
Expansion of COVID-19 PCR Diagnostic Capacity to the Subnational Level: *Ethiopian Experience*

Adisu Kebede
Ethiopian Public Health Institute
Addis Ababa, Ethiopia
May 22/2020



Outline

- Background
- Laboratory Expansion
 - Considerations for selection
 - Current Testing Labs
 - Instrument Platforms
- Integration with HIV Program
- Quality Assurance
- Sample Referral linkage
- Challenges

Background

- The National Influenza and Arbovirus Reference Laboratory (NIARL) is pioneer labs in COVID-19 Testing
 - Established in 2008
 - Scope of service
 - Influenza and other respiratory virus
 - Corona Virus strains(except SARS and COVID-19)
 - Arbovirus (Yellow Fever, Dengue fever, Chikungunya, Zika, Westnile..)
 - Hepatitis A and E

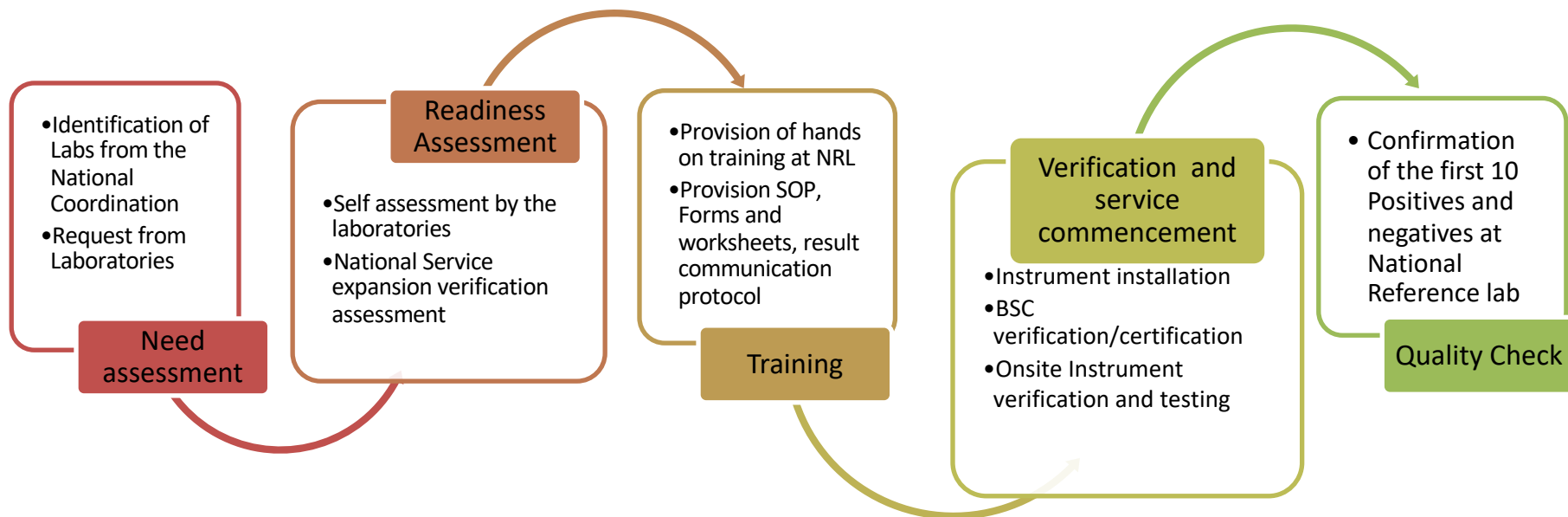
Background...

- COVID-19 Testing in Ethiopia
 - Referral Testing Service from South Africa Started on January 28/2020
 - Personnel trained in Dakar and at EPHI
 - NIARL Started COVID-19 Diagnosis - February 07/2020
 - NIARL was the only Laboratory in the country until April 07

Laboratory Expansion


- Ever increasing testing need couldn't be met by the National Reference Lab only
- National Capacity and readiness assessment undertaken

Laboratory Selection and Test Expansion Process



Considerations in Expansion

- Site Readiness Assessment Check List for COVID-19 Testing Sites(Customized from WHO)


Ethiopian Public Health Institute
Site Readiness Assessment Check List for COVID Testing Sites

Name of Health Facility/Laboratory:				
Region:				
Date of Visit:				
S.N	Contact Person	Position/Role	Telephone	E-mail

I. General Information



Checklist Components

Functional RT PCR machine

Availability of functional and certified Biosafety Cabinet class II

Infrastructures (UPS ,Backup generator, Water supply,Adequate electric supply)

Adequate ventilated space for molecular techniques(minimum of two separate rooms

Dedicated specimen collection/reception area

Critical Auxiliary instruments:(Micro centrifuge ,Micropipettes, Refrigerator (2-8oc),Freezers (-20°C and -70 °c,Vortex mixer/ Shaker, Heat block/ water bath

Availability of sufficient manpower on RT PCR technique

Practice of Biosafety and Biosecurity
Access Control System(PCR lab, Refrigerators ,store room)

Implementation of LQMS (availability of Quality Manual, SOPs, Job aids, Document control system)

COVID-19 Testing Laboratories



-Functional/Testing Labs- 29
-Ready -7
Candidates--27
Total-53 sites and 62 instruments

Laboratory: Testing Surge Capacity

Status	Number	Testing Capacity/day
Functional Laboratories(Testing And Reporting)	29(4 in EPHI)	7597
Ready	7	
Under Verification Process	1	100
Candidates(training and Verification planned)	26	6900
Total(instruments)	53 (61 instruments)	14597

Instrument Platforms in use

	Model	Manufacturer	In use	Potential for use
1	ABI7500	Thermo fisher	6	
2	Quantastidio5	Thermo fisher	6	
3	Quantastidio7	Thermo fisher	1	
4	Roter Gene Q	QIAGEN	2	
5	Abbott m2000 rt	Abbott	10	20
6	Light Cycler480 II	Roche	1	
7	Cobas 4800	Roche	2	6
8	Line Gene9600	Bioer	5	
9	CFX96TM	Bio Rad	1	
10	Aria mx3005P	Agilent	9	

Integration with HIV program

	Model	Manufacturer	Available	operational
1	Abbott m2000 rt	Abbott*	20	10
2	Cobas 4800(Z480)	Roche**	8	6

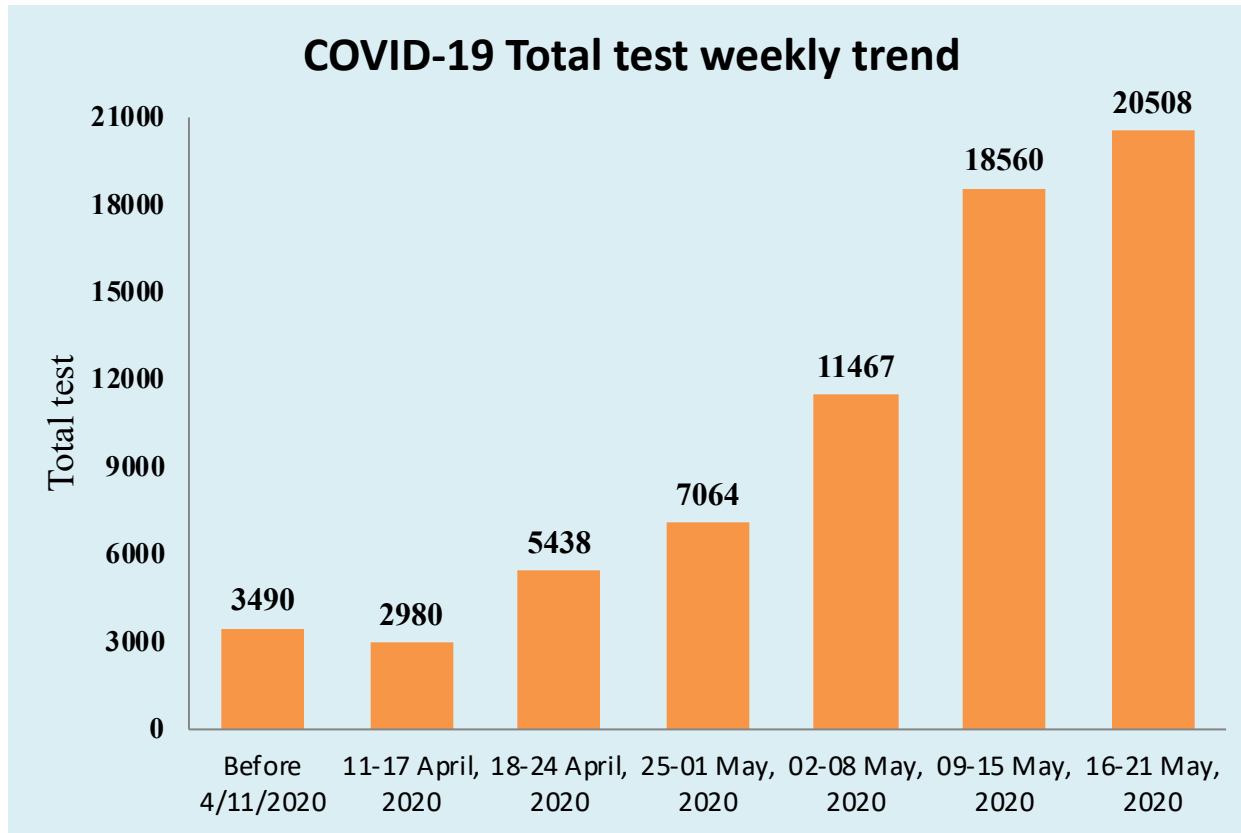
*Repurposing Abbott DNA PCR extraction kits with automated extraction and Amplification/detection using third party reagents

**Negotiated to use third party reagents with manual extraction and amplification/detection

Considerations while integrating


- Analysis of current utilization rate for HIV VL and EID
- Training of More professionals
- Institutions 24/7 work schedule
- Making use of extra instruments for COVID-19 testing

Trend of Weekly Testing Volume



Quality Assurance

- Training
 - 3-5 days hands on training at EPHI
- Verification
 - 2-3 days onsite training
 - known samples run blindly
- EQA
 - Ongoing PT EQA (NEQAS)
 - Periodic confirmatory retesting at NICD/NHLS
 - Onsite technical support
 - Weekly Quality Performance indicators collected and

	Ethiopian Public Health Institute National Influenza & Arboviral Laboratory	Doc. No: EPHI/NAL/PS/6-03	
		Effective date: February 13, 2020	
	COVID-19 Testing Capability Verification Summary	Page No. 1 of 1	Version No: 1

Laboratory Name: Amhara Public Health Institute-Dessie Branch


COVID -19 Testing Capability Verification Summary Table

Sample Code	Verification result	Expected result	Final result
1849	Positive	Positive	Acceptable
1849D	Positive	Positive	Acceptable
1868	Negative	Negative	Acceptable
1872	Negative	Negative	Acceptable
1850	Negative	Negative	Acceptable


Conclusion: The laboratory fit for testing COVID-19 test using Agilent, Stratega, Mx 3000P RT-PCR analyzer.


Note: The laboratory shall ensure the quality of COVID-19 testing by performing them under defined conditions.

Prepared By: Nebiyou Yemanehirsane

Signature: 

Date: 4/21/2020

Approved By:  Adisu Kebede
A /Director, National Laboratory Capacity Building Directorate



Documents Development

- COVID-19 Laboratory Testing Strategy
- COVID-19 Laboratory QA document
- Specimen Pooling Protocol
- Specimen Management and Result communication Protocol



Specimen Referral Linkage

- Specimen Transportation
 - Dedicated Specimen transportation system
 - EPHI
 - Hospitals(Public/Private)
 - Regional Health Bureaus
- Referral Network
 - All health facilities are linked to nearby PCR testing sites through optimized referral network

Challenges

- Inconsistent Supply of reagents and consumables
- Timely reaching all sites for technical support and QA activities

Thank you



Public Health Emergency Operations Center



ጠና ማኅተር - ኢትዮጵያ
MINISTRY OF HEALTH-ETHIOPIA
ጤንና ጤናማ ሕይወት