



Ministry of Health and Sports

# **Addressing the Challenges of COVID-19 in Myanmar “Laboratory Perspectives”**

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# Outline of Presentation

- 1. Beginning of the pandemic
- 2. Sequences of laboratory preparedness
- 3. Testing strategy practiced align with country needs
- 4. Updated testing SOPs & Analysis
- 5. Challenges & opportunities
- 6. Moving forward



# Beginning of the pandemic



- In Myanmar, the government swiftly responded to the crisis under the direction of **The National-Level Central Committee on Prevention, Control and Treatment of Coronavirus Disease 2019 (COVID-19)**
- The **Ministry of Health and Sports (MoHS)** continues to lead the country's response to curtail the spread of the virus, to strengthen the health systems, to increase prevention measures, to ensure adequate testing capacity and to bring about behavioral change through risk communication.



- The laboratory testing and diagnosis play the vital role in COVID management.
- **National Health Laboratory** : the main laboratory diagnostic center
- Responsible for laboratory investigations through out all states and regions
- Assigned activities for the COVID-19 pandemic have been turned out to be an **outstanding achievement** for the Ministry of Health and Sports as well as for the country.



# The mile stones

- Conducting table top exercises
- Recruitment of required human resources as well as laboratory facilities including laboratory sites, materials and equipment for COVID testing
- Development of SOPs, guidelines for sample collection, handling and testing of COVID-19 samples
- Intensive training of laboratory personnel,
- Systematic QA, QC controlled COVID-19 testing
- Timely data recording , reporting and documentation , seriously keeping in public health orientation manner.



# Mandated table top exercises

- • Clinical management GL of C-19 acute respiratory disease
- • Laboratory diagnosis analysis
- • Summary of Guidelines
- • Point of Care strengthening
- • Epidemiological situation
- • Biosafety and Biosecurity
- • Contact tracing and quarantine guidelines



# Beginning of the 1st wave ( January - February 2020)

- The Laboratory task group has launched sequences of laboratory preparedness
- (1) Proposal and practice of testing strategy which are convenient in flexible mode align with country needs
- (2) Updated testing analysis (collative thinking with containment, risk stratification, risk mitigation linked with quarantine, isolation, admission, discharge criteria policy)





# **Beginning of the 1st wave ( January - February 2020)**

- (3) The Ministry of Health and Sports in collaboration with International development partners, UN consortium and individual donors
- (4) Energetic forcing of budget, laboratory work force manpower and all the possible best efforts enable to establish and start the new Public Health Laboratories in short crisis period.



# **Sequences of laboratory preparedness**



- **Feb** .. rt-pCR QC passed from NIH Thailand ..
- **NHL Started self rt-PCR testing**
- **First confirmed Covid-19 case was detected in Myanmar on March 23 , 2020**
- **April** .. Installed Cobas 6800M platform at National Health Laboratory
- **April** .. **DMR started rt-PCR testing**
- **June** .. **PHL Mandalay started rt-PCR testing**
- **June** .. **PHL Mawlamyine started rt-PCR testing**
- **June**.. **New lab construction** by Mandalay Urban Development Committee



- Regular biweekly meeting Epidemiology and Laboratory group meeting since June 2020
- **August** ( 2<sup>nd</sup> wave violence happened in Rakhine State)
- **August** .. Gene X pert platform started
- **September**.. **Taunggyi PHL started rt-PCR testing**
- **September \_ Oct..** High lab testing loading
- **September**.. RDT antigen testing starting ( Under SOP& GL)in high prevalence region
- **October** .. RDT antigen testing to high way travellers
- **November**.. **New PHL Mandalay**
- **December** .. RDT antigen & rt-PCR testing started in private sector
- **December**.. **UM 1 started rt-PCR testing**

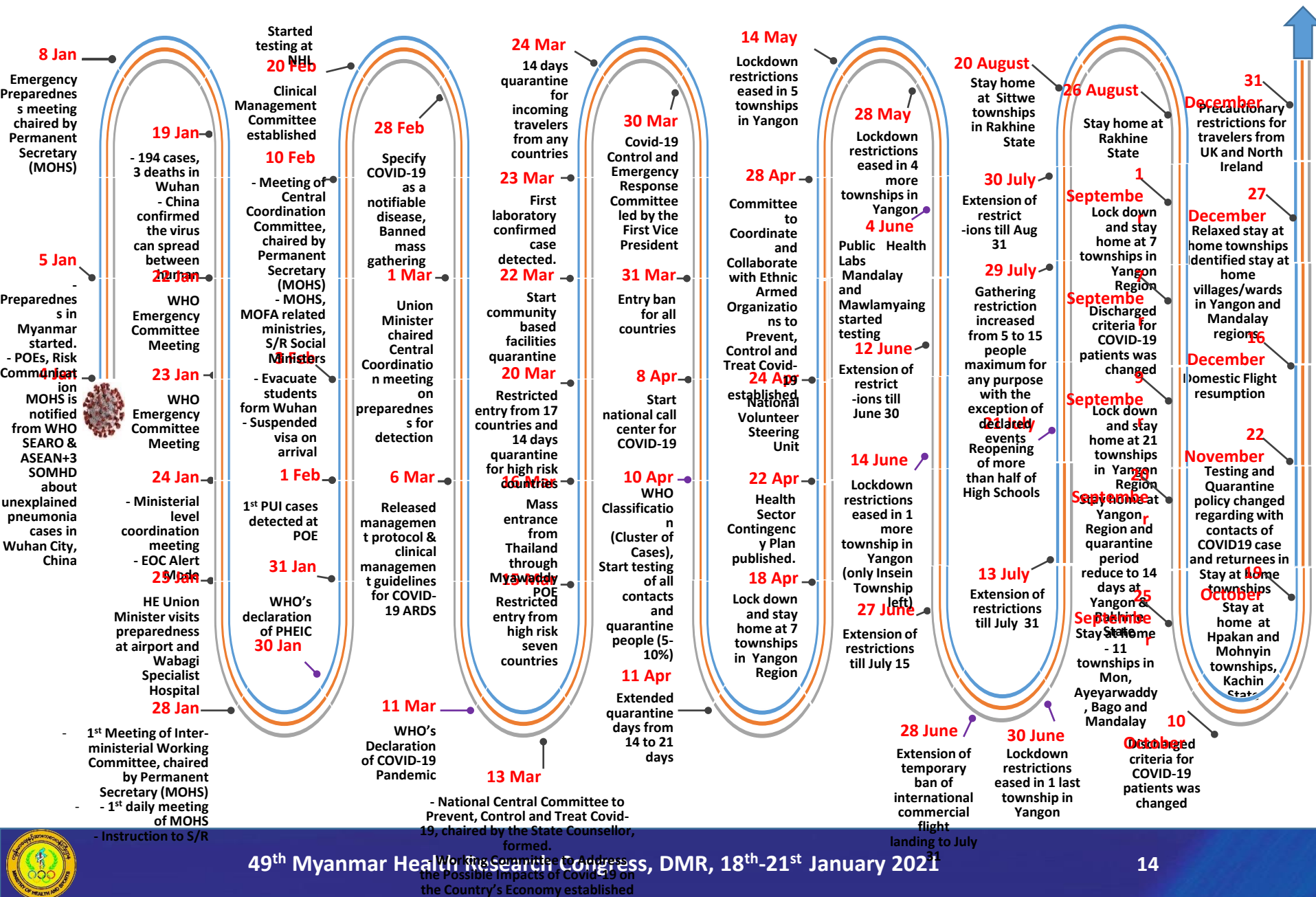


# Key Local & International Development Partners

- Wai Aung Gabar Jewellery Group
- ICAP
- AFD
- JICA
- UNICEF
- UNOPS,
- Access to Health
- ADB
- DFID
- Good Neighbor International
- US-CDC
- Switzerland Embassy
- Singapore Embassy
- CHAI
- MSI
- PSI
- USAID
- WFP
- WHO
- Fondation Merieux
- ECOMORE 2 project
- Japan Government
- World Bank
- Global Fund/ GFATM



