Rx Only, IVD, For Use Under an Emergency Use Authorization (EUA) Only

TANGEN™

TangenDx™ SARS-CoV-2 Molecular Test

INSTRUCTIONS FOR USE (IFU)

TANGENBIOSCIENCES.COM

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Version 22.0, P/N: LBL-000218

TANGENDx SARS-CoV-2 MOLECULAR TEST

Intended Use

TangenDx SARS-CoV-2 Molecular Test performed on the Tangen GeneSpark instrument is an isothermal nucleic acid amplification assay intended for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal (NP) swab, mid-turbinate nasal swab, and anterior nasal swab specimens from individuals suspected of COVID-19 by their healthcare provider. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high, moderate, or waived complexity tests. The TangenDx SARS-CoV-2 Molecular Test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Results are for the identification of SARS-CoV-2 RNA. SARS-CoV-2 RNA is generally detectable in nasopharyngeal, mid-turbinate nasal, and anterior nasal swab specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definitive cause of disease. Laboratories within the United States and its territories are required to report all test results to the appropriate public health authorities.

Negative results should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, should be confirmed with a different authorized or cleared molecular test in a CLIA-certified laboratory that meets requirements to perform high or moderate complexity tests. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and/or epidemiological information.

The TangenDx SARS-CoV-2 Molecular Test is intended for use by operators who have received specific training in the use of the TangenDx SARS-Cov-2 Molecular Test and the Tangen GeneSpark instrument. The TangenDx SARS-CoV-2 Molecular Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

Product Overview/Test Principle

The TangenDx SARS-CoV-2 Molecular Test is a reverse transcriptase loop-mediated isothermal amplification (RT-LAMP) test. The SARS-CoV-2 primer sets are designed to detect the RNA from the SARS-CoV-2 in nasopharyngeal, mid-turbinate nasal or nasal swabs from patients suspected of COVID-19 by their healthcare provider. The TangenDx SARS-CoV-2 Molecular Test includes two primers sets targeting two distinct regions in the N gene of SARS-CoV-2 viral RNA. The LAMP reaction is detected by the fluorophore which binds double stranded DNA to become fluorescent under blue light excitation. Green fluorescence is detected in each well of the Tangen Assay Disk as the disk spins past an amber filtered photo detector. The TangenDx SARS- CoV-2 Molecular Test is to be used with the Tangen GeneSpark instrument equipped with onboard analysis. No additional software or nucleic acid extraction instruments are required.

TangenDx SARS-CoV-2 Molecular Test Materials

TangenDx SARS-CoV-2 Molecular Test Kit (PN KRW0164) includes:

1. 25 single use TangenDx Assay Disks
2. 30 single use Tangen Assay Buffer tubes
3. 30 single use Filter Devices
4. 30 single use Reagent Containers
5. 30 single use exact volume Transfer Pipettes
6. 30 single use nasopharyngeal, mid-turbinate nasal or nasal swabs
7. 25 Patient ID Barcode and Sample ID QR Code labels
8. TangenDx SARS-CoV-2 Molecular Test Quick Reference Instructions (not shown)
9. Product Information Card (PIC) (not shown)
10. TangenDx SARS-CoV-2 Molecular Test Control Kit

TangenDx SARS-CoV-2 Molecular Test Control Kit (PN KRW0256)* contains:

1. 2 Positive Control TangenDx Assay Disks, and 2 Negative Control TangenDx Assay Disks
2. 2 Vials of Positive Control Lyophilized Control Material and 2 Vials of Negative Control Lyophilized Control material
3. 2 Positive Control QR Code Stickers and 2 Negative Control QR Stickers
4. TangenDx SARS-CoV-2 Molecular Test Quick Reference Instructions (not shown)

*Tangen Assay Buffer, Reagent Container, Filter Device, Transfer Pipette and NS/NP Swab are common components for both the Assay and the Control kits.

When ordering, specify the nasal swab by part number (PN):

- Nasophayngeal (NP Swab, PN NP-KRR0195)
- Mid-turbinate (MT Swab, PN MT-KRR0195)
- Anterior Nasal (NS swab, PN AN-KRR0195)

Reagent Information

- TangenDx Assay Disks contain dried components to support the LAMP reaction: reaction buffer, sugars, primers, surfactant, and fluorescent dye.
- Tangen Assay Buffer includes molecular grade water, reaction buffer, protein and preservatives.
- Reagent Containers contain lyophilized beads. Lyophilized materials include excipients to support drying, dNTPs, protein stabilizers, MgSO4, and reverse transcriptase and DNA polymerase enzyme.

Warnings and Precautions

- If you are new to the TangenDx SARS-CoV-2 Molecular Test or Tangen GeneSpark™ Instrument, you must read the GeneSpark Operator's Manual, the Quick Reference Instructions, and these entire Instructions for Use.
- For in vitro diagnostic use.
- For use under Emergency Use Authorization (EUA) only.
- For prescription use only.
- This product has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.
- This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- For use only in authorized laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, 42 U.S.C. §263a, that meet requirements to perform high, moderate or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
- Federal Law restricts sale of this product to or on the order of a licensed practitioner.
- To be used only with TangenDx reagents and the GeneSpark instrument and software.
- Observe established precautions against viral hazards during use and disposal.
- Do not use the test component or controls beyond the expiration date of the kit.
- Do not use any damaged kit contents.
- Not for patient use.
- Wear protective clothing such as laboratory coats, disposable gloves, and eye protection when handling samples.
- Follow proper infection control guidelines for handling all specimens, control swabs and related items. Properly dispose of all contaminated waste according to federal, state, and local requirements.

Sample Collection and Handling

Collect the sample for the TangenDx SARS-CoV-2 Assay using the provided nylon flocked nasopharyngeal, or mid-turbinate nasal or nasal swab and 5 mL Tangen Assay Buffer tube (**Figure A**). Follow universal collection procedures or guidelines for your organization.

Note: It is recommended to blow nose before collection.

1. Apply Patient ID Barcode to Tangen Assay Buffer tube (Figure A).
2. Uncap the Tangen Assay Buffer Tube.
3. Collect the patient sample with the NP (nasopharyngeal), MT (mid-turbinate nasal) or NS (anterior nasal) swab using standard techniques.
4. **Vigorously mix** the patient swab up and down in the buffer **10 times** and rotate the swab in the at least buffer **10 times**, **ensuring contact with the bottom and sides of tube** (**Figure B**), then discard swab according to biohazard controls.
5. Replace the cap on the Tangen Assay Buffer.

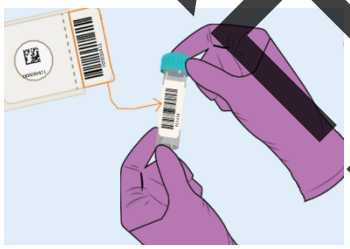


FIGURE A

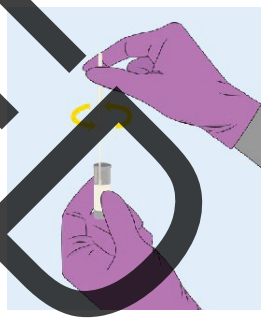


FIGURE B

Sample Preparation

⚠ Initiate Sample preparation for the SARS-CoV-2 Assay with the GeneSpark within 15 minutes of sample collection.

Remnant samples can be refrigerated at 4°C for 24 hours.

Note: If using a frozen sample, allow sample to thaw completely at room temperature (no longer than one hour) before transferring sample to the Reagent Container as described in Step 8. below. Once thawed, process the sample within fifteen (15) minutes.

6. Remove the tear-off Sample ID QR Code label and place it onto the **bottom** of the Reagent Container (**Figure C**).

⚠ Match the barcode on Reagent Container to the barcode on the sample tube. Failure to do so will misattribute patient results.

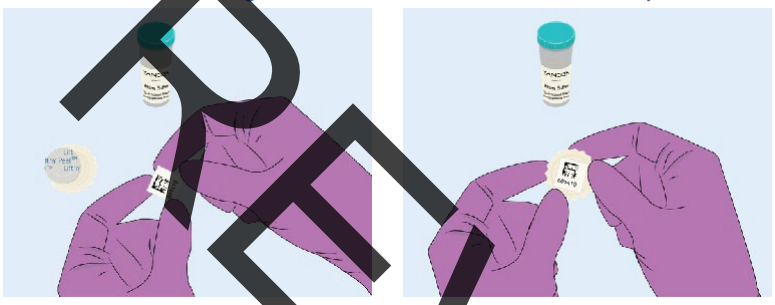


FIGURE C

7. Place the Reagent Container onto the Reagent Container Holder and carefully remove the peel-off seal (**Figure D**).
8. Use the Transfer Pipette to transfer the prepared Tangen Assay Buffer solution into the Reagent Container secured in the Reagent Container Holder (**Figure E**).

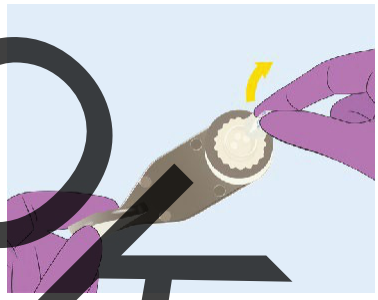


FIGURE D

- ☐ **Draw fluid so it completely fills the stem into the overflow bulb of the Transfer Pipette. Ensure there are no air bubbles in the stem.**
- ☐ **Discharge all fluid from the stem into the Reagent Container. The fluid in the overflow bulb will remain in the overflow bulb.**

⚠ If there is an error in drawing up fluid with the Transfer Pipette, discard the pipette and repeat with a new, unused pipette (extras are provided).

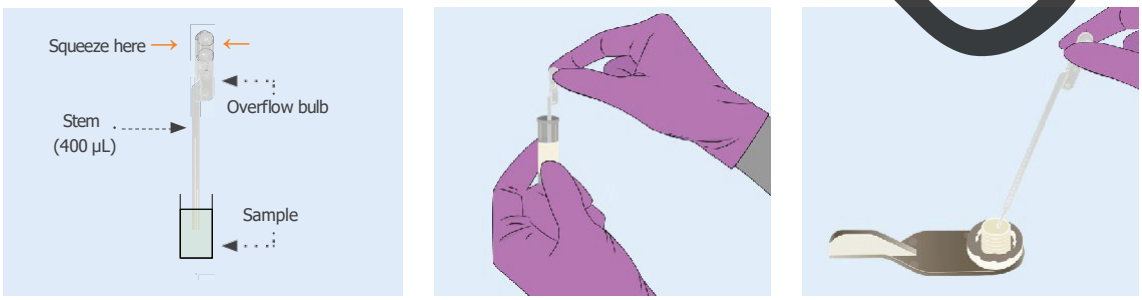


FIGURE E

9. Place the Filter Device over the filled Reagent Container **(Figure F). Avoid touching the tip of the Filter Device.**

10. Screw the Filter Device onto the Reagent Container while secured in the Reagent Container holder then tighten using the Tightening Tool **(Figure G)**. **Tighten as firmly as possible**. You cannot over tighten. Do not remove the protective cover from the Filter Device until ready to insert Filter Device assembly into GeneSpark instrument.

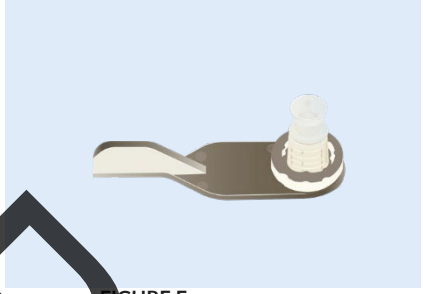


FIGURE F

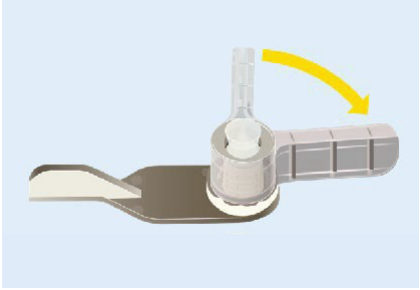


FIGURE G

⚠ Securely tighten the Filter Device as far as it can go using the Tightening Tool. You cannot over tighten. An insufficiently tightened Filter Device assembly may cause an invalid result.

Note: It is recommended to clean the Tightening Tool and Reagent Container Holder after each patient sample by wiping them with 10% bleach followed by 70% isopropanol.

11. **THE SAMPLE MUST SIT FOR 5 MINUTES AFTER ADDING THE TANGEN ASSAY BUFFER TO THE REAGENT CONTAINER TO ALLOW PROPER DISSOLUTION OF REAGENT BEADS.**

    Samples should be run within 15 minutes after adding the Tangen Assay Buffer to the Reagent Container. Proceed with running the GeneSpark instrument.

Set Up the GeneSpark

Running the GeneSpark instrument requires the GeneSpark, Barcode Reader, TangenDx SARS-CoV-2 Assay Disk, and prepared Filter Device assembly (**Figure H**).

a. Attach the power cord to the GeneSpark instrument and plug into an electrical outlet. Then plug the Barcode Scanner into the GeneSpark instrument USB port (**Figure I**).

b. Slide the GeneSpark latch open and lift the disk housing cover (**Figure J**).

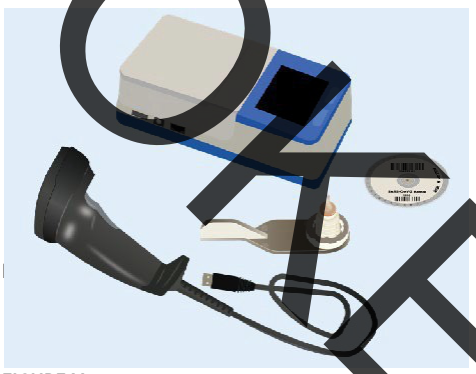


FIGURE H

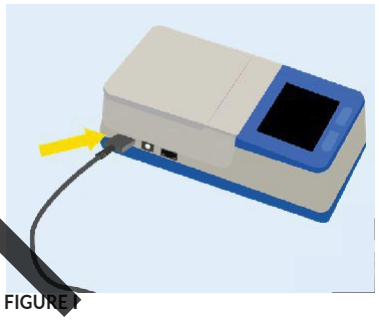
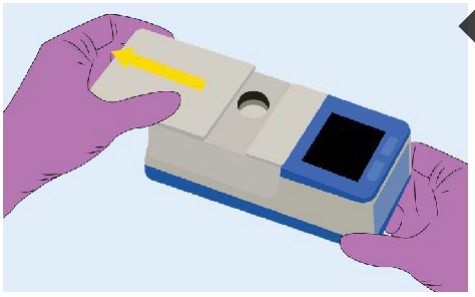


FIGURE I



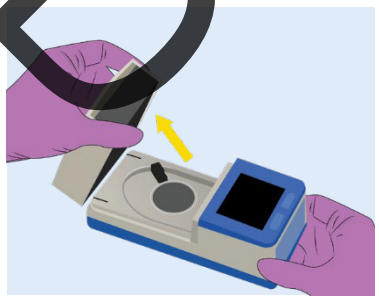


FIGURE J

c. Remove the TangenDx SARS-CoV-2 Assay Disk from its foil wrapper and load it on the instrument by firmly pushing the disk onto the circular disk mount **(Figure K)**. Force can be applied in the area shaded in blue. The disk will audibly click when attached to the disk mount.

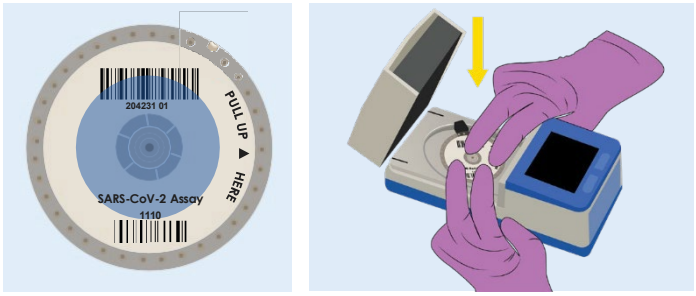


FIGURE K

⚠ An improperly mounted disk will generate an error code.

d. Scan the 8-digit Kit Lot barcode found on the disk label and the 4-digit Assay ID barcode found on the bottom of the disk label **(Figure L)**.

FIGURE L

e. Firmly close the cover of the instrument. If a rotor calibration failure occurs, remount the Assay Disk as described in the troubleshooting guide.

f. Remove the protective cover from the Filter Device by squeezing the tip and discard. Place Filter Device assembly into the disk housing cover **(Figure M)**. Ensure it is seated properly. Scan the sample ID barcode **(Figure N)**.

⚠ Improper loading of the Filter Device assembly will result in an error code.

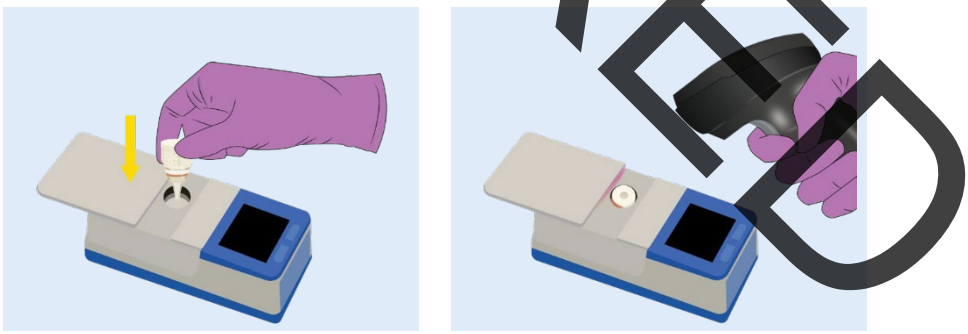


FIGURE M FIGURE N

To manually enter the Sample ID, touch the Sample ID button on the screen and use the onscreen keyboard to key in the Sample ID. After keying in the Sample ID, touch the checkmark (lower right of screen) to accept. Pressing the X (lower left of screen) will cancel. Note that the run is not permitted to start without filling this field **(Figure O)**.

