Gap Analysis of Public Health Laboratories in Andhra Pradesh Cluster

Labs for Life Project

2017

Ministry of Health and Family Welfare, Government of India
In collaboration with
U.S Centers for Disease Control and Prevention (HHS/CDC/CGH)-Division of Global HIV/AIDS, India,
and
Christian Medical Association of India (CMAI)

Acronyms

ABG	:	Arterial Blood Gas
AMC	:	Annual Maintenance Contract
ART	:	Anti-Retroviral Therapy
BD	:	Becton Dickinson
BPL	:	Below Poverty Line
BMW	:	Bio-Medical Waste Management
CAPA	:	Corrective Action Preventive Action
CDC	:	Centers for Disease control and Prevention
CLABSI	:	Central Line-associated Bloodstream Infection
CMAI	:	Christian Medical Association of India
CMC	:	Comprehensive Maintenance Contract
EQAP	:	External Quality Assessment Program
EQAS	:	External Quality Assurance Scheme
FNAC	:	Fine Needle Aspiration Cytology
GLP	:	Good Laboratory Practices
HIV	:	Human Immunodeficiency Virus
HMIS	:	Health Management Information System
ICMR	:	Indian Council of Medical Research
ICTC	:	Integrated Counseling and Testing Centre
IDSP	:	Integrated Disease Surveillance Program
IHR	:	International Health Regulations
ISO	:	International Organization for Standardization
IPHS	:	Indian Public Health Standards
IQAP	:	Internal Quality Assessment Program
IQC	:	Internal Quality Control
JSSY	:	Janani Shishu Suraksha Yojna
KPI	:	Key Performance Indicator
LBC	:	Liquid Based Cytology
LIMS	:	Laboratory Information Management System
MoHFW	:	Ministry of Health and Family Welfare
MP	:	Malaria Parasite
MSDS	:	Material Safety Data Sheet
NACP	:	National AIDS Control Program
NLEP	:	National Leprosy Eradication Program
NHM	:	National Health Mission
NVBDCP	:	National Vector Borne Disease Control Program
PHEIC	:	Public Health Emergency of International Concern
QI	:	Quality Indicator
RNTCP	:	Revised National Tuberculosis Control Program
SOP	:	Standard Operating Procedure
SPSS	:	Statistical Product and Service Solutions
SSI	:	Surgical Site Infection
STI	:	Sexually Transmitted Infections
TAT	:	Turnaround Time
UTI	:	Urinary Tract Infection
VAP	:	Ventilator Associated Pneumonia
WDI	:	Work Desk Instruction

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Gap Analysis of Public Health Laboratories in Andhra Pradesh Cluster

1. Background

Strong laboratory services and systems are critical for delivering timely and quality health services that are vital to reduce patient attrition in the HIV treatment and prevention cascade (Alemnji et al., 2014). Laboratory testing plays a central role in this cascade which includes diagnosis, linkages, retention in care, determining eligibility for ART and/or prophylaxis, commencement of ART, HIV treatment monitoring, adherence, and viral load suppression that translates to reduced risk of death and HIV transmission (Kilmarx & Mutasa-Apollo, 2013). It is also essential that effective linkages and referrals to other services after laboratory testing within the cascade are ensured.

The U.S. President's Emergency Plan for AIDS Relief (PEPFAR) in collaboration with CDC works with countries to build high-quality laboratory systems and services that are critical for HIV prevention, care and treatment, as well as for other diseases (CDC, 2017). Strengthening the national health systems to improve HIV program outcomes through investments in laboratory systems strengthening, human resource capacity building and the introduction of health information systems is one of the key priority areas.

In India, the National AIDS Control Organization (NACO), Ministry of Health and Family Welfare, Government of India has created a huge laboratory network for HIV testing across the country. However, as defined in the NACO operational guidelines, patients diagnosed with HIV/AIDS need additional supporting investigations to assess the baseline parameters and comorbidities, adverse effects of medications, tests for opportunistic infections etc.

Currently, only 40% of pre-ART and 60% of patients on ART are getting these investigations done (NACO, 2015). Therefore, it is essential that all public health laboratories with ART centers need to be strengthened and capacitated to not only provide these laboratory investigations but also ensure quality in service provision. This could be achieved by adopting new technologies for collection, testing and processing, with efficient supply chain

management systems and ongoing capacity enhancement of human resources. It is also essential that there is continuous development, maintenance and update of SOPs, the practice of internal quality control, external quality assessment schemes (EQAS) and assessment of performance through internal and external audits.

In this context, the Ministry of Health and Family Welfare, with the technical and financial support of U.S. Centers for Disease Control and Prevention (CDC), proposes to strengthen 22 Public health laboratories in institutions co-located with ART Centers, in specific districts of Andhra Pradesh and Maharashtra. Christian Medical Association of India, through the Labs for Life (L4L) project, is the implementing partner of this initiative. The specific objectives of this project are to;

- Bridge the gaps in supporting investigations required as per NACO operational guidelines for Pre-ART and on- ART patients and Free Diagnostic Services Initiative
- Establish Quality Management Systems in selected co-located district level laboratories with ART facility;
- Establish linkages between ART Centers and the general public health laboratories;
- Develop mechanisms for detecting Opportunistic Infections (OI).

As the first step of this project, a baseline assessment was proposed in all the 22 public health laboratories which is essential for planning, coordination, implementation and monitoring activities related to the quality of HIV/AIDS laboratory services and establishing referral linkages.

2. Purpose and Objectives of the Baseline Assessment

The purpose of the assessment is to understand the existing laboratory practices, identify areas of gaps/deficiencies, emerging challenges, and to decide on the strategies and interventions for implementing quality management systems.

The specific objectives are,

- To review the existing structure and the services provided by the selected laboratories.
- To identify facility-specific challenges and systemic areas in terms of availability of laboratory services related to HIV and AIDS, Quality Management Systems and referral linkages.
- To understand the factors facilitating or hindering the progress/achievements.
- To formulate a facility-specific strategic plan for improving quality management systems.

3. Methodology

All selected public health laboratories under the project were included in the assessment. These laboratories were from priority districts for CDC that have been identified as having high HIV burden and large unmet need in Maharashtra and Andhra Pradesh states. The districts are Thane, Mumbai and Pune districts of Maharashtra state and East Godavari, Krishna and Guntur districts of Andhra Pradesh state.

The geographical distribution of selected states and districts is illustrated in figure-1&2 and the details of the institutions are given in Table 1 & 2

Figure 1 - Districts in Andhra Pradesh

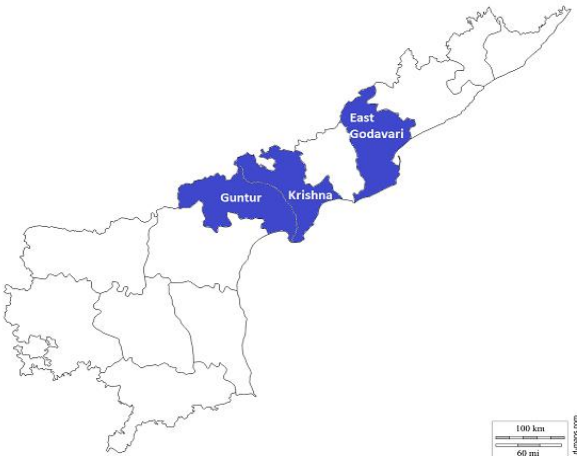


Table 1 - Institutions in Andhra Pradesh State

S.no	District	Name of the Hospital	Type of the Hospital
1	East Godavari	Rangaraya Medical College, Kakinada	Medical College
2	East Godavari	District Hospital, Rajahmundry	District Hospital
3	Krishna	Old Government General Hospital, Vijayawada	District Hospital
4	Krishna	Siddhartha Medical College, Vijayawada	Medical College
5	Krishna	District Hospital, Machilipatnam	District Hospital
6	Guntur	Government Medical College, Guntur	Medical College
7	Guntur	Narasaraopet Area Hospital	District Hospital
8	Guntur	District Hospital, Tenali	District Hospital

3.1 Laboratory Assessment Tool

The laboratory assessment was primarily was carried out using a validated Laboratory Assessment Tool - Checklist 13 of National Quality Assurance Standards, designed by National Health Mission (NHM), Ministry of health and family welfare, Government of India, under Quality Guidelines for District hospitals. This tool is based on ISO, IPHS, and GLP guidelines of ICMR. Additional sheets for General & contact information and summary were added. Specific questions on the availability of investigations related to HIV and AIDS diagnosis and investigations on comorbidities and Opportunistic Infections were included in the tool. Both quantitative and qualitative Information were elicited through staff interviews, patient interview, observations and record review.

The key components included in the lab assessment tool are:

- Service provision
- Patient rights
- Inputs
- Support services
- Clinical Services
- Infection Control
- Quality Management
- Outcome measurement

3.2 Discussion with key staff and officials

Before administering the tools, a group discussion was conducted among the staff that included the heads of the institutions, department heads, professional and technical staff. The objectives of the project were explained. In addition, broader details such as the scope of the institution, coverage, facilities available in general, demographic details, key gaps and challenges of institutions were obtained.

After completion of the assessment, another debriefing session was also conducted to provide a brief summary of the assessment and to clarify doubts related to the assessment.

3.3 Assessment Team and Duration

An independent external assessor and an observer from CDC/CMAI/NACO constituted the assessment team. Technically qualified personnel, with a background of Microbiology/Pathology/Biochemistry with experience in laboratory assessments, were chosen. One day orientation was given to the assessors and observers to brief them on the objectives, methods, tool and the process of conducting the assessment. The role of the observers was to facilitate the assessment process by interaction with the institution and the assessors.

Two days were allocated for the assessment which includes a day for compiling the data and finalizing the qualitative summary section. The assessment was conducted from 24th to 29th July 2017.

3.4 Data Quality Assurance

In order to ensure quality in data collection, process, and analysis, a series of activities were carried out, that are,

- A sensitization meet was conducted for nodal officers about the program. The objectives and methods of the assessments were explained and an overview of the assessment tools was given.

- The tools were tested for correctness in formulae, summation, and consolidation.
- A list of documents required for assessment was sent to the institution one week prior to the assessment, in order that the record review part of the assessment is conducted smoothly.
- The labs were given formats in advance to capture the general information of total patient load, department-wise patient load and the contact information of key functionaries
- A PDF formatted version of the tools was shared with the labs prior to the assessment in order to familiarize them with the elements that will be assessed
- One day orientation meeting on the assessment was conducted for the assessors and observers to brief the objectives, methods, and tools in detail.
- In the case of medical colleges where 3 labs are present, to ensure data quality, the findings in the microbiology departments have been captured in the quantitative reports and the other departments covered in the qualitative reports
- After the assessments were done, the tools were cross checked for completeness, summation within subsections and overall summation of the score.

3.5 Data Analysis

The tool is in MS Excel format. Each question under each component/sub section carried equal marks and calculated for 100 percent. The overall score was calculated for 100 marks. Formulas were developed in the Excel sheet itself to calculate the scores of sub sections, scores of components and overall score. These Excel sheets were converted into SPSS file to carry out further analysis.

Table 2 - Lab Assessment Tool – Specific area of concern & key information

	Area of Concern	Information Captured
A	Service provision	1. Availability of testing disciplines of laboratory medicine: hematology / biochemistry/ microbiology/ clinical pathology/ microbiology/ serology/cytology/histopathology 2. Availability of national programs 3. Availability of services appropriate to local problems: Infections/ sickle cell anemia/thalassemia/ others
B	Patient rights	1. Availability of information for patients and users regarding lab services 2. Sensitivity to gender, physical disabilities 3. Privacy, Courtesy 4. Confidentiality 5. Informed consent procedures 6. Complaint redressal system 7. Financial protection: Cashless services to pregnant women and children, availability of prescribed tests, free services to BPL, reimbursement of beneficiaries for tests not available in the lab
C	Inputs	1. Infrastructure: Compatibility of physical infrastructure with the work flow. Power supply 2. Safety measures: Fire 3. Staff availability: Pathologists/ Microbiologists/ Technical staff 4. Staff training 5. Availability of reagents and consumables 6. Availability of equipment
D	Support services	1. Equipment maintenance: Daily maintenance, scheduled maintenance, calibration, AMC/CMC 2. Inventory management: Indenting system, storage, stock verification, emergency purchases 3. Lab safety: Chemical, equipment, fire. Safety of female staff 4. Building maintenance: general upkeep, work stations, furniture, pest control 5. Power backup, running water 6. Compliance with statutory requirements like disease notification 7. HR: Awareness of job descriptions, dress codes, duty rosters 8. Monitoring of outsource services: Laundry, dietary, security
E	Clinical Services	1. Patient identification procedure 2. Referrals: Patients/ samples 3. Record maintenance

		4. Disaster management 5. Medico legal cases 6. Pre-analytical: Sample collection procedure 7. Pre-analytical: Sample transportation procedure 8. Analytical: Testing processes, biological reference ranges, critical call outs 9. Post-Analytical: Review of results, reporting formats, report transcription, stat reporting, data archival 10. Post-Analytical: Sample retention, discarding process 11. Referral Services - ART Care 12. Availability of Investigations (NACO and Free Diagnostics)
F	Infection Control	1. Passive and active culture surveillance of high-risk areas 2. Staff immunizations, check ups 3. Hospital Antibiotic policy 4. Hand hygiene protocols 5. Availability and use of personal protective equipment 6. Spill management protocol 7. Decontamination of equipment 8. Cleaning and disinfection of patient care areas 9. Biomedical Waste management: Segregation at source, sharps disposal 10. Post exposure prophylaxis 11. Liquid wastes management
G	Quality Management	1. Availability of a nodal officer [Quality manager] 2. Surveys of satisfaction: Patients/ referring doctors 3. Availability of Internal Quality Assurance Program 4. Availability of External Quality Assurance Program 5. Corrective action protocols 6. Availability of Standard Operating Procedures 7. Internal Audits 8. Defined Quality Policy 9. Defined Quality Objectives which are monitored 10. Continual improvement protocols
H	Outcome	1. Productivity Indicators e.g. Number of HIV tests done/ 1000 population 2. Proportion of tests done for BPL patients 3. Efficiency Indicators e.g. Z scores, TAT for routine tests, emergency tests 4. Safety Indicators e.g. Percent of critical call outs 5. Service Quality Indicators e.g. waiting time, stock-outs

4. Key Results and Findings

4.1 General Information of Selected Laboratories

The basic details of the laboratories are given in Table – 3.

