

Principle and clinical evaluation of Rapid diagnostic kits for COVID-19 IgM/IgG

2020 HEMA

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01. COVID-19

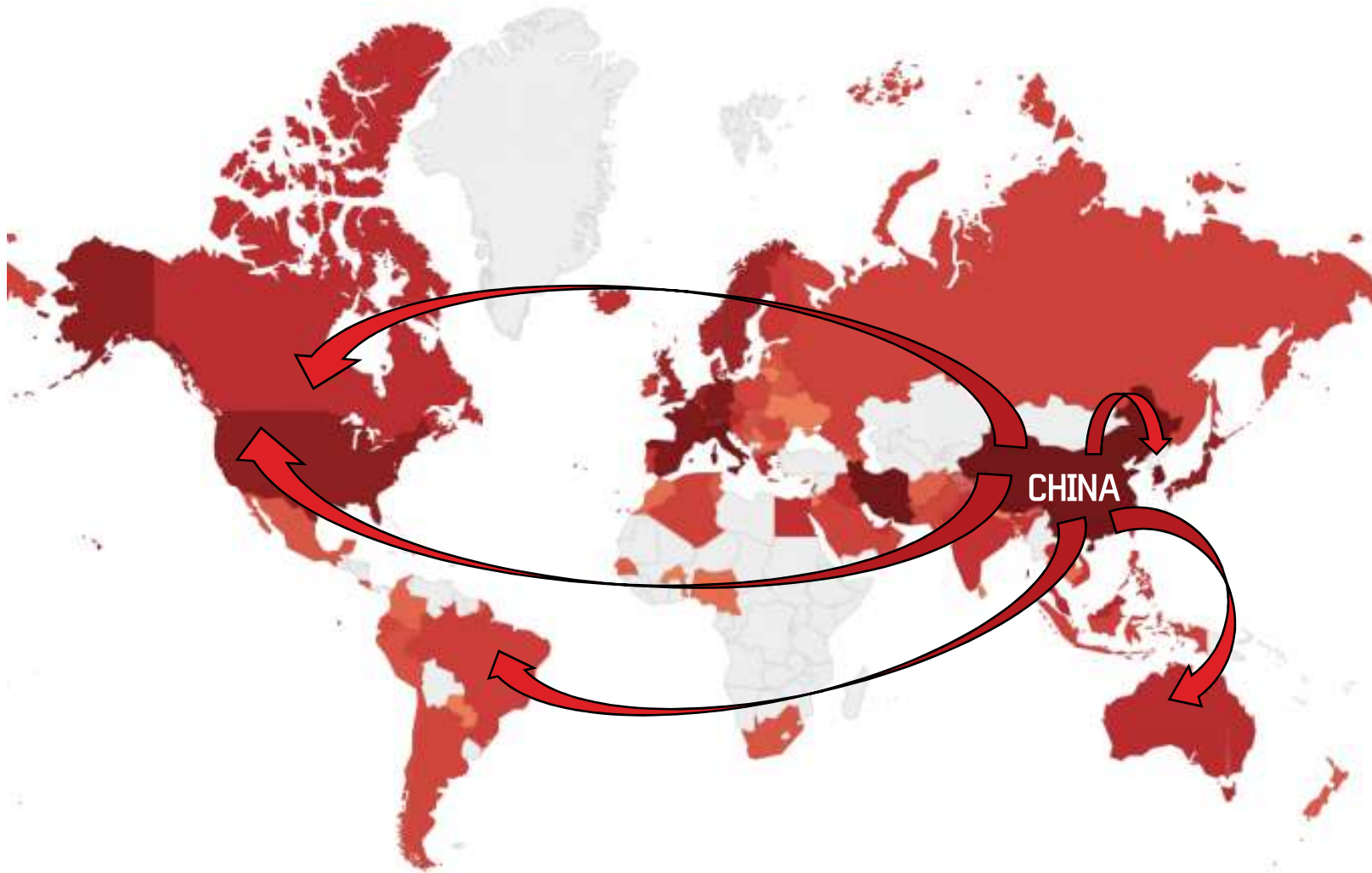


COVID-19 배경

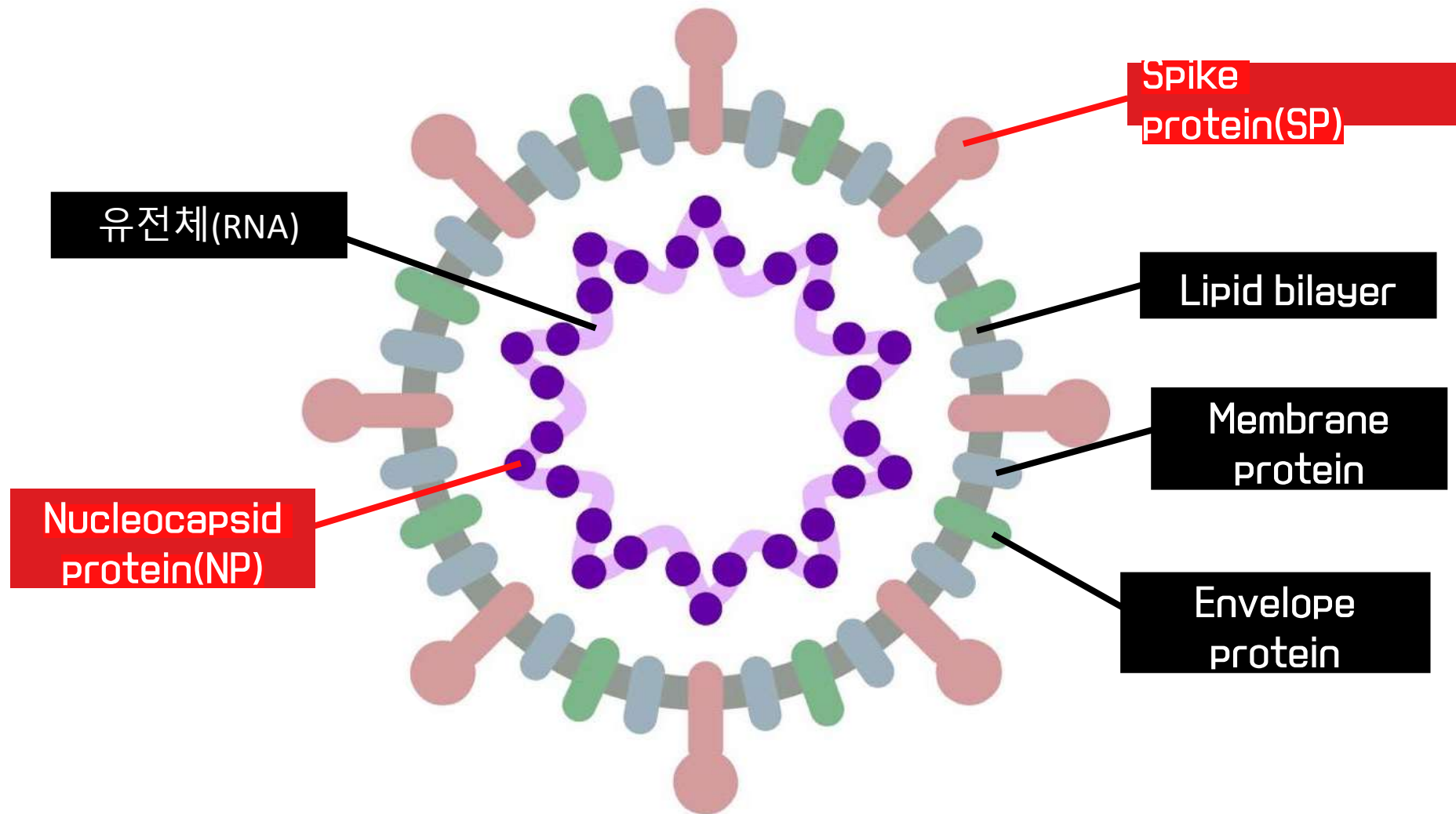
- 1 중국 후베이성 우한시에서 처음 발생
- 2 전파경로: 비말, 접촉을 통한 전파
- 3 증상: 발열, 기침 등 호흡기 감염증
- 4 백신, 치료제 없음

