



IntelliPlex™ SARS-CoV-2 Detection Kit

Instructions for Use

REF 82303-U **96 Reactions**

IVD **In Vitro Diagnostic Use**

For use under an Emergency Use Authorization (EUA) only.

For Rx Use only

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**IMPORTANT: Read the instructions
carefully prior to Use**

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1. INTENDED USE

The *IntelliPlex™ SARS-CoV-2 Detection Kit* is a molecular test based on reverse transcription-polymerase chain reaction (RT-PCR) in combination with π Code technology and the IntelliPlex 1000 π Code Processor and PlexBio 100 Fluorescent Analyzer with DeXipher software, and is intended for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal (NP), oropharyngeal (OP), anterior nasal and mid-turbinate nasal swabs, nasopharyngeal wash/aspirate or nasal aspirates, and bronchoalveolar lavage (BAL) specimens from individuals who are 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 complexity tests.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in respiratory 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 definite cause of disease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

The *IntelliPlex™ SARS-CoV-2 Detection Kit* is intended for use by qualified laboratory personnel specifically instructed and trained in the techniques of PCR, PlexBio's instrument platform, and in vitro diagnostic procedures. The IntelliPlex SARS-CoV-2 Detection Kit is only for use under the Food and Drug Administration's Emergency Use Authorization.

2. SUMMARY AND EXPLANATION

An outbreak of pneumonia of unknown etiology in Wuhan City, Hubei Province, China was initially reported to WHO on December 31, 2019. Chinese authorities identified a novel coronavirus (SARS-CoV-2), which has resulted in thousands of confirmed human infections in many countries including the United States. Cases of

asymptomatic infection, mild illness, severe illness, and some deaths have been reported.

The *IntelliPlex™ SARS-CoV-2 Detection Kit* is a molecular *in vitro* diagnostic test that aids in the detection of SARS-CoV-2 and is based on widely used nucleic acid amplification technology. The product contains oligonucleotide primers, labeled oligonucleotide probes, and control material used for the *in vitro* qualitative detection of SARS-CoV-2 RNA in respiratory specimens.

3. PRINCIPLES AND PROCEDURE

Coronaviruses are a large family of viruses that may cause illness in animals or humans. In humans, several coronaviruses are known to cause respiratory infections ranging from the common cold to more severe diseases such as Severe Acute Respiratory Syndrome (SARS) and Coronavirus Disease 2019 (COVID-19). The COVID-19 is the infectious disease caused by the most recently discovered coronavirus, SARS-CoV-2. This new virus and disease were unknown before the outbreak began in December 2019. In a few months' time, COVID-19 has become a global pandemic, resulting in over four million cases world-wide. SARS-CoV-2 is the single-stranded RNA virus. Detection of SARS-CoV-2 nasopharyngeal (NP), oropharyngeal (OP), anterior nasal and mid-turbinate nasal swabs, nasopharyngeal wash/aspirate or nasal aspirates, and bronchoalveolar lavage specimens are feasible due to the optimal primer and probe design in combination with π Code MicroDisc technology.

The assay includes primers/probe sets designed to detect SARS-CoV-2 specific target sequences including regions within the RdRP, E, and N genes.

π Code MicroDisc

π Code MicroDiscs are manufactured to generate more than 85,000 distinct circular image patterns for multiplexing applications. Each π Code has a distinct circular image pattern, which corresponds to a specific capture agent conjugated to the surface of the disc. π Code tagged with different capture agents are pooled, enabling specific detection of multiple analytes in one-well reaction.

Detection Principle

The procedure is based on the following processes:

- I. Viral RNA purified from acceptable respiratory specimens using the QIAamp Viral RNA Mini Kit.
- II. RT-PCR amplification of viral RNA.

- III. Hybridization of PCR amplicons with virus-specific probes conjugated to π Code MicroDiscs in a single well reaction.
- IV. Incubation with SA-PE (Streptavidin-phycoerythrin) for fluorescent labeling.
- V. Image pattern decoding and fluorescent signal detection by the PlexBio™ 100 Fluorescent Analyzer.

4. MATERIALS PROVIDED

The *IntelliPlex™ SARS-CoV-2 Detection Kit* contains sufficient reagents for 96 tests. The kit components supplied are listed as follows.

- 1) **SARS-CoV-2 KIT Primer Mix**
Ref. No.: 20559-U
Quantity & Volume: 1 vial, 384 μ L
Description: For RT-PCR amplification
Contents: ~4 μ M Primer (including biotin-labeled primers)
- 2) **SARS-CoV-2 KIT RT-PCR Buffer**
Ref. No.: 20561-U
Quantity & Volume: 2 vials, 1 mL/vial
Storage: Store at -15°C to -25°C upon arrival
Description: For RT-PCR amplification
Contents: 6 mM MgSO₄, 0.4 mM of each dNTP in buffered solution
- 3) **SARS-CoV-2 KIT RT-PCR Enzyme Mix**
Ref. No.: 20560-U
Quantity & Volume: 1 vial, 96 μ L
Storage: Store at -15°C to -25°C upon arrival
Description: For RT-PCR amplification
Contents: RT/Hot-Start Taq Mix (0.1 to 0.5 Units/ μ L): Moloney Murine Leukemia Virus (M-MLV) Reverse Transcriptase and HotStart Taq DNA Polymerase, RNase Inhibitor
- 4) **SARS-CoV-2 KIT π Code MicroDisc**
Ref. No.: 20562-U
Quantity & Volume: 2 vials, 1 mL/vial
Description: For RT-PCR amplicon capture
Contents: π Code MicroDiscs (8-plex including RdRP, E, N, MS2, GUSB, Blank, SA-PE, Lot ID), Glycerol, Phosphate buffered saline, 0.1% Albumin-from bovine (Biological), <0.1% EDTA and <0.1% Sodium azide
- 5) **SARS-CoV-2 KIT POS (Positive) Control**
Ref. No.: 20563-U
Quantity & Volume: 3 vials, lyophilized
Description: Assay positive control; reconstituted

20 µL ddH₂O per vial prior to use. Single use only.
Contents: RNA representing SARS-CoV-2 E, N and RdRP gene mixed with human total RNA; preserved in RNA stable.