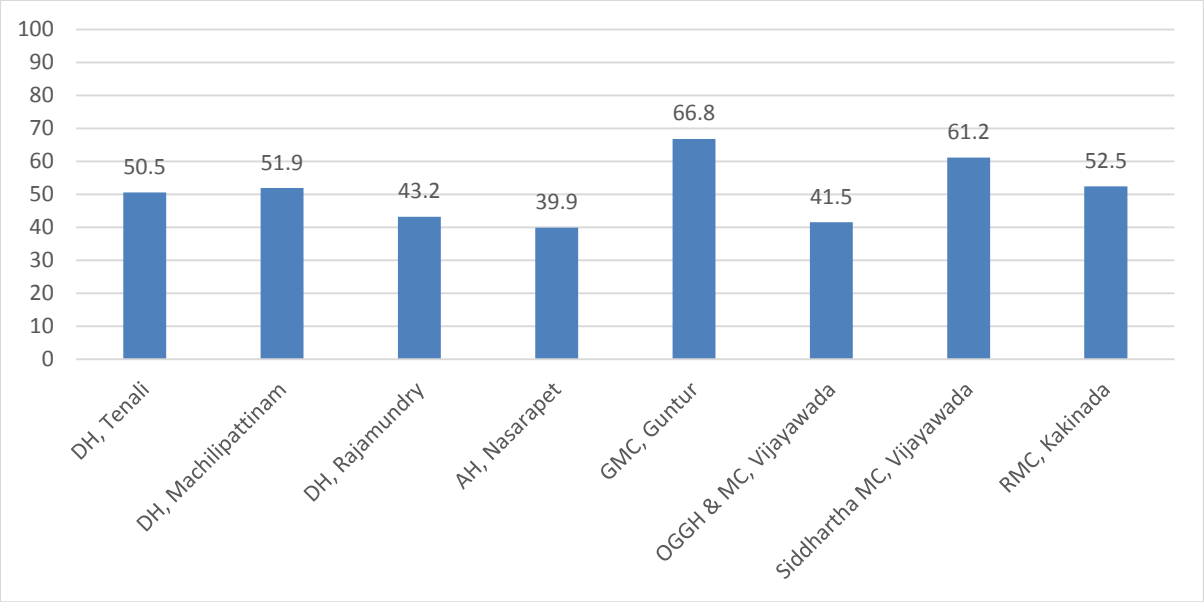
Table 3 - General Information of the laboratories

	DH, Tenali	DH, Machilipatnam	DH, Rajahmundry	AH, Narasaraopet	GMC, Guntur	OGGH & MC, Vijayawada	Siddhartha MC, Vijayawada	RMC, Kakinada
District Population (Lakhs)	64.7	45.1	51.5	64.7	64.7	45.1	45.1	51.5
Population Covered (Lakhs)	-	1.7	-	3	4.9	10	-	4.4
No of beds	200	350	350	100	10423	270	-	1065
Number of OP/day	-	-	254	-	2389	383	-	800
Number of OP/year	-	-	80645	-	757164	101628	-	749000
Laboratory-type	DH	DH	DH	DH	MCH	MCH	MCH	MCH
Number of disciplines	3	3	3	5	9	4	-	12
samples received/yr	-		454961	65000	388347	53364	-	454961
Accreditation Status	No	No	No	No	No	No	No	No

4.2 The overall Institution scores

The overall score of public health laboratories in Andhra Pradesh cluster ranges from 66.8% for Government Medical College, Guntur to 39.6% for Area Hospital, Narasaraopet. The average score of all laboratories was 50.9% (SD: 9.4).

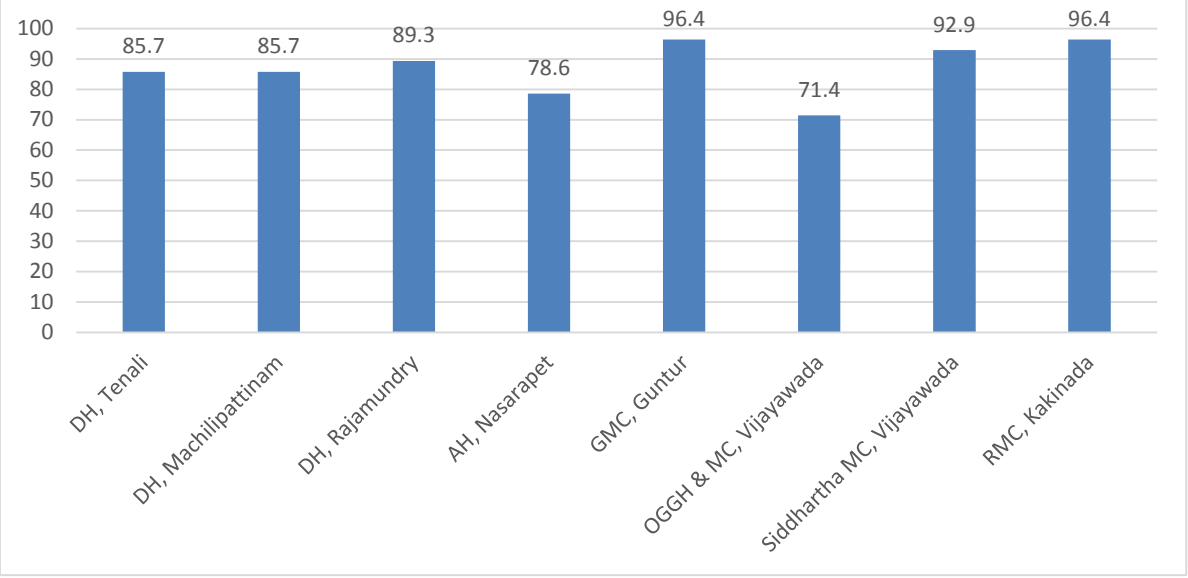
Figure 2 - Overall Score



4.3 Service provision

Service Provision includes the availability of testing disciplines of laboratory medicine such as hematology, biochemistry, microbiology, clinical pathology, microbiology, serology, cytology, histopathology; availability of national programs, availability of services appropriate to local problems (Infections/ sickle cell anemia/thalassemia/ others). The service provision score of public health laboratories in Andhra Pradesh cluster ranges from 96.4% for Government Medical College, Guntur to 67.9% for Old Govt. General Hospital and Medical College, Vijayawada. The average score was 87.05% (SD: 8.7).

Figure 3 - Service Provision

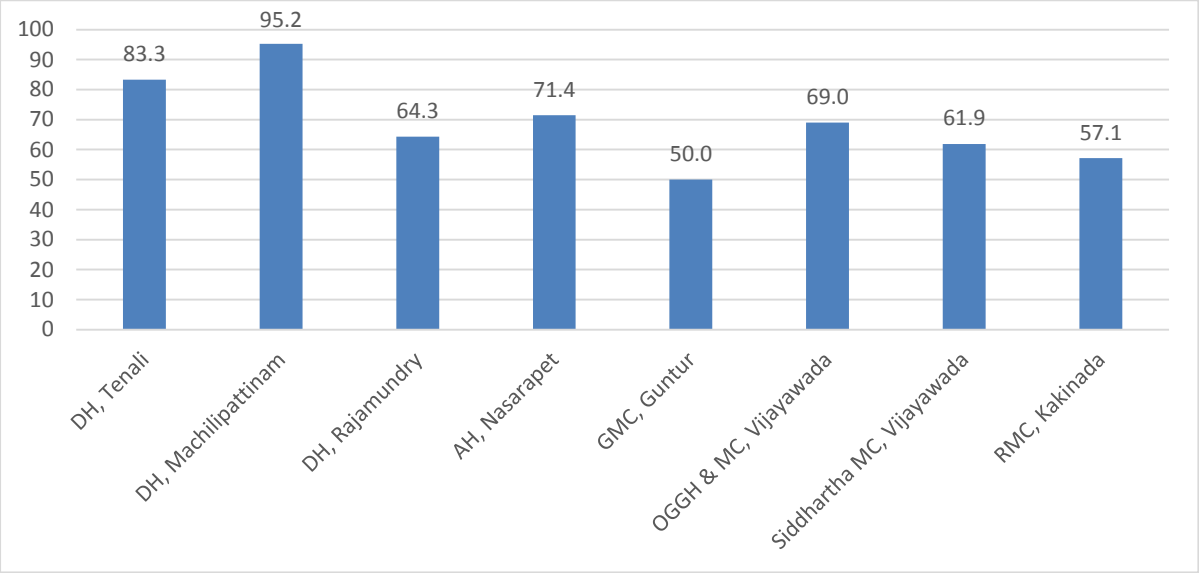


4.4 Patient rights

This component includes, availability of information for patients and users regarding lab services, sensitivity to gender differences and physical disabilities, privacy, courtesy, confidentiality, informed consent procedures, complaint redressal system, financial protection (cashless services to pregnant women and children, availability of prescribed tests, free services to BPL, reimbursement of beneficiaries for tests not available in the lab) etc.

The score for patient rights ranges from 95.2% for District Hospital, Machilipatnam to 50.0% for Government Medical College, Guntur. The average score was 69.05% (SD: 14.51).

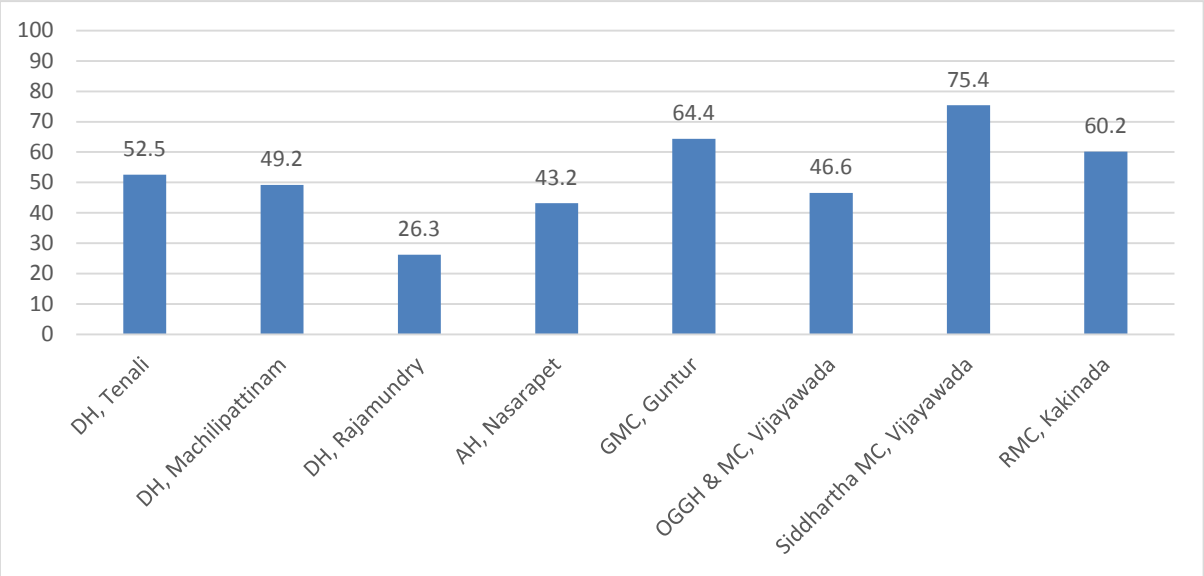
Figure 4 - Patient rights



4.5 Inputs

Inputs include infrastructure adequacy, compatibility of physical infrastructure with the work flow, power supply, safety measures (Fire safety equipment), staff availability (pathologists/ microbiologists/ technical staff), staff training, availability of reagents and consumables and availability of equipment. The score for this component ranges from 75.4% for Siddhartha Medical College, Vijayawada to 26.3% for District hospital, Rajahmundry. The average score was 52.2% (SD: 14.8).

