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Laboratory optimization of the production of guanidium-based inactivated transport media to support SARS-CoV-2 PCR testing in Indonesia

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ABSTRACT

The availability of a viral transport medium (VTM) is often an obstacle to COVID-19 testing, especially for countries that are not VTM producers, including Indonesia. Therefore, the Parasitology Laboratory of Medicinal Faculty, Universitas Padjadjaran, Indonesia, developed an inactivation transport medium called "VITPAD®" that uses a guanidium-based buffer solution. This study evaluated VITPAD® as a transport medium for swab samples and scaled-up production from 2,000 tubes per month to 60,000 per month to support COVID-19 testing in Indonesia. VITPAD® has good stability and sterility, with a lifespan of over 2 years, and it performs well as a transport medium for COVID-19 samples. The production capacity was successfully scaled-up by implementing scheduling and capacity management, with the first large-scale production of VITPAD® distributed to 26 teaching hospitals in Indonesia.

INTRODUCTION

The COVID-19 pandemic has depleted healthcare resources around the world, particularly in diagnostic and sample collection centers. The gold standard for diagnosing COVID-19 is real-time reverse transcription-quantitative polymerase chain reaction (RT-qPCR) using a swab sample which is usually transported to the laboratory in a viral transport medium (VTM) (Lam *et al*., 2020). During the COVID-19 pandemic, millions of tests were performed globally, thus increasing the demand for VTM, with some VTM-producing countries, such as China, Korea, and several European countries, reporting a scarcity of VTM stock for COVID-19 diagnosis (Petersen *et al*., 2021), further exacerbating the lack of VTM stocks in non-VTM-producing countries, including Indonesia.

VTM is a key reagent for COVID-19 testing as the nasopharyngeal (NP) or oropharyngeal swabs are stored in VTM for subsequent transport to the laboratory for real-time PCR (Smith *et al*., 2020). However, real-time PCR procedures are compatible with several medium types, including buffer solution-based media and cell/tissue culture-based media (Johnson, 1990; Rodino *et al*., 2020), with the selection of medium based on its intended use. VTM is used to transport viruses so that they can be isolated in tissue culture facilities for diagnosis by the RT-qPCR

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test, but live viruses are not required for RT-qPCR diagnosis (Borkakoty *et al*., 2021). Cell/tissue culture-based VTM keep the viral samples alive until the RNA is extracted; therefore, they require refrigeration (2°C–8°C) during transportation (WHO, 2020), whereas buffer-based media can be stored at room temperature (Luinstra *et al*., 2011; McAuley *et al*., 2021). Another medium that can store nucleic acids is the inactivation transport medium (ITM) (van Bockel *et al*., 2020) which protects nucleic acids from degradation while also inactivating viruses. Transport can be performed at room temperature, and samples can be kept for up to 20 days. This type of medium is used for the collection, storage, and transportation of viruses, *Chlamydiae*, *Mycoplasma*, and *Ureaplasma* (Wuxi NEST Biotechnology, 2020). Several commercial products have also used this type of media for COVID-19 testing, for example, the NEST Disposable Nasopharyngeal ITM Sampler kits from Wuxi NEST Biotechnology. The advantage of using ITM is room temperature storage without refrigeration. The inactivated virus content in the reagent makes sample handling safer due to a lower risk of infection, but the use of ITM needs to be studied in depth for culture-based applications (van Bockel *et al*., 2020; Kirkland and Frost, 2020).

To respond to the limited availability of VTM for COVID-19 testing in Indonesia, the Parasitology Laboratory of Universitas Padjadjaran developed a guanidium-based ITM, named "VITPAD®." The rationale for using ITM over VTM is that Indonesia is a large country with many islands and cities that are far apart, so swab samples must be transported using a cool box to test laboratories. Furthermore, the high infectious potential of swab samples makes health workers more vulnerable to COVID-19 infection, necessitating multiple layers of security when transporting swab samples. Consequently, the Parasitology Laboratory of Universitas Padjadjaran has innovated to develop in-house ITM for transportation between remote areas without the use of a cool box.

Guanidinium salt is a strong chaotrope and one of the most powerful denaturants utilized in protein folding physiochemical research. It can also reduce enzyme activity while increasing the solubility of hydrophobic substances. Proteins lose their ordered structure at high concentrations of guanidinium chloride and tend to become randomly coiled, i.e., they have no residual structure. Guanidine hydrochloride is a potent ribonuclease inhibitor (Wingfield, 2001); thus, guanidine-based buffers are considered safe in Indonesia, and the availability of locally produced guanidium salt makes the supply chain more cost-effective. This paper reports the production process model with a capacity of more than 2,000 kits per day or 60,000 kits per month and quality assurance of VITPAD®.