6) SA-PE Solution

Ref. No.: 20320-U

Quantity & Volume: 1 bottle, 10 mL/bottle

Description: Streptavidin-phycoerythrin for fluorescent signal acquisition

Contents: Phosphate buffered saline, 0.5% Streptavidin-phycoerythrin, 1% Albumin- from bovine (Biological), <0.1% Sodium azide

7) Hy Buffer

Ref. No.: 20565-U

Quantity & Volume: 1 bottle, 9.6 mL/bottle

Description: For assay hybridization

Contents: Saline-Sodium Phosphate-EDTA, <0.1% Sodium Azide as preservative

8) 10X Wash Buffer

Ref. No.: 20546-U

Quantity & Volume: 2 bottles, 50 mL/bottle

Description: For πCode washing

Contents: Phosphate buffered saline, 1% Tween-20, and <0.1% Sodium azide

9) NEG (Negative) Control

Ref. No.: 20549-U

Quantity & Volume: 1 vial, 500 µL

Description: Assay negative control

Contents: Nuclease-free water

10) SARS-CoV-2 KIT Extraction Control

Ref. No.: 20564-U

Quantity & Volume: 1 vial, 1 mL

Description: Assay external control

Contents: MS2 bacteriophage with RNA sequence serving as extraction control

11) ddH₂O

Ref. No.: 20548-U

Quantity & Volume: 1 vial, 1.5 mL/vial

Description: For reconstitution of SARS-CoV-2 KIT POS Control

Contents: Nuclease-free water

NOTE: POS Control, NEG Control and Hy Buffer refer to positive control, negative control and hybridization buffer, respectively.

The kit contains sufficient reagents for 3 independent test runs (including POS and NEG controls) and for a maximum of 96 tests.

REQUIRED BUT NOT PROVIDED

Required products for compatibility with IntelliPlex kits:

- 96-well plate (PlexBio; Cat. No. 80025 or Greiner Bio-one; Cat. No. 655101)
- IntelliPlex™ 1000 πCode Processor (PlexBio; Cat. No. 80033)
- PlexBio 100 Fluorescent Analyzer (PlexBio; Cat. No. 80000)
- IntelliPlex™ Calibration Kit (PlexBio; Cat. No. 80035)
- U Tray (PlexBio; Cat. No. 80023)
- V Tray (PlexBio; Cat. No. 80024)
- DeXipher™ MD (PlexBio; Cat. No. 80051)
 - Lot ID, Completeness πCode MicroDiscs

Required components:

- QIAamp Viral RNA Mini Kit (Qiagen, Cat. No. 52904/ 52906)
- Clean tubes for PCR reaction (Gunster; Cat. No. MB-P08A or equivalent)
- Disposable gloves, powder-less
- Dedicated micropipette*
- Filter tips for micropipette*
- ddH₂O for dilution of 10X Wash Buffer
- Vortex mixer
- Micro-centrifuge
- Eppendorf® PCR Cooler or comparable (Recommended)
- Thermocycler: MiniAmp Thermal cycler (Thermo Fisher; Cat. No. A37834)
- Industrial Computer (Recommended: PlexBio; Cat. No. 80002)

* Use dedicated pipettes for sample purification, sample preparation, and sample hybridization. Do not share equipment between procedures. Pipettes should be accurate within 3% of the stated volume. Aerosol barrier or positive displacement DNA- and RNase-free tips must be used

6. WARNINGS AND PRECAUTIONS

- Federal Law restricts this device to sale by or on the order of a licensed practitioner.
- For emergency use only.
- For *in vitro* diagnostic use only (IVD).
- For Prescription Use Only (Rx).
- This test has not been FDA cleared or approved; the test has been authorized by FDA under an Emergency Use Authorization (EUA) for use by laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

5. MATERIALS AND EQUIPMENT

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For In-Vitro Diagnostic Use/For Use Under an Emergency Use Authorization (EUA) Only/For Rx Use Only

