



Declaration of Conformity



in accordance with Directive 98/79/EC

Manufacturer:

Name: HANGZHOU REALY TECH CO., LTD.

Address: 4th Floor, #12 Building, Eastern Medicine Town, Xiasha Economic & Technology Development, 310018 Hangzhou, Zhejiang, P. R. China

Product/s	Catalogue number
Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Device (saliva)	K590516D

Category: Other Devices (All devices except Annex II and self-testing devices)

Conformity assessment route: Annex III, except Point 6, of Directive

Applicable Standards: EN ISO 13485: 2016; EN ISO 15223-1:2016; EN ISO 14971: 2012; EN ISO 13612:2002; EN ISO 17511:2003; EN ISO 18113-1:2011; EN ISO 18113-2:2011, EN ISO 23640:2015.

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint Luxus Lebenswelt GmbH, located at Kochstr.1,47877, Willich, Germany to act as our European Authorised Representative as defined in the aforementioned Directive.

Hangzhou 2020.12.15

(Place and date of issue)

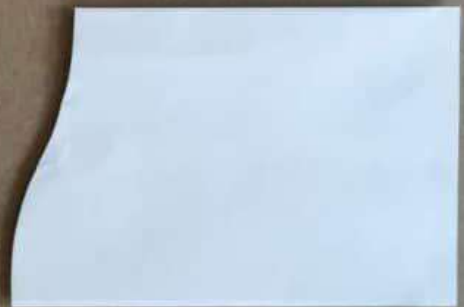
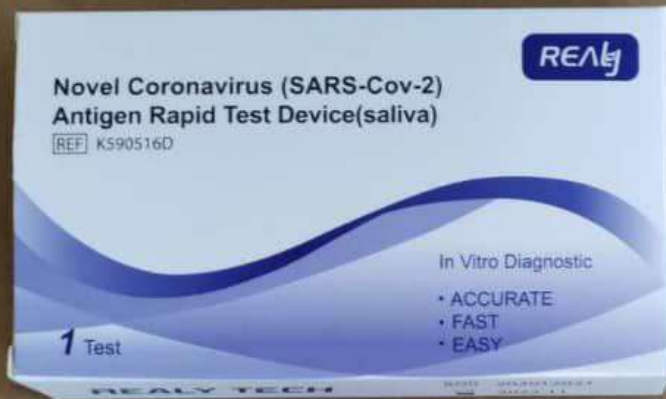


(Signature and position)

Signed for and on behalf of the manufacturer







Antigenní rychlostestovací zařízení (přes sliny) na nový koronavirus (SARS-CoV-2)

Příbalová informace

LOTES[®] NA KVALITATIVNÍ ZJIŠTĚNÍ ANTIGENŮ NOVÉHO KORONAVIRU V LIDSKÝCH SLINÁCH.

Pouze pro profesionální diagnostické použití *in vitro*.

URČENÉ POUŽITÍ

Antigenní rychlostestovací zařízení (přes sliny) na nový koronavirus (SARS-CoV-2) je *in vitro* diagnostický test na kvalitativní detekci antigenů nového koronavi ru v lidských slinách pomocí rychlé imunochromatografické metody. Identifikace je založena na monoklonálních protilátkách specifických pro antigen nového koronavirus. Poskytne klinickým lékařům informace o předepisování správných léků.

PŘEHLED

Nové koronavi ry patří do rodu řgenus. COVID-19 je akutní respirační infekční onemocnění. Lidé jsou obecně náchylní. V současnosti jsou hlavním zdrojem infekce pacienti infikováni novým koronavirem; asymptomatictí infikováni lidé mohou být také infekčním zdrojem. Na základě současného epidemiologického vyšetření je inkubační doba 1 až 14 dní, většinou 3 až 7 dní. Mezi hlavní projevy patří horečka, únava a suchý kašel. V několika případech se může vyskytnout ucpaní nosu, rýma, bolest v krku, myalgie a průjmy.

PRINCIP

Antigenní rychlostestovací zařízení (přes sliny) na nový koronavirus (SARS-CoV-2) je imunochromatografický membránový test, který využívá vysoce citlivé monoklonální protilátky proti novému koronaviru.

Testovací proužek se skládá ze tří částí, konkrétně ze vzorkové podložky, reagenční podložky a reakční membrány. Reagenční membrána obsahuje koloidní zlato konjugované s monoklonálními protilátkami proti novému koronaviru; reakční membrána obsahuje sekundární protilátky proti novému koronaviru a polyklonální protilátky myšího globulinu, které jsou předem imobilizované na membráně.

Když je testovací zařízení vloženo do vzorku slin, konjugáty vysušené v reagenční vložce se rozpustí a migrují spolu se vzorkem. Pokud je ve vzorku přítomen nový koronavirus, komplex vytvořený mezi konjugátem protilátek proti novému koronaviru a virům bude zachycen specifickým monoklonální proti novému koronaviru, kterým je potažena oblast T.

Bez ohledu na to, zda vzorek obsahuje virus nebo ne, roztok pokračuje v migraci a setkává se s dalším čidlem (protilátka proti myšího IgG), které se váže na zbývající konjugáty, čímž vytváří červenou čáru v oblasti C.

Produkty Antigenní rychlostestovací zařízení (přes sliny) na nový koronavirus (SARS-CoV-2) mohou rozpoznávat SARS-COV-2 nukleoprotein (hlavní) a spike protein.

Více než 90% protilátek použitých v Antigenní rychlostestovací zařízení (přes sliny) na nový koronavirus (SARS-CoV-2) je SARS-COV-2 antinukleoprotein a cílovým proteinem je SARS-COV-2 nukleoprotein.

Zbytek protilátek použitých v Antigenní rychlostestovací zařízení (přes sliny) na nový koronavirus (SARS-CoV-2) je anti-spike protein a cílový protein je konstantní fragment SARS-COV-2 spike proteinu. Ať už je to v současné době N501Y ve Velké Británii nebo 501Y.V2 v Jižní Africe, mutační fragment je primárně RBD fragment S proteinu, zatímco cílový fragment protilátky Antigenní rychlostestovací zařízení (přes sliny) na nový koronavirus (SARS-CoV-2) nemutoval. Proto může Antigenní rychlostestovací zařízení (přes sliny) na nový koronavirus (SARS-CoV-2) spolehlivě detekovat varianty SARS-COV-2.

Proto Antigenní rychlostestovací zařízení (přes sliny) na nový koronavirus (SARS-CoV-2) může spolehlivě rozpoznat nukleoprotein a špičkový protein mutací genu SARS-COV-2.

REAKCE

Reagenční membrána obsahuje koloidní zlato konjugované s monoklonálními protilátkami proti novému koronaviru; reakční membrána obsahuje sekundární protilátky proti novému koronaviru a polyklonální protilátky myšího globulinu, které jsou předem imobilizované na membráně.

UPOZORNĚNÍ

- Jen diagnostické použití *in vitro*.
- Nepoužívejte po uplynutí doby použitelnosti.
- Před otevřením před použitím zkontrolujte, zda není poškozeno fóliový sáček obsahující testovací zařízení.
- Proveďte test při pokojové teplotě 15 až 30 °C.
- Při zavěšování vzorků noste rukavice, nedotýkejte se membrány čidla a okénka vzorky.
- Všechny vzorky a použití příslušenství by měly být považovány za infekční a likvidovány v souladu s místními předpisy.
- Nepoužívejte krvavé vzorky.

SKLADOVÁNÍ A STABILITA

Antigenní rychlostestovací zařízení (přes sliny) na nový koronavirus (SARS-CoV-2) uchovávejte při pokojové teplotě nebo v chladu (2–30 °C). Chraňte před mrazem. Všechny čidla jsou stabilní až do data expirace vyznačeného na jejich vnějším obalu a lahvičce s pufrem.

ODEBRÁNÍ PŘÍPRAVA VZORKU

1. Odběr vzorků:

Vzorek orální tekutiny by se měl odebírat pomocí odběrových nástrojů dodaných se soupravou. Postupujte podle podrobných pokynů na použití uvedených níže. Při tomto testu by se neměly používat žádné další odběrové nástroje. Může se použít perorální tekutina shromážděná kdykoliv během dne.

2. Příprava vzorků:

Když jsou sliny odebrány, postupujte podle pokynů pro přípravu vzorku s pufrem dodaným se soupravou..

MATERIÁL

Dodaný materiál

- Testovací zařízení
- Příbalová informace
- Stojan na zkumavky *
- Plastový pytlík
- Tryska
- Pohárek / kapsa na odběr sliny
- Extrakční pufr
- Extrakční zkumavka
- Kapátko

* Balení s 20 testy obsahuje stojan na zkumavky, balení s 1 testem a 5 testy používá samotnou krabičku s testy jako stojan na zkumavky.

Potřebný materiál, který není součástí soupravy

- Časovač

NÁVOD K POUŽITÍ

Před testováním nechte testovací zařízení, vzorek a extrakční pufr ustálit na pokojovou teplotu (15–30 °C). 10 minut před odběrem vzorku orální tekutiny do úst nic nevkládějte, včetně jídel, nápojů, žvýkačky, tabáku, vody a výrobků na vyplachování úst.

