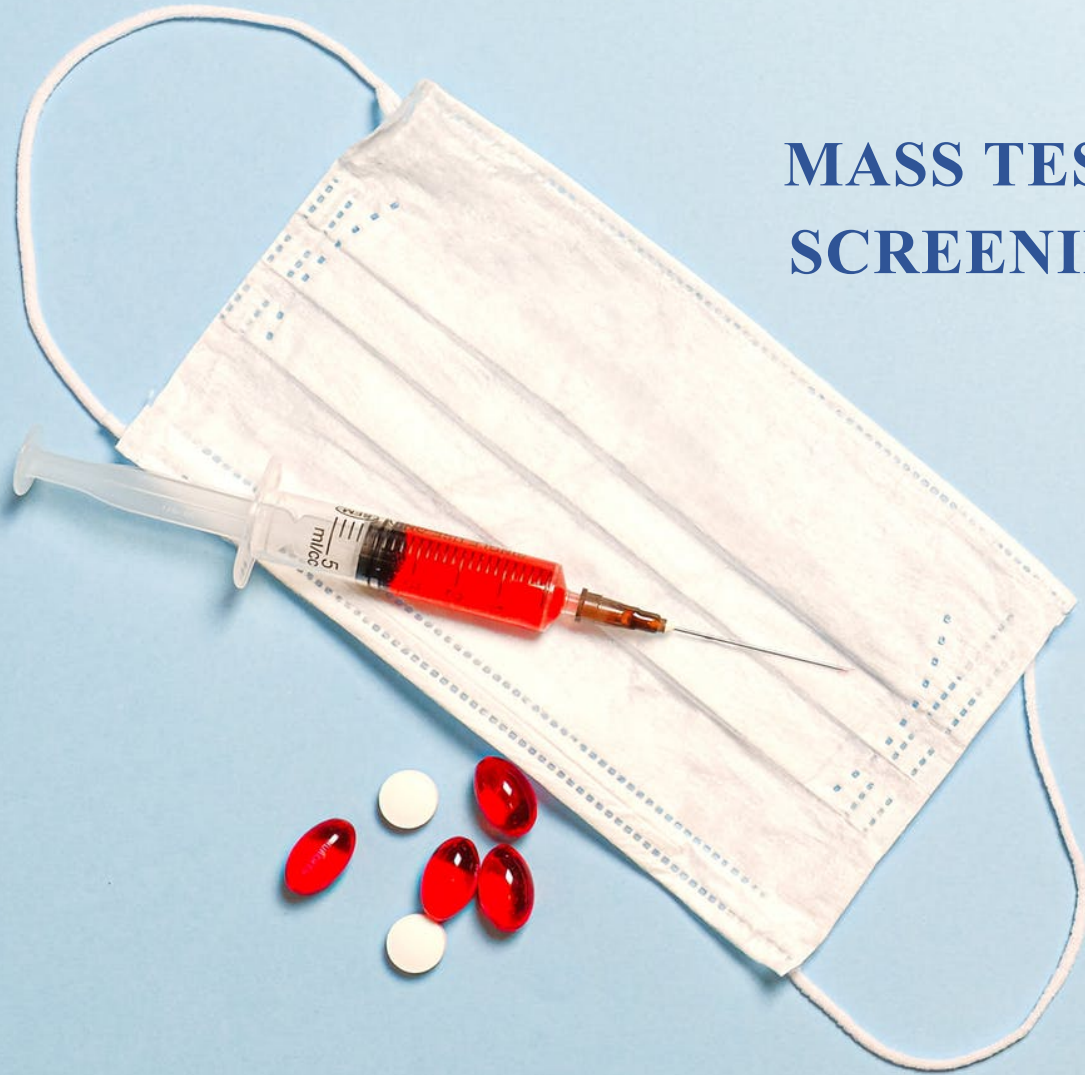


MASS TESTING PREPARATION FOR COVID-19 SCREENING IN INDIA WITH RECOMMENDED SWADESH-PROTOCOL



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EXECUTIVE SUMMARY



- Mass Testing for COVID-19 after lockdown is necessary.
- 3 methods or protocols include RT-PCR (Testing for RNA), POCT Method (Testing for Antibodies), and SWADESH-Protocol (Testing Inflammatory Markers).
- Cost of testing 5% of population, or 68.9 million people, for RT-PCR is estimated at 32,520 Crores, POCT is estimated at 9,110 Crores, while SWADESH-Protocol is estimated at 5,240 Crores.
- RT-PCR capacity and access is limited and hence should be used as a confirmatory test only after preliminary screening for COVID-19.
- POCT is a qualitative test and the manual data entry can cause pre-analytical errors. Thus, proper SOPs for entering patient results must be published. Delays in transporting samples for confirmatory cases can cause delay in treating critical patients.
- SWADESH-Protocol has capacity in urban and rural India and can be effective for screening and early treatment.
- Implementation plan for Mass Testing needs to be developed
- Testing, Tracing, & Treating is very important.
- Patients tested must be traced using a created application that can be easily downloaded on cellphones, and treatment protocols must be published quickly.