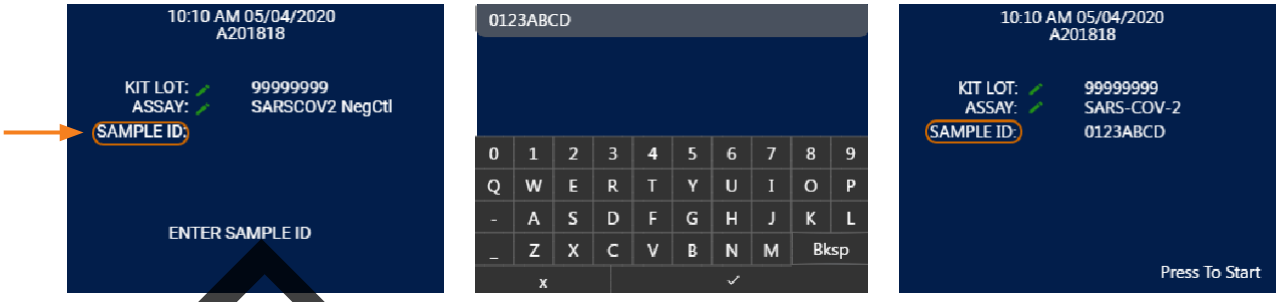


FIGURE O

⚠ Erroneous entry of sample ID will cause misattributed patient result.

g. Slide the GeneSpark latch closed **(Figure P)**.

⚠ Improper closure of latch will result in an error code.

h. The words "Press To Start" will appear on the screen above the right-hand pushbutton after the set-up is complete. Start the instrument run by pushing the right-hand button **(Figure Q)**. After pressing the start button, the run screen will appear.

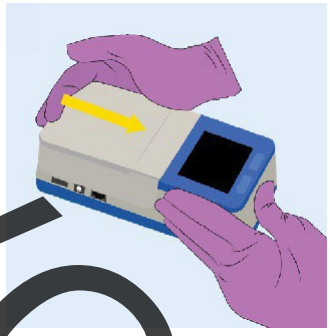


FIGURE P

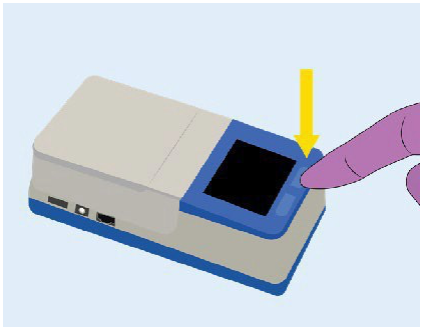


FIGURE Q

⚠ Ensure button is pressed or the instrument will not start.

Please Note: The instrument has a sonicator that sonicates for 90 seconds at 66-76 dBA. Users will hear the instrument at levels similar to loud talking.

i. GeneSpark will complete the Assay in approximately 30 minutes. The result of the run will be displayed on the screen. The instrument screen will indicate when the run is complete. Record the result.

⚠ While the instrument is running, the countdown timer will pause for a few minutes while the instrument reaches the required temperature. This pause is normal, and the countdown timer will resume as the assay progresses.

Results

RESULT	INTERPRETATION
SARS-CoV-2 PRESUMPTIVE NEGATIVE	SARS-CoV-2 target RNA is **not detected**. The result should be verified using a highly sensitive SARS-CoV-2 assay.
SARS-CoV-2 POSITIVE	SARS-CoV-2 target RNA is **detected**.
SARS-CoV-2 INVALID	If the result is **SARS-CoV-2 INVALID**, then retest the patient sample with a **new Assay kit**.

⚠ Negative results should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, should be confirmed with a different authorized or cleared molecular test in a CLIA-certified laboratory that meets the requirements to perform high or moderate complexity tests.

FIGURE R

j. Press the Done button to exit the result screen.

⚠ If an Invalid result is produced, the patient sample must be re-analyzed. Use the prepared patient buffer along with new, unused assay supplies (Reagent Container, Filter Device, Transfer Pipette, and Assay Disk) to re-run the sample.

Following Completion of Assay

Remove the Filter Device assembly from the instrument **(Figure S)**.

Remove the TangenDx SARS-CoV-2 Assay Disk from GeneSpark. When unmounting the disk, pry up only from the indicated point **(Figure T)**.

⚠ Improper removal of the disk can damage the disk mount.

Discard the disk and Filter Device assembly by placing into a sealed plastic bag, remove from area and dispose per appropriate environmental controls.

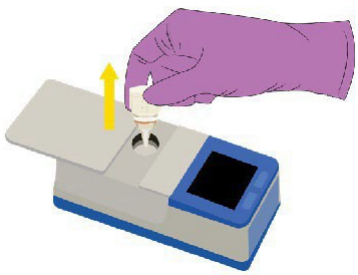


FIGURE S

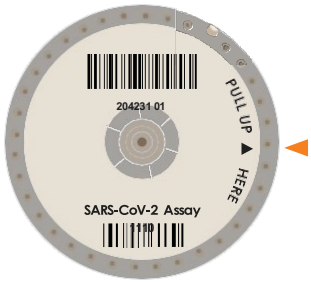


FIGURE T

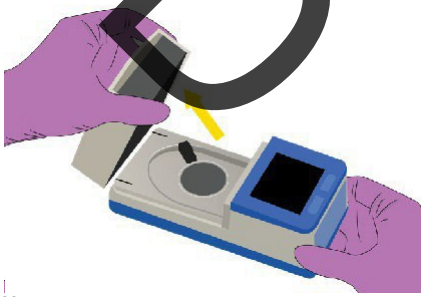
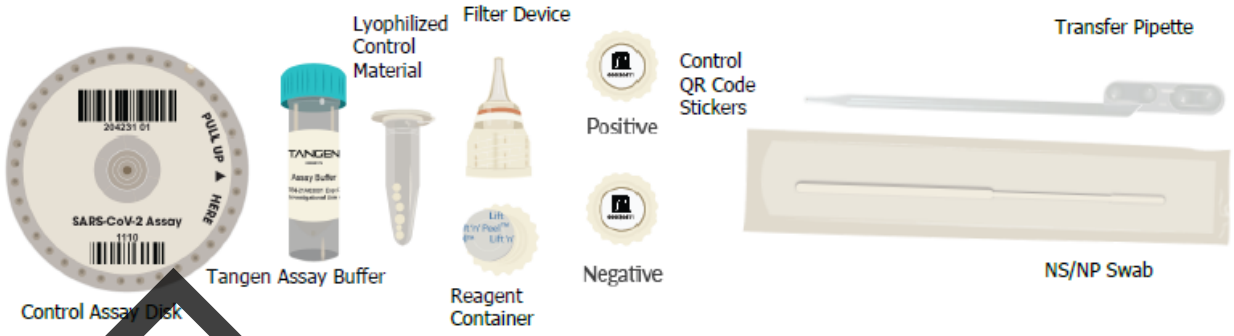


FIGURE U

Keep instrument cover open after analysis is complete and disk and Filter Device assembly have been removed and after cleaning the instrument with 70% isopropanol following patient runs. (See Cleaning Instructions on Page 16)
Keep cover closed when storing the instrument **(Figure U)**.

Running External Quality Controls



TangenDx SARS-CoV-2 Molecular Test Control Kit (PN KRW0256)* contains:

2 Positive Control TangenDx Assay Disks, and
2 Negative Control TangenDx Assay Disks
2 Vials of Positive Control Lyophilized Control Material and 2 Vials of Negative Control Lyophilized Control material
2 Positive Control QR Code Stickers and 2 Negative Control QR Stickers
TangenDx SARS-CoV-2 Molecular Test Quick Reference Instructions (not shown)
*Tangen Assay Buffer, Reagent Container, Filter Device, Transfer Pipette and NS/NP Swab are available in assay kit

It is recommended to run the external positive and negative controls:

- ☐ Once after each new device setup
- ☐ Once for each new lot or shipments of test kits
- ☐ Once for each new operator
- ☐ When problems are suspected or identified, or
- ☐ As required to conform with your internal quality control procedures, with local, state and/or federal regulations, or accrediting groups.

Running Positive Control

Use the TangenDx SARS-CoV-2 External Control Kit (included) to run the positive and negative External Controls.

1. Retrieve one (1) vial of Positive Control Material, two (2) Tangen Assay Buffer tubes, one (1) NP/NS swab, one (1) Reagent Container, one (1) Filter Device, one (1) Transfer Pipette, and (1) Positive Control Assay Disk.
2. Retrieve Reagent Container and apply the Positive Control QR Code to the bottom before placing it into the Reagent Container holder and carefully removing the seal.
3. Retrieve a tube of Tangen Assay Buffer and use the Transfer Pipette to transfer 400uL to the vial of positive control material. Allow vial to sit for three (3) minutes to fully dissolve.
4. Dip the swab into the vial of rehydrated control material. Swirl the swab around the sides of the vial.
5. Elute the swab into a tube of new, unused Tangen Assay Buffer, as if it was a patient sample. Twirl the swab ten times and ensure contact with the sides of the tube.
6. Use the Transfer Pipette to transfer the Tangen Assay Buffer with the control material into the Reagent Container secured in the Reagent Container Holder. Refer to **Figure E** for proper use of the Transfer Pipette. Replace cap on the buffer tube.
7. Proceed with preparing the control as though you are running a patient sample (See page 5).
8. Proceed with running the GeneSpark instrument. Set up the instrument and load the Positive Control Assay Disk.
9. Scan the **Kit Lot barcode** and **Positive Control Assay ID barcode** on the assay disk in any order. The fields will populate with the correct barcode.
10. Close the instrument cover and scan the **Positive Control QR code** on the Reagent Container as the Sample ID. Continue instrument setup as though you are running a patient sample (See page 9).

⚠ If a control barcode is not scanned, the Assay will not proceed. Incorrect barcodes will produce an error message.

11. Check that the ASSAY field indicates the expected type of run being performed SARS-COV-2, SARSCOV2 PosCtl, or SARSCOV2 NegCtl (**Figure V**). The words "Press To Start" will appear on the screen above the right-hand pushbutton. Start the instrument run by pushing the right-hand button. After pressing the start button, the run screen will appear.

FIGURE V

12. GeneSpark will complete the Assay in approximately 30 minutes. The result of the run will be displayed on the screen. The instrument screen will indicate when the run is complete. Record the result.

Results for Assay Type: SARS-CoV-2.
Positive Control: Pass, Fail (**Figure W**).

13. Press the Done button to exit the result screen.

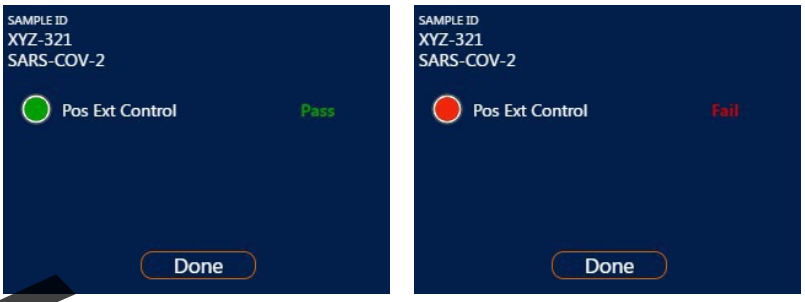


FIGURE W

Running Negative Control

14. Repeat the process above described for the positive control using a Lyophilized Negative Control Material and Negative Control Assay Disk. Be sure to scan the negative control QR Code on the reagent container as the Sample ID.

⚠ Scanning the wrong control Assay ID barcode will result in a failed control run.

Assay Type: SARS-CoV-2 Negative Control.
Possible Outcomes: Pass, Fail (**Figure X**).

15. Press the Done button to exit the result screen.
16. If a control run fails (Positive or Negative), do not start any patient sample runs until the following procedure is completed:

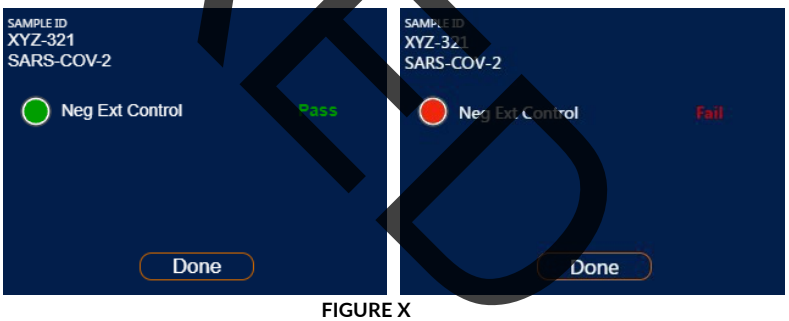


FIGURE X

16.1. Repeat the control run type that failed on the instrument that produced the failed result.

16.2. If the repeated control run passes, continue with analytical study runs.

If the repeated control run fails, remove the instrument from circulation and do not start any patient sample runs on the failed instrument. Contact Tangen Biosciences immediately at 833-975-6100.

TROUBLESHOOTING

Latch Open	The latch covering the Filter Device assembly in the instrument is not fully closed or engaged. Close the latch and the run will continue automatically.
Cover Open	The instrument cover enclosing the Assay Disk is not fully closed or engaged. Close the cover and the run will continue automatically.
No Disk Found	An Assay Disk was not placed on the disk mount as described in procedure step 3 **(Figure K)**. Place an Assay Disk on the assay disk mount, close the instrument cover and latch, and the run will continue automatically.
Disk Remount	The Assay Disk is not fully seated on the disk mount. Open GeneSpark and ensure the disk is fully secure on the disk mount. The instrument run will automatically continue when the disk housing cover and instrument latch are closed.
Insert Filter Device	The Filter Device assembly has not been placed in the disk housing cover. Ensure the Filter Device assembly is present and fully seated in the disk housing cover. The instrument run will automatically continue when the disk housing cover and instrument latch are closed.
All Other System Errors	All other system errors are detailed in the GeneSpark instrument Operator's Manual. Report any system errors with the associated error code to Tangen Biosciences immediately. If the error occurs before the instrument run begins, the disk and Filter Device assembly may be transferred to another instrument to analyze the sample.

For additional assistance, please contact Tangen Biosciences at 833-975-6100.

LIMITATIONS

- The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
- The performance of the TangenDx SARS-CoV-2 Molecular Test was determined using the procedures provided in these Instructions For Use. Failure to follow these procedures may alter test performance.
- Negative results should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, should be confirmed with a different authorized or cleared molecular test in a CLIA-certified laboratory that meets the requirements to perform high or moderate complexity tests.
- The TangenDx SARS-CoV-2 Molecular Test is for use with anterior nasal, mid-turbinate nasal, or nasopharyngeal swab specimens.
- Improper collection, storage or transport of specimens may lead to false negative or invalid results.
- Collection of patient samples into media other than the supplied Tangen Assay Buffer is off-label use and may adversely impact test performance.
- Test results should be interpreted in conjunction with the patient's medical history, clinical signs and symptoms, and the results of other diagnostic tests performed.
- As with other tests, negative results do not rule out SARS-CoV-2 infections and should not be used as the sole basis for patient management decisions.
- Detection of SARS-CoV-2 RNA may be affected by sample collection methods, patient factors (e.g., presence of symptoms), and/or stage of infection.
- The interference with the assay was only evaluated for the substances listed in this Package Insert and the effect of other substances is unknown.
- False negative results were observed if insufficient volume of the sample was added.
- False negative results may occur if virus is present at levels below the test's limit of detection.
- False negative results may occur if mutations are present in the regions targeted by the test.
- Cross-reactivity with respiratory tract organisms other than those listed in the Analytical Specificity Study may lead to erroneous results.
- This test cannot rule out diseases caused by other viral or bacterial agents.

Conditions of Authorization for Laboratories

The TangenDx SARS-CoV-2 Molecular Test Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: https://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas. To assist clinical laboratories and patient care settings (authorized laboratories[1]) using the TangenDx SARS-CoV-2 Molecular Test, the relevant Conditions of Authorization are listed below:

A. Authorized laboratories using the TangenDx SARS-CoV-2 Molecular Test must include with test result reports, all

authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

B. Authorized laboratories using the TangenDx SARS-CoV-2 Molecular Test must perform the TangenDx SARS-CoV-2 Molecular Test as outlined in the authorized labeling. Deviations from the authorized procedures, including authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use the TangenDx SARS-CoV-2 Molecular Test are not permitted.

C. Authorized laboratories that receive the TangenDx SARS-CoV-2 Molecular Test must notify the relevant public health authorities of their intent to run the TangenDx SARS-CoV-2 Molecular Test prior to initiating testing.

D. Authorized laboratories using the TangenDx SARS-CoV-2 Molecular Test must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

E. Authorized laboratories must collect information on the performance of the TangenDx SARS-CoV-2 Molecular Test and report to DMD/OHT7/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Tangen Biosciences, Inc. (via email: info@tangenbiosciences.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the TangenDx SARS-CoV-2 Molecular Test of which they become aware.

F. All operators using the TangenDx SARS-CoV-2 Molecular Test must be appropriately trained in performing and interpreting the results of the TangenDx SARS-CoV-2 Molecular Test, use appropriate personal protective equipment when handling this kit, and use the TangenDx SARS-CoV-2 Molecular Test in accordance with the authorized labeling.

G. Tangen Biosciences, Inc., authorized distributors, and authorized laboratories using the TangenDx SARS-CoV-2 Molecular Test must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records must be made available to FDA for inspection upon request.

[1] The Letter of Authorization refers to "laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high, moderate, or waived complexity tests" and "the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation" as "authorized laboratories."

