

A Study on COBAS 6800 system based COVID 19 Testing in a Tertiary Care Teaching Hospital with Special Emphasis on Work Flow and Break-Even Analysis.

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I. Introduction

COBAS SARS-CoV-2 is a qualitative test for use on the **COBAS 6800** System for the detection of the 2019 novel coronavirus (SARS-CoV-2) RNA in individual or pooled nasal, nasopharyngeal, and oropharyngeal swab samples collected in 0.9% physiological saline. The RNA Internal Control, used to monitor the entire sample preparation and PCR amplification process, is introduced into each specimen during sample processing. In addition, the test utilizes external controls. This test is also intended for the qualitative detection of nucleic acids from SARS-CoV-2 in pooled samples containing up to and including six individual samples from healthcare provider-instructed self-collected nasal swab specimens (collected on site), or healthcare provider-collected nasal, nasopharyngeal, and oropharyngeal swab specimens. Negative results from pooled samples should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, pooled samples should be tested individually. Specimens included in pools with a positive or presumptive positive result must be tested individually prior to reporting a result.

Specimens with low SARS-CoV-2 RNA concentrations may not be detected in sample pools due to the decreased sensitivity of pooled testing. Results are for the detection of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, recent exposures and epidemiological information. **COBAS SARS-CoV-2** is intended for use by qualified clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and on the use of the **COBAS 6800** Systems. **COBAS SARS-CoV-2** is only for use under the Food and Drug Administration's Emergency Use Authorization.

Twentieth Century has witnessed exceptional advances in technology which has brought scientific marvels into hospitals with unprecedented demand on medical services, particularly in areas such as surgery and clinical laboratory. While the physicians have in recent years acknowledged the desirability of providing more cost-effective medical care, this theoretical goal is infrequently attained in practice due to absence of adequate financial data in respect of alternative diagnostic and therapeutic strategies. In an era of limited resources and unlimited demand for health care, health economists tend to weigh benefit against cost when making informed choices. Those responsible for allocating resources will need to prioritize between competing claims so that maximum benefit can be obtained from a given budget. The diagnostic market is the fastest growing segment in India, with forecasted to grow to US \$17 billion by 2021 according to Price water house Coopers (PwC). The most important and effective managerial tool is Break even analysis (BEA), also called as cost- Volume Profit Analysis (CVPA). It is an important analytical technique used to study relations among expenses, revenue and profits. When considering the purchase of new diagnostic equipment, the HCM behave to estimate the BEA or Break-Even Point (BEP), by this the HCM can determine approximately how long, based on the current number of services in HCO, it will take to recoup the expenses of a given expenditure. The estimation of BEP is also useful in assessing the established diagnostic facility in HCO.

AIM

To study the COBAS 6800 unit at Nizam's Institute of Medical Sciences with special emphasis on work flow and break-even analysis.

II. Methodology:

The study was a biphasic study consisting of retrospective study and prospective study. The retrospective study was a record study done period of 1 months whereas the prospective study was record study, observational study, interviewing method and reviewing of material having a bearing on the study done for a period of 1 month. Both studies consist of record study from the following sources.

1. Academic section, human resources department and claims department in assessing the expenditure incurred in terms of salaries paid to staff working in COBAS unit.
2. Planning section, Finance department in calculating the expenditure on equipment in COBAS unit. Civil Engineering department, Electrical Engineering department, Biomedical Engineering department, NIMS laundry, NIMS laboratory stores, nursing stores for assessing the maintenance costs/overheads.
3. Literature review of procedures and protocols of Microbiology lab was reviewed. Microbiology department and COBAS unit of Nizam's Institute of Medical Sciences was visited and the requisite data collected.
4. Personal interviews were conducted with staff of these areas. People interviewed were included Doctors, lab Technicians, nurses, & staff. To study the physical facilities and work flow of the COBAS unit, direct observational study was conducted.

III. Results And Discussion

The COBAS 6800 System in Nizam's Institute of Medical Sciences is situated in the 7th floor of the Millennium Block. Total built up area of COBAS unit is 52.5sq.mtr / 565.1sq. feet. COBAS SARS-CoV-2 for use on the COBAS 6800 System is a real-time RT-PCR test intended for the qualitative detection of nucleic acids from SARS-CoV-2 in healthcare provider-instructed self-collected anterior nasal (nasal) swab specimens (collected on site), and healthcare provider-collected nasal, nasopharyngeal, and oropharyngeal swab specimens collected from any individuals, including those suspected of COVID-19 by their healthcare provider, and those without symptoms or other reasons to suspect COVID-19

AIR CONDITIONING:

COBAS unit is provided with a 7.5 TR ductable split air conditioning system and the remaining area of is provided with 35TR of Centralized A/C. Each console room is provided with a 2 TR split A/C. Total load of the COBAS unit is 15 TR+35 TR+ 4 TR=54 TR.