01. COVID-19

COVID-19 발생현황

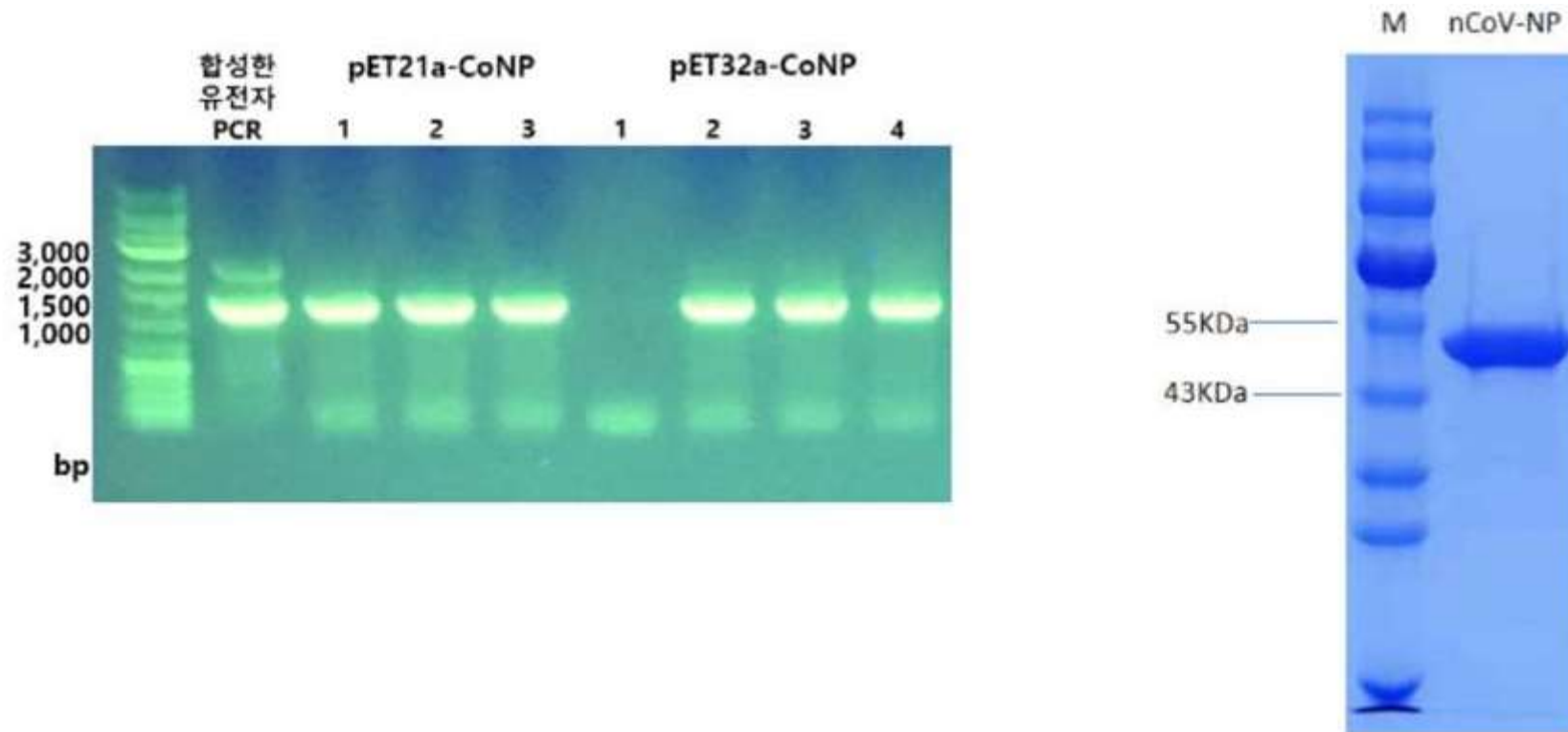


01. COVID-19



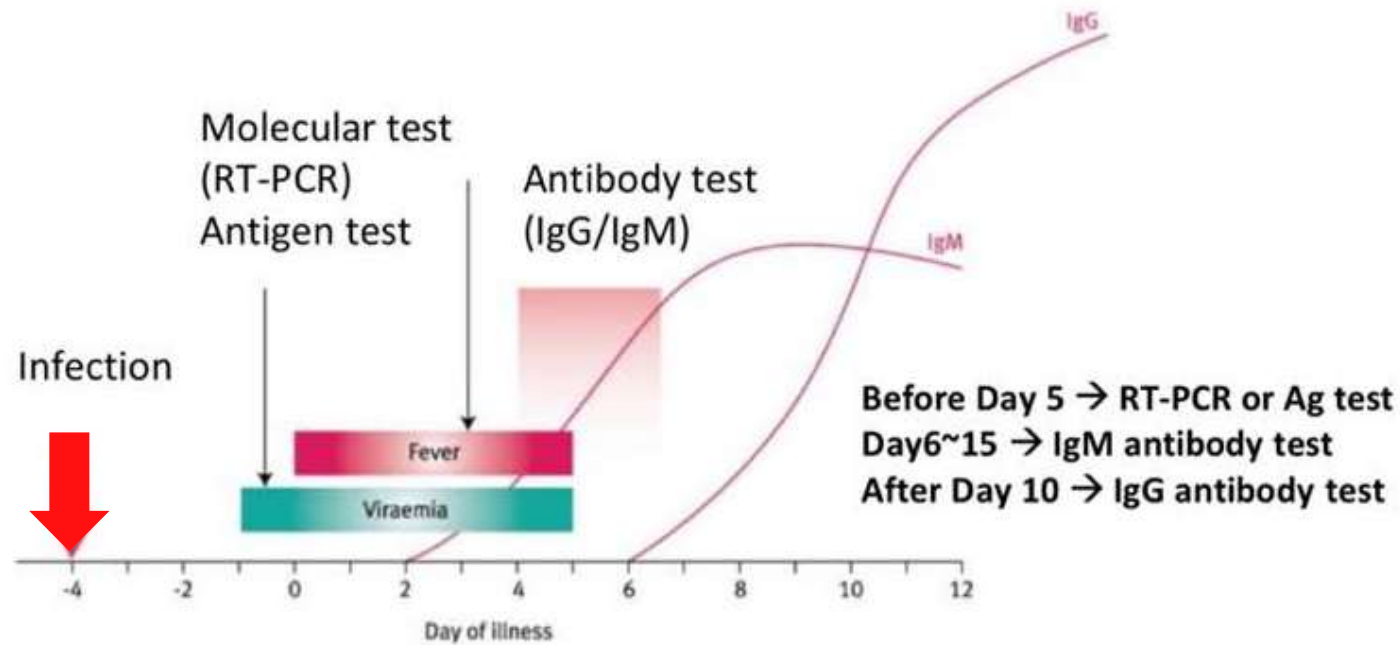
01. COVID-19