Performance Characteristics

1. Limit of Detection (LoD) - Analytical Sensitivity

Limit of Detection (LoD) studies determine the lowest detectable concentration of SARS-CoV-2 at which at least 95% of all (true positive) replicates test positive. LoD was determined in two steps: first, a preliminary LoD concentration was determined by testing a series of two-fold dilutions of live SARS-CoV-2 (isolate NY-PV08410/2020) spiked into pooled negative nasopharyngeal matrix (PNM). Swabs were prepared by pipetting 50 µL of each SARS-CoV-2 test concentration in PNM onto a dry swab and eluting the swab in Tangen Assay Buffer. Swabs were prepared in triplicate for each SARS-CoV-2 concentration and tested per the Instruction for Use (Table 1a). To confirm the LoD, twenty individual swabs were prepared and tested per the IFU to identify the concentration that produced at least 95% positive results. The final LoD was determined to be 500 copies/mL (Table 1b).

Table 1a. Range-finding LoD Comparison

Final Concentration in TAB, GC/mL	Swab Concentration (copies/swab)	# Positive/# Tested,
1000	5000	3/3
500	2500	3/3
250	1250	3/3
125	625	2/3
63	315	1/3

Table 1b. Confirmatory LoD Results Summary

Final Concentration in TAB, GC/mL	Swab Concentration (copies/swab)	# Positive/# Tested,
500	2500	20/20 = 100%
250	1250	16/20 = 80%

2. Inclusivity (analytical reactivity)

Inclusivity analysis was performed using the Rosalind DXM platform (https://radx.rosalind.bio/). Primer fragments were compared with the sequences in the Rosalind database identified during the last 90 days and the last 30 days prior to the query date of March 10, 2023 (Table 2).

Table 2. Rosalind Database Homology of primer sequences over 90 Days prior to March 10, 2023.

Primer set	Primer or fragment	N of sequences analyzed	Any position with ≥ 1% prevalence	Position and percentage
CovN2	F3	587,682	No	N/A
	B3	587,682	No	N/A
	F2	587,682	No	N/A
	B2	587,682	Yes	GGG28881AAC / 99%
	F1c	587,682	No	N/A
	B1c	587,682	No	N/A
	LF	587,682	No	N/A
	LB	587,682	No	N/A
CovN3	F3	587,682	Yes	GAGAACGCA28362 / 96%
	B3	587,682	No	N/A
	F2	587,682	No	N/A
	B2	587,682	No	N/A
	F1c	587,682	No	N/A
	B1c	587,682	No	N/A
	LF	587,682	No	N/A
	LB	587,682	No	N/A

GGG28881AAC (primer B2, amplicon CovN2) (INC20220304-08912)

Description:	This mutation set affects the positions 2, 3 and 4 (5' end) of primer B2 (amplicon CovN2).
Lineages affected:	This mutation is found in Omicron sublineages (B.1.1.519, BA.1, BA1.1. and BA.2) as well as in previously relevant variants, namely Alpha (B.1.1.7) and Gamma (P.1).
Frequency trend:	This mutation is present in the vast majority of sequences from the last 90 and 30 days (99% and 99%, respectively).
Severity score and Differential Melting Temperature:	This mutation has a severity of "5" and a differential melting temperature of -3.9 °C.
Effect on assay performance:	Due to the position of the mutation towards the 5'end of the primer, close to the loop structure this mutation has a moderate risk of affecting the performance of the assay. Experimental analysis compared the limit of detection (LOD) of the assay using Omicron variant RNA against the reference Wuhan-Hu RNA, which revealed that assay performance was likely not impacted by the presence of this mutation.

GAGAACGCA28362 (primer F3, amplicon CovN3) (INC20220304-05612)

Description:	This deletion affects the 5' end of primer F3 (amplicon N3).
Lineages affected:	This deletion is found in Omicron sublineages (BA.1, BA.1.1, B1.1.529 and BA.2).
Frequency trend:	This deletion is present in the vast majority of sequences from the last 90 and 30 days (96% and 97%, respectively).
Severity score and Differential Melting Temperature:	This mutation has a severity of "5" and a differential melting temperature of -21.41°C.
Effect on assay performance:	Although primer F3 is not essential for the assay, this large deletion could potentially have a significant impact in the assay sensitivity. Experimental analysis compared the limit of detection (LOD) of the assay using Omicron variant RNA against the reference Wuhan-Hu RNA, which revealed that assay performance was likely not impacted by the presence of this mutation.

3. Cross-reactivity (Analytical Specificity) and Microbial Interference Studies

Cross Reactivity and Microbial Interference studies were conducted to determine if other respiratory pathogens/flora that could be present in a direct nasal swab sample could cause a false-positive test result or interfere with a true positive result. A panel of seventeen (17) viruses, twelve (12) bacteria, two (3) yeast/fungi at the concentrations listed in Table below, and pooled nasal matrix (PNM) was evaluated for these studies (Table 3). No false positives were observed during cross reactivity testing and no false negatives were observed during microbial interference testing.

Table 3. Microbial Cross-Reactivity and Interference Analyzed by Wet Testing

Microorganism	Source	Part #	Concentration Tested	# Negative / # Valid No SARS-CoV-2 Percent Agreement with expected results	# Positives / # Valid 3x LoD SARS-CoV-2 Percent Agreement with expected results
Adenovirus (Adenoid 71)	ATCC	VR-1	1.43E+05 $TCID_{50}$/mL	3/3 = 100%	3/3 = 100%
Bordetella pertussis	ATCC	9797	1.00E+06 CFU/mL	3/3 = 100%	3/3 = 100%
Candida albicans	ATCC	14503	1.00E+06 CFU/mL	3/3 = 100%	3/3 = 100%
Chlamydia pneumoniae	ATCC	53592	1.00E+06 CFU/mL	3/3 = 100%†	3/3 = 100%
Enterovirus EV68	ATCC	VR-1826	1.43E+05 $TCID_{50}$/mL	3/3 = 100%	3/3 = 100%
Haemophilus influenzae	ATCC	49247	1.00E+06 TCFU/mL	3/3 = 100%	3/3 = 100%†
Human coronavirus 229E	ATCC	VR-740	1.44E+05 $TCID_{50}$/mL	3/3 = 100%	3/3 = 100%

Microorganism	Source	Part #	Concentration Tested	# Negative / # Valid No SARS-CoV-2 Percent Agreement with expected results	# Positives / # Valid 3x LoD SARS-CoV-2 Percent Agreement with expected results
Human coronavirus HKU1	ATCC	VR-3262SD	1.00E+-6 GC/mL	3/3 = 100%	3/3 = 100%
Human coronavirus NL63	Zeptometrix	0810228CF	1.43E+05 $TCID_{50}$/mL	3/3 = 100%	3/3 = 100%
Human coronavirus OC43	Zeptometrix	0810024CF	1.43E+05 $TCID_{50}$/mL	3/3 = 100%	3/3 = 100%
Human Metapneumovirus (hMPV)	Zeptometrix	0810157CF	1.43E+05 $TCID_{50}$/mL	3/3 = 100%	3/3 = 100%
Influenza A	ATCC	VR-1895	1.43E+05 $TCID_{50}$/mL	3/3 = 100%	3/3 = 100%
Influenza B	ATCC	VR-101	1.43E+05 $TCID_{50}$/mL	3/3 = 100%	3/3 = 100%
Legionella pneumophila	Zeptometrix	0801645	1.00E+06 CFU/mL	3/3 = 100%	3/3 = 100%
MERS-coronavirus	BEI Resources	NR-50171	1.43E+05 $TCID_{50}$/mL	3/3 = 100%	3/3 = 100%
Mycobacterium tuberculosis	Zeptometrix	0801660	1.00E+06 CFU/mL	3/3 = 100%	3/3 = 100%
Mycoplasma pneumoniae	ATCC	15531	1.00E+06 CFU/mL	3/3 = 100%	3/3 = 100%
Parainfluenza virus 1	Zeptometrix	0810014CF	1.43E+05 $TCID_{50}$/mL	3/3 = 100%	3/3 = 100%
Parainfluenza virus 2	ATCC	VR-92	1.43E+05 $TCID_{50}$/mL	3/3 = 100%	3/3 = 100%
Parainfluenza virus 3	ATCC	VR-93	1.43E+05 $TCID_{50}$/mL	3/3 = 100%	3/3 = 100%
Parainfluenza virus 4B	Zeptometrix	0810060BCF	1.43E+05 $TCID_{50}$/mL	3/3 = 100%	3/3 = 100%
Pneumocystis carinii	ATCC	PRA-159	1.00E+06 CFU/mL	3/3 = 100%	3/3 = 100%
*Pneumocystis jirovecii-S. cerevisiae**	Zeptometrix	801698	1.00E+06 CFU/mL	3/3 = 100%	3/3 = 100%†
Pooled Human Nasal Wash	N/A	N/A	10% v/v	3/3 = 100%	3/3 = 100%
Pseudomonas aeruginosa	ATCC	10145	1.00E+06 CFU/mL	3/3 = 100%	3/3 = 100%
Respiratory syncytial virus	ATCC	VR-26	1.00E+05 PFU/mL	3/3 = 100%	3/3 = 100%
Rhinovirus	ATCC	VR-1601	1.47E+05 $TCID_{50}$/mL	3/3 = 100%†	3/3 = 100%
SARS-coronavirus	BEI Resources	NR-9324	1.00E+05 PFU/mL	3/3 = 100%	3/3 = 100%
Staphylococcus aureus	ATCC	12600	1.00E+06 CFU/mL	3/3 = 100%	3/3 = 100%
Staphylococcus epidermidis	ATCC	12228	1.00E+06 CFU/mL	3/3 = 100%	3/3 = 100%
Streptococcus pneumoniae	ATCC	49619	1.00E+06 CFU/mL	3/3 = 100%	3/3 = 100%
Streptococcus pyogenes	ATCC	19615	1.00E+06 CFU/mL	3/3 = 100%†	3/3 = 100%
Streptococcus salivarius	ATCC	13419	1.00E+06 CFU/mL	3/3 = 100%	3/3 = 100%

* recombinant

† There were 5 invalid results, all of which repeated successfully. The invalid rate for cross-reactivity, microbial interference and endogenous/exogenous interfering substances is 5/334 = 1.5%.

4. Endogenous/Exogenous Interfering Substances

Potentially interfering substance studies were performed using a panel of twenty-four (24) endogenous and exogenous substances tested at concentrations indicated in Table 4 to evaluate the potential for a given substance to cause a false-positive test result. Each interfering substance sample was tested in triplicate. Test results are summarized in Table 4. At the concentrations tested none of the substances caused a false-positive test result in unspiked samples or interfered with the detection of a true positive test result in samples spiked with SARS-CoV-2 at 3x LoD.

Table 4. Testing with Potentially Interfering Endogenous and Exogenous Substances

Potential Interfering Substances	Interferent Concentration	#Negative/#Observed, NO SARS-CoV-2 Percent Agreement with expected results	#Positive/#Observed, 3x LoD SARS-CoV-2 Percent Agreement with expected results
Alkalol (Homeopathic)	10% v/v	3/3 = 100%	3/3 = 100%
Blood (Human, Whole)	4% v/v	3/3 = 100%	3/3 = 100%
Budesonide (Nasal Spray)	5% v/v	3/3 = 100%	3/3 = 100%
Chloraseptic/Menthol and Benzocaine (Lozenge)	1.5 mg/mL	3/3 = 100%	3/3 = 100%
Cold and Flu Combo Medication: acetaminophen, dextromethorphan, guaifenesin, and phenylephrine	1.5 mg/mL	3/3 = 100%	3/3 = 100%
Cough Syrup Robitussin (Wal-tussin)	5% v/v	3/3 = 100%	3/3 = 100%
Cromolyn (Nasal Spray)	15% v/v	3/3 = 100%	3/3 = 100%
Emergen-C	1.5 mg/mL	3/3 = 100%	3/3 = 100%
Ethyl Alcohol	5% v/v	3/3 = 100%	3/3 = 100%
Fisherman's Friend/Menthol (Lozenge)	1.5 mg/mL	3/3 = 100%	3/3 = 100%
Fluticasone propionate (Nasal Corticosteroid)	5% v/v	3/3 = 100%	3/3 = 100%
Mucin: Bovine submaxillary type I-S	2.5% w/v	3/3 = 100%	3/3 = 100%
Mupirocin (Topical antibiotic)	10.0 mg/mL	3/3 = 100%	3/3 = 100%

Potential Interfering Substances	Interferent Concentration	#Negative/#Observed, NO SARS-CoV-2 Percent Agreement with expected results	#Positive/#Observed, 3x LoD SARS-CoV-2 Percent Agreement with expected results
Nasal Drops (Plenylephrine)	5% v/v	3/3 = 100%	3/3 = 100%
OTC mouthwash	5% v/v	3/3 = 100%	3/3 = 100%
Oxymetazoline (Nasal Spray)	15% v/v	3/3 = 100%	3/3 = 100%
Sodium hyaluronate (Nasal Gel)	5% v/v	3/3 = 100%	3/3 = 100%
Sore throat phenol spray	15% v/v	3/3 = 100%	3/3 = 100%
Sucrets/Dyclonin and Menthol (Lozenge)	1.5 mg/mL	3/3 = 100%	3/3 = 100%
Tamiflu/Oseltamivir phosphate (Antiviral)	5.0 mg/mL	3/3 = 100%	3/3 = 100%
Tobacco	1.5 mg/mL	3/3 = 100%	3/3 = 100%
Tobramycin (Nasal antibiotic)	4.0 mg/mL	3/3 = 100%	3/3 = 100%
Toothpaste	0.5% w/v	3/3 = 100%	3/3 = 100%
Zicam (zinc)	5% v/v	3/3 = 100%	3/3 = 100%

Clinical Evaluation

A prospective clinical study was conducted at CLIA waived sites by non-laboratory personnel. Two (2) nasopharyngeal swabs were collected from subjects suspected of SARS-CoV-2 infection by their healthcare provider. Specimens were obtained from each subject enrolled using standard collection methods. The TangenDx SARS-CoV-2 Molecular Test was performed at POC sites by intended use operators in accordance with the Instructions for Use.

The overall test results for the TangenDx SARS-CoV-2 Molecular Test (candidate) and a highly sensitive EUA authorized molecular test (comparator) were compared in a contingency table for the 106 evaluable subjects. Percent positive and negative agreements and 95% confidence intervals (Wilson score method) are provided in Table 5.

Table 5. Overall Candidate vs Comparator

TangenDx SARS-CoV-2 Molecular Test	Highly Sensitive EUA Authorized Molecular Test (Comparator)		
	Positive	Negative	Total
Positive	44	0	44
Negative	6	52	58
Subtotal	**50**	**52**	**102**

PPA = 44/50 = 88.0% (95% CI = 76.2%-94.4%)
NPA = 52/52 = 100.0% (95% CI = 93.1%-100.0%)

TangenDx SARS-CoV-2 Molecular Test Controls – Positive, Negative, and Internal

The Internal Control (IC) is introduced into specimen during sample processing on the GeneSpark instrument. Three wells in the assay disk are dedicated to the detection of an RNA fragment from a non-COVID virus and the bead reagents contain a primer for the IC gene. The IC is designed to verify the RNAse activity and detect the presence of any RNAse inhibitors in the clinical specimen. The software will flag a result as "invalid" if the IC is not within range.

The External Controls are processed like a patient sample and verify that the procedure was performed correctly and that the test system and all the reagents are performing as expected. The Positive Control includes both CovN2 and CovN3 targets and both must be positive in order to generate a "pass" result. The CovN2 and CovN3 targets are detected independently. For the positive control to pass, both the CovN2 and CovN3 genes must be detected in at least a single well each.

Examination and Interpretation of Patient Specimen Results

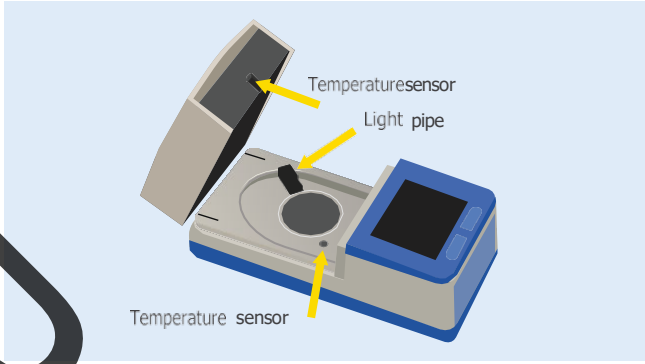
Assessment of clinical specimen test results will be performed after the positive and negative controls have been examined and determined to be valid and acceptable. If the controls are not valid, the patient results cannot be interpreted.

The Tangen SARS-CoV-2 Assay Disks contain an internal positive control and two primer sets targeting the SARS-CoV-2 viral RNA. The GeneSpark software calculates the Cq (Quantification cycle) values for each positive reaction in every well. A positive result in one well for each target (i.e., CovN2, CovN3, and internal control) means a positive result overall for that target. A positive reaction is determined by an algorithm that assesses the amplitude of fluorescent signals in each well and rate of fluorescent accumulation. The results will be reported as positive for COVID-19 if either target (CovN2 and CovN3) is positive, and negative for COVID-19 if both targets are negative. The result is "Invalid" if the internal control is not present.

⚠ Note: Negative results should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, should be confirmed with a different authorized or cleared molecular test in a CLIA-certified laboratory that meets the requirements to perform high or moderate complexity tests.

Cleaning the GeneSpark Instrument, Tightening Tools, and the Reagent Container Holder

Cleaning procedure for the GeneSpark is outlined in the GeneSpark Operator's Manual. The GeneSpark should be cleaned with a 10% bleach wipe followed by 70% isopropanol wipe after every patient sample run. Take caution to avoid touching the temperature sensors and light pipe during cleaning (see below).