# Timeline of Preparedness and Response to COVID-19 in Myanmar



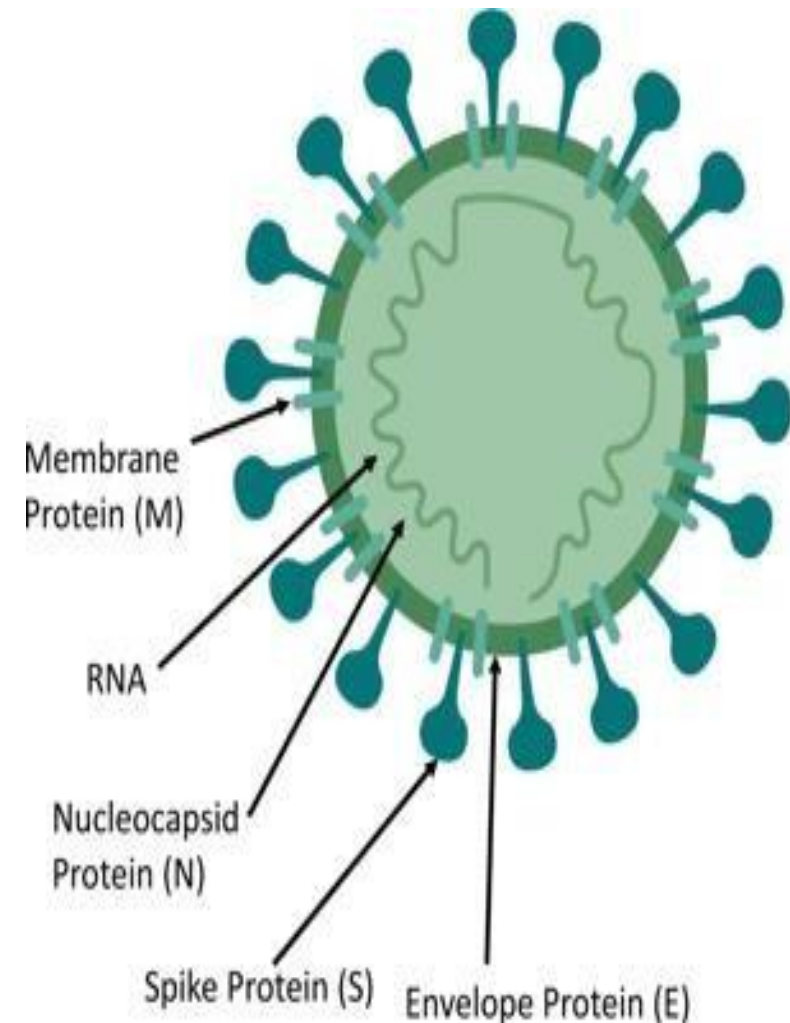
# Public Readiness and Emergency Preparedness Act (PREP Act in first & second wave)

- **EOC Alert Mode** - - Meeting of Central Coordination Committee
- Released management protocol & clinical management guidelines for COVID-19 ARDS
- Covid-19 Control and Emergency Response Committee led by the First Vice President
- Committee to Coordinate and Collaborate with **Ethnic Armed Organizations** to Prevent, Control and Treat Covid-19 established





# MAIN STRUCTURE OF CORONA VIRUSES



Structural Protein	Function of Protein
Nucleocapsid Protein (N)	<ul style="list-style-type: none"> <li>Bound to RNA genome to make up nucleocapsid</li> </ul>
Spike Protein (S)	<ul style="list-style-type: none"> <li>Critical for binding of host cell receptors to facilitate entry of host cell</li> </ul>
Envelope Protein (E)	<ul style="list-style-type: none"> <li>Interacts with M to form viral envelope</li> </ul>
Membrane Protein (M)	<ul style="list-style-type: none"> <li>Central organiser of CoV assembly</li> <li>Determines shape of viral envelope</li> </ul>

- It has been noted that some CoVs do not need to have the full ensemble of structural proteins to make virions, highlighting that certain proteins may be dispensable or compensated by the function of non-structural proteins.