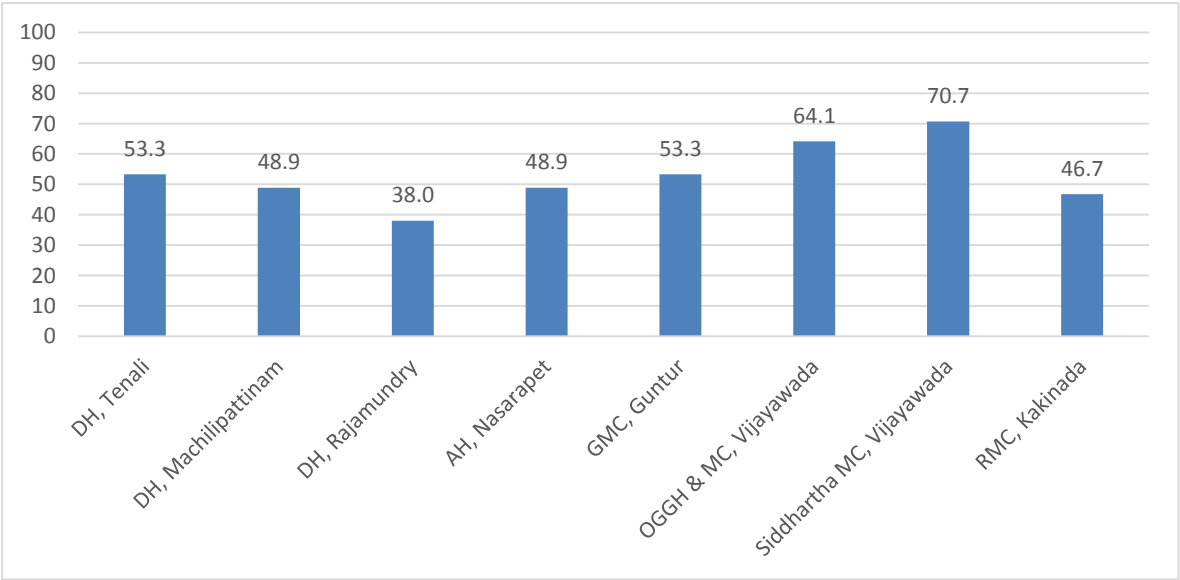
Figure 5 - Inputs



4.6 Support services

This component includes – Equipment maintenance (Daily maintenance, scheduled maintenance, calibration, AMC/CMC), Inventory management (Indenting system, storage, stock verification, emergency purchases), Lab Safety (Chemical, equipment, fire), Safety of female staff, Building maintenance: general upkeep, work stations, furniture, pest control, power backup, running water, compliance to statutory requirements like disease notification, HR: Awareness of job descriptions, dress codes, duty rosters, monitoring of outsourced services: Laundry, dietary, security.

Figure 6 - Support Services



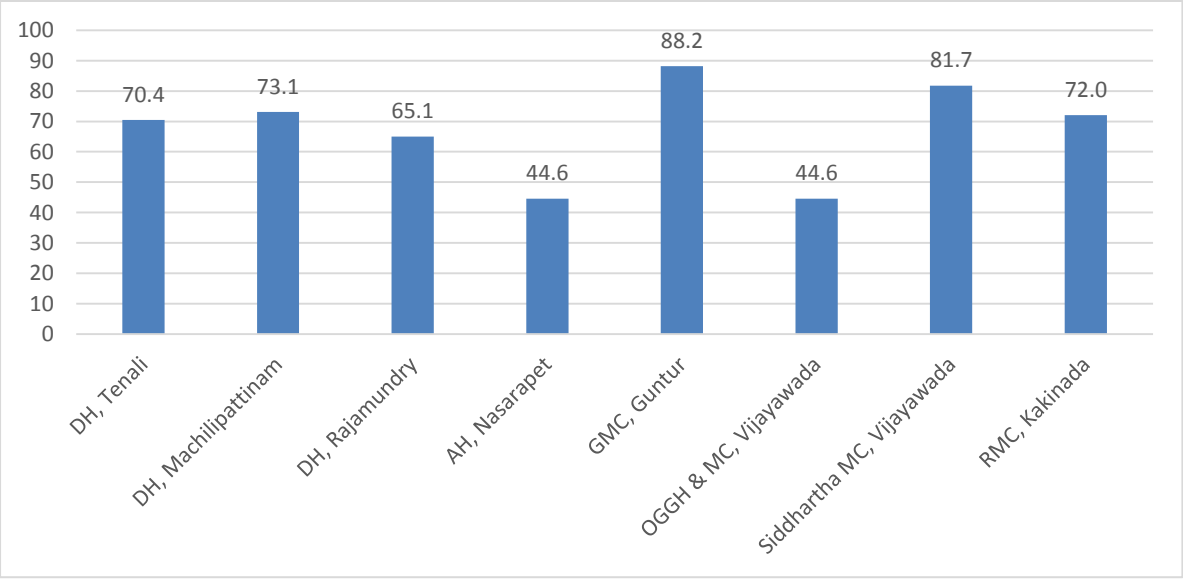
The support services score of public health laboratories in Andhra Pradesh cluster ranges from 70.7% for Siddhartha Medical College, Vijayawada to 38.0% for District Hospital, Rajahmundry. The average score was 52.9% (SD: 10.2).

4.7 Clinical Services

This component includes patient identification procedures, referrals (patients/ samples), record maintenance, disaster management, medico-legal cases, pre-analytical- sample collection procedure, sample transportation procedure, analytical- testing processes, biological reference ranges, critical call outs, post-Analytical- review of results, reporting formats, report transcription, stat reporting, data archival, sample retention and discarding process, referral Services - ART Care and availability of Investigations (NACO and Free Diagnostics).

The score for clinical services ranges from 88.2% for Government Medical College, Guntur to 44.6% for Area Hospital, Narasaraopet. The average score was 67.5% (SD: 15.7).

Figure 7 - Clinical Services

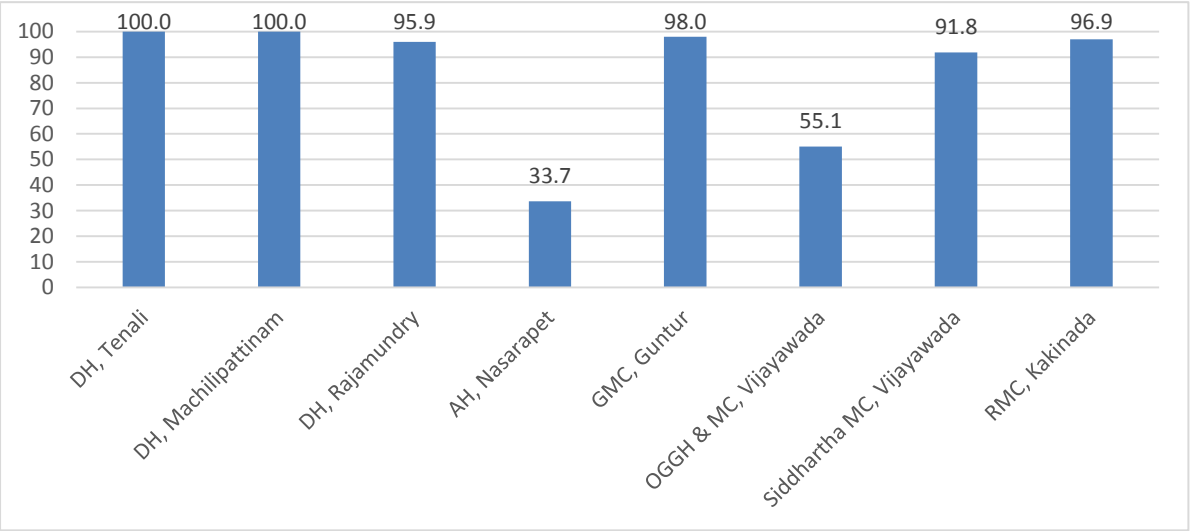


The clinical services included three major subsections which are critical for programme planning and HIV/AIDS-related service delivery. They are, availability of services as per NACO guidelines, referral services for ART care, and laboratory tests for opportunistic investigations. The status of the laboratories in each of the subsections is given below,

4.7.1 Services availability as per NACO guidelines

This component includes the availability of laboratory investigations in the facility as prescribed under Free Diagnostics Service Initiative and National AIDS Control program guidelines. The score ranges from 100% for District hospital Tenali and Machilipattinam to 33.7% for area hospital Narasaraopet.

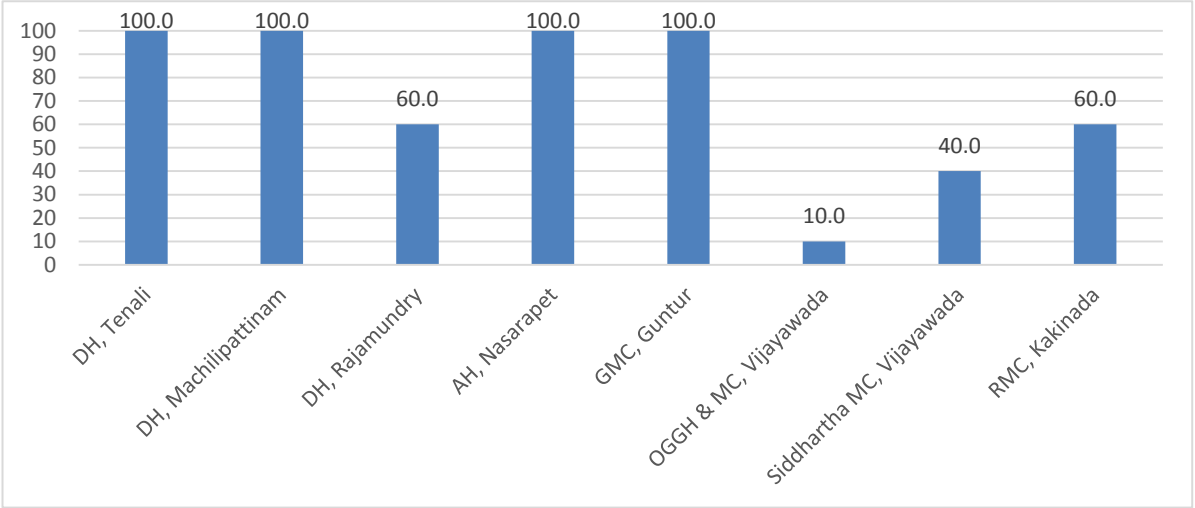
Figure 8 - Services availability as per NACO guidelines



4.7.2 Referral services for ART Care

This component includes linkages between facility and ART centre, referral protocol and its awareness, tracking the performance of referral system and guidelines for referral system. Around half of the Hospitals scored 100%. The score ranges from 100% to 10%.

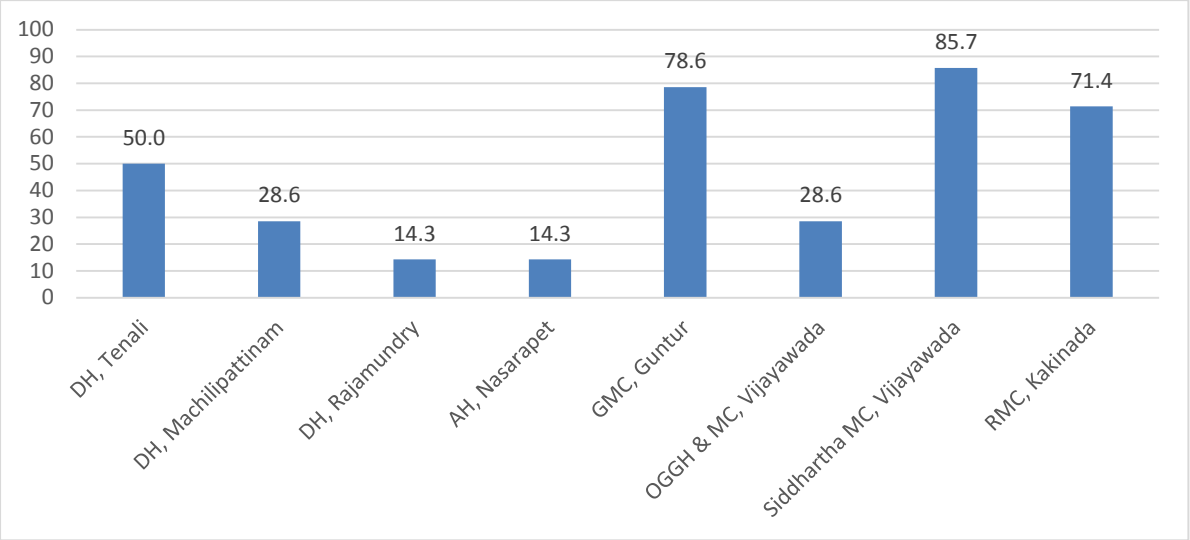
Figure 9 - Referral services for ART Care



4.7.3 Laboratory Investigations for Opportunistic Infections

This component includes the availability of diagnostic facilities for opportunistic infections in PLHIV as required under National AIDS Control Program guidelines. The score ranges from 85.7% for District hospital, Machilipatnam and Siddhartha Medical College, Vijayawada to 14.3% for Area hospital, Narasaraopet and District Hospital, Rajahmundry.

