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Laboratory Information Considerations for Supporting COVID-19 Response and Beyond

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Who is APHL?

- A non-profit, non-governmental US based organization with a global perspective
- Over 800 members from public health, environmental and agricultural laboratories, federal agencies and academic institutions
- Supports government laboratories that conduct testing of public health significance
- Advocates at the national level to shape public health policy
- Provides training, model practices and technical assistance domestically and internationally



Learning Objectives

Upon completion of this webinar participants will be able to:

- Describe strategies used to support the data management needs of laboratories for COVID-19 testing
- Learn about common challenges faced and lessons learned and implemented in 2 countries
- Describe actions needed to support management of COVID-19 and other immediately notifiable diseases





CHALLENGES ENCOUNTERED

Turnaround Time

Data Quality

Reporting

Data Sharing

Strategies for Laboratory Data Management

LIMS EXPANSION

Enhancing LIMS to add COVID-19 testing and reporting

DATA EXCHANGE

Linking laboratory analyzers used for COVID-19 testing with LIMS and sharing data between systems

CENTRALIZED LABORATORY DATA REPOSITORY

Submitting laboratory data from multiple data sources to a central repository

ELECTRONIC SAMPLE REFERRAL

Capturing laboratory data electronically at points of sample collection and submitting to LIMS at testing laboratory; results returned similarly

LIMS: OVERVIEW, BENEFITS, FUNCTIONS AND ROLE IN PUBLIC HEALTH



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APHL LIMS Guidebook

<https://www.aphl.org/aboutAPHL/publications/Documents/GH-2019May-LIS-Guidebook-web.pdf>



Laboratory Information Systems Project Management:

A Guidebook for International Implementations

A Guidebook for International Implementations



- To share
 - Best practices development
 - Lessons learned
 - Successes achieved
- We have been doing this for a while
 - Over two decades with multiple experts, staff, various MOH

What is a LIMS?



LIMS GETS DATA OUT

Reports test results for patient care
Reports data to administration, MOH,
national and international agencies

LIMS SUPPORTS WORKFLOWS

Tracks laboratory information
during testing
Collects, stores, archives and
analyzes laboratory data



DEMAND FOR LIMS



Technological advances resulting in higher specimen volumes and greater demand and reliance on laboratory data



Inefficiencies from paper based record keeping and results reporting



Tremendous growth for LIMS adoption

Role of a LIMS



 **Decrease transcription errors**

 **Meet quality standards**

 **Reduce Turnaround Time**

 **Improved patient outcomes and public health**

Core Functions of a LIMS

DATA FOLLOWS THE SPECIMEN



PRE ANALYTICAL

- Specimen management and tracking
- Patient management
- Physician management
- Testing management
- Test Orders
- Referral system



ANALYTICAL

- Electronic transfer of data
- Test queue
- Test performed
- Test result/QC data from instrument to LIMS
- Test results verified and released



POST ANALYTICAL

- Reports management
- Types of reports
- Report distribution
- Long term result storage
- Data Exchange with other system
- Billing

SECURE DATA EXCHANGE WITH OTHER INFORMATION SYSTEMS

To be impactful



Data needs to get into the right hands quickly

Data must be provided to multiple stakeholders across clinical and public health

Data must be accurate and consistent

Informatics solutions to evolve to meet new data sharing demands of laboratory and surveillance