Preparation



Nucleoprotein(NP)와 target gene 추출을 위한 RT-PCR

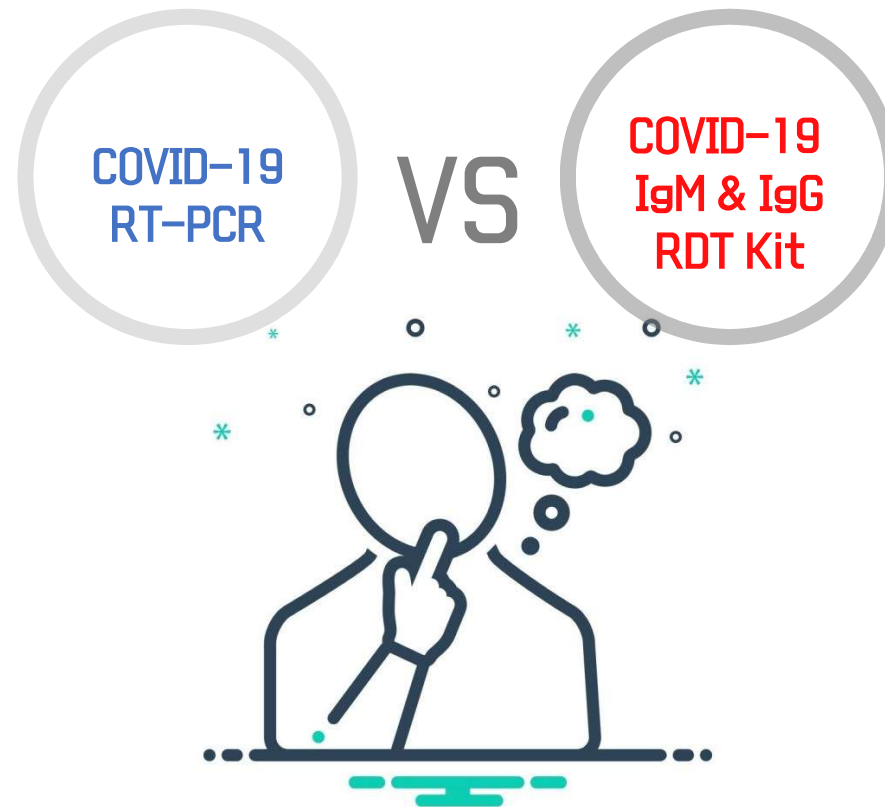
Immunity



COVID-19 면역

- 1 감염 후 3~4일 후 Antigen 검출