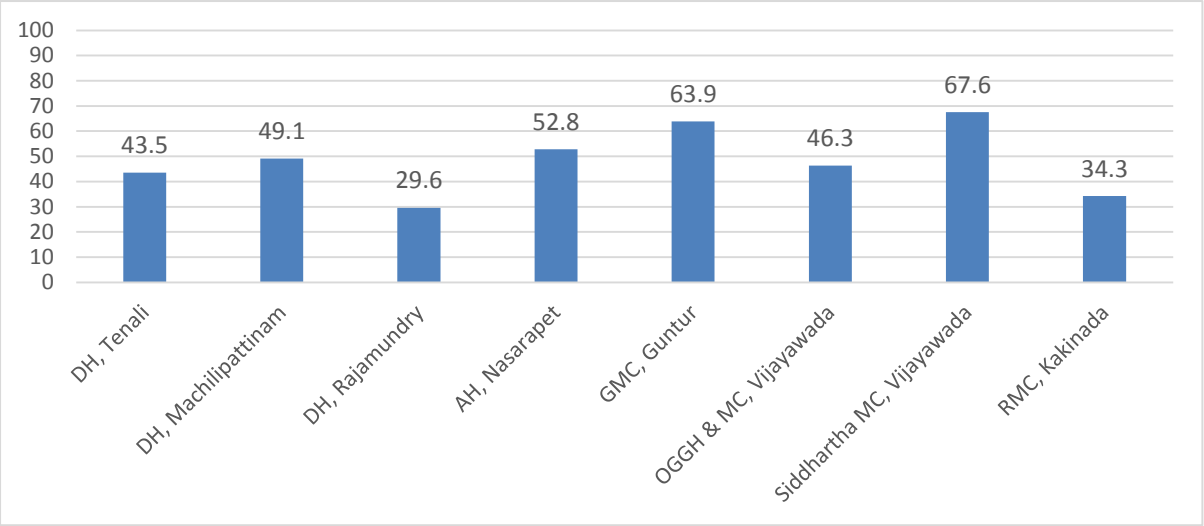
Figure 10 - Laboratory Investigations for Opportunistic Infections



4.8 Infection Control

Infection control includes, passive and active culture surveillance of high-risk areas, staff immunizations, check-ups, hospital Antibiotic policy, hand hygiene protocols, availability and use of personal protective equipment, spill management protocol, decontamination of equipment, cleaning and disinfection of patient care areas, biomedical waste management - segregation at source, sharps disposal, post-exposure prophylaxis and liquid waste management. The score for infection control ranges from 67.6 % for Siddhartha Medical College, Vijayawada to 29.6% District Hospital, Rajahmundry. The average score was 48.3% (SD: 13.1).

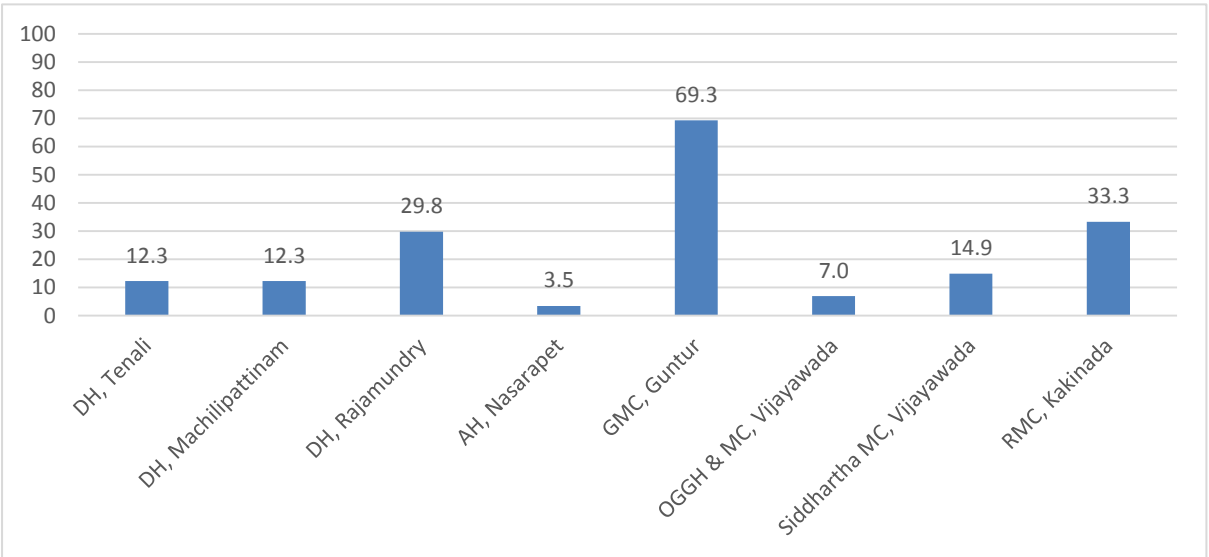
Figure 11 - Infection Control



4.9 Quality Management

Quality management includes, designation of a nodal officer [Quality manager], surveys of satisfaction from patients/ referring doctors, availability of internal quality assurance program(IQAP), external quality assurance program(EQAP), corrective action protocols, standard operating procedures(SOP), periodic internal audits, defined quality policy, defined quality objectives which are monitored and continual improvement protocols. The score for quality management ranges from 69.3% for Government Medical College, Guntur to 3.5% for Area Hospital, Narasaraopet. The average score was 22.8% (SD: 21.5).

Figure 12 - Quality Management



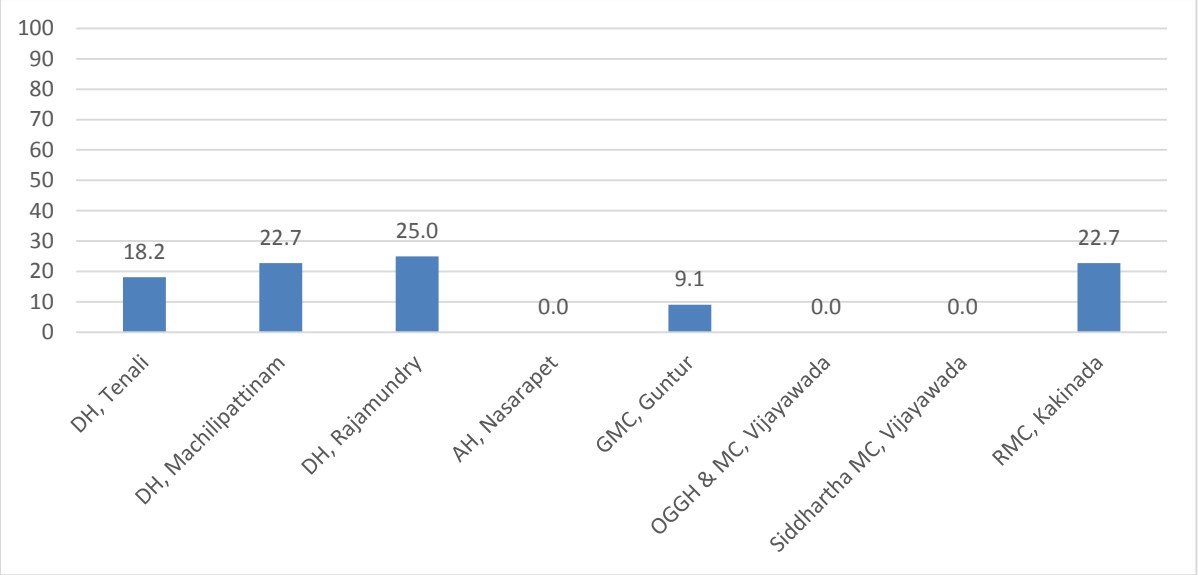
4.10 Outcome measurement

Outcome measurement indicates, developing various performance indicators for outcomes to ensure compliance with State/National benchmark

- productivity indicators e.g. number of HIV tests done/ 1000 population, proportion of tests done for BPL patients,
- efficiency Indicators e.g. Z scores, Turnaround time (TAT) for routine tests, emergency tests
- Safety Indicators e.g. percent of critical call outs, report correlation rate ~~and~~
- Service quality Indicators e.g. waiting time, stock-outs.

The outcome score ranges from 25.0 % to 0%. The average score was 12.2 % (SD: 11.2).

Figure 13 - Outcome measurement



5. Key Observations and Recommendations

The following are the key observations and recommendations, based on the assessment findings, site observations, group discussion and interviews with different stakeholders.
The broad and major suggestions to the state are as follows,

1. ***Sample Collection in the ART facilities:*** In order to make it easier to PLHIVs, it is recommended that sample collection for the supporting laboratory investigations (Biochemistry, Pathology, and Microbiology) be made available in the ART center itself, along with other HIV specific investigations. This will increase the uptake of supporting lab services as per NACO guidelines.
2. ***Enhancing the scope of the Information Management System***: Though the existing Information Management System is focused largely on capturing population-based data on PLHIV, it has a laboratory page but captures only the information related to CD4 cell counts of individual patients. It is suggested that the scope may be widened to capture supporting investigations. This would facilitate comprehensive tracking of patients to monitor conformance to NACO operational guidelines for ART centers.
3. ***Training for Lab Staff:*** To strengthen care, support and treatment of PLHIV, it is suggested that laboratories are capacitated to perform mandated supporting investigations, testing for Opportunistic Infections, STI and HIV-HPV co-infections. In this context, training may be given to lab personnel in,
    a. Quality System Essentials – including Sample Collection, Quality Control, Post-analytical Best practices, Safety, Documentation, Quality Management systems
    b. Diagnostic techniques of Opportunistic Infections and Sexually Transmitted Infections.
    c. Staff training for PAP screening program at all level of healthcare institutions is recommended through short courses in cytology techniques offered by ICMR's National Institute of Cancer Prevention and Research (NICPR). This includes 3 months training for technicians and 4 days orientation for doctors for which suitable candidate may be identified. As IPHS guidelines mandate

cytotechnicians in district hospitals, the existing technician may be trained on cytopathology as per the need and requirement.

d. To ensure sustained capacity building, workplace training centers are recommended.

4. ***Building in-house capacity for sustainability:*** Majority of the investigations in district hospitals are currently provided through Public-Private Partnership initiatives. Enhancing the in-house capacity is critical for sustainable healthcare provision in the long run.
5. **Resource mobilization through PIP:** In order to address the financial resource shortages, training and orientation on "Resource mobilization" are required. Appropriate mechanisms are to be developed for resource mapping and availing funds from districts authorities, hospital funds, corporation funds and NHM.

The institute specific broad observations and recommendation are given below.

Table 4 - District Hospital Tenali, Guntur

District Hospital Tenali, Guntur		
Area of Concern	**Summary**	**Recommendations**
Service Provision	1. The laboratory provides only limited test menu for the patients and majority of tests are outsourced to Medall Diagnostics (PPP)	1. Though services are made available through FDSI, it would be ideal to develop in-house capacities
Patient Rights	1. There was no printed TRF/Report format, tests and reports are handwritten in the OP slip. 2. No restricted area signage displayed in testing labs	1. Report should be given in a standard format along with reference intervals and validated by an authorized signatory 2. Biohazard/entry restriction signage need to be displayed at labs.
Inputs	1. There was no demarcation of Pre-analytical, Analytical and Post analytical activities. 2. There is equipment like cell counter that can be used if reagent supply is provided. 3. Inadequate Fire Safety awareness. 4. Telephone intercom service was not available.	1. Demarcation of Pre-analytical, Analytical and Post analytical activities are to be considered. 2. Adequate competent staff and automated equipment along with respective reagents/QC materials need to be provided for improving the in-house services as per IPHS guidelines. 3. Bio-Safety and Fire Safety awareness should be created among the staff and a sufficient number of relevant equipment should be furnished along with training. 4. Telephone/Intercom facility should be made available
Support Services	1. The equipment management is outsourced to TBS and all equipment are tagged.	1. Equipment should be managed well with AMC/PM/Calibration. 2. Inventory management can be improved and relevant records to be maintained. TBS NABL certificate needs to be checked.

Clinical Services	1. The clinical services not streamlined. 2. No standardized TRF/Report formats. 3. No documented TAT for routine and emergency services. 4. There is no defined reference intervals and critical alert values	1. Proper workflow management and unique ID labeling should be implemented. 2. Standard TRF/Report formats need to be utilized. 3. There should be a system to report results within the defined time for routine cases (TAT) and emergency cases (STAT). 4. The lab must establish biological reference intervals and critical alert values.
Infection Control	1. No Compliance on Infection control practices and disaster management.	1. There is a need for intensive training and implementation of Infection control and disaster management.
Quality Management	1. There is no Quality Management System for the Laboratory.	1. Internal Quality Control and External Quality Control needs to be implemented. 2. Quality Manual, SOPs, Work Instructions and bench aids need to be introduced.
Outcome	1. The are no key performance indicators to monitor outcomes, no awareness on data analysis, metrics, and quality indicators to measure outcomes.	1. Outcome indicators must be evolved and tracked as per the NHM mandate.

