AGHAM AT KAALAMAN PARA SA BAYAN!

PAASE BULLETIN #13

ON PAASE STRATEGIC ACTION GROUP 3: MASS TESTING & FAST-TRACKING

Addressed to: COVID-19 IATF, NEDA, DOH, FDA

COVID-19 MASSIVE SCREENING USING ANTIBODY RAPID TESTING AND RT-PCR TESTING OF ASYMPTOMATIC AND SYMPTOMATIC INDIVIDUALS AND SECTORS OF INDIVIDUALS

PAASE strongly recommends the immediate implementation of a COVID-19 massive screening program

A. PAASE recommends the following basic specifications to ensure that accurate and timely results are obtained from the COVID-19 testing program:

1. Use of rapid antibody testing in combination with RT-PCR testing
2. Use only of PH FDA-approved antibody and RT-PCR kits with high quality specifications (specificity, selectivity, sensitivity-detection limit, ROC curve expressed as coincidence with RT-PCR, true positive rate vs. false positive rate, based on statistically significant number of samples), e.g. CE mark (Europe)
3. Antibody and RT-PCR kit manufacturers must disclose their specifications; prospective users from the government and private sector must verify this critical information from the manufacturer/distributor
4. Antibody tests must be performed by certified competent health workers and results analyzed and released by certified MDs/laboratories
5. RT-PCR tests must be performed only at DOH-certified RT-PCR testing centers
6. Antibody and RT-PCR tests must be performed in a timely way, simultaneously or in succession, with repeats, based on the clinical picture, e.g. asymptomatic, symptomatic, recovered.

B. PAASE recommends regular updating from clinical and biomedical publications and official reports as source of most recent data on COVID-19:

1. Transmission and average incubation period
2. Levels of virus, IgM ad IgG from day 0 onset of symptoms to 14 days, correlated with clinical picture
3. Reliability of individual RT-PCR and antibody tests, and significantly increased reliability when RT-PCR and antibody tests are combined, and correlated with the clinical picture

Visit: https://www.youtube.com/watch?feature=youtu.be&v=E93qxUIq6Qg&app=desktop

To assist the DOH in updating its guidelines and implementation plan, PAASE recommends the creation of an advisory group of MDs, PhDs and other experts. Further, PAASE recommends the creation of a massive screening data monitoring system and dashboard.

C. Proposed General Testing Standards for Rapid Antibody Testing and RT-PCR:

1. All symptomatic patients must go for medical consultation, impose self-quarantine and be tested via Antibody and RT-PCR. Negative results for both tests must be evaluated by an MD using other risk assessment tools (CTScan, pulse oximetry, epi history, etc.) and retests must be conducted to confirm non-COVID-19 status.
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2. All high-risk asymptomatic individuals must impose self-quarantine and be tested via Antibody and RT-PCR. Negative results for both tests must be evaluated by an MD using other risk assessment tools (CTScan, pulse oximetry, epi history, etc.) and retests must be conducted to confirm non COVID-19 status.

D. PAASE proposes massive screening by priority sectors:

1. To serve as basis for selective easing of quarantine and lockdown of essential on-the-ground members of the workforce, to ensure delivery of food, basic goods and services, and to ease the burden on the economy; e.g.:  
   1.1. Perform rapid Antibody testing or alternatively RT-PCR, on essential, on-the-ground workers, asymptomatics, without high risk conditions, e.g. 20-50 years old. Consider sample pooling of asymptomatics.
   1.2. Two Antibody tests performed 5 days or TBD days apart, both with NEGATIVE results, or two negative RT-PCRs, 5 or TBD days apart, would qualify for Q/LD-exempt WORKER PASS for a specified period. Renewable every TBD months after another 2 NEGATIVE Antibody or RT-PCR results, 5 or TBD days apart. If a worker tests positive in Antibody, the worker is subjected to RT-PCR test and quarantined until release of results. If the worker tests negative for RT-PCR twice, 5 or TBD days apart, the worker will receive a WORKER PASS noting IMMUNE status and not require additional testing.