1. Naplňte dostatek slin do pohárku/pytlíku na sliny.
2. Kapátkem odeberte sliny z pohárku, přeneste 4 kapky sliny do extrakční zkumavky.
3. Vyberte extrakční zkumavku a láhev s extrakčním pufrem, odstraňte uzávěr láhve s pufrem a do extrakční zkumavky přidejte všechen extrakční pufr.
4. Vyberte trysku a připevňte ji na extrakční zkumavku, jemně s ní kolmo protřepávejte asi 5 sekund, aby se sliny dobře promíchaly s extrakčním pufrem.
5. Použitý pohárek/pytlík přeložte na polovinu av souladu s místními předpisy zlikvidujte do plastového sáčku jako lékařský odpad



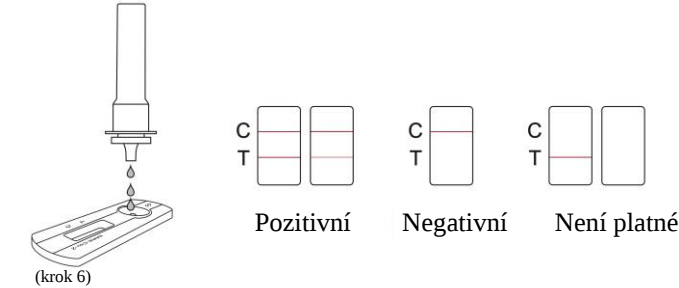
(krok 1)

(krok 2)

(krok 3)

(krok 4)

6. Vyberte testovací zařízení z uzavřeného fóliového pytlíku a použijte ho co nejdříve. Nejlepších výsledků dosáhnete, pokud se test uskuteční ihned po otevření fóliového pytlíku. Položte testovací zařízení na čistý a rovný povrch.
7. Přeneste vertikální 3 kapky vzorku do jamky na testovací zařízení a spusťte časovač.
8. Výsledek bude za 10 až 20 minut. Výsledek neinterpretujte po více než 20 minutách.



Pozitivní

Negativní

Není platné

INTERPRETACE VÝSLEDKŮ

(Viz obrázek výše)

POZITIVNÍ: Objeví se dvě červené čáry. Jedna červená čára se objeví v kontrolní oblasti (C) a jedna červená čára v testovací oblasti (T). Odstín barvy se může lišit, ale test by měl být považován za pozitivní vždy, když je přítomna i jen slabá čára.

NEGATIVNÍ: V kontrolní oblasti (C) se objeví pouze jedna červená čára a v testovací oblasti (T) žádná. Negativní výsledek naznačuje, že ve vzorku nejsou žádné částice nového koronavirus nebo počet virových částic je pod detekovatelným rozsahem.

NENÍ PLATNÉ: V kontrolní oblasti (C) se neobjeví žádná červená čára. Test je neplatný, i když je v testovací oblasti (T) čára. Nedostatečný objem vzorku nebo nesprávné procedurální techniky jsou nejpravděpodobnějšími důvody selhání kontrolní oblasti. Zkontrolujte postup testu a opakujte test s novým testovacím zařízením. Pokud problém přetrvává, ihned přestaňte testovací soupravu používat a kontaktujte místního distributora.

OMEZENÍ

• Antigenní rychlostestovací zařízení (přes sliny) na nový koronavirus (SARS-CoV-2) je screeningový test akutní fáze na kvalitativní detekci. Odebraný vzorek může obsahovat koncentraci antigenu pod prahem citlivosti čidla, takže negativní výsledek testu nevylučuje infekci novým koronavirem.

• Antigenní rychlostestovací zařízení (přes sliny) na nový koronavirus (SARS-CoV-2) detekuje životaschopný a životaneschopných antigen proti novému koronaviru. Výkon testu závisí na množství antigenu ve vzorku a nemusí korelovat s buněčnou kulturou provedenou na stejném vzorku. Pozitivní test nevylučuje možnost, že mohou být přítomny další patogeny, proto je pro přesnou diagnózu nutné porovnat výsledky se všemi ostatními dostupnými klinickými a laboratorními informacemi.

• Negativní výsledek testu se může vyskytnout, pokud je hladina extrahovaného antigenu ve vzorku nižší než citlivost testu nebo pokud je vzorek špatné kvality.

• Účinnost testu nebyla stanovena při monitorování antivirové léčby nového koronavi ru.

• Pozitivní výsledky testů nevylučují současnou infekci jinými patogeny.

• Negativní výsledky testů nejsou určeny k tomu, aby zjišťovali jinou koronavirovou infekci kromě SARS-CoV-2.

• Děti mají tendenci šířit virus déle než dospělí, což může vést k rozdílu v citlivosti mezi dospělými a dětmi.

• Koncentraci viru ve slinách velmi ovlivňují faktory jako jídlo, strava, kouření, osvěžovače dechu atd. Proto před odběrem vzorků důsledně dodržujte tento návod

Negativní výsledek může dojít, pokud je koncentrace antigenu ve vzorku pod detekčním limitem testu nebo pokud byl vzorek odebrán či příprava nesprávně, proto negativní výsledek testu nevylučuje možnost infekce SARS-CoV-2 a měl by se potvrdit virovou kultivací nebo PCR.

CHARAKTERISTIKY VÝKONNOSTI

Klinické hodnocení

Klinické hodnocení se uskutečnilo na srovnání výsledků získaných pomocí antigenního rychlostestovacího zařízení (přes sliny) na nový koronavirus (SARS-CoV-2) a PCR. Výsledky jsou shrnuty níže:

Antigenní rychlostestovací zařízení (přes sliny) na nový koronavirus (SARS-CoV-2) vs. PCR

Metoda	Souprava pro testování nukleových kyselin 2019-nCoV (RT-PCR)		Celkové výsledky
	Výsledky	Pozitivní	Negativní
Antigenní rychlostestovací zařízení (přes sliny) na nový koronavirus (SARS-CoV-2)	Pozitivní	157	1
	Negativní	12	235
Celkové výsledky	169	236	405

Klinická citlivost =157/169= 92,9 % (95 % CI *87,89 % až 96,00 %)

Klinická specifčnost = 235/236=99,58% (95 % CI * 97,39 % až >99,99 %)

Přesnost: (157+235) / (157+1+12+235) *100%=96,79% (95 % CI *94,53 % až 98,17 %)

Interval spolehlivosti

limit detekce	
Kmen 2019-nCoV testován	Produkt Reallly Tech
Koncentrace 2019-nCoV1 X 10 ³ TCID ₅₀ / mL	1 X 10 ³ TCID ₅₀ / ml
naředění	1: 100 1: 1000 1: 1000 1: 200 1: 400 1: 400 1: 800 1:1600
Testovaná koncentrace v zředění (TCID ₅₀ / ml)	1x10 ³ 5x10 ² 2,5x 10 ² 1,25X10 ² 5.
Míry 20 replikací blízko cut-off	100 (20/20) 100 (20/20) 100 (20/20) 95 (19/20) 10 (2/20)
Limit detekce (LOD) na kmen viru	1,25 X 10 ² TCID ₅₀ / ml

křížová reakce

Výsledky zkoušky jsou pod odpovídající koncentraci látek v tabulce níže, což nemá žádný vliv na negativní a pozitivní výsledky zkoušek tohoto čidla a nedochází k křížové reakci.

Virus / Bakterie / Parazit	Kmen	Koncentrace
MERS-koronavirus	Neuvedeno	72 mikrogramů / ml
adenovirus	Typ 1	1,5 x 10 ⁶ TCID ₅₀ / ml
	Typ 3	7,5 x 10 ⁶ TCID ₅₀ / ml
	Typ 5	4,5 x 10 ⁶ TCID ₅₀ / ml
	Typ 7?	1,0 x 10 ⁶ TCID ₅₀ / ml
	typ 8	1,0 x 10 ⁶ TCID ₅₀ / ml
	Typ 11	2,5 x 10 ⁶ TCID ₅₀ / ml
	Typ 18	2,5 x 10 ⁶ TCID ₅₀ / ml
	Typ 23	6,0 x 10 ⁶ TCID ₅₀ / ml
In fl uenza A	Typ 55	1,5 x 10 ⁶ TCID ₅₀ / ml
	H1N1 Denver	3,0 x 10 ⁸ TCID ₅₀ / ml
	H1N1 WS / 33	2,0 x 10 ⁸ TCID ₅₀ / ml
	H1N1 A / Mě / 302/54	1,5 x 10 ⁸ TCID ₅₀ / ml
	H1N1 Nová Kaledonie	7,6 x 10 ⁸ TCID ₅₀ / ml
	H3N2 A / Hong Kong / 8/68	4,6 x 10 ⁸ TCID ₅₀ / ml
In fl Enza B	Nevada / 03/2011	1,5 x 10 ⁸ TCID ₅₀ / ml
	B / Lee / 40	8,5 x 10 ⁸ TCID ₅₀ / ml
	B / Taiwan / 2/62	4,0 x 10 ⁸ TCID ₅₀ / ml
Respirační syncytiální virus	Neuvedeno	2,5 x 10 ⁶ TCID ₅₀ / ml
Legionella pneumophila	Bloomington-2	1 x 10 ⁵ PFU / ml
	Los Angeles-1	1 x 10 ⁵ PFU / ml
	82A3105	1 x 10 ⁵ PFU / ml
Rhinovirus A16	Neuvedeno	1,5 x 10 ⁶ TCID ₅₀ / ml
Mycobacterium tuberculosis	K	1 x 10 ⁵ PFU / ml
	Erdman	1 x 10 ⁵ PFU / ml
	HN878	1 x 10 ⁵ PFU / ml
	CDC1551	1 x 10 ⁵ PFU / ml
	H37Rv	1 x 10 ⁵ PFU / ml
Streptokoková pneumonie	4752-98 [Maryland (D1) 6B-17]	1 x 10 ⁵ PFU / ml
	178 [Polsko 23F-16]	1 x 10 ⁵ PFU / ml
	262 [CIP 104340]	1 x 10 ⁵ PFU / ml
	Slovensko 14-10 [29055]	1 x 10 ⁵ PFU / ml
Streptococcus pyrogens	Typický kmen T1 [NCIB 11841, SF 130]	1 x 10 ⁵ PFU / ml
Mycoplasma pneumoniae	mutant 22	1 x 10 ⁵ PFU / ml
	FH kmen Eaton Agent [NCITC 10119]	1 x 10 ⁵ PFU / ml
	36M129-B7	1 x 10 ⁵ PFU / ml
Koronavirus	229E	1,5 x10 ⁶ TCID ₅₀ / ml
	OC43	1,5 x10 ⁶ TCID ₅₀ / ml
	NL63	1,5 x 10 ⁶ TCID ₅₀ / ml
	HKU1	1,5 x 10 ⁶ TCID ₅₀ / ml