Table 5 - District Headquarter Hospital Machilipatnam, Krishna

District Headquarter Hospital Machilipatnam, Krishna		
Area of Concern	**Summary**	**Recommendations**
Service Provision	1. The laboratory provides very limited in-house test menu for the patients. Majority of tests are outsourced to Medall Diagnostics (PPP).	1. The scope of services should be adequate to the patient needs. 2. The facility may consider initiating services in-house.
Patient Rights	1. There is signage to guide in the local language. 2. The Patient does not incur any charges towards the testing. 3. Process for HIV Testing is as per NACO Guidelines.	1. Biohazard/ Entry restriction signage should be kept at routine labs as well.
Inputs	1. There is no demarcation of Pre-analytical, Analytical and Post analytical activities. 2. There is no adequate in-house equipment, reagents and staff as per IPHS Guidelines and tests are outsourced to meet the needs of the population served. 3. There are no Telephone intercom and Fire safety devices available. 4. There is inadequate Fire safety awareness.	1. Demarcation of Pre-analytical, Analytical, and Post analytical activities to be considered. 2. Adequate competent staff and automated equipment along with respective reagents/QC materials need to be provided for in-house service provision as per IPHS guidelines. 3. Telephone/ Intercom and Fire safety devices are required in the facility. 4. Bio-Safety and Fire Safety awareness should be created. Relevant equipment should be made available in addition to training.
Support Services	1. The equipment management is outsourced to TBS and all equipment are tagged. 2. The inventory was not well managed. There were stockouts for routine reagents/kits. 3. Most utilized reagents and	1. Equipment should be managed well with AMC/PM/Calibration. NABL certification of TBS should be looked for. 2. Stock register with lot numbers, dates of expiry and buffer stock levels should be maintained to

	consumables are locally purchased (GOD POD, K3 EDTA TUBES).	prevent stock outs.
Clinical Services	1. In-house Clinical Services are not streamlined. There is no standardized formats for test request, no unique Laboratory Numbers, no proper labeling of samples, and traceability for its activities. 2. No documented TAT available. 3. There are no defined BRI and Critical alert values. 4. Reports are handwritten in printed formats, the copies of the report can be traced back to the date and patient number to the master test results register.	1. Proper workflow management and unique ID labeling should be implemented. 2. There should be a system to report results within the defined time for routine cases (TAT) and emergency cases (STAT). 3. The lab should establish biological reference intervals and critical alert values.
Infection Control	1. There is a compromise in the safety for patients, staff, and visitors.	1. Safety and Infection control practices need to be strengthened such as the provision and proper use of PPE, hand washing practices, handling spillages and segregation of biomedical waste at source.
Quality Management	1. There is no Quality Management System in the in-house Laboratory Process.	1. The Laboratory should establish, develop and implement a Quality Management System. 2. There should be written SOPs, Work Instructions, Bench aids, pictograms, etc., as required to the testing process. 3. The lab needs to enroll in an IQC program and EQA program to assess the validity of test results.
Outcome	1. The Laboratory maintains year wise data for the number of OP Cases, laboratory tests performed, however, it is not mapped to the outcome and efficiency indicators.	1. Laboratory should map its productivity to meet the needs of state / national benchmarking (such as number of Hb tests done per 1000 population) and efficiency outcome (TAT / Z Scores)

Table 6 - District Hospital- Rajahmundry, East Godavari

District Hospital- Rajahmundry, East Godavari		
Area of Concern	**Summary**	**Recommendations**
Service Provision	1. The laboratory offers limited in-house test menu. Majority of tests are outsourced to Medall Diagnostics (PPP)	1. The scope of services should be adequate to the patient needs, facility may consider initiating services in-house
Patient Rights	1. The laboratory is not maintaining TAT 2. The facility does not have bilingual signboards 3. There was no ramp in sample collection area 4. Bio-medical waste segregation is not proper 5. There was no privacy in sample collection area 6. There was no requisition form for sample collection. The laboratory does not have waiting area, toilets and water facility, in the sample collection area. There is no phlebotomy chair 7. The Reports are not in prescribed format	1. TAT (Turn Around Time) to be defined and displayed 2. Bi-lingual signage boards to be displayed 3. Ramp railings should be installed 4. Training to be given on Biomedical waste segregation 5. Separate cabins to be made 6. Standard requisition form to be made 7. Formats are to be made available to generate reports 8. The gaps in terms of waiting area, toilet, and water facility need to be addressed
Inputs	1. There was no intercom in the laboratory 2. Bio-medical waste segregation is not proper 3. Fire extinguishers were not found and no awareness 4. The facility did not have sufficient staff and there is no housekeeping staff 5. Expired kits were found 6. There was no Clinical or Patient feedback/complaint box and grievance handling policy was	1. Intercom to be installed 2. Training to be given on Biomedical waste segregation 3. Fire extinguishers to be installed and training to be given to staff 4. Eligible candidates to be recruited. Training to be given for Housekeeping staff 5. Expired kits should be replaced and regular audits should be done to keep it updated. 6. Feedback for patients and clinicians should be installed and

	available. 7. Equipment calibration details are not available 8. Registers were not well maintained 9. Quality indicators are not maintained 10. SOPs are available	grievance policies should be made 7. Equipment calibration details to be labeled 8. Registers should be maintained 9. Quality Indicators should be maintained 10. SOP's are to be prepared according to the standard format
Support Services	1. Equipment IQ, OQ & PQ is not done 2. Equipment maintenance is not active 3. Entry is not restricted in testing area 4. Job descriptions are not available	1. There should an appropriate and efficient equipment management system 2. Hardcopy to be maintained for all equipment management activities 3. The entry should be restricted in testing area to be implemented. 4. The job description of each staff needs to be defined
Clinical Services	1. No requisition form for sample collection 2. There is no register for sample transport 3. Samples were sent through Needle and syringe from Ward 4. There was no mechanism for hand over 5. Reporting formats were not appropriate	1. Standard requisition form to be made 2. Register for tracking/monitoring the sample transport is required 3. Policy to be made to eliminate sample transport in syringe completely. Sample collection tube to be procured 4. Hand over registers should be maintained 5. Proper reporting should be done
Infection Control	1. Immunization for staff was not done 2. No training registers on needle stick injury, hand wash, spill management, etc. 3. No Bio-medical waste segregation posters	1. To be implemented and record to be maintained 2. Continuous training class to be taken 3. Bio-medical waste segregation posters to be displayed
Quality Management	1. Quality indicators, quality standards, SOPs and IQA programs are not available 2. No CAPA is available	1. The Facility needs a quality management team 2. CAPA register to be maintained
Outcome	1. No Quality indicator maintained	1. Quality indicators need to be maintained

Table 7 - Area Hospital, Nasaraopet, Guntur

Area Hospital, Nasaraopet, Guntur		
Area of Concern	**Summary**	**Recommendations**
Service Provision	1. Emergency services are not available. 2. Test facilities as per the NVBDCP guidelines are not provided Eg: kala-azar, chikungunya etc. 3. The tests as per Free Diagnostic Services are made available through PPP.	1. Emergency services to be facilitated in the facility. 2. NVBDCP guidelines to be followed as applicable 3. The deficiencies may be addressed in order to build the capacity of the lab.
Patient Rights	1. Departmental Signage are not available. 2. List of services, sample collection & reporting timings are not displayed. 3. Proper reporting formats are not available 4. Ramps are not available.	1. Departmental signage in local language should be displayed. 2. List of services, sample collection & report timing need to be displayed at the entrance. 3. Proper reporting formats need to be prepared. 4. Ramps need to be constructed.
Inputs	1. The lab lacks the adequate space and infrastructure. There are no demarcated areas in the facilities such as hand washing area, functional, toilets & drinking water. 2. There is a shortage of staff 3. Fire safety equipment is not available 4. Staff are not trained on IQC & EQAS. 5. Emergency tray & first aid box are not available. 6. Autoclave, hot air oven & ELISA reader-washer are not available 7. Disinfectant is not available	1. Provision of analytical and supporting equipment recommended. More space must be allotted for proper segregation of washing and testing areas 2. Staff recruitment/deputation must be made according to requirement 3. Fire extinguishers need to be installed and training need to be given to staff. 4. IQC/EQA training must be made compulsory for all lab technologists. 5. First aid box must be maintained and accessible for emergency purposes 6. Disinfectant to be made available

Support Services	1. There is no proper Equipment management, calibration, periodic maintenance, cleaning, disinfection & equipment ID. 2. There is no operational manual/SOP of equipment. 3. CAPA is not maintained in case of breakdown of equipment & troubleshooting. 4. Temperature monitoring of refrigerators & defrosting is not maintained. 5. The Illumination & ventilation is not proper in the laboratory. 6. Eyewash facility is not available. 7. There is inadequate drinking water & toilet facility. 8. Staff are not aware of their job responsibilities.	1. Good support services for equipment management, inventory management, lab environment monitoring, safety of staff and patients may be considered 2. Protocols must be developed for equipment management, preventive maintenance, decontamination, and calibration. All equipment must be tagged with labels identifying model/serial no., past & due dates of calibration. 3. SOPs should be prepared for operation of all equipment 4. Corrective and Preventive action records must be maintained for equipment breakdown 5. Temperature charting should be done regularly 6. The lab should be properly ventilated. A/C should be installed 7. Eyewash station should be installed 8. Drinking water filters and separate toilets for male/female should be available. 9. Job descriptions should be clearly laid out and communicated for staff.

Clinical Services	1. Standard formats are not available. 2. Lab records are not labeled & indexed. 3. Staffs are unaware of the disaster management plan. 4. There is no identification of person collecting the sample. 5. Sample transportation box is not available. 6. The lab lacks the retention policy for reports	1. Standard formats for test request and report should be available 2. Lab records should be indexed and stored. 3. Disaster plan should be drafted and communicated to all staff. 4. TRF should bear the name of the person collecting the sample. 5. Sample transport to testing areas should be in refrigerated containers. 6. A copy of the patient reports should be preserved in the lab.
Infection Control	1. HIC policy is not followed 2. There is no provision of immunization & medical check-up for the staff. 3. Hand hygiene facility is not adequate & no drinking water facility. 4. SOPs are not available. 5. Unavailability of hand & floor disinfectant. 6. There is inadequate BMW management and Staff are unaware of mercury spill management.	1. HIC committee & policy need to be developed and followed. 2. All staff need to be vaccinated. 3. Hand disinfectant & drinking water facility are to be made available 4. SOPs need to be prepared. 5. Hand sanitizer and floor cleaner need to be made available. 6. BMW management needs to be understood and implemented. Staff are to be trained on mercury spill.
Quality Management	1. There is no designated staff for quality improvement. 2. There is no record for patient & clinician satisfaction. 3. No IQC, EQAS, control charts & CAPA. 4. SOP's & WDIs are not available. 5. Quality policy & objectives do not exist.	1. There should be dedicated staff for QMS implementation. 2. Regular feedback from patients and clinicians are essential. 3. The lab needs to implement IQC, EQAS, control charts & CAPA 4. SOP & WDI are to be prepared & displayed. 5. Quality policy & objectives are to be defined.
Outcome	1. Quality, clinical care & safety indicators not identified.	1. Quality, clinical care & safety indicators need to be maintained.

