

Raba ku co bitekeyemwo ukurikize ingingo zose. Soma ukuntu igipimo cose gikora, harimwo ibisabwa n'igenzura ry'ubwiza imbere yo gukora igipimo.

Ibikoresho vyose vyo mu bitaro bitegerezwa kubikwa mu cumba kirimwo ubushuhe imbere y'uko bikoreshwa.

Gukora ibipimo hanze y'umwanya n'ubushuhe ni kimwe mu bishobora gutanga inyishu z'impfagusa.

Ibimipimo bidakozwe mu mwanya wagenywe hamwe n'ubushuhe buzwi bitegerezwa gusubirwamwo.

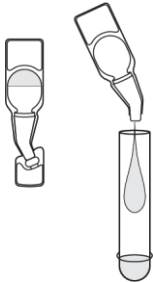
Igenekerezo rya nyuma: Raba igenekerezo rya nyuma kuri buri karato canke inyuma yayo imbere yo kuyikoresha. *Ntukoresheje igipimo ico arico cose cataye igihe nk'uko biboneka.*

Uko igipimo kigenda

1

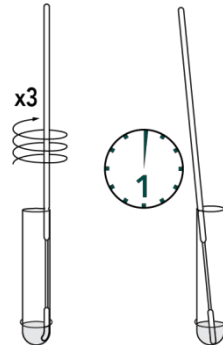
Tanga uruvange rwose mu gacupa ku ruvange. Vanga uruvange mu gacupa kugira ibikagize bivangane.

MENYA NEZA: Agacupa ku ruvange gategerezwa kuguma mu gifashe agacupa igihe cose co gupima



2

Gushira ico bageragerezako c'umurwayi mu ruvange. Agacupa. Zungurutsa agacupa n'imiburiburi incuro 3 mu gihe co kuzungurutsa umutwe uje hasi imbere n'iruhande y'icupa ry'uruvange.



Gumiza **umunota 1** akaringoti mw'icupa ry'uruvange. **Sivyo canke inyishu zimpfagusa zishobora kubaho nimba igihe co kwerekana indwara ari kigufi cane canke kirekire cane.**

3

Kura amazi yose hejuru mu gacupa mu kukazungurutsa incuro zigeze kuri 3 uko ugenda ukuramwo agacupa. Kuramwo agacupa wisunze amategeko yo guta imicafu.



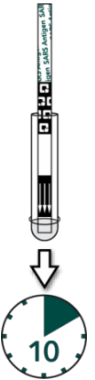
4

Shira akaringoti mu gacupa ku ruvange gacuritse karaba hasi. Ntukoreko canke ngo ukuremwo ico bageragerezako kugeza igipimo kirangiye kandi hageze ko gisomwa.

Ku **munota wa 10**, kuramwo akaringoti

hama usome inyishu mu minota (5) nk'uko ingingo y'insiguro y'inyishu ku rundi ruhanda rw'iyi karata.

Inyishu zitegerezwa gusomwa hagati y'iminota 10-15. Inyishu yerekana indwara kandi atari ukuri, inyishu iterekana indwara kandi atari ukuri, canke inyishu z'impfagusa zishobora kuboneka igihe inyishu isomwe igihe cemewe n'amategeko carenze.



Kugenzura ubwiza

Kwubaka uburyo bwo kugenzura

Igipimo cizewe SARS ca antijene kirimwo uburyo bwo kugenzura iyubakwa. Itegeko ry'uwuhingura rya buri muni rigenzura ni ukumenya uko kwiyubaka kw'uburyo bwo kugenzura ku ma shantiyo yambere yabimwe buri muni.

Amarangi abiri aboneka ku nyishu asigura ko inyishu yerekana indwara canke inyishu iterekana indwara. Uguseruka kw'irangi ry'ubururu mu kugenzura bitanga inyishu yerekana indwara mu gusigura ko amazi yatemye bihagije kandi ugukora neza kw'igipimisho kwa gumyeho. Nimba akarongo k'ubururu kagenzura katabonetse mu minota 10 ku gipimisho, n'ukuvuga ko inyishu ari impfagusa.