   1.3. Management should protect the worker with TB BCG vaccine, impose handwashing, face masks/shields, 2-meter physical distancing, provide reinforced nutrition, ensure adequate ventilation (air-exchange rate; open windows/open air) at the workplace; government should require reports, check compliance of workplace.
   1.4. Implement frequent (TBD days) testing and isolation or segregation of test positives (including asymptomatics) and the sick. In this way work can continue with the remaining healthy workforce. Strict social/physical distancing, and protection measures in place in these sectors will increase the chance that some workers may escape infection. Thus, there may not be need to revert to lockdown. In cases of severe noncompliance cases resulting in significant infections, revoke permit, revert to lockdown.

   1.5. Government office or private company should identify a dedicated health care provider partner to perform the antibody testing either in a clinic or through a roving testing vehicle, and identify the dedicated DOH-certified RT-PCR testing center to perform the RT-PCR testing.

2. to detect COVID-19 in contact-traced individuals, PUMs, PUIs (exhibiting symptoms) at pre-symptomatic and earliest symptomatic stages: to prioritize for triage and hospital-based treatment

3. to detect COVID-19 in frontliners; i.e., health care workers in hospitals and clinics, and law enforcers in the field

4. to monitor COVID-19 among symptomatics (mild, moderate, severely sick, convalescent, recovered) in the hospital, as basis to prioritize treatment, monitor recovery, issue discharge, identify candidate donors for convalescent plasma therapy, taken together with the clinical picture

5. to track transmission in community hotspots, rural and urban centers, with COVID-19 positive groups and exposed individuals, asymptomatics and early symptoms

6. to test travelers at airports and ports and other entry points, those with elevated temperatures; to identify those required to be placed under Quarantine; combined
with strict enforcement of thermal scanning and declaration of travel history, and
efficient contact tracing
7. to perform immuno-surveillance studies and monitor extent of herd immunity

#To Be Determined
+reported false positives and false negatives for both tests
+shown to have highest viral load and shedding, with average incubation of 5.1 days,
stretching from 1-14 days

D. PAASE proposes a prioritization of implementation of the above sector-based testing, and
an online registration/application for testing and reporting system should be established.

ANNEXES:
Figure 1: INFOGRAPHIC on Who to test
Table 1: Testing plan
Table 2: Test results
Figure 2: Example of implementation plan for asymptomatic essential workers

References:
https://www.youtube.com/watch?feature=youtu.be&v=E93qxUQpq60&app=desktop
1 PAASE BULLETIN # 9: Rapid Antibody Testing for Developing Treatment
2 PAASE BULLETIN # 5: RT-PCR DOH T B DOTS Testing Centers
3 Guo L et al. 2020. Profiling Early Humoral Response to Diagnose Novel Coronavirus Disease
4 PAASE BULLETIN # 3: Instituting a system of balanced COVID-19 suppression and the gradual rise to
economic normality
5 PAASE BULLETIN # 10: Age-based easing of lockdown measures
6 PAASE BULLETIN # 4: Sample pooling in a resource-limited situation
7 PAASE BULLETIN # 8: Tuberculosis vaccine to contain COVID-19 outbreak
8 PAASE BULLETIN # 7: Healthy diet to combat COVID-19
http://doi.org/10.1016/S2468-1253(20)30083-2

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ANNEX A

Figure 1: INFOGRAPHIC on Who Should Test
Phase 1 Testing

Who to Test?
- PUI Symptomatics or contact with Covid19 +
- Asymptomatics
  - Healthcare Workers
  - AFP/PNP
  - Basic Necessities Supply Chain (Food, Med, etc)
    - Raw Material Providers
    - Truck Drivers
    - Warehouse Personnel
    - Supermarket Personnel

What Tests?
- Antibody + RTPCR
- Antibody Test

Who Will Test?
- Hospitals + Barangay HCWs and DTTBs, Mobile Testers
- Hospitals/DTTBs
- Barangay HCWs and DTTBs, Mobile Testers

What Actions to Take?
(Refer to Table 2)
- Quarantine all and Hospitalize those in respiratory distress
- Positive Antibody Classified as PUI (Take the purple route)
Phase 2 Testing

