

Ka eeg Waraaqda Tilmaamaha ee Bushqada tilmaamaha dhamaystiran. Akhri nidaamka shaybaadhka oo dhamaystiran, oo ay ku jiraan nidaamka Ilaalinta Tayada lagu taliyay, kahor inta aanad samaynin shaybaadhka.

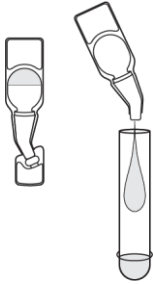
Dhamaan muunadaha caafimaad waa inay noqdaan heerkulka qolka kahor inta aan la bilaabin shaybaadhka. In la qaado shaybaadhka wakhti iyo heerkulka loogu talo galay mid aan ahayni waxay keeni kartaa natiijo khaldan. Shaybaadhka aan la qaadin wakhtiga loogu talo geley iyo heerkulka loogu talo geley waa in lagu celiyo.

Taariikhda dhacistaanka: Eeg taariikhda dhacistaanka ee bushqad kasta oo shaybaadhka shakhsi ahaaneed ah ama sanduuqa sare kahor inta aanad isticmaalin. *Ha isticmaalin hadii shaybaadhku uu dhaafto wakhtigiisa taariikhda ee ku dul qoran.*

Nidaamka Shaybaadhka

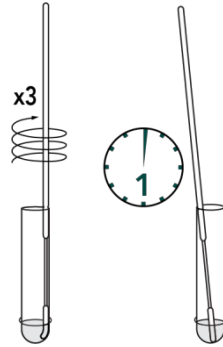
1

Ku shub dhamaan Milanka Shaybaadhka Tuunbada Shaybaadhka. Lul Tuunbada Shaybaadhka si aad u misho waxa ku jira. OGOW: Tuunbada Shaybaadhka waa inay ku jirtaa tuunbe hayaha inta la wado shaybaadhka oo dhan



2

Waxa aad gelisaa cudbida muunada bukaanka Tuunbada Shaybaadhka. Waxa aad wareejiisaa cudbida 3 jeer adiga oo ku haya madaxa xaga hoose iyo dhinaca Tuunbada Shaybaadhka.



Ku daa Cudbida Tuunbada Shaybaadhka **1 daqiiqo**. Natiijada khaldan ama aan saxa ahayn waxay timaadaa marka mudada ay ku jirtaa ay gaaban tahay ama aad u badan tahay.

3

Waxa aad kaga reebtaa dareeraha madaxa cudbida adiga oo wareejinaya cudbiga ugu yaraan sadex (3) jeer marka cudbida lasoo saarayo. U tuur cudbida sida uu dhigayo nidaamka tuurista wasakhda waxyeelada nooleed leh.



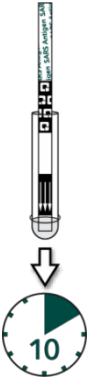
4

Waxa aad ku ridaa Miiqa Shaybaadhka Tuunbada Shaybaadhka iyada oo falaadhu hoos u jeedo. Ha taaban ama dhaqaajin Miiqa Shaybaadka ilaa inta shaybaadhku dhamaanayo oo uu diyaar u noqonayo akhriska.

10 daqiiqo, marka la gaadho ka saar Miiqa Shaybaadka

oo u akhri natiijada shan (5) daqiiqo gudaheed sida ay dhigayso qaybta Turjubaada Natiijada ee ku qoran dhinaca kale ee kaadhkan.

Miiqa shaybaadhka waa in la akhriyaa 10-15 daqiiqo inta u dhaxaysa. Natiijada beenta ah ee laga heley, laga waayay, ama natiijada khaldan waxay timaadaa hadii miiqa la akhriyo mudo ka badan wakhtiga loogu talo geley in la akhriyo.