TYPES OF TESTS AVAILABLE

TEST	METHOD	APPROVED	AVAILABLE	ACCESSABLE	AFFORDABLE (Approximation)	CAPACITY
Test for RNA	RT-PCR	Yes	Yes, only in major Metros & some Tier 1 Cities	?	MRP ₹4500	Low
Test for Antibodies (IgG or IgM)	POCT	No (Not Yet)	To be Imported	Yes, once procured	MRP ₹1000 - ₹1500	High
	CLIA	No	Kits from leading makers not yet available (like Roche, Abbot, Beckman, Siemens)	Yes	MRP ₹1600 - ₹2000	High
	ELISA	No	Kits not yet available. Machines available.	Yes	MRP ₹1500	Medium
SWADESH-Protocol	Biochemistry Hematology Lab Tests	No	Yes	Yes	MRP ₹600	Very High
	X-Ray	Yes	Yes	Yes	MRP ₹250	Very High

PROS & CONS OF METHODS

	RT-PCR	CLIA	ELISA	POCT	SWADESH-Protocol
PROS	<ul style="list-style-type: none"> Quantitative Method for detecting RNA All countries use it for confirmatory testing MyLabs from Pune has got the approval to produce the test kits, and the Indian Government is now authorising private labs to perform this test. Barcoded – preanalytical and analytical errors are minimal and can be easily managed 	<ul style="list-style-type: none"> Leading manufactures of CLIA machines available in India This has high output capability and can help test millions of samples a day. Risk to healthcare workers in this form of diagnosis is low 	<ul style="list-style-type: none"> Qualitative and Semi-Quantitative India has several government and private labs with this methodology and thus could use this test in major metros, tier1 and tier 2 cities. 	<ul style="list-style-type: none"> Qualitative Test Half a million to million tests a day once scaled up Less price Minimal risk to healthcare worker 	<ul style="list-style-type: none"> Easily Accessible in Urban and Rural Cities Infrastructure already available with trained healthcare workers Minimal risk of infection transmission to healthcare worker Less Price, affordable Turnaround Time can be controlled Half a million to million tests a day
CONS	<ul style="list-style-type: none"> False Positives have been reported The viral load reduces once the antibodies develop after 8-10 days. When viral load reduces, PCR will be negative. Capacity is a Serious Issue RT-PCR is a very expensive machine and requires clean air testing environments Contamination of environment / Healthcare worker and lab at risk of contracting infection and contaminating environment when swab sample is taken from infected patient. 	<ul style="list-style-type: none"> CLIA machines are proprietary or closed systems and the reagent kits are manufactured by the specific Equipment manufacturers Antibodies will only be detected from the 7th day of infection. Test performed too early will yield False Negative. 	<ul style="list-style-type: none"> The accuracy is dependent on kits supplied and adherence to the SOP. Testing process is more rigorous and time consuming 	<ul style="list-style-type: none"> Procurement of kit is most likely imported Will take some time to produce the kit in India Infrastructure and Coordination is very difficult in India. Pre-analytical Error High: Test Strip does not contain patient ID or barcode. Data entry must be manual at point of care. Sensitivity is a little poor 	<ul style="list-style-type: none"> Can only be used as a screening tool Accurate parameters not yet defined

MASS TESTING & VOLUME

“The country [South Korea], with a population of 51 million, tests more than 20,000 people a day at more than 600 testing sites nationwide.”
Foreignpolicy.com

Hence, in 120 days it can be assumed South Korea would have done approximately 2.4 million tests in a population of 51 million, which is roughly **5-10%** of the population.