Table 8 - Government Medical College, Guntur

Government Medical College, Guntur		
Area of Concern	**Summary**	**Recommendations**
Service Provision	1. Emergency lab services are available only for Microbiology & biochemistry.	1. Emergency lab services are to be made available for selected tests of hematology & serology also.
Patient Rights	1. Departmental signage are not up to mark as some of the signage are not appropriately placed as per the location of the department. 2. None of the laboratories have restricted area signage. 3. List of services of only bacteriology, mycology & serology is displayed that too inside the laboratory. 4. Sample collection timings are not displayed except the ICTC. 5. There is no specific reporting format. 6. There was no separate queue for female patients. 7. HIV consent forms & complaint box are not available in the lab.	1. Departmental signage should be displayed properly. 2. There should display restricted entry signage at the entrance of each laboratory. 3. The list of services of each department needs to be displayed at the entrance. 4. Sample collection timings are to be displayed at the sample collection site of both OPD/IPD. 5. Laboratory reports having a specified printed reporting format duly signed by the authorized signatory. 6. For the convenience of patients, a separate queue for females & ramp should be built in the building as well as collection sites. 7. Complaint box is required
Inputs		
Biochemistry	1. Space is adequate but utilization of space is not up to the mark. Out of order equipment and old patient records occupying space. 2. Staff is not properly trained for BMW, infection control & lab safety 3. Telephone & intercom services are not available. 4. Unavailability of functional	1. Lab design must be suitable. Articles to be condemned must be processed and removed from lab 2. Staff training on Infection control, safety and BMW management to be planned 3. Telephone connectivity for critical reporting and other clinician/patient communication 4. Toilets should be made available and accessible to the differently

	toilets near to the testing laboratory 5. Unavailability of fire extinguishers 6. Improper storage of samples. 7. Inadequate supply of lab material	abled 5. Fire safety apparatus should be installed and monitored. Lab staff should receive hands-on training and also participate in mock drills 6. Adequate facilities for sample storage and retention 7. Regular supply of reagents and consumables should be ensured
Pathology	1. Space is adequate but utilization of space is not up to the mark 2. Telephone & intercom services are not available. 3. Unavailability of fire extinguishers & improper storage of samples. 4. Staff are not properly trained for BMW, infection control & lab safety including the spill management. 5. Inadequate supply of lab materials	1. Out of order equipment must be condemned, separate space/ overhead cabinets for storing old records to clear lab space 2. Telephone connectivity should be provided 3. Fire extinguishers need to be installed and training imparted 4. Staff training related to BMW, infection control 5. Regular supply of reagents and consumables should be ensured
Microbiology	1. Space is sufficient in the lab but not properly utilized. Out of order equipment and old reports and kits not disposed 2. There is no functional toilets & drinking water facility. 3. Washing & staining area is common and no proper waste disposal area. 4. Telephone & intercom services are not available. 5. Improper storage of samples. 6. HIC not properly followed. 7. In ICTC, no demarcated sample collection area as sample collection as well as testing performed in the same room 8. Fire safety equipment not	1. Lab design should be according to available space with separate areas for sample receiving, analysis, and reporting 2. Facilities for drinking water and toilets must be provided 3. Washing area should be separate from other lab function areas. Provision for space for BMW disposal 4. Telephone and intercom facilities should be ensured 5. Samples should be stored for analysis, repeat/additional testing under proper conditions (2-8^{0}C) and according to date. Facilities (refrigerator) must be available and maintained.

	present 9. No working incubator in serology, existing equipment out of order	6. Hospital Infection Control policy must be clearly communicated to staff. There should be training and documentation of BMW management and Infection control activities (Immunization etc.) 7. Regular supply of lab materials should be ensured. Periodic monitoring of sample collection area to ensure availability of supplies. 8. Fire extinguishers must be available, and staff trained in its proper use
Support Services	1. AMC with TBS, but providing only breakdown & repair services. There is no scheduled preventive maintenance of equipment. 2. The lab lacks the system to label the out of order equipment. 3. Calibration & daily maintenance of the equipment was not proper. 4. No temperature monitoring & defrosting of refrigerators. 5. Temperature control and ventilation appropriate in Microbiology & Biochemistry; not adequate in Haematology labs (both IPD/OPD) 6. No written job description for lab staff 7. Eyewash facility not available	1. AMC should be properly documented, preventive maintenance scheduled, and due date clearly mentioned on the equipment. NABL certification of TBS should be checked. 2. Out of order equipment must be clearly labeled 3. Policy for preventive maintenance of equipment should be drafted, SOPs should be made and communicated, maintenance logs periodically examined. Equipment should be periodically calibrated and records maintained. 4. Daily Temperature charting should be done for each refrigerator; they should be regularly defrosted 5. Air conditioning in Haematology labs is required for proper ventilation 6. Detailed job description of lab staff must be available and updated 7. Eyewash station for accidental splashing of body fluids

Clinical Services		
Biochemistry	1. No printed TRFs, stamps used 2. Final computer generated Reports released without authorization 3. Sample transported without temperature control device (Icebox etc.) 4. The facility does not have a policy for retention & disposal of samples 5. Staff not aware of role in disaster response	1. Printed TRFs to be made available detailing patient identifiers, requester's details, type of sample, brief clinical history 2. Printed reports to be authorized before release, by manual/digital signature to avoid transcription errors. 3. Sample Transport boxes to be used for transporting samples from collection point to lab 4. Samples need to be retained for additional/repeat testing. Sample storage policy should be documented and communicated & facilities for the same (tubes, refrigerator) should be made available Sample disposal should be according to BMW management guidelines of the institute/state. Generally, they should be pretreated with 1% Na hypochlorite before draining 5. Disaster policy needs to be drafted and communicated. Staff should be trained and mock drills conducted
Pathology	1. No printed TRFs, stamps used 2. Final computer generated Reports released without authorization 3. Lab records were labeled but not indexed. 4. No awareness of disaster response	1. Printed TRFs to be used, containing patient identifiers, requester's details, type of sample, brief clinical history 2. Printed reports to be authorized before release, by manual/digital signature to avoid transcription errors 3. Lab records should be properly indexed and stored 4. Disaster response policy needs to

		be drafted and communicated with defined role and responsibility
Microbiology	1. Printed formats available for test request, but in some places stamps being used. Printed formats available for reports. Due authorization process followed before release 2. Records being maintained and labeled, but need proper indexing 3. Sample transport box used but conditions not monitored 4. TORCH ELISA is not available. Disaster plan available. Roles and responsibilities of various staff defined	1. Printed TRFs to be used at all places 2. Records to be properly indexed and stored 3. Sample transport conditions to be monitored before acceptance 4. TORCH ELISA testing must be available for screening of ART patients 5. Mock disaster drills should be periodically conducted
Infection Control	1. There was no provision of periodic medical check-up for the staff. 2. Hand washing procedure is not displayed & staff is not fully aware. 3. Staff are not trained well on spill management & BMW. 4. Puncture proof box & color-coded bags are not available.	1. Vaccination of all the staff including a routine check for all laboratory personnel is essential. 2. The staff need to be trained on BMW and Spill management. 3. BMW guidelines 2016 along with the state pollution control guidelines need to be followed strictly.
Quality Management	1. Microbiology lab equipped with QMS – a designated Quality manager, Quality manual, IQC/EQA practices, Test SOPs, patient feedbacks. But Quality objectives not defined, Quality indicators not set. 2. In Biochemistry and, IQC used but Control charts (LJ charts) are not prepared nor outliers identified. No EQAS participation	1. Along with quality policy quality objectives are to be defined and Quality indicators should be set for monitoring and continual improvement 2. Control charts need to be maintained & actions taken documented. 3. Along with quality policy quality objectives are to be defined. EQAS participation for biochemistry & hematology is essential.

	3. Quality objectives are not available. No IQC/ EQAS practice in Pathology lab 4. No proper authorized SOPs in Biochemistry and Pathology 5. No QMS in Biochemistry and Pathology	4. IQC for hematology should be started along with documentation of CV% and corrective or preventive actions taken 5. SOPs need to be prepared and communicated in both Biochemistry and Pathology 4. QMS needs to be established for Biochemistry and Pathology with the designation of Quality manager, formulation & communication of Quality policy, and preparation of Quality manual detailing the procedures and documentation practices followed.
Outcome	1. There was no EQAS participation for biochemistry & hematology by the facility 2. Service Quality Indicators are not monitored & analyzed.	1. EQAS participation for biochemistry along with the IQCs & hematology are essential. 2. Quality Indicators are to be monitored & analyzed every month

Table 9 - Old Government General Hospital, Vijayawada, Krishna

Old Government General Hospital, Vijayawada, Krishna		
Area of Concern	**Summary**	**Recommendations**
Service Provision	1. Routine Lab services are not provided to ART patients. No linkage/sample referral procedure. ART patients are forced to travel to SMC/NGGH for routine lab tests (Sample referral only available for CD4) 2. Not all biochemistry tests are offered during routine hours. Serum electrolytes, lipid profile tests are not available. 3. Peripheral smear examination is only available in routine hours 4. No microbiology tests are performed other than RDTs 5. No cytology or histopathology tests are available at the lab. Surgical pathology samples transported to SMC Lab. In other cases, patients (& not samples) are referred. Pap smears transported after fixation to SMC for examination but fixing inadequate, and transport infrequent (2-3 days) 6. CSF/Body fluid examination is not available. Occasionally, samples transported to SMC, but most commonly sent to private labs in the vicinity	1. Routine lab services (Biochemistry, Pathology, Microbiology) should be made available to ART patients 2. Serum/Urine electrolyte examination should be made available, at least for the indoor patients, and emergency patients 3. Basic microbiology (microscopy, some culture tests) must be made available, as the hospital caters to the maternal and child population 4. Cytology services, esp. Pap smear examination, must be made available. Till such time, validated procedures for sample fixation and transport must be documented, communicated and monitored to ensure good quality specimen for PAP smear 5. Clinical pathology tests viz. ascitic fluid/CSF examination must be made available, at least for indoor patients
Patient Rights	1. Facility has Patient-friendly infrastructure especially for the differently abled. Social scheme beneficiaries recognized. 2. ART patients are not allowed in the routine sample collection	1. Sample collection and lab facilities must be accessible for ART patients 2. Sample collection area needs to be integrated. The lab requires sitting/waiting area, separate

	area. No routine lab services are provided to ART patients, reason cited is lack of enough space in sample collection area, posing increased risk to immune compromised patients 3. No common sample collection area. Sample collection areas are different for pediatric, female and psychiatric patients 4. Inadequate sitting/waiting area in sample collection area. There is no patient privacy 5. Patient communication is inadequate/verbal. Report collection timings are not displayed in the collection area. Test census data are available at sample collection area. 6. Patient reports do not carry all details like BRI and interpretation. 7. No restricted area signage near lab entrances 8. No feedback/complaint redressal system	male/female queues, and patient privacy at phlebotomy point. 3. Need improvement in patient communication 4. Feedback/complaint redressal system must be established and effectively communicated to patients through notices, registers, and forms available at points of contact. 5. Sample referral for basic tests (electrolytes, lipid profile, clinical pathology tests etc.) must be made available routinely, or patients need to be reimbursed 6. BRI and interpretation to be mentioned in the reports. 7. Restricted signage to be displayed. 8. Feedback/complaint box should be in place.
Inputs		
Biochemistry	**Personnel** 1. Pathologist (Medical Biochemist) and three technicians are available during routine working hours. 2. No pathologist and single lab technician in emergency hours. 3. Staff are not trained in lab safety, BMW, Internal/External QA	**Personnel** 1. At least one more technical staff for the emergency lab is required. 2. Staff training on (a) BMW & infection control including PPE, NSI, Spill management (b) Disaster response, fire safety etc. (c) Critical callouts (d) TAT monitoring (e) maintaining Lab records (f) First aid

	Accommodation & Environment 1. Lab space is inadequate. No separate area for sample receiving, reporting, washing & disposal, store areas. 2. Paediatric/Neonatal lab is congested 3. There are different sample collection area for pediatric, female and psychiatric patients 4. Sitting/waiting area inadequate in sample collection area. No/minimal patient privacy maintained **Equipment, reagent, and consumables** 1. No evacuated tubes are available for sample collection 2. Only semi-automatic analyzer, colorimeter available. No electrolyte analyzer. Bilirubinometer available in neonatal lab 3. No ELISA facilities for hormone testing 4. No telephone/intercom available 5. No power backup available for reagent refrigerator. Frequent stock-outs of Amylase. 6. No Lab safety plan, no fire extinguishers or fire exit signage.	**Accommodation & Environment** 1. Central laboratory and central collection area need to be designated to organize workflow 2. There is a need for restricted area, Biohazard & Fire exit signage's 3. Separate washing & waste disposal area are required **Equipment, reagent, and consumables** 1. There should be a shift to closed collection data, with evacuated tubes. 2. Telephone/Intercom services need to be made available to facilitate clinician queries, getting important patient information (from wards/clinicians), critical call outs. 3. Electrolyte Analyzer, Fully automatic analyzers with ion-selective electrodes are required. 4. System calibrators (multiple parameters) and Quality control samples (preferably third party) are required. 5. ELISA for female hormone tests especially Thyroid profile, FSH/LH, Insulin should be made available. 6. Decontamination tubs for cleaning of reusable glass bottles, disinfection of serum samples before discarding. 7. Regular reagent supply should be

		ensured (especially, Amylase) 8. Power backup for reagent refrigerator is essential.
Pathology	**Personnel** 1. One pathologist is available during routine working hours. 2. Lab technicians are available in routine working hours, but single technician handles all responsibilities (Biochemistry, Pathology) during emergency hours. **Equipment, reagent, and consumables** 1. No automatic cell counter, microscopy used for counting 2. Sahli's method used for hemoglobin estimation 3. No facilities for FNAC 4. No histopathology setup, surgical samples transported to SMC. Patients referred to SMC for biopsy	**Personnel** 1. A Pathologist should be available round the clock for reporting on peripheral smears, CSF/Ascitic fluid reporting in view of pediatric & infectious workload 2. Staff training as mentioned above (Biochemistry) **Equipment, reagent and consumables** 1. Automatic 3-part or 5-part cell counter should be procured 2. Sahli's method for Haemoglobin assessment should be gradually phased out as it is an obsolete method 3. Cytology facilities need to be made available 4. Histopathology facility may be made available.
Microbiology	**Personnel** 1. No dedicated microbiologist available 2. Technicians trained in using RDT kits **Equipment, reagent and consumables** 1. No microbiology setup	**Personnel** 1. Microbiologist should be made available for basic microscopy and culture for infectious diseases 2. Staff training for ELISA, culture, active & passive surveillance using surface swabs **Equipment, reagent and consumables** 1. Basic microbiology services need