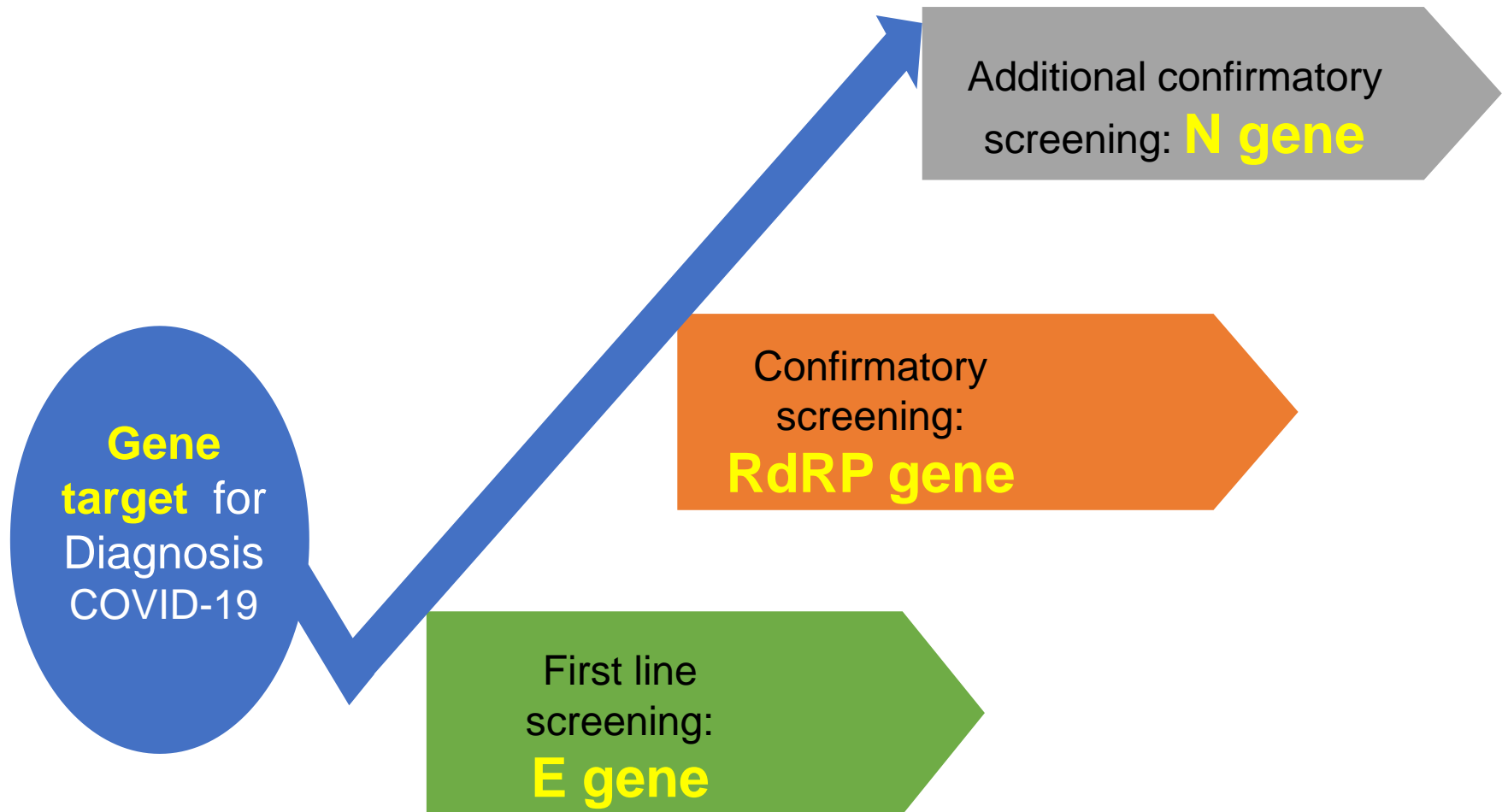


# DIFFERENT TYPE OF ANALYTE LABORATORY TESTING RELATED COVID-19

RNA	Antigen	Antibody	Host Response	Potential Susceptibility
ORF1a/b Gene N Gene E Gene S Gene	N Protein S Protein	IgG IgG IgA	CBC CRP D Dimer Liver & renal profile Procalcitonin Ferritin Troponin-T	ACE2 Gene HLA Gene
rRTPCR, LAMP, NGS	ELISA, Immuno- chromatography	ELISA, Immunochromatography, Chemiluminoscent immunoassay	Enzymatic, colorimetry, flowcytometry, impedance	Genotyping microarray, RT-PCR, Sanger Seq, NGS



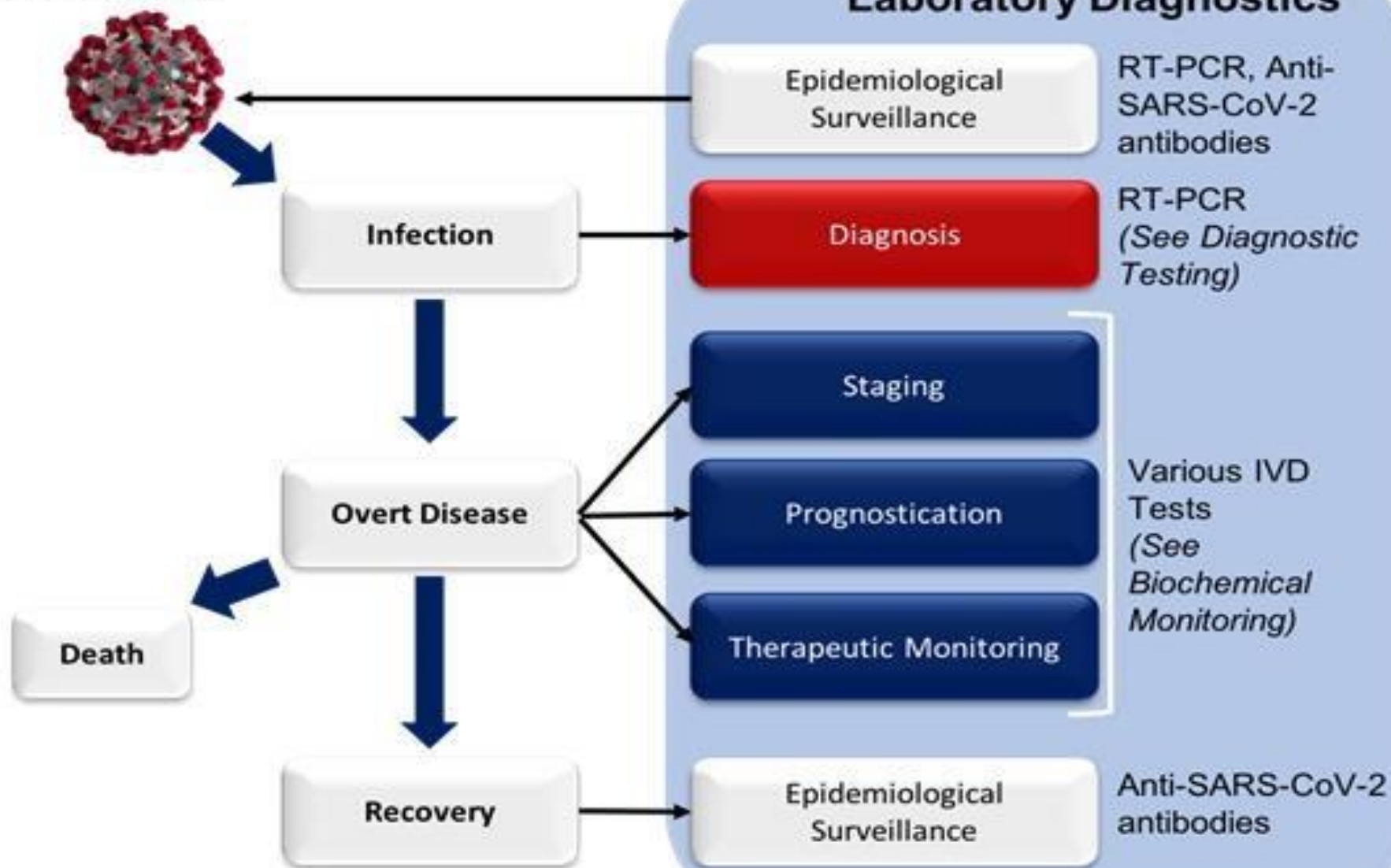
# Gold standard for Diagnosis COVID-19



# The Critical Role of Laboratory Medicine in COVID-19

(Modified from: Lippi et al, PMID: 32191623)

Sars-CoV-2



# WHY MIGHT COVID-19 TESTS FAIL?

They may be in the **early stage** of the disease with a **viral load that is too low to be detected**.

They may have **no major respiratory symptoms**, so there could be **little detectable virus** in the patient's throat

There may have been a **problem with sample collection**, meaning there was very little sample to test.

There may have been **poor handling and shipping** of samples and test materials.

There may have been **technical issues inherent in the test**, e.g. virus mutation.



# **Testing strategy practiced align with country needs**



# Antigen-detection in the diagnosis of SARS-CoV-2 infection

- Ag-RDTs could play a significant role in guiding patient management, public health decision making and in surveillance of COVID-19 if correctly performed and interpreted.
- High specificity is necessary to avoid many false-positive results.
- Sensitivity will depend on the status of patients studied (degree of illness, days since onset of symptoms, etc.) as well as the product quality, but should reach a minimum of  $\geq 80\%$ .