Igipimo co kugenzura neza kica gikorwa mu gukuraho akarangi gatukura, gusuzuma neza ko igipimo cakoze neza. Mu minota 10, aho inyishu ziserukira hategerezwa kwera kugira hamurikire irangi ry'ikivuvu kandi bitange insiguro y'inyishu iboneka. Nimba irangi ry'ubwambere rigumyeho kandi rigatuma hataboneka insiguro y'inyishu, aho rero inyishu ni impfagusa. Ibi vyongeye gushika, subiramwo uko bigenda hama usubiremwo igipimo ku murwayi ukoreshe shantiyo nshasha hamwe n'igipimisho gisha. Amashantiyo yo ku barwayi canke uruvange ntibishobora gukoreshwa kabiri.

Kugenzura ubwiza bw'inyuma

Kugenzura ubwiza bw'inyuma bishobora gukoreshwa mu kwerekana ko uruvange hamwe n'ukuntu ibipimo bigenda bikorwa neza.

Quidel isaba ko igenzura ry'inyishu zerekana indwara n'iziterekana indwara bikorwa rimwe kuri buri mukozi atabifitiye ubumenyi, rimwe kuri buri bikoresho bishasha — ku buryo buri bikoresho bitandukanye vyakiriwe bipimwa — nk'uko bisabwa neza n'ubwiza bw'igenzura ry'imbere, hamwe n'ukuntu akarere, intara n'amategeko y'igihugu canke amabwirizwa asabwa.

Ukuntu igipimo gikora vyerekanywe ku gapapuro kari imbere mu gakarato bitegerezwa gukoreshwa mu gupima ubwiza bw'inyuma.

Nimba igenzura ridakoze nk'uko vyari vyitezwe, subiramwo igipimo canke hamagara umutangabufasha mu buhinga wa Quidel imbere yo gupima ivyafashwe ku murwayi.

Gusigura inyishu

Inyishu zerekana indwara*:

Ku munota wa (10), ukuboneka kw'igitutu **ICO ARICO COSE c'ikivuvu gisa n'igitukura ku karongo k'igipimo HAMWE** ukuboneka kw'akarongo ku bururu kagenzura gasigura inyishu yerekana indwara muri antijene ya SARS. Inyishu zizoguma zitekanye mu minota (5) inyuma y'umwanya usabwa wo gusoma. Ntusome inyishu inyuma y'iminota itanu. Inyishu ibesha yerekana indwara, inyishu ibesha iterekana indwara, canke inyishu z'impfagusa zishobora kuboneka igihe inyishu isomwe igihe cemewe n'amategeko carenze.

*Inyishu zerekana indwara ntizigera zanduza ibindi bihimba vyegeranye.

***Birasa cane!** Iyi ni inyishu yerekana indwara. Naho wobona akarongo k'igipimo katabona neza, hamwe n'akarongo kagenzura ku bururu, utegerezwa gutanga raporo y'inyishu nk'YEREKANA INDWARA.

C = Akarongo kagenzura

T = Akarongo k'igipimo

Inyishu ziterekana indwara**:

Ku munota wa (10), ukuboneka kw'umurongo w'ubururu ugenzura **GUSA** vyerekana ko ata antijene SARS zabonetse. Inyishu zizoguma zitekanye mu minota (5) inyuma y'umwanya usabwa wo gusoma. Inyishu ibesha yerekana indwara, inyishu ibesha iterekana indwara, canke inyishu z'impfagusa zishobora kuboneka igihe inyishu isomwe igihe cemewe n'amategeko carenze igihe.

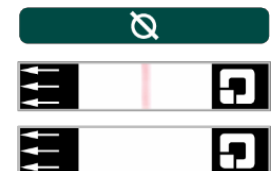
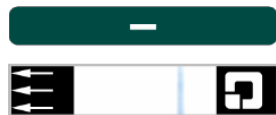
**** Menya neza:** Inyishu ziterekana indwara zitegerezwa gufatwa nk'izemeza kandi zishimangira hamwe n'igipimo ca morekire, nimba bikenewe, kubwo kwitaho umurwayi, zishobora gukorwa. Ku rukurikirane rwa porogarama yo gupima, igipimo c'inyongera cemeza igipimo ca morekire ku nyishu ziterekana indwara ko gishobora kuba ngombwa inyuma y'ubugira kabiri haboneka inyishu iterekana indwara ku bantu batagaragaza ibimenyetso, nimba hari ivyago vyinshi vy'ubwandu bwa SARS-CoV-2 canke, nko mu muntu yanduye COVID-19 canke yoba yarahuye n'uwurwaye COVID-19 canke mu miryango irimwo ubwandu bwinshi. igipimo c'inyongera ca morekire ku nyishu zerekana indwara bishobora kuba kandi bikenewe, nimba hari ivyago bike vyo kwandura SARS-CoV-2, nko mu bantu batazi ko bahuye n'uwurwaye SARS-CoV-2 canke baba mu miryango irimwo ubwandu buke.