UNINTERRUPTED POWER SUPPLY:

Uninterrupted power supply is provided by the 120KVA UPS located in the UPS room of the COBAS unit.

EQUIPMENT:

COBAS6800 SARS-CoV-2 Assay equipment by Roche Diagnostics, India pvt Ltd. Was installed in NIMS, Hyderabad on 05-09-2020 to carry out COVID 19 tests. COBAS 6800 unit is based on fully automated sample preparation (nucleic acid extraction and purification) followed by PCR amplification and detection. The COBAS unit consist of the sample supply module, the transfer module, the processing module, and the analytic module. Automated data management is performed by the COBAS6800 software, which assigns test results for all tests. Results can be reviewed directly on the system screen, and printed as a report.

STAFFING: COBAS6800 services are provided on 24*7 basis for the convenience of the patients. The details of staff posted at COBAS unit is depicted in the following table:

STAFF OF COBAS unit

Sl No	Designation	No of staff
1	Professor	1
2	Associate professor	1
3	Resident doctors	4
4	Nurse	1

5	Technicians	5
6	Record assistant	4
7	Class IV Employees	3

WORK LOAD:

Total number of tests month wise

Sl No	Month	No. of tests
1	October	8148
2	November	7204
3	December	4218
	Total	19,570

Average tests per day= 217

Sl No	Consumable Name	Price per 20,000 reactions
1	COBAS8800 SARS CoV 2 (RT PCR lit) - 192 reactions	21798370
2	COBAS8800 SARS CoV 2 RMC EUA	1185938
3	COBAS8800 SARS CoV 2 NEG CONTROL	120302
4	COBAS8800 SARS CoV 2 WASH	335758
5	COBAS8800 SARS CoV 2 DILUENT	217520
6	COBAS8800 SARS CoV 2 LYSIS BUFFER	486360
7	COBAS8800 SARS CoV 2 MGP	354363
8	COBAS8800 SARS CoV 2 AMPLIFICATION PLATE	161294
9	COBAS8800 SARS CoV 2 PIPETTE TIPS	476226
10	COBAS8800 SARS CoV 2 PROCESSING PLATES	106353
11	COBAS8800 SARS CoV 2 SECONDARY TUBES	658619
	Total	25901103

TABLE : COST CENTRES ASSOCIATED WITH COBAS unit

Sl No	COST CENTRE	COST CATEGORY	COST TYPE
1	Salaries of staff	Direct cost	Fixed
2	Material	Direct cost	Variable
3	Equipment	Direct cost	Fixed
4	Building	Indirect cost	Fixed
5	Air Conditioning	Indirect cost	Fixed
6	Electricity	Indirect cost	Variable
7	Laundry	Indirect cost	Variable
8	Linen	Indirect cost	Fixed
9	Water	Indirect cost	Variable

Man power cost for 3 months (study period) = 52,18,319/-

MATERIAL COST:

Other Consumables required for processing at COBAS		
S No	Consumable Name	Price per 20,000 reactions
1	100-1000ul Barrier Tips Racked pack of 1000	882800
2	Micro Centrifuge Tubes 1.5ml (3461) pack of 500	87350
3	Tissue Rolls pack of 10 rolls	472
4	Kimberlev Gloves Large-KC 500-L pack of 10	5042
5	Kimberlev Gloves Large-KC 500-M pack of 10	5042
6	Kimberlev Gloves Large-KC 500-S pack of 10	5042
7	Ethanol (500ml)	32000
8	IPA (1 lit)	32000
	Total price of Other Consumables	1049748

EQUIPMENT COST: COBAS6800 SARS-CoV-2 Assay equipment by Roche Diagnostics, India pvt Ltd. Was installed in NIMS, Hyderabad on 05-09-2020. As per the information from the records of planning department COBAS6800 is purchased for a sum of Rs 2,59,01,103/- in the year 2020. The equipment is under

warranty for a period of 3 years. The life of equipment is taken as 10 years as per the advice of the Biomedical engineering department of the NIMS. Hence, the depreciation amount was calculated by using sum of the years digits depreciation method of the equipment value which amounts for Rs 12,95,055/-

BUILDING COST:

Building cost was determined under three heads

- Construction cost
- Maintenance cost and

1. CONSTRUCTION COST: As per the CPWD cost index April 2015 with 01/10/12 (as base 100) issued by the director general (DG) CPWD is 104. The building cost for 1sqm area calculated after incorporating this cost index and after discussion with the civil engineering department was Rs 37,465/- Taking the life of building as 100 years, depreciation is calculated as 1% of the capital cost. For area of 52.5 sqm, construction cost is Rs 19,66,912/-. Depreciation cost is Rs 49,172/- for 3months.