- 2 감염 후 4~9일 동안 발열반응
- 3 IgM: 2일부터 나타나며 6~15일에 최고치
IgG: 6일부터 나타나며 10일 쯤에 최고치

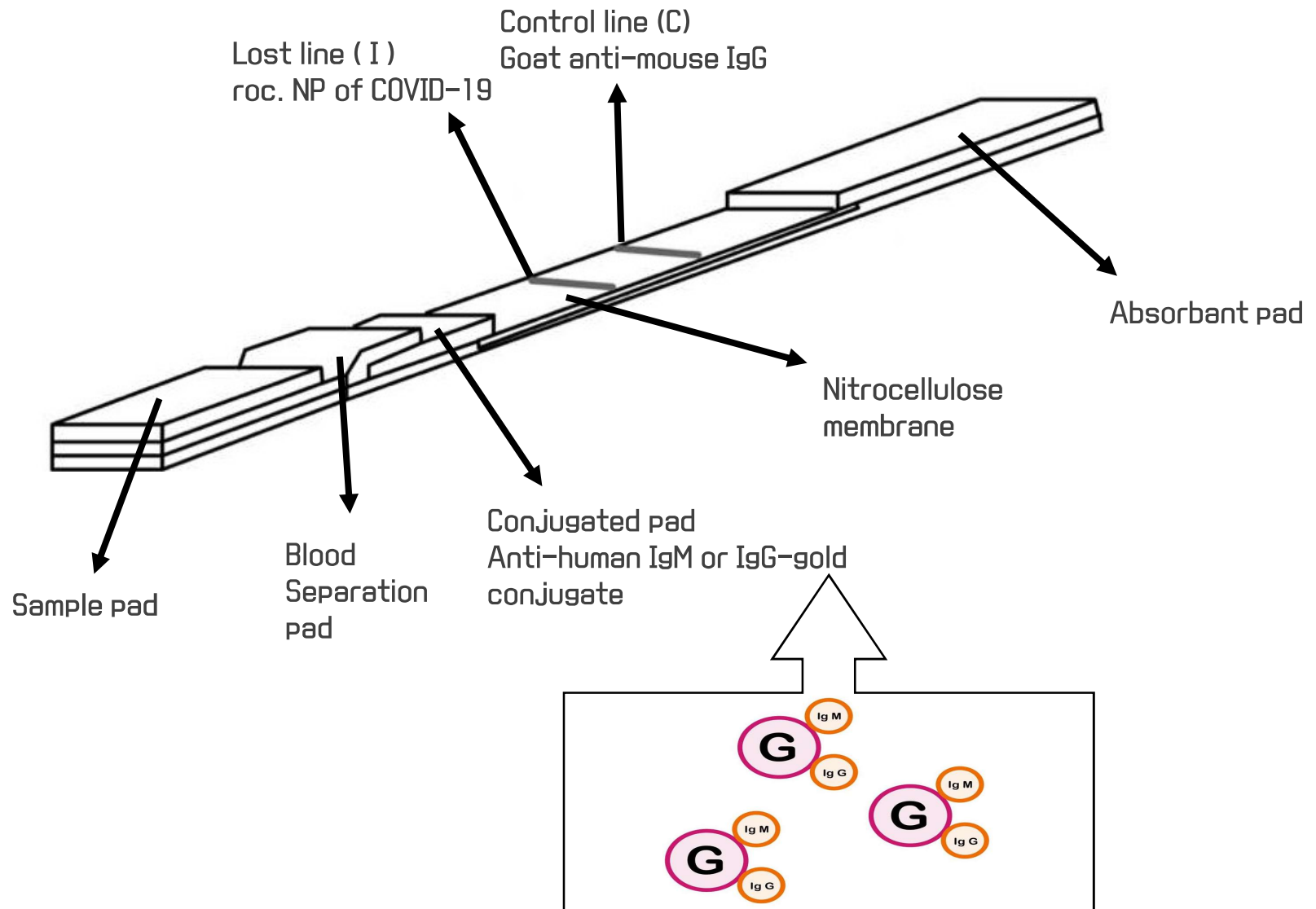
RDT(Rapid Diagnostic Test)