- This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
 - This test 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 Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.
 - Positive results are indicative of the presence of SARS-CoV-2 RNA.
 - Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.
 - Follow standard precautions. All patient specimens and positive controls should be considered potentially infectious and handled accordingly.
 - Do not eat, drink, smoke, apply cosmetics or handle contact lenses in areas where reagents and human specimens are handled.
 - Handle all specimens as if infectious using safe laboratory procedures. Refer to Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with 2019-nCoV <https://www.cdc.gov/coronavirus/2019-nCoV/lab-biosafety-guidelines.html>. Dispose of hazardous or biologically contaminated materials according to the practices of your institution.
 - Please read the package insert carefully prior to operation. The *IntelliPlex™ SARS-CoV-2 Detection Kit* is only for emergency use with a prescription, as an *in vitro* diagnostic test. Each step of operation, from specimen collection, storage and transportation, and laboratory testing, should be strictly conducted in line with relevant biosafety regulations and molecular laboratory management.
 - False positive and false negative results can be caused by poor specimen quality, improper sample collection, improper transportation, improper laboratory processing, or a limitation of the testing technology. The operator should understand the principles of the procedures, including its performance limitations, in advance of operation to avoid potential mistakes.
 - Separate, dedicated rooms and equipment for pre- and post-PCR process with a unidirectional workflow to avoid any contaminations is required.
 - All pre-PCR steps should be carried out in the laminar flow hood to further reduce contamination risk.
 - Do not use a kit or reagent past its expiration date.
- Sample preparation, RT-PCR reaction set up and PCR product analysis should be performed according to approved guidelines such as those published by Clinical And Laboratory Standards Institute; clean all equipment and surface areas regularly (e.g., The workspace including racks and pipettes should be thoroughly cleaned and wiped with 0.5% sodium hypochlorite solution followed by wiping with a 70% ethanol solution).
 - Component reagents have been diluted optimally. Further dilution of the component reagents is not recommended.
 - All chemicals, biological materials and human origin samples should be considered as potentially hazardous and/or infectious and should be treated accordingly.
 - Some reagent contains EDTA and/or Sodium Azide in highly diluted concentration. Follow Good Laboratory Practices and Universal Precautions guidelines to avoid any risk.
 - Store assay kits and reagents according to the product label and instructions.
 - Do not mix reagents from different lots.
 - Dispose of unused reagents, specimens, and waste according to applicable central/federal, state, and local regulations.
 - Wear powderless gloves and do not touch and make any markings on the bottom of the plate at any time, as fingerprints and markings would interfere with decoding and signal acquisition. Do not mark the top of the plate.
 - General laboratory precautions should be taken:
 - Do not pipette by mouth.
 - Wear protective clothing (e.g., disposable powderless gloves and laboratory coats) and eye protection.
 - Do not eat, drink or smoke in the laboratory.
 - Wash hands thoroughly after handling samples and reagents.
 - Avoid RNase contamination:
 - Create an RNase-free working environment.
 - Wear gloves during all steps of the procedure.
 - Change gloves frequently.
 - Use only certified RNase-free sterile, disposable polypropylene tubes and filter strips.
 - Keep tubes closed whenever possible during the preparation.
 - Use RNase removing product to clean bench surfaces, pipettes and other components used in the experiment.
 - Material Safety Data Sheets (SDS) are available upon request from PlexBio Customer Service.

7. REAGENT STORAGE, HANDLING AND STABILITY

Storage

The RT-PCR Buffer and RT-PCR Enzyme Mix of the *IntelliPlex™ SARS-CoV-2 Detection Kit* should be stored at -15°C to -25°C separately upon arrival.

Other kit components of the *IntelliPlex™ SARS-CoV-2 Detection Kit* should be stored at 2°C to 8°C. Once opened, the reagent components are stable for 6 months or until the expiration date, whichever comes first.

Stability

Do not use the *IntelliPlex™ SARS-CoV-2 Detection Kit* when it is expired. All components are guaranteed up to the expiration date on the label if handled and stored under the recommended conditions.

Transportation

The shipping temperature for the *IntelliPlex™ SARS-CoV-2 Detection Kit* is at 2-8°C. If the kit package or components are incomplete, please contact PlexBio customer service (service@plexbio.com).

8. QUALITY CONTROL

The *IntelliPlex™ SARS-CoV-2 Detection Kit* contains a series of internal control πCode MicroDiscs that monitor the specimen preparation, RT-PCR amplification, SA-PE incubation procedure, and background noise. These controls must always meet specifications and should have approximately the same intensity in each test well in the same test run. Otherwise, the test is invalid. The external controls (positive control and negative control) monitor the whole testing procedure to prevent false-positive or false-negative results. The test is considered invalid if any of the controls fail to meet the specified value.

| Controls | | Monitored Condition |
|----------------------------|--------------------------------|---|
| Assay Performance Controls | Positive Control | RT-PCR amplification and all downstream procedures |
| | Negative Control | (Extraction contamination control), Non-specific amplification, cross-contamination |
| Sample Specific Controls | Reference Gene Control (GUSB)* | Specimen quality, RNA extraction, and all downstream procedures |
| | Extraction Control (MS2) | RNA extraction, RT-PCR amplification, and all downstream procedures |

| Controls | Monitored Condition |
|----------------------------------|--|
| Blank πCode MicroDiscs | Hybridization and washing conditions; fluorescence background |
| SA-PE πCode MicroDiscs | Fluorescence labeling with SA-PE |
| Lot ID πCode MicroDiscs | Lot expiration date |
| Completeness of πCode MicroDiscs | Eight πCode MicroDisc types (with five or more MicroDiscs each) must be detected |

*GUSB - Human glucuronidase Beta [GUSB] gene mRNA

9. INSTRUMENT AND SOFTWARE

Instrument

Refer to the instrument user manual for complete operation instructions (Thermo Fisher MiniAmp Thermal cycler, IntelliPlex 1000 πCode Processor and PlexBio 100 Fluorescent Analyzer).

Software Installation

The *IntelliPlex™ SARS-CoV-2 Detection Kit* has a designated Kit App and ENC file. The Kit App contains the πCode target assignments and the ENC file includes the lot number and expiration date. Please make sure you have the Kit App installed and the ENC file imported into DeXipher before your first assay run.

Kit App Installation

1. Log into www.plexbio.com and download the *IntelliPlex™ SARS-CoV-2 Detection Kit* App.
2. Click on the “Installer” in the APP folder and follow the instructions to complete the Kit App installation.

NOTE:

The Kit App only needs to be installed once. Version updates will be notified by customer service.

ENC File Installation

1. Log into www.plexbio.com and download the *IntelliPlex™ SARS-CoV-2 Detection Kit* ENC file. Each kit lot number will have a unique ENC file, so you will need to download a new ENC file each time you purchase a kit with a different lot number. Make sure to select the ENC file with the lot number that corresponds to your kit.
2. Save the ENC file to your computer.
3. Follow the PlexBio 100 Fluorescent Analyzer User Manual to import the ENC file.

10. SPECIMENS

This kit is intended to be used with nasopharyngeal (NP), oropharyngeal (OP), anterior nasal and mid-turbinate nasal swabs, nasopharyngeal wash/aspirate or nasal aspirates, and bronchoalveolar lavage specimens. Specimen collection, shipping and handling must follow the published guidelines from the Center of Disease Control and Prevention (CDC):

<https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html>

Specimen Collection

Follow specimen collection devices manufacturer instructions for proper collection methods.