Table A depicts an **approximate number of people to be tested** in a few Indian States and Pan-India, and highlights the number of people to be tested in rural areas if 5-10% of the population were to be tested in 120 days,

Table A: MASS TESTING								
	Uttar Pradesh	Maharashtra	Bihar	West Bengal	Goa	Tamil Nadu	Andra Pradesh	INDIA
Population	200	112	104	91	1.58	72	56	1369
Urban %	25%	46%	12%	32%	62%	48%	31%	32
Urban	50	51	13	29	0.98	34	17	438
Rural	150	61	91	62	0.6	38	39	931
Mass Testing at 5%								
Pop. Tested	10	5.6	5.2	4.6	0.079	3.6	2.8	68.5
Urban	2.5	2.6	0.6	1.5	0.049	1.7	0.9	21.9
Rural	7.5	3.0	4.6	3.1	0.030	1.9	1.9	46.6
Mass Testing at 10%								
Total	20	11.2	10.4	9.2	0.158	7.2	5.6	137.0
Urban	5	5.2	1.2	3.0	0.098	3.4	1.8	43.8
Rural	15	6.0	9.2	6.2	0.060	3.8	3.8	93.2

India needs to plan for **68.5 million to 137 million** tests in total, of which **46.6 million to 93.2 million** people are in rural, tier 3 cities, tier 4 cities, taluks, small towns and villages, of India

*All Values in Millions Except Urban Percentage

THE SWADESH-PROTOCOL

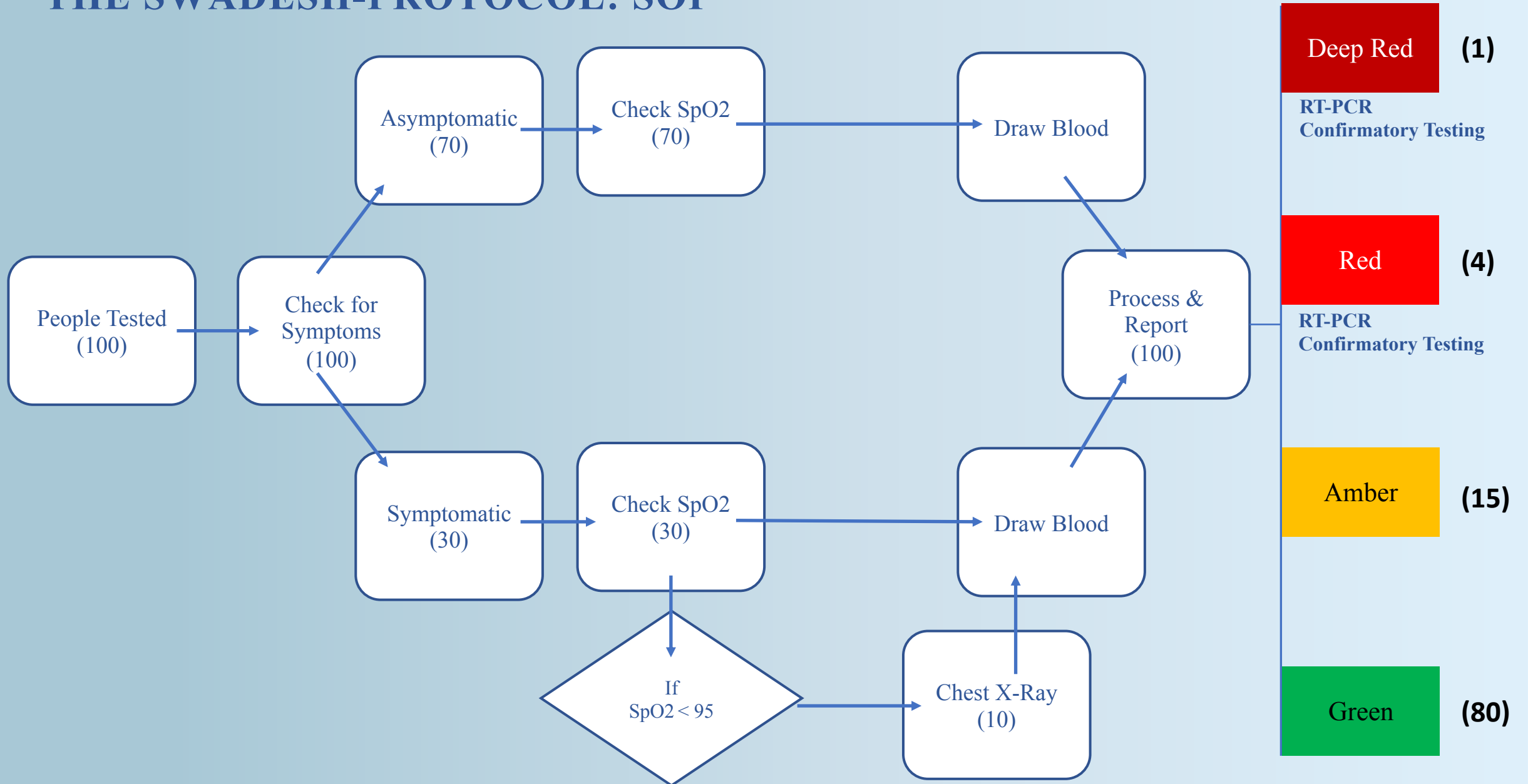
1. SYMPTOMOLOGY	Dry cough, No Runny Nose, Fever, Throat Pain, Chest Pain, Shortness of Breath (COVID-19 Suspicion)		Runny Nose, Productive Cough, Sputum (Alternate Diagnosis)	
2. LAB TEST	DEEP RED Highly Likely to have COVID-19 Requires immediate attention!	RED Likely to have COVID-19	AMBER Suggestive of COVID-19	GREEN Unlikely to have COVID-19
