

**TO STUDY THE EXISTING PROCESS AND FIND OUT
THE GAPS BASED ON THE PREPARED STANDARD
MANUAL IN A SATELLITE LABORATORY at APOLLO
DIAGNOSTICS, HYDERABAD**

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ABOUT ORGANISATION

➤ **APOLLO GROUP**

Counted among Asia's leading healthcare providers today, Apollo Hospitals Group has scripted one of the most magnificent stories of success that India has seen. Born as a 150-bed hospital in 1983, the Group has blossomed into a global health care system by itself, with an expanding footprint in the Country and overseas. The Group's futuristic vision has ensured that it continues to be in a position of strength at every touch point of the healthcare delivery chain.

➤ **VISION**

For the next phase of development is to ‘Touch a Billion Lives.’

➤ **MISSION**

Our mission is to bring healthcare of International standards within the reach of every individual. We are committed to the achievement and maintenance of excellence in education, research and healthcare for the benefit of humanity.

Apollo also pioneered the sensibility of Tender Loving Care (TLC) which continues to inspire hope, warmth and a sense of ease in patients and their families.

- Apollo Health and Lifestyle Limited (AHLL) is an Apollo Group initiative to take healthcare services from the hospitals settings closer to home within neighborhood locations in order to serve the community better.
- **Apollo Clinic** was introduced with the vision of servicing local communities and making world-class healthcare for day-to-day needs accessible with a presence in neighborhoods.
- **Apollo Sugar** provides end-to-end care and management of Diabetes and related complications.
- **Apollo Cradle** was the first to introduce the concept of an exclusive, standalone healthcare center for women and pediatric care.
- **Apollo Spectra** provides world-class surgical care that is accessible and at an affordable cost.
- **Apollo Diagnostics** provides a full spectrum of high precision diagnostic services based on which Apollo's healthcare practitioners design and deliver the most appropriate treatment plan to reduce patient's mortality and morbidity levels

APOLLO DIAGNOSTICS

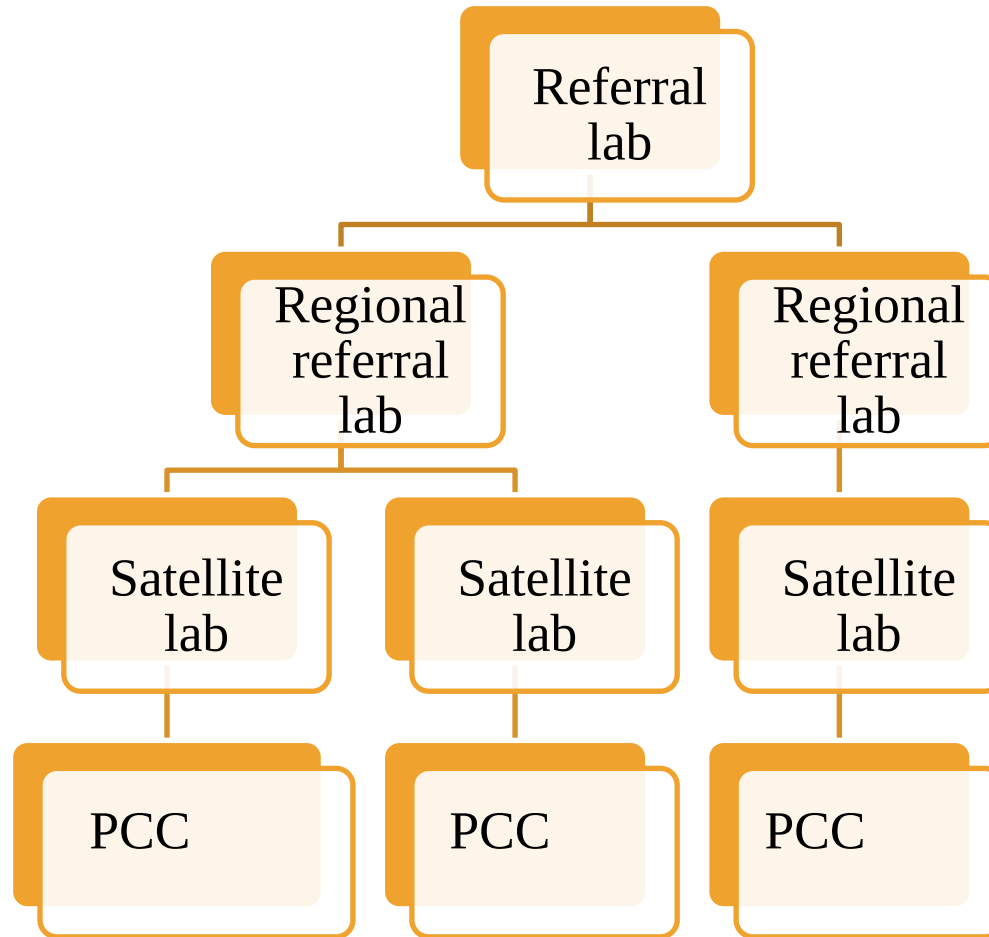
- Apollo Diagnostics, a service fully dedicated to providing diagnostics for all age groups.
- The diagnostic services provide Apollo's healthcare practitioners with information about the presence, severity and cause of diseases in patients.
- A team of expert pathology technologist and state-of-the-art diagnostic equipment, guided by Apollo's 30-year legacy of excellence, ensure the quality and accuracy of test results.
- With years of experience, Apollo diagnostics has been providing domestic and international patients with superior- quality and patient-focused medical care.
- Quality healthcare will always be among their top concerns.