Lidský etapneumovirus (hmpv) 3, typ B1	Peru2-2002	1,5 x 10 ⁶ TCID ₅₀ / ml
Lidský metapneumovirus (hmpv) 16, typ A1	IA10-2003	1,5 x 10 ⁶ TCID ₅₀ / ml
Virus parachřipky	Typ 1	7,5 x 10 ⁶ TCID ₅₀ / ml
	Typ 2	4,5 x 10 ⁶ TCID ₅₀ / ml
	Typ 3	1,0 x 10 ⁶ TCID ₅₀ / ml
	Typ 4A	1,0 x 10 ⁶ TCID ₅₀ / ml

Reakce rušivých látek

Při testování s použitím nového koronavirového (SARS-CoV-2) antigenního rychlého testovacího zařízení (sliny) nedošlo k žádným interferencím mezi reagensními zařízení a potenciálními interferenčními látkami uvedenými v tabulce níže, což by způsobilo falešně pozitivní nebo negativní výsledky pro SARS-CoV. -2 antigen.

Látka	Koncentrace	Látka	Koncentrace
Mucin	100µg/mL	Kyselina acetylsalicylová	3,0 mM
Plná krev	5% (v/v)	Ibuprofen	2,5 mM
Biotin	100µg/mL	Mupirocin	10 mg/mL
Neosynefrin (fenylefrin)	5%(v/v)	Tobramycin	10µg/mL
Afrin nosní sprej (oxymetazolin)	5%(v/v)	Erytromycin	50uM
Solný nosní sprej	5%(v/v)	Ciprofloxacin	50uM
Homeopatie	5%(v/v)	Ceftriaxon	110mg/mL
Kromoglykát sodný	10 mg/mL	Meropenem	3.7µg/mL
Olopatadin hydrochlorid	10 mg/mL	Tobramycin	100µg/mL
Zanamivir	5 mg/mL	Histamin hydrochlorid	100µg/mL
Oseltamivir	10 mg/mL	Peramivir	1mmol/mL
Artemeter / lumefantrin	50uM	Flunisolid	100µg/mL
Doxycyklin hyklát	50uM	Budesonid	0,64nmol/ L
Chinin	150uM	fFutikazón	0,3ng/mL
Lamivudin	1 mg/mL		6µg/mL
		Lopinavir	
Ribavirin	1 mg/mL	Ritonavir	8,2mg/mL
Daclatasvir	1 mg/mL	Abidor	1mmol/mL
Acetaminofen	150uM	Shromážděné nosní stěry u lidí	Neuvedeno

SYMBOL			
Značka	Význam	Značka	Význam
	Diagnostická zdravotnický prostředek in vitro		Limit skladovací teploty
	Výrobce		Autorizovaný zástupce pro Evropské společenství
	Datum výroby		Datum spotřeby
	Nepoužívejte opakovaně		Přečtěte si návod k použití
	Kód šarže		Splňuje požadavky směrnice ES 98/79 / ES



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Číslo: 1100003201
Verze: 1.5
Datum účinnosti: 22. 1. 2021



Clinical Validation report of Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test device (saliva)

Product name: Novel Coronavirus (SARS-Cov-2) Antigen Rapid
Test device (saliva)

Package Specification: 20 tests/kit

Manufacturer: Hangzhou Realy Tech Co., Ltd

I. Clinical validation time

This clinical evaluation was conducted from October 2020 to November,2020.

II. Background information for clinical evaluation

Since December 2019, world has successively discovered multiple cases of patients with new-type coronavirus pneumonia. With the spread of the epidemic, China and abroad have also been found. As an acute respiratory infectious disease, the disease has been included in the Class B infectious diseases stipulated in the Law of the People's Republic of China on the Prevention and Control of Infectious Diseases, and is managed as a Class A infectious disease. Based on the current epidemiological investigation, the incubation period is 1-14 days, mostly 3-7 days.

The main manifestations are fever, dry cough, and fatigue. A few patients have symptoms such as nasal congestion, runny nose, sore throat, myalgia and diarrhea. Severe patients usually have dyspnea and / or hypoxemia one week after the onset of symptoms, and severe patients can quickly progress to acute respiratory distress syndrome, septic shock, difficult to correct metabolic acidosis, coagulation dysfunction and multiple organ Functional failure, etc. It is worth noting that in the course of severe and critically ill patients, there may be moderate to low fever, even without obvious fever.

Mild patients showed only low fever, mild fatigue, and no pneumonia. Judging from the current cases, most patients have a good prognosis, and a few patients are critically ill. The elderly and those with chronic underlying disease have a better prognosis. Symptoms in children are relatively mild.

The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test device (saliva) developed by our company can help diagnose whether patients are infected with the Novel Coronavirus. It has further enriched the detection methods of Novel Coronavirus, expanded the supply of detection reagents, and fully served the needs of epidemic prevention and control.

III. Test purposes

The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test device (saliva) produced by Hangzhou Realy Technology Co., Ltd. was used to verify the feasibility of clinical evaluation and the reliability of test results for Chinese subjects.

The purpose of research of the clinical test is to calculate the consistency percentage of negative/positive and the total consistency percentage and Kappa coefficient by statistically analyzing test results through comparative experimental research.

IV. Test design

1. Test plan selection and reasons

In vitro diagnostic reagents for testing and reference reagents were used to conduct comparative research tests on clinically suspected Novel Coronavirus saliva samples, and it was proved that the in vitro diagnostic reagents used in the test can achieve the expected assistance in infection of the Novel Coronavirus.

2. Sample volume required

The total number of clinical trials of this product is not less than 100 cases. The samples is classified into the positive group and the negative group as per the test results of the reference product. Meanwhile, the (unfrozen) nasopharyngeal swab samples shall be tested via the RT-PCR from the same patient at same time , then the saliva sample test results of the product tested and the

nasopharyngeal swab sample RT-PCR test results shall be compared, with statistical analysis being made.

3. Sample inclusion/exclusion certification.

The positive group and negative group in this experiment are applicable to the following inclusion/exclusion criteria.

Positive group inclusion:

PCR Test is positive;
symptoms are clinically positive;

Negative inclusion:

PCR test is negative;

Sample collection, processing

It is applicable to the diagnosis of the Novel coronavirus from the samples of saliva. Use freshly collected samples for optimal test performance. Inadequate sample collection or improper sample handling may yield a false-negative result.

Sample collection procedure: The oral fluid specimen should be collected using the saliva collect cup provided with the kit. Follow the detailed Directions for Use refer to product IFU. No other collection cup should be used with this assay. Oral fluid collected at any time of the day may be used. **NOTE: Do not place anything in the mouth including food, drink, gum, tobacco, water and mouthwash products for at least 10 minutes prior to collection of oral fluid specimen.**

Specimen preparation:

When the saliva is collected, follow the direction to prepare the specimen with buffer provided with the kit.

4. In vitro diagnostic reagents and reference products for testing

5.1 Test in vitro diagnostic reagents

Name: Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test device (saliva)

Specification: 20 tests/kit

LOT: 202010001

Expiry: October, 2022 (Tentative)

Storage Conditions: Store in a dry place at 2-30°C, protected from light. After opening the inner package, the test card will become invalid due to moisture absorption. Please use it within 1 hour.

Source: Hangzhou Realy Tech Co., Ltd

5.2 Reference products

Name: Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing)

Manufacturer: Sansure Biotech Inc.

Storage Conditions: Store in a dry place at 2-8°C, protected from light.