CENTRALIZED LABORATORY DATA REPOSITORY

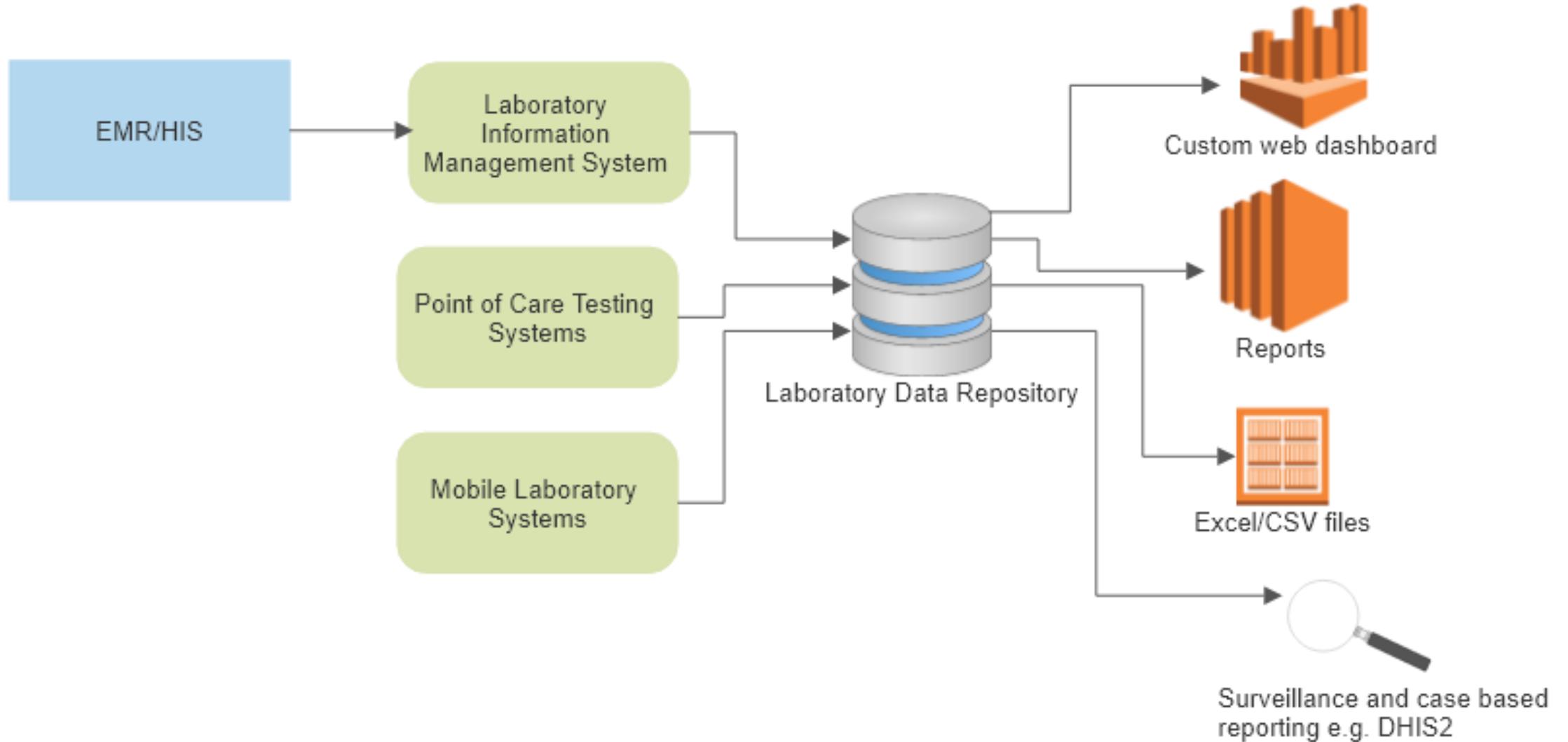


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Centralized Laboratory Data Repository

- A single storage location for all data



DATA EXCHANGE



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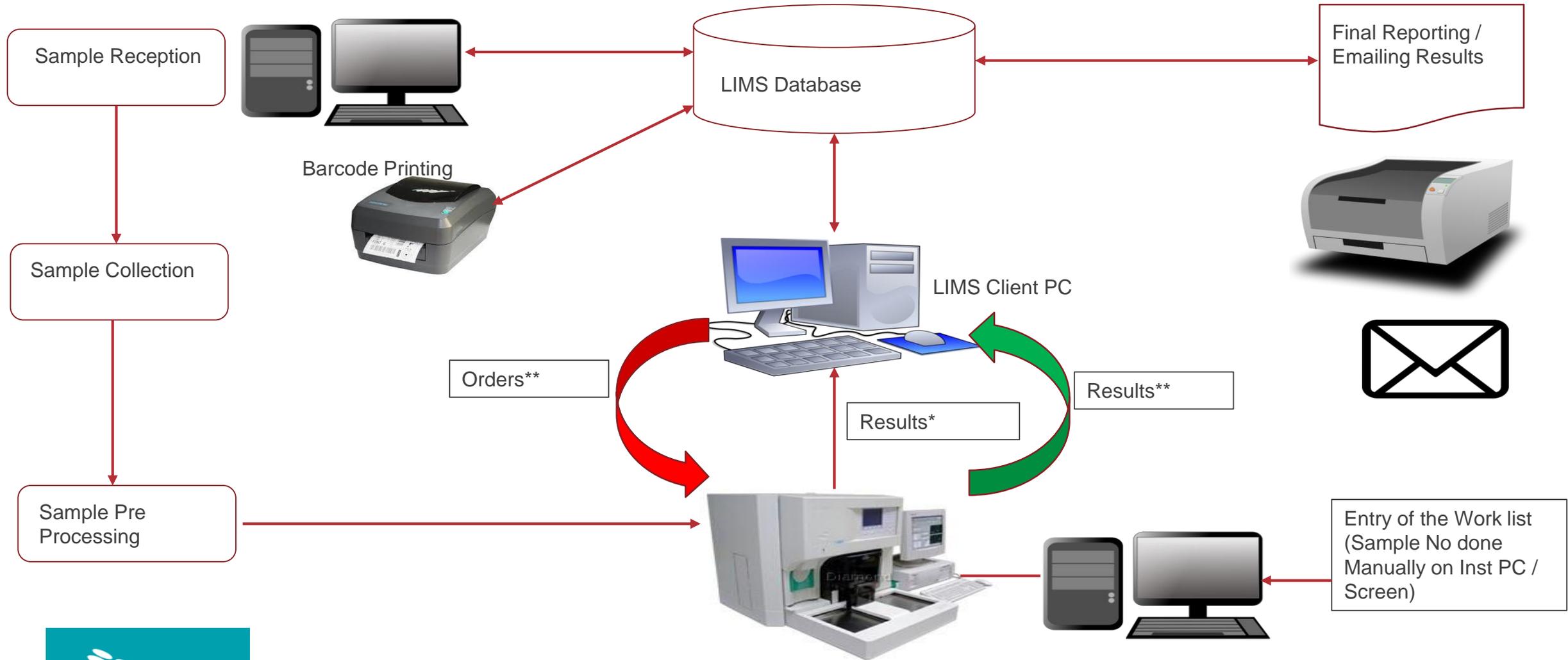
DATA EXCHANGE