	(incubators, inoculators, biosafety cabinets, ELISA etc.) RDT kits for Malaria, dengue, HBsAg, HCV available	to be available
Support Services	**<u>Biochemistry/pathology/ Microbiology</u>** 1. AMC with TBS, providing breakdown support but no periodic preventive maintenance or equipment calibration service 2. No instrument log book detailing minor/major maintenance or repair (Only service reports kept loosely) 3. Technicians performing routine maintenance but no SOPs or maintenance log 4. No lot verification performed before switching reagent lot 5. Stock register not well maintained (difficult to have a fair idea of reagent & lot wise on-hand inventory). No proper indenting policy or buffer stocks. 6. No temperature charting is done for refrigerators. No power backup for reagent refrigerator. 7. Running water available 8. Poor temperature control in collection & testing areas. 9. No detailed job description of employees. No strict adherence to dress code 10. Duty roster present but No biometric attendance system for staff. No mention of time in attendance records.	**<u>Biochemistry/pathology/ Microbiology</u>** 1. Equipment - Periodic preventive maintenance must be scheduled and documented. NABL certification of TBS should be checked. 2. SOPs for operations and daily/weekly/monthly maintenance must be framed in consultation with technical support persons of the manufacturer. They should be regularly updated. WDIs or flowcharts may be used for easy communication with all lab staff 3. Equipment calibration must be performed and certified periodically (by an ISO 17025 accredited body) 4. Stock registers should be maintained in a proper format for easy reference, highlighting Expired/Near expired reagents, buffer stock levels, and indent schedule 5. Refrigerators must be periodically serviced and temperature logs maintained. 6. Lot verification must be done before using a new lot of reagents for patient testing. 7. Job descriptions of all employees must be clearly laid out and communicated 8. Air conditioners to be provided in the collection area and the lab

Clinical Services	**Biochemistry/pathology/ Microbiology** 1. Printed TRFs are inadequate, do not list the tests, no time of sample collection, type of primary sample. TRFs were not regularly used and test requests sent on X-ray request form. 2. There was no sample collection manual detailing patient preparation, the procedure for collection, transport, acceptance/rejection criteria, etc. Samples not labeled with unique lab id no. 3. Tests for electrolytes, hormones, microbiology were not available. No referral links were established 4. Release of reports by authorized signatory only in office hours. Operations unsupervised outside office hours 5. No testing SOPs, WDIs updated, authorized and communicated 6. Samples were disposed of the same day; not retained for repeat/additional testing 7. BRI list not updated, not communicated to OPDs, wards. BRIs not mentioned on patient reports. 8. No critical alert values identified for various parameters 9. Results not reviewed against IQC data, patient's previous results 10. TAT was not documented 11. There was no equipment print	**Biochemistry/pathology/ Microbiology** 1. TRF and report formats need to be updated. 2. Sample collection manual must be designed 3. Referral linkages with other labs for tests were not being performed. 4. All tests reports should be validated by authorized signatories. All labs must have technical supervisory teams. 5. Testing SOPs must be drafted and communicated and updated. 6. Procedure for retaining the samples for additional/repeat testing, and proper disposal after analysis needs to be documented and followed. 7. BRI must be updated and communicated to physicians and patients 8. Documentation of Critical alert values and system to communicate the same 9. IQC/EQA practices must be introduced. Results must be reviewed against IQC and previous patient reports. 10. TAT to be displayed. 11. Equipment printouts should be preserved for cross-validation 12. Fire and other safety workshops should be initiated. 13. Training on disaster management needs to be conducted. MSDS (material safety data sheet) sheet need to be made available.

	out available for transcription verification 12. There was lack of awareness regarding Hazard and disaster	
Infection Control	1. There was no antibiotic policy. 2. There was no training to technologists on infection control and BMW 3. There was No system of regular immunization of lab staff against HBV, No periodic medical check-up 4. The lab was lacking documented spill management protocol. Staff was untrained and unable to demonstrate steps of managing hazardous spills safely. 5. Staff was not well versed with Handwashing steps. No boards displaying correct hand wash technique 6. Staff was unaware of PEP guidelines 7. No regular decontamination of equipment was carried out. Working surfaces were wiped using spirit. Staff was not well versed with making hypochlorite working solution Blood/serum samples disposed of without treatment into the drain	1. Hospital Infection Control policy must be drafted and there should be a designated Infection Control team and antibiotic policy need to prepared. 2. A documented schedule for periodic medical examination including immunization of lab staff against HBV 3. Infection control training to lab staff to decrease the transmission of HAI-including hand hygiene, PPE, spill management, biomedical waste management, Post-exposure prophylaxis 4. Regular monitoring to encourage and ensure the proper use of PPE, especially in the sample collection and processing areas 5. Decontamination log must be maintained for all equipment parts coming into direct contact with sample tubes, especially centrifuge rotors, sample racks in auto-analyzers 6. BMW bins and bags need to be made available at the point of use 7. Proper treatment of liquid waste including effluents from the analyzer and leftover serum/blood samples with hypochlorite before disposal
Quality Management	1. There was no defined Quality policy or Quality objectives and No Quality Manager	1. Quality policy should be defined and quality objectives and quality indicators are to be developed;

	appointed. 2. No IQC/EQA practices were followed in Biochemistry and Haematology. 3. No corrective action records were maintained 4. No updated, authorized SOPs for tests were available or communicated 5. No patient feedback was taken, No SOP or records of complaint resolution were maintained. Internal audits were not done	Quality Manager should be appointed. 2. IQC materials should be procured for Biochemistry and Haematology tests. Multi-parameter calibrators should be preferred over kit standards for calibration in biochemistry. 3. Corrective and Preventive action records should be regularly maintained and updated. 4. SOPs for test must be drafted in consultation with application personnel of Reagent/Equipment for the respective tests and communicated to all lab staff 5. Regular Internal Audits must be planned and actions taken on nonconformities should be documented Regular feedbacks must be sought from patients, clinicians. Actions taken for complaint resolution must be documented
Outcome	1. No outcome monitoring was done in the laboratory.	1. Productivity, Efficiency, Safety, and Service Quality indicators must be monitored.

Table 10 - Siddhartha Medical College, Vijayawada, Krishna

Siddhartha Medical College, Vijayawada, Krishna		
Area of Concern	**Summary**	**Recommendations**
Service Provision	**Routine services** - 1. The Patients have to bear the additional cost of a very basic investigation like electrolytes, despite the availability of instrument. 2. Samples of renal biopsy being outsourced to private labs (by the clinicians) despite histopathology facility being available in-house **Emergency services** - 1. The Emergency services were very inadequate in context of a medical college and a tertiary health care center	**Routine services** - 1. There is a need to expand routine services which include serum and urine electrolytes and Hormone investigations need to be expanded on ELISA/Chemi. 2. Better coordination and communication with clinical departments to ensure full utilization of in-house histopathology facility Immunohematology and Immunohistochemistry (IHC) services should be started in the interests of patients and postgraduate students attending a prominent medical college. **Emergency services** - 1. The facility must provide serum/urine electrolytes, hematology, clinical pathology (Urine/Ascitic fluid /CSF examination)
Patient Rights	1. The facility infrastructure is friendly to the differently abled. Social scheme beneficiaries are recognized. 2. Patient communication is inadequate/verbal. 3. The patient reports do not carry all details. 4. There was no proper information/feedback/grievance redressal system available in the facility 5. The patient safety mechanism	1. There is a need for separate queues for female attendees/transgender 2. Provision for a separate toilet for transgender should be made available. 3. The departmental signage need to be improved including restricted area signage. 4. Information about the list of tests, timings of sample collection/report despatch and TAT must be made available at the

	was not emphasized	registration/sample collection area. 5. The sample collection area must provide information on best practices, precautions, first aid facilities 6. Separate information kiosk for inquiries should be made available. 7. Consent format for invasive tests like FNAC with better communication from the pathologist detailing the test and its complications is required. 8. Training should be imparted on Infection control practices/ Safety precautions especially in sample collection area 9. Feedback/Suggestion/Complaint forms should be made available at points of patient contact.
Inputs		
Biochemistry	**Personnel** 1. The 24-hour lab requires human resource and technical resources (only colorimeter present) **Accommodation & Environment** 1. There is lack of space in the lab making it too cramped.	**Personnel** 1. At least one more technical staff is required for the emergency lab 2. Staff training should be made available on (a) BMW & infection control including PPE, NSI, Spill management (b) Disaster response, fire safety etc. (c) Critical callouts (d) TAT monitoring (e) maintaining Lab records (f) First aid **Accommodation & Environment** 1. There should be restricted area, Biohazard & Fire exit signage's in the facility

		2. Separate washing & waste disposal area must be maintained 3. There is a requirement of more lab space for the 24X7 lab; the external room can be absorbed into the lab, and the patient relatives' waiting area moved away
	Equipment, reagent and consumables 1. The facility has only semi-automatic analyzers and ELISA available. 2. Electrolyte analyzers and Chemiluminescence instruments are being hampered by a lack of reagents, supplies and technical support. 3. There is no availability of sample storage facility (separate refrigerators) and deep freezers. 4. The facility has no system for calibrators, Quality Control samples. 5. The reusable glass vials with rubber caps are used for sample collection	**Equipment, reagent and consumables** 1. Fully automatic analyzers with ion-selective electrodes needs to be installed 2. Reagents should be available for existing electrolyte analyzers and automated chemiluminescence instrument 3. The facility must have system calibrators (multiple parameters) and Quality control samples (preferably third party) 4. Refrigerators and deep freezers should be made available 5. The lab has availability of decontamination tubs for cleaning of reusable glass bottles and disinfection of serum samples before discarding 6. Semi/Fully automatic analyzer with Ion selective electrodes for the 24X7 lab should be installed. 7. The facility should have reagents for other tests to expand the emergency services offered. 8. Pre-evacuated tubes for sample collection and transport for both routine and emergency lab services should be made available. 9. Telephone and intercom services should be installed in the lab

Pathology	**Haematology** 1. Haematology department needs major thrust. The 3-part cell counter is not functional. The 7-part cell counter was lying unused due to non-availability of reagents. 2. PT/aPTT testing equipment/reagents not available 3. The Histopathology department is equipped with microtome, tissue processor	**Haematology** 1. Supplies and services for cell counters should be made available 2. Sahli's method for Haemoglobin assessment should be gradually phased out as it is an obsolete method. 3. PT/aPTT testing facility (automatic/manual) should be made available 4. Flow cytometer for immunohematology services should be provided **Histopathology** 1. Automated microtome is required in the lab 2. There is a need for fume hood for grossing 3. Special stains and fluorescence microscopy for IHC should be made available 4. Multi-head teaching microscope is required in the lab
Microbiology	**Personnel** 1. The facility is in need lab technicians and lab attendants, **Accommodation & Environment** 1. The Lab space was sufficient and was well ventilated **Equipment, reagent and consumables** 1. There were sufficient Autoclaves 2. There were no Biosafety cabinets and deep freezers 3. The Vitek 2 Automated BC	**Personnel** 1. At least 1 Lab attendant and 1-2 Lab technicians needed. Staff training on lab safety, BMW **Accommodation & Environment** 1. A/C required for serology lab **Equipment, reagent and consumables** The following need to be made available: 1. Biosafety cabinets 2. Deep freezers 3. Vitek 2 culture cards

	system was lying unused 4. There is irregular supply of BMW bins and bags	4. BMW bins and bags
Support Services		
Biochemistry	1. AMC with TBS, providing breakdown support is available but lack periodic preventive maintenance or equipment calibration service 2. There was no instrument log book detailing minor/major maintenance or repair (Only service reports filed) 3. Technicians performing routine maintenance were available but there are no SOPs or maintenance log 4. Power backup was available in the lab	1. Equipment - Periodic preventive maintenance must be scheduled and documented. NABL certification of TBS to be checked. 2. SOPs for operations and daily/weekly/monthly maintenance must be framed in consultation with technical support persons of the manufacturer. They should be regularly updated. WDIs or flowcharts may be used for easy communication with all lab staff 3. Equipment calibration must be performed and certified periodically (by an ISO 17025 accredited body) 4. Defective equipment needs to be clearly labeled in documented format 5. Refrigerators must be periodically serviced and temperature logs should be maintained. 6. Lot to lot verification must be done before using a new lot of reagents for patient testing. 7. Job descriptions of all employees must be clearly laid out and communicated
Pathology	1. Three-part cell counter was defective and not labeled 2. There was no routine maintenance of SOPs/Register for microtome, tissue processor 3. AMC with TBS, providing breakdown support was	1. Periodic Equipment calibration and preventive maintenance must be pre-scheduled and communicated 2. Instrument logs must be maintained (in addition to the present practice of filing service reports)