- Myanmar is using WHO EUL Antigen based RDTs
  - **STANDARD Q COVID-19 Ag - SD BIOSENSOR**
  - **Abbott PanbioTM Covid-19 Ag Rapid Tests**
- MoHS provided **Antigen based RDTs in September 2020** to all state and Region using in accordance with MoHs SOP & GL
- **Some State and Regional Government & authorized private centers** procure MoHS approved RDT antigen test kits for use in their respective areas



# SEROLOGICAL TESTING FOR SARS COV- 2

- Much debate regarding the current value of serological testing in COVID-19 **diagnosis and monitoring**.
- Antibodies testing is considered a tool to understand the pandemic dynamics better and broaden the information base for response management. Systematic seroprevalence studies to increase their understanding of where they are in the pandemic.
- **Valuable in research & evaluation of immunization program**
- **A supportive guidance in convalescence plasma therapy**





# By ..Elecsys® Anti-SARS-CoV-2 Immunoassay for the qualitative detection of antibodies (incl. IgG) against SARS-CoV-2 Among Yangon Region Health Care Providers (2020, November and December)

	Number	%
Positive	553	7.3
Negative	7048	92.7
Total	7601	100.0

# Summary of some differences between RT-PCR test and Rapid Antigen test

	RT-PCR test	RDT Antigen test
Intended use	Detect current infection	Detect current infection
Analyte detected	Viral RNA	Viral antigen
Specimen type	Nasal swab, sputum swab, saliva	Nasal swab
Sensitivity	High	Moderate
Specificity	High	Moderate
Test complexity	Varies	Relatively easy to use
Authorized to use at POC	Most are not, some are	Yes
Turn around time	Up to 2 days	Approximately 15 minutes
Cost/Test	Moderate	Low



- **With PCR and Cobas platforms**

1. National Health Laboratory, **Yangon**
2. Department of Medical Research, **Yangon**
3. Public Health Laboratory, **Mandalay**
4. Public Health Laboratory, **Mawlamyine**
5. Public Health Laboratory, **Taunggyi**
6. Public Health Laboratory, **Muse**
7. **University of Medicine (1). Yangon**
8. No.1 Defense Service General Hospital, **Yangon**
9. No.2 Defense Service General Hospital, **Naypyitaw**
10. Defense Medical Research Center, **Naypyitaw**
11. **17/100** Defense Service General Hospital, **Sittwe**
12. **1/700** Defense Service General Hospital, **Pyinoolwin**

- **With GeneXpert testing platform –**

29 sites across the country

**COVID-19 Labs**  
**(\* 12 rt- PCR Labs**  
**&**  
**\* 29 GeneXpert**  
**sites)**



# COVID-19 (GeneXpert) testing Labs in Myanmar

No.	Location	No.	Location
1.	National Health Laboratory	16.	Magway Reigional General Hospital
2.	Naypyitaw 1000 bedded Hospital	17.	Taungoo General Hospital
3.	Myitkyina General Hospital	18.	Pyay General Hospital
4.	Bhamaw General Hospital	19.	Bago General Hospital
5.	Kawthaung General Hospital	20.	Kyaingtone General Hospital
6.	Dawei General Hospital	21.	Tachilek General Hospital
7.	Myeik General Hospital	22.	Muse General Hospital
8.	Hpa-Ann General Hospital	23.	Loikaw General Hospital
9.	Myawaddy General Hospital	24.	Hahka General Hospital
10.	Patheingyi General Hospital	25.	Tedim General Hospital
11.	Myaungmya General Hospital	26.	Pyinoolwin General Hospital
12.	Sittwe General Hospital	27.	Specialist Hospital Waibargi , Yangon
13.	Kyaukphyu General Hospital	28.	Yangon General Hospital
14.	Monywa General Hospital	29.	University of Medicine 2
15.	Kalay General Hospital		



# Ongoing new PHLs & new Covid-19 laboratories

Developer	Testing platform	City / Region
World Food Program	(4)Cobas Liats Machines	Sittwe , Pauktaw , Thandwe and Kyawkphyu General Hospitals in Yakhine Region
Switzerland/ Swiss Agency for Development and Cooperation (SDC)	(6)Cobas Liats Machines	Maungdaw, Sittwe , Tarchilek, Myikyenar ,Myawadi General Hospitals and in local health community center in Karen State
MoHS	One rt-PCR laboratory	Public health laboratory , Lashio



# Ongoing new PHLs & new Covid-19 laboratories

Developer	Testing platform	City / Region
Thailand International Cooperation Agency	rt-PCR laboratory	Myawaddi General Hospital
Myanmar Wonpaung Co-Ltd	One rt-PCR laboratory	Monywa General Hospital, Sagaing Region
World Bank , Pandemic Emergency Facility (PEF) Grant	Ten Roche Cobas e411 Fully automated immunology analyzer together with 19,000 reagents for Sars-CoV-2 antibody	Sittwe ,Myawaddy, Myitkyina, Hpa-an, Loikaw, Hakha , Kyaingtone, Kyauk Phyu , Monywa and Myeik _ General Hospitals



# Training on Covid-19 testing at Hospital Laboratories

- Training on COVID-19 Testing using the GeneXpert platform with safety precautions was conducted on

**11 & 12 August 2020**  
**by two batches.**



# **The most updated testing SOPs**

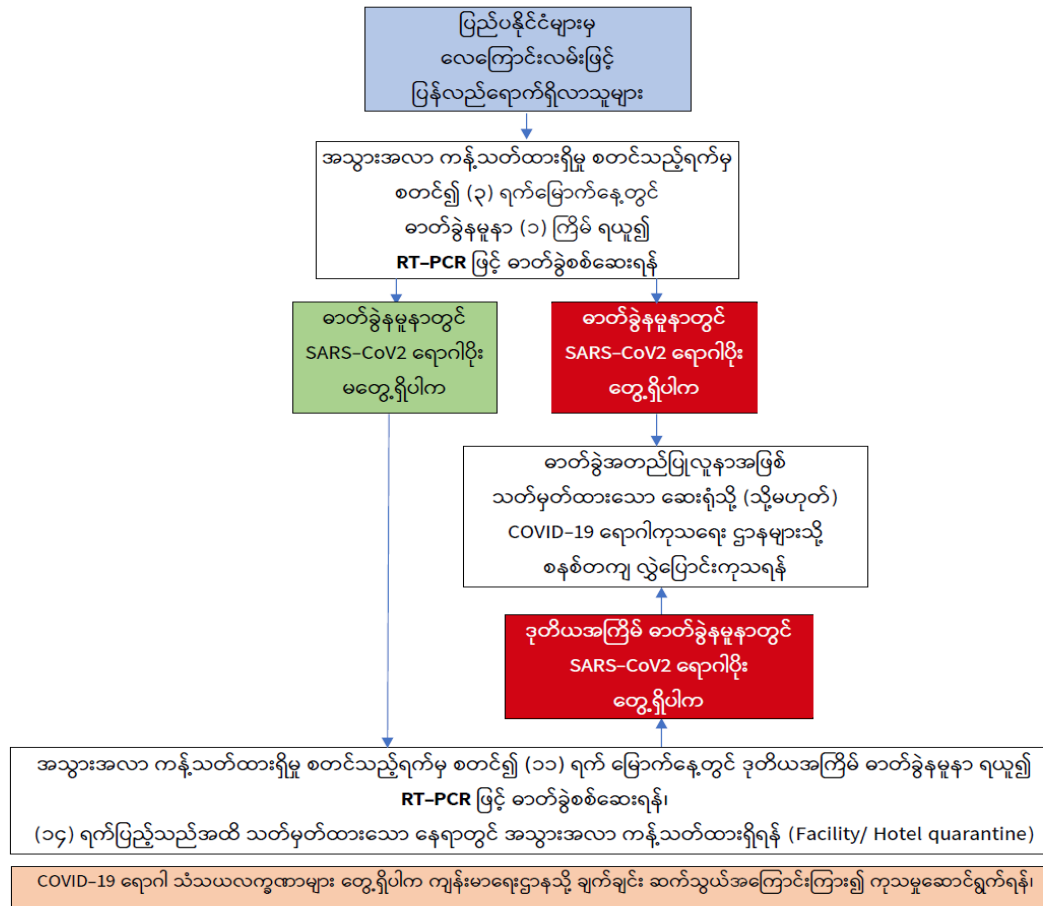
## **6.1.2021**







လေကြောင်းလမ်းဖြင့် ဝင်ရောက်လာသူများအား  
 COVID-19 ဓာတ်ခွဲစစ်ဆေးခြင်းနှင့်ပတ်သက်၍ ပြောင်းလဲဆောင်ရွက်မည့် အစီအစဉ်  
 (၆-၁-၂၀၂၁)