**INSTRUMENT INTERFACING
SYSTEM INTEGRATION**

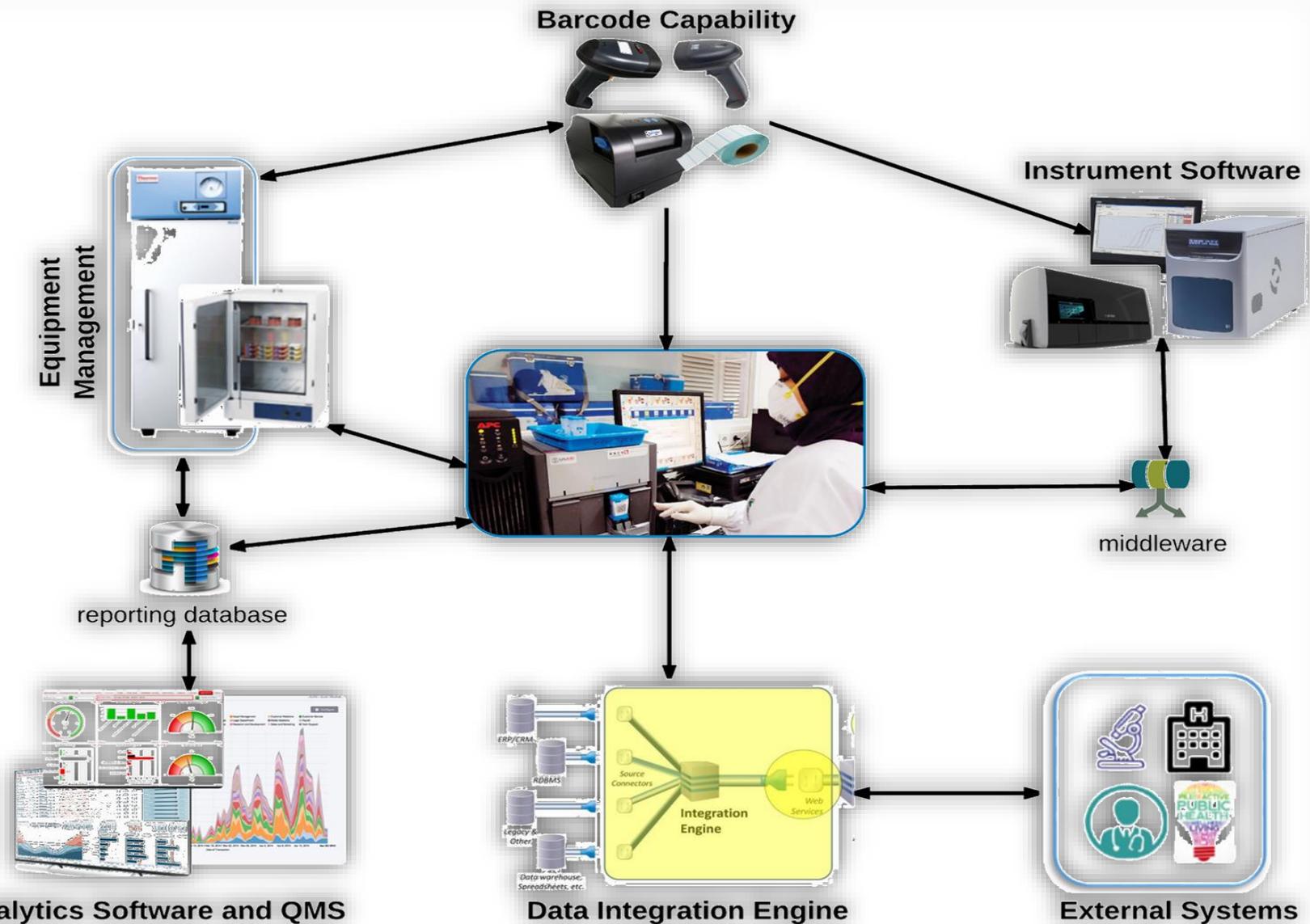
Instrument Interfacing

- Capture of COVID-19 test results from PCR analyzers and sharing of these data with **LIMS** and **repository**
- Capture of COVID-19 test results from Point of Care/Rapid Diagnostic instruments and sharing of data with **repository**

LIMS Instrument Interfacing



Integration with External Systems



Analytics Software and QMS
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ELECTRONIC SAMPLE REFERRAL



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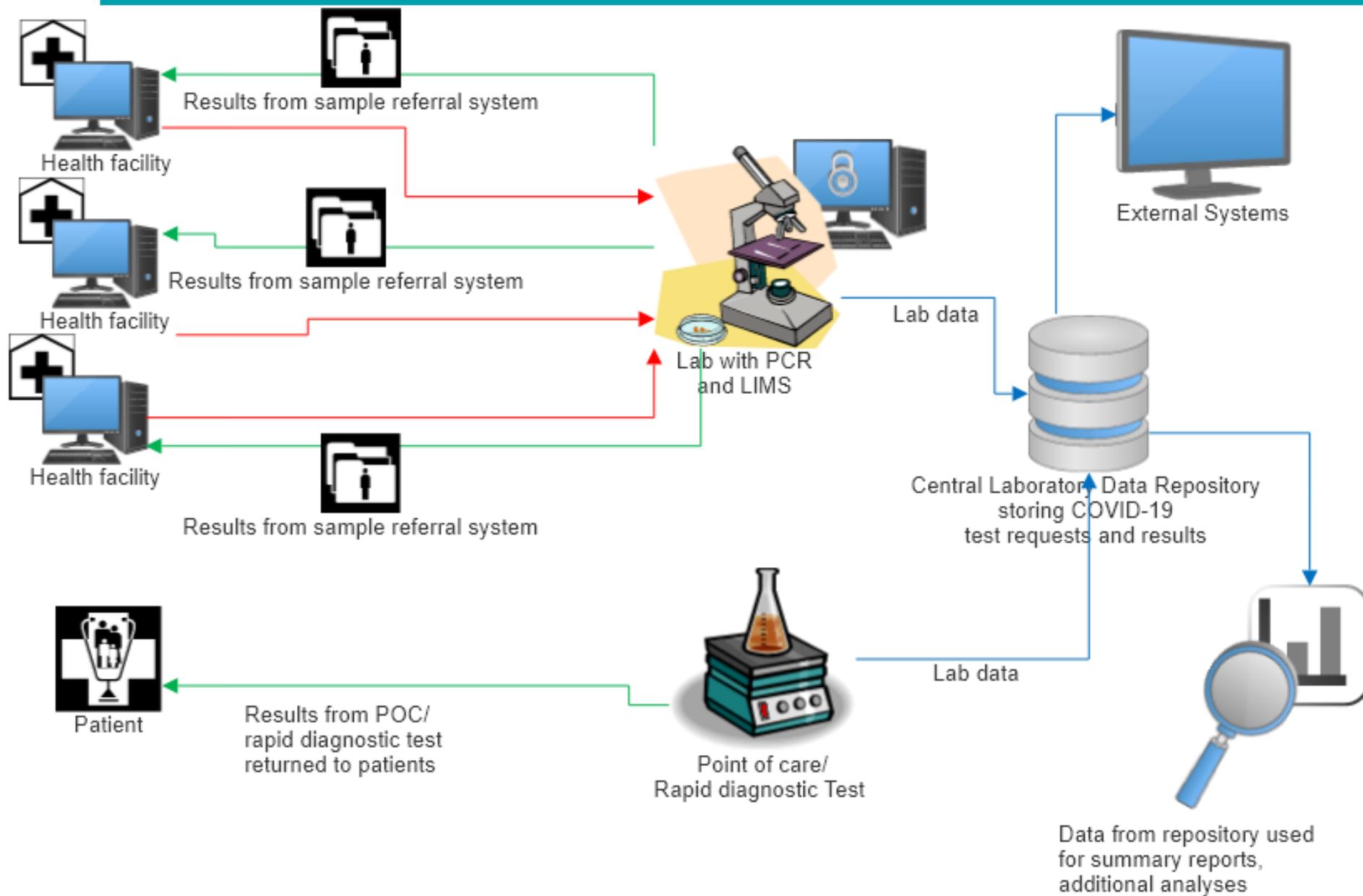
GOAL OF ELECTRONIC SAMPLE REFERRAL