V. Experiment method

Allow the test device, specimen, extraction buffer to equilibrate to room temperature (15-30°C) prior to testing. Do not place anything in the mouth including food, drink, gum, tobacco, water and mouthwash products for at least 10 minutes prior to collection of oral fluid specimen.

1. Spit enough saliva into the saliva collect cup/bag.

2. Draw the saliva from the cup with a dropper, transfer 4 drops of saliva to the extraction tube.
 3. Take out an extraction tube and a bottle of extraction buffer, remove the extraction buffer bottle cap, add all the extraction buffer into the extraction tube.
 4. Take out a nozzle and close into the extraction tube, gently shake the extraction tube vertically for about 5 seconds to allow saliva mix well with extraction buffer.
 5. Fold the used cup/bag in half and discard it into the plastic bag as medical waste in accordance with local regulations
- Note: The detection steps need to be completed under protection against infection.

VI. Statistical methods of statistical analysis of clinical research data

A Methods evaluating clinical performance

Whether various indexes can reach the standards of clinical evaluation shall be judged by calculating the consistency percentage of negative/positive and the total consistency percentage in the test results of the product tested and the reference product, to validate the accuracy and applicability of the product in clinical applications. The product tested shall be subject to tests through the sample of different types, with statistics on the results. Meanwhile, different types of sample of the subjects shall be subject to determination by the product tested synchronously, and then the determination results of both shall be compared. The test results recorded shall be subject to statistical analysis upon completion of determination of all clinical samples, to calculate the consistency percentage of negative/positive and the total consistency percentage. Afterwards, equivalence of both shall be evaluated as per these statistical indexes

B Statistical method

The products launched on the market shall be subject to comparative study and evaluation. Kappa inspection: each sample shall be tested with the product tested and the reference product respectively, and then the consistency in statistical results of these two inspection methods shall be compared through Kappa inspection.

The data shall be subject to Kappa inspection and analysis and the Kappa coefficient shall be calculated. Favorable consistency can be proven if Kappa is > 0.8 . The consistency in test results of the product tested and the reference product is evaluated as per the evaluation standards.

VII Standards of clinical evaluation

The coincidence rate shall be calculated by comparing with the reference product whose marketing is approved. The product performance shall meet the following requirements.

- 1) Coincidence rate of negative: the sample whose test results are negative for both the product tested and the reference product and the proportion in the sample whose test results are negative for the reference product shall be more than 95%.
- 2) Coincidence rate of positive: the sample whose test results are positive for both the product tested and the reference product and the proportion in the sample whose test results are positive for the reference product shall be more than 85%.
- 3) Total coincidence rate: the sample whose test results are the same for the product tested and the

reference product and its proportion in the total number of samples shall be more than 90%.

Method		2019-nCoV nucleic acid test kit (RT-PCR)		Total Results
The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test device (saliva)	Result	positive	negative	
	positive	A	B	A+B
	negative	C	D	C+D
Total Results		A+C	B+D	A+B+C+D

Clinical sensitivity = $A/(A+C)*100\%$

Clinical specificity = $D/(B+D)*100\%$

Accuracy: $(A+D)/(A+B+C+D)*100\%$

If the coincidence rate of positive/negative can meet clinical requirements, two methods or Products are considered as equivalent; If the coincidence rate of positive/negative is greatly different, the clinical scheme should be re-designed.

4)Kappa consistency analysis shall be adopted for statistical analysis of reference reagents.

The results of the product tested are statistical materials and can be per the table below:

Method		2019-nCoV nucleic acid test kit (RT-PCR)		Total Results
The Novel Coronavirus (SARS- Cov-2) Antigen Rapid Test device (saliva)	Result	positive	negative	
	positive	A	B	A+B
	negative	C	D	C+D
Total Results		A+C	B+D	A+B+C+D

$P_0 = (A+D)/(A+B+C+D)*100\%$

$P_e = ((A+B)(A+C) + (A+B)(B+D)) / (A+B+C+D)^2$

Kappa: $(P_0 - P_e)/(1 - P_e)$

If conducting Kappa consistency analysis for the base data above, high consistency can be judged if the Kappa coefficient is >0.8 , and both systems are considered as equivalent. Consistency is considered if $0.4 < \text{Kappa coefficient} < 0.8$, and the coincidence rate of positive/negative shall be compared, with statistical analysis being made. Two such systems are considered as inconsistent and in-equivalent if the Kappa coefficient is <0.4 .

VIII Provisions for amendments to clinical validation

In general, the clinical validation should not be changed. Any modification to the project during the test should be explained, and the time, reason, process of change, and whether there is a record of the change are explained in detail and its impact on the evaluation of the entire research result is explained.

IX. Results and Analysis of Clinical Tests

In total, 405 patients' samples are included for the unit, all the saliva samples and nasopharyngeal swab samples are tested. Statistics on rapid test results and those of the RT-PCR tested are as follows:

Method		2019-nCoV Nucleic Acid Test Kit (RT-PCR)		Total Results
The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test device (saliva)	Results	Positive	Negative	
	Positive	157	1	158
	Negative	12	235	247
Total Results		169	236	405

Clinical sensitivity = $157/169 = 92.9\%$ (95%CI*:87.89% to 96.00%)

Clinical specificity = $235/236 = 99.58\%$ (95%CI*:97.39% to >99.99%)

Accuracy: $(157+235)/(157+1+12+235) * 100\% = 96.79\%$ (95%CI* 94.53% to 98.17%)

$P_e = (158*169+158*236)/(405*405) = 0.39$

Kappa: $(P_0 - P_e)/(1 - P_e) = 0.95$

*:95% confidence interval

According to the above table, 235 are proven negative of 236 negative specimens, 157 are proven positive of 169 positive specimens. The sensitivity and accuracy are more than 90%, indicating favorable consistency with the reference product. The Kappa=0.95>0.8, indicating favorable and high consistency of two methods and equivalence of two such systems.

X Analysis on Inconsistency in Test Results

NO.	Age	Gender	Rapid Test	RT-PCR	Clinical diagnostic
5	21	F	Negative	Positive (RdRP gene)	Infection 6 days
14	39	F	Negative	Positive (N gene)	Infection 6 days
25	43	F	Negative	Positive (N gene)	Infection 7 days
37	36	M	Negative	Positive (N gene)	Infection 6 days
49	30	M	Negative	Positive (RdRP gene)	Infection 6 days
66	58	F	Negative	Positive (N gene)	Infection 7 days
78	43	F	Negative	Positive (N gene)	Infection 7 days
96	55	M	Negative	Positive (N gene)	Infection 7 days
125	49	F	Negative	Positive (N gene)	Infection 6 days
134	36	F	Negative	Positive (RdRP gene)	Infection 7 days
144	22	M	Negative	Positive (N gene)	Infection 6 days
163	68	M	Negative	Positive (N gene)	Infection 7 days
284	32	M	Positive	Negative(Ct/Cq) >40	Infection 7 days

XI Discussion and Conclusions

1. discussion

A Results of comparative analysis of the product tested and the reference product:

Test results of saliva specimen tested and the reference result: both the coincidence rate of negative/positive and the total coincidence rate are larger than 85%, indicating favorable consistency with the reference product. In the analysis results of Kappa inspection, Kappa was proven >0.8, indicating favorable and high consistency of both methods. Both systems were proven equivalent.

2. Test conclusions

By analyzing the test results of the product tested and the reference product, the consistency percentage of negative/positive and the total consistency percentage are proven high. Moreover, according to the results of statistical analysis, there is no remarkable difference in test results of both, indicating favorable consistency in diagnosis and equivalence of two such systems and can be used for auxiliary diagnosis of those suffering from pneumonia triggered by COVID-19.

X. Quality control methods

On-site quality control

1) During the course of this study, clinical implementors appointed clinical inspectors to conduct regular on-site supervision visits to the research hospital. Through monitoring visits, it was found that all the contents of the research plan were strictly observed, and the correctness of the research data was also guaranteed. Participating researchers have undergone unified training, unified recording methods and judgment standards. The entire clinical trial process is conducted under strict operation, and the test content is complete and authentic. All observations and findings in the clinical trials have been verified and the data are reliable. The conclusions in the clinical trials are derived from the original data.

2) Quality control of clinical experiment process

During the evaluation, quality control was performed daily to ensure that the product was under control. Strict quality control is performed for each trial to ensure the quality of clinical trials.

XI. Prediction of adverse events

Because the Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test device (saliva) is an in vitro diagnostic reagent product, no direct contact with patients is required in clinical trials, no test report is provided to patients, and the test results are only used for comparative studies. It involves personal privacy, does not serve as a basis for auxiliary diagnosis, does not bring any risk to the subject, and does not cause adverse events.

Annex I : Package Insert

**Novel Coronavirus (SARS-Cov-2) Antigen Rapid
Test Device (saliva)
Package Insert**

A RAPID TEST FOR THE QUALITATIVE DETECTION OF NOVEL CORONAVIRUS

ANTIGENS IN HUMAN SALIVA
For professional in vitro diagnostic use only.

INTENDED USE
The Novel Coronavirus (SARS-CoV-2) Antigen Rapid Test Device (saliva) is an *in vitro* diagnostic device for the qualitative detection of novel coronavirus antigens in human saliva, using the immunochromatographic method. The identification is based on the monoclonal antibodies specific for the novel coronavirus antigen. It will provide information for clinical doctors to prescribe correct medications.