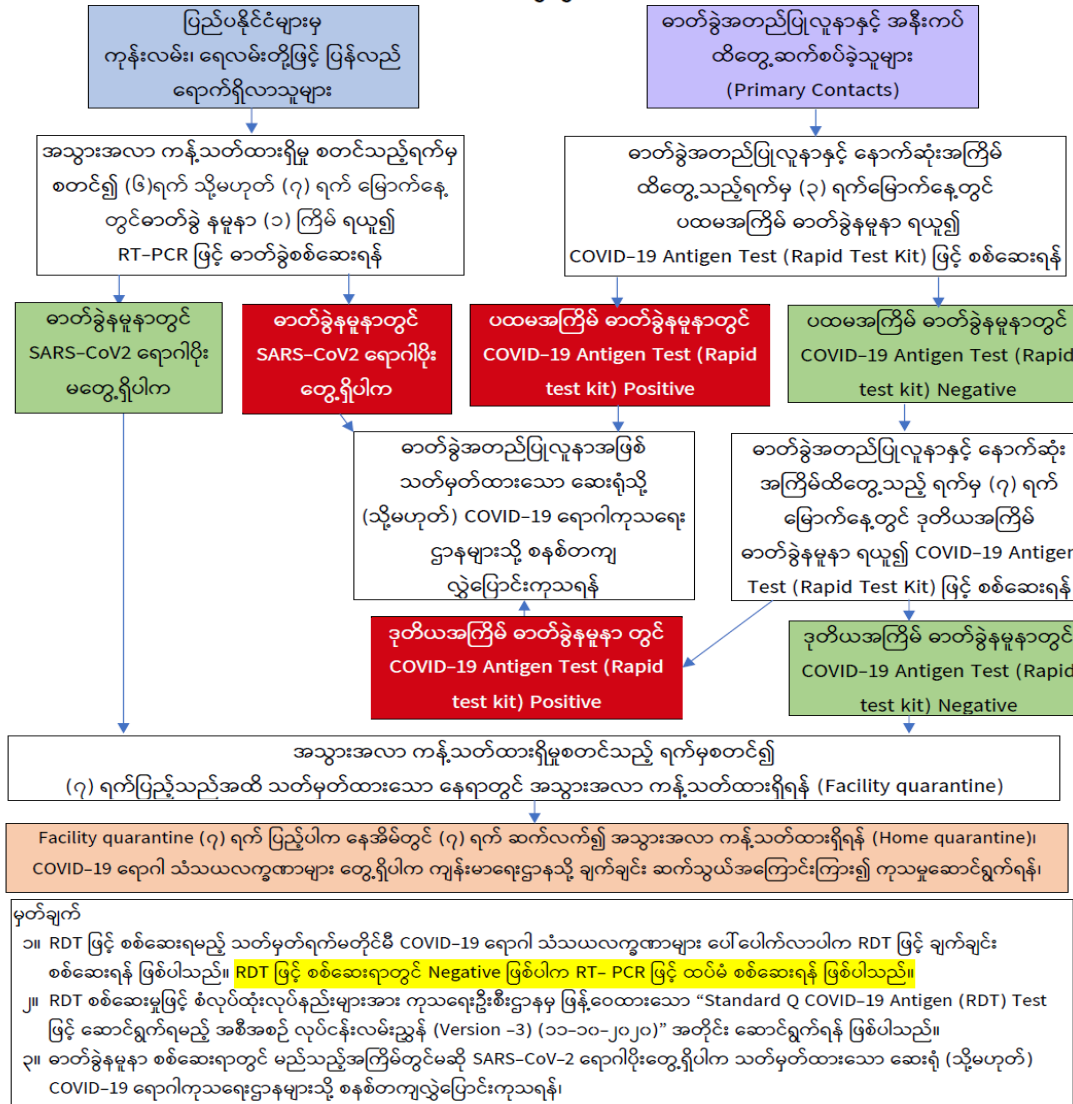


မှတ်ချက် -

(၇-၁၂-၂၀၂၀) ရက်စွဲဖြင့် ထုတ်ပြန်ထားသော လုပ်ငန်းလမ်းညွှန်အစား ဖော်ပြပါ (၆-၁-၂၀၂၁) ရက်စွဲပါ လုပ်ငန်းလမ်းညွှန်ဖြင့် ပြောင်းလဲ အသုံးပြုရန် ဖြစ်ပါသည်။



**နေအိမ်တွင် နေထိုင်ရေးအစီအစဉ် (Stay at home)**  
**သတ်မှတ်ထားသော မြို့နယ်များတွင် COVID-19 ဓာတ်ခွဲစစ်ဆေးခြင်းနှင့်ပတ်သက်၍**  
**ပြောင်းလဲဆောင်ရွက်မည့် အစီအစဉ်**  
**(၆-၁-၂၀၂၁)**



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ပြည်သူ့ကျန်းမာရေးဦးစီးဌာန

# Laboratory Biosafety

- Develop **Laboratory Biosafety Training Curriculum** and distribution to all level laboratories
- **ToT Training** on Laboratory Biosafety Training Curriculum
- Provide **biosafety practices** especially on COVID-19 specimen collection and transport
- **Decontamination** procedures for biohazard waste
- **Proper use of PPE** through biosafety trainings and distribution of Laboratory Biosafety Training Curriculum

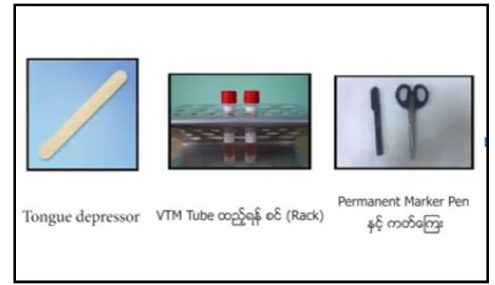


## Development and dissemination of guidelines and SOPs

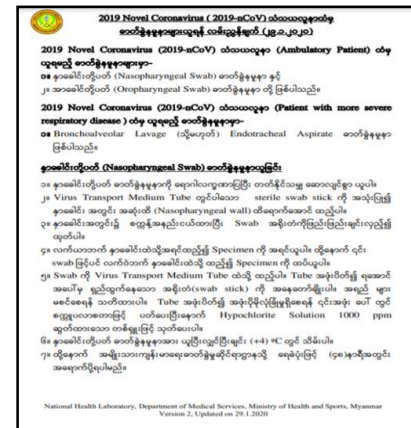
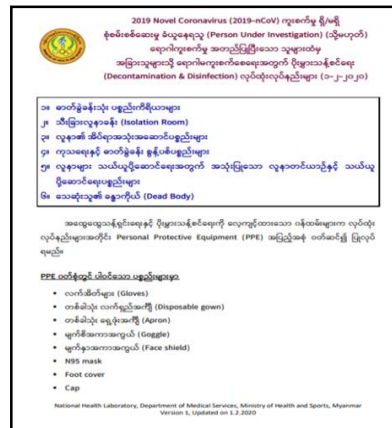
**Video clip creation on proper donning and doffing of full level PPE and distributed to all laboratories for reference**



