

DIAGNOSTIC CENTRE

1 INTRODUCTION

Laboratory diagnostic service is required for providing effective diagnosis of the disease suffered by the patient, measure the quantum of medicines to be provided, quantify the extent of cure effected, identify the medical sensitivities of the patient to avoid wrong/under/over medication resulting in adverse effects and to extend the research and development capabilities of the medical process.

District hospitals providing secondary medical care are supposed to have a certain bandwidth of lab tests as per the availability of specialties and the type of medical care to be provided as per IPHS norms, but most hospitals in India are not equipped to this extent.

This shortage of essential medium to high-end diagnostic service severely handicaps the effectiveness of service delivery at the hospital and results in unwanted referrals resulting in overloading of patients in higher delivery centre.

The objective of this project is to establish district diagnostic centers at district hospitals on PPP mode



2 PRODUCTS AND ITS APPLICATION

This is a service sector project.

Medical diagnosis has evolved from visual and aural observation, tasting of body fluids, primitive testing with basic chemicals and heat to advanced atomic level measurements at present. Medical diagnosis presents a truer picture of the nature of disease, status of penetration of the disease, degree of cure and the health of the cellular components of the body.

Medical treatment procedures have become highly dependent on diagnostic service to provide measured and accurate inputs. Keeping in view the requirement of evidence based medicine in this era of consumer protection act; it is not surprising that more than 80% of the medical treatment is dependent on proper diagnostic inputs.

The branches of Laboratory diagnosis is conventionally divided into two, anatomical pathology and clinical pathology. Anatomical pathology includes histopathology, cystopathology, electro microscopy etc and Clinical pathology includes, microbiology, bio chemistry, hematology, genetics, reproductive biology etc, each of these sub sections have further specialized fields of study which offer an in depth view of the disease and the body. While the advantages medical diagnosis is well documented and proved in medical treatment efficacy, it is also equally costly to provide for high-end diagnostics.

Diagnostic centers originally associated as a part of hospitals have branched out as a separate business, so as to economize the service and provide a wide spectrum of service. A laboratory diagnostic service has to be mandatorily approved by a qualified pathologist in India

District Hospitals are secondary level health care providers in India with basic specialties, though IPHS has laid down norms with respect to the number of specialties, types of treatments, and requirement for diagnostic services, most states in India are not able to adhere to the same for want of one or more factors. It is observed in most public

hospital laboratories that the diagnostic centres are not adequately equipped with equipment, technology and manpower.

Factors that influence the inadequate availability of diagnostic services are,

1. Non availability of modern automatic and semi automatic equipments which increase efficiency of the output
2. High capital cost of high-end equipments required for advanced tests
3. Shortage of skilled manpower for operating the diagnostic centre
4. Insufficient supply chain and logistics of consumables and other chemicals required for the service
5. Inadequate resources to meet the diagnostic load of the hospital
6. Lack of standard operating procedures for sample collection, management, and testing, reporting, patient management and infection control
7. Inadequate bio medical waste management practices

These lacunae in the system adversely effects the efficiency and operation of the hospital by,

1. Delaying the treatment procedure
2. Restricting the treatment capacity of the medical practitioners
3. Absence of proper diagnostics may lead to judgmental errors on the condition of the patients
4. Everyone is immune or counter reactive to certain drugs and chemicals, lack of diagnostic service may adversely affect the treatment out comes
5. Inhibits the continuity of medical treatment
6. De-motivates the medical practitioners as they are not able to extend to their fullest capacity

3 DESIRED QUALIFICATIONS FOR PROMOTER

The promoter should be having formal qualifications in the field of Science (preferably with relevant specialization such as Microbiology / Pharmacology, etc.) or pharmacy (B.Pharm. or M. Pharm). Further he / she should have experience of working in a Diagnostic laboratory

4 INDUSTRY OUTLOOK / TREND

In India, majority (70-80 per cent) of medical treatments are based on laboratory diagnostic tests, thus making it one of the most promising sectors in the healthcare industry. In India, the medical diagnostics industry accounts for almost 10 per cent of the healthcare sector's revenues.

With the growth in income and health insurance coverage, there is an increasing demand for better healthcare services among the growing population of the country. The sector's growth will be driven by the country's growing middle-class, which can afford quality healthcare.

Healthcare diagnostics is growing at the rate of 15-20 per cent per annum. The major driver is the growing population burden and the dual burden of chronic lifestyle diseases along with the earlier communicable diseases and the dependency on diagnostics for all treatments. Medical tourism too has grown and today, patients from neighboring countries in Asia are coming to India to receive specialized medical treatment. This has helped in further surge in demand for high end diagnostics meeting international standards.