- The inside and outside of the GeneSpark should be cleaned with 70% isopropanol after every assay run. Leave the instrument cover open after cleaning until isopropanol has evaporated.
- Keep the touch screen clean from excessive fingerprints and moisture by gently wiping it with a soft, lint-free cloth.
- Additional cleaning instructions are provided in the GeneSpark Operator's Manual.
- The Tightening Tool and Reagent Container Holder should be cleaned with a 10% bleach wipe followed by 70% isopropanol after every patient sample run.
- Keep instrument cover open after analysis is complete and disk and filter device assembly have been removed.
- Store instrument with cover closed when not in use.

⚠ Take caution to avoid touching the temperature sensors and light pipe during cleaning.

SYMBOLS USED

Symbols used	Meaning
IVD	*In vitro* diagnostic reagent
	Storage temperature range
	Expiration Date
REF	Catalogue Number
LOT	Lot Number
SN	Serial Number
	Consult Instructions for Use
	Caution
	Manufacturer

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Version 22.0, P/N: LBL-000218

TANGEN™

QUICK REFERENCE INSTRUCTIONS (QRI)

TangenDx SARS-CoV-2 Molecular Test

Rx Only | IVD | For Use Under an Emergency Use Authorization (EUA) Only. See Special Conditions for Use Statements on next page.

STORAGE HANDLING AND WARNINGS

STORAGE AND HANDLING

Wear gloves. Change gloves between processing each sample. The TangenDx SARS-CoV-2 molecular test kit can be stored at room temperature (15°C – 30°C) prior to use.

Initiate sample preparation for the SARS-COV-2 Assay with the GeneSpark within fifteen (15) minutes of sample collection. Remnant sample can be refrigerated at 4°C for 24 hours or frozen at -20°C for up to one month in the event testing or retesting is necessary. Once the remnant sample has reached room temperature, proceed with sample preparation for the SARS-CoV-2 Assay with the GeneSpark within one (1) hour.

WARNING

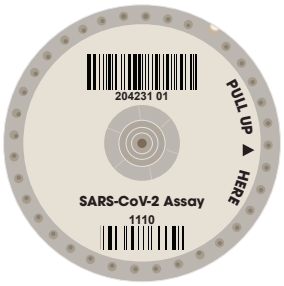
DO NOT use an assay disk or filter device that has been dropped or is damaged or wet.

DO NOT turn off or unplug the instrument while a test is in progress.

DO NOT use expired kit components.

Note: The GeneSpark sonicator will be audible at 66-72 dBA for the first 90 seconds of running the assay. An operator would have to stay within 21cm fof the GeneSpark for 8 hours to reach the threshold for hearing protection requirements.

KIT CONTENTS



1 Assay Disk

2 Tangen Assay Buffer

3 Reagent Container
(contains lyophilized reagent beads)

4 Patient ID Barcode and Sample ID QR Code

5 Filter Device
(Shown without protective cover)

6 Transfer Pipette

7 NP/NS Swab

When ordering, specify the nasal swab by part number (PN):
Nasophayngeal (NP Swab, PN NP-KRR0195)
Mid-turbinate (MT Swab, PN MT-KRR0195)
Anterior Nasal (NS swab, PN AN-KRR0195)

CONTROL KIT MATERIALS (INCLUDED)

Positive and Negative Control Assay Disks

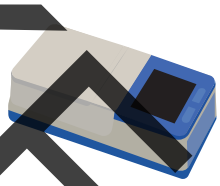
Control QR Code Stickers:

Positive

Negative

Positive and Negative Lyophilized Control Material

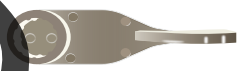
MATERIALS NEEDED BUT NOT INCLUDED



1 GeneSpark Instrument

2 Barcode Scanner

3 Tightening Tool*



4 Reagent Container Holder*

*GeneSpark Instrument comes with the Accessory Kit (IMA0001), which includes: 1 GeneSpark Instrument, 1 Barcode Scanner, 1 Reagent Container Holder and 1 Tightening Tool.

Wear appropriate personal protective equipment while handling patient samples. Refer to the **GeneSpark™ Instrument User Manual** for initial set-up and cleaning. This test is only for anterior nasal (nasal or nasopharyngeal swab) specimens. Read the complete **Quick Reference Instructions** before performing the test. For assistance, call Tangen Technical Support at (833) 975-6100. Refer to IFU for detailed instructions and images of test execution.

TANGENBIOSCIENCES.COM

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20 Commercial St, Branford CT 06405

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Version 21.0, P/N: LBL-000220

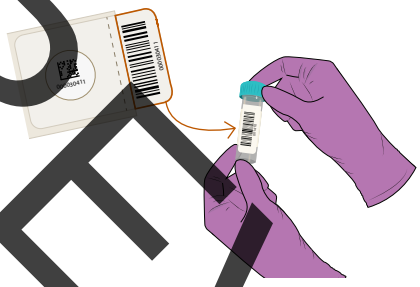
SPECIAL CONDITIONS FOR USE STATEMENT

- Rx Only. For in vitro Diagnostic Use. For Use Under an Emergency Use Authorization (EUA) Only.
- This product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories certified under the CLIA that meet requirements to perform high, moderate, or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificateof Compliance, or Certificate of Accreditation.
- This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

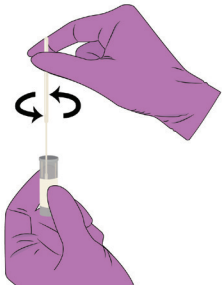
COLLECTING A PATIENT SAMPLE

Note: It is recommended for patient to blow nose before collection.

1 **Apply patient ID barcode to Rangen Assay Buffer tube.** Save QR code for step 1 of PROCESSING THE SAMPLE.



2 **Collect patient sample using NP (nasopharyngeal), MT (mid-turbinate) or NS (anterior nasal) swab.** Vigorously mix the patient swab in buffer by moving it up and down and swirling ten (10) times, ensuring contact with sides and bottom of the tube.

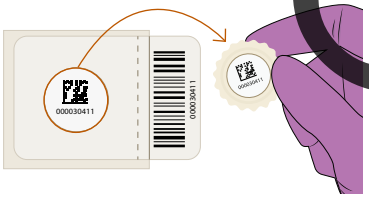


NOTE: IF USING A FROZEN SAMPLE
Allow sample to thaw completely at room temperature for **no longer than one hour** before transferring sample to the Reagent Container as described in Step 2 of PROCESSING THE SAMPLE below. Once thawed, process the sample within fifteen (15) minutes.

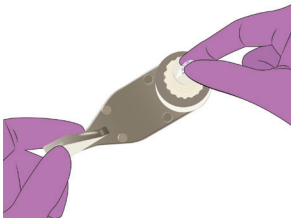
COLLECTING A PATIENT SAMPLE

⚠ Match the barcode on the Reagent Container to the barcode on the Assay Buffer tube containing the sample. Failure to do so will misattribute patient results.

1 **Apply the sample ID QR code to the bottom of the Reagent Container.**

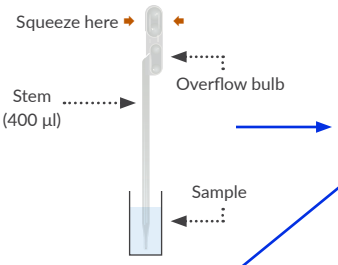


2 **Place the Reagent Container into the Reagent Container Holder and carefully peel off the seal.**



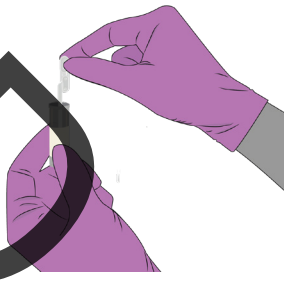
3 **Transfer the sample to the Reagent Container using the Transfer Pipette:**

Squeeze top bulb of **Transfer Pipette** and submerge the stem into the Sample in the **Assay Buffer** tube.

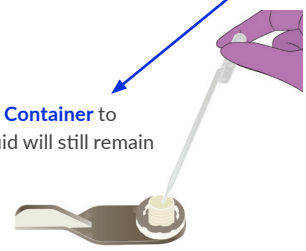


⚠ *Ensure sufficient volume is added. Insufficient sample volume can lead to false results.

Release top bulb to fill the entire pipette shaft until fluid enters the overflow bulb. **Visually confirm that the entire shaft is filled with fluid before proceeding. Note:** Do not invert the Transfer Pipette when filled with fluid. If there is a bubble formed when drawing up fluid, or if no fluid enters the overflow bulb, discard and re-try with a new pipette.

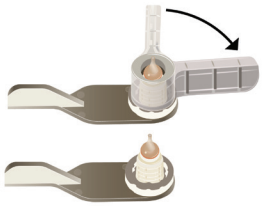


Squeeze **top bulb** of pipette over the **Reagent Container** to discharge all fluid from pipette shaft. Some fluid will still remain in the bottom bulb of the pipette.



⚠ **SAMPLE MUST SIT IN REAGENT CONTAINER FOR FIVE (5) MINUTES TO DISSOLVE LYOPHILIZED REAGENTS.**

4 Screw the **Filter Device** onto the filled Reagent Container using the **Tightening Tool** as tightly as possible. Inade-quate tightening may result in invalid results.



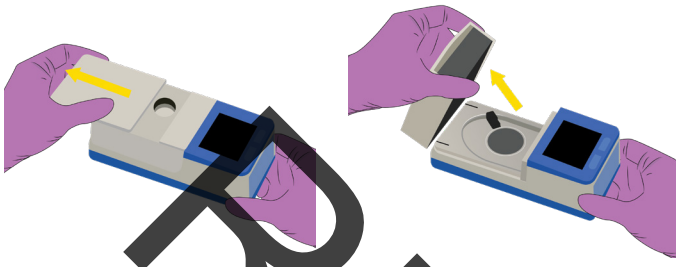
⚠ **Avoid touching the tip of the filter device.**

LOADING ASSAY DISK IN GENESPARK INSTRUMENT

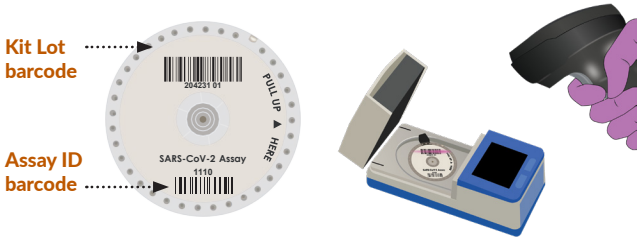
Running GeneSpark requires barcode scanner, TangenDx SARS- CoV-2 Assay Disk, and Filter Device assembly.

1. Ensure the GeneSpark is plugged in and the barcode reader is connected in USB port.

2. **Slide cover latch** open and **lift the lid** of the GeneSpark.



3. Remove **Assay Disk** from foil pouch and **mount onto GeneSpark. Force can be applied in the area shaded in blue.** It will audibly click once in place. Using the barcode scanner, scan the **Assay Kit lot** and **Assay ID** in any order. The fields will populate with the correct barcode. Then close the lid of the GeneSpark.

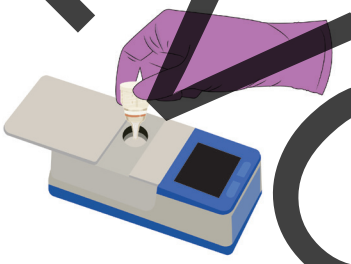


⚠ **An improperly mounted disk will generate an error code. If a rotor c alibration failure occurs, remount the Assay Disk.**

RUNNING THE ASSAY

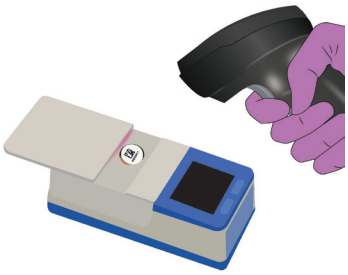
1. **Remove protective cover** from the Filter Device and discard. Place the **Filter Device** assembly into the instrument.

⚠ **Improper loading of the filter device will result in an error code.**



2. **Scan* sample ID QR code** on the Reagent Container and slide latch to close.

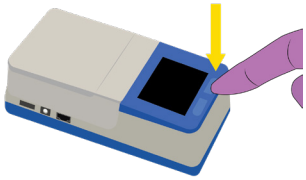
⚠ **Improper closure of latch will result in an error code.**



*Instructions to manually enter Sample ID are on the last page.

Note: Once in the Reagent Container, the sample must be processed within 15 minutes to obtain valid results.

3. Once the Assay Disk has been mounted and scanned, the Filter Device assembly has been inserted, and the latch has been closed, the words **"Press To Start"** will appear on the screen.



Press the button on the right to start.

Ensure button is pressed or instrument will not start.

Note: The GeneSpark sonicator will be audible at 66-72 dBA for the first 90 seconds of running the assay.

FOLLOWING COMPLETION OF ASSAY

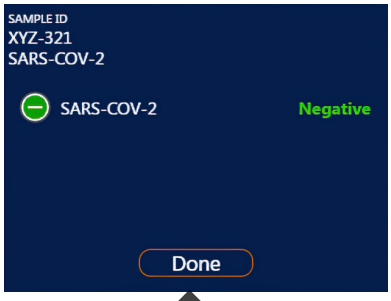
Press "Done" on the screen to exit results screen. Remove the Assay Disk and Filter Device assembly from the instrument and place in a sealed plastic bag, remove from area and discard according to environmental controls.

4. A countdown timer will appear on the screen while the instrument is running. The results will appear on the screen when the run is complete in approximately 30 minutes.

Note: While the instrument is running, the countdown timer will pause for a few minutes while the instrument reaches the required temperature. This pause is normal, and the countdown timer will resume as the assay progresses.

⚠ **When unmounting the disk, pry up only from the indicated point.**

HOW TO INTERPRET RESULTS



RESULT	INTERPRETATION
SARS-CoV-2 PRESUMPTIVE NEGATIVE	SARS-CoV-2 target RNA is **not detected**. The result should be verified using a highly sensitive SARS-CoV-2 assay.
SARS-CoV-2 POSITIVE	SARS-CoV-2 target RNA is **detected**.
SARS-CoV-2 INVALID	If the result is **SARS-CoV-2 INVALID**, retest the patient sample with a **new Assay kit**.

⚠ *Note: Negative results should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, should be confirmed with a different authorized or cleared molecular test in a CLIA-verified laboratory that meets the requirements to perform high or moderate complexity tests.

RUNNING POSITIVE AND NEGATIVE EXTERNAL CONTROLS


Control Assay Disk


Tangen Assay Buffer


Lyophilized Control Material

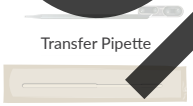
Control QR Code Stickers:


Positive


Negative


Filter Device


Reagent Container


Transfer Pipette

NP/NS Swab

The TangenDx SARS-CoV-2 Molecular Test Control Kit contains the following:

1. 2 positive and 2 negative control assay disks
2. 2 vials positive control material and 2 vials negative control material
3. Positive and negative control QR code stickers

***Tangen Assay Buffer, Reagent Container, Filter Device, Transfer Pipette and NS/NP Swab are available in assay kit.**

1. Plug in power cord and attach to **GeneSpark**.
2. Place a reagent container into the reagent container holder. Place the respective **positive or negative control QR code** sticker onto the bottom of the reagentcontainer before removing **peel off seal**.
3. Use **transfer pipette** transfer 400uL of **Tangen Assay Buffer** to vial of positive or negative control material. **Allow vial to sit for 3 minutes** to fully dissolve. **NOTE: This tube of assay buffer will be used for both positive and negative control.**
4. **Dip swab** into vial of **rehydrated control material** and swirl around sides of the vial.
5. Elute swab into new, **unused tube of Tangen Assay Buffer** as if it were a patient sample; swirl vigorously ten (10) times and ensure contact with sides of thetube.
6. Transfer **Tangen Assay Buffer** to **Reagent Container** using the transfer pipette as described in step 3 PROCESSING THE SAMPLE.
7. When preparing the Assay disk described in LOADING ASSAY DISK IN GENESPARK INSTRUMENT, Scan the barcode on the Control Assay Disk.
8. Scan the corresponding **Control QR code** on the Reagent Container as the **Sample ID** and proceed with running the assay as in Step 2 of RUNNING THE ASSAY.

⚠ **Note: If a control QR code is not scanned as the sample iD, the assay will not proceed. Scanning the wrong control QR code will result in a failed control.**

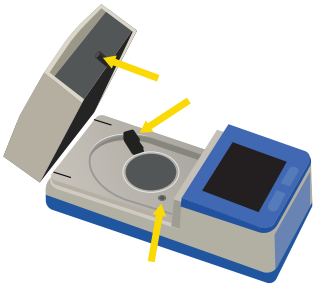
POSSIBLE OUTCOMES		
POSCTL or NEGCTL PASS: Control run passed and you can proceed running the GeneSpark	**POSCTL or NEGCTL FAIL:** Control run failed, run must be repeated to obtain a 'pass' result before proceeding to run the GeneSpark	**POSCTL or NEGCTL INVALID:** Control run must be repeated to obtain a valid result before proceeding to run the GeneSpark.

⚠ If the repeated control run fails, remove the instrument from circulation and do not start any patient sample runs on the failed instrument. Contact Tangen Biosciences immediately at (833)-975-6100.