Swab: Only synthetic fiber swabs with plastic shafts should be used. Do not use calcium alginate swabs or swabs with wooden shafts (inactivate some viruses and inhibit PCR testing). Place swabs immediately into sterile tubes containing 2-3 ml of viral transport media.

Wash/Aspirate: Use 1 mL-1.5 mL of non-bacteriostatic saline (pH 7.0). Place specimen in a sterile viral transport media tube.

BAL: Samples should be collected into a sterile, leakproof collection cup or dry container without preservative matrix.

Specimen Transport

Suspected and confirmed SARS-CoV-2 patient specimens, cultures, or isolates must be packed and shipped according to UN 3373 Biological Substance, Category B, and in accordance with the current edition of the International Air Transport Association (IATA) Dangerous Goods Regulations. Personnel must be trained to pack and ship according to the regulations and in a manner that corresponds to their function-specific responsibilities.

Store specimens at 2-8°C and ship overnight on ice pack. If a specimen is frozen at -70°C or lower, ship overnight on dry ice.

Specimen Storage

If samples cannot be processed immediately upon receipt in the laboratory, specimens can be stored at 2-8°C for up to 72 hours after collection. If longer storage is expected due to a delay in processing or shipping, store specimens at -70°C or lower.

Purification and Storage of Extracted RNA

Before extraction, add 10 µL SARS-CoV-2 KIT Extraction Control to each specimen.

Samples are purified by using QIAamp Viral RNA Mini Kit according to manufacturer's instruction. The minimum specimen volume needed for purification processing is 140 µL, eluted in 50 µL buffer.

The NEG Control is included in the extraction process to monitor for contamination and is carried throughout the complete workflow including RT-PCR. A volume of 140 µL NEG Control is required for purification using QIAamp Viral RNA Mini Kit. **Extraction Control (MS2) must not be added to the NEG Control.** Elute in 50 µL buffer.

Extracted RNA can be stored at 2°C to 8°C for up to 4 hours, or at -15°C to -25°C for up to 7 days. Long term storage is not recommended.

11. ASSAY PROCEDURE

Warning: *Read the instructions carefully and follow every step of the assay protocol correctly.*

Important Handling Instructions:

Separate, dedicated areas and equipment for sample purification, sample preparation and sample hybridization must be used. Equipment (including lab coats) must not be shared between areas. All equipment and surface areas should be cleaned before and after each run (e.g., using a 0.5 – 1 % Sodium hypochlorite solution). All work should be performed according to approved guidelines such as those published by Clinical and Laboratory Standards Institute.

11.1 RT-PCR Amplification

1. If stored below -20°C, thaw purified samples on ice (4°C).
2. Label RT-PCR tubes with unique numbers/names assigned. Include one tube for Positive Control and one tube for Negative Control.
Positive Control must be reconstituted with 20 µL ddH₂O before use. Positive Control vials are single use only. Discard of unused leftovers.
3. Prepare the PCR reaction.

For each PCR reaction:

| | |
|----------------------------------|-------|
| SARS-CoV-2 KIT RT-PCR Enzyme Mix | 1 µL |
| SARS-CoV-2 KIT RT-PCR Buffer | 20 µL |
| SARS-CoV-2 KIT Primer Mix | 4 µL |
| Sample/PC/NC | 15 µL |
| Total volume | 40 µL |

NOTE:

- The amount of RT-PCR reaction mix and primer mix required for a Master Mix depends on the number of reactions. Always prepare a surplus.
 - Both POS Control and NEG Control are required for test validity and report generation and must be included in each assay run.
4. Mix by tapping the tubes and spin down before placing the tubes on the thermocycler. Set up the PCR program conditions as shown below:

| Step | Temp. | Time | Cycles |
|----------------------|-------|--------|--------|
| RT | 55°C | 15 min | 1 |
| Initial Denaturation | 95°C | 2 min | 1 |
| Denaturation | 95°C | 15 sec | 36 |
| Annealing/extension | 60°C | 30 sec | |
| | 4°C | ∞ | 1 |

NOTE: Ramp rate: 3 °C/sec (ABI MiniAmp)

11.2 DNA Hybridization and SA-PE Reaction

- 1) **Prepare 1X Wash Buffer:** Transfer 50mL of the 10X Wash Buffer to the IntelliPlex 1000 πCode Processor 1L Wash Buffer bottle and add 450 ml ddH₂O. Mix by swirling.

NOTE: The prepared 1X Wash Buffer can be used for up to one week.

IntelliPlex 1000 πCode Processor Wash Buffer consumption:

| Procedure | Wash Buffer Consumption (mL) |
|--|------------------------------|
| Self-test | 50 |
| DNA/RNA program (1 lane, up to 8 tests) | 150 |
| DNA/RNA program (12 lanes, up to 96 tests) | 535 |

- 2) **Add 20 μL πCode MicroDisc to 96-well plate:** Mix by vortexing the **SARS-CoV-2 KIT πCode** for 10 seconds, then add 20 μL of the πCode to each well directly. Vortex the tube of πCode every four wells in between dispensing to ensure homogeneous suspension.

NOTE: Each amplified PCR product (including samples, POS and NEG control) should be added into wells respectively in order of A1, B1...H1 and

followed by A2, B2...H2 and so on.