SUMMARY

The novel coronaviruses belong to the β genus COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Small vesicular lesions, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

PRINCIPLES

[illegible]

producing a red line on the region C.

[illegible]

the nucleoprotein and spike protein of genetic sub-

The reagent membrane contains the colloidal-gold conjugated with the monoclonal antibodies against Novel coronavirus, the reaction membrane contains the secondary antibodies for Novol coronavirus and the polyclonal antibodies against the mouse globulin which are conjugated with the colloidal-gold.

PRECAUTIONS
pre-immobilized on the membrane.

- For *in vitro* diagnostic use only
- Do not use after the expiration date
- Ensure full pouch containing test device is not damaged before opening for use
- Perform touch at room temperature 15 to 20°C
- Wear gloves when handling the samples, avoid touching the reagent membrane and sample window
- All samples and used accessories should be treated as infectious and discarded according to local regulations
- Do not use on pregnant women or on pregnant blood samples

*** Avoid using bloody samples.**

Store The Novel Coronavirus (SARS-CoV-2) Antigen Rapid Test device (saliva) at room temperature or refrigerated (2-30°C). Do not freeze. All reagents are stable until the expiration date, marked on their outer packaging and in the vial.

dates marked on their outer packaging and better was

1. **Specimen collection:**
The oral fluid specimen should be collected using the collection tools provided with the kit. Follow the detailed Directions for Use below. No other collection tool should be used with this assay.
Oral fluid collected at any time of the day may be used.
2. **Specimen preparation:**
When the saliva is collected, follow the direction to prepare the specimen with buffer provided with the kit.

MATERIALS

- Test device
 - Dropper
 - Extraction buffer
 - Package insert
 - Nozzle
 - Extraction tube
 - Tube stand^a
 - Saline cooled tubing
 - Plastic bag
- ^a The 20-test package contains the tube stand, the 1-test and 5-test packages use the test box itself as tube stand.
- Materials required but not provided**

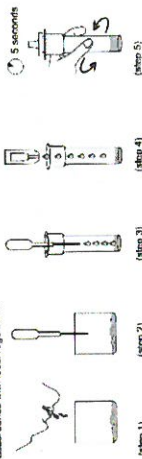
• **Timer**

DIRECTIONS FOR USE

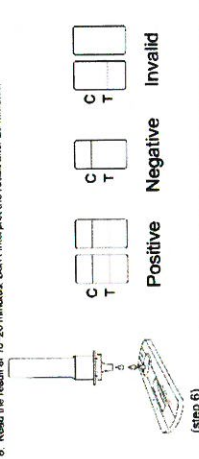
Allow the last device, specimen, extraction buffer to equilibrate to room temperature (18-30°C) prior to testing. Do not place anything in the mouth including food, drink, gum, tobacco, water and mouthwash products for at least 10 minutes prior to collection of oral fluid specimen.

Soak mouth swab into the saline collect package.

1. Draw the saliva from the cup with a dropper; transfer 4 drops of saliva to the extraction tube (see Figure 1).
2. Open the extraction tube and add a bottle of extraction buffer.
3. Take out an extraction tube and a bottle of extraction buffer; gently shake the extraction tube vertically for about 5 seconds to allow saliva mix well with extraction buffer.
4. Take out a nozzle and close into the extraction tube, gently shake the extraction tube vertically for about 5 seconds to allow saliva mix well with extraction buffer.
5. Find the used cuppling in half and discard it into the plastic bag as medical waste in accordance with local regulations.



6. Remove the test device from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch. Put the test device on a clean and flat surface.
7. Transfer 3 drops of sample into the sample well of test device vertically, start the timer.
8. Read the color change at 10–20 minutes. Don't interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE: Two red lines appear. One red line appears in the control region(C), and one red line appears in the test region(T). The shades of color may vary, but it should be considered positive whenever there is even a faint line.

NEGATIVE: Only one red line appears in the control region(C), and no line in the test region(T). The negative result indicates that the test is invalid. The control is invalid in the sample or the test is invalid.

INVALID: No red line appears in the control region(C). The test is invalid if there is no line on the control region. This result is below the detectable range.

WARNINGS: Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the test procedure and repeat the test using a new test line and/or a new control line sample. If the problem persists, discontinuous using the test kit immediately and contact your distributor.

LIMITATIONS

below the reagent's sensitivity threshold, so a negative test result does not exclude infection with novel coronavirus.

• The Novel Coronavirus (SARS-CoV-2) Antigen Rapid Test device (saliva) detects infection with non-viable novel coronavirus antigen. Test performance depends on the pool in the sample and may not correlate with cell culture performed on swabs. A positive test does not rule out the possibility that the patient may not have the virus at the present, therefore, the results must be confirmed with a reference laboratory. A negative test result does not rule out the possibility that the patient may have the virus at the present, therefore, the results must be confirmed with a reference laboratory. Information linking an accurate result to a specific patient is not possible.

• The Novel Coronavirus (SARS-CoV-2) Antigen Rapid Test device (saliva) is an adjunctive screening test for qualitative detection. Sample collection may contain antigen concentration below the reagent's sensitivity threshold, so a negative test result does not exclude infection with novel coronavirus.

• The Novel Coronavirus (SARS-CoV-2) Antigen Rapid Test device (saliva) is an adjunctive screening test for qualitative detection. Sample collection may contain antigen concentration below the reagent's sensitivity threshold, so a negative test result does not exclude infection with novel coronavirus.

diagnosis.

- Children lived in shared flats for longer periods of time than adults, which may result in increased exposure to allergens. The concentration of virus in saliva is greatly affected by factors such as breath, salt, smoking, coughing, sneezing, and crying. The concentration of virus in saliva is also affected by the concentration of virus in a specimen to be tested. The detection limit of the test for the specimen was calculated to be 1000 copies of virus per ml of the test. If the specimen was collected or transcribed improperly, therefore a negative test result does not eliminate the possibility of SARS-CoV infection, and should be confirmed.

PERFORMANCE CHARACTERISTICS

Clinical Evaluation

Clinical evaluation was performed to compare the results obtained by Novel Coronavirus (SARS-CoV-2) Antigen Rapid Test device (saliva) and PCR. The results were summarized below.

RESULTS: NOVEL CORONAVIRUS (COVID-19)			
Method	2019-nCoV Nucleic Acid Test Kit (RT-PCR)		Total Results
	Results		
The Novel Coronavirus (SARS-CoV-2) Antigen Rapid Test device (saliva)	Positive	157	158
	Negative	12	247
		169	405

TOTAL RESULTS		100	200
Clinical sensitivity = 157/169 = 92.9 % (95%CI* 87.89% to 96.00%)			
Clinical specificity = 235/238 = 98.74% (95%CI* 97.39% to 99.59%)			
Accuracy (152+235)/(157+1+2+235) *100% = 96.79% (95%CI* 94.53% to 98.47%)			

*Confidence Interval

2019 mCoV Strain Tested	Limit of Detection (LOD)
Stock 2019-mCoV Concentration	Ready Tox prepared 1 X 10 ⁷ TCID ₅₀ /mL
Dilution	1/100 1/200 1/400
Concentration in Chicken Intestine (TCID ₅₀ /mL)	1810 ³ 2.58 10 ³ 6.35 10 ²
Cell counts of 20 replicates near cut-off	1000-2020 1000-2020 961-1920
Limit of detection (LOD) per Virus Run	2.28 X 10 ³ TCID ₅₀ /mL

Cross-Section

The test results are below the corresponding concentration of the substances in the table below which has no effect on the negative and positive test results of this reagent and there is no cross reaction.

Cross-reactant	Strain	Concentration
Influenza A H1N1-Colorado	Type 1	75 µg/mL
	Type 2	1.5 x 10 ⁷ ID ₅₀ /mL
	Type 3	7.5 x 10 ⁷ ID ₅₀ /mL
	Type 5	4.5 x 10 ⁷ ID ₅₀ /mL
	Type 7	1.0 x 10 ⁷ ID ₅₀ /mL
Adenovirus	Type 8	1.0 x 10 ⁷ ID ₅₀ /mL
	Type 11	2.5 x 10 ⁷ ID ₅₀ /mL
	Type 18	2.5 x 10 ⁷ ID ₅₀ /mL
	Type 23	6.0 x 10 ⁷ ID ₅₀ /mL
	Type 55	1.5 x 10 ⁷ ID ₅₀ /mL
Influenza B	H1N1 Denver	3.0 x 10 ⁷ ID ₅₀ /mL
	H1N1 VBSG3	2.0 x 10 ⁷ ID ₅₀ /mL
	H1N1 A/Mal/02/54	1.5 x 10 ⁷ ID ₅₀ /mL
	H2N1 New Guinea	7.5 x 10 ⁷ ID ₅₀ /mL
	H3N2 A/Hong Kong/98/8	4.8 x 10 ⁷ ID ₅₀ /mL
Influenza B	Newad/03/2011	8.5 x 10 ⁷ ID ₅₀ /mL
	Blue4/0	1.5 x 10 ⁷ ID ₅₀ /mL
	B/Texas/29/2	1.5 x 10 ⁷ ID ₅₀ /mL
	Respiratory syncytial virus	5.0 x 10 ⁷ ID ₅₀ /mL
	Legionella pneumophila	1 x 10 ⁷ PFU/mL
Pneumonia	Loq. Inq. 2	1 x 10 ⁷ PFU/mL
	Loq. Inq. 3	1 x 10 ⁷ PFU/mL
	52A1105	1 x 10 ⁷ PFU/mL
	N/A	1.5 x 10 ⁷ ID ₅₀ /mL
	K	1 x 10 ⁷ ID ₅₀ /mL
Mycobacterium tuberculosis	NCIM 107	1 x 10 ⁷ ID ₅₀ /mL
	H37Rv	1 x 10 ⁷ ID ₅₀ /mL
	H37R6	1 x 10 ⁷ ID ₅₀ /mL
	CDC 152	1 x 10 ⁷ ID ₅₀ /mL
	4752/88 Maryland	1 x 10 ⁷ ID ₅₀ /mL
Streptococcus pneumoniae	6758-17	1 x 10 ⁷ ID ₅₀ /mL