**Video clip creation on Method of proper sample collection and sample transportation and proper handling of samples and distributed for reference**



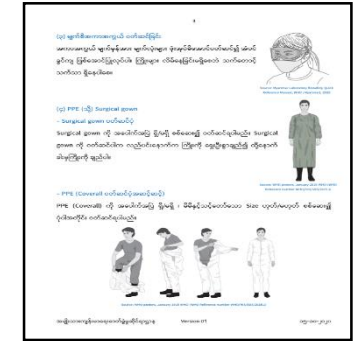
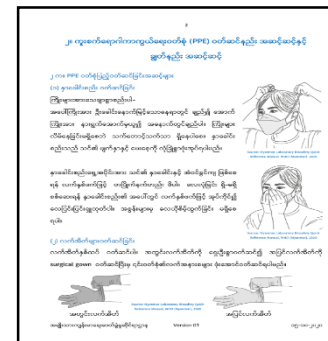
## Distribution of Guidelines on Sample collection, packaging and transportations, Decontamination and Disinfection procedures



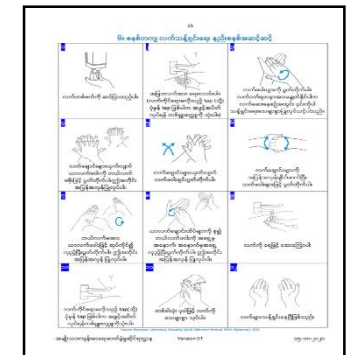
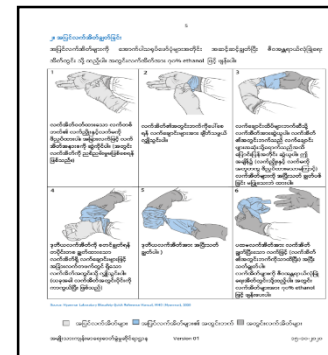


# Development and dissemination of guidelines and SOPs

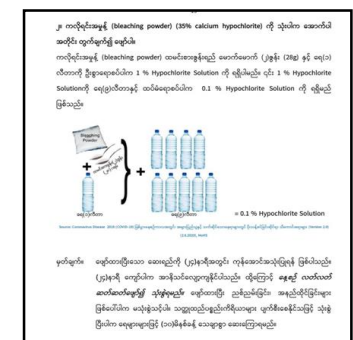
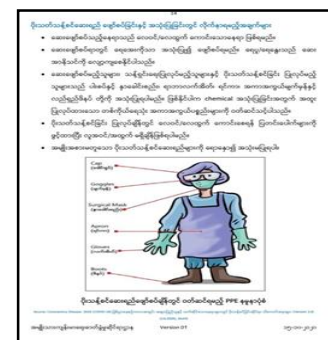
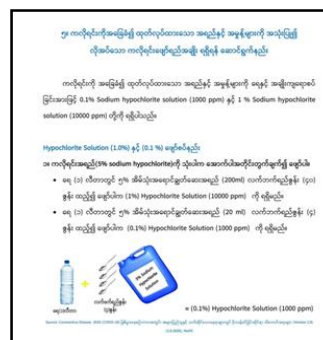
Develop guidelines on using Rapid diagnostic testing (RDT) (V 01)



Develop guidelines on laboratory waste management system



Guidelines on using disinfectants



# Active role as well as cooperated tasks in development of Training Guidelines on COVID-19 Testing at Hospital Laboratories and Public Health setting

- Laboratory Testing Guideline of COVID-19 Testing by Standard Q Antigen (RDT) Version 01 to Version 04 (10 October 2020)
- Guidelines on laboratory biosafety using COVID-19 Rapid antigen testing ( 15.10.2020)
- Laboratory Biosafety Training Curriculum ( February 2020)
- Guidelines on laboratory waste management system (7.4.2020)
- Instructions on PPE donning and doffing (16.4.2020)
- Guidelines on using disinfectants ( version 1.1 -6.4.2020) & ( version 2.0-2.6.2020)
- Guidelines on nasopharyngeal and oropharyngeal swab sample /taking, packaging and transportation ( 14.4.2020)
- RDT Antigen testing Algorithm ( version 3-10.11.2020)
- Testing Algorithm for close contact at Q center
- Changed testing SOP in stay at Home Designated township Program (6.1.2021)
- Changed testing SOP in stay at Home Non-designated township Program (6.1.2021)



# Testing Analysis \_ through 2020



# Lab confirmed positive cases in - 2020

Months	Total
Mar	21
Apr	130
May	313
Jun	71
Jul	54
Aug	609
Sep	13551
Oct	37922
Nov	37774
Dec	34185
<b>Grand Total (Positive)</b>	<b>124630</b>

Week42	77976	8544	69432
Week43	99190	9085	90105
Week44	91707	8739	82968
Week45	90899	7408	83491
Week46	102215	7664	94551
Week47	118874	9838	109036
Week48	124741	10128	114613
Week49	136772	10070	126702
Week50	149638	9436	140202
Week51	154190	7972	146218
Week52	147057	6093	140964
Week53	94823	3350	91473
<b>Total</b>	<b>1724874 (Tested)</b>	<b>124630 (Positive)</b>	<b>1600244 ( Not detected)</b>