Who to Test?
- Asymptomatics:
  - BJMP and Prisoners
  - Public Transport Personnel
  - Communications personnel
  - Public/Private Security
  - Utilities and General Community Services (water supplies, drinking water stations, sanitation)
  - LGU Personnel (barangay captains and staff included)

What Tests?
- Antibody Test

Who Will Test?
- Hospitals/DTTBs
- Barangay HCWs and DTTBs, Mobile Testers

What Actions to Take?
(Refer to Table 2)
- Positive Antibody Classified as PUI (Take the purple route)
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ANNEX B

Table 1: Testing Plan
<table>
<thead>
<tr>
<th>Target Population</th>
<th>Implementing Plan</th>
<th>Timing</th>
<th>Testing Method</th>
<th>RT PCR Sample pooling</th>
<th>Result/Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>PUI symptomatic</td>
<td>Testing at Point of Care</td>
<td>April-May 2020</td>
<td>Antibody/RTPCR</td>
<td>n/a</td>
<td>Refer to Table 2</td>
</tr>
<tr>
<td>PUI asymptomatic</td>
<td>Mobile Testing at place of quarantine</td>
<td>April-May 2020</td>
<td>Antibody/RTPCR</td>
<td>n/a</td>
<td>Refer to Table 2</td>
</tr>
<tr>
<td>Frontline Workers</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HCWs in High Risk Hospitals (Hospital that has treated COVID19 patients)</td>
<td>Testing at Hospital</td>
<td>April-May 2020</td>
<td>Antibody</td>
<td>applicable</td>
<td>If Ab test is positive, quarantine and do RT-PCR. Do sample pool of ALL HCW for RT-PCR. If RT-PCR pool is positive in Hospital X then proceed to individual testing. If negative, continue to monitor new sample pools every week</td>
</tr>
<tr>
<td>HCWs in Low Risk Hospitals (Hospital that has no exposure to COVID19 patients)</td>
<td>Testing at Hospital</td>
<td>May-June 2020</td>
<td>Antibody</td>
<td>applicable</td>
<td>If Ab test is positive, quarantine and do RT-PCR. Do sample pool of ALL HCW for RT-PCR. If RT-PCR pool is positive in Hospital X then proceed to individual testing. If negative, continue to monitor new sample pools every week</td>
</tr>
<tr>
<td>PNP/AFP in checkpoints</td>
<td>Mobile Testing</td>
<td>April-May 2020</td>
<td>Antibody</td>
<td>applicable</td>
<td>If Positive with Antibody test, quarantine confirm with RT PCR and monitor - refer to Table 2</td>
</tr>
<tr>
<td>Supply chain ecosystem for food and medicine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Raw material suppliers</td>
<td>Mobile Testing</td>
<td>April-May 2020</td>
<td>Antibody</td>
<td>applicable</td>
<td>If Positive with Antibody test, quarantine confirm with RT PCR and monitor - refer to Table 2</td>
</tr>
<tr>
<td>Warehouse workers</td>
<td>Mobile Testing</td>
<td>May-June 2020</td>
<td>Antibody</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Transportation/Truck drivers</td>
<td>Mobile Testing</td>
<td>May-June 2020</td>
<td>Antibody</td>
<td>applicable</td>
<td></td>
</tr>
<tr>
<td>Supermarket workers esp Cashiers</td>
<td>Mobile Testing</td>
<td>April-May 2020</td>
<td>Antibody</td>
<td>applicable</td>
<td></td>
</tr>
</tbody>
</table>
Annex C

