7. Recommendation

Pooled RT-PCR testing can be utilized for screening and surveillance in low prevalence population. The responsible unit of DOH must undertake the necessary prevalence study to determine appropriate populations for pooled RT-PCR testing. For diagnosis of COVID-19, individual RT-PCR testing must be done regardless of the prevalence.

Provided that RT-PCR test kits to be used for pooled COVID-19 testing must undergo and pass the validation requirements for pooled testing by RITM, local authorities (e.g., FDA), or other authorized institutions. Likewise, the RT-PCR test kits to be used for pooled COVID-19 testing must meet the **minimum technical specifications** and **requirements of HTAC**.

Parameter	Requirement
Regulatory Requirement	RT-PCR test kits **must be authorized by the Philippine FDA** for pooled COVID-19 testing and must be validated for use in pooled testing by local or international agencies.
Validation	All kits to be used for pooled testing should also undergo additional validation for pooled testing by RITM or other authorized institutions similar to what the US FDA requires
Cost	Must include all necessary accessories per test, including extraction reagents, consumable, & viral transport media. The detailed breakdown of the cost must be provided by the supplier The ceiling cost is Php 1,800 per assay, excluding the cost of the PCR machine, and the consumption of personal protective equipment.
PCR Machine Compatibility	Must be compatible with the existing machine/s of the testing facility, noting other prerequisites needed in order to operate such as appropriate containment and biosafety procedures.
Storage, expiration and stability	The expiration date must be no less than six (6) months from date of manufacture. The storage and working temperature must be -20 degrees Centigrade. Must pass the acceptance testing by RITM at the cost of the winning supplier.
Human resource	Must not require more than the basic competency of personnel equipped with skills on RT-PCR techniques and in-vitro diagnostic procedures and instrumentation, with **additional training** conducted by the RITM and

	the Philippine Society of Pathologists (PSP) for pooled testing
Analytical Sensitivity (Gene Targets)	Must have been tested for confirmatory gene (i.e., RdRP, ORF1ab, & N) and screening gene (i.e., E gene)
Analytical Specificity (Cross-Reactivity)	Must have no significant cross-reactivities identified among the RT-PCR test kits. For cross-reactivity testing, must use at least both of the following organisms: Influenza A and Influenza B
Clinical Sensitivity	Must have at least **90% clinical sensitivity**
Clinical Specificity	Must have at least 99% clinical specificity
Processing Time	Must be six (6) hours or less (excluding repeat test and specimen transport)
Reference Standard	Refer to RITM validation protocol for pooled RT-PCR testing
Sample Size Requirement	Refer to RITM validation protocol for pooled RT-PCR testing
Cycle threshold (Ct) values	Refer to RITM validation protocol for pooled RT-PCR testing
Pool size	Should be at most five (5)
Pooling method	Any appropriate pooling method is acceptable
List of accredited laboratories for pooled testing	The pooled COVID-19 testing must only be performed by laboratories identified and authorized by RITM.

In terms of research, the HTAC recommends exploring the **correlation of cycle threshold (Ct) values** with **viral load concentration**, and the **correlation of Ct values** with **infectivity**.

Given the available evidence from rapid review and the study of Lo et al., pooled COVID testing is recommended to be used for screening and surveillance in populations or settings with low prevalence. Use of pooled COVID-19 testing for specific populations is yet to be determined pending the prevalence data from the Epidemiology Bureau. As the national reference laboratory, there should be clear validation standards from the RITM. Lastly, it is recommended that the FDA Philippines issue guidance as to the appropriate device to be used for pooled testing. The FDA should have authorization for RT-PCR test kits that may be used for pooled COVID-19 testing.

9. References

Unless specified, the references cited in this document were derived from the rapid review report on pooled COVID-19 testing.