Enable patient data and test request information to be transferred electronically from a health facility to a LIMS in a designated testing laboratory

Enable results from the LIMS in the testing laboratory to be returned electronically to health facilities



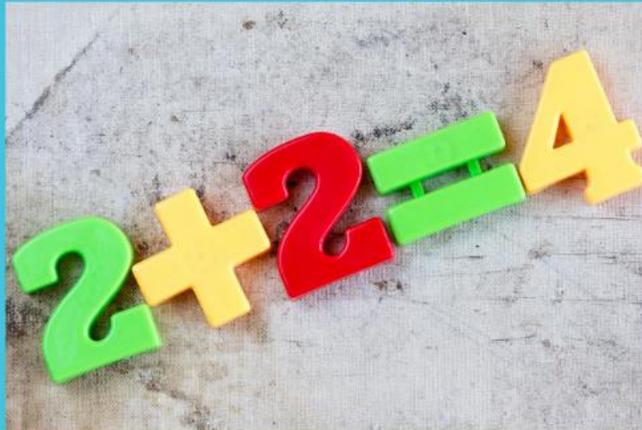
COVID-19 Sample Referral and Testing



Lessons learned from Electronic Sample Referral

DO

- Define critical data elements
- Build in data quality checks
- Harmonize specimen identifiers
- Use standard health facility codes
- Establish help desk for resolving requests



AVOID

- Build stand-alone systems
- Distribute the system without planning for designated collection sites to use it e.g. High volume facilities, hubs

Country Experiences



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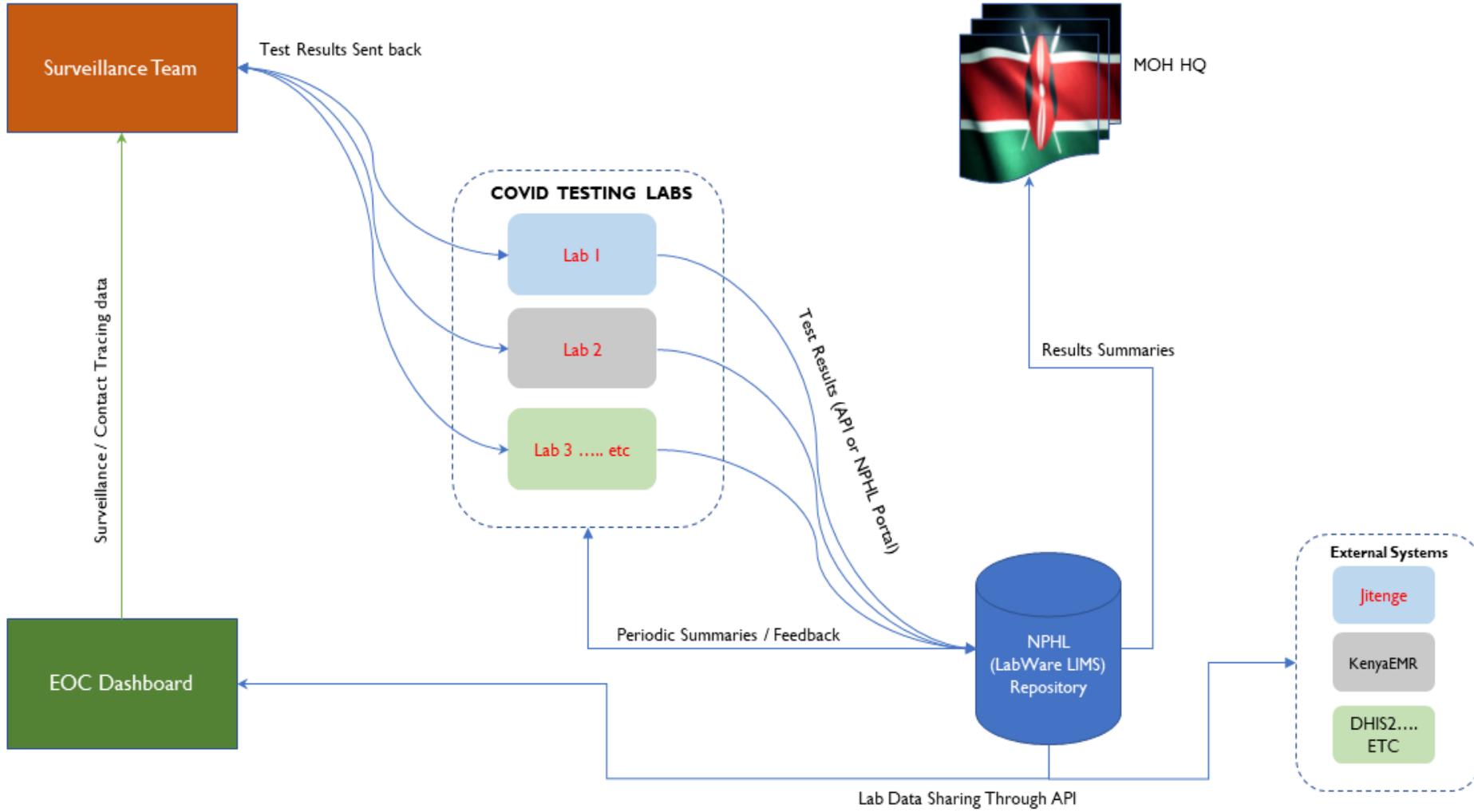
KENYA EXPERIENCE