APOLLO DIAGNOSTICS

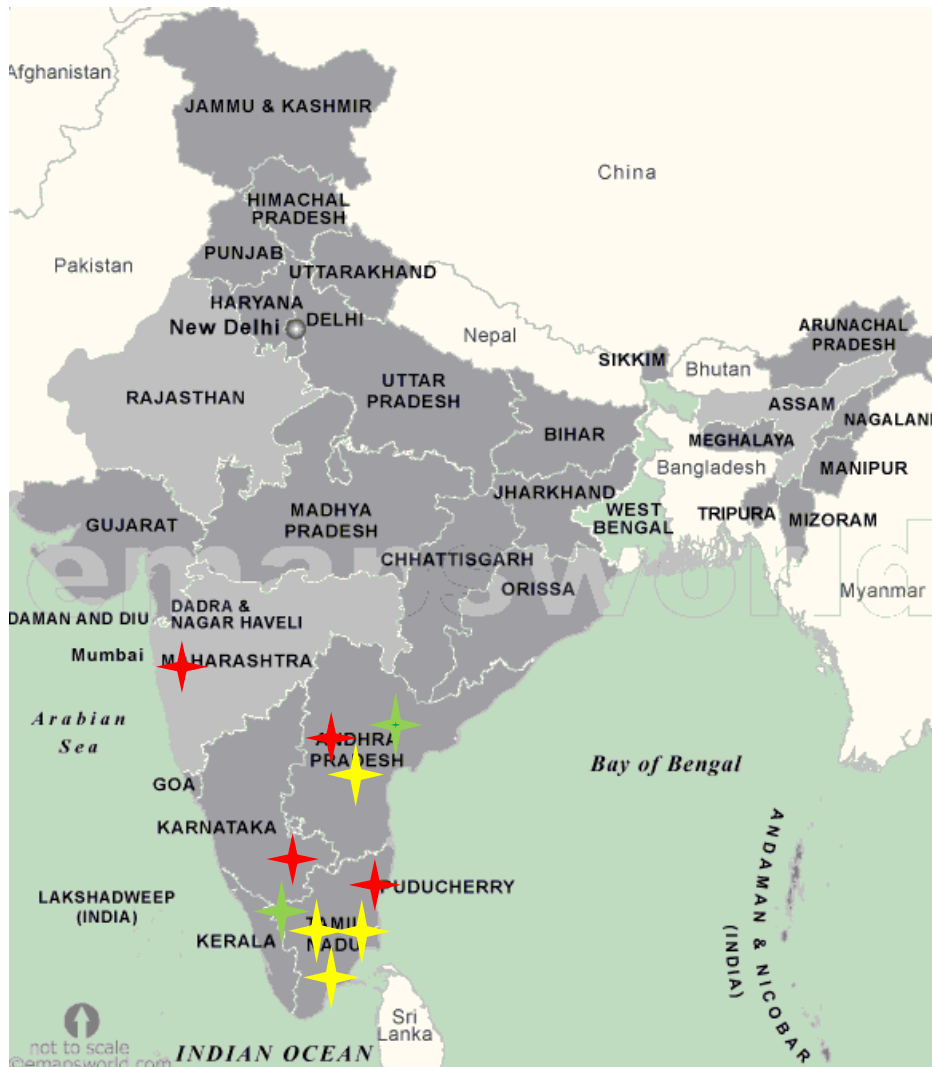
✕ Services Provided

1. Biochemistry
2. Clinical pathology
3. Cytopathology
4. Hematology
5. Histopathology
6. Immunology
7. Microbiology
8. Molecular genetics
9. Molecular diagnostics
10. Serology

LABS HIERARCHY



REGIONAL LAB AND SATELLITE LAB



- ★ GGH Lab
- ★ Deepam Lab
- ★ Deva Lab
- ★ Shankara Lab
- ★ Mysore Lab
- ★ Vijayawada Lab
- ★ Vimannagar lab
- ★ Kondapur lab
- ★ Koramangala lab
- ★ Thagyarajavnagar lab
- ★ HLM Lab
- ★ Regional lab
- ★ Satellite Lab

INTRODUCTION

Satellite Laboratory:

- Satellite laboratories, or limited service laboratories, are located permanently away from the central laboratory
- The objective of creating a satellite laboratory is to reach over the maximum population and provide the quality diagnostic services at tier II cities.