It is recommended to run the external positive and negative controls:

- once after each new device setup
- once for each new lot or shipment of test kits
- once for each new operator
- when problems are suspected or identified, or
- to conform with your internal QC procedures, with local, state and federal regulations, or accrediting groups

IF THE REPEATED CONTROL RUN FAILS



- The inside and outside of the GeneSpark should be cleaned with 70% is oproanol after every assay run. Leave the instrument cover open after cleaning and between patient runs to ensure proper drying.
- Keep the touch screen clean from excessive fingerprints and moisture by gently wiping it with a soft, lint-free cloth.
- Additional cleaning instructions are provided in the GeneSpark Operator's Manual.
- The Tightening Tool and Reagent Container Holder should be cleaned with a 10% bleach wipe followed by 70% isopropyl alcohol wipe after every patient sample run.
- Keep instrument cover open after analysis is complete and disk and filter device assembly have been removed.
- Store instrument with cover closed when not in use.

⚠ **Take caution to avoid touching the temperature sensors and light pipe during cleaning.**

MANUAL ENTRY OF SAMPLE ID

To manually enter the Sample ID, touch the Sample ID button on the screen and use the onscreen keyboard to key in the Sample ID. After keying in the Sample ID, touch the checkmark (lower right of screen) to accept. Pressing the X (lower left of screen) will cancel. Note that the run is not permitted to start without filling this field.

⚠ **Erroneous entry of sample ID will cause misattributed patient result.**

TangenDx SARS-CoV-2 Molecular Test
Product Information Card (PIC)

℞ Prescription Use Only IVD For *In Vitro* diagnostic use

For use under Emergency Use Authorization (EUA) only.

This is not the complete Instructions for Use. The complete Instructions for Use may be downloaded at https://tangenbiosciences.com/covid-19/.

The Fact Sheet for Healthcare Providers and the Fact Sheet for Patients are also available at https://tangenbiosciences.com/covid-19/.

Please contact Tangen Biosciences **Technical Support** at **833-975-6100** or email **Info@tangenbiosciences.com** for questions or if you require a printed copy free of charge or need technical support to access the Instructions for Use.

- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories;
- This product has been authorized only for the detection of nucleic acid of SARS-CoV-2, not for any other viruses or pathogens;
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb- 3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

TANGEN™

GENEDISPARK™

Operator's Manual

Version 14
September 2023

TANGENBIOSCIENCES.COM

Tangen Biosciences, Inc.
20 Commercial St, Branford CT 06405

833-975-6100
PHONE

Software Version 2.6.13.0,
Version P/N: LBL-000096

Edition Notice

This publication is intended for operators of the GeneSpark™ molecular diagnostic instrument.

Every effort has been made to ensure that all the information contained in this publication is correct at the time of publishing. However, Tangen Biosciences reserves the right to make any changes necessary without notice as part of ongoing product development.

Where to find information

The GeneSpark ™ molecular diagnostic instrument Operator's Manual contains all information about the product, including the following:

- Safety
- Installation
- Routine operation
- Maintenance and calibration
- Troubleshooting information
- Configuration information
- Background information

The GeneSpark ™ molecular diagnostic instrument Quick Start Guide is intended as a reference during the GeneSpark ™ molecular diagnostic set-up.

⚠ General attention

To avoid incorrect results, ensure that you are familiar with the instructions and safety information.

- Pay particular attention to all safety notices.
- Always follow the instructions in this publication.
- Do not use the software in a way that is not described in this publication.
- Store all publications in a safe and easily retrievable place.

Screenshots

The screenshots in this publication have been added exclusively for illustration purposes. Configurable and variable data, such as tests, results, or path names visible therein must not be used for laboratory purposes.

Warranty

Any customer modification to the instrument and the use of unauthorized assay disks, Filter Device or accessories renders the warranty null and void.

Do not open the GeneSpark ™ molecular diagnostic instrument, change any

component or install unauthorized software.

Trademarks

The following trademarks are acknowledged:

GeneSpark ™ is a trademark of Tangen Biosciences, Inc. All other product names and trademarks are the property of their respective owners.

Software Acknowledgement

This software includes the "levmar" optimization library which is developed and owned by the Institute of Computer Science of the Foundation for Research and Technology - Hellas, Greece and is being used under license terms and conditions.

Patents

US20170204456A1: Isothermal methods for amplifying nucleic acid samples

US20150307927A1: Apparatus for centrifuge mountable manifold for processing fluidic assays

WO2016073353A1: Apparatus and method for cell, spore, or virus capture and disruption

Support

For support, contact us at the following numbers:

US Customer Support: 833-975-6100.

Approvals

The GeneSpark ™ molecular diagnostic instrument meets the requirements of the Directive 98/79/EC. It also meets the requirements laid down in Council Directive 89/336/EEC relating to “Electromagnetic compatibility” and Council Directive 73/23/EEC relating to “Low Voltage Equipment.” The following standards were applied: IEC 60601-1-2 (EMC), IEC/EN 61010-1 (Safety).

NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

The following marks demonstrate compliance:

For in vitro diagnostic use.

For prescription use only.
For Use Under Emergency Use Authorization (EUA) Only. This product has not been FDA cleared or approved but has been authorized by FDA under an EUA for use by authorized laboratories certified under the CLIA that meet requirements to perform high, moderate, or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564b1 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3b1, unless the declaration is terminated or authorization is revoked sooner.

Tested Bureau Veritas in compliance with Underwriters Laboratories, Inc. (UL) for Canada and the US. Issued by CSA Group for Canada and the US.

Feedback Every effort has been made to ensure that this publication fulfills the intended use. All feedback on any aspect of this publication is welcome and is considered during updates. Contact your Tangen Biosciences Service representative, should you have any such feedback. In the U.S., call the following number: (833) 975-6100

Contact Address

Manufactured by Tangen Biosciences, Inc
20 Commercial St
Branford, CT 06405

Table of Contents

Preface

Intended Use

The GeneSpark ™ molecular diagnostic instrument is for use with Tangen Biosciences' assay kits, including the TangenDx SARS-CoV-2 Molecular Test, to perform in vitro diagnostics.

Symbols and abbreviations

The following symbols can be found on the instrument, on assay kits, or throughout this manual. Use the definitions below as a guideline to interpreting the symbols.

ISO 15223-1:2016 **Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied**					
	Manufacturer		USE BY (YYYY-MM_DD)		Batch Code (Lot Number)
	Catalog Number		Serial Number		Temperature Limit
	Biological Risks		Consult Instructions for Use		Caution
	*In Vitro* Diagnostic Medical Device				
Other symbols used					
	Bureau Veritas Listing Mark		USB		

 Symbols used in this publication

Product names

Except where the context clearly indicated otherwise, the following product names and descriptors are used.

Product Name	Description
GeneSpark molecular diagnostic instrument	Diagnostic instrument
TangenDx Filter Device	Assay sample concentrating tube
TangenDx flow rotor	Assay disk

Product Names

Abbreviations

The following abbreviations are used

Abbreviation	Definition
IVD	In Vitro Diagnostic
ANSI	American National Standards Institute
GB	Gigabyte

Abbreviations

Symbols used in this document

Symbol	Definition
	Table
	Extra information within a task
	Tip. Extra information on correct use or useful hints
	Materials required for a task
	Prerequisites of a task
	Related topics containing further information
	Duration of a task

Symbols used in this document

Safety Classification

The safety precautions and important user notes are classified according to ANSI. Familiarize yourself with the following meanings and icons:

Safety alert symbol

- The safety alert symbol is used to alert you to potential physical injury hazards. To avoid possible injury or death, comply with all safety messages that follow this symbol.

These symbols and signal words are used for specific hazards:

⚠ WARNING

Warning…

- …indicates a hazardous situation that, if not avoided, could result in death or serious injury.

⚠ CAUTION

Caution…

- …indicates a hazardous situation that, if not avoided, could result in minor or moderate injury.

Notice…

- …indicates a hazardous situation that, if not avoided, may result in damage to the instrument.

Safety Summary

To avoid serious injury, read and comply with the following safety precautions.

⚠ WARNING

Insufficient knowledge and skills

As an operator, ensure that you know the relevant safety precaution guidelines and standards and the information and procedures contained in these instructions.

- Only trained personnel may operate the GeneSpark ™ instrument. Operators must have received and read the comprehensive instructions for the use, quality control, and care of the GeneSpark ™ instrument.

⚠ WARNING

Infectious materials

There is a potential risk of infection. Staff using the GeneSpark ™ instrument to perform tests on patient samples must be aware that any object contacting biologic specimens is a potential source of infection.

- Use gloves.
- Use a new assay kit for each sample.
- Follow all health and safety regulations applicable to your institution.

Electromagnetic Interference

⚠ CAUTION

Strong electromagnetic fields (originating from unshielded radio frequency sources) can interfere with proper operation and may lead to malfunction of the instrument and incorrect results.

- Do not use this instrument near sources of strong electromagnetic fields.

Disposal

The instrument must be disposed of in accordance with relevant local regulations and in coordination with your local authorities, as appropriate. Please note that the instrument may potentially be infectious. It should therefore be decontaminated before disposal.

Installation

Installing the instrument

Place the instrument on a suitable level surface and connect it to the mains power supply. Connect it to a local area network, if required. When the instrument is starting up, a series of initialization diagnostic tests are performed automatically.

⚠ CAUTION

Incorrect results or malfunctions due to incorrect installation.

Performing installation actions other than those mentioned in this documentation may lead to malfunction and incorrect results.

- Do not carry out any installation actions that are not described in this documentation or for which you were not trained by a Tangen Biosciences Inc Service representative.

⚠ CAUTION

Injury by tripping over cables

Cables between the instrument and wall outlets cause a potential tripping hazard.

- Position the instrument as close to the wall as possible.
- Take care not to trip if you must walk behind instrument

⚠ WARNING

Stacked or Adjacent Equipment

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

⚠ WARNING

Degradation of performance

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the instrument, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Malfunction due to use of inappropriate power supply unit

Using an inappropriate power supply unit may cause malfunction.

- Only use the supplied power supply unit.

Make sure that the package includes the following items:

☐ GeneSpark ™ Molecular Diagnostic Instrument

☐ Power Supply Unit

☐ Power Cable

If the packaging is damaged or an item is missing or damaged, immediately contact your Tangen Biosciences Service representative.

Retain the shipping container and packaging materials for the event that the instrument needs to be returned to Tangen Biosciences for service.

☐ GeneSpark ™ Molecular Diagnostic Instrument

☐ Power Supply Unit

☐ Power Cable

☐ RJ-45 data cable. If you intend to connect the instrument to a data network or computer.

☐ USB Handheld Barcode scanner

☐ USB flash drive, 4GB or greater, if you intend to transfer data from the instrument with this method

☒_
☐_ ☐ If the instrument is cold due to shipping or storage, allow it to come to room temperature before opening the package and applying power to avoid possible condensation inside the instrument.

➢ To install the instrument

1. Place the instrument on a level, vibration free surface, and away from direct sunlight.

   Allow at least 10 cm (4 inches) of space at the rear of the instrument for airflow. Ensure vents are not blocked.

2. Connect the power supply cable to the power supply unit.

3. Connect the power supply unit to the instrument's DC inlet (Located on the right side of the instrument).

4. Connect the power supply unit to a properly grounded mains outlet.

5. Connect the instrument to a local area network, if required.

   Use a standard Cat5e cable and connect to an appropriate wall connector or switch.

Refer to LBL-000217, GeneSpark Network Guide for more information on connecting the instrument to a local network.

About the instrument

Instrument functions

Overview

The instrument and the associated disposable assay kit are for *in vitro* diagnostic use. The instrument identifies and/or measures the presence of genetic material in a biological sample. The instrument automates all nucleic acid test (NAT) processes, including nucleic acid extraction, amplification, real-time detection, and result interpretation in a rapid manner.

The Filter Device and Assay disk are the interface to the patient sample. They contain all assay reagents necessary for analysis. The instrument will extract the nucleic acid from the Filter Device via mechanical lysis and deliver the sample to the Assay disk.

After receiving the extracted nucleic acid from the Filter Device, the instrument will resolubilize dried reagents with the sample. The sample is then delivered to the 35 wells located on the perimeter of the disk, where a target specific Isothermal Amplification reaction will occur.

Insert and test automation

A light detection module monitors the reaction in real time, while an on-board computer analyzes the collected data and interprets a result.

The GeneSpark ™ instrument automates all testing processes from sample preparation to amplification and real-time detection. The GeneSpark workflow has been simplified enabling non-specialized personnel to perform complex testing.

Before the Filter Device is inserted into the instrument, the tube is capped and remains

capped for the remainder of the diagnostic test. No further materials need to be added or removed from the Filter Device. The assay disk requires no addition or removal of reagents, and seals amplicon in the disk upon test completion. This approach avoids amplicon contamination, cross-contamination, reduces biohazard risks, and helps preserve sample integrity.

Rapid Testing

This technology automates liquid flow and mixing to provide rapid results. Result generation typically occurs in less than 1 hour.

Filter Devices and Assay Disks can only be used once.

NOTICE

Damage to the instrument due to unauthorized Filter Devices or assay disks

The use of unauthorized or unapproved Filter Devices, assay disks or accessories may damage the instrument. Damage caused by unauthorized Filter Devices, assay disks or accessories voids the instrument warranty.

- Only use the assay kit listed in the standard supplies table in this manual.

Self Checks

When the instrument is powered up and at the beginning of running an assay, a series of diagnostic tests are performed by the instrument automatically. Furthermore, the instrument monitors its operations during assay processing, and performs an automated calibration before every assay run. If an error occurs, a message is displayed on the screen and the event is logged in internal memory.

Running assays

The testing process is comprised of a few simple steps:

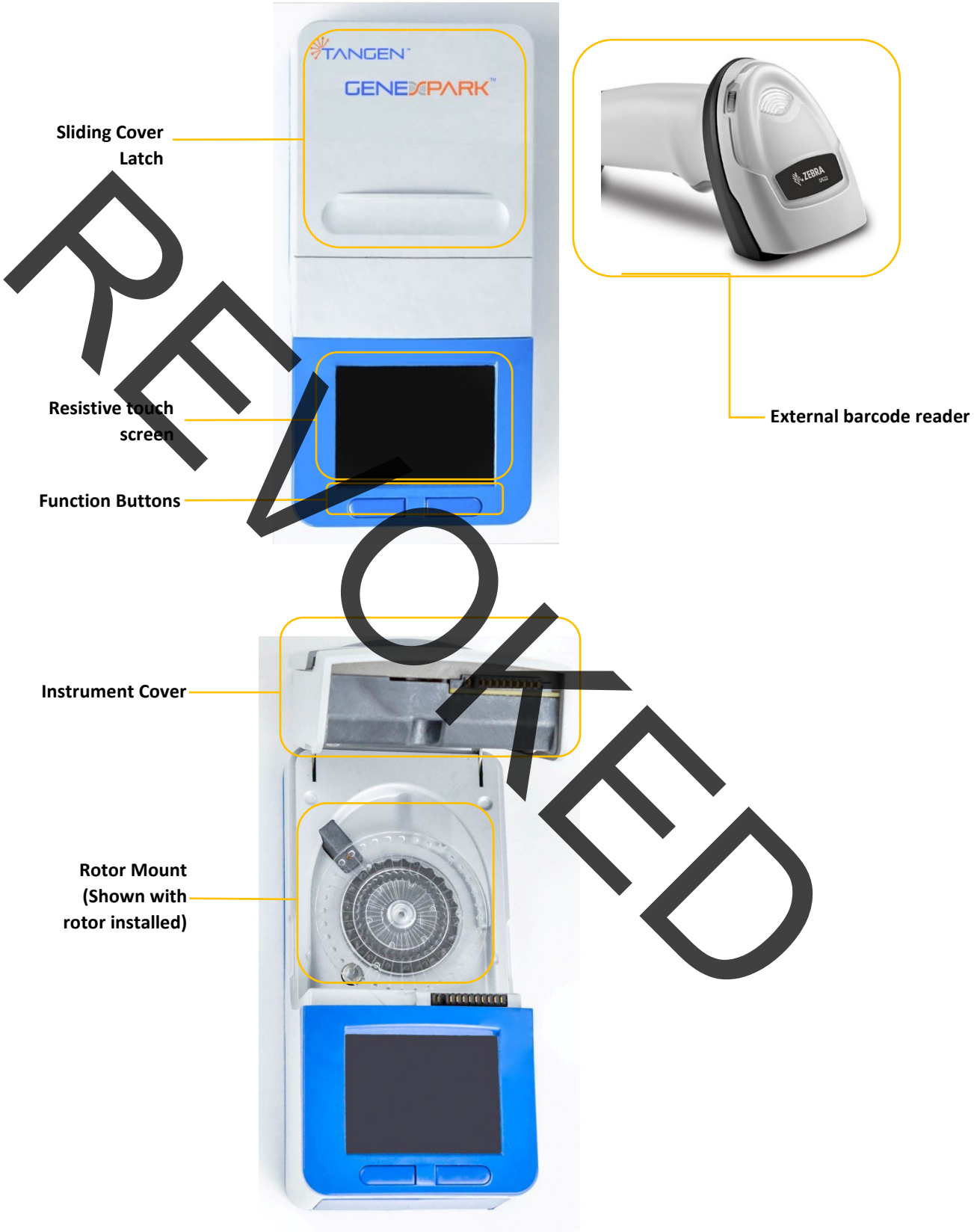
- Preparing a patient sample (See Patient Information Card (PIC)).
- Installing the Filter Device with the processed sample into the instrument.
- Installing the assay disk into the instrument.
- Scanning the serial number and assay ID barcodes located on the assay disk with the handheld barcode scanner.
- Press the right pushbutton to start analysis. The instrument automatically executes all the required steps.
- Assay is completed and test results are reported.
- Dispose of the assay disk and Filter Device.
- Review the result.

Before using the instrument for the first time, make sure it is set up correctly and the TangenDx SARS-CoV-2 Molecular Test is installed and validated.

Related topics

- Setting up the instrument
- Installing a new assay

Overview of the instrument user interface



Function Buttons

Two function buttons are located beneath the touch screen.