Inyishu z'impfagusa:

Nimba ku munota wa (10), irangi ry'ubururu rigenzura ritaboneka, naho igitutu ico arico cose c'akarongo k'igipimo gasa n'agatukura, inyishu ni impfagusa.

Nimba ku munota wa (10), ibara ryo hasi ritaboneka neza hama rituma igipimo kidasomeka neza, inyishu ni impfagusa kandi.

Nimba inyishu ari impfagusa, igipimo gishasha gutegerezwa gukorwa hakoreshejwe ishantiyo nshasha y'umurwayi hamwe n'ibikoresho bishasha.



Kirundi

IKOresha Ryateguwe

Igipimo cizewe SARS antijene ni igipimo gitemba gifasha igipimo cihuta, gupima neza poroteyine za antijene nucleocapsid muri SARS-CoV-2 imbere mu myenge (NS) uturingoti bageragerezako ku bantu bikekwa n'abatangabufasha mu vy'ubuvuzi ko banduye COVID-19 mu minsi itanu yambere ibimenyetso vyibonekeje canke ku bantu batagira ibimenyetso canke izindi mpanvu z'uburwayi ku bikekwa ko banduye COVID-19 igihe bapimwe kabiri mu minsi ibiri canke iminsi itatu n'imiburiburi mu masaha 24 kandi bitarenze amasaha 36 hagati y'ibipimo. Ugupima bikorerwa mu mazu y'igeragerezo ry'imiti atwarwa n'amategeko agenga uko amazu y'igeragerezo ry'imiti mu bitaro ameze yo muri 1988 (CLIA), 42 U.S.C. §263a, akwije ibisabwa kugira akore, ibipimo vyo kurwego rwo hejuru canke bihanitse. Iki gipimo kirarekuwe gukoreshwa ku kibanza bitaho (POC), ni kuvuga, mu bijanye no kwitaho umurwayi bitwarwa muri CLIA urupapuro rutanga uburenganzira, urupapuro rwo kwifatanya, canke urupapuro rwo kwemeza. Igipimo cizewe SARS antijene ntigitandukanya hagati ya SARS-CoV hamwe na SARS-CoV-2.

Igipimo cizewe SARS antijene ntigitandukanya hagati ya SARS-CoV hamwe na SARS-CoV-2.

Inyishu ni iz'ubushakashatsi bwa SARS-CoV-2 antijene ya poroteyine nucleocapsid. Antijene muri rusangi ipimwa imbere mu myenge hakoreshejwe uturingoti mu gihe c'ubwandu bukaze. Inyishu zerekana ko urwaye zivuga ko hari imigera ya antijene yibonekeza, ariko kahise k'umurwayi n'ibitaro hamwe n'ayandi makuru y'ibipimo birakenewe kugira hamenyekane urugero rw'ubwandu. Inyishu nziza ntizitwara ubwandu bw'indwara yibonekeje canke ubwandu hamwe n'iyindi migera. Ivyibonekeje bishobora kutaba inkomoko y'indwara. Amazu y'igeragerezo ry'imiti muri reta zunze ubumwe hamwe n'uburere bwaho asabwe gutanga raporo ku nyishu zose ku barongozi b'amagara y'abantu.