METHODS

VITPAD® has previously been tested, validated, and approved by the Ministry of Health of the Republic of Indonesia (Registration No. AKD 10302120146). VITPAD® is also registered in the Intellectual Property Database of the Republic of Indonesia under the code BRM2054A. The Ethics Committee of the Faculty of Medicine, Universitas Padjadjaran, approved this study (No. 0720121265). The key constituents in the ITM formulation were tris-buffer, guanidium-based chaotropic agents, antibiotics, and pH indicators. The kit also contained a swab stick made from nylon fibers produced by Dongguan Mejaju Medical Co., Ltd.

The production capacity of VITPAD® was increased from 2,000 tubes to 60,000 tubes per month, with ITM made on the same day combined into one batch, with an average of four batches per month. Each batch underwent quality control, including stability and sterility testing, before release, and the performance test involved the ability of each batch to preserve NP swab samples through RNA extraction followed by qPCR.

Sterility and stability tests

Sterility testing was performed in stages. First, the pH was measured in the 6.2–8.2 range using a PEAK Instrument S-610 Series pH meter. The optical density (OD) was then measured at 600 nm using an Eppendorf BioPhotometer Plus UV/Vis Photometer. In addition, 100 µl of a VITPAD® solution was spread on a solid Luria-Bertani medium and incubated at 37°C overnight for total colony counting (TCC).

The product lifetime was determined using the accelerated stability test method, with at least three tubes of VITPAD® used for each test. The VITPAD® (4 ml each) was incubated at 50°C and 75% relative humidity (RH) for 0, 7, 14, 21, 28, 35, 42, 49, and 56 days corresponding to product stability of 3, 6, 9, 12, 15, 18, 21, and 24 months, respectively. The pH, OD, and TCC of each tube were then determined. The concept of accelerated stability testing is based upon the Arrhenius equation and modified Arrhenius equation (Anderson and Scott, 1991; Bajaj *et al*., 2012). These equations describe the relationship between storage temperatures and degradation rate. The Arrhenius equation can be used to calculate the projection of stability for various degradation processes based on degradation rates at high temperatures (Bajaj *et al*., 2012).

Real-time PCR of VITPAD® swab samples for detection of SARS-CoV-2

All VITPAD®s utilized in this test have undergone stability and sterilizing testing. Swab samples were collected from 55 patients at Universitas Padjadjaran's C.29 Laboratory and placed in VITPAD® before total RNA was extracted using MagMAX™-96 Total RNA Isolation Kit with a "KingFisher™ Flex Purification System" machine. Then, the SARS-CoV-2 virus was detected using the Roche LightCycler® 480 Real-Time PCR System and two different PCR kits, SD Biosensor RT-PCR nCoV Real-Time Detection Kit and Allplex™ 2019-nCoV Assay kit. The target genes of the Biosensor kit were the ORF1 gene and E-gene, while the Allplex kit would detect the presence of the RdRp gene, N-gene, and E-gene.

Infrastructure, team organisation, and management

The infrastructure for VITPAD® production consists of an ISO-8 space equipped with a HEPA filter (0.5 µm). The space consists of a clean room for mixing, filling, and packaging area, with the floors and the walls coated with epoxy to support sterilization. Outside, there are two storage sheds for raw materials and finished goods. The production process involves a team of seven workers who are directly supervised by the operation manager.

VITPAD® production comprises three fundamental processes: mixing, filling, and packaging. The mixing process is performed in the Labconco™ Purifier™ Class II Biosafety Cabinet

(BSC) in the cleanroom. The filling process is arranged carefully to avoid contaminants with the tubes stored in sealed plastic and only opened inside the BSC previously sterilized using alcohol and UV light. The tubes are arranged on an acrylic tube rack to facilitate the tube filling, then tightly closed, and transported to the packaging room. After the mixing and filling processes are complete for the day, the room and the BSC are sterilized with alcohol and UV irradiation. The filled tubes are packed into a polypropylene plastic bag and sealed using the Heavy Pack™ FR-900 Continuous Band Sealer in the packaging room and then placed into the packaging box with the same number of flocked swabs. To maintain product quality, the packaging box is sealed and placed in a corrugated cardboard box.