Press the buttons to perform various functions such as starting a run or powering down the instrument.

Resistive Touch screen

Touch the items on the screen with a finger (also when wearing gloves), or use a stylus designed for use with hand-held devices.

External barcode reader

Scan the Assay disk barcodes with an external barcode reader.

Sliding Cover latch

Slide the cover latch open to install or remove a Filter Device. Slide the latch closed prior to running the assay.

Instrument cover

Open the cover to install or remove an assay disk. Close the cover prior to installing a Filter Device.

Rotor mount

Install an assay disk onto the rotor mount and remove it when the assay run is complete.

About assays

The instrument runs a specific assay as determined by the scanned barcode of an assay disk.

The instrument requires a program, called an assay script, to conduct a specific assay.

New assays can be added to the assay menu by installing assay panel definition files. These files contain the definitions for the assay and the program required to run the

assay. The currently installed assays are listed on the **APD** screen located in the settings menu.

Related topics

- Installing an assay
- Running an assay

Overview of the touch screen

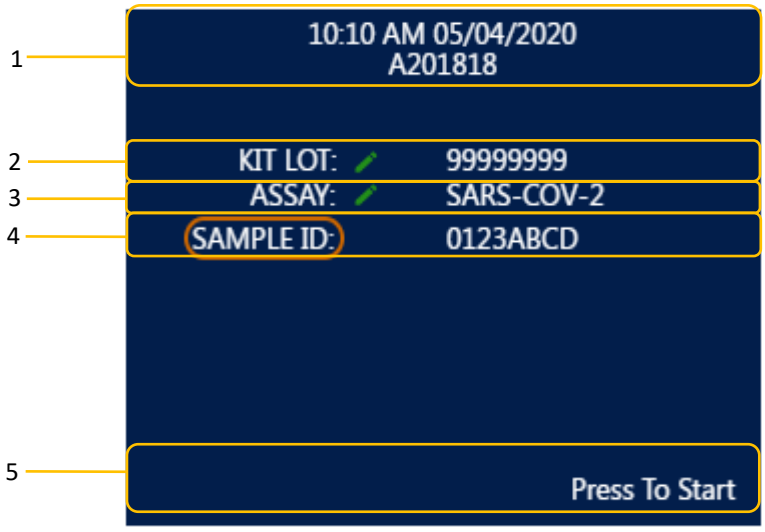
To operate the touch screen, use a finger (gloved hands are acceptable) or a stylus designed for use with resistive touchscreen devices.

NOTICE

Damage to the touch screen due to use of sharp objects

Using sharp objects on the touch screen may cause damage and lead to malfunction.

➢ Do not use sharp objects when operating the touchscreen.



Main Touch Screen

The main touch screen is divided into several information and operating areas.

1. Time/Status/Settings Bar
2. Assay disk lot number
3. Assay ID
4. Sample ID
5. Messages

Touch screen elements

Time/Status/Settings Bar — Current date and time are displayed in the center. Press the to access the settings menu. The indicates connection to a local area network via Ethernet cable or Wi-Fi.

Assay Disk Lot Number — This field is filled in after the lot number barcode is scanned from the Assay Disk.

Assay ID — This field is filled in after the Assay ID barcode is scanned from the Assay Disk.

Sample ID — This field is filled in after the Sample ID barcode is scanned from the patient sample.

Messages — This field will provide various messages to the user.

Common User Actions

Starting the instrument

The instrument will perform an initialization process after power up to ensure proper functionality.

Up to 30 seconds

To start the instrument

- The instrument will initialize after any of the following actions:

For instrument disconnected from power:

- Apply power to the instrument by connecting the power supply.

For instrument connected to power and in low power mode:

- Press the left or right pushbutton.

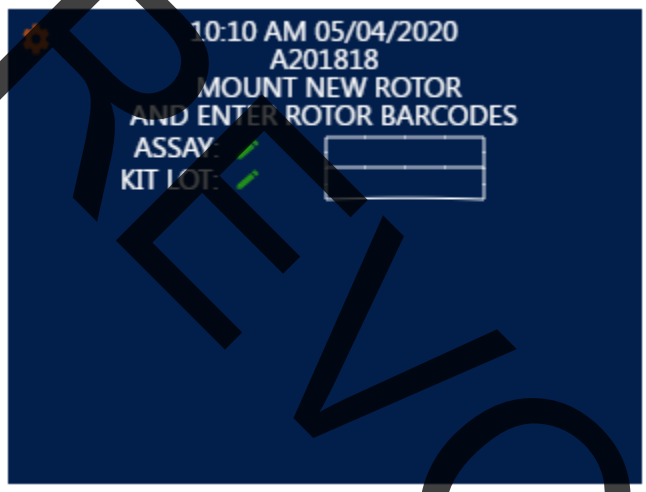
The following will occur on the instrument:

- Touch screen lights up.
- Assy disk motor will spin.
- Self-checks are performed.
- Wait until the main screen is displayed.

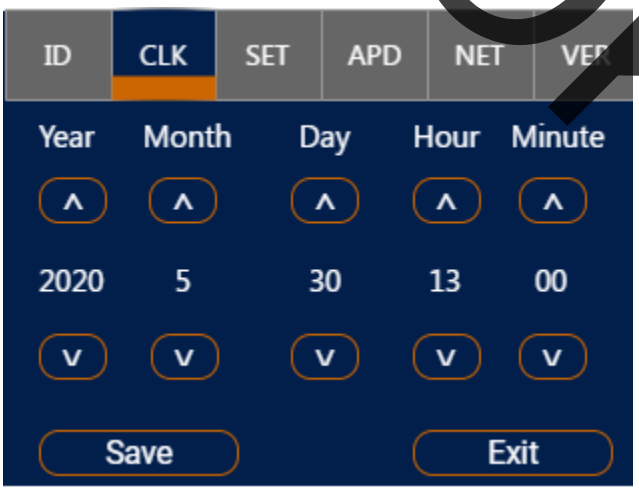
Setting Date/Time

You can set the time by entering the settings menu.

➢ To set the date and time



➢ Press the icon located in the upper-left hand corner of the main display. This will enter the settings menu.



➢ Press the CLK tab at the top of the settings menu. The time and date can be set by pressing either up or down arrows until the desired value is achieved.

ℹ Hour setting is in 24-hour format, however it will be displayed in 12-hour format.

➢ Press the save button on the display to set the new date/time setting, otherwise press exit to exit the menu without change.

Entering text and numbers

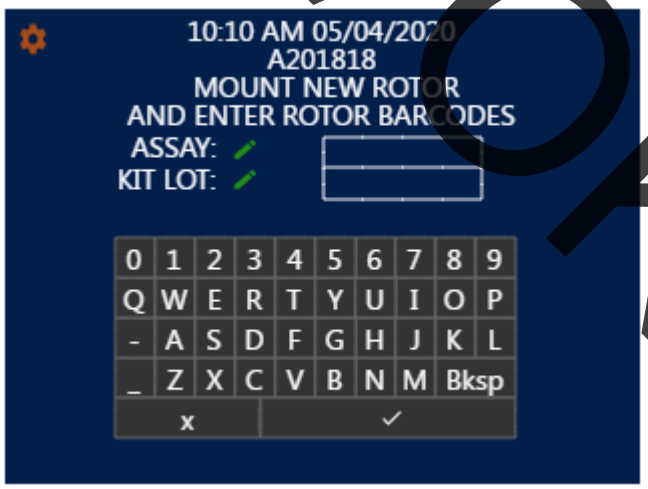
➢ To enter text and numbers

An alphanumeric keyboard will be displayed.

Key	Function
X	Exit without changes
✓	Exit with changes
< >	Move cursor left or right

Selected keys on the QWERTY keyboard

Confirm the entry by pressing the ✓ button.



Key	Function
X	Exit without changes
✓	Exit with changes
< >	Move cursor left or right

Selected keys on the numeric keyboard

Confirm the entry by pressing the ✓ button.

Scanning barcodes

You use the barcode reader for scanning assay disk lot, assay disk type, sample, and username barcodes.

To maintain patient confidentiality and privacy standards, do not use patient identifiable data as part of the patient and sample ID barcode.

The sample barcode must comply with one of the following standards:

- Code 39
- Code 93
- Code 128
- Code 128-A
- Code 128-B
- Codabar
- GS1 Databar-14

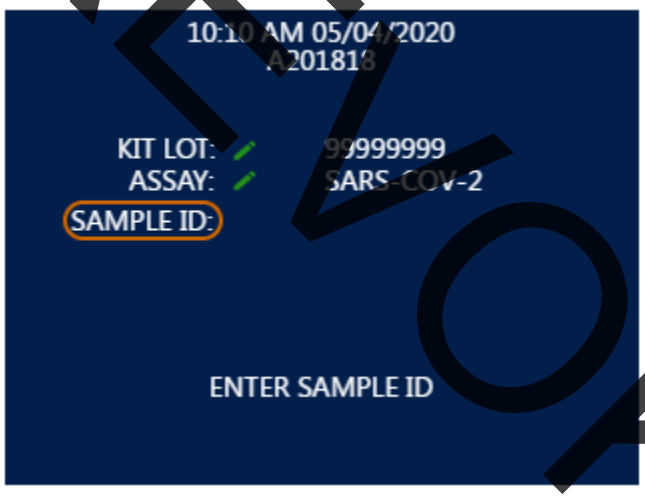
The barcode reader must be attached to the USB port before any barcodes can be read by the instrument.

➢ To scan barcodes

➢ Mount the assay disk on the instrument.

Use the attached barcode scanner to read assay disk barcodes or sample barcodes. . The barcodes should be placed in parallel to the scanner light. Ensure the scanner light extends beyond the barcode on both sides. The barcodes can be read in any order.

- If assay disk barcodes cannot be read, press the green pen icon next to the associated field on the screen to manually enter it. An alphanumeric keyboard will appear on the display for entry.



- If sample barcodes cannot be read, press the SAMPLE ID field on the GUI to manually enter it.

An alphanumeric keyboard will appear on the display for entry.

Turning off the instrument

Turning off the instrument shuts down the software and puts the instrument into a low power state.

CAUTION

Loss of power

- In the event of power loss while an assay is running, do not attempt to remove the assay disk or Filter Device.
- The instrument cannot be turned off while running an assay, power can be removed from the instrument by disconnecting the power supply. Do not disconnect power from the instrument while it is running an assay.

☒_
☐_ ☐ There is no activity on the instrument.

➢ To turn off the instrument

- Hold the left pushbutton until the display turns dark.

Safety

Make sure you are familiar with the safety instructions: Safety

Performing a run

CAUTION

Incorrect results due to using inappropriate assay components
Using a non-certified Filter Device or assay disk may lead to incorrect results.

- Only use GeneSpark ™ assay components.
- Never re-use assay components.

CAUTION

Incorrect results or malfunction due to inappropriate handling of assay tubes

Inappropriate handling of the Filter Device may lead to
incorrect results or malfunction.

- Do not remove or insert a Filter Device while the instrument is performing an assay.
- Do not force or rotate the Filter Device when inserting it.
- Do not reuse a spent Filter Device.
- Do not attempt to open the instrument cover during a run.
- Do not attempt to open the sliding Filter Device latch during a run.

NOTICE

Malfunction due to inappropriate handling of the instrument.
Inappropriate handling of the instrument may lead to malfunction.

- Do not attempt to force the instrument cover open before opening the sliding cover latch.

Running an assay

The instrument runs a specific assay as determined by the scanned barcode of an assay disk.

Running an assay comprises the following actions:

- Inserting assay disk into the instrument.
- Scanning the assay disk and sample barcodes.
- Inserting the Filter Device into the instrument.
- The instrument performs the required assay steps and reports the test results.

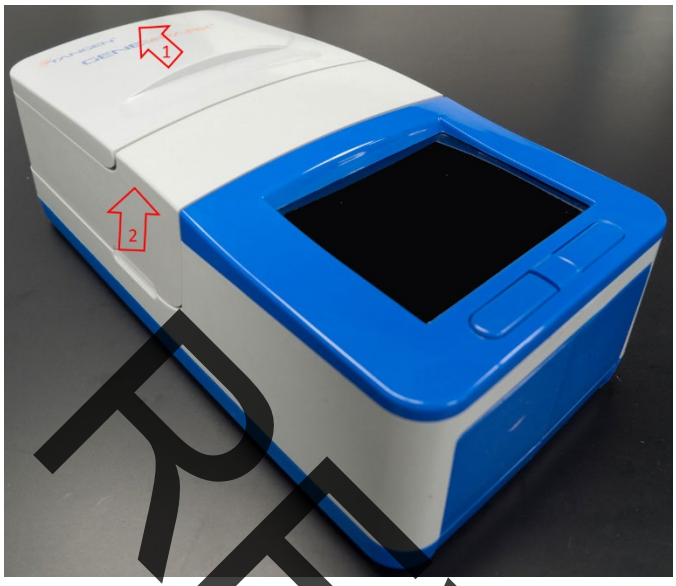
For information on transferring sample into the Filter Device, see the instructions in the package insert of the TangenDx SARS-CoV-2 Molecular Test.

Make sure you use the correct sample type as indicated on the instructions found in the assay kit.

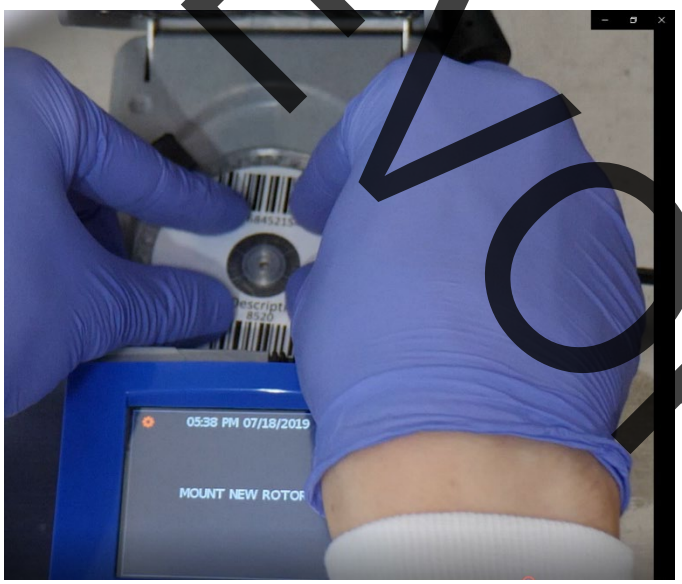
☐ Filter Device
☐ Assay disk
☐ Sample barcode

To run an assay

- Process the sample following the instructions included with the assay kit you intend to use.
- Check the assay disk and Filter Device included in the assay kit for damage; for example, leaks or broken seals.

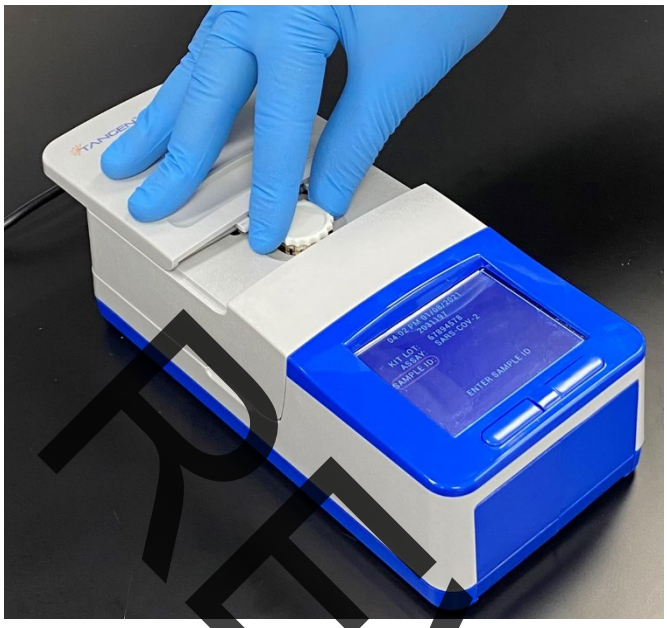


- Open the instrument cover by sliding the latch back, then pulling the cover up.



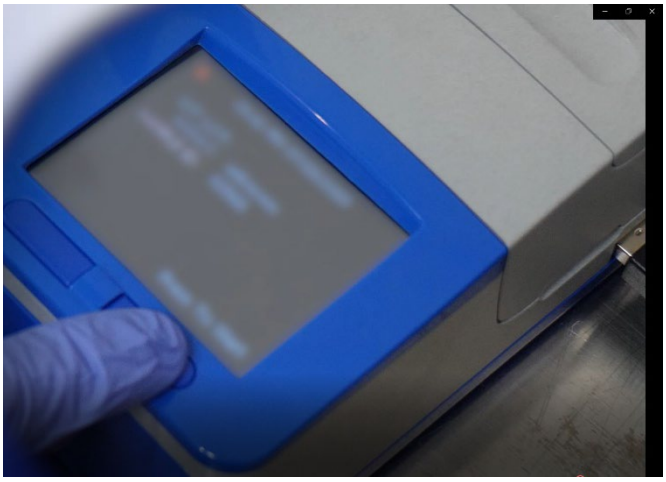
- Mount the assay disk to the instrument.

- Scan the Assay disk barcodes with the barcode reader. The Kit Lot and Assay fields will fill with the barcodes scanned from the rotor.



- Close the instrument cover and install the Filter Device. Close the sliding cover latch to secure the Filter Device.

- Scan the sample barcode.



- Press the right pushbutton to start the run.

- Check the progress if required.

  At the top of the screen, the assay and sample ID are displayed. The estimated time remaining is displayed in the center of the display.