- 01. 소요시간 단축
- 02. 현장검사 용이
- 03. 간편한 검사법
- 04. 비용 감소

02. COVID-19 kit

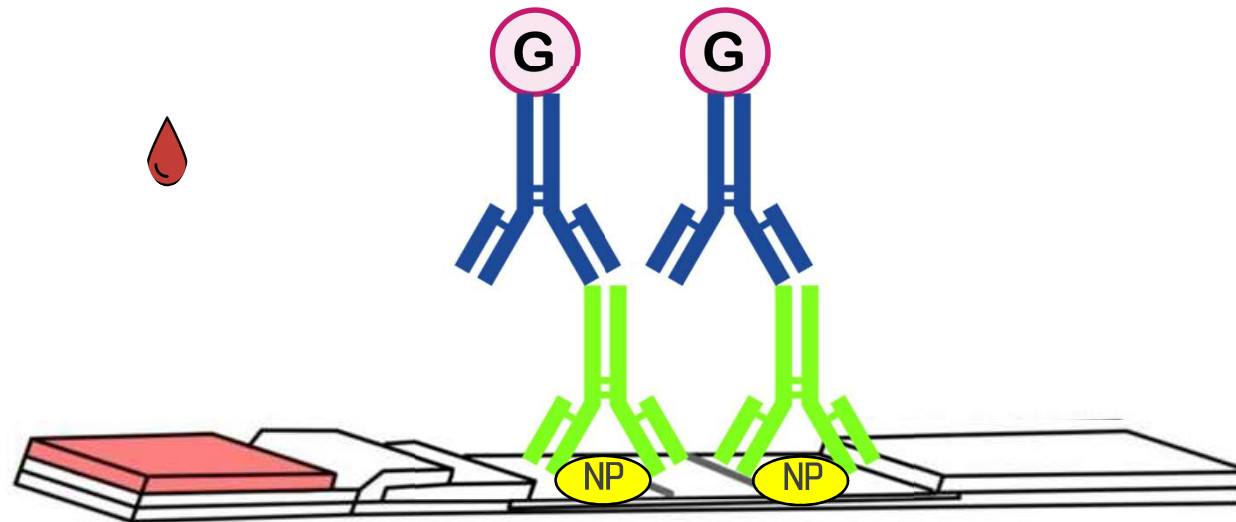
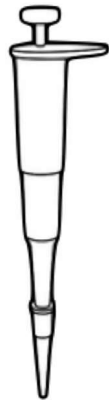
COVID-19 원리