SPO ₂	< 90	< 93	93-95	>95
C- Reactive Protein (CRP)	> 10	> 6.0	> 5.5	< 5.5
Neutrophil : Lymphocyte Ratio	> 6.0	4.8 – 6.0	3 - 4.8	3
Leukocyte Count	<500	2500 – 500	3000 – 4000	> 4000
X- Ray Refer to Appendix A for X-Ray Imaging according to Colour-Classification.	Bilateral peripheral air space disease.	Focal or multifocal, unilateral, ill-defined air-space opacities in the middle and lower peripheral lung zones, with progressive multifocal consolidation over a course of 6 to 12 days involving one or both lungs.	Does not fit into Deep red, red and green patterns Manifests above patterns, but the clinical context is wrong, or suggests an alternative diagnosis (e.g. an interstitial lung disease in a connective tissue disease setting).	Lobar pneumonia Cavitating infections Lymphadenopathy, effusions Established pulmonary fibrosis
	 <ul style="list-style-type: none"> Confirmatory Tests for COVID-19 Immediate Hospitalization Immediate Treatment 	 <ul style="list-style-type: none"> Confirmatory Tests for COVID Isolation of Patient Treatment Repeat CRP & Chest X-Ray in 2-3 days 	 <ul style="list-style-type: none"> Prophylactic Treatment Self-Isolation of Patient Repeat CRP & Chest X-Ray in 2-3 days. 	 <ul style="list-style-type: none"> Unlikely to be COVID-19, only Caution is Advised.

