rendered invalid by any court of law or competent authority, the portions not affected thereby shall remain in full force and effect.

#### **XIII. EFFECTIVITY**

This Order shall take effect immediately.

**FRANCISCO T. DUQUE III, MD, MSc**  
Secretary of Health