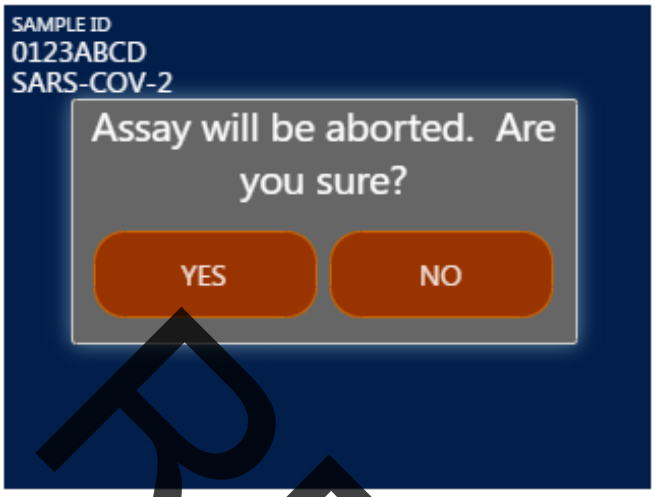
  To abort the assay run, press and hold the left pushbutton for 5 seconds.

- When the assay run is complete, the results for the assay are displayed. Press the "Done" button and the instrument will display the idle screen. The assay disk and Filter Device may be removed from the instrument. Dispose of the assay disk and Filter Device in accordance with the disposal policy in your institution.
- If the instrument is set up to automatically send results to a host, the result will be accepted and sent to the host after the done button is pressed.

Related Topics

- Reviewing results
- About assays
- Scanning barcodes
- Aborting an assay run

Aborting an assay run



➢ To abort an assay run

- Press and hold the left pushbutton.
- On the confirmation message, choose the **Yes** button.

ⓘ You can choose 'No' to return to the previous screen.

- The instrument stops assay processing.
- The instrument creates a results report.
- The results screen will be displayed indicating the run has been aborted.
- Dispose of the assay disk and Filter Device in accordance with the disposal policy of your institution.
- Press the "Done" button to return to the main menu.

Result handling

About results

The way results are calculated and displayed depends on the intended use of each individual assay.

Results are reported on the display at the end of a run.

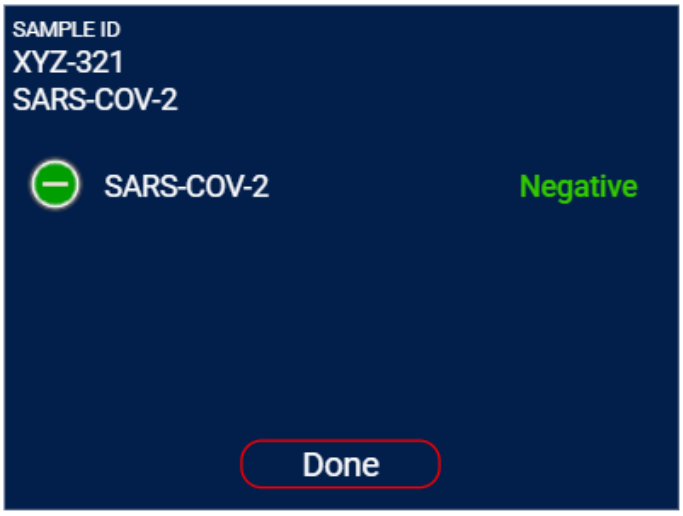
```
GeneSpark Instrument Test Results
==================================
DATE: 2020-06-13 10:48:06
SAMPLE: 1234567890ABCXYZ
INSTRUMENT: TD-12345-12345
FIRMWARE VERSION: 2.6.0.0
ASSAY: SARS-COV-2
KITLOT: 99998888
COMMENT: None
TARGET:          RESULT:
SARS-COV-2       Negative
==================================
```

Printed Result Report.

Reviewing results

You typically review results as part of assay processing.

If the instrument is set up to send results automatically to a laboratory, hospital, or data management system, reviewing is not done on the instrument.



➢ To review results from the results screen

➢ Allow an instrument run to finish. Results for the assay are automatically displayed after the run is completed.

Once the "Done" button is pressed after reviewing results, you can no longer view them on the display. You will need to review the results from a connected information system or LIS interface.

Downloading results

Results can be downloaded via the USB port located on the right side of the instrument.

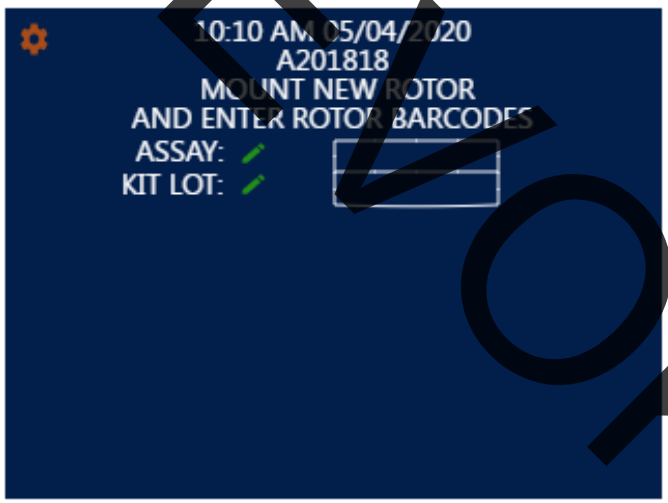
Tangen recommends regularly backing up all results.

☒_
☐_ ☐USB flash drive with a minimum of 1GB of available memory.

➢ To download results

➢ Install a USB flash drive into the USB port.

➢ On the **idle** screen, press the icon in the upper left-hand corner of the display.



➢ Press the "DD" tab. This will display the data dump screen. Select "RESULTS" or "RAW DATA". The number of runs available to download will be displayed above the exit button. You must select "ALL" and press "DUMP" to download all data from the instrument.

A dump needs to be performed separately for Raw Data and results.

- The progress bar will be displayed, wait for the transfer to complete. Press "EXIT" to return to the Idle screen.

⚠ CAUTION

Loss of power or early removal of USB drive can damage transferred data or cause damage to the flash drive.

- Do not remove USB flash drive during data transfer.
- Do not remove power during data transfer.

Setting up the instrument

Setup tasks are performed from the **settings** screen

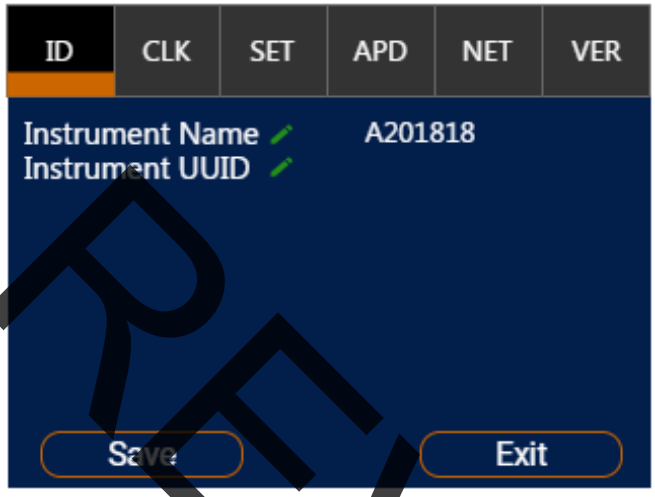
Setup tasks can only be performed with Administrator security level.

Results and setup data are retained on the instrument even if it is not connected to a mains power supply.

Defining Values

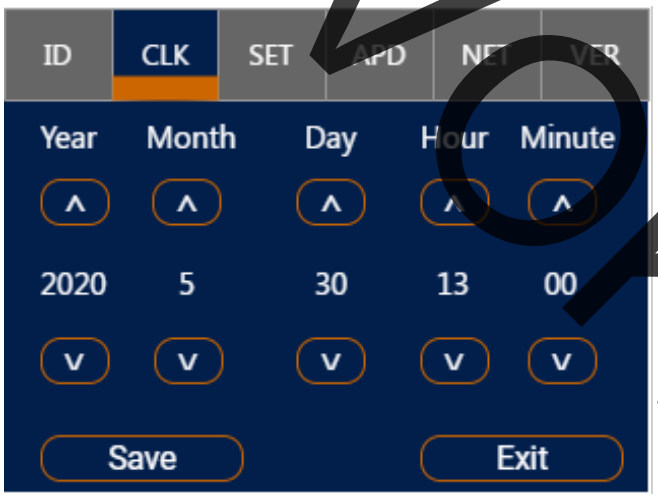
- Defining values
- Installing assays
- System settings
- Network definitions
- Updating software

You define values by entering text or by selecting a predefined value.



➢ To enter Text

1. Press the tab of the configuration item you want to modify. Press the ✎ to change the value.
   ➔ The alphanumeric keyboard is displayed.
2. Enter the desired value and choose the save button.
   ➔ The value will be saved to memory and the Idle screen will be displayed.



➢ To select a predefined value

1. To select a predefined value, use the ↑ or ↓ button.
2. Enter the desired value and choose the save button to save the change.
   ➔ The value will be saved to memory and the Idle screen will be displayed.

Installing assays

The instrument is delivered with all currently available assays installed.

Assays may also need to be updated after they have been installed.

Do not disconnect the instrument's power supply when installing or updating an assay.

- Installing assays from a USB Flash Drive

You can install an assay from a USB flash drive.

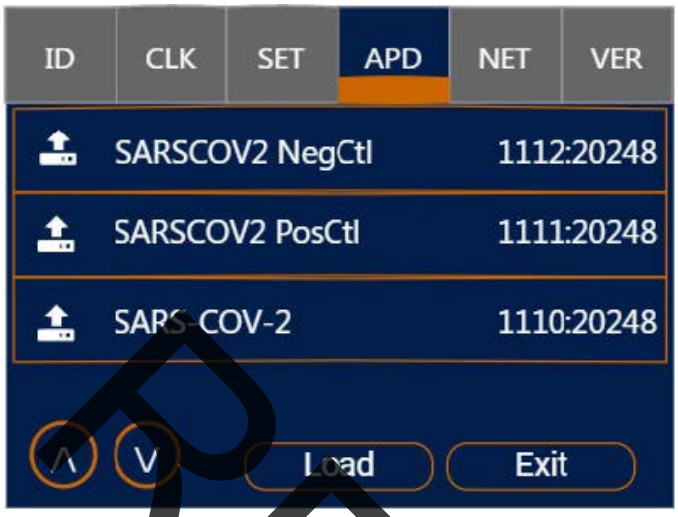
Contact your local Tangen Representative to obtain access to secure assay files used for installation.

Installing an assay

➢ To install an assay from a USB flash drive

1. Install a USB flash drive into the USB port on the side of the instrument. The USB flash drive should have secure assay files stored to the root directory of the drive.
2. Enter the **settings** menu by pressing the icon.

   Press the **"APD"** tab. All installed assays will be listed on the display.



Use the ↑ or ↓ button to scroll through the available assays.

3. Press the "**Load**" button to load the available assays.

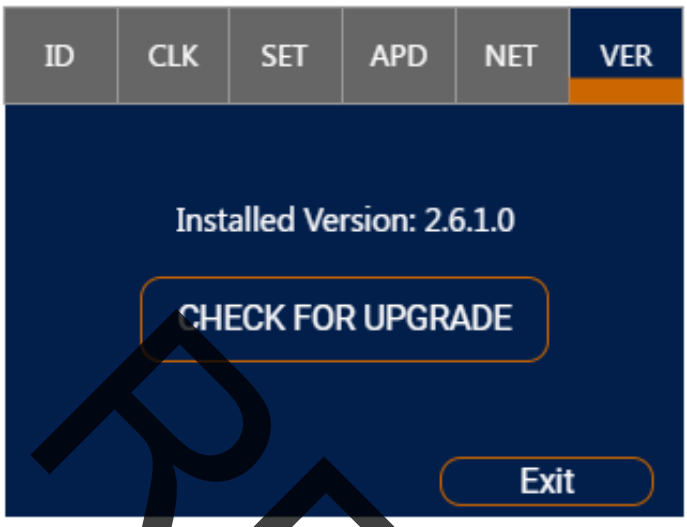
The instrument is delivered with all currently available assays installed. If a new assay is developed, it will require installation to enable use of the new assays.

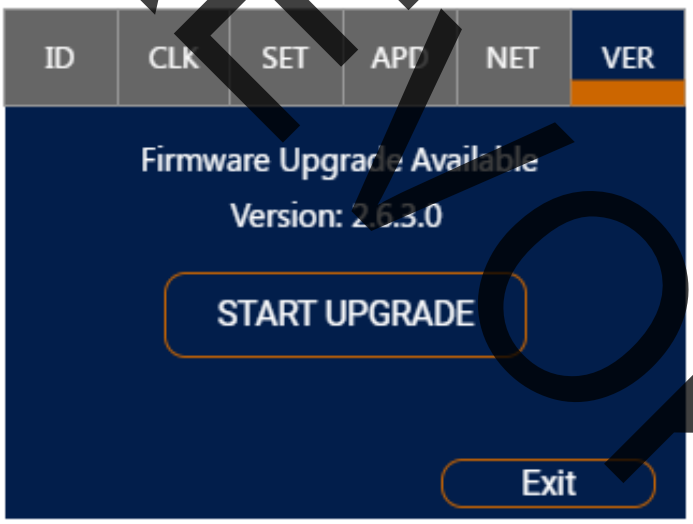
Instrument software can be updated using secure software upgrade files provided by Tangen. Contact your local Tangen representative to obtain access to secure software upgrade files.

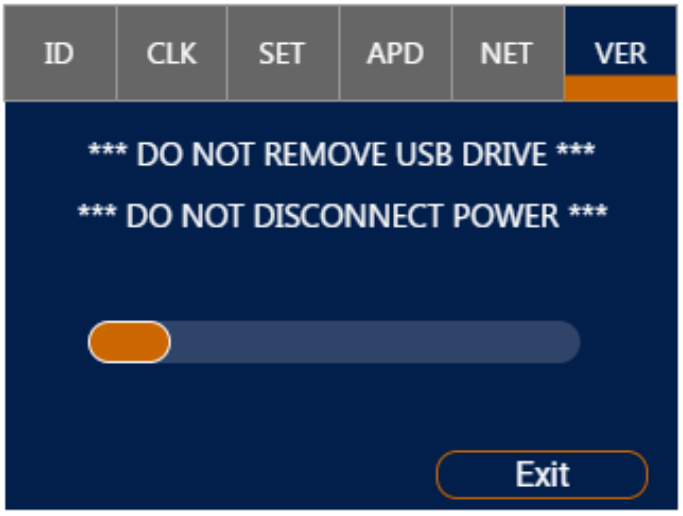
Updating Software

To upgrade firmware from a USB flash drive

- Attach a USB flash drive to the instrument's USB port. The USB flash drive should have secure software upgrade files installed to the root directory of the drive.
- Enter the **settings** menu by pressing the ⚙ icon.
- Press the "VER" tab. The display will show the current version of software installed.
  Press the "CHECK FOR UPGRADE" button. The instrument will search the USB drive for valid update files.







- Press the "START UPGRADE" button.
- Press "YES" when asked "Ready to begin?" The update process will begin.

NOTICE

Loss of power during software update may cause the instrument to permanently stop working. Do not disconnect power when updating software.

- Do not disconnect power during software update.

- A progress bar is shown to indicate overall update status. After software update is complete, the instrument will re-boot and the display will indicate the new software version.

Define the general operating environment.

➔ Settings

System settings

System item	Configuration Item	Comment
Time and Date	Time and Date	Time format: hh:mm Date format: mm-dd-yyyy
ID	Instrument Name	Up to 7 alphanumeric characters. By default, this is the last seven digits of the instrument's serial number.

System Configuration Items

Network settings

CAUTION

Breach of confidentiality and privacy

Unprotected network connections may allow access by unauthorized persons and confidential personal information may be obtained.

- When connecting the instrument to a network make sure the connection is secure and monitored for security breaches.

You can connect the instrument to a 10/100 Ethernet network, or a 2.4G or 5G Wi-Fi network. Refer to document LBL-000217, GeneSpark Network Guide for further information.

Quality Control

Internal Process Control (IPC) is included in every assay disk. It verifies the adequate processing of the biological sample. The IPC passes, if sample concentration and target amplification meet validated acceptance criteria.

Quality control kits for each TANGENDx™ Assay are available from Tangen Biosciences. The quality control kits contain positive and negative control sample materials.

Refer to the TangenDx™ assay kit for detailed instructions.

Maintenance and calibration

An operator is not required to perform any maintenance.

- About self-check
- About auto monitoring
- About auto calibration
- About service
- Cleaning the instrument

About self-check

The instrument performs self-diagnostics during startup (instrument initialization) and uses an error diagnostic system to monitor the instrument's performance during an assay run. Under normal operation, the instrument alerts the operator in the event of a malfunction or when an error is detected.

Each instrument is calibrated to factory standards prior to shipping. The instrument

requires no adjustment or calibration from the operator.

About auto monitoring

The instrument performs continuous auto monitoring to ensure data integrity and accuracy during assay runs. If an error is detected during an assay run, the run will be invalidated, and a message will be displayed for the user with instructions on how to proceed.

About auto calibration

The instrument will perform automatic calibration prior to starting a run after the instrument cover has been closed. Calibration takes approximately 3 seconds and requires no action from the user.

About service

Please contact your local Tangen Biosciences representative if you have questions regarding the instrument, its service needs or if you have other questions.

⚠ CAUTION

Electrical Hazards

There are no serviceable parts inside the instrument. Disassembling the instrument could result in electrical hazards.

- Never attempt to repair or adjust the instrument yourself.

- Contact your local Tangen Biosciences representative if the instrument fails to operate properly.