Table 2: Test results
<table>
<thead>
<tr>
<th>RT-PCR</th>
<th>IgM</th>
<th>IgG</th>
<th>Status</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>(-)</td>
<td>(-)</td>
<td>(-)</td>
<td>Patient does not have COVID-19 or It is too soon after initial exposure for test sensitivity or Symptoms due to another illness.</td>
<td>If PUI/exposed to COVID-19, quarantine and retest in 3-5 days. If second negative and asymptomatic release patient. Consider other illnesses and treat accordingly.</td>
</tr>
<tr>
<td>(-)</td>
<td>(+)</td>
<td>(-)</td>
<td><strong>Active infection</strong> Too early for IgG to be produced. RT-PCR negative because body has cleared the virus and begun recovery or false negative.</td>
<td>Quarantine and Treat. Retest with RT-PCR and antibody until asymptomatic and RT-PCR and IgM are both negative</td>
</tr>
<tr>
<td>(-)</td>
<td>(+)</td>
<td>(+)</td>
<td><strong>Active infection</strong> RT-PCR negative because body has cleared the virus and begun recovery or false negative.</td>
<td>Quarantine and Treat. Retest with RT-PCR and antibody until asymptomatic and RT-PCR is negative</td>
</tr>
<tr>
<td>(-)</td>
<td>(-)</td>
<td>(+)</td>
<td>Past infection If asymptomatic, body has cleared the infection. If symptomatic, late stage or secondary infection.</td>
<td>If asymptomatic, release patient. If symptomatic, Quarantine and Treat. Retest with RT-PCR and antibody until asymptomatic and RT-PCR is negative</td>
</tr>
<tr>
<td>(+)</td>
<td>(-)</td>
<td>(-)</td>
<td><strong>Active infection.</strong> Too soon after initial exposure for antibodies to develop</td>
<td>Quarantine and Treat. Retest with RT-PCR and antibody until asymptomatic and RT-PCR is negative</td>
</tr>
<tr>
<td>(+)</td>
<td>(+)</td>
<td>(-)</td>
<td><strong>Active infection</strong> Too early for IgG to be produced.</td>
<td>Quarantine and Treat. Retest with RT-PCR and antibody until asymptomatic and RT-PCR is negative</td>
</tr>
<tr>
<td>(+)</td>
<td>(+)</td>
<td>(+)</td>
<td><strong>Active infection</strong></td>
<td>Quarantine and Treat. Retest with RT-PCR and antibody until asymptomatic and RT-PCR is negative</td>
</tr>
<tr>
<td>(+)</td>
<td>(-)</td>
<td>(+)</td>
<td>Past infection or recurrent infection or Late stage infection or Symptoms due to secondary infection.</td>
<td>Quarantine and Treat. Retest with RT-PCR and antibody until asymptomatic and RT-PCR is negative</td>
</tr>
<tr>
<td>Test Results</td>
<td>Status and Treatment</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>RT-PCR</td>
<td>IgM</td>
<td>IgG</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Symptomatic</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| (-) | (-) | (-) | Patient does not have COVID-19 and symptoms are due to another illness or it is too soon after initial exposure for test sensitivity. Consider other illnesses and treat accordingly. Quarantine and retest in 3-5 days. |
| (-) | (+) | (-) | **Active infection.** Too early for IgG to be produced. RT-PCR negative because body has cleared the virus and begun recovery or false negative. Quarantine and Treat. Retest with RT-PCR and antibody until asymptomatic and RT-PCR is negative. |
| (-) | (+) | (+) | **Active infection.** RT-PCR negative because body has cleared the virus and begun recovery or false negative. Quarantine and Treat. Retest with RT-PCR and antibody until asymptomatic and RT-PCR is negative. |
| (-) | (-) | (+) | **Late stage or secondary infection.** Quarantine and Treat. Retest with RT-PCR and antibody until asymptomatic and RT-PCR is negative. Consider other illnesses and treat accordingly. |
| (+) | (-) | (-) | **Active infection.** Too soon after initial exposure for antibodies to develop Quarantine and Treat. Retest with RT-PCR and antibody until asymptomatic and RT-PCR is negative |
| (+) | (+) | (-) | **Active infection.** Too early for IgG to be produced. Quarantine and Treat. Retest with RT-PCR and antibody until asymptomatic and RT-PCR is negative. |
| (+) | (+) | (+) | **Active infection** Quarantine and Treat. Retest with RT-PCR and antibody until asymptomatic and RT-PCR is negative. |
| (+) | (-) | (+) | **Past infection or recurrent infection or late stage infection or symptoms are due to secondary infection.** Quarantine and Treat. Retest with RT-PCR and antibody until asymptomatic and RT-PCR is negative. |
| Asymptomatic | |

