

Development and large-scale validation of a highly accurate SARS-COV-2 serological test using regular test strips for autonomous and affordable finger-prick sample collection, transportation, and storage: Supplementary material

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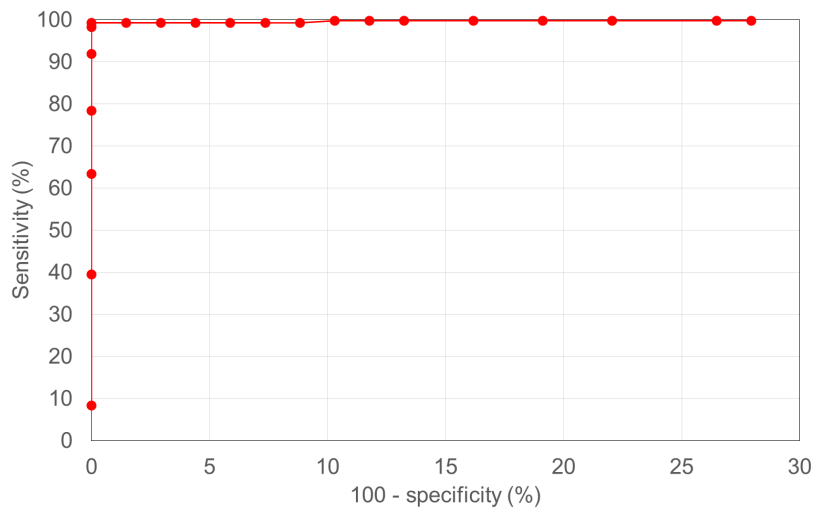
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Supplementary Figure S1: Receiver operating characteristic (ROC) curve of S-UFRJ test. The curve is based on calculating the sensitivity and specificity as a function of varying cut-off values (each data point represents one cut-off value). Sensitivity and specificity were determined based on a panel comprising 420 positive and 68 negative samples.



Supplementary Table S1: Cost estimate of consumables needed for S-UFRJ test, considering two scenarios: (1) purchase of materials sold by international suppliers in the country and with no saving efforts; (2) purchase of materials from domestic suppliers and making saving efforts that were validated as not interfering in test performance (data not shown): use of skim milk (2% m/v) instead of BSA (1% m/v); in-house preparation of PBS; finger prick using just the sterile lancet, with no lancing device; and reuse of buffer reservoirs for an equivalent of 30 ELISA plates. As a conservative estimate to account for controls included in each plate and for any eventual repetition needs or failures, a total of 80 tests were considered per each ELISA plate. All quotes for consumables in this table were obtained in June-July 2020 for purchase in the local market in Brazilian reais (BRL). The conversion to USD was done considering an exchange rate of 1 USD = 5.34 BRL (as of July 16, 2020).

Consumables	Supplier	Amount used (per 80 samples or per plate)	Unit cost (converted to USD)	Package size	Cost per plate (USD)
Scenario 1 (international suppliers)					
Dilution plate	Sarstedt, #821581 (Germany)	1	63.67	per 100	0.64
ELISA plate	Corning, #3590 (USA)	1	146.07	per 100	1.46
S protein	Produced at UFRJ	20 µg	140.45	per mg	2.81
PBS 10x	Sigma, #11666789001-4L (USA)	350 mL after 1:10 dilution	166.67	per 4000 mL	1.46
BSA (at 1% m/v)	Sigma, #A2153-100G (USA)	0.35 g BSA	344.57	per 100 g	1.21
HRP-conjugated antibody	Sigma, #SAB3701282-2MG (USA)	5 mL after 1:8000 dilution	261.61	per mL @ 2 mg/mL	0.16
TMB	Thermo Fisher, #002023 (USA)	5 mL	186.30	per 500 mL	1.86
HCl 37%	Sigma, #30721-2.5L (USA)	5 mL after 1:10 dilution	32.58	per 2500 mL	0.01
Pipette tips	Axygen (USA)	400 yellow tips	176.03	per 20000	3.52
Reagent reservoir	Corning Costar (USA)	6 reservoirs for 30 plates	146.07	per 1000	0.88
Plastic strips w/ 3 pads	Organicoat (Brazil)	80	243.45	per 5000	3.90
Lancet	G-Tech (Brazil)	80	1.22	per 100	0.97
Lancing device	G-Tech (Brazil)	1	2.79	per 1	2.79
Personal protective equipment (PPE)	Several suppliers	All PPEs (sample collection/analysis)	2.50	set of PPEs	2.50
Additional minor non-listed consumables		20% of all previous items together	4.83		4.83
				Total costs per plate:	28.99
				Cost per test:	0.36

Scenario 2 (domestic suppliers, skim milk, in-house PBS, reservoir reuse, no lanceting device)					
Dilution plate	Alfa (Brazil)	1	28.09	per 50	0.56
ELISA plate	Corning, #3590 (USA)	1	146.07	per 100	1.46
S protein	Produced in-house	20 µg	140.45	per mg	2.81
PBS (1x) (in-house prep)	Synth Chemicals (Brazil)	350 mL	0.09	per liter	0.03
Skim milk (at 2% m/v)	Nestlé (Switzerland)	0.7 g milk	3.04	per 280 g	0.01
HRP-conjugated polyclonal antibody	Rhea Biotech (Brazil)	5 mL after 1:20000 dilution	196.63	per mL	0.05
TMB	Scienco Biotech (Brazil)	5 mL	209.74	per 1000 mL	1.05
HCl 37%	Sigma, #30721-2.5L (USA)	5 mL after 1:10 dilution	32.58	per 2500 mL	0.01
Pipette tips	Olen-Econolab (Brazil)	400 yellow tips	3.75	per 1000	1.50
Reagent reservoir	Corning Costar (USA)	6 reservoirs for 30 plates	146.07	per 1000	0.03
Plastic strips w/ 3 pads	Organicoat (Brazil)	80 per plate	243.45	per 5000	3.90
Lancet	G-Tech (Brazil)	80 per plate	1.22	per 100	0.97
Personal protective equipment (PPE)	Several suppliers	All PPEs (sample collection/analysis)	2.50	set of PPEs	2.50
Additional minor non-listed consumables		20% of all previous items together	2.97		2.97
				Total cost per plate:	17.85
				Cost per test:	0.22

Supplementary Table S2: Estimate of the final S-UFRJ test price taking 1 million tests as a calculation basis, including in the cost computation the raw materials shown in Table S1, other manufacturing costs (that include labor, utilities, laboratory charges, insurance, among others) and general expenses (which account for administrative, research, development, distribution and marketing costs)⁷. Profit margin and taxes were also accounted for to estimate the final S-UFRJ test price, since large-scale use of the test for epidemiological surveillance would probably require its industrial production.

Type of cost	Calculation	Scenario 1 (USD)	Scenario 2 (USD)
<i>Raw materials (RM) for 1 million tests</i>	<i>See Table S1</i>	220000	360000
<i>Other manufacturing costs for 1 million tests</i>	<i>145% of RM</i>	319000	522000
<i>General expenses for 1 million tests</i>	<i>20% of TPC</i>	134750	220500
Total product costs (TPC) for 1 million tests		673750	1102500
Profit margin (PR) (10% of TPC)		67375	110250
Taxes (35% of PR)		23581	38588
Sum of TPC, PR and taxes		764706	1251338
Estimated unit price per test		0.76	1.25
Final estimated price per test (average of the 2 scenarios)		1.01	