2. MAINTENANCE COST: As per CPWD manual, cost of maintenance persq.mt is Rs 5104/- per year which amounts to Rs **65,331/-**

Total building cost for 3months = construction cost + maintenance cost
8465+65331 = 73796 for 3months

i) INSTALLATION COST OF AC:

Load of COBAS unit in the central A.C plant is 35TR. By this information, installation cost for COBAS unit (i.e., 35 TR load) is Rs 10,50,000.

b) Installation cost of ductable split AC in console rooms is Rs 9,00,000/-

c) Installation cost of Two 2TR split AC in reporting rooms is Rs 80,000/-

TOTAL INSTALLATION COST OF AC IN COBAS unit = a+b+c = Rs.20,30,000/-.

Assuming life of the air conditioning system as 10 years depreciation rate is taken as 10%,

TOTAL INSTALLATION COST OF AC IN COBAS unit = a+b+c = Rs.20,30,000/-.

ii) MAINTENANCE COST OF AC: calculated maintenance cost central AC of COBAS unit is equal to Rs 52,000/- per annum. Two split air conditioners and ductable split air conditioners are under warranty. So, there is no maintenance charges for them.

COST OF ELECTRICITY

With the help of electrical engineer total electricity consumed in a day is calculated and the cost incurred is calculated @ Rs 8.5 per unit of the electricity. Estimated power consumption is equal to 3340.48 KWH per day which is equivalent to amount Rs 28394.08/- at unit price @Rs 8.5/- Estimated Cost incurred per month on electricity of the COBAS unit =Rs 8,51,820 /-

Cost incurred on electricity for three months = 25,55,460/-

7) COST OF LINEN AND BEDSHEETS:

The linen gowns are given on yearly basis, value of 3500/- and bed sheets of quantity 2 at Rs. 280/- per bed sheet. The total cost for the laundry is Rs.4060/-.

8) WATER CHARGES: As per the estimates of the assistant executive engineer of civil department of NIMS the average daily consumption of water in COBAS unit per month is 80KL (kilo litres). The Cost per 1 kl of water is Rs 130/-.

Water charges for three months = Rs 10,400/- * 3 = 31,200/-

9) MISCELLANEOUS ITEM CHARGES: Data about Miscellaneous items like Stationary items, Housekeeping materials etc, was collected from registers of the Microbiology department and general store items. Estimated charges of miscellaneous items is Rs 45,000/- per month on an average. The total miscellaneous charges for 3 months of study period is Rs.1,35,000/-

BREAK EVEN POINT:

BEA = $\frac{\text{Fixed Cost (Equipment Direct+ Labour Direct+ overhead indirect)}}{\text{(Selling price - Variable Cost)}}$

FIXED COST

Sl. No	Cost Center	Fixed Cost
1	Equipment cost	2,59,01,103
2	Manpower cost	52,18,319
3	Equipment maintenance	12,95,055
4	Building cost	19,66,912
5	Building maintenance	1,22,968
6	Air conditioning cost	20,30,000
7	Air conditioning maintenance	63,750
8	Total fixed cost	3,65,98,107

VARIABLE COST:

Sl. No	Cost center	Variable cost
1	Materials	10,49,748
2	Electricity bill	2,55,460
3	Linen and bed sheets	4,060
4	Water consumption	31,200
5	Miscellaneous	1,35,000
6	Total	14,75,468

PRICE PER TEST

The price of each test is Rs 500/-

$$\begin{aligned}
 \text{BEA} &= \frac{3,65,98,107}{500 - 348} \\
 &= \mathbf{2,40,777 \text{ tests}}
 \end{aligned}$$

On an average 217 tests are done per day.

No. of days required to reach the breakeven point = $240777 / 217 = \mathbf{1109}$ days (3years, 14 days)

RECOMMENDATIONS

1. Nizam’s Institute of Medical Sciences should have a costing system which will help in developing the user charge packages as per the expenditure occurred on the service and also helps in forecasting of the budget.
2. Average number of tests done in COBAS unit of NIMS per day is 217 which can be improved by effective patient flow in the Increasing the number of procedures performed per day or week can add to overall income.

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