Interfering Substances Reaction

When tested using the Novel Coronavirus (SARS-CoV-2) Antigen Rapid Test Device (saliva), there was no interference between the device reagents and the Potential interference substances listed in below table that would create false positive or negative results for SARS-CoV-2 antigen.

SYMBOL			
Symbol	Meaning	Symbol	Meaning
	In vitro diagnostic medical device		Storage temperature limit
	Manufacturer		Authorized representative in the European Community
	Date of Manufacture		Use by date
	Do not reuse		Consult instruction for use
	Batch code		Mark the requirements of CE marking

EC	REP
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Number 1901431601
Version 1.5
Effective Date 2021-01-22



Annex II: Data of Clinical Tests

NO.	Age	Gender	Rapid Test	(RT-PCR)
1	49	F	Positive	Positive (RdRP and N gene)
2	32	F	Positive	Positive (RdRP and N gene)
3	31	F	Positive	Positive (RdRP and N gene)
4	32	F	Positive	Positive (RdRP and N gene)
5	21	F	Negative	Positive (RdRP gene)
6	51	M	Positive	Positive (RdRP and N gene)
7	22	F	Positive	Positive (RdRP and N gene)
8	46	F	Positive	Positive (RdRP and N gene)
9	23	F	Positive	Positive (RdRP and N gene)
10	14	M	positive	Positive (RdRP and N gene)
11	42	M	Positive	Positive (RdRP and N gene)
12	51	M	Positive	Positive (RdRP and N gene)
13	80	M	Positive	Positive (RdRP and N gene)
14	39	F	Negative	Positive (N gene)
15	67	M	Positive	Positive (RdRP and N gene)
16	44	M	positive	Positive (RdRP gene)
17	26	F	Positive	Positive (RdRP and N gene)
18	33	F	positive	Positive (N gene)
19	38	F	Positive	Positive (RdRP and N gene)
20	36	F	Positive	Positive (RdRP and N gene)
21	3	F	Positive	Positive (RdRP and N gene)
22	35	F	Positive	Positive (RdRP and N gene)
23	23	F	Positive	Positive (RdRP and N gene)

NO.	Age	Gender	Rapid Test	(RT-PCR)
24	43	M	Positive	Positive (RdRP and N gene)
25	43	F	Negative	Positive (N gene)
26	46	F	Positive	Positive (RdRP and N gene)
27	55	F	Positive	Positive (RdRP and N gene)
28	22	F	Positive	Positive (RdRP and N gene)
29	20	M	positive	Positive (N gene)
30	42	M	Positive	Positive (RdRP and N gene)
31	56	F	Positive	Positive (RdRP and N gene)
32	55	M	Positive	Positive (RdRP and N gene)
33	26	F	Positive	Positive (RdRP and N gene)
34	54	M	Positive	Positive (RdRP and N gene)
35	43	F	Positive	Positive (RdRP and N gene)
36	69	M	Positive	Positive (RdRP and N gene)
37	36	M	Negative	Positive (N gene)
38	37	F	Positive	Positive (RdRP and N gene)
39	44	F	Positive	Positive (RdRP and N gene)
40	43	F	Positive	Positive (RdRP and N gene)
41	67	F	Positive	Positive (RdRP and N gene)
42	51	F	Positive	Positive (RdRP and N gene)
43	75	F	Positive	Positive (RdRP and N gene)
44	60	F	Positive	Positive (RdRP and N gene)
45	25	M	Positive	Positive (RdRP and N gene)
46	75	F	Positive	Positive (RdRP and N gene)



NO.	Age	Gender	Rapid Test	(RT-PCR)
47	43	F	Positive	Positive (RdRP and N gene)
48	30	F	Positive	Positive (RdRP and N gene)
49	30	M	Negative	Positive (RdRP gene)
50	26	F	Positive	Positive (RdRP and N gene)
51	32	F	Positive	Positive (RdRP and N gene)
52	73	M	Positive	Positive (RdRP and N gene)
53	58	F	Positive	Positive (RdRP and N gene)
54	66	F	Positive	Positive (RdRP and N gene)
55	29	F	Positive	Positive (RdRP and N gene)
56	56	M	Positive	Positive (RdRP and N gene)
57	24	M	Positive	Positive (N gene)
58	36	M	Positive	Positive (RdRP and N gene)
59	70	F	Positive	Positive (RdRP and N gene)
60	45	M	Positive	Positive (RdRP and N gene)
61	38	F	Positive	Positive (RdRP and N gene)
62	42	M	Positive	Positive (RdRP and N gene)
63	55	M	Positive	Positive (RdRP and N gene)
64	33	M	Positive	Positive (RdRP and N gene)
65	39	M	Positive	Positive (RdRP and N gene)
66	58	F	Negative	Positive (N gene)
67	20	F	Positive	Positive (RdRP and N gene)
68	42	F	Positive	Positive (RdRP and N gene)
69	56	M	Positive	Positive (RdRP and N gene)
70	55	F	Positive	Positive (RdRP and N gene)

NO.	Age	Gender	Rapid Test	(RT-PCR)
71	26	F	Positive	Positive (RdRP and N gene)
72	54	M	Positive	Positive (RdRP and N gene)
73	45	F	Positive	Positive (RdRP and N gene)
74	38	M	Positive	Positive (RdRP and N gene)
75	42	M	Positive	Positive (RdRP and N gene)
76	55	F	Positive	Positive (RdRP and N gene)
77	33	F	Positive	Positive (RdRP and N gene)
78	43	F	Negative	Positive (N gene)
79	67	M	Positive	Positive (RdRP and N gene)
80	51	F	Positive	Positive (RdRP and N gene)
81	75	M	Positive	Positive (RdRP and N gene)
82	60	M	Positive	Positive (RdRP and N gene)
83	25	F	Positive	Positive (RdRP and N gene)
84	75	M	Positive	Positive (N gene)
85	43	F	Positive	Positive (RdRP and N gene)
86	49	F	Positive	Positive (RdRP and N gene)
87	32	F	Positive	Positive (RdRP and N gene)
88	31	M	Positive	Positive (RdRP and N gene)
89	32	M	Positive	Positive (RdRP and N gene)
90	21	M	Positive	Positive (RdRP and N gene)
91	51	F	Positive	Positive (RdRP and N gene)
92	22	M	Positive	Positive (RdRP and N gene)
93	46	F	Positive	Positive (RdRP and N gene)
94	23	M	Positive	Positive (RdRP and N gene)

NO.	Age	Gender	Rapid Test	(RT-PCR)
95	14	F	Positive	Positive (RdRP and N gene)
96	55	M	Negative	Positive (N gene)
97	33	M	Positive	Positive (RdRP and N gene)
98	43	F	Positive	Positive (RdRP and N gene)
99	67	M	Positive	Positive (RdRP and N gene)
100	51	M	Positive	Positive (RdRP and N gene)
101	75	M	Positive	Positive (N gene)
102	60	M	Positive	Positive (RdRP and N gene)
103	25	M	Positive	Positive (RdRP and N gene)
104	75	M	Positive	Positive (RdRP and N gene)
105	43	M	Positive	Positive (RdRP and N gene)
106	49	M	Positive	Positive (RdRP and N gene)
107	32	F	Positive	Positive (RdRP and N gene)
108	31	M	Positive	Positive (RdRP and N gene)
109	32	M	Positive	Positive (RdRP and N gene)
110	21	F	Positive	Positive (RdRP and N gene)
111	51	F	Positive	Positive (RdRP and N gene)
112	26	F	Positive	Positive (RdRP and N gene)
113	33	M	Positive	Positive (RdRP and N gene)
114	38	F	Positive	Positive (RdRP and N gene)
115	36	M	Positive	Positive (RdRP and N gene)
116	3	M	Positive	Positive (RdRP and N gene)
117	35	F	Positive	Positive (RdRP and N gene)
118	23	M	Positive	Positive (RdRP and N gene)