02. COVID-19 kit



03. Principle & Methods



03. Principle & Methods



Add 10 μ l of serum/plasma or
Load 20 μ l of whole blood



Add 3 drops (~100 μ l)
of assay buffer

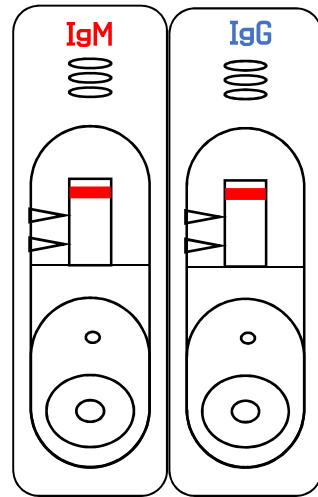


10 min

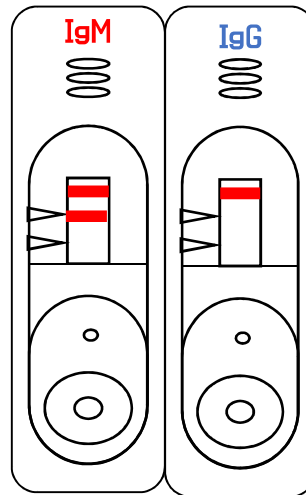


Reading

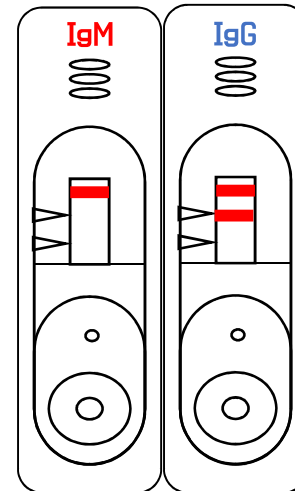
04. Results



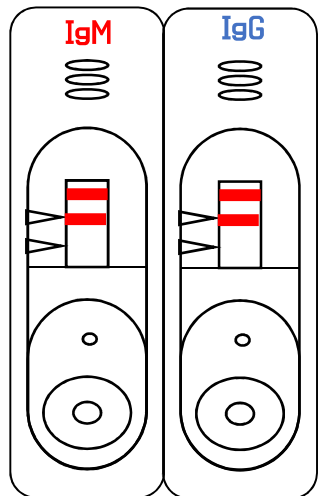
Negative



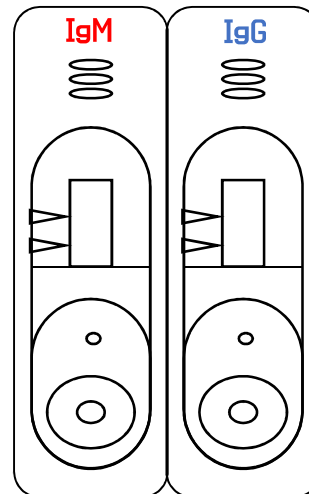
IgM
positive



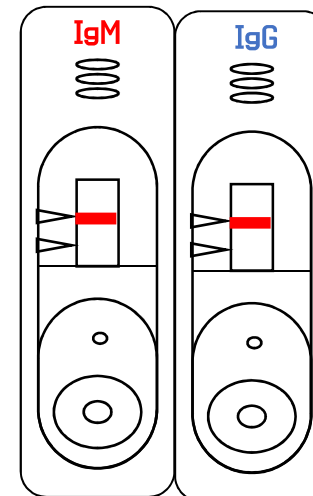
IgG
positive



IgM/IgG
positive



Invalid



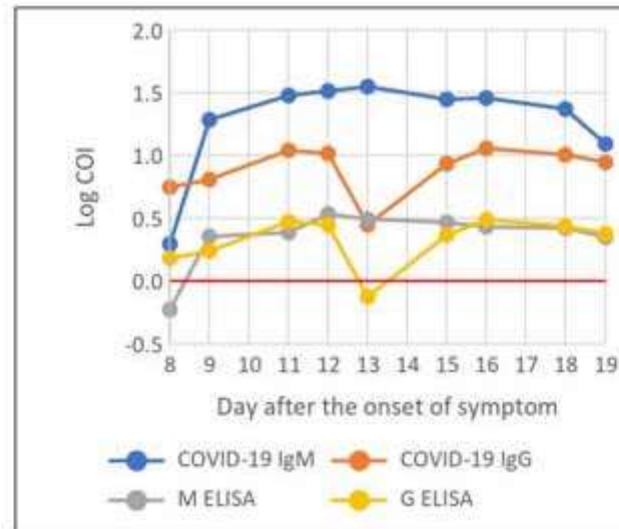
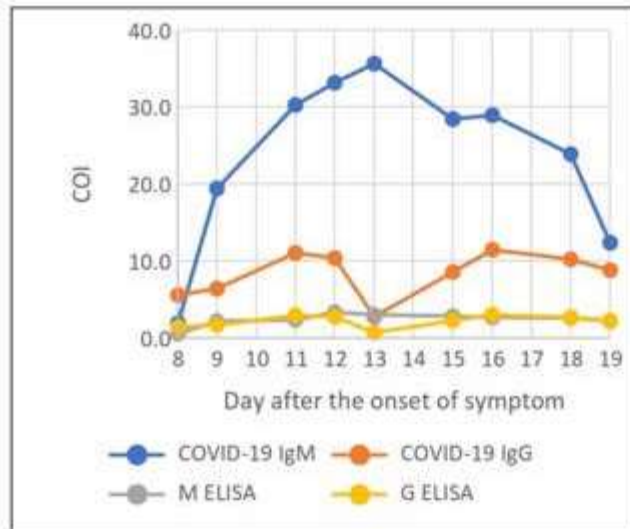
04. Results

Patient	Onset of symptom	Symptom	Date of Sampling
ID-XXX11	Feb. 24, 2020	Nasal congestion	Mar. 03 (sampling 1, sampling 2), 04, 06, 07, 08, 10, 11, 13, 14 – 9 samples
*Sampling at same day, the bloodling was performed at different time.			



Sample	2020-03-03		2020-03-04		2020-03-06		2020-03-07		2020-03-08		2020-03-10		2020-03-11		2020-03-13		2020-03-14	
Result	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Confiscscope G20	692,568	227,498	1,753,798	588,523	2,733,377	1,005,350	2,991,387	941,854	3,219,816	254,585	2,568,183	781,915	2,608,995	1,043,229	2,156,418	928,574	1,121,481	801,497
Raw data																		
ELISA (S/CO)	2.31	0.68	2.29	1.76	2.47	3.02	3.44	2.82	3.13	0.76	2.96	2.34	2.73	3.12	2.67	2.78	2.27	2.4