Cleaning the instrument

- Keep the touch screen clean from excessive fingerprints and moisture by gently wiping it with a soft, lint-free cloth.
- The exterior of the instrument and push buttons can also be cleaned using a soft lint-free cloth moistened with either 70% isopropanol or 5-10% bleach solution. If bleach is used, it must be wiped twice using 70% isopropanol to remove all bleach residues.
- Periodically check the rear vents for excessive dust or debris.
- The inside and outside of the instrument should be cleaned after every assay run.

Make sure you are familiar with the safety instructions below

Safety

CAUTION

Electric Shock

Spraying or applying liquid to the instrument may damage the instrument or pose an electrical hazard.

- Do not spray or apply liquid directly on the instrument.
- Do not attempt to clean the interior of the instrument through the rear vents.
- Do not apply an excessive amount of liquid to the cleaning cloth, which may lead to liquid dripping onto the instrument.

NOTICE

Damage to the instrument due to use of unsuitable cleaning materials

Using unsuitable cleaning materials can damage the touch screen and other surfaces.

- Do not use harsh, abrasive cleaners or wipes.

Cleaning the outside of the instrument

- Cleaning the outside of the instrument
- Cleaning spillages or leakages from a Filter Device or rotor

☒_ ☐ Soft lint-free cloth

☐_ ☐ 5-10% bleach wipe followed by a 70% isopropanol wipe

➢ To clean the touch screen

1. Wipe the touch screen gently with a soft,lint-free cloth.

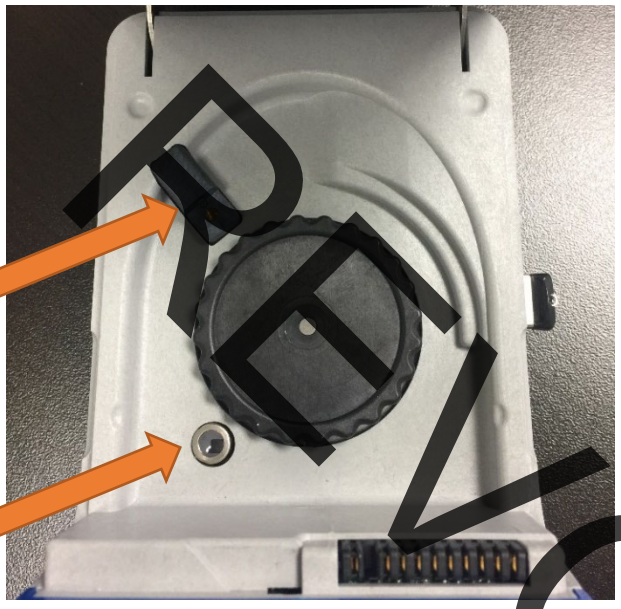
➢ To clean the push buttons and the exterior of the instrument

1. Using a 5-10% bleach wipe, gently clean the surfaces as required.
2. Let dry for approx 5 minutes
3. Using a 70% isopropanol wipe, clean the instrument to remove all bleach residues.
4. Let dry, approximately 2 minutes

☒_ ☐ 5-10% bleach wipe

☐_ ☐70% isopropanol wipe

Cleaning the inside of the instrument



CAUTION

Potential Damge to Instrument

- **Never clean lightpipe assembly or temperature sensors with a wipe.**
- These components should only be cleaned with a dry, lint-free cloth.
- Components indicated with arrows in the pictures to the left should be avoided.

To clean the inside surfaces of the instrument

1. Using a 5-10% bleach wipe, gently clean the surfaces as required.
2. Let dry for approx 5 minutes
3. Using a 70% isopropanol wipe, clean the instrument to remove all bleach residues.
4. Let dry, approximately 2 minutes
5. Follow up with a fresh, dry lint-free cloth and wipe the surface of the light pipe assembly and temperature sensors shown.
6. Leave Instrument lid and cover open when instrument is not in use.

Cleaning spillages or leakages from a Filter Device or disk

In the unlikely event of a spillage or leak of a Filter Device or assay disk, the instrument may need to be cleaned or sent to a Tangen representative.

➢ To deal with a leak from a Filter Device or Assay disk

1. If a leak is detected inside the instrument, stop using the instrument immediately and contact your Tangen Biosciences representative for further instructions.
2. Follow standard laboratory practices.
   - Follow standard laboratory practices for working with biohazardous materials.
   - Refer to the appropriate assay tube Material Safety Data Sheet and package insert for assay specific information.

Troubleshooting

The instrument monitors its operation and logs abnormal events. Based on the severity, the instrument tries to recover or fix the error while running. If the situation cannot be resolved, the instrument stops.

In many situations, error messages are displayed on the screen. Read them carefully and follow the instructions provided in them.

Basic Troubleshooting Guide

A basic troubleshooting guide is shown below

Problem	Additional Symptoms or Indications	Possible Cause	Recommended	Notes/Additional Info
Rotor not recognized by instrument	The following message is displayed: "ROTOR FAULT, REMOUNT DISK"	Excessive wobble detected from rotor.	Remove rotor and re-mount in a different position.	Care should be taken when removing or installing a rotor. Be sure to only remove the rotor from the position indicated on the label. When installing the rotor, only apply enough force to snap the rotor onto the mount. Try spinning the rotor by hand to check for excessive wobble. If minimal wobble is detected, close the instrument cover to attempt rotor check again.
Rotor not recognized by instrument	The following message is displayed: "ROTOR FAULT, CHECK MOUNT"	Rotor is locked or spinning slow	Check instrument for debris or anything that can impede the free movement of the rotor. Check the rotor for abnormalities that may interfere with rotation.	Try spinning the rotor by hand to check for free movement. If rotor spins freely, close the cover to attempt rotor check again.
Rotor not recognized by instrument	The following message is displayed: "NO ROTOR MOUNTED"	Rotor is missing, or has poor optical properties	Make sure rotor is installed properly. Try using another kit.	NA

Problem	Additional Symptoms or Indications	Possible Cause	Recommended course of action	Notes/Additional Info
Rotor not	The following message is displayed: “ROTOR CALIBRATION FAILED”	Excessive wobble detected from rotor, poor light transduction	Remove rotor and re-mount in a different position. Make sure rotor is installed properly. Try using another rotor.	Care should be taken when removing or installing a rotor. Be sure to only remove the rotor from the position indicated on the label. When installing the rotor, only apply enough force to snap the rotor onto the mount. Try spinning the rotor by hand to check for excessive wobble. If minimal wobble is detected, close the instrument cover to attempt rotor check again.
Instrument	The following message may be displayed: "CLOSE COVER LATCH", "INSERT SAMPLE TUBE".	Cover sliding latch not fully closed. Filter Device not installed. Filter Device cap not fully tightened.	Close cover sliding latch fully. Ensure capped Filter Device is installed. Ensure Filter Device cap is fully tightened.	If “CLOSE COVER LATCH” message persists, try sliding the cover latch open and then slide it closed again. If this still doesn’t clear the message, perform a power cycle, and attempt to start the run again.

Basic Troubleshooting Guide

List of error messages

If you have any questions or problems, contact your Tangen Biosciences representative with the following instrument information ready:

☐ Instrument serial number. You can find this on the product label on the bottom of the instrument.

☒_ ☐ Assay name

☐_ ☐ Error message and code (if displayed)

- List of error messages

Error messages are generated in exceptional situations. They provide a brief description of the error and provide information on how to resolve the situation.

Some error messages contain a unique alphanumeric error code displayed at the end of the error messages. Provide this code when contacting your Tangen Biosciences representative.

CAUTION

Potential Biohazard

If any error code is displayed while running an assay, this indicates the assay run is invalid and has been halted. The assay disk and Filter Device will need to be removed from the instrument.

- Follow standard laboratory practices for working with biohazardous materials.
- Refer to the appropriate Material Safety Data sheet and package insert for assay specific information.

The table on the following page lists the real-time messages and suggested troubleshooting actions for them.

Instrument Error Codes

Error Code	Message	Action
0x8001	CRITICAL ERROR, CYCLE POWER ERROR CODE: LCD 0x8001 IND WATCHDOG RESET LCD	Restart the instrument by performing a power cycle. If this error continues, call Tangen Biosciences Service.
0x8006	CRITICAL ERROR, CYCLE POWER ERROR CODE: LCD 0x8006 I2C WRITE FAIL LCD	Restart the instrument by performing a power cycle. If this error continues, call Tangen Biosciences Service.
0x8007	CRITICAL ERROR, CYCLE POWER ERROR CODE: LCD 0x8007 I2C READ FAIL LCD	Restart the instrument by performing a power cycle. If this error continues, call Tangen Biosciences Service.
0x8008	CRITICAL ERROR, CYCLE POWER ERROR CODE: LCD 0x8008 UART CHECKSUM ERROR LCD	Restart the instrument by performing a power cycle. If this error continues, call Tangen Biosciences Service.
0x8009	CRITICAL ERROR, CYCLE POWER ERROR CODE: LCD 0x8009 SPI COMMUNICATION ERROR LCD	Restart the instrument by performing a power cycle. If this error continues, call Tangen Biosciences Service.
0x800A	CRITICAL ERROR, CYCLE POWER ERROR CODE: LCD 0x800A MAIN MICRO COMM TIMEOUT	Restart the instrument by performing a power cycle. If this error continues, call Tangen Biosciences Service.
0x800B	CRITICAL ERROR, CYCLE POWER ERROR CODE: LCD 0x800B EXTERNAL FLASH ERROR LCD	Restart the instrument by performing a power cycle. If this error continues, call Tangen Biosciences Service.
0x800C	CRITICAL ERROR, CYCLE POWER ERROR CODE: LCD 0x800C LOCKER ROTOR	Restart the instrument by performing a power cycle. If this error continues, call Tangen Biosciences Service.
0x800D	CRITICAL ERROR, CYCLE POWER ERROR CODE: LCD 0x800D PERIPHERAL INIT ERROR	Restart the instrument by performing a power cycle. If this error continues, call Tangen Biosciences Service.
0x800E	CRITICAL ERROR, CYCLE POWER ERROR CODE: LCD 0x800E ADS1148 FAULT	Restart the instrument by performing a power cycle. If this error continues, call Tangen Biosciences Service.
0x800F	CRITICAL ERROR, CYCLE POWER ERROR CODE: LCD 0x800F INSTRUMENT COVER FAULT	Restart the instrument by performing a power cycle. If this error continues, call Tangen Biosciences Service.
0x8010	CRITICAL ERROR, CYCLE POWER ERROR CODE: LCD 0x8010 BOOST CONVERTER FAULT	Restart the instrument by performing a power cycle. If this error continues, call Tangen Biosciences Service.
0x8012	CRITICAL ERROR, CYCLE POWER ERROR CODE: LCD 0x8012 FLUID SENSOR ERROR LCD	Restart the instrument by performing a power cycle. If this error continues, call Tangen Biosciences Service.
0x8014	CRITICAL ERROR, CYCLE POWER ERROR CODE: LCD 0x8014 FIRMWARE VERSION MISMATCH	Restart the instrument by performing a power cycle. If this error continues, call Tangen Biosciences Service.

Error Code	Message	Action
0x8015	CRITICAL ERROR, CYCLE POWER ERROR CODE: LCD 0x8015 TEMPERATURE CONTROL FAULT	Restart the instrument by performing a power cycle. If this error continues, call Tangen Biosciences Service.
	CRITICAL ERROR, CYCLE POWER ERROR CODE: LCD 0x8016 SYSTEM CLOCK ERROR	Restart the instrument by performing a power cycle. If this error continues, call Tangen Biosciences Service.
	CRITICAL ERROR, CYCLE POWER ERROR CODE: MAIN 0xB001 WINDOW WATCHDOG RESET MAIN	Restart the instrument by performing a power cycle. If this error continues, call Tangen Biosciences Service.
	CRITICAL ERROR, CYCLE POWER ERROR CODE: MAIN 0xB006 I2C COMMUNICATION ERROR MAIN	Restart the instrument by performing a power cycle. If this error continues, call Tangen Biosciences Service.
	CRITICAL ERROR, CYCLE POWER ERROR CODE: MAIN 0xB007 SPI COMMUNICATION ERROR MAIN	Restart the instrument by performing a power cycle. If this error continues, call Tangen Biosciences Service.
	CRITICAL ERROR, CYCLE POWER ERROR CODE: MAIN 0xB008 FLUID SENSOR ERROR MAIN	Restart the instrument by performing a power cycle. If this error continues, call Tangen Biosciences Service.
	CRITICAL ERROR, CYCLE POWER ERROR CODE: MAIN 0xB009 MOTOR CONTROL ERROR	Restart the instrument by performing a power cycle. If this error continues, call Tangen Biosciences Service.
	CRITICAL ERROR, CYCLE POWER ERROR CODE: MAIN 0xB00A MOTOR TACH ERROR	Restart the instrument by performing a power cycle. If this error continues, call Tangen Biosciences Service.
	CRITICAL ERROR, CYCLE POWER ERROR CODE: MAIN 0xB00B EXTERNAL FLASH ERROR MAIN	Restart the instrument by performing a power cycle. If this error continues, call Tangen Biosciences Service.
	CRITICAL ERROR, CYCLE POWER ERROR CODE: MAIN 0xB00C SYSTEM INIT ERROR MAIN	Restart the instrument by performing a power cycle. If this error continues, call Tangen Biosciences Service.
	CRITICAL ERROR, CYCLE POWER ERROR CODE: MAIN 0xB00D SAMPLE ILLUMINATION ERROR	Restart the instrument by performing a power cycle. If this error continues, call Tangen Biosciences Service.
	CRITICAL ERROR, CYCLE POWER ERROR CODE: MAIN 0xB00E SELF TEST FAIL	Restart the instrument by performing a power cycle. If this error continues, call Tangen Biosciences Service.
	CRITICAL ERROR, CYCLE POWER ERROR CODE: MAIN 0xB00F SFFS ERROR	Restart the instrument by performing a power cycle. If this error continues, call Tangen Biosciences Service.
	CRITICAL ERROR, CYCLE POWER ERROR CODE: MAIN 0xB013 EMPTY SAMPLE ID	Restart the instrument by performing a power cycle. If this error continues, call Tangen Biosciences Service.
	CRITICAL ERROR, CYCLE POWER ERROR CODE: MAIN 0xB014 ANALYSIS MEMORY FAILURE	Restart the instrument by performing a power cycle. If this error continues, call Tangen Biosciences Service.

Error Code	Message	Action
0xB015	CRITICAL ERROR, CYCLE POWER ERROR CODE: MAIN 0xB015 SYSTEM CLOCK ERROR	Restart the instrument by performing a power cycle. If this error continues, call Tangen Biosciences Service.
0xB016	CRITICAL ERROR, CYCLE POWER ERROR CODE: MAIN 0xB016 ERASE FLASH MEMORY FAILED	Restart the instrument by performing a power cycle. If this error continues, call Tangen Biosciences Service.
0xB017	CRITICAL ERROR, CYCLE POWER ERROR CODE: MAIN 0xB017 MAIN MCU HARD RESET	Restart the instrument by performing a power cycle. If this error continues, call Tangen Biosciences Service.

Instrument Error Codes

Analysis Error Codes for Invalid Runs

Error Code	Description	Source of Error
400F	Fluid Temperature	Fluid temperature was not within threshold bounds during scanning for > 2 minutes
4010	Filter Device Temperature	Filter Device Temperature did not reach setpoint
4011	Sonication	At least one sonication burst did not produce current
4013	Motor Speed During Scanning	Motor Speed outside threshold during rotor scanning
4014	Plate Temperature	Plate temperature did not achieve minimum threshold
4015	Fluid Temperature Mixing	Fluid temperature did not reach mixing temperature
4016	Fluid Temperature Overshoot	Fluid temperature exceeded maximum value for running assay
401D	Fluid Temperature Calibration	A Fluid temperature Sensor is out of calibration
Err01	Data analysis failed	Software computational error
Err02	Sample loading failed	Signal level indicates no fluid transfer to well
Err03	Controls failed	Internal control wells have no positive signal

Analysis Error Codes for Invalid Runs

Technical Data

The instrument has the following technical characteristics:

Characteristic	Data
User Interface	Built in resistive touchscreen & 2 push buttons
Internal Storage Capacity	Approximately 5000 test results with date and time can be stored on the instrument (depending on result file size)
Connectivity	Ethernet, RJ-45, TCP/IP 1 Universal Serial Bus (maximum load of 500mA) 2.4G/5G 802.11 WLAN
Power Supply	15VDC/4.9A input
WLAN	Transmit Power: +17dBm (max) Receiver Sensitivity: @802.11g 6 Mbps: -92.6dBm @802.11g 54 Mbps: -75.56dBm @802.11a 6 Mbps: -88.7dBm @802.11a 54 Mbps: -73.7dBm @802.11n 5Ghz MCS7 HT20: -72.0dBm @802.11n 5Ghz MCS7 HT40: -68.8dBm
Total Power Consumption	73.5W
Safety Class	II
Dimensions (Lx W x H)	190mm x 94mm x 64mm (7.5in x 3.7in x 2.5in)
Weight	800g (1.8 lbs.)

Technical Data

Operating conditions

For operation, the following ambient conditions must be met.

Characteristic	Data
Temperature range	+15°C to +30°C (59°F to 86°F) recommended
Relative Humidity	10% to 80% (non-condensing)
Maximum altitude	2000m (6500 ft) above sea level

Operating Conditions

Storage and transport conditions

For storage and transport, the following ambient conditions must be met.

Characteristic	Data
Temperature range for	-18°C to +40°C (-0.4°F to 104°F)
Temperature range for storage	4°C to +40°C (39.2°F to 104°F)
Storage relative humidity	10% to 80% (non-condensing)

Storage and transport conditions

Standard supplies

For trouble free operation, use the following standard supplies:

Name
GeneSpark™ Instrument
GeneSpark™ Power Supply with US Cord
TangenDx™ Assay Kits
Read the package insert for detailed product data and usage limitations.

Standard Supplies