- Dispense 100 μL of Hy Buffer** to each well.
 - Spin down the RT-PCR products.
 - Denature the RT-PCR products** on the thermocycler by heating at 95°C for 7 minutes followed by immediate cooling at 4°C (Ramp rate: 100%) immediately.
- NOTE:** Pay attention to the lid temperature of thermocycler while taking out the denatured PCR products.
- Spin down the RT-PCR products and keep PCR products on ice (4°C; e.g., in Thermocycler or use Eppendorf® PCR Cooler or comparable). Use immediately (within 1 hour after denaturation).
 - Add 20 μL of each freshly denatured sample** to corresponding well of 96-well plate (containing Hybridization buffer and πCode MicroDisc).
 - Add 20 μL freshly denatured Positive Control** sample to corresponding well.
 - Add 20 μL freshly denatured Negative Control** sample to corresponding well.
 - Pipet the required volume of SA-PE solution** into the SA-PE solution tank (V Tray).

Required SA-PE Solution by Lane(s):

| Number of Processed Lane(s) | Required SA-PE Solution (μL) |
|-----------------------------|------------------------------|
| 1 | 900 |
| 2 | 1300 |
| 3 | 1700 |
| 4 | 2100 |
| 5 | 2500 |
| 6 | 2900 |
| 7 | 3600 |
| 8 | 4000 |
| 9 | 4400 |
| 10 | 4800 |
| 11 | 5200 |
| 12 | 5600 |

- 11) **Run hybridization and wash:** This assay uses the **DNA/RNA program** in the **Molecular Assay** window of the IntelliPlex 1000 πCode Processor. Refer to the IntelliPlex 1000 πCode Processor

operation manual and follow the instructions to run the built-in assay program (Homepage/ Molecular Assay/ Well Selection/ DNA/RNA/ Confirm procedure conditions / Start Running). The plate will be ready for decoding once the program finished (~60 minutes).

NOTE:

- SA-PE solution should be kept in the dark.
- **Do not** reuse the leftover SA-PE solution and V Tray. Replace a new V Tray with every assay run.
- **Do not** open the door when the instrument is in operation.
- The kit contains sufficient reagents for 3 independent test runs (including POS and NEG controls) and for a maximum of 96 tests. Please note that the included Wash Buffer is only sufficient for up to three independent runs. Additional Wash buffer can be ordered from PlexBio (Ref. No: 80210).

11.3 Image Decoding and Fluorescent Detection

1. Follow the PlexBio 100 Fluorescent Analyzer User Manual to set up the analysis.

NOTE:

- PlexBio 100 Fluorescent Analyzer must be calibrated regularly (once per month) using the IntelliPlex™ Calibration Kit .
- Check that the correct ENC file has been imported.

2. Launch DeXipher to run the qualitative assay.
3. Mark the wells for sample, positive and negative controls.
4. Enter sample information and assay name. Place the plate into the device with the correct orientation as shown on the screen.
5. The raw data will be analyzed through the kit ENC to generate the genotype call report.

NOTE:

- A single run can include from 2 to 96 tests (including POS and NEG controls) per 96 microwell plate.

| Step (for 94 specimens) | Time requirements | Description |
|-------------------------|-------------------|--|
| Sample Extraction | 60 minutes | QIAamp Viral RNA Mini Kit |
| Setup/ Run RT-PCR | 90 minutes | MiniAmp Thermal cycler |
| Hybridization/ SAPE | 60 minutes | IntelliPlexTM 1000 πCode Processor |
| Analyzing Results | 60 minutes | PlexBio 100 Fluorescent Analyzer + DeXipher software |

12. INTERPRETATION OF RESULTS

The DeXipher software will analyze specimen samples only if the external controls (Positive Control and Negative Control) and internal controls (Reference Gene Control, Blank and SAPE Monitor Control) are all shown as “Pass”. Failed Positive or Negative Control renders the whole assay invalid. Failed Reference Gene Control, Blank or SAPE Monitor Control renders the affected sample invalid.

Please also refer to the chapter “Disclaimer and Limitations” and “Troubleshooting” for additional information.

The RdRP, E, and N targets are all specific to SARS-CoV-2. Detection of any one, two, or three targets is considered a valid positive result. Only qualitative results of SARS-CoV-2 Detected/Not Detected is shown on the test report.

Result Interpretation

| Reported Result | Interpretation | Action |
|--------------------|---|---|
| “Detected” | SARS-CoV-2 positive | Report results to health care provider and appropriate public health authorities |
| “Not Detected” | SARS-CoV-2 negative | |
| No result reported | Assay was not valid due to external or internal control failure | Troubleshoot to address the control issue or contact PlexBio customer service team; retest or obtain new specimen as necessary. |

13. DISCLAIMERS AND LIMITATIONS

- The use of this assay as an *in vitro* diagnostic under FDA Emergency Use Authorization (EUA) is limited to laboratories that are certified under the Clinical Laboratory Improvement Amendments of 1988

- (CLIA), 42 U.S.C. § 263a, that meet requirements to perform high complexity tests.
- The performance of this test was evaluated using the procedures provided in this product insert. Alteration from the procedure may affect test performance.
 - The performance of *IntelliPlex™ SARS-CoV-2 Detection Kit* was established using nasopharyngeal swab samples. Anterior nasal, oropharyngeal and mid-turbinate nasal swabs, nasopharyngeal wash/aspirate or nasal aspirates, and bronchoalveolar lavage are also considered acceptable specimen types for use with the *IntelliPlex™ SARS-CoV-2 Detection Kit* but performance has not been established.
 - A negative test result means the *IntelliPlex™ SARS-CoV-2 Detection Kit* was unable to detect the virus in the sample. It does not preclude the possibility that the specimen did in fact contain the virus. Only samples with detectable amounts of the virus matching the reference sequences are detected; false negative test results may be due to experimental errors or other causes. Interpretation of the results should consider these possibilities.
 - A positive test result means that the *IntelliPlex™ SARS-CoV-2 Detection Kit* was able to determine SARS-CoV-2 in the sample. False positive test results may be caused by experimental errors or other causes. Interpretation of the results should consider these possibilities.
 - Based on the *in silico* analysis, SARS-CoV and other SARS-like coronaviruses in the same subgenus (Sarbecovirus) as SARS-CoV may cross react with the RdRP, E, and N primer/probe sets of the *IntelliPlex™ SARS-CoV-2 Detection Kit*. SARS-CoV is not known to be currently circulating in the human population, therefore it is highly unlikely to be present in patient specimens.
 - Laboratories are required to report all positive results to the appropriate public health authorities.