NO.	Age	Gender	Rapid Test	(RT-PCR)
119	43	F	Positive	Positive (RdRP and N gene)
120	75	F	Positive	Positive (RdRP and N gene)
121	60	M	Positive	Positive (RdRP and N gene)
122	25	M	Positive	Positive (N gene)
123	75	F	Positive	Positive (RdRP and N gene)
124	43	F	Positive	Positive (RdRP and N gene)
125	49	F	Negative	Positive (N gene)
126	32	F	Positive	Positive (RdRP and N gene)
127	31	F	Positive	Positive (RdRP and N gene)
128	32	F	Positive	Positive (RdRP and N gene)
129	21	F	Positive	Positive (RdRP and N gene)
130	51	F	Positive	Positive (RdRP and N gene)
131	26	F	Positive	Positive (RdRP and N gene)
132	33	M	Positive	Positive (RdRP and N gene)
133	38	M	Positive	Positive (RdRP and N gene)
134	36	F	Negative	Positive (RdRP gene)
135	3	M	Positive	Positive (RdRP and N gene)
136	75	M	Positive	Positive (RdRP and N gene)
137	43	M	Positive	Positive (RdRP and N gene)
138	49	M	Positive	Positive (RdRP and N gene)
139	32	M	Positive	Positive (N gene)
140	31	M	Positive	Positive (RdRP and N gene)
141	32	M	Positive	Positive (RdRP and N gene)
142	21	M	Positive	Positive (RdRP and N gene)



NO.	Age	Gender	Rapid Test	(RT-PCR)
143	51	M	Positive	Positive (RdRP and N gene)
144	22	M	Negative	Positive (N gene)
145	46	F	Positive	Positive (RdRP and N gene)
146	23	M	Positive	Positive (RdRP and N gene)
147	14	M	Positive	Positive (RdRP and N gene)
148	55	F	Positive	Positive (RdRP and N gene)
149	33	M	Positive	Positive (RdRP and N gene)
150	26	F	Positive	Positive (RdRP and N gene)
151	32	M	Positive	Positive (RdRP and N gene)
152	73	M	Positive	Positive (RdRP and N gene)
153	58	M	Positive	Positive (RdRP and N gene)
154	66	M	Positive	Positive (RdRP and N gene)
155	29	M	Positive	Positive (RdRP and N gene)
156	56	F	Positive	Positive (N gene)
157	24	F	Positive	Positive (RdRP and N gene)
158	36	F	Positive	Positive (RdRP and N gene)
159	70	M	Positive	Positive (RdRP and N gene)
160	45	F	Positive	Positive (RdRP and N gene)
161	74	M	Positive	Positive (RdRP and N gene)
162	43	M	Positive	Positive (RdRP and N gene)
163	68	M	Negative	Positive (N gene)
164	29	F	Positive	Positive (RdRP and N gene)
165	54	F	Positive	Positive (RdRP and N gene)
166	49	F	Positive	Positive (RdRP and N gene)

NO.	Age	Gender	Rapid Test	(RT-PCR)
167	20	M	Positive	Positive (RdRP and N gene)
168	26	F	Positive	Positive (N gene)
169	22	F	Positive	Positive (RdRP and N gene)
170	32	M	Negative	Negative(Ct/Cq) >40
171	28	F	Negative	Negative(Ct/Cq) >40
172	44	M	Negative	Negative(Ct/Cq) >40
173	18	F	Negative	Negative(Ct/Cq) >40
174	71	F	Negative	Negative(Ct/Cq) >40
175	37	M	Negative	Negative(Ct/Cq) >40
176	44	M	Negative	Negative(Ct/Cq) >40
177	79	F	Negative	Negative(Ct/Cq) >40
178	67	M	Negative	Negative(Ct/Cq) >40
179	61	F	Negative	Negative(Ct/Cq) >40
180	59	F	Negative	Negative(Ct/Cq) >40
181	28	F	Negative	Negative(Ct/Cq) >40
182	82	M	Negative	Negative(Ct/Cq) >40
183	63	F	Negative	Negative(Ct/Cq) >40
184	53	M	Negative	Negative(Ct/Cq) >40
185	43	M	Negative	Negative(Ct/Cq) >40
186	46	M	Negative	Negative(Ct/Cq) >40
187	46	F	Negative	Negative(Ct/Cq) >40
188	21	F	Negative	Negative(Ct/Cq) >40
189	46	F	Negative	Negative(Ct/Cq) >40
190	71	M	Negative	Negative(Ct/Cq) >40

NO.	Age	Gender	Rapid Test	(RT-PCR)
191	60	F	Negative	Negative(Ct/Cq) >40
192	31	F	Negative	Negative(Ct/Cq) >40
193	72	M	Negative	Negative(Ct/Cq) >40
194	62	M	Negative	Negative(Ct/Cq) >40
195	39	F	Negative	Negative(Ct/Cq) >40
196	45	M	Negative	Negative(Ct/Cq) >40
197	21	M	Negative	Negative(Ct/Cq) >40
198	33	M	Negative	Negative(Ct/Cq) >40
199	83	M	Negative	Negative(Ct/Cq) >40
200	15	M	Negative	Negative(Ct/Cq) >40
201	59	M	Negative	Negative(Ct/Cq) >40
202	54	M	Negative	Negative(Ct/Cq) >40
203	84	F	Negative	Negative(Ct/Cq) >40
204	84	F	Negative	Negative(Ct/Cq) >40
205	42	F	Negative	Negative(Ct/Cq) >40
206	63	F	Negative	Negative(Ct/Cq) >40
207	29	M	Negative	Negative(Ct/Cq) >40
208	50	M	Negative	Negative(Ct/Cq) >40
209	74	F	Negative	Negative(Ct/Cq) >40
210	43	M	Negative	Negative(Ct/Cq) >40
211	68	M	Negative	Negative(Ct/Cq) >40
212	29	M	Negative	Negative(Ct/Cq) >40
213	54	M	Negative	Negative(Ct/Cq) >40
214	49	M	Negative	Negative(Ct/Cq) >40

NO.	Age	Gender	Rapid Test	(RT-PCR)
215	20	M	Negative	Negative(Ct/Cq) >40
216	26	M	Negative	Negative(Ct/Cq) >40
217	22	M	Negative	Negative(Ct/Cq) >40
218	32	F	Negative	Negative(Ct/Cq) >40
219	28	M	Negative	Negative(Ct/Cq) >40
220	44	M	Negative	Negative(Ct/Cq) >40
221	57	F	Negative	Negative(Ct/Cq) >40
222	64	F	Negative	Negative(Ct/Cq) >40
223	39	F	Negative	Negative(Ct/Cq) >40
224	38	F	Negative	Negative(Ct/Cq) >40
225	73	M	Negative	Negative(Ct/Cq) >40
226	45	M	Negative	Negative(Ct/Cq) >40
227	61	M	Negative	Negative(Ct/Cq) >40
228	13	F	Negative	Negative(Ct/Cq) >40
229	64	F	Negative	Negative(Ct/Cq) >40
230	26	F	Negative	Negative(Ct/Cq) >40
231	28	M	Negative	Negative(Ct/Cq) >40
232	58	M	Negative	Negative(Ct/Cq) >40
233	35	F	Negative	Negative(Ct/Cq) >40
234	51	M	Negative	Negative(Ct/Cq) >40
235	60	M	Negative	Negative(Ct/Cq) >40
236	17	M	Negative	Negative(Ct/Cq) >40
237	18	F	Negative	Negative(Ct/Cq) >40
238	15	M	Negative	Negative(Ct/Cq) >40



NO.	Age	Gender	Rapid Test	(RT-PCR)
239	52	M	Negative	Negative(Ct/Cq) >40
240	33	M	Negative	Negative(Ct/Cq) >40
241	41	F	Negative	Negative(Ct/Cq) >40
242	11	M	Negative	Negative(Ct/Cq) >40
243	19	F	Negative	Negative(Ct/Cq) >40
244	10	F	Negative	Negative(Ct/Cq) >40
245	62	F	Negative	Negative(Ct/Cq) >40
246	68	F	Negative	Negative(Ct/Cq) >40
247	38	M	Negative	Negative(Ct/Cq) >40
248	59	M	Negative	Negative(Ct/Cq) >40
249	76	F	Negative	Negative(Ct/Cq) >40
250	24	M	Negative	Negative(Ct/Cq) >40
251	68	M	Negative	Negative(Ct/Cq) >40
252	82	F	Negative	Negative(Ct/Cq) >40
253	64	F	Negative	Negative(Ct/Cq) >40
254	59	M	Negative	Negative(Ct/Cq) >40
255	59	M	Negative	Negative(Ct/Cq) >40
256	83	M	Negative	Negative(Ct/Cq) >40
257	58	F	Negative	Negative(Ct/Cq) >40
258	68	M	Negative	Negative(Ct/Cq) >40
259	77	M	Negative	Negative(Ct/Cq) >40
260	47	F	Negative	Negative(Ct/Cq) >40
261	71	M	Negative	Negative(Ct/Cq) >40
262	21	F	Negative	Negative(Ct/Cq) >40