Ilaalinta Tayada

Qaybaha Maamulka ee Ku Samaysan

Shaybaadhka QuickVue SARS Antigen waxa uu leeyahay qaybo maamul oo nidaameed oo ku samaysan. Talooyinka warshada ee maamulida maalin kasta waxaa weeye in lagu duwaan geliyo qaybahaan maamul ee nidaameed ee ku samaysan muunada kowaad ee la baadho maalin kasta.

Qaabka natiijada labada midab ahi waxay bixisaa turjubaad fudud oo natiijada laga heley iyo ta laga waayay ah. Muuqaalka Laynka Maamulida nidaamka ee buluuga ah waxa uu bixiyaa maamul wanaagsan iyada oo lagu muujinayo in socod ku filan uu dhacay oo la ilaaliyey badqabka shaqeed ee Miiqa Shaybaadhka. Hadii Laynka Maamulida nidaamka ee buluuga ahi aanu ka soo bixin 10 daqiiqo gudaheed Miiqa Shaybaadhka, markaa natiijadu way khaldan tahay.

Maamulaha natiijada laga waayay ee ku samaysan waxa uu bixiyaa midab danbe oo casaan ah, taas oo xaqiijinaysa in shaybaadhka loo sameeyay sidii saxda ahayd. 10 daqiiqo gudahood, aaga natiijadu waa inay noqotaa cadaan ilaa soosali cadaati ah oo waxaanay keeneysaa in si cad loo turjubo natiijada shaybaadhka. Hadii midabka danbe uu sii jiro oo uu turjubaada natiijada shaybaadhka carqaladeeyo, markaa natiijada shaybaadhku way khaldan tahay. Hadii ay dhacdo tani, eeg nidaamka oo ku celi shaybaadhka adiga oo isticmaalaya muunad bukaan iyo Miiq Shaybaadh oo cusub. Muunada ama milanka bukaanka dib looma isticmaali karo.

Ilaalinta Tayada Banaanka

Maamulida Banaanka ayaa sidoo kale la isticmaali karaa si loo muujiyo in nidaamka milanka iyo shaybaadhka loo sameeyay sidii saxda ahayd.

Quidel waxay ku telisaa in maamulaha ka helitaanka iyo ka waayitaanka in loo bilaabo halmar hawlwadeen kasta oo aan lagu tabo barin, halmar buqshad kasta oo lasoo diro oo cusub — iyada oo ay shardi u tahay in alaab kasta oo gaar ah oo buqshadda la socota la tijaabiyo — iyo sida loogu arko dheeraad ahaan daruuri cida idiin samaysa nidaamyada ilaalinta tayada gudaha, si waafaqsan shuruucda ama shuruudaha la aqoonsan yahay ee deegaanka, gobolka, iyo federaalka.

Nidaamka Shaybaadhka ee lagu sheegey Waraaqda Tilmaamaha ee Bushqada waa in la isticmaalo marka maamulida banaanka la tijaabinayo.

Hadii maamulida aan lagu arag waxa laga filanayay, ku celi shaybaadhka ama la xidhiidh Taageerada Farsamo ee Quidel kahor inta aanad baadhin muunada bukaanka.

Fasiraada Natiijada

Natiijada Laga Heley*:

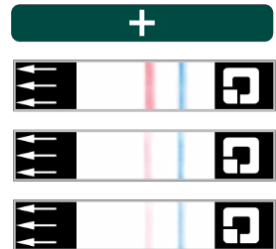
Toban (10) daqiiqo, soo bixitaanka **WIXII hadh ah ee Laynka Shaybaadhka ee soosliga-ilaa-casaanka ah iyo** soo bixitaanka Laynka Maamulaha nidaamka ee buluuga ah waxa uu muujinayaa natiijada laga heley ee jiritaanka SARS antigen. Natiijadu way sii shaqayn doontaa ilaa shan (5) daqiiqo kadib wakhtiga lagu taliyay ee akhriska. Ha akhriyin natiijada wixii ka danbeeya shantaa daqiiqo. Natiijada laga heley, waayay ee beenta ah ama khaldan waxay dhacdaa marka miiqa la akhriyo wakhti ka baxsan wakhtida lagu taliyay.