5 MARKET POTENTIAL AND MARKETING ISSUES, IF ANY

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In addition to this, the vast difference in costs between Western countries and India, the country is being seen as the preferred destination for quality health solutions. This has been reflected by increasing medical tourism.

The Indian diagnostic market is broadly divided into equipment and services. The service sector is found to be largely unorganized, with a large presence of players located at the regional or city level. However, a clear and structured format is being established to have better regulations and proper definition for the market.

The use of advanced and cutting-edge technologies in understanding a disease prognosis has further strengthened the sophistication level of participants in the sector.

The need for high-end diagnostic service is dependent on availability of medical treatment facilities that support such service. Region / districts having sufficient hospitals offer good scope. Existing laboratories, most of the times lack the technology, automation, and scale required to provide high-end diagnostic service. The number of patients who would require diagnostic service at the district hospital level is the key parameter for market prospects.

6 RAW MATERIAL REQUIREMENTS

The project would require a range of reagents, chemicals and other products. These are illustrated below.

CARDIOLOGY AND LIPIDS

1. Adiponectin
2. Lipoprotein (a)
3. H-FABP.
4. sLDL
5. TxBCardio™HDL3.
6. Homocysteine
7. Apolipoprotein
8. C-IIApolipoprotein
9. C-IIIApolipoprotein E

DIABETES

1. Cystatin C
2. Enzymatic Creatinine.
3. Micro albumin

CLINICAL CHEMISTRY

1. Aldolase
2. Vanadate Oxidation Bilirubin
3. 5th Generation Bile Acids
4. G-6-PDH
5. Immunoglobuline E
6. Copper
7. Zinc...

ANTIOXIDANTS

1. Total Antioxidant Status (TAS)
2. Glutathione Peroxidase (Ransel)
3. Glutathione Reductase
4. Superoxide Dismutase (Ransod)

The project would also require packaging materials and consumables. These include empty hard gelatin capsules, boxes, bottles, caps, etc.

Most of the above are easily available in India.

7 MANUFACTURING PROCESS

It has to be noted that there are Guidelines for **Good Clinical Laboratory Practices (GCLP)** in India. Regulatory authorities at the Central level and the State level monitor the same.

At the Central level, the **Central Drugs Standard Control Organisation (CDSCO)**, Ministry of Health & Family Welfare, Government of India is the apex organisation. At the state level the **Food and Drugs Control Authority (FDCA)** is the regulatory authority.

Indian Council of Medical Research (IMRC) is the nodal organisation in this regards.

Medical diagnosis is the process of determining which disease or condition explains a person's symptoms and signs. It is most often referred to as **diagnosis** with the medical context being implicit. The information required for diagnosis is typically collected from a history and physical examination of the person seeking medical care. Often, one or more **diagnostic procedures**, such as diagnostic tests, are also done during the process. Sometimes Posthumous diagnosis is considered a kind of medical diagnosis.

Diagnosis is often challenging, because many signs and symptoms are nonspecific. For example, redness of the skin (erythema), by itself, is a sign of many disorders and thus doesn't tell the healthcare professional what is wrong. Thus differential diagnosis, in which several possible explanations are compared and contrasted, must be performed. This involves the correlation of various pieces of information followed by the recognition and differentiation of patterns. Occasionally the process is made easy by a sign or symptom (or a group of several) that is pathognomonic

When someone provides blood, urine, or other body substances, these samples are sent to the medical laboratory, where the technical and professional staff process the sample, test it and report the results to your physician.

An indicative step wise process could be as follows

➤ **Collection**

It all starts with the collection of a proper blood or other specimen. A doctor, nurse, technician, or phlebotomist will draw your blood. Several tubes of blood may need to be drawn for different types of tests.

Depending on what illness you might have, your doctor may want to obtain a urine sample, throat swab, or other sample. Follow the instructions carefully; the right sample leads to the right answers.

After the sample is collected, the container is labeled with your name and other information. If you are bringing a sample to the lab, make sure it has your name and number on it so that we do the proper tests and report them on the right patient.

➤ **Processing**

When the sample gets to the laboratory, it is logged into the hospital computer. In some cases, the liquid portion of blood is separated from the cells to prepare it for testing. It's then given to the laboratory staff that will perform the testing.

➤ **Testing**

- **Chemistry**

In the Chemistry section of the lab, blood and other body fluids are tested for chemicals, drugs and substances that indicate disease. Examples of Chemistry tests include cholesterol and other tests for risk of heart disease, glucose to

monitor diabetes, cyclosporine to help physicians give the correct dose of this powerful drug, and thyroxin to monitor the thyroid gland.