The SWADESH-protocol uses easily available tests like

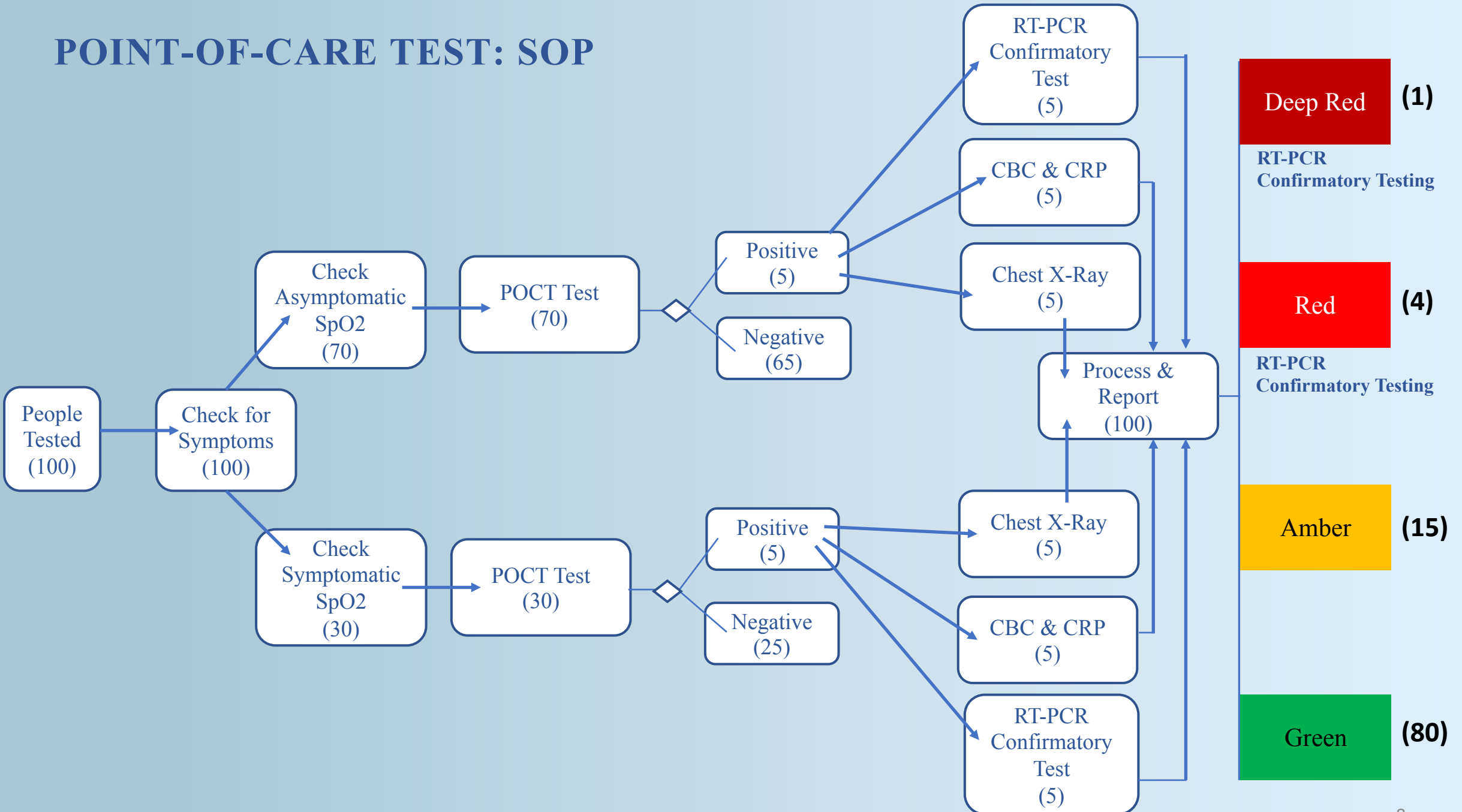
- Complete Blood Count (CBC)
 - Neutrophils to Lymphocyte Ratio,
 - Leukocyte counts
- Patient Symptoms
- SPO₂
- CRP
- X-Ray

The SWADESH-protocol classifies a patient's likelihood of contracting an infection as Deep Red, Red, Amber, and Green; where deep red is highly likely, red is likely, amber is suggestive, and green is unlikely of infection.