Each production batch has its own set of subprocesses (Fig. 1) and is performed sequentially as the result of the mixing process is used as input material for the filling process, and the output of the filling process is the input material for the packaging process. Each subprocess takes a different amount of time to complete, which is calculated by averaging the times of four individual operators, each of whom has three distinct running times.

RESULTS AND DISCUSSION

Sterility and stability tests

The results of the sterility test showed that the pH of VITPAD® at 0 hours was 7.04 and after incubation was in the range of 6.97–7.18 (Table 1), an acceptable range for the storage of SARS-CoV-2 RNA (Chan *et al*., 2020). The OD_{600} value indicated no contamination during production and is consistent with the TCC findings, which indicated that no bacterial colonies grew during the overnight incubation period.

Accelerated testing is frequently used in the development of clinical reagents to indicate product lifetime and subsequently abbreviate the development plan. The reagent is incubated at higher temperatures and relative humidity (75% RH) at different times. This testing was also used to compare the relative steadiness of the product (Anderson and Scott, 1991), showing that the VITPAD® solution had a lifespan of 2 years, the pH was stable at 6.9–7.2, and there was no contamination during production.

RT-PCR of VITPAD® swab samples for detection of SARS-CoV-2

The swab samples in VITPAD® were extracted and tested using a real-time PCR system to detect the SARS-CoV-2 genes. Figure 2 shows the amplification plots of the target genes identified by the two kits used in this study. SARS-CoV-2 was detected in 30 of the 55 samples analyzed with Allplex™ 2019-nCoV or SD Biosensor RT-PCR nCoV. The internal control was identified in all 55 samples, indicating that the extraction and PCR procedures were effective (Appendix). The PCR results demonstrated that VITPAD® performs well as a VTM and the results were consistent between the two separate PCR kits tested (Table 2).

VITPAD® was not compared to commercial VTM in this study since it had already been validated (data not shown). Also, the Ct from different VITPAD® storage batches was not evaluated due to sampling restrictions. However, as indicated by the Ct values from the two kits used, VITPAD® performed well over time and yielded relatively accurate results.

Infrastructure, team organisation, and management

Capacity and scheduling management aims to determine the maximum limit of input and output capabilities within a certain time, as well as how to reach this maximum limit.

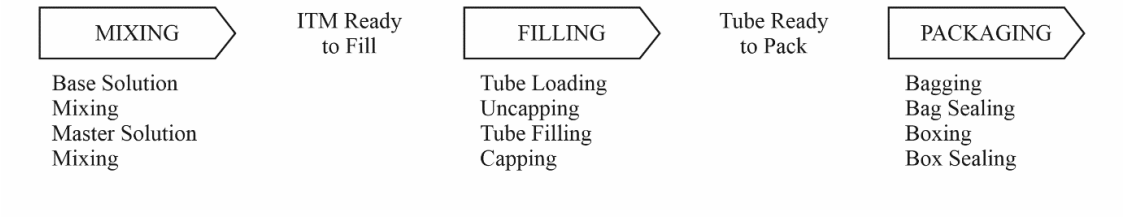

Figure 1. VITPAD® production process and subprocesses.

Table 1. Result of accelerated stability testing of VITPAD® at 50°C.

Incubation time (Day)	Optical density (A)	Colony counting	pH
0	0	0	7.04
7	0	0	6.97
14	0.001	0	7.12
21	0	0	7.18
35	0	0	7.04
42	0.001	0	7.2
49	0	0	7.07
56	0.024	0	7.13