**Natiijada laga heley meesha kama saarto inay jiraan caabuqyo kale.*

***U firso!** Tani waa natiijo laga heley. Xataa hadii aad aragto Laynka Shaybaadhka oo aan si wanaagsan u muuqan, oo soosali ah iyo Laynka Maamulida oo buluug ah, waa inaad uga warbixisaa natiijada in LAGA HELEY.

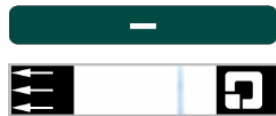
C = Laynka Maamulida

T = Laynka Shaybaadhka



Natiijo Laga Waayay**:

Daqiiqada tobnaad (10), soo bixitaanka **KALIYA Laynka Maamulida ee nidaamka ee buluuga ah** waxa uu muujinayaa in antigenka SARS aan la dareemin. Natiijadu way sii shaqayn doontaa ilaa shan (5) daqiiqo kadib wakhtiga lagu taliyay ee akhriska. Natiijada laga heley, laga waayay ee beenta ah ama khaldan waxay iman kartaa hadii miiqa la akhriyo wakhti ka baxsan wakhtiga loogu talo geley.



*** Oggow: Natiijada muujinaysa in laga waayay waa in loo arkaa mid hordhac ah oo xaqin baaritaanka molikiyuuleed ah, hadii loo baahdo, ee maamulka bukaanka, ayaa la samayn karaa. Barnaamijyada shaybaadhka taxanaha ah, shaybaadh dheeraad ah oo lagu xaqiijinayo oo wata shaybaadhka molecular-ada ee natiijada laga waayay ayaa loo baahan karaa kadib natiijada shaybaadhka labaad ee laga waayay ee bukaanka aan lahayn astaamaha, hadii ay jirto macquuliyada sare oo caabuq SARS-CoV-2 ah, sida shakhsiyaadka u dhawaaday cida qabta COVID-19 ama looga shakiyay inuu u baylahay COVID-19 ama bulshooyinka leh caabuqa aadka u badan.*

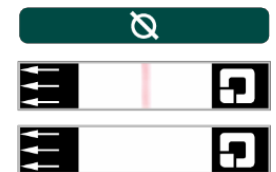
Shaybaadhdo xaqiijin oo dheeraad ah oo ah shaybaadhada molekulaarada ee natiijada laga heley ayaa sidoo kale loo baahan karaa, hadii ay jirto macquuliyad hoose oo caabuqa SARS-Co V-2 ah, sida shakhsiyaadka aan lahayn u baylihitaan la ogyahay oo SARS-CoV-2 ah ama degan bulshooyinka heerkooda caabuqu yar yahay.

Natiijada Khaldan:

Hadii toban (10) daqiiqo gudahood, Laynka Maamulida nidaamka ee buluuga ah uu soo bixi waayo, xataa hadii uu soo baxo waxoogaa Laynka Shaybaadhka ee soosali-ilaa-casaanka ahi, natiijadu way khaldan tahay.

Hadii toban (10) daqiiqo gudahood, midabka danbe aanu si cad u soo bixin oo uu caqabad ku noqdo akhriska natiijada, natiijadu way khaldan tahay sidoo kale.

Hadii natiijadu ay khaldan tahay, shaybaadh cusub waa in la sameeyaa iyada oo la adeegsanayo muunad cusub oo bukaanka ah iyo Miiq Shaybaadh oo cusub.