Inyishu zerekana ko utarwaye zifatwa nk'imfatakibanza zidakuraho ubwandu bwa SARS-CoV-2 kandi ntizitegerezwa gukoreshwa k'inyishu ngenderwako mu kuvura canke ingingo zo kwitaho umurwayi, harimwo kwihweza ingingo z'ubwandu. Inyishu zerekana ko utarwaye zitegerezwa gufatwa mu bijanye n'uko umurwayi yafashwe, akahise hamwe n'ukuba ho kw'ibimenyetso vyamahoro hamwe na COVID-19, vyemejwe n'igipimo ca morekire, nimba ari ngombwa mu kwitaho umurwayi. Ku rukurikirane rwa porogarama yo gupima, igipimo c'inyongera cemeza igipimo ca morekire ku nyishu ziterekana indwara ko gishobora kuba ngombwa inyuma y'ubugira kabiri haboneka inyishu iterekana indwara ku bantu batagaragaza ibimenyetso, nimba hari ivyago vyinshi vy'ubwandu bwa SARS-CoV-2 canke, nko ku muntu yanduye COVID-19 canke yoba yarahuye n'uwurwaye COVID-19 canke mu miryango irimwo ubwandu bwinshi. igipimo c'inyongera ca morekire ku nyishu zerekana indwara bishobora kuba kandi bikenewe, nimba hari ivyago bike vyo kwandura SARS-CoV-2, nko mu bantu batazi ko bahuye n'uwurwaye SARS-CoV-2 canke baba mu miryango irimwo ubwandu buke.

Igipimo kinyaruka ca SARS antijene kigamije gukoreshwa n'abakozi bo mu mazu ageregeza imiti babifite ubumenyi hamwe n'abandi bantu baherewe ubumenyi mu bibanza vyo gukurikirana abarwayi. Igipimo cihuta SARS antijene gikoreshwa gusa biciye mu ruhusha rwo gukoresha imfungurwa hamwe n'imiti mu buryo bwihuse.

Raba ku co bitekeyemwo imbere kugira umenye *ibibujijwe n'ivyitonderwa, ivyegeranijwe, ukubikorakora, hamwe n'igenzura ry'ubwiza.*

URUHUSHA RW'IKOresha Ryihuse— IGABISHA HAMWE N'IVYITONDERWA

Muri reta zunze ubumwe za Amerika, uyu muti ntiwemejwe na FDA; ariko wahawe uruhusha na FDA biciye kuri EUA kugira ukoreshwe mu mazu agerageza imiti yahawe uruhusha; ukoreshwe n'amazu agerageza imiti yahawe icete na CLIA, 42 U.S.C. §263a, akwije ibisabwa vyo gukora ibipimo vyo ku rwego rwo hejuru, canke bihanitse. Uwu muti urekuwe gukoreshwa ku kibanza bitaho (POC), ni kuvuga, mu bijanye no kwitaho umurwayi bitwarwa muri CLIA urupapuro rutanga uburenganzira, urupapuro rwo kwifatanya, canke urupapuro rwo kwemeza. Uwu muti waremejwe kugira upime poroteyine gusa ivuye kuri SARS-CoV-2, atari imigera iyo ariyo yose canke ibiyitera. Uyu muti wemerewe gusa mu kiringo c'itangazo ko ibibazo biriho bisigura uruhusha rwo gukoresha vyihuse igipimo gikoresha ikiyo kugira hapimwe COVID-19 biciye ku kigabane ca 564(b)(1) cerekeye imfungurwa mu gihugu, imiti n'itegeko rigenga ivyo kwisiga, 21 U.S.C. § 360bbb-3(b)(1), kiretse iryo tangazo rihagaritswe canke uruhusha rufuswe vuba cane.

UBUFASHA

Nimba ufise ikibazo icarico cose kijanye n'ikoreshwa ry'uwu muti, usabwe guhamagara abatangabufasha ba Quidel mu vy'ubuhinga ku nomero 800.874.1517 (muri reta z'unzuzwe ubumwe) canke 858.552.1100, kuwa mbere kugeza kuwa gatanu, kuwa isaha imwe yo mu gitondo 7:00 kugeza isaha cumi n'imwe yo ku mugoroba 5:00, ufatiye k'umwanya wa pasifike. Nimba uri hanze ya reta zunze ubumwe., hamagara ababijewe bo mu karere canke technicalsupport@quidel.com. Ingorane z'ukuntu igipimo kimeze zishobora gushikirizwa FDA biciye kuri terefone ya MedWatch: 800.FDA.1088; fax: 800.FDA.0178; <http://www.fda.gov/medwatch>).



Iga neza ibiri mu gakarato imbere yo kubikoresha ningoga Ingingo zo kwisunga. Iki ntabwo ari igikoresho gikwiye Shiramwo.



Ihunguriro Quidel
San Diego, CA 92121 USA
quidel.com

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