NO.	Age	Gender	Rapid Test	(RT-PCR)
263	52	M	Negative	Negative(Ct/Cq) >40
264	70	M	Negative	Negative(Ct/Cq) >40
265	63	M	Negative	Negative(Ct/Cq) >40
266	59	M	Negative	Negative(Ct/Cq) >40
267	26	M	Negative	Negative(Ct/Cq) >40
268	36	F	Negative	Negative(Ct/Cq) >40
269	47	F	Negative	Negative(Ct/Cq) >40
270	45	M	Negative	Negative(Ct/Cq) >40
271	29	F	Negative	Negative(Ct/Cq) >40
272	30	M	Negative	Negative(Ct/Cq) >40
273	25	F	Negative	Negative(Ct/Cq) >40
274	73	M	Negative	Negative(Ct/Cq) >40
275	76	M	Negative	Negative(Ct/Cq) >40
276	25	M	Negative	Negative(Ct/Cq) >40
277	49	F	Negative	Negative(Ct/Cq) >40
278	62	M	Negative	Negative(Ct/Cq) >40
279	38	M	Negative	Negative(Ct/Cq) >40
280	33	M	Negative	Negative(Ct/Cq) >40
281	39	M	Negative	Negative(Ct/Cq) >40
282	69	M	Negative	Negative(Ct/Cq) >40
283	79	F	Negative	Negative(Ct/Cq) >40
284	32	M	Positive	Negative(Ct/Cq) >40
285	35	M	Negative	Negative(Ct/Cq) >40
286	39	M	Negative	Negative(Ct/Cq) >40



NO.	Age	Gender	Rapid Test	(RT-PCR)
287	61	F	Negative	Negative(Ct/Cq) >40
288	10	F	Negative	Negative(Ct/Cq) >40
289	37	M	Negative	Negative(Ct/Cq) >40
290	52	F	Negative	Negative(Ct/Cq) >40
291	41	M	Negative	Negative(Ct/Cq) >40
292	74	M	Negative	Negative(Ct/Cq) >40
293	51	F	Negative	Negative(Ct/Cq) >40
294	56	M	Negative	Negative(Ct/Cq) >40
295	62	F	Negative	Negative(Ct/Cq) >40
296	60	F	Negative	Negative(Ct/Cq) >40
297	54	F	Negative	Negative(Ct/Cq) >40
298	81	F	Negative	Negative(Ct/Cq) >40
299	79	F	Negative	Negative(Ct/Cq) >40
300	73	F	Negative	Negative(Ct/Cq) >40
301	35	F	Negative	Negative(Ct/Cq) >40
302	76	F	Negative	Negative(Ct/Cq) >40
303	23	M	Negative	Negative(Ct/Cq) >40
304	13	F	Negative	Negative(Ct/Cq) >40
305	14	M	Negative	Negative(Ct/Cq) >40
306	43	M	Negative	Negative(Ct/Cq) >40
307	30	F	Negative	Negative(Ct/Cq) >40
308	57	M	Negative	Negative(Ct/Cq) >40
309	30	F	Negative	Negative(Ct/Cq) >40
310	65	M	Negative	Negative(Ct/Cq) >40

NO.	Age	Gender	Rapid Test	(RT-PCR)
311	66	F	Negative	Negative(Ct/Cq) >40
312	38	F	Negative	Negative(Ct/Cq) >40
313	49	M	Negative	Negative(Ct/Cq) >40
314	23	F	Negative	Negative(Ct/Cq) >40
315	51	M	Negative	Negative(Ct/Cq) >40
316	64	F	Negative	Negative(Ct/Cq) >40
317	67	M	Negative	Negative(Ct/Cq) >40
318	34	M	Negative	Negative(Ct/Cq) >40
319	55	M	Negative	Negative(Ct/Cq) >40
320	58	M	Negative	Negative(Ct/Cq) >40
321	67	F	Negative	Negative(Ct/Cq) >40
322	20	F	Negative	Negative(Ct/Cq) >40
323	42	M	Negative	Negative(Ct/Cq) >40
324	59	M	Negative	Negative(Ct/Cq) >40
325	12	M	Negative	Negative(Ct/Cq) >40
326	30	M	Negative	Negative(Ct/Cq) >40
327	65	M	Negative	Negative(Ct/Cq) >40
328	66	F	Negative	Negative(Ct/Cq) >40
329	38	F	Negative	Negative(Ct/Cq) >40
330	49	M	Negative	Negative(Ct/Cq) >40
331	23	F	Negative	Negative(Ct/Cq) >40
332	51	M	Negative	Negative(Ct/Cq) >40
333	64	M	Negative	Negative(Ct/Cq) >40
334	67	F	Negative	Negative(Ct/Cq) >40



NO.	Age	Gender	Rapid Test	(RT-PCR)
335	34	M	Negative	Negative(Ct/Cq) >40
336	55	F	Negative	Negative(Ct/Cq) >40
337	58	F	Negative	Negative(Ct/Cq) >40
338	67	F	Negative	Negative(Ct/Cq) >40
339	20	F	Negative	Negative(Ct/Cq) >40
340	42	F	Negative	Negative(Ct/Cq) >40
341	59	F	Negative	Negative(Ct/Cq) >40
342	12	F	Negative	Negative(Ct/Cq) >40
343	23	F	Negative	Negative(Ct/Cq) >40
344	51	M	Negative	Negative(Ct/Cq) >40
345	64	F	Negative	Negative(Ct/Cq) >40
346	67	M	Negative	Negative(Ct/Cq) >40
347	34	M	Negative	Negative(Ct/Cq) >40
348	55	F	Negative	Negative(Ct/Cq) >40
349	58	M	Negative	Negative(Ct/Cq) >40
350	67	F	Negative	Negative(Ct/Cq) >40
351	20	M	Negative	Negative(Ct/Cq) >40
352	42	F	Negative	Negative(Ct/Cq) >40
353	59	F	Negative	Negative(Ct/Cq) >40
354	12	M	Negative	Negative(Ct/Cq) >40
355	30	F	Negative	Negative(Ct/Cq) >40
356	65	M	Negative	Negative(Ct/Cq) >40
357	66	F	Negative	Negative(Ct/Cq) >40
358	38	M	Negative	Negative(Ct/Cq) >40

NO.	Age	Gender	Rapid Test	(RT-PCR)
359	49	F	Negative	Negative(Ct/Cq) >40
360	23	M	Negative	Negative(Ct/Cq) >40
361	51	F	Negative	Negative(Ct/Cq) >40
362	64	M	Negative	Negative(Ct/Cq) >40
363	67	M	Negative	Negative(Ct/Cq) >40
364	34	F	Negative	Negative(Ct/Cq) >40
365	51	M	Negative	Negative(Ct/Cq) >40
366	64	F	Negative	Negative(Ct/Cq) >40
367	67	F	Negative	Negative(Ct/Cq) >40
368	34	F	Negative	Negative(Ct/Cq) >40
369	55	F	Negative	Negative(Ct/Cq) >40
370	58	F	Negative	Negative(Ct/Cq) >40
371	67	F	Negative	Negative(Ct/Cq) >40
372	20	F	Negative	Negative(Ct/Cq) >40
373	42	F	Negative	Negative(Ct/Cq) >40
374	59	M	Negative	Negative(Ct/Cq) >40
375	12	M	Negative	Negative(Ct/Cq) >40
376	23	F	Negative	Negative(Ct/Cq) >40
377	51	F	Negative	Negative(Ct/Cq) >40
378	64	M	Negative	Negative(Ct/Cq) >40
379	67	M	Negative	Negative(Ct/Cq) >40
380	34	M	Negative	Negative(Ct/Cq) >40
381	55	F	Negative	Negative(Ct/Cq) >40
382	58	M	Negative	Negative(Ct/Cq) >40

NO.	Age	Gender	Rapid Test	(RT-PCR)
383	67	M	Negative	Negative(Ct/Cq) >40
384	20	F	Negative	Negative(Ct/Cq) >40
385	42	M	Negative	Negative(Ct/Cq) >40
386	59	F	Negative	Negative(Ct/Cq) >40
387	12	M	Negative	Negative(Ct/Cq) >40
388	30	M	Negative	Negative(Ct/Cq) >40
389	65	M	Negative	Negative(Ct/Cq) >40
390	66	M	Negative	Negative(Ct/Cq) >40
391	38	M	Negative	Negative(Ct/Cq) >40
392	49	F	Negative	Negative(Ct/Cq) >40
393	23	F	Negative	Negative(Ct/Cq) >40
394	67	F	Negative	Negative(Ct/Cq) >40

Director: 

Date: 2021.01.23

Seal of company signature



NO.	Age	Gender	Rapid Test	(RT-PCR)
395	20	F	Negative	Negative(Ct/Cq) >40
396	42	F	Negative	Negative(Ct/Cq) >40
397	59	F	Negative	Negative(Ct/Cq) >40
398	12	F	Negative	Negative(Ct/Cq) >40
399	30	F	Negative	Negative(Ct/Cq) >40
400	65	M	Negative	Negative(Ct/Cq) >40
401	66	M	Negative	Negative(Ct/Cq) >40
402	30	F	Negative	Negative(Ct/Cq) >40
403	65	F	Negative	Negative(Ct/Cq) >40
404	66	M	Negative	Negative(Ct/Cq) >40
405	67	M	Negative	Negative(Ct/Cq) >40