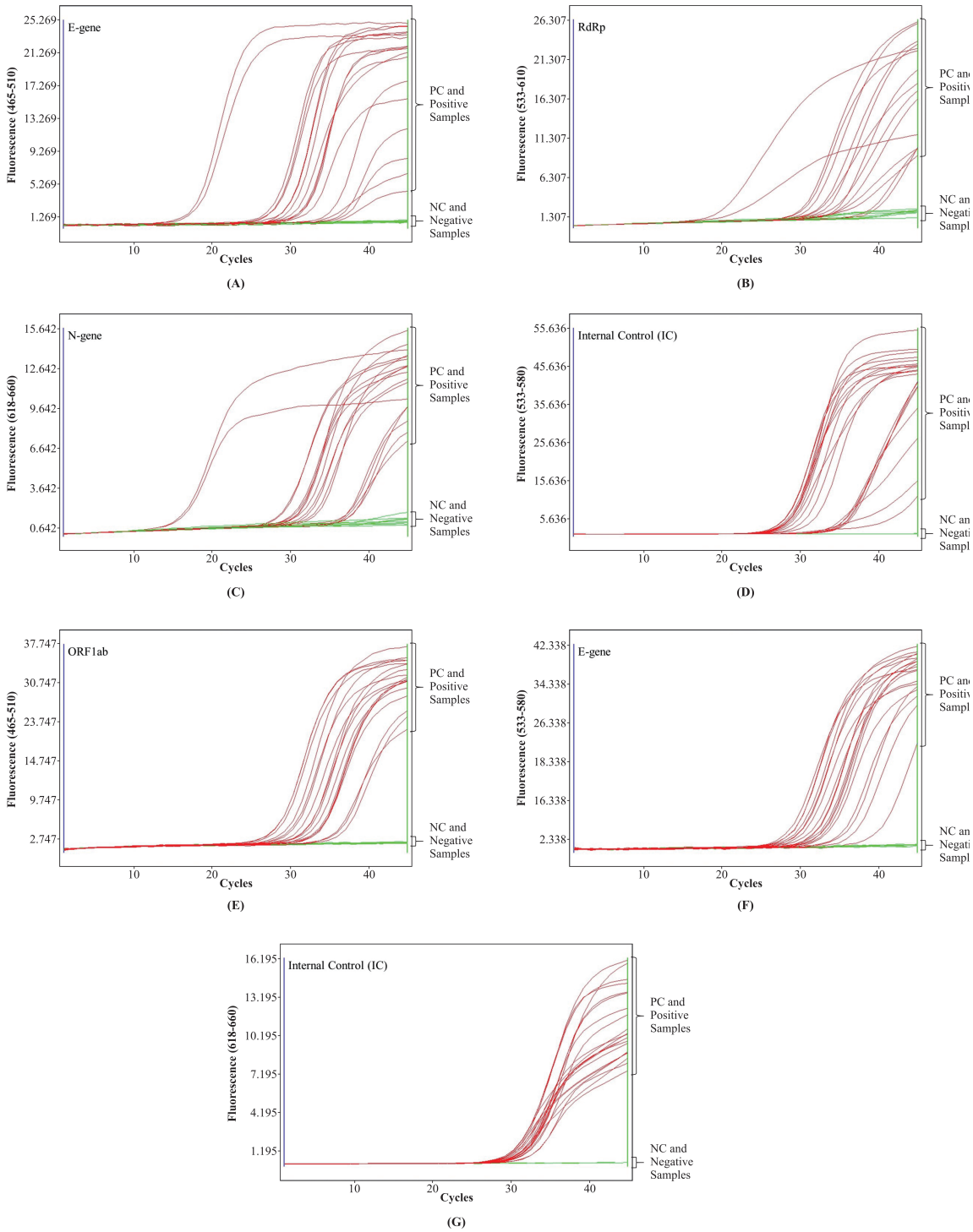

Figure 2. RT-PCR amplification plots of SARS-CoV2 genes of the patient samples by using AllplexTM 2019-nCoV (A-D), SD Biosensor RT-PCR nCoV (E-G). PC= positive control, NC = negative control.

Table 2. PCR results of swab samples in VITPAD®.

Diagnostic test results	SD Biosensor RT-PCR nCoV	Allplex™ 2019-nCoV
Positive SARS-CoV-2 n (%)	30 (54.5%)	30 (54.5%)
Negative SARS-CoV-2 n (%)	25 (45.5%)	25 (45.5%)

Regarding capacity management, one of the most significant aspects to consider is the bottleneck problem. A bottleneck in the manufacturing process is a point in the production flow where the workstation is operating at maximum capacity but the workload volume is increasing rapidly (Koenig, 1994). This can inhibit the rate of the overall production process, eventually consuming more

time and costs (Barone, 2020). Based on our previous production experiences, bottlenecks occurred in the filling process and material availability, which stopped the entire production process; therefore, proper scheduling and task allocation are obligatory to ensure no bottlenecks occur. The proper work scheme must be scheduled and allocated; hence, managers need to determine production capacity beforehand. Time measurements were conducted to estimate a completion time for each subprocess, which was then used as an output capacity variable for daily scheduling (Table 3).