14. CONDITIONS OF AUTHORIZATION FOR THE LABORATORY

The *IntelliPlex™ SARS-CoV-2 Detection Kit* 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/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>. However, to assist clinical laboratories using the *IntelliPlex™ SARS-CoV-2 Detection Kit*, the relevant Conditions of

Authorization are listed below:

- A. Authorized laboratories¹ using *IntelliPlex™ SARS-CoV-2 Detection Kit* will 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 *IntelliPlex™ SARS-CoV-2 Detection Kit* will use your product as outlined in the authorized labeling. Deviations from the authorized procedures, such as the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use *IntelliPlex™ SARS-CoV-2 Detection Kit* are not permitted.
- C. Authorized laboratories that receive *IntelliPlex™ SARS-CoV-2 Detection Kit* will notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- D. Authorized laboratories using *IntelliPlex™ SARS-CoV-2 Detection Kit* will have a process in place for reporting test results to healthcare providers and relevant public health authorities.
- E. Authorized laboratories will collect information on the performance of *IntelliPlex™ SARS-CoV-2 Detection Kit* and report to DMD/OHT-OIR/OPEQ/CDRH (via email: CDRH-EUAREporting@fda.hhs.gov) and PlexBio Co. Ltd. (Adverse event reporting: <https://www.plexbio.com/intelliplex%20sars-cov-2-detection-kit>) if they become aware of any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product .
- F. All laboratory personnel using *IntelliPlex™ SARS-CoV-2 Detection Kit* must be appropriately trained in molecular techniques and use appropriate laboratory and personal protective equipment when handling this kit and use *IntelliPlex™ SARS-CoV-2 Detection Kit* in accordance with the authorized labeling.
- G. PlexBio Co. Ltd., authorized distributors, and authorized laboratories using *IntelliPlex™ SARS-CoV-2 Detection Kit* will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will 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 complexity tests” as “authorized laboratories.”

15. ANALYTICAL PERFORMANCE

Limit of Detection (Analytical Sensitivity)

Limit of detection (LoD) was determined as the lowest concentration of SARS-CoV-2 that can be detected at a ≥95% positive rate with the *IntelliPlex™ SARS-CoV-2 Detection Kit*. Samples were prepared by spiking target RNA (i.e., produced by transfecting HEK-293 cells with plasmids expressing either the N, E or RdRP mRNA of SARS-CoV-2) at different concentration into confirmed negative nasopharyngeal (NP) swabs in viral transport media (VTM). A dilution series ranging from 420 copies/mL – 70 copies/mL with six replicates per concentration were tested to determine the preliminary LoD.

The final LoD concentration was confirmed by testing 20 contrived replicates using SARS-CoV-2 Reference Material (SeraCare; AccuPlex™ SARS-CoV-2 Reference Material Kit, Cat 0505-0126).

The LoD for the *IntelliPlex™ SARS-CoV-2 Detection Kit* is 140 copies/mL.

| Replicate | Median Fluorescence Intensity (MFI)* | | | Detection of SARS-CoV-2 |
|----------------------|--------------------------------------|-------|-------|-------------------------|
| | RdRP | E | N | |
| 140 copies/mL | | | | |
| 1 | 14013 | 9625 | 18421 | Positive |
| 2 | 9821 | 7770 | 6381 | Positive |
| 3 | 13945 | 3764 | 14112 | Positive |
| 4 | 11003 | 12579 | 13018 | Positive |
| 5 | 16604 | 5417 | 10074 | Positive |
| 6 | 15413 | 5978 | 12942 | Positive |
| 7 | 15436 | 9415 | 8534 | Positive |
| 8 | 15072 | 11946 | 19621 | Positive |
| 9 | 18751 | 6154 | 13692 | Positive |
| 10 | 12918 | 3859 | 11761 | Positive |
| 11 | 12087 | 12189 | 21597 | Positive |
| 12 | 8045 | 9852 | 15830 | Positive |
| 13 | 9613 | 7046 | 9708 | Positive |
| 14 | 10479 | 7491 | 7905 | Positive |
| 15 | 6427 | 8679 | 7054 | Positive |
| 16 | 6196 | 0 | 4463 | Positive |
| 17 | 15539 | 12060 | 15610 | Positive |
| 18 | 13324 | 13542 | 16762 | Positive |
| 19 | 7935 | 13807 | 16372 | Positive |
| 20 | 5048 | 12696 | 16204 | Positive |

| Replicate | Median Fluorescence Intensity (MFI)* | | | Detection of SARS-CoV-2 |
|----------------------|--------------------------------------|------|-------|-------------------------|
| | RdRP | E | N | |
| 140 copies/mL | | | | |
| Average MFI | 11883 | 8693 | 13003 | 20/20 (100%) |

*MFI – values after subtraction of the threshold

| Replicate | Median Fluorescence Intensity* | | | Detection of SARS-CoV-2 |
|---------------------|--------------------------------|------|-------|-------------------------|
| | RdRP | E | N | |
| 70 copies/mL | | | | |
| 1 | 493 | 0 | 0 | Positive |
| 2 | 0 | 0 | 0 | Negative |
| 3 | 0 | 2669 | 4301 | Positive |
| 4 | 0 | 0 | 11 | Positive |
| 5 | 0 | 0 | 0 | Negative |
| 6 | 0 | 0 | 0 | Negative |
| 7 | 3747 | 423 | 0 | Positive |
| 8 | 1535 | 307 | 0 | Positive |
| 9 | 0 | 0 | 3134 | Positive |
| 10 | 0 | 506 | 862 | Positive |
| 11 | 524 | 693 | 10146 | Positive |
| 12 | 1609 | 1440 | 0 | Positive |
| 13 | 947 | 6497 | 8184 | Positive |
| 14 | 0 | 0 | 0 | Negative |
| 15 | 1130 | 827 | 1874 | Positive |
| 16 | 0 | 1600 | 8950 | Positive |
| 17 | 0 | 658 | 0 | Positive |
| 18 | 4898 | 0 | 0 | Positive |
| 19 | 850 | 0 | 0 | Positive |
| 20 | 0 | 1012 | 2758 | Positive |
| Average MFI | 787 | 832 | 2011 | 16/20 (80%) |