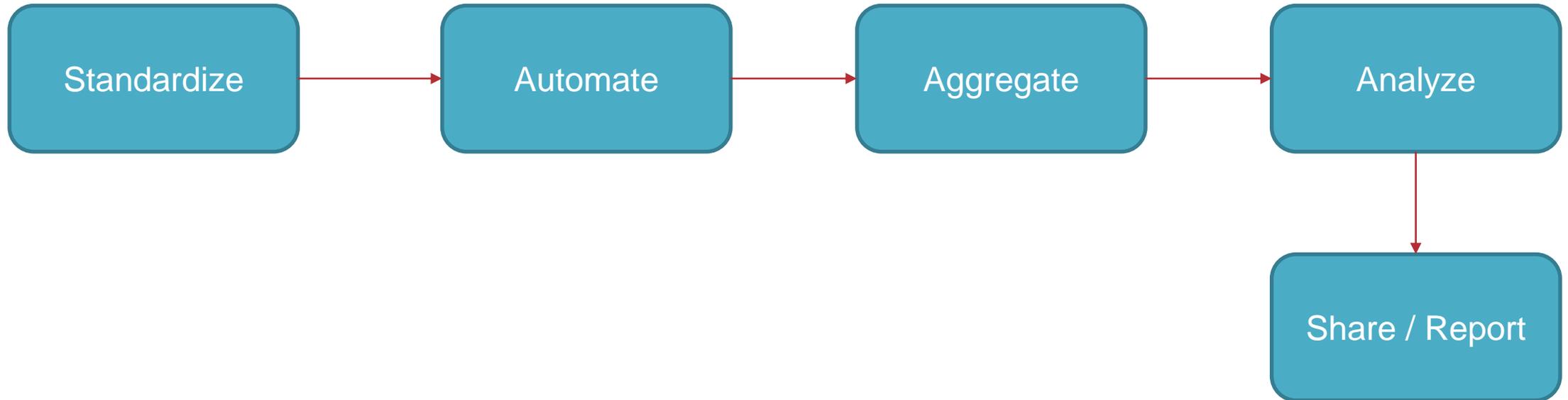
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COVID-19 LABORATORY DATA FLOW



COVID-19 Repository Design Summary



2. Data Repository at NPHL

Integration Tools

- Standardized Excel data collection tool
- API for system integration with external systems.

TESTING LAB	CASE ID	TYPE OF CASE (INITIAL/REPEAT)	SAMPLE NUMBER	NAME	ID/PASSPORT NUMBER	AGE	AGE UNIT (DAYS/M ONTHS/Y (ABS))	GENDER (M/F)	PHONE NUMBER	OCCUPATION	NATIONALITY	COUNTY OF RESIDENCE	SUB COUNTY OF RESIDENCE	VILLAGE/STATE OF RESIDENCE	WA

Parameter	Description
USERNAME	Mandatory
PASSWORD	Mandatory
TESTING_LAB	Mandatory
CASE_TYPE	Either <i>Initial</i> or <i>Repeat</i> . Mandatory
SAMPLE_TYPE	One of: <i>NP Swab</i> , <i>OP Swab</i> , <i>Serum</i> , <i>Sputum</i> or <i>Tracheal Aspirate</i> . Mandatory
SAMPLE_NUMBER	Unique identifier for the sample at the testing lab. Mandatory
SAMPLE_COLLECTION_DATE	Date format is Y-m-d e.g. 2020-05-31. Mandatory
RESULT	<i>Negative</i> or <i>Positive</i> . Mandatory
LAB_CONFIRMATION_DATE	Date format is Y-m-d e.g. 2020-05-31. Mandatory
FIRST_FOLLOW_UP_DATE	Date format is Y-m-d e.g. 2020-05-31
FIRST_FOLLOW_UP_RESULT	



LIMS Configuration at NPHL

The screenshot displays the LabWare LIMS interface for the NHRL COVID Workflow. The main dashboard includes a sidebar with navigation options like Exit, Log In, Log Out, Sample Login, Edit Tests, Enter Results, Review, Folder Manager, Batch Manager, Project Manager, Reports, and Contents. The main area features a 'NIRL Summary' section with a pie chart and a grid of workflow tasks: Sample Registration, Folder: Remote Samples, Fetch Remote samples/Unreceived, Incomplete Samples, Worksheet (96, 72, 48, 24), Review Samples, and Patient Reports. Action buttons for Manual CSV Upload, Excel Summary, and Print Worksheet Labels are also visible.

Two configuration windows are overlaid on the dashboard:

- Table: ANALYSIS**
Name: SARS_COV_2
Description: [Empty]
Components:
 - N-gene CT
 - N-gene Result
 - ORF1ab CT
 - ORF1ab Result
 - SARS - CoV - 2 Result
- Table: ANALYSIS**
Name: H_SARS_COV_2
Description: [Empty]
Components:
 - Target 1 Result
 - Target 2 Result
 - SARS - CoV - 2 Result



COVID-19 System Outputs


 MINISTRY OF HEALTH
 National Public Health Laboratories (NPHL)
 National Influenza Centre (NIC)
 P.O. Box 29750 - 00200, Nairobi
 Tel: (020) 2011 660
 nic@nphl.go.ke

Patient Report

County Name: NAKURU Lab ID: [Redacted]
 Patient Name: [Redacted] Client reference no.: [Redacted]
 Gender: [Redacted] Collection Date: 2020-05-12
 Age: [Redacted] Submitted on: 2020-05-13
 Specimen source: [Redacted] Released on: 2020-05-13

Test	Result Value	Analyst
N-gene Result	NEG	[Redacted]
O-RTT-13 Result	NEG	[Redacted]
SARS-CoV-2 Result	NEG	[Redacted]

Review Note: The patient sample tested NEGATIVE for SARS-CoV-2.

NB: All patients testing negative should continue adhering to government recommendations to minimize risk of infection.