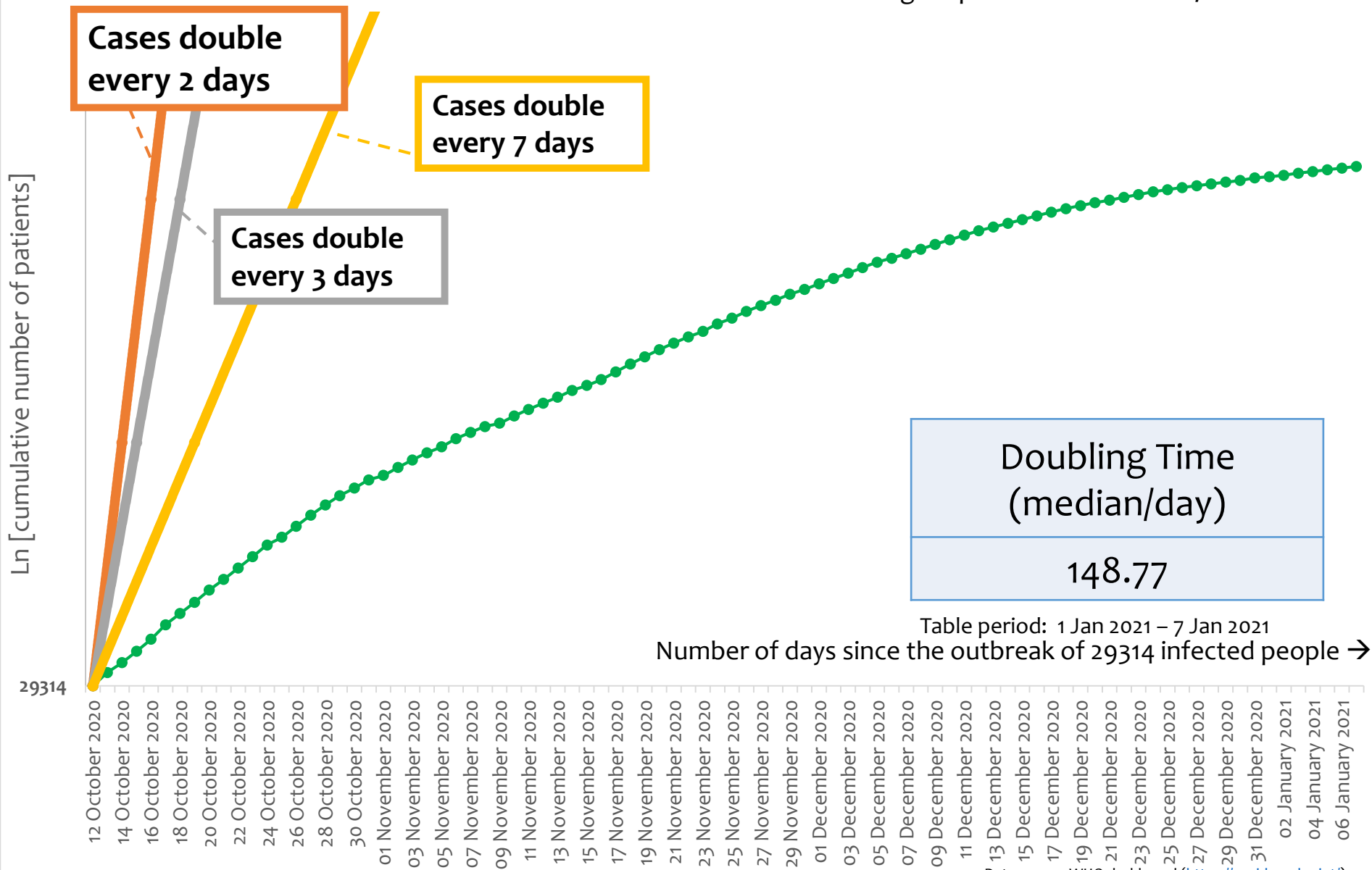
State and Region	Total
Ayeyarwaddy	4797
Bago	7745
Chin	214
Kachin	585
Kayah	44
Kayin	208
Kayin	893
Magway	2775
Mandalay	13731
Mon	2337
Naypyitaw Council	947
Rakhine	4138
Sagaing	1903
Shan (East)	141
Shan (North)	212
Shan (South)	452
Tanintharyi	573
Yangon	82935
<b>Total</b>	<b>124630 (Lab confirmed Positive)</b>





# Cumulative cases with the indicator of doubling time - median of last 7 days

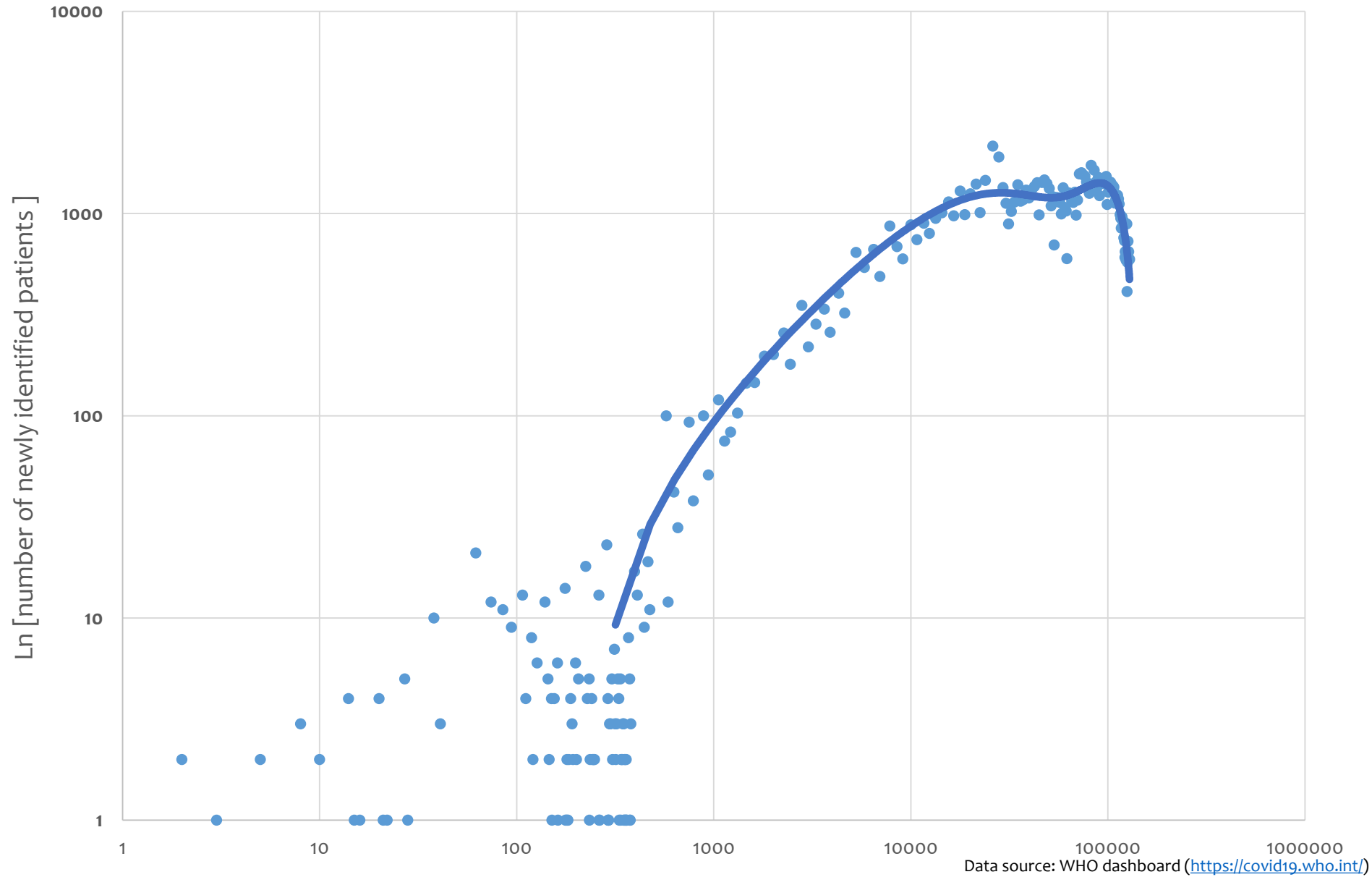
Figure period: 12 Oct 2020 - 7 Jan 2021



Data source: WHO dashboard (<https://covid19.who.int/>)  
 Myanmar ministry of health and sports  
 CORONAVIRUS DISEASE 2019 (COVID-19)  
 SITUATION REPORTS (MYANMAR)  
 (<https://mohs.gov.mm/page/9575>)