- **Hematology**

The Hematology section of the lab analyzes the amount and function of blood cells and plasma. Examples of Hematology tests include the Complete Blood Count (CBC) that tells the doctor how many cells of each type are in your blood and the prothrombin time (PT), to monitor patients on the drug Coumadin.

- **Microbiology**

The Microbiology section of the lab tests patients for infections caused by bacteria, fungi or parasites. Many types of specimens -- including blood, urine, sputum, stool and others are tested. An example of a Microbiology test is a urine culture for urinary tract infections.

- **Virology**

The Virology laboratory tests for viral infections. Depending on the virus suspected, the laboratory might look for the virus directly, or test your blood to see if your immune system has reacted to a virus. Examples of Virology tests include rapid tests for respiratory viruses such as influenza, molecular tests for noroviruses, and antibody tests for HIV.

- **Immunology/Molecular Diagnostics**

The Immunology/Molecular Diagnostics laboratory performs a wide variety of complex tests. Some tests are used by your doctor to determine whether your immune system is functioning properly. State-of-the-art analysis of DNA and RNA is used to test for a variety of diseases. and for the risk of developing certain diseases. Other specialized tests include the ANA, used to screen for autoimmune disease, and Factor V Leiden genotyping for patients with blood clots.

- **Blood Bank (Transfusion Services)**

The Blood Bank is a unique laboratory which not only tests patients' blood types but also provides blood products to patients who need them. It does additional tests to assure the safety of transfused blood.

Reporting

After the tests are done, results are reviewed and entered into the hospital computer system. For results that indicate the patient may be very ill, the laboratory calls the doctor with the results.

Depending on how long it takes to carry out a particular test, the length of time between the drawing of the blood and when your provider gets the results can vary greatly, from as little as a few minutes to as much as several weeks. Most laboratory testing is done here, but some specialized testing is sent to other labs which are expert in particular tests.

Using the Results

Once the information is reported, your provider will interpret them based his or her knowledge of you. The test results may help to rule out or diagnose disease, or to do the best possible job of managing a known disease. You should ask your provider to explain your lab results to you, so you can participate in maintaining your health.

8 MANPOWER REQUIREMENTS

Sr. No.	Designation	Number	Approx. Annual Total Salary
1	Laboratory Analysts	3	45000
2	Supervisor	1	20000
3	Manager	1	20000
4	Office staff & marketing executive	5	50000
5	Lab assistants	5	35000
6	Unskilled workers	7	28000

9 IMPLEMENTATION SCHEDULE

Sr. No	Activity	Time
1	Preparation of Project report	One month
2	E M Registration & approval from FDCA	One month
3	Financial/Loan from Banker or Financial Institutions	Two months
4	Power connection/Building construction Six months	One month
5	Machinery procurement & Trial run.	Two months

6	Recruitment of Staff & Labour	One month
7	Actual commercial production	One month

10 COST OF PROJECT

The total cost of project is estimated as below:

Sr. No	Component	Particulars	Rs. In lakhs
1	Land	1500 sq. mts.	7.00
2	Building	800 sq. mts.	30.00
3	Plant & Machinery including QC		45.00
4	Other Assets		2.00
5	P & P Expenses		1.00
6	Contingencies		5.00
7	WC Margin		3.00
		Total	93.00

11 MEANS OF FINANCE

- Term Loan : Rs.65. 00 lacs
- Promoter own contribution : Rs.18.00 lacs

12 WORKING CAPITAL CALCULATION

Particulars	Duration	Total Estimated cost (Rs. Lacs)
Raw materials/ Packing materials	1 month	6.00
Working expenses	1 month	3.00
Finished goods	15 days	2.00
Receivable	30 days	4.00
	Total	15.00

13 LIST OF MACHINERY REQUIRED AND THEIR MANUFACTURERS

All machinery to be of GMP standards

Sr. no.	Machine	Number	Approx. Cost
1	Mechanical sifter, 30" diameter	1	1,00,000
2	Powder and mass mixer	1	3,00,000
3	Multi mill	1	90,000
4	Granulator	1	60,000
5	Double cone blender	2	5,00,000
6	Tray drier with 48 trays	2	3,60,000
7	Peristaltic pumps	1	50,000
8	Rotary tablet machine	2	24,00,000
9	Semi automatic Capsule filling & Sealing Machine	1	75,000
10	Automatic capsule loader machine	1	1,30,000
11	De dusting unit	1	55,000
12	Coating machine with SS coating pan 30 " diameter (Optional)	1	2,90,000
13	Strip packing machine	2	4,00,000
14	Quality Assurance & Quality Control equipments	-	3.00 lakhs
15	SS Storage Tanks		2,50,000
	Total		45.00 Lakhs