Reviewed by: [Redacted] Signature: [Redacted] Date Reviewed: 13-May-2020

Registered by the Kenya Medical Laboratory Technicians and Technologists Board. No. [Redacted]
MOH/PHL/NIC/ [Redacted] Page 1 of 1 2020-05-14

Patient's Report

National HIV Reference Laboratory (NHRL)
 SARS-CoV-2 Worksheet COBAS_8800

COVID-20200423-2 Batch Date: 23-Apr-2020 12:14 am Analyzed By: [Redacted]

3 KANU 024 22-Apr-20	4 KANU 025 22-Apr-20	5 KANU 026 22-Apr-20	6 KANU 027 22-Apr-20	7 KANU 027 22-Apr-20	8 KANU 028 22-Apr-20
9 KANU 029 22-Apr-20	10 KANU 030 22-Apr-20	11 KANU 031 22-Apr-20	12 KANU 032 22-Apr-20	13 KANU 033 22-Apr-20	14 KANU 034 22-Apr-20
15 KANU 035 22-Apr-20	31 KANU 51 22-Apr-20	32 KANU 52 22-Apr-20	33 KANU 53 22-Apr-20	34 KANU 54 22-Apr-20	35 KANU 55 22-Apr-20

Sample Worksheet

Patient Name	Gender	DOB	AGE	Reason for Testing	Reason for Examination	Sample Number	External Code	County	Sub County	Quarantine Center	Collection Date	Submission Date	Rejection reason	Symptoms	Origin City	Transit City	Current town	Phone number	ID/Passport Number	Contact with case	Probable	Patient Temperature	Final Result
[Redacted]	M		42	SURVEILLAN		NIRL20-4155	6023355	NAIROBI															Negative
[Redacted]	F		26	SURVEILLAN		NIRL20-4156	SG046	NAIROBI															Negative
[Redacted]	M		29	SURVEILLAN		NIRL20-4157	SG047	NAIROBI															Negative
[Redacted]	M		30	SURVEILLAN		NIRL20-4158	SG048	NAIROBI															Negative
[Redacted]	F		43	SURVEILLAN		NIRL20-4281		1	NAIROBI														Negative
[Redacted]	M		51	SURVEILLAN		NIRL20-4282		2	NAIROBI														Negative
[Redacted]	M		43	SURVEILLAN		NIRL20-4283		3	NAIROBI														Negative
[Redacted]	F		23	SURVEILLAN		NIRL20-4284		4	NAIROBI														Negative
[Redacted]	F		36	SURVEILLAN		NIRL20-4285		5	NAIROBI														Negative
[Redacted]	F		44	SURVEILLAN		NIRL20-4286		6	NAIROBI														Negative
[Redacted]	F		21	SURVEILLAN		NIRL20-4287		7	NAIROBI														Negative
[Redacted]	F		42	SURVEILLAN		NIRL20-4288		8	NAIROBI														Negative
[Redacted]	M		53	SURVEILLAN		NIRL20-4289		9	NAIROBI														Negative
[Redacted]	F		36	SURVEILLAN		NIRL20-4290		10	NAIROBI														Negative
[Redacted]	M		36	SURVEILLAN		NIRL20-4291		11	NAIROBI														Negative
[Redacted]	F		27	SURVEILLAN		NIRL20-4292		12	NAIROBI														Negative
[Redacted]	F		33	SURVEILLAN		NIRL20-4293		13	NAIROBI														Negative
[Redacted]	M		30	SURVEILLAN		NIRL20-4294		14	NAIROBI														Negative
[Redacted]	F		29	SURVEILLAN		NIRL20-4295		15	NAIROBI														Negative
[Redacted]	M		29	SURVEILLAN		NIRL20-4296		16	NAIROBI														Negative
[Redacted]	M		47	SURVEILLAN		NIRL20-4297		17	NAIROBI														Negative
[Redacted]	M		38	SURVEILLAN		NIRL20-4298		18	NAIROBI														Negative

Excel Export to Data Center



Lessons Learnt from the Kenya Experience

- Collaboration.
- Enable Systems to “talk” aka system Integration
- Capacity building – Let the MOH team drive!
- Simplicity always wins.



MOZAMBIQUE EXPERIENCE



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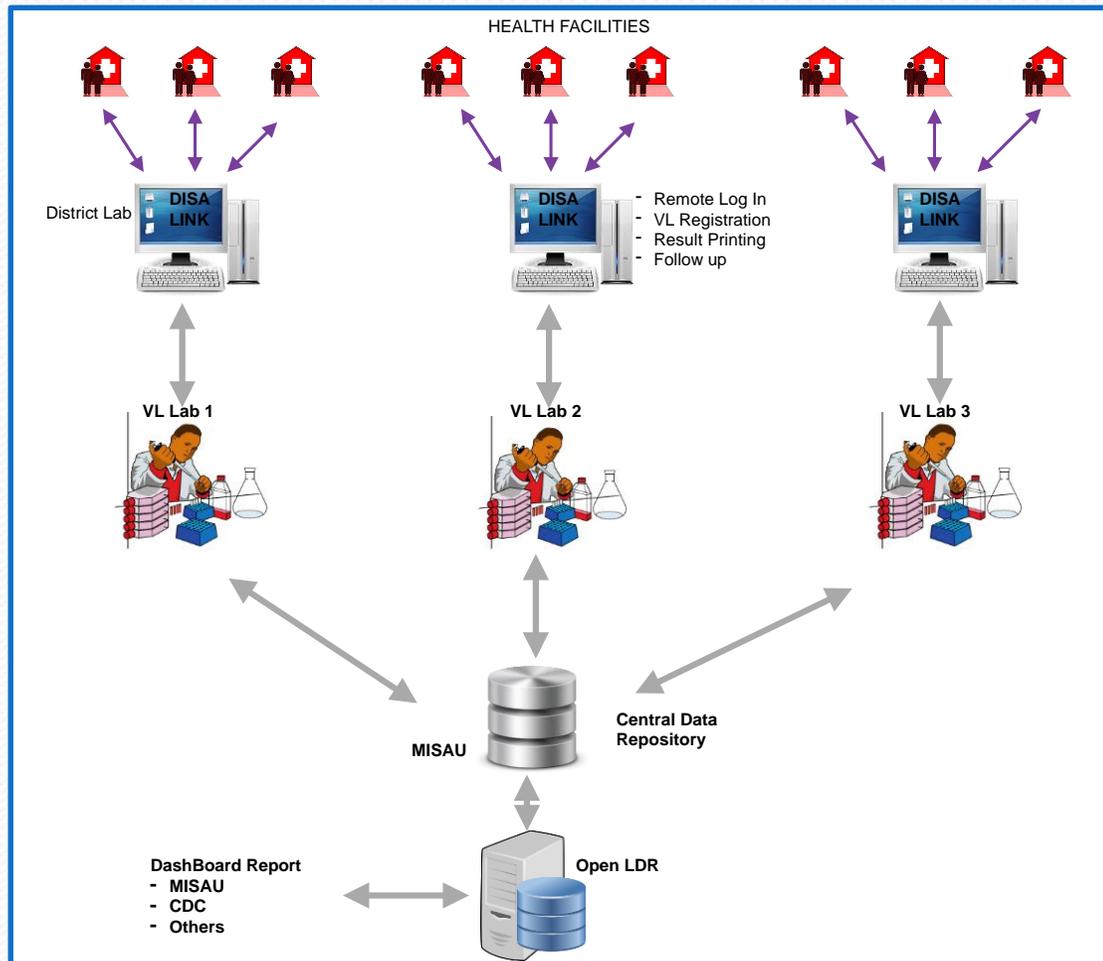
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MOZAMBIQUE EXPERIENCE IMPLEMENTING LABORATORY INFORMATION SYSTEM TO SUPPORT COVID-19 RESPONSE