Managers also need to allocate production operators based on the maximum production capacity in the daily schedule. Tables 4a and 4b present an example of the daily schedule during the VITPAD® 10 liters/5,000 tube filling process with an allocation of 4 production operators. Based on Tables 4a and 4b, each subprocess (workstation) has a different production capacity, so the output is also different. The output capacity in a 30-minute window for each subprocess is taken from the time measurement, whereas the output of a subprocess is calculated by multiplying the number of allocated operators by the output capacity. Managers need to allocate production operators appropriately to avoid bottlenecks; thus, it is necessary to ensure that four operators were allocated, as well as ensure that the accumulated output of the tube loading subprocess is greater than the input requirements of the uncapping subprocess and so on, until the entire filling process is complete. The accumulated outputs are obtained by adding the previous subprocesses together; for example, at time stamp 15:00, the capping subprocess accumulated output is 2,848 derived from the subprocess 14:30 accumulated output (2,492 tubes) plus its output at 15:00 (356 tubes).

Apart from daily scheduling, it is highly recommended to schedule monthly so that the overall production activities for that month can be described, thereby minimizing potential bottlenecks or risks that may arise and also serving as a working reference for the production team so as not to fall behind the scheduled target. An example of monthly scheduling during the VITPAD® production process with an allocation of four production operators is shown in Table 5.

Regarding the monthly scheduling process, production targets and inputs from the previous month need to be considered, i.e., ITM ready to fill, tube ready to bag, and bag ready to box, where one tube contains 2 ml of ITM, one bag contains 10 tubes, and one box contains five bags. Daily tasks need to be allocated for maximum output, with no bottlenecks between subprocesses, processes, and daily production activities. It should be noted that the output of mixing (ITM waiting for QC results) must go through the QC process before the filling process can be carried out. Five lots were accumulated in advance of the QC process for the efficient use of materials, which was performed simultaneously with the mixing or filling process because it was performed by a separate team from the production team. This cycle was repeated while keeping track of the input count, as well as the minimum production target that must be achieved by avoiding all bottlenecks.

To ensure the achievement of production targets, it is necessary to control the availability of production inputs or raw materials, given that inadequate controls will stop production (Monczka, 2016). Therefore, we need a sympathetic system of inventory and supply chain management.

The main challenge in inventory management is to ensure that the required raw materials can be used at the specified time; therefore, material requirement planning (MRP) was applied for VITPAD® production. MRP is a planning and decision-making tool in the production process that analyzes the current inventory level with the production capacity and the need to produce goods (Orlicky, 1975). The output of MRP is the forecast data of raw material orders, as well as the time required by each supplier to fulfill these orders so management can make the best decisions in determining the time of the order. MRP systems involve the management of the (1) gross requirement (the total quantity of material needed to produce planned output in a period); (2) scheduled receipts (inventory already ordered and expected to be received from suppliers, which can be assumed to be in stock for the planning period); (3) available inventory or stock on hand (actual stock available for any period); and (4) planned order release (the quantity of output planned for a period to satisfy planned order receipts) (Brown *et al*., 2005). An example of a basic MRP calculation for one raw material is shown in Figure 3.

Each raw material has various conditions, including the availability of stock at suppliers, supplier locations, and the ability of suppliers to deliver raw materials on time (Monczka, 2016). Some materials take up to 2–3 months to procure (lead time), while others only take a week. Therefore, it is important for each type of goods to be calculated using MRP analysis to determine the quantity that must be bought and when the material must be ordered.

Table 3. Results of time measurements.

No	Subprocess	Average time required	Amount of output in 30 minutes
1	Base solution mixing	—	—
2	Master solution mixing	782 seconds/tube	2.3 l
3	Tube loading	3.11 seconds/tube	578 tubes
4	Uncapping	4.21 seconds/tube	427 tubes
5	Tube filling	4.63 seconds/tube	388 tubes
6	Capping	5.05 seconds/tube	356 tubes
7	Bagging	24.25 seconds/bag	74 bags
8	Bag sealing	6.74 seconds/bag	267 bags
9	Boxing	58.11 seconds/box	30 boxes
10	Box sealing	10.54 seconds/box	170 boxes

Table 4a. Daily schedule during the VITPAD® 10 l/5,000 tube filling process (subprocess tube loading and uncapping).