*MFI – values after subtraction of the threshold

Inclusivity (Analytical Reactivity)

BLASTn analysis query alignments were performed with the SARS-CoV-2 E, N and RdRP oligonucleotide primer and probe sequences with full length or near-full-length (>29 kb) nucleic acid sequences for SARS-CoV-2 in NCBI’s Severe Acute Respiratory Syndrome Coronavirus 2 Data Hub (<https://www.ncbi.nlm.nih.gov/labs/virus/vssi/#/>). The analysis demonstrated the following:

- 1 mismatch in the “N F Primer” binding site (GenBank: MT246456, MT263410, MT291836 and MT293159)

- 2 mismatches in the “N R Primer” binding site (GenBank: MT263411),
- 3 mismatches in the “N R Primer” (GenBank: MT258379, MT259250, MT259263, MT246470, MT246451, MT233522)
- 1 mismatch in the “E probe” (GenBank: MT263433).

The primers and probe set targeting the RdRP had no mismatch against any of the published sequences.

Despite these mutations in SARS-CoV-2, the IntelliPlex assay is still expected to detect all SARS-CoV-2 strains. Because the assay detects 3 targets that are specific to SARS-CoV-2, even if new or not previously reported nucleotide mutations affect amplification/detection of one of the targets, the presence of the other two targets can still generate a valid positive result.

Cross Reactivity (Analytical Specificity)

Cross-reactivity of the *IntelliPlex™ SARS-CoV-2 Detection Kit* was evaluated by *in silico* analysis and by performing wet lab testing.

BLASTn analysis queries of the *IntelliPlex™ SARS-CoV-2 Detection Kit* primers and probes were performed against the sequences of the organisms listed in the table below.

The *in silico* analysis predicted that SARS-CoV and other SARS-like coronaviruses in the same subgenus (Sarbecovirus) as SARS-CoV may cross react with the RdRP, E, and N primer/probe sets of the IntelliPlex SARS-CoV-2 Detection Kit.

The RdRP F primer showed homology > 80% to human coronavirus HKU1 (90.9%) and OC43 (90.9%). The RdRP R primer showed homology > 80% to human coronavirus HKU1 (82.7%), OC43 (82.7%), NL63 (89.6%) and MERS coronavirus (82.7%). The RdRP probe showed homology >80% to HKU1 (81.2%), OC43 (81.2%) and MERS coronavirus (87.5%).

The reverse primer for the Reference Gene Control (GUSB R Primer) showed homology > 80% to *Pseudomonas aeruginosa* sequences, and the forward primer for SARS-CoV-2 E gene showed homology > 80% to *Pseudomonas aeruginosa* sequences. None of the other amplification primers showed homology > 80% to any of the sequences included in the analysis.

The RdRP probe sequence showed high homology (>80%) to off-target sequences. Specifically, the probe is 100% complementary to *Candida albicans* and shows homology >80% to *Mycoplasma pneumoniae*, *Staphylococcus epidermidis* and *Pseudomonas*

aeruginosa. In addition, the GUSB probe sequence showed high homology (>80%) to off-target sequences. The probe is >80% complementary to *Candida albicans* and *Pseudomonas aeruginosa*, and *Pneumocystis jirovecii*.

| High priority pathogens from the same genetic family | | |
|--|---------|--|
| Organism | Taxid | Notes |
| SARS coronavirus | 694009 | 100% homology to RdRP F Primer; 96.5% homology to RdRP R Primer; 93.8% homology to RdRP Probe; 100% homology to E F Primer; 100% homology to E R Primer; 83.3% homology to E Probe; 90.9% homology to N F Primer; 90.9% homology to N R Primer; 80% homology to N Probe; |
| Human coronavirus 229E | 11137 | No homology >80% |
| Human coronavirus OC43 | 31631 | 90.9% homology to RdRP F Primer; 82.7% homology to RdRP R Primer; 80.2% homology to RdRP Probe |
| Human coronavirus HKU1 | 290028 | 90.9% homology to RdRP F Primer; 82.7% homology to RdRP R Primer; 80.2% homology to RdRP Probe |
| Human coronavirus NL63 | 277944 | 89.6% homology to RdRP R Primer |
| MERS coronavirus | 1335626 | 82.7% homology to RdRP R Prime; 87.5% homology to RdRP Probe |

| High priority organisms likely in the circulating area | | |
|--|---------|------------------|
| Organism | Taxid | Notes |
| Adenovirus 4 | 28280 | No homology >80% |
| Adenovirus 7 | 10519 | No homology >80% |
| HMPV | 162145 | No homology >80% |
| Human parainfluenza 1 virus | 12730 | No homology >80% |
| Human parainfluenza 2 virus | 1979160 | No homology >80% |
| Human parainfluenza 3 virus | 11216 | No homology >80% |
| Human parainfluenza 4a virus | 11224 | No homology >80% |
| Human parainfluenza 4b | 11226 | No homology >80% |