04. Results



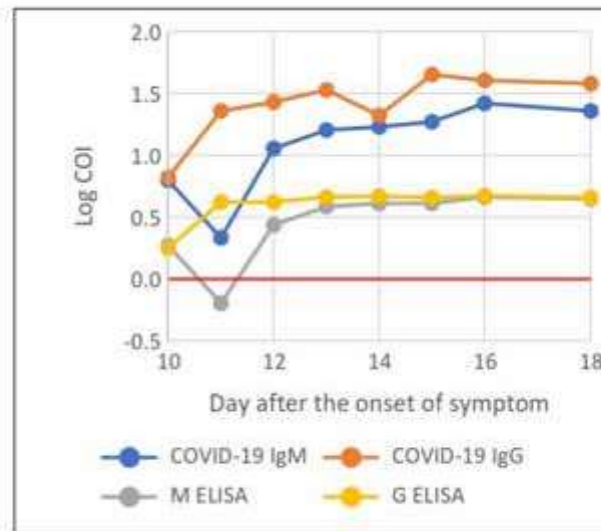
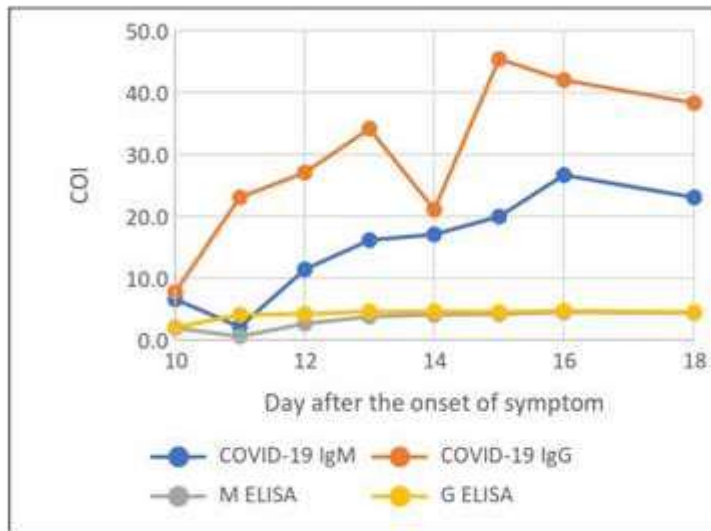
IRB No.: 202003026.
Period: Mar. 1, 2020 ~ Mar.
31, 2020.
ELISA (in house): s/CO
Band intensity: measured by
Confiscope G20
*COI, cutoff index

04. Results

Patient	Onset of symptom	Symptom	Date of Sampling
ID-XXX15	Mar. 01, 2020	Fever, cough	Mar, 11 (sampling 1, sampling 2, sampling 3), 12, 13,14,15,16(sampling 1, sampling 2), 17(sampling 1, sampling 2, sampling 3), 19 – 12 samples
*Sampling at same day, the blooding was performed at different time.			

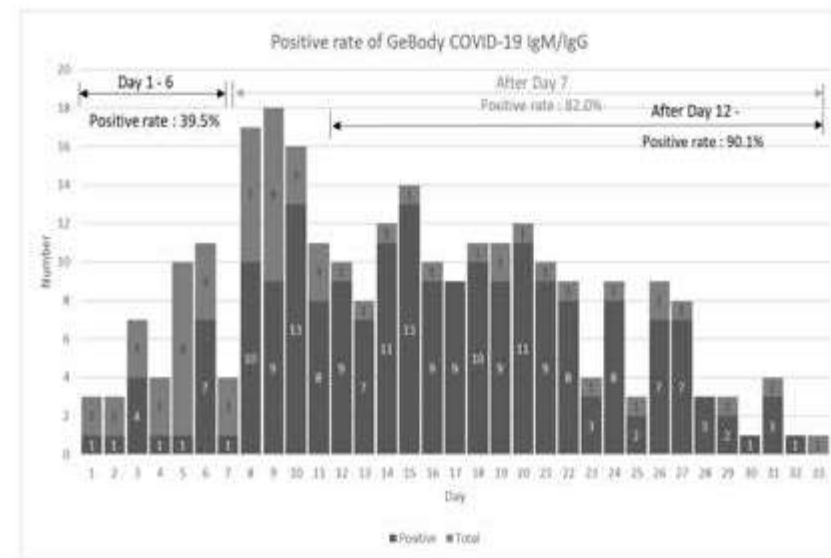
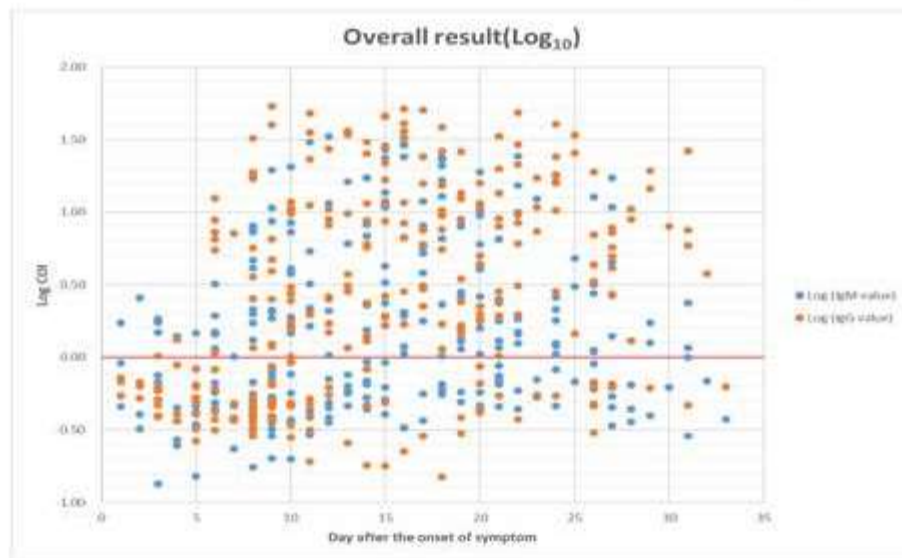
Sample result	2020-03-11(1)	2020-03-11(2)	2020-03-11(3)	2020-03-12	2020-03-13	2020-03-14	2020-03-15	2020-03-16(1)	2020-03-16(2)	2020-03-17(1)	2020-03-17(2)	2020-03-19												
Confiscate G20	655,366	936,251	718,728	950,036	368,965	246,545	195,441	2,081,137	1,815,130	2,445,731	1,460,743	3,089,387	1,546,642	1,907,032	2,418,757	4,106,909	1,190,445	4,093,522	2,649,952	4,655,336	2,166,324	2,928,624	2,090,084	1,458,473
ELISA (BICO)	2.18	2.80	2.53	2.86	1.22	0.74	0.64	6.22	2.75	6.24	3.89	6.66	6.13	6.72	5.42	6.62	3.18	6.60	6.69	6.80	4.58	6.70	6.47	6.58