	available but there was no periodic preventive maintenance or equipment calibration service 4. Stock registers were not easily accessible. 5. No job description available for different levels of functionaries	3. SOPs for operation & daily/weekly/monthly routine maintenance must be prepared, validated and communicated to all lab staff. WDIs or flowcharts may be used for easy communication 4. Equipment calibration must be performed and certified periodically (by the manufacturer or an ISO 17025 accredited body) 5. Defective equipment needs to be clearly labeled in documented format 6. Job descriptions of all lab staff should be laid out 7. Stock register for reagents needs to be maintained / accessible.
Microbiology	1. There is no SOPs/Register for routine maintenance activities. 2. No equipment calibration was done for incubators, water bath, thermometers, micropipettes, ELISA washer etc.	1. Periodic Equipment calibration and preventive maintenance must be pre-scheduled and communicated 2. Instrument logs must be maintained (in addition to the present practice of filing service reports) 3. SOPs for operation & daily/weekly/monthly routine maintenance must be prepared, validated and communicated to all lab staff 4. Temperature charting of refrigerators should be made available 5. Job descriptions of all lab staff should be laid out. 6. Dress code should be adhered to by all concerned
Clinical Services		
Biochemistry	1. There are printed formats for TRF and report, but is inadequate and needs to be	1. TRF and report formats need to be updated. TRF must include type of primary sample, type of container,

	updated 2. There are no sample collection manual and training made available to phlebotomists 3. Unique lab Id is generated but samples are not labeled with the unique ID. The samples are not retained for testing, and disposed of according to BMW norms; Medico-legal case samples are handled separately according to protocol. 4. Electrolytes are not done for last three years, and no referral linkages established 5. BRI is documented within the lab, but not updated. The Report format does not include BRI 6. There is no review of results against IQC or previous patient results. 7. Documentation of Critical alert values are available. 8. Only Urea, creatinine is being offered in emergency hours (after 2 pm). 9. Hazard and disaster awareness is very low among staff 10. Referral linkages with other labs for tests are not being performed.	time of collection, clinical features including drug history, test requisitioning menu. Report must include BRI 2. There is a need to increase the test menu offered in emergency lab 3. Sample collection manual must be designed containing details about collection, handling, labeling & tracing of the primary sample and monitoring sample transport. 4. Procedure for retaining the samples for additional/repeat testing, and proper disposal after analysis needs to be documented and followed. 5. Testing SOPs must be drafted, communicated and updated. 6. IQC/EQA practices must be introduced. Results must be reviewed against IQC and previous patient reports. 7. Documentation of Critical alert values and system to communicate the same immediately to the physician/patient; There should be provision for intercom services. 8. BRI must be updated and communicated to physicians and patients 9. Fire and other safety workshops must be provided.
Pathology	1. TRF & Report formats are available, but inadequate. 2. There are no sample collection manual or training available for phlebotomists. 3. No documented, validated SOPs available in the lab 4. There is no review of results in hematology against IQC.	1. TRF and report forms should be updated 2. Sample collection manual must be prepared 3. Procedure for retaining the samples for additional/repeat testing, and proper disposal after analysis needs to be documented and followed

	5. Peripheral smears, body fluid examination are not available during emergency hours	4. Test SOPs need to be prepared, updated and communicated 5. Emergency pathology services need to be improved which includes peripheral blood smears, CSF/Body fluid analysis 6. Critical call outs for haematology parameters should be made available
Microbiology	1. Formats for TRF and Report are available. 2. There was no sample collection manual or training for phlebotomists and no adequate monitoring of sample transport (samples routinely received from OGGH, Vijayawada) 3. Clinical records are well maintained. The Demographic details of the patient are entered in lab registers. 4. No detailed authorized testing SOPs made. WDI present for ELISA not dated and authorized. 5. Samples are retained for stipulated time periods. Sample disposal followed according to guidelines. 6. Awareness regarding disaster preparedness is minimal/absent among staff.	1. Sample collection manual must be prepared. 2. Better monitoring of sample transport, especially samples received from OGGH should be present in the lab 3. Testing SOPs, WDIs must be prepared, updated and communicated 4. Training on disaster management needs to be conducted. 5. Documents need to be controlled.
Infection Control	1. The facility has no antibiotic policy. 2. No training to technologists in infection control and BMW has been provided 3. The BMW bins/bags not available at all points 4. Passive culture surveillance is	1. Hospital Infection Control policy must be drafted and Infection Control teams prepared 2. Lab technologists need to be trained in collecting swabs for active microbiological surveillance 3. A documented schedule for periodic immunization of lab staff

	carried out (registers not verified) 5. Staff immunization was carried out recently for microbiology lab staff, but there is no policy for regular vaccination/booster dose for all lab staff 6. Phlebotomy technicians are not using PPE 7. There is no documented regarding spill management protocol. Staffs are not trained and unable to demonstrate steps of managing hazardous spills safely. 8. Staff are not well versed with Handwashing steps 9. No regular decontamination of equipment. Working surfaces are wiped using spirit and staff not well versed with making hypochlorite working solution 10. The staff has inadequate knowledge on Needlestick injury, AEB, PEP 11. Blood/serum samples are disposed of without treatment into the drain	against HBV, and also examination of anti-HBs titers in serum, & provision of boosters is needed 4. Infection control training needs to be given to lab staff to decrease the transmission of HAI-including hand hygiene, PPE, spill management, biomedical waste management and Post-exposure prophylaxis 5. Regular monitoring is required to encourage and ensure proper use of PPE, especially in the sample collection and processing areas 6. Decontamination log must be maintained for all equipment coming into direct contact with sample tubes, especially centrifuge rotors, sample racks in autoanalyzer 7. BMW bins and bags need to be made available at the point of use 8. There is a requirement of proper treatment of liquid waste including effluents from the analyzer and leftover serum/blood samples with hypochlorite before disposal
Quality Management	1. There was no defined Quality policy, Quality objectives and no Quality Manager appointed in the lab for Quality Management 2. No IQC/EQA practices have been followed in Biochemistry and Pathology. 3. In microbiology, Kit controls are used for ELISA and there were no in-house borderline positive controls prepared 4. ATCC strains were used for IQC	1. Quality policy should be defined and quality objectives and quality indicators need to be identified; The lab should appoint Quality Manager 2. IQC materials should be procured for Biochemistry and Haematology. Multi-parameter calibrators should be preferred over kit standards for calibration in biochemistry 3. Corrective and Preventive action records should be regularly

	5. There was no EQA program available in the facility and no corrective action records were maintained 6. The facility had no updated, authorized SOPs for available tests 7. There were no availability of patient feedback records of complaint resolution and SOP regarding quality management in the facility	maintained and updated 4. SOPs for test must be drafted in consultation with application personnel of Reagent/Equipment for the respective tests 5. Regular Internal Audits must be planned and actions taken on nonconformities should be documented 6. Regular feedbacks must be sought from patients and clinicians. Actions taken for complaint resolution must be documented
Outcome	1. The facility had no outcome monitoring done	1. Productivity, Efficiency, Safety and Service Quality indicators must be monitored and documented.

Table 11 - Rangaraya Medical College, Kakinada, East Godavari

Rangaraya Medical College, Kakinada, East Godavari		
Area of Concern	**Summary**	**Recommendations**
Service Provision	1. Laboratory services are available 24 hours. All tests as mandated by NHM and NACO are available	
Patient Rights	1. The laboratory is not maintaining TAT (Turn Around Time) 2. There are no bilingual signage and ramps found in sample collection area 3. There is no proper bio-medical waste segregation. 4. The facility has no requisition forms for sample collection 5. The facility has no waiting area, toilets, water facility, and privacy in the sample collection area 6. There are no phlebotomy chairs available 7. The reports are not in prescribed format.	1. The TAT (Turn Around Time) should be defined and displayed along with the scope of services. 2. The facility should display bi-lingual signage and ramp with railing to be installed 3. Training on Biomedical waste segregation should be provided to staff 4. There should be standard requisition form for sample collection 5. There is a need for proper availability of waiting area, toilets, provision of water facility and privacy in the sample collection area. 6. There should be a format to generate report.
Inputs	1. There is no telephone intercom system in the laboratory 2. There is a lack of proper Bio-medical waste segregation in the facility. 3. There are no fire extinguishers found and awareness among staff regarding fire safety is lacking. 4. The facility has no sufficient staff available and there is a lack of proper housekeeping 5. It was found that there were kits	1. Intercom system needs to be installed in the facility. 2. Training has to be given on Biomedical waste segregation to the staff 3. Proper fire extinguishers should be installed and training should be given to staff regarding fire safety 4. Regular training for housekeeping department must be provided by the facility. 5. The expired Kits needs to be

	which were expired. 6. There was no feedback/complaint box, grievance handling policy and system for clinician feedback. 7. There were no details of Equipment calibration and no registers were maintained for the same. 8. The facility does not maintain Quality indicators and SOPs are not available.	replaced and regular auditing is required to keep an update 6. Complaint Box needs to be made available and Grievance policy needs to be formulated. 7. The Clinical feedbacks in the facility should be registered 8. The details of the Equipment calibration should be labeled and proper registers must be maintained 9. Quality indicators to be maintained 10. SOP to be prepared
Support Services	1. Equipment IQ, OQ & PQ is not done 2. Equipment maintenance is not active 3. There is no strict policy for restricted areas 4. The staff are not aware of their respective JD/JS	1. It is essential to maintain records of equipment maintenance 2. The equipment maintenance should be done on time 3. Policy for entry restriction should be formulated 4. The JD needs to be documented and made available to the staff
Clinical Services	1. Requisition forms for sample collection are not available in the lab 2. There is no register for sample transportation system 3. The lab lacks the system for hand over mechanism 4. There is a lack of proper registers, formats and reporting Patterns	1. Standard requisition form is to be established and register to be maintained 2. Hand over mechanism should be established 3. Reporting formats need to be developed. 4. Registers/log need to be maintained.
Infection Control	1. There was no provision for staff immunization 2. There was a lack of documentation on training regarding needle stick injury, hand hygiene, spill management, etc. 3. Bio-medical waste segregation posters were not displayed	1. Staff must be immunized and record should be maintained 2. Training should be provided to the staff on needle stick injury, hand wash techniques, spill management, etc., 3. Bio-medical waste segregation posters should be displayed

Quality Management	1. There is no effective implementation of quality standards 2. No SOPs were found in the lab regarding any of the procedures and there was no internal quality assurance program 3. Quality indicators were not maintained in the lab	1. It is essential to maintain quality standards in the lab 2. SOPs regarding lab procedures to be formulated. 3. Internal quality assurance program to be made available. 4. Quality indicators to be maintained in the lab.
Outcome	1. Indicators are not maintained and monitored in the lab	1. It is essential to maintain standard indicators

6. Conclusion

Strong laboratory services and systems are critical for delivering timely and quality health services in the HIV treatment and prevention cascade which includes diagnosis, linkages, retention in care, and commencement of ART, HIV treatment monitoring, adherence, and viral load suppression. In order to achieve the UNAIDS treatment target 90-90-90, optimizing the use of diagnostics will be critical. In particular, it essential to have appropriate strategies to achieve the first and third parts of the target, ensuring the earliest possible diagnosis of HIV infection and measuring viral suppression for people receiving HIV treatment. This also emphasizes the need for consistent and continuous improvement in the quality of laboratory services by improving the systems, processes, and technology to ensure quality health services across the country.

The gap analysis carried out in eight public health laboratories in Andhra Pradesh state has brought out crucial information related to the existing structure, systems, processes, gaps and challenges in terms of availability of laboratory services related to HIV and AIDS, quality management systems, referral and linkages. From the current status of laboratories, the gaps and challenges vary significantly between institutions, though several of them are common across the laboratories. However, it is essential to focus each institution with need-based, specific strategies and approaches.

The key focus areas for improvement are

- Expedient establishment of quality management systems to enable continual improvement of the lab systems. This would involve training in all quality system components; pre-analytical, analytical and post-analytical.
- Addressing the deficiencies in tests availability with reference to the Free Diagnostics Service Initiative as well as NACO guidelines
- Enabling mechanisms to detect Opportunistic Infections
- Strengthening the referral linkages between the laboratories and the ART centers to enable better uptake of supporting investigations

The project seeks to address the above through a 360^0 approach which comprises of training, mentoring, advocacy and e-learning. Most gaps elicited can be addressed through effective training and workforce skill development. Gaps that need resources will be sought to be addressed through advocacy and sensitization. Developing linkages and synergy at all levels, starting from institutional level, between ART centers and the institutional labs; to state and national levels, between state health departments, state NHM and SACs, and the corresponding national agencies.

To summarize, the identified administrative, management and technical shortages in the laboratories not only justifies the need for immediate interventions but also gives an opportunity to strengthen the selected public laboratories. This is very much possible as there is a willingness, strong commitment, and motivation from the institutions, states and other stakeholders involved in the program.

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