| High priority organisms likely in the circulating area | | |
|--|--------|---|
| Organism | Taxid | Notes |
| virus | | |
| Human Influenza A Virus | 11320 | No homology >80% |
| Influenza B virus | 11520 | No homology >80% |
| Human enterovirus EV68 | 42789 | No homology >80% |
| Human respiratory syncytial virus | 11250 | No homology >80% |
| Rhinovirus | 12059 | No homology >80% |
| <i>Chlamydia pneumoniae</i> | 83558 | No homology >80% |
| <i>Haemophilus influenzae</i> | 727 | No homology >80% |
| <i>Legionella pneumophila</i> | 446 | No homology >80% |
| <i>Mycobacterium tuberculosis</i> complex | 77643 | 81.3% homology to MS2 probe |
| <i>Streptococcus pneumoniae</i> | 1313 | No homology >80% |
| <i>Streptococcus pyogenes</i> | 1314 | No homology >80% |
| <i>Bordetella pertussis</i> | 520 | No homology >80% |
| <i>Mycoplasma pneumoniae</i> | 2104 | 80% homology to RdRP probe |
| <i>Pneumocystis jirovecii</i> | 42068 | 81.3% homology to GUSB probe |
| <i>Candida albicans</i> | 5476 | 100% homology to RdRP probe; 93.8% homology to GUSB probe |
| <i>Pseudomonas aeruginosa</i> group | 136841 | 80% homology to RdRP probe; 81% homology to E F primer; 85% homology to GUSB R primer; 81.3% homology to GUSB probe |
| <i>Staphylococcus epidermidis</i> | 1282 | 93.8% homology to RdRP probe |

Cross-reactivity wet testing was performed to demonstrate that the *IntelliPlex™ SARS-CoV-2 Detection Kit* does not react with other organisms that are reasonably likely to be encountered in the clinical specimen. The study included the organisms listed below using the Zeptometrix NATtrol Respiratory Panel 2 (Catalog Number: NATRVP2-BIO), NATtrol BC/GM Panel (Catalog Number: NATBCGN-NNS), Zeptometrix: NATtrol BC/GP Panel and *C. albicans* strain from the Taiwan Bioresource Collection and Research Center (BCRC).

All organisms were tested in triplicate and at high pathogen concentrations (>10⁶ copies/ assay). None of the wet-tested organisms produced a positive signal for the *IntelliPlex™ SARS-CoV-2 Detection Kit*.

| Organism | Source | Results |
|-----------------------------------|----------------------------|---------------------|
| Human coronavirus 229E | Zeptometrix (NATRVP2-BIO) | No Cross Reactivity |
| Human coronavirus OC43 | Zeptometrix (NATRVP2-BIO) | No Cross Reactivity |
| Human coronavirus HKU1 | Zeptometrix (NATRVP2-BIO) | No Cross Reactivity |
| Human coronavirus NL63 | Zeptometrix (NATRVP2-BIO) | No Cross Reactivity |
| Human Metapneumovirus (hMPV) | Zeptometrix (NATRVP2-BIO) | No Cross Reactivity |
| Parainfluenza virus 1 | Zeptometrix (NATRVP2-BIO) | No Cross Reactivity |
| Parainfluenza virus 2 | Zeptometrix (NATRVP2-BIO) | No Cross Reactivity |
| Parainfluenza virus 3 | Zeptometrix (NATRVP2-BIO) | No Cross Reactivity |
| Parainfluenza virus 4 | Zeptometrix (NATRVP2-BIO) | No Cross Reactivity |
| Influenza A -H1 | Zeptometrix (NATRVP2-BIO) | No Cross Reactivity |
| Influenza A -H1 2009 | Zeptometrix (NATRVP2-BIO) | No Cross Reactivity |
| Influenza A -H3 | Zeptometrix (NATRVP2-BIO) | No Cross Reactivity |
| Influenza B | Zeptometrix (NATRVP2-BIO) | No Cross Reactivity |
| Respiratory syncytial virus | Zeptometrix (NATRVP2-BIO) | No Cross Reactivity |
| Rhinovirus | Zeptometrix (NATRVP2-BIO) | No Cross Reactivity |
| <i>Chlamydia pneumoniae</i> | Zeptometrix (NATRVP2-BIO) | No Cross Reactivity |
| <i>Streptococcus pyogenes</i> | Zeptometrix (NATRVP2-BIO) | No Cross Reactivity |
| <i>Bordetella pertussis</i> | Zeptometrix (NATRVP2-BIO) | No Cross Reactivity |
| <i>Pseudomonas aeruginosa</i> | Zeptometrix (NATBCGN-NNS) | No Cross Reactivity |
| <i>Staphylococcus epidermidis</i> | Zeptometrix (NATBC/GP-NNS) | No Cross Reactivity |
| <i>Mycoplasma pneumoniae</i> | Zeptometrix (NATRVP2-BIO) | No Cross Reactivity |
| <i>Candida albicans</i> | BCRC | No Cross Reactivity |

16. CLINICAL STUDY

The performance of the *IntelliPlex™ SARS-CoV-2 Detection Kit* was evaluated using contrived clinical nasopharyngeal (NP) swab specimens. Samples were prepared by spiking SARS-CoV-2 Reference Material (SeraCare; AccuPlex™ SARS-CoV-2 Reference Material Kit, Cat. No. 0505-0126) at different concentrations into individual, unique confirmed negative nasopharyngeal (NP) swab matrix. Negative NP swab samples were also tested. Samples were blinded and randomized for testing.

The results are shown below.

Performance Evaluation

| | | | |
|---|---------------------------|---------------------------|----------|
| Conc. RNA RdRP, E and N Gene | 2x LoD (280 copies/mL) | 1x LoD (140 copies/mL) | Negative |
| Number of NP Swabs | 10 | 20 | 30 |
| Detection Rate | 10/10 | 20/20 | 0/30 |
| Agreement with Expected Result (%) | 100 | 100 | 100 |

PlexBio obtained and tested 5 clinical positive nasopharyngeal swab samples that were previously evaluated using the EUA authorized Hologic Panther