04. Results



IRB No.: 202003026.
Period: Mar. 1, 2020 ~ Mar. 31, 2020.
ELISA (in house): s/CO
Band intensity: measured by
Confiscscope G20
*COI, cutoff index

04. Results



04. Results

N= 266		RT-PCR Positive at the first day of hospitalization			Total
GenBody COVID-19 IgM/IgG		Day 1 ~ 6	After Day 7	*After Day 12	
	Positive	15	187	146	266
	Negative	23	41	16	
Total		38	228	162	
Positive rate		39.5 %	82%	90.1%	

04. Results

Patient ID	Onset day	Symptom	Sampling date	Day after Symptom	Result of GenBody COVID-19 IgM/IgG	
					IgM	IgG
ID-XXX243	21-Mar-20	sore throat	24-Mar-20	3	Negative	Negative
ID-XXX122	24-Feb-20	fever	1-Mar-20	6	Positive	Positive
ID-XXX132	27-Feb-20	headache	4-Mar-20	6	Positive	Negative
ID-XXX142	25-Feb-20	sore throat	2-Mar-20	6	Negative	Negative
ID-XXX248	20-Mar-20	myalgia	26-Mar-20	6	Negative	Positive
ID-XXX165	1-Mar-20	fever	8-Mar-20	7	Negative	Negative
ID-XXX14	22-Feb-20	fever, chest X-ray	1-Mar-20	8	Positive	Positive
ID-XXX143	24-Feb-20	nasal congestion	3-Mar-20	8	Positive	Positive
ID-XXX195	29-Feb-20	rhinorrhea	8-Mar-20	8	Positive	Positive
ID-XXX09	20-Feb-20	Cough	29-Feb-20	9	Positive	Positive
ID-XXX111	24-Feb-20	fever	4-Mar-20	9	Negative	Positive
ID-XXX39	23-Feb-20	cough,fever	4-Mar-20	10	Negative	Positive
ID-XXX84	20-Feb-20	fever	1-Mar-20	10	Negative	Positive
ID-XXX139	22-Feb-20	sore throat	3-Mar-20	10	Positive	Negative
ID-XXX175	1-Mar-20	fever, cough	11-Mar-20	10	Positive	Positive
ID-XXX225	9-Mar-20	cough	19-Mar-20	10	Positive	Positive
ID-XXX162	23-Feb-20	sore throat	5-Mar-20	11	Negative	Negative
ID-XXX202	6-Mar-20	anosmia	17-Mar-20	11	Negative	Negative
ID-XXX67	21-Feb-20	cough	4-Mar-20	12	Negative	Positive
ID-XXX241	12-Mar-20	myalgia,fever	24-Mar-20	12	Positive	Positive
ID-XXX166	22-Feb-20	fever	7-Mar-20	14	Positive	Positive
ID-XXX196	28-Feb-20	cough	13-Mar-20	14	Positive	Negative
ID-XXX208	2-Mar-20	myalgia	16-Mar-20	14	Positive	Positive
ID-XXX204	28-Feb-20	cough	17-Mar-20	18	Positive	Positive
ID-XXX263	2-Mar-20	fever	21-Mar-20	19	Positive	Positive
ID-XXX233	28-Feb-20	cough	19-Mar-20	20	Positive	Positive
ID-XXX258	24-Feb-20	sore throat	19-Mar-20	24	Positive	Positive
ID-XXX217	21-Feb-20	myalgia	18-Mar-20	26	Positive	Negative
ID-XXX253	23-Feb-20	myalgia	20-Mar-20	26	Positive	Positive
ID-XXX249	19-Feb-20	fever	19-Mar-20	29	Positive	Positive



감사합니다