| (-) | (-) | (-) | Patient does not have COVID-19 or it is too soon after initial exposure for test sensitivity and symptoms to arise. If PUI/exposed to COVID-19, quarantine and retest in 3-5 days. If second negative and still asymptomatic, release patient. |
| (-) | (+) | (-) | **Active, mild infection. Infectious.** Too early for IgG to be produced. RT-PCR negative because body has cleared the virus and begun recovery or false negative. Quarantine and retest with RT-PCR and antibody until RT-PCR is negative. |
| (-) | (+) | (+) | **Active, mild infection. Infectious.** RT-PCR negative because body has cleared the virus and begun recovery or false negative. Quarantine and retest with RT-PCR and antibody until RT-PCR is negative. |
| (-) | (-) | (+) | Past infection. Body has cleared the infection. Release patient. |
| (+) | (-) | (-) | **Active, mild infection. Infectious.** Too soon after initial exposure for antibodies to develop Quarantine and retest with RT-PCR and antibody until RT-PCR is negative. |
| (+) | (+) | (-) | **Active, mild infection. Infectious.** Too early for IgG to be produced. Quarantine and retest with RT-PCR and antibody until RT-PCR is negative. |
| (+) | (+) | (+) | **Active, mild infection. Infectious.** Quarantine and retest with RT-PCR and antibody until RT-PCR is negative. |
| (+) | (-) | (+) | Active, mild, late stage infection or recurrent infection. **Assume patient is infectious.** Quarantine and retest with RT-PCR and antibody until RT-PCR is negative. |
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ANNEX D

Figure 2: Implementation plan for asymptomatic essential workers
**Figure 2: Example of implementation plan for asymptomatic essential workers**

**IMPLEMENTING ENTITY**
- DOH/FDA

**MAIN IMPLEMENTING ACTIONS**
- Issue guidelines on massive screening
- Set up online registration & application
- Set up easy-to-fill template on all required information
- Set up template for list of workers
- Provide information on kits used, health provider of testing, workers, etc.
- Central testing mode or roving testing vehicle mode
- Provide specifications of chosen FDA-approved antibody testing kit and PCR testing
- Identify workers with essential on-the-ground work, asymptomatic, age range/limit, no chronic or high-risk conditions
- Issue strict warning on accuracy and completeness of above information
- Act on applications

**APPLICANT PARTNER ENTITIES**
- Government office
  - Provide information on kits used, health provider of testing, workers, etc.
- Private companies
  - Central testing mode or roving testing vehicle mode
  - With health provider (hospital, clinic) with certified technicians/MDs for Antibody test and DOH-certified center for PCR test
  - Provide specifications of chosen FDA-approved antibody testing kit and PCR testing
  - Identify workers with essential on-the-ground work, asymptomatic, age range/limit, no chronic or high-risk conditions
  - Issue strict warning on accuracy and completeness of above information
  - Act on applications

**APPROVED PARTNER ENTITIES**
- Asymptomatics with added criteria undergo testing
  - Antibody testing
    - Individual: yes
    - Sample pooling: possible
  - PCR testing
    - Individual: yes
    - Sample pooling: possible
- Follow two negative rule in positive Ab
  - Antibody testing: deconvolute, do PCR, negative Ab
  - PCR testing: wait 5/TBD days, negative Ab
- Double negative in antibody test or double negative in PCR: candidate for WORKER PASS
- DOH/FDA & sign contract between approved partner entities and DOH/FDA on compliance
- Approved partner entities
  - Issue Q/LD-exempt WORK PERMIT (indicate period)
  - Provide worker with TB BCG vaccine
  - Establish auxiliary measure for support of workers
  - Monitor compliance internally
  - Report early symptomatics
  - Perform Antibody testing
  - Monitor compliance externally
  - Apply for renewal
  - Submit report
  - Repeat antibody testing of workers as above

**AUXILIARY ACTIONS OF OFFICE/COMPANY**
- In the workplace and during travel:
  - Implement handwashing and hygiene measures
  - Provide face masks/shields
  - Impose 2 meter distance in workplace, canteen, RRs
  - Provide vitamins and other defense supplements
  - Ensure good air-exchange and ventilation
  - Monitor implementation
- Monitor complaince internally
- Report early symptomatics
- Perform Antibody testing
- Monitor compliance externally
- Apply for renewal
- Submit report
- Repeat antibody testing of workers as above