ISTICMAALKA LOOGU TALO GELEY

Shaybaadhka QuickVue SARS Antigen waxaa weeye shaybaadh difaaca jidhka ah oo kuwa qalabka fudud ah oo sahla in baadhis tayeed, oo degdeg ah lagu sameeyo antigenka borootiinta nucleocapsid ee SARS-CoV-2 ee muunada si toos ah looga qaaday gudaha dulka sanko (NS) ee sakhsiyadka uu uga shakiyo inay qabaan COVID-19 biyaha daryeelkooga caafimaad shanta maalmood ee kowaad ee bilawga astaamaha ama shakhsiyadka aan lahayn astaamaha ama sababo kale oo safmarka ah looga shakiyo COVID-19 marka shaybaadhka la baadho laba jeer mudo ka badan laba ama sadex maalmood gudahood ugu yaraan 24 saacadood iyo in wax aan ka badnayn 36 saacadood ay u dhaxeeyaan shaybaadhada. Shaybaadhku waxa uu ku xadidan yahay shaybaadhada haysta shahaado waafaqsan Wax ka Badalka Hormarinta Shaybaadhka Caafimaadka ee 1988 (Clinical Laboratory Improvement Amendments, CLIA), 42 U.S.C. §263a, taas oo buuxisa shuruudaha lagu samaynayo shaabado dhexe, sare ama lagaga tanaasulayo midka murugsan. Shaybaadhkan waxaa loo ogolaaday in lagu isticmaalo Meesha Daryeelka (Point of Care, POC), sida, xarunta daryeelka bukaanka ee ku shaqeeya Shahaadada Ka Tanaasulka ee CLIA, Shahaadada U Hogaansanka, ama Shahaadada Aqoonsiga. Shaybaadhka QuickVue SARS Antigen ma kala saaro SARS-CoV iyo SARS-CoV-2.

Shaybaadhka QuickVue SARS Antigen ma kala saaro SARS-CoV iyo SARS-CoV-2.

Natiijada waxaa lagu ogaadaa antigen-ka borotiinka nucleocapsid SARS-CoV-2. Antigen-ka waxa guud ahaan lagu ogaadaa muunada duufka gudaha sanko wakhtiyada caabuqu xoogan yahay. Natiijada togan waxay muujisaa jiritaanka antigen-nada fayraska, balse caafimaad ahaan inay la xidhiidho taariikhda bukaanka iyo macluumaadka kale ee xanuun ee daruuriga ah ayaa daruuri ah si loo go'aamiyo xaalada caabuqa. Natiijada muujinaysa in laga heley meesha kama saarayo caabuqa baakteeriyada ama caabuq wada socda oo fayrasyada kale ah. Waxa lagu arko waxaa macquul ah inayna ahayn waxa keenaya xanuunka. Shaybaadhada Maraykanka gudihisa iyo deegaanadiisa ayaa looga baahan yahay in ay gaadhsiyaan dhamaan natiijoyinka maamulada caafimaadka dadwaynaha ee ay khusayso.

Natiijada laga waayay waa in loo arkaa mid hordhac ah, oo meesha kama saarayo caabuqa SARS-CoV-2 oo waa in kaligeed aan loo isticmaalin in looga duulo daawaynta ama go'aamada maamulka bukaanka, oo ay ku jiraan go'aamada xakamaynta caabuqa. Natiijada laga waayay waa in la eegaa xaaladda in dhawaan bukaanka uu u baylahay cid qabta, taariikhda iyo jiritaanka calaamadaha caafimaad iyo astaamaha waafaqsan COVID-19, oo lagu xaqiijiyo shaybaadhka molokularka, hadii ay u baahdaan, maamulka bukaanku. Wixii barnaamijyada shaybaadhka ee taxanaha ah, shaybaadh dheeraad ah oo xaqiijin ah oo wata shaybaadhka molokulaarka ee natiijoyinka laga waayay ayaa loo baahan karaa, hadii ay jirto macquuliyad sare oo ah caabuqa SARS-CoV-2, sida shakhsi u dhawaaday cid qabta COVID-19 ama shakhsiyadka looga shakiyo inuu u baylahay COVID-19 ama bulshooyinka uu ku badan tahay caabuqu. Shaybaadhka xaqiijin oo dheeraad ah oo ah shaybaadhada molekulaarada ee natiijada laga heley ayaa sidoo kale loo baahan karaa, hadii ay jirto macquuliyad hoose oo caabuqa SARS-CoV-2 ah, sida shakhsiyadka aan lahayn u baylihitaan la ogyahay oo SARS-CoV-2 ah ama degan bulshooyinka heerkooda caabuqu yar yahay.