Time stamp	Preparation	Tube loading				Uncapping				
		Operator (person)	Capacity/operator (tube)	Output (tube)	Accumulated output (tube)	Operator (person)	Capacity/ operator (tube)	Output (tube)	Accumulated output (tube)	Bottleneck status
08:00										
08:30	4			0	0			0	0	None
09:00		2	578	0	0	2	427	0	0	None
09:30		2	578	1,156	1,156	1	427	854	854	None
10:00		1	578	1,156	2,312	1	427	427	1,281	None
10:30		1	578	578	2,890	1	427	427	1,708	None
11:00		1	578	578	3,468	1	427	427	2,135	None
11:30		1	578	578	4,046	1	427	950	3,085	None
12:00				578	4,624			567	3,652	None
12:30				0	4,624			0	3,652	None
13:00		1	578	0	4,624	1	427	0	3,652	None
13:30				376	5,000	1	427	427	4,079	None
14:00				0	5,000	1	427	427	4,506	None
14:30				0	5,000	1	427	427	4,933	None
15:00				0	5,000			67	5,000	None
15:30				0	5,000			0	5,000	None
16:00				0	5,000			0	5,000	None
16:30				0	5,000			0	5,000	None
17:00				0	5,000			0	5,000	None
TOTAL					5,000				5,000	

The grey shade is indicating no production.

Table 4b. Daily schedule during the VITPAD® 10 l/5,000 tube filling process (subprocess tube filling and capping).

Time stamp	Tube filling					Capping					Closing & sterilization
	Operator (person)	Capacity/ operator (tube)	Output (tube)	Accumulated output (tube)	Bottleneck status	Operator (person)	Capacity/ operator (tube)	Output (tube)	Accumulated output (tube)	Bottleneck status	
08:00											
08:30			0	0	None			0	0	None	
09:00			0	0	None			0	0	None	
09:30	1	388	0	0	None			0	0	None	
10:00	1	388	388	388	None	1	356	0	0	None	
10:30	1	388	388	776	None	1	356	356	356	None	
11:00	1	388	388	1,164	None	1	356	356	712	None	
11:30	1	388	388	1,552	None	1	356	356	1,068	None	
12:00			388	1,940	None			356	1,424	None	
12:30			0	1,940	None			0	1,424	None	
13:00	1	388	0	1,940	None	1	356	0	1,424	None	
13:30	2	388	388	2,328	None	1	356	356	1,780	None	
14:00	2	388	776	3,104	None	1	356	356	2,136	None	
14:30	2	388	776	3,880	None	1	356	356	2,492	None	
15:00	1	388	776	4,656	None	3	356	356	2,848	None	
15:30			344	5,000	None	3	356	1,084	3,932	None	1
16:00			0	5,000	None			1,068	5,000	None	4
16:30			0	5,000	None			0	5,000	None	
17:00			0	5,000	None			0	5,000	None	
TOTAL				5,000					5,000		

The grey shade is indicating no production.

Table 5. Monthly schedule.

Time stamp		Day																								
		0	**1**	**2**	**3**	**4**	**5**	**6**	**7**		**8**	**9**	**10**	**11**		**12**	**13**	**14**	**15**		**16**	**17**		**18**		**19**	**20**
08:25		PREVIOUS MONTH	BG	MX	MX	MX	MX	MX	QC	MX	MX	MX	MX	QC	FL2	FL2	FL2	FL2	BG	BG		BG	BX		BX		EVAL UATION
09:00																											
09:30																											
10:00																											
10:30																											
11:00				BG	BX	FL1	FL1	FL1		FL1	FL1	FL1	FL1															
11:30																											
12:00																											
13:00			BG	BG	BX	FL1	FL1	FL1	FL1		FL1	FL1	FL1	FL2		FL2	FL2	FL2	BG	BG		BG	BX		BX		
13:30																											
14:00																											
14:30																											
15:00				BX																							
15:30																											
16:00																											
16:35																											
TOTAL OUTPUT	ITM 1 (liters)			8	16	24	32	40	48		16	24	32	32													
	ITM 2 (liters)	24	24	24	24	18	12	6			34	28	22	12		34	24	14	14	14		14	14		14		14
	Ready to bag (tube)	8,000	2,000			2,500	5,500	8,500	12,000		15,000	18,000	21,000	26,000		31,000	36,000	41,000	27,000	13,000							
	Ready to box (bag)	1,200	1,800	1,500															1,400	2,800		4,100	2,050				
	Ready to ship (box)			100	400	400	400	400	400		400	400	400	400		400	400	400	400	400		400	810		1,220		1,220

The grey shade is indicating no production. BG = Bagging; MX = Mixing (8 l); QC = Quality control; FL1 = Filling (6 l); FL2 = Filling (10 l); BX = Boxing; ITM1 = ITM waiting for QC result; ITM2 = ITM ready to fill.