PURPOSE OF THE STUDY

➤ Aim

To study the existing process and find out the gaps based on the prepared standard manual in a satellite laboratory at Apollo Diagnostics, Hyderabad.

➤ Objectives

1. To set a standard manual of all requirements in a satellite laboratory.
2. To study and compare the existing process with the standard manual in a satellite laboratory and recommend process improvement.

RESEARCH METHODOLOGY

- **Study Setting** – Satellite Labs of Apollo diagnostics, Hyderabad
- **Study Type** – Descriptive cross sectional study
- **Study Duration-** 15- February-2016 to 30- April- 2016
- Methodology** – There were two sets of data generated during the course of the study:
 - First set of data was based on the standards established in NABL guidelines and ISO 15189 2012 for medical laboratories.

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- Second set of the data was based on the review of existing laboratory documents and telephonic as well as face to face interviewing of the employees.
- The motive of the study was to analyze the gaps and recommend process improvement that fills the gap, for a laboratory to consistently deliver satisfactory results

✕ LAB MANUAL

- ✕ Can be divided into two phases:
- ✕ Phase 1 (infrastructure and staff hiring)
- ✕ Phase 2 (technical process)

✕ Phase 1

✕ Infrastructure requirement:

✕

1 .Space (600sft)

- ✕ Waiting area
- ✕ Reception area
- ✕ Sample collection area
- ✕ Sample processing area
- ✕ Chief of lab area

2. Privacy and Confidentiality®

✖ Almirha 1

✖ Lockers 1

3. Power (electricity for essentials)

✖ Consumed electricity load

✖ Power generator (small) 10 KVA capacity 1

✖ UPS capacity – (15 KVA capacity) 1

4. **Water supply** (water, sanitation and hygiene for infection control 1k)

- ✗ Safe drinking water

5. **Environment maintaince** (for maintaining temperature and humidity)

- ✗ AC's 3 (two ton)
- ✗ Temperature monitor (room temp) 1
- ✗ Refrigerator temp monitor

6. **IT requirements**

- ✗ Phone (1 set)
- ✗ Internet (1 Broadband and 1 ILL system used with capacity of 2MBPs)
- ✗ Interface
- ✗ LIS (2 computers, 1 barcode printer, 1 barcode scanner, 2 thin client, 1printer with scanner)

7. Legal requirements

- ✗ Shop and establishment
- ✗ Pollution control
- ✗ Trade license
- ✗ Biomedical waste agreement
- ✗ DM and HO registration
- ✗ Police clearance

11. Bio medical waste management and agreements

12. Toilets (1)

- ✗ Staff

- ✗ Patients

13. Fire safety

- ✗ Fire extinguisher 2

14. Security /2 CCTV

15. Technical representative visit

Phase-2

✖ Technical requirement

1. Manpower

- ✖ Appointment of pathologist
- ✖ Recruitment of technician by pathologist
- ✖ Job specific training, education and assessments: pathologist
- ✖ Medical Examination of Staff
- ✖ Vaccination of Staff
- ✖ Planning of different training programmes

2. Visit by regional technical representative for training

3. Laboratory equipments

- ✗ Ortho clinical diagnostic(vitros 250)BIOCHEM
- ✗ Horiba -60(sysmax 3 parts)HAEMO
- ✗ Centaur CP(semen's diagnostic)IMMUNO
- ✗ Incubator 1
- ✗ Microscopes(high resolution) 2
- ✗ Differential counter 2

✕ Centrifuge	1
✕ Vidal shaker	1
✕ Thermometer	2
✕ Stopwatch	2
✕ Refrigerators	3
✕ Water bath	1
✕ Pipettes(variable)	3

4. Reagents (listed ones)*

5. IQ, OQ& PQ verification

6. Validation of the equipment

7. Quality

Handing over quality documents from HO

QSP and SOP's

- ✕ SOP for on and off procedure of all instruments and their maintaince daily/weekly/monthly.
- ✕ SOP for recording temperature and relative humidity.
- ✕ SOP for micropipettes operations.
- ✕ SOP for patient preparation.
- ✕ SOP for patient handling.
- ✕ SOP for sample collection.