Shaybaadhka QuickVue SARS Antigen waxaa loogu talo geley inay isticmaalaan shaqaalaha shaybaadhka caafimaadka ee la tabo baray iyo shakhsiyadka lagu tabo baray goobaha daryeelka meesha "point of care". Shaybaadhka QuickVue SARS Antigen waxa uu keliya ku shaqeeyaa Oggolaanshaha Isticmaalka Xaalada Degdega ah ee Maamulka Cuntada iyo Dawooyinka.

Ka eeg Bushqada Waraaqda Tilmaamaha wixii ah *Digniinta iyo Taxadirka, Uruurinta iyo Ka Shaqaynta Muunada, iyo Ilaalinta Tayada.*

OGOLAANSHAHA ISTICMAALKA XAALADA DEGDEGA AH – DIGNIINTA IYO TAXADIRKA

Maraykanka, alaabtan may ansixin ama fasixin FDA; laakiin waxay u ogolaatay FDA inay u isticmaalaan EUA shaybaadhada loo ogol yahay; isticmaalaan shaybaadhada haysta shahaadada CLIA, 42 U.S.C. §263a, ee buuxiyay shuruudaha samaynta shaybaadhada dhexe, sare ama ka tanaasulka murugsanaanta. Shaygan waxaa loo ogolaaday in lagu isticmaalo Meesha Daryeelka (Point of Care, POC), sida, xarunta daryeelka bukaanka ee ku shaqeeya Shahaadada Ka Tanaasulka ee CLIA, Shahaadada U Hogaansanka, ama Shahaadada Aqoonsiga. Alaabtan waxaa kaliya loo ogolaaday in lagu ogaado borotiinka ka yimi SARS-CoV-2, ee looguma talo gelin fayras ama geermis kale. Maraykanka, isticmaalka xaalada degdega ah ee alaabtan waxaa kaliya la ogolaaday mudada bayaaminta jiritaanka duruuf loogu cudurdaarayo ogolaanshaha adeegsiga xaalada degdega ah ee shaybaadhada vitro ee lagu ogaanayo oo/ama lagu baadhayo xanuunka COVID-19 siday dhigayso Qaybta 564(b)(1) ee Sharciga Federalka ee Cuntada, Dawooyinka iyo Waxyaabaha La Isku Qurxiyo, 21 U.S.C. § 360bbb-3(b)(1), iyada oo bayaanka meesha laga saaro ama ogolaanshaha laga noqdo xilli hore mooyee.

KAALMO

Hadii aad qabto wax su'aalo ah oo ku saabsan isticmaalka alaabtan, fadlan kala hadal Lambarka Taageerada Farsamada Quidel 800.874.1517 (Maraykanka dhaxdiisa) ama 858.552.1100, Isniin ilaa Jimce, laga bilaabo 7:00 subaxnimo ilaa 5:00 galabnimo, Saacada Baasifiga. Hadii aad ka baxsan tahay Maraykanka, la xidhiidh shirkadaada deegaanka ama technicalsupport@quidel.com. Mushkiladaha nidaamka shaybaadka waxaa sidoo kale lagaga warbixin karaa FDA iyada oo la adeegsanayo barnaamijka ka warbixinta alaabadka caafimaadka ee MedWatch (taleefanka: 800.FDA.1088; faakis: 800.FDA.0178; <http://www.fda.gov/medwatch>).



U daraasadee Waraaqda Tilmaamaha ee Bushqada si wanaagsan kahor inta aanad isticmaalin Tilmaamaha Tixraaca ee Degdega ah. Tani maaha Waraaqda Tilmaamaha ee Bulshad dhamaystiran.



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