06.08.2020

SOFIA VIEGAS, DIRECTOR OF PUBLIC
HEALTH LABORATORIES

Structure of the Mozambique LIMS



Mozambique repurposed a structure previously established through PEPFAR

- 15 Labs with LIS
- 180 sites with electronic sample referral
- Over 1250 health facilities participating in sample referral

Mozambique Solutions for COVID-19

- **Updated the LIMS to include COVID testing**
 1. Barcoded samples (tracking)
 2. Equipment interface (result interpretation)
 3. Improved workflow (improved TAT)
- **Laboratory Data Repository**
 1. Central reporting system (press conference)
 2. Data management and analysis
- **Sample referral**
 1. Set up electronic COVID test order system
 2. Real time result reporting

Mozambique Solutions for COVID-19 testing

- **Reporting**

1. Daily email alerts with individual patient result to surveillance team (Automated)
2. Summary report to Health authorities on daily basis
3. Patient results returned through electronic sample referral

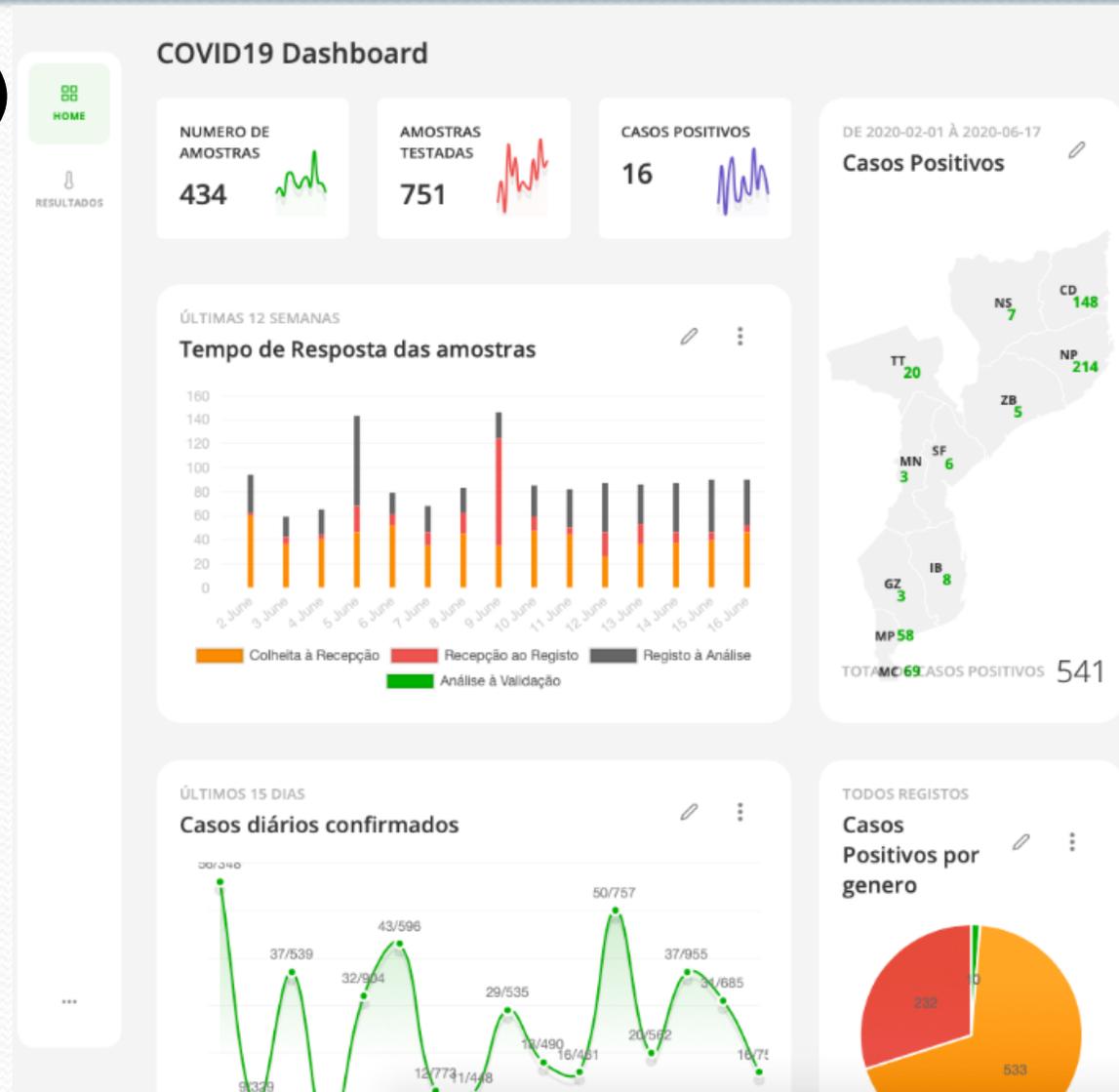


Microsoft Excel
Worksheet

Mozambique Solutions for COVID-19 testing

- **Dashboard (under improvement)**

1. Real time interactive COVID dashboard- Only lab data.
2. Several indicators.



Advantages to COVID-19 data management

- Results available in real time for action;
- Reduction of TAT;
- Allows the provinces to manage their own samples;
- Reduces registration time in the testing lab;