- ✘ SOP for spillage of sample.
 - ✘ SOP for sample rejection
 - ✘ SOP for sample transportation and packaging.
 - ✘ SOP for post exposure prophylaxis.
 - ✘ SOP for sample tracking.
 - ✘ SOP for sample archiving.
 - ✘ SOP for hand washing technique.
 - ✘ SOP for barcode breakdown.
 - ✘ SOP for authentication release of report.
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- ✗ SOP for report delay.
 - ✗ SOP for attach and transcribe report.
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- ✗ SOP for urgent sample.
 - ✗ SOP for Risk Assessment.
 - ✗ SOP for Bio Medical and waste management.
 - ✗ SOP for fire safety.
 - ✗ Logs (unity software, QC rejection and corrective action form, QC rejection logs)
 - ✗ QC reconstitution procedure and aliquot preparation
 - ✗ Special request forms

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- ✗ Informed consent and Counseling forms
 - ✗ Internal audit
 - ✗ Quality indicators(assessed monthly)
 - ✗ EQAS (reviewed monthly)
 - ✗ Quality manuals DOS
 - ✗ Sample collection manuals
 - ✗ Safety manuals
 - ✗ **Verbal Test Authorization**

✘ **Test Order Read Back**

8. Reference Laboratory Selection

9. Reporting Outside Results

10. Reference Laboratory Report Retention

11. Reference Laboratory Results Reporting

12. Quality control program & software requirements (runs different program for every department)

✘ 25 samples: 1 control level

✘ >25 samples: 2 control levels

13. Review of Quality control (daily bases)

14. Labeling of reagents and equipments

15. Inventory Management

Standards for records and reports

- ✗ Report format
- ✗ **Standard reference ranges**
- ✗ **Standard Interpretations written in the reports**
- ✗ Result modification log and errors in test results
- ✗ Archiving reports
- ✗ Report Retention and Retrieval
- ✗ Revised Report or Multiple revisions

17. Standards for personnel safety (safety manuals)

- ✗ Safety equipment and material safety data sheets
- ✗ Safety training
- ✗ Safety incident reporting
- ✗ Fire drill training

18. IT requirements

- ✗ Installation of computers
- ✗ Certificate for insta software
- ✗ Mail id creation for lab and staff

- ✗ Tagging of authorized doctor signature to the report
- ✗ Interface verification for all the reports by the pathologist
- ✗ Indenting system for login id credentials or rights
- ✗ IT dummy checks(report format)
- ✗ Reference range
- ✗

19. Fire Prevention Policies

20. Chemical Hygiene Plan

21. Safety eye wares and Emergency Eyewash

22. Suggestion box

23. Continual Improvement

DATA COLLECTED ON THE BASIS OF STANDARD MANUAL

LABORATORY(S L)

Standard Requirements	Warangal	Rajamandry	Hubli	Mysore	Mangalore	Vizag
Space	1000sqf	790sqf	500sqf	650sqf	570sqf	570sqf
Privacy&Confidentiality	No	No	No	No	No	No
Power						
UPS	1 (10 kva)	1 (10 kva)	1 (10 kva)	1 (10 kva)	1 (15 kva)	1 (15 kva)
Generator	1(10 kva)	1(10 kva)	1(10 kva)	1(10 kva)	1(10 kva)	1(10 kva)
Safe Water supply	Yes	Yes	Yes	Yes	Yes	Yes
Environment maintaince AC's	4	2	3	3	3	3
Temperature monitor (room temp)	No	No	No	No	No	No

Refrigerator temp monitor	No	No	No	No	No	No
Legal Requirements						
Shop and establishment	No	No	No	No	Applied	Applied
Pollution Control	No	applied	Yes	No	Yes	Yes
Trade license	Applied	Applied	No	Yes	Applied	Applied
Biomedical waste agreement	YES	YES	Yes	Yes	Yes	Yes
DM and HO registration	No	applied	Applied	Yes	Applied	Yes
Housekeeping	1 part time	1 part time	1 part time	1 part time	Two	1 part time
Equipment installation (IQ,OP,PQ)	YES	YES	Yes	Yes	Yes	Yes
Fire safety(Extinguisher)	No	No	No	No	No	No

Bio medical waste management and agreements	Yes	Yes	Yes	Yes	Yes	Yes
Security /2 CCTV	No	No	No	Yes	No	No
Manpower	Five	five	Five	Six	Four	Four
Job specific training, education and assessments	Yes	yes	Yes	Yes	Yes	Yes
Medical Examination of Staff	No	No	No	No	No	No
Vaccination of Staff	No	No	No	No	No	No
Visit by regional technical representative for training	No	No	No	No	No	No