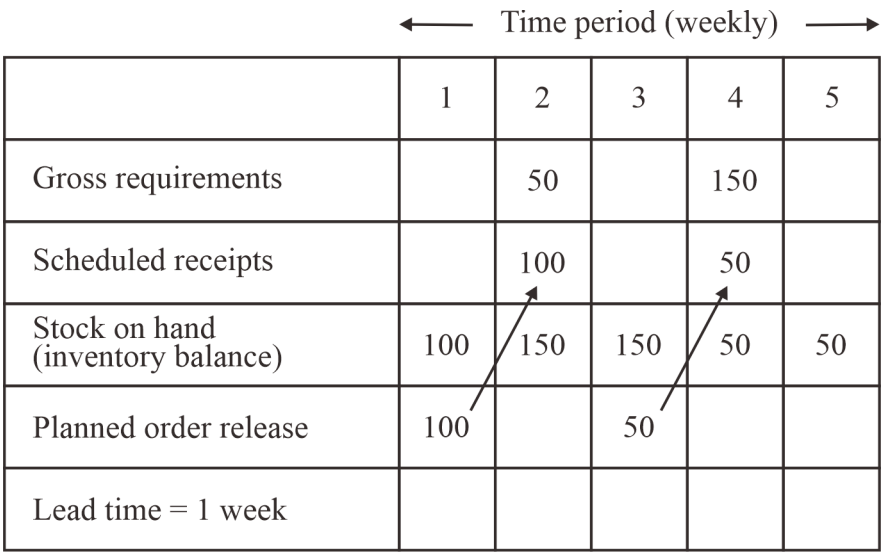

Figure 3. Example of basic material requirement planning (MRP) calculation of raw material.

Overall, the VITPAD® team continually strives to make improvements in every production and managerial sector. The production conditions that are now being implemented are the result of the efforts and contributions of all VITPAD® team personnel through countless trials and errors. The first VITPAD® batches were distributed to 26 teaching hospitals in Indonesia.

CONCLUSION

The in-house guanidium-based ITM, brand name VITPAD®, has good stability and sterility, with a lifespan of over 2 years, and it performs well as a transport medium for COVID-19 samples. The production capacity was successfully scaled-up and increased to at least 2,000 tubes per day or 60,000 tubes per month by implementing scheduling and capacity management.

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AUTHOR CONTRIBUTIONS

All authors made substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; took part in drafting the article or revising it critically for important intellectual content; agreed to submit to the current journal; gave final approval of the version to be published; and agree to be accountable for all aspects of the work. All the authors are eligible to be an author as per the international committee of medical journal editors (ICMJE) requirements/guidelines.

CONFLICTS OF INTEREST

The authors report no financial or any other conflicts of interest in this work.

ETHICAL APPROVALS

The Ethics Committee of the Faculty of Medicine, Universitas Padjadjaran, approved this study (No. 0720121265).

DATA AVAILABILITY

All data generated and analyzed are included within this research article.

PUBLISHER'S NOTE

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APPENDIX

Table A1. PCR results of swab samples in VITPAD® using SD Biosensor RT-PCR nCoV and Allplex™ 2019-nCoV.