# Trajectory Analysis

Figure period: 24 Mar 2020 - 7 Jan 2021



Data source: WHO dashboard (<https://covid19.who.int/>)

Myanmar ministry of health and sports  
CORONAVIRUS DISEASE 2019 (COVID-19)  
SITUATION REPORTS (MYANMAR)  
(<https://mohs.gov.mm/page/957/>)

18. Jan 2021

49<sup>th</sup> Myanmar Health Research Congress, DMR, 18<sup>th</sup>-21<sup>st</sup> January 2021



# Explored activities to opportunities

Strengthen the testing capacity of SARS COV 2 in NHL



providing reagents ,  
consumables , training and  
technical assistance

Organize training courses  
and technical assistance

Implement the epidemiological,  
serological , molecular  
biology and other  
studies



Discuss to choose the topic  
to do epidemic-laboratory  
protocols

Think of knowledge based  
inputs to immunization

Strengthen the testing  
capacities of new  
regional PHLs



Initiate new PHL in short  
period by Gov't & donor  
access

Needs of equipment  
,receive , allocate and install  
them to earlier start of PCR

Conduct NEQAS  
provider and IEQAS  
coordination with  
WHO, ASEAN and RPHL  
network



Assessment / QA survey on  
IQAS system

Distribute EQAS samples to all  
regional PHLs



# Explored activities to opportunities

Title	
Strengthen the testing capacity of SARS COV 2 in NHL	➡
Strengthen the testing capacities of new regional PHLs	➡
Implement the epidemiological, serological, molecular biology and other studies	➡
Strengthen the testing capacities of all PHLs	➡
	Manage to procurement of rt-PCR reagents, GX reagents, Cobas 6800 M reagents, consumables and delivering to all PHL labs
	Forecasting of national needs in 6 months ahead, direct reporting to Ministry Organize training courses, QC courses & technical assistance
	Biweekly Joint Task Force Meeting meeting with UNs agencies, INGOs and DPs through Epi and Lab meeting
	Total (12+29) PCR labs across the country together with new advanced molecular lab in upper Myanmar All PHLs have direct access of QC to WHO IEQAS

# Challenges

- **Budget** .. High cost for nucleic acid testing , sustainability by Govt , international development partners and local donors for the sustainability

## **\*Long term journey\***

- A need to establish an **internal industrial resource of lab testing consumables.**
- **Proper / Medical grade protective gears for Laboratory Health Care Providers!!**

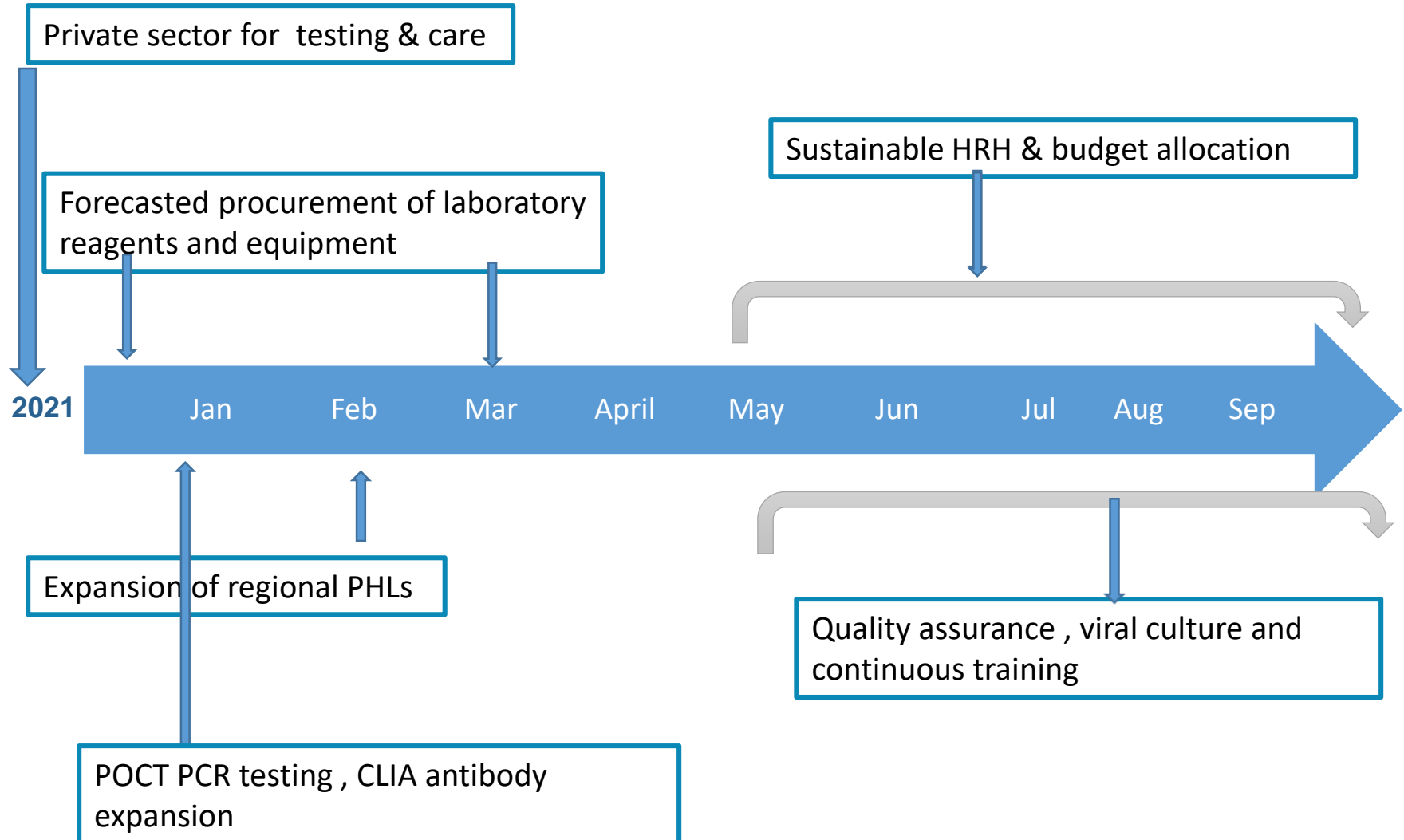


# Challenges

- Energetic budget allocation , manpower and huge **effort made to recruit laboratory resources** for new PHLs in short crisis period
- Year 2021 plan to expand new laboratories in critical areas
- **Going to resume** normal trade, international travel , travelling , school , factory .. **Applicable new laboratory strategy ?**



# Moving forward



# Forwarding...

- The MoHS has prioritized increasing testing capacity for COVID-19 with significant results.
- At current daily output, **approximately 4.2 million tests will be needed until the end of September 2021.**
- **As per 2020, December, the total COVID-19 test per 1000 people is 28.93**
- Fund contribution by both the government and the UN by regular forecasting of reagents and consumables
- Considering Seroprevalence survey as a critical element of the testing strategy and public health response.





# Forwarding...

- **Scale-up testing information system** to know the source of new infection and the coverage of each target group
- **Laboratory logistics management system align with expanding laboratories at strategic sites especially in EHO areas and POE**
- Continuing **quality assured capacity building**
- **Increasing private sector involvement** in test and care area bearing the huge work load of public health sector for faster rolling out of daily new normal life



To All The Wonderful  
Healthcare Workers



Thank You ! Thank you !  
**THANK YOU !**