Ortho clinical diagnostic(vitros 250)BIOCHEM	One	One	One	One	One	One
Horiba - 60(sysmax 3 parts)HAEMO	One	One	One	One	One	One
Centaur CP(semen's diagnostic)IMM UNO	One	One	One	One	One	One
Incubator	One	One	One	One	One	One
Microscopes(high resolution)	Two	Two	Two	Two	Two	Two
Differential counter	One	One	One	One	One	One
Centrifuge	One	One	One	One	One	One
Thermometer	No	No	No	One	No	No
Stopwatch	One	One	One	One	One	Two

Refrigerator	Two	No	three	Two	Two	Two
Water bath	One	No	one	One	One	One
Pipettes	Three	three	three	Three	Three	Three
Reagents lists	Yes	yes	Yes	Yes	Yes	Yes
IQ, OQ& PQ verification	Yes	Yes	Yes	Yes	Yes	Yes
<u>Handing over quality documents from HO</u>						
QSP and SOP	No	No	yes	Yes	No	Yes
QC reconstitution procedure and aliquot preparation	No	yes	Yes	No	Yes	Yes
Logs (unity software, QC rejection and corrective	Yes	No	yes	Yes	No	No

SOP for Report Rejection(Haemolyzed sample)	No	No	No	No	No	No
Work instructions form	No	No	Dnt Know	yes	No	Yes
Special request forms	No	yes	yes	Yes	Yes	Yes
Counseling forms	No	No	no	No	No	Yes
Quality indicators(assessed monthly)		yes	-	Yes	Yes	-
EQAS	Yes	-	no	Yes	Yes	Yes
Quality manuals DOS	No	yes	yes	Yes	Yes	Yes
Sample collection manuals	Yes	yes	no	Yes	Yes	-
Safety manuals	No	No	no	Dnt Know		Yes
Verbal Test Authorization	-	--	Yes	-	-	Yes

Test Order Read Back	Yes	-Dnt Know	Yes	Dnt Know	Dnt Know	Yes
Reporting Outside Results	Yes	Dnt Know	Dnt Know	Dnt Know	Yes	Dnt Know
Reference Laboratory Report Retention	Yes	Dnt Know	Dnt Know	Dnt Know	Yes	Dnt Know
Reference Laboratory Results Reporting	No	No	No	No	No	No
Quality control program & software requirements	Yes	yes	yes	yes	Yes	Yes
Review of Quality control	Yes	yes	yes	Dnt Know	Yes	Yes
Labeling of reagents and equipments	Yes	Yes	Yes	Yes	Yes	Yes
Inventory control	Yes	Yes	Yes	Yes	Yes	Yes
Standards for records and reports						

Report format							
Result modification log and errors in test results		No	No	No	No	No	No
Revised Report or Multiple revised		No	No	No	No	No	No
Standards for personnel safety (safety manuals)*		No	No	Yes	Not Aware	Yes	Yes
☐ Safety equipment and material safety data sheets		Yes	No	No	yes	Yes	Yes
☐ Safety training		Yes	Not Aware	Not Aware	Not Aware	Not Aware	Not Aware
☐ Safety incident reporting		Yes	Not Aware	Not Aware	Not Aware	Not Aware	Not Aware
☐ Fire drill training		No	No	No	No	No	No

Reference range updated	No	No	No	No	No	No
Safety eye wares and *Emergency Eyewash	-	No	No	No	No	No
Fire Prevention Policies	-	No	No	No	No	No
Chemical Hygiene Plan	-	No	No	No	No	No
Fist Aid Box	No	No	No	No	No	Yes
Interface Problem	Yes	No	No	Yes	Network problem	Sometimes
	Network				Manpower	
	Problem					

RECOMMENDATIONS

- For environment maintenance temperature monitor and refrigerator temperature monitors should be there.
- CCTV/Security guard should be there in the satellite labs.
- Fire Extinguishers are important requirements for satellite labs.
- Manual thermometers and first aid box are required in any satellite labs.
- Medical examination of the staff is important part of hiring process.
- Vaccination of laboratory staff.
- Basic Life support training for lab staff should be there.

- Fire drill training is mandatory for all lab staff.
- Provision for revised reports or error modification should be there.
- Safety training should be there.
- Fire prevention policies should be implemented.
- All legal documents should be there in lab at the time of auditing.
- Training of staff is mandatory.
- Sample rejection form and SOP to be present in labs

*Thank
you*