No	Sample name	SD Biosensor RT-PCR nCoV				Allplex™ 2019-nCoV				
		Ct ORF1ab	Ct E-gene	Ct IC	Interpretation	Ct RdRp	Ct N-gene	Ct E-Gene	Ct IC	Interpretation
1	VITPAD1	29.38	29.43	22.71	Positive	36.68	35.18	31.35	24.42	Positive
2	VITPAD2	21.87	22.32	22.63	Positive	29.05	27.27	24.51	23.60	Positive
3	VITPAD3	27.00	27.78	22.27	Positive	34.10	33.55	30.54	23.91	Positive
4	VITPAD4	25.2	28.01	24.50	Positive	33.07	31.52	28.71	23.86	Positive
5	VITPAD5	29.99	32.98	24.48	Positive		36.10	32.75	23.70	Positive
6	VITPAD6	32.67	36.54	24.63	Positive		38.78		24.39	Positive
7	VITPAD7	29.91	34.84	23.71	Positive		36.95	33.90	23.55	Positive
8	VITPAD8	29.96	32.97	24.78	Positive		34.78	32.20	23.75	Positive
9	VITPAD9	26.3	28.98	24.68	Positive	33.65	32.52	29.43	23.85	Positive
10	VITPAD10	20.71	24.14	25.29	Positive	28.67	26.85	23.76	24.39	Positive
11	VITPAD11	30.68	34.74	24.54	Positive		36.32	33.29	23.70	Positive
12	VITPAD12	25.46	28.40	23.90	Positive	33.57	31.71	28.79	23.61	Positive
13	VITPAD13	31.32	30.86	24.89	Positive		34.80	33.79	22.81	Positive
14	VITPAD14	24.91	24.52	23.37	Positive	32.44	31.45	27.78	22.62	Positive
15	VITPAD15	24.43	24.15	23.98	Positive	31.84	30.34	27.92	22.60	Positive
16	VITPAD16	30.40	29.49	23.97	Positive		35.29	33.73	22.74	Positive
17	VITPAD17	26.56	25.42	23.56	Positive	34.84	30.66	30.43	23.51	Positive
18	VITPAD18	25.91	24.99	23.74	Positive	33.96	29.38	28.83	23.43	Positive
19	VITPAD19	28.43	27.81	25.88	Positive	36.49	32.37	30.99	23.63	Positive
20	VITPAD20	23.37	23.29	24.96	Positive	31.00	29.57	26.60	23.54	Positive
21	VITPAD21	28.31	27.62	24.36	Positive	34.82	32.32	31.54	23.40	Positive
22	VITPAD22	26.66	26.39	23.98	Positive	33.77	31.23	29.59	22.88	Positive
23	VITPAD23	27.93	27.36	24.63	Positive	35.34	32.02	30.82	23.36	Positive
24	VITPAD24	27.49	26.49	23.56	Positive	34.81	32.14	30.38	22.91	Positive
25	VITPAD25	24.76	24.64	23.50	Positive	31.96	29.82	26.86	22.94	Positive
26	VITPAD26	26.75	26.43	24.85	Positive	33.36	31.63	29.98	22.81	Positive
27	VITPAD27	27.63	26.61	24.67	Positive	35.11	32.19	30.76	23.52	Positive
28	VITPAD28	22.51	22.55	22.80	Positive	30.79	29.21	26.23	22.63	Positive
29	VITPAD29	30.26	29.42	25.78	Positive	36.43	34.07	32.71	23.75	Positive
30	VITPAD30	25.20	24.42	24.25	Positive	33.30	31.04	28.46	23.43	Positive
31	VITPAD31			28.23	Negative				23.68	Negative
32	VITPAD32			28.70	Negative				23.75	Negative
33	VITPAD33			27.88	Negative				24.00	Negative
34	VITPAD34			36.04	Negative				23.63	Negative
35	VITPAD35			21.86	Negative				25.32	Negative
36	VITPAD36			21.49	Negative				26.80	Negative
37	VITPAD37			22.20	Negative				25.71	Negative
38	VITPAD38			21.99	Negative				26.32	Negative
39	VITPAD39			21.86	Negative				25.59	Negative
40	VITPAD40			21.85	Negative				25.91	Negative
41	VITPAD41			21.72	Negative				25.25	Negative
42	VITPAD42			22.23	Negative				25.58	Negative
43	VITPAD43			22.67	Negative				26.94	Negative
44	VITPAD44			22.38	Negative				28.23	Negative

Continued

No	Sample name	SD Biosensor RT-PCR nCoV				Allplex™ 2019-nCoV				
		Ct ORF1ab	Ct E-gene	Ct IC	Interpretation	Ct RdRp	Ct N-gene	Ct E-Gene	Ct IC	Interpretation
45	VITPAD45			21.39	Negative				26.43	Negative
46	VITPAD46			21.71	Negative				26.27	Negative
47	VITPAD47			22.01	Negative				25.63	Negative
48	VITPAD48			20.44	Negative				25.80	Negative
49	VITPAD49			21.42	Negative				25.78	Negative
50	VITPAD50			21.96	Negative				26.24	Negative
51	VITPAD51			21.89	Negative				27.74	Negative
52	VITPAD52			21.95	Negative				26.36	Negative
53	VITPAD53			22.14	Negative				27.94	Negative
54	VITPAD54			21.76	Negative				25.61	Negative
55	VITPAD55			21.89	Negative				25.55	Negative