Indicative sources:

- Remi Electrotechnik Ltd, Thane, Mumbai
- Swastik Scientific company, Gopal niwas, Mumbai
- Ambica Machineries, Vatva, Ahmedabad
- ARV Engineering, Thane

14 PROFITABILITY CALCULATIONS

The main basis for income is the charges for various services (tests / research work, etc.) from patients / clients. Further assumption also has to be taken regarding the estimated number of patients per day. In view of diversity of patients and services offered, an average and approximate revenue per patient is assumed.

Income to the Centre per patient		175	175	193	193	212
OPERATING REVENUE	Project Year					
	0	1	2	3	4	5
Per day patients in Lab from OPD	334	339	344	349	354	360
Per day patients in Lab from IPD	120	130	140	140	150	150
Per day patient volume in Lab	454	469	484	489	504	510
TOTAL OPERATING REVENUE (in crores)		2.543	2.625	2.918	3.009	3.345
OPERATING EXPENDITURE						
Manpower		0.71	0.74	0.78	0.82	0.86
Supplies & Consumables		0.89	0.92	1.02	1.05	1.17
Logistics		0.5	0.53	0.55	0.58	0.61
Insurance Cost		0.15	0.12	0.1	0.08	0.06
NABL cost (third year onwards)				0.01	0.003	0.003
TOTAL OPERATING EXPENDITURE (in crores)		2.25	2.31	2.46	2.53	2.7
NET (SURPLUS / -DEFICIT)		-1.2	0.32	0.46	0.48	0.64

Key Assumptions and The basis of profitability calculation:

As mentioned above, The Unit is a service unit offering a wide and long range of **Diagnostic services**. Accordingly the capacity has been considered in terms of patients per day. The capacity build up is taken considering the sales related from OEM/ Retail network that is built up by the entrepreneur based on his prior experience in the industry.

This project has to have diverse grange of services. The sales prices of these products vary. Accordingly a range of service charge has been assumed. The cost of production,

inclusive of major cost heads such as raw materials, labour & power has been considered based on prevailing industry standards and assumed @ 70 %.

On indicative basis, power Costs are considered at Rs 7/- per Kwh and fuel cost is considered at Rs. 60/- per litre. The depreciation of plant is taken at 10-12 % and Interest costs are taken at 12 % depending on type of industry. All these are wherever applicable.

It may be kindly noted that basis / assumptions for such kind and size of the projects in a profile can be on indicative basis only. At the same time it does provide a reasonably accurate scenario.

15 BREAKEVEN ANALYSES

$$FC \times 100: 15.00 \times 100 = 1500$$

$$FC + Profit: 15.00 + 18.00 = 33$$

$$BEP = 45.00 \%$$

16 STATUTORY/ GOVERNMENT APPROVALS

Diagnostic centers and laboratories require approval from the Food and Drugs Control Authorities of respective states. Further, it has to be noted that there are Guidelines for Good Clinical Laboratory Practices (GCLP) in India. Regulatory authorities at the Central level and the State level monitor the same.

MSME & GST registration, IEC Code for Export of end products and local authority clearance may be required for Shops and Establishment, for Fire and Safety requirement and registration for ESI, PF and Labour laws may be required if applicable. And promoter has to take approval from Pollution Control Board.

17 BACKWARD AND FORWARD INTEGRATION

As backward integration, Entrepreneur may think of going for the production of diagnostic reagents and reactants.

18 TRAINING CENTERS/COURSES

Training and short term courses may be availed from the Institutions such as NIPER , B V Patel PERD Centre and Pharmacy collages.

Udyamimitra portal (link : www.udyamimitra.in) can also be accessed for handholding services viz. application filling / project report preparation, EDP, financial Training, Skill Development, mentoring etc.

Entrepreneurship development programs help to run businesses successfully and are available from Institutes like Entrepreneurship Development Institute of India (EDII) and its affiliates all over India.

Disclaimer:

Only few machine manufacturers are mentioned in the profile, although many machine manufacturers are available in the market. The addresses given for machinery manufacturers have been taken from reliable sources, to the best of knowledge and contacts. However, no responsibility is admitted, in case any inadvertent error or incorrectness is noticed therein. Further the same have been given by way of information only and do not carry any recommendation.