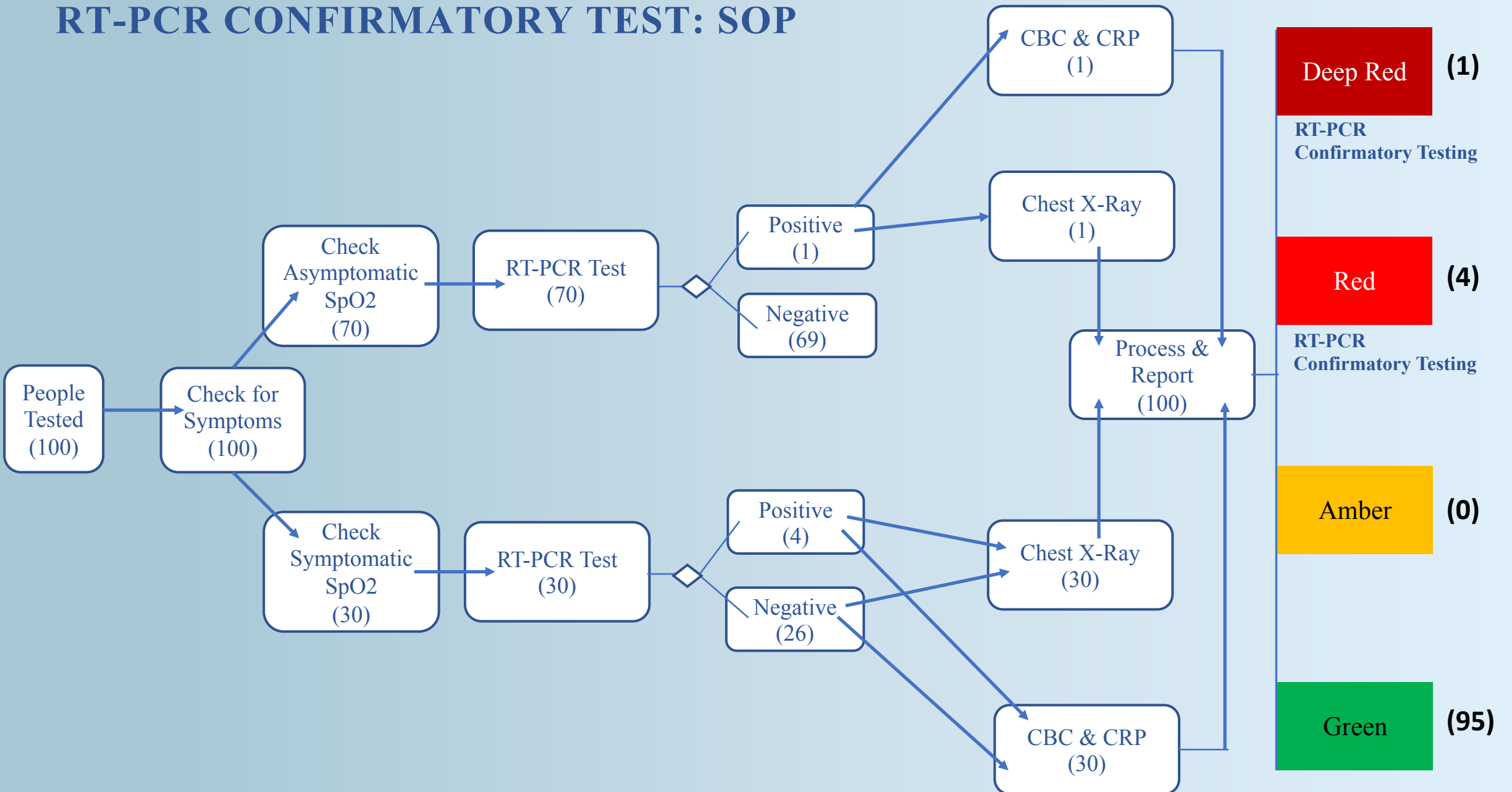
THE SWADESH-PROTOCOL: SOP



POINT-OF-CARE TEST: SOP



RT-PCR CONFIRMATORY TEST: SOP



COSTING OF MASS TESTING USING VARIOUS METHODS

RT-PCR (For 100 people)			
Test	Cost of Test (₹)	Quantity	Cost for 100 people (₹)
SpO2	₹15	100	₹1,500
RT-PCR Confirmatory Test	₹4500	100	₹4,50,000
CBC & CRP Blood Test	₹500	31	₹15,500
X-Ray	₹250	31	₹7,750
Cost to Patient			₹4,74,750

SWADESH-Protocol + RT-PCR (For 100 people)			
Test	Cost of Test (₹)	Quantity	Cost for 100 people (₹)
SpO2	₹15	100	₹1,500
RT-PCR Confirmatory Test	₹4500	5	₹22,500
CBC & CRP Blood Test	₹500	100	₹50,000
X-Ray	₹250	10	₹2,500
Cost to Patient			₹76,500

POCT + RT-PCR (For 100 people)			
Test	Cost of Test (₹)	Quantity	Cost for 100 people (₹)
SpO2	₹15	100	₹1,500
POCT Kits	₹1000	100	₹1,00,000
RT-PCR Confirmatory Test	₹4500	6	₹27,000
CBC & CRP Blood Test	₹500	6	₹3,000
X-Ray	₹250	6	₹1,500
Cost to Patient			₹1,33,000

Summary Cost Per Person	
RT-PCR	₹4,747.50
POCT + RT-PCR	₹1,330.00
SWADESH-Protocol	₹765.00

COSTING OF MASS TESTING USING VARIOUS METHODS

Total Cost at 5% Mass Testing for Each Method

	Uttar Pradesh	Maharashtra	Bihar	West Bengal	Tamil Nadu	Andra Pradesh	Goa	INDIA
People Tested (in millions)	10	5.6	5.2	4.6	3.6	2.8	0.079	68.5
RT-PCR	₹4,474 Cr	₹2,658 Cr	₹2,469 Cr	₹218 Cr	₹1,708 Cr	₹1,329 Cr	₹37.5 Cr	₹32,520 Cr
POCT + RT-PCR	₹1,330 Cr	₹745 Cr	₹692 Cr	₹612 Cr	₹479 Cr	₹372 Cr	₹10.5 Cr	₹9,110 Cr
SWADESH-Protocol + RT-PCR	₹765 Cr	₹428 Cr	₹398 Cr	₹351 Cr	₹275 Cr	₹214 Cr	₹6.0 Cr	₹5,240 Cr

*All Cost in Crores. People Tested in Millions