| DR. PABLO O. TORRE MEMORIAL HOSPITAL<br>B.S. Aquino Drive, Bacolod City, Negros Occidental, 6100 | Document Code: | DPOTMH-ANC-MOLE-P001 |
|---|---|---|
| | Revision Number: | 00 |
| | Effective Date: | May 15, 2020 |
| | Document Type: | Policy |
| | Page Number: | 1 |
| | Department/Section: | Laboratory-Molecular Biology Section |
| | Document Title: | COVID-19 RAPID ANTIBODY **(LATERAL FLOW-FDA-APPROVED)** |

**PURPOSE:**

It is a rapid qualitative detection of IgM and IgG antibodies to Covid-19 in human serum, plasma or whole blood.

**LEVEL:**

Medical Doctors, Nurses, Medical Technologist, Pathologist, Clerks and Receptionist

**DEFINITION OF TERMS:**

Covid-19 Rapid Antibody test is a marker of immune response such as the IgM and IgG antibodies. This test is not intended to identify active SARS-COV-2 infection and cannot be used as a stand-alone test to definitively diagnose COVID-19. RT-PCR test kit remains to be the gold standard in determining whether a person is infected or infectious.

**POLICY:**

1. Only **medical doctors** can **prescribe** and **interpret** results of rapid antibody-based test kits and with reference to Department Circular no. 2020-0160 and Department Memorandum No 2020-0151 of the Department of Health.

2. Collection, handling, storage and transport of the specimen shall adhere to the Standard Operating Procedures of the Hospital Laboratory and in accordance to the standards set forth by the regulating government agencies.

3. No specimens shall be accepted and processed without completing the documentary requirements and corresponding payment is done.

4. All reagents, test kits and consumables must be checked and validated as to its potency, expiration and integrity on weekly basis. No test strips shall be opened unless it is immediately used to the patient, or is immediately necessary in the processing of specimen.

5. The components in the kit shall be quality tested before the actual usage. No mixing of the components from different lot numbers shall be allowed.

6. No test strips shall be reused.

7. All tubes to be used to the patient must be properly labeled prior to blood extraction; and, a sufficient amount of blood shall be extracted to ensure that additional examinations could be performed.

8. Proper endorsement of specimens shall be strictly observed.

9. Results shall be released within **two (2) hours** and can be viewed using the Patient Portal. Confidentiality of Result TAT shall be maintained at all times in compliance with Data Privacy Law.

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**APPROVAL:**

| | Name/Title | Signature | Date |
|---|---|---|---|
| Prepared by: | **MELISSA THERESE B. LABAYEN, RMT**<br>Laboratory Supervisor | | 26 May 2020 |
| Reviewed: | **DENNIS C. ESCALONA, RN, MN, FPSQua**<br>Quality Assurance Supervisor | | 05-20-2020 |
| Recommending Approval: | **MELANIE ROSE B. ZERRUDO, MD, FPSP**<br>**Chief Pathologist** | | May 26, 2020 |
| | **MONICA B. VILLANUEVA, RMT, RN, PhD**<br>**Laboratory Director** | for Ads. | may 26, 2020 |
| | **ROSARIO D. ABARING, MAN, PhD, FPCHA**<br>**Ancillary Division Officer** | | 06.02.2020 |
| | **HENRY F. ALAVAREN, MD, FPSMID, FPSQua**<br>**Total Quality Division Officer** | | 6/11/20 |
| Approved: | **GENESIS GOLDI D. GOLINGAN**<br>President and CEO | | 06/15/2020 |





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| Prepared by: | **MELISSA THERESE B. LABAYEN, RMT**<br>Laboratory Supervisor | | 26 May 2020 |
| Reviewed: | **DENNIS C. ESCALONA, RN, MN, FPSQua**<br>Quality Assurance Supervisor | | 05-20-2020 |
| Recommending Approval: | **MELANIE ROSE B. ZERRUDO, MD, FPSP**<br>**Chief Pathologist** | | May 26, 2020 |
| | **MONICA B. VILLANUEVA, RMT, RN, PhD**<br>**Laboratory Director** | for Lods. | may 26, 2020 |
| | **ROSARIO D. ABARING, MAN, PhD, FPCHA**<br>**Ancillary Division Officer** | | 06.03.2020 |
| | **HENRY F. ALAVAREN, MD, FPSMID, FPSQua**<br>**Total Quality Division Officer** | | 6/11/20 |
| Approved: | **GENESIS GOLDI D. GOLINGAN**<br>President and CEO | | |





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## PROCEDURE:

1. Allow all kit components and specimen to room temperature prior to testing.
2. Add 20 uL of venous whole blood or 10 uL of serum/plasma specimen into the top of the specimen well.
3. Add 2 drops (80uL) of specimen diluent into the bottom of the specimen wells.
4. Wait for the colored line to appear.
5. Interpret test results within 15 minutes.

## INTERPRETATION OF THE RESULT:

***IgM Positive*** - The control line and IgM line are visible on the test strip. This is positive for IgM antibodies to Covid-19.

***IgG Positive*** - The control line and IgG line are visible in the test strip. This is positive for IgG antibodies.

***Negative*** - The control line is only visible on the test strip. No IgG and IgM antibodies were detected.

***Invalid*** - The control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Repeat test using a new test device.

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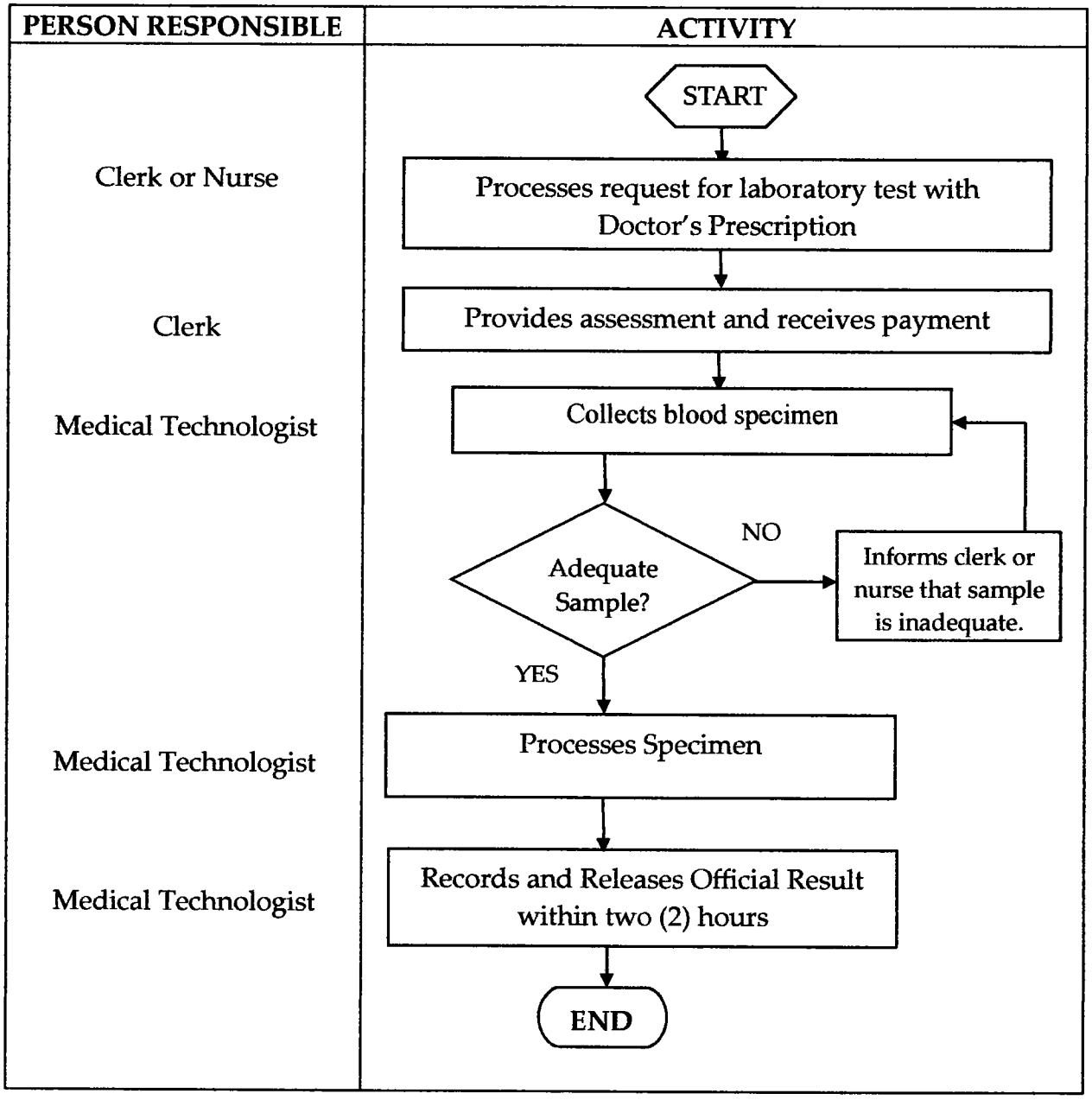
**FLOWCHART**



## WORK INSTRUCTIONS:

### Medical Doctors:

1. Make prescription for IgG and IGM.
2. Interpret results and manages pateints.

### Clerk and Nurses:

1. Encode the request of the patient to BizBox System.
2. Endorse the patient's specimen to the Molecular Laboratory.
3. Endorse the patient's results to the patient or the doctor.

### Medical Technologists:

1. Ensure specimen is acceptable.
2. Register the specimen to its corresponding logbooks.
3. Collect, prepare, processe and analyze specimens.
4. Release results thru BizBox system.

## DOCUMENTATION:

1. Logbooks for specimen registry and records of results.
2. Miscellaneous paper or laboratory request form.
3. Laboratory results print-out.
4. Nurses remarks for in-patients.

## DISSEMINATION:

1. Orientation to clerks and new employees.
2. Attached to manual of operations, copy furnished QC Division.

## REFERENCE:

INNOVITA 2019-nCoV ANTIBODY TEST (Colloidal Gold) package insert.