- Daily reports allow provincial authorities to follow provincial data before the press conference;
- Daily reports support the preparation of data for the press conference, daily bulletin and other reports;
- Daily reports supports the monitoring of TAT;
- Allows continuous improvement.

Challenges

- Internet connection;
- Registration some times is slow;
- Complete registration of all data is a challenge;
- Changing reagents, there is a setup interface;
- IT staff dedicated is essential;

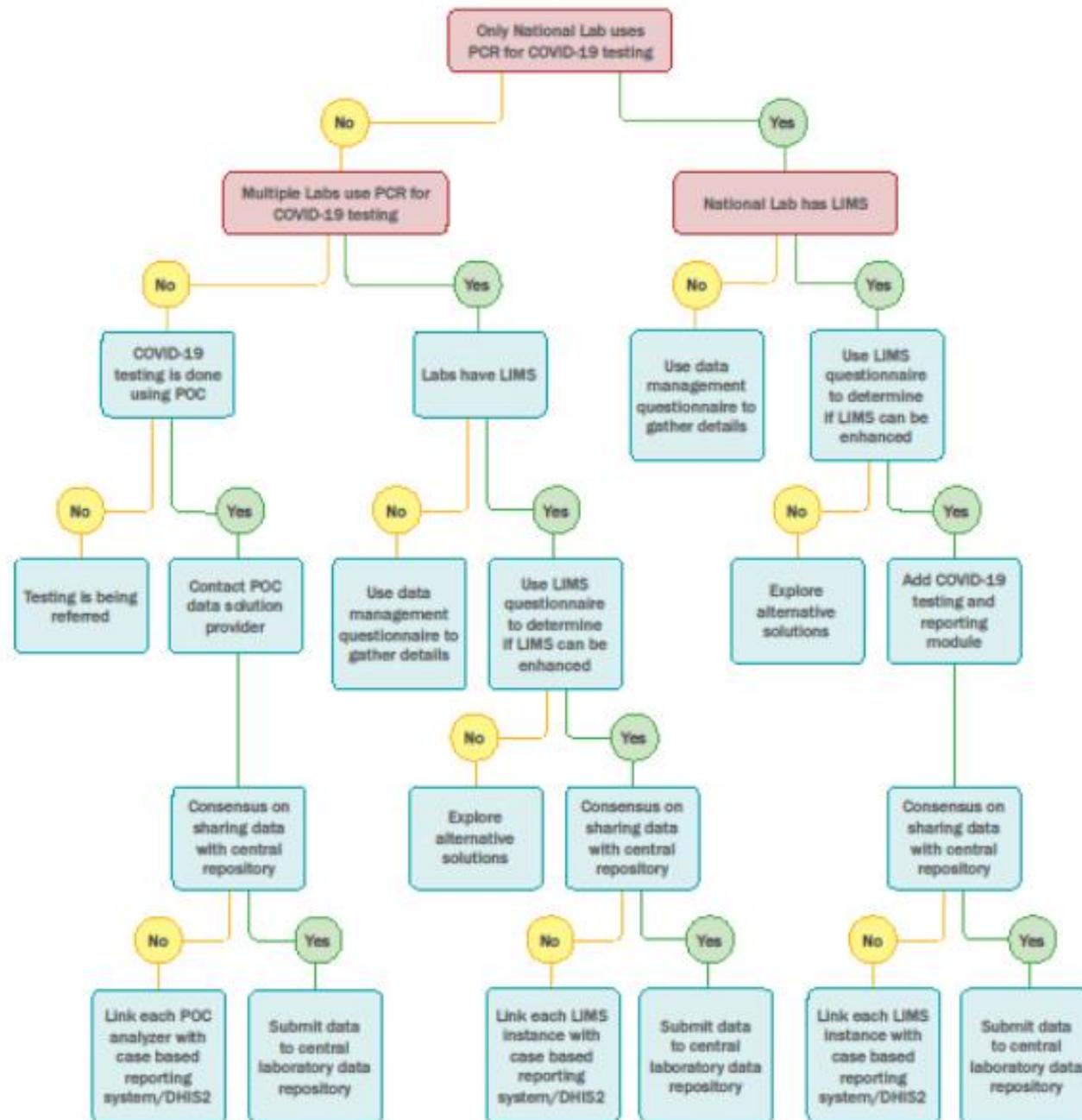
NEXT STEPS



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Supporting Informatics Needs of COVID-19 Testing



MINISTRY OF HEALTH LEADERSHIP AND ACTIONS



WORKING GROUP CO-CHAIRLED BY EPI AND LAB

Define minimum critical lab data elements

Map workflow

Develop data access guidelines

Develop data sharing agreements

Review national privacy rules

Develop data use policy

NATIONAL LABORATORY DEVELOP PLANS

Assess existing laboratory data systems

Identify specimen collection sites and link with testing laboratory

Document specimen referral

Develop implementation timeline

DATA UTILIZATION

MOH and stakeholders utilize data for informing policy, updating laboratory testing strategy and other response measures

Expanding infrastructure and applying lessons learned to support other immediately notifiable diseases



ACKNOWLEDGEMENTS

National Public Health Laboratory, Kenya

INS Mozambique

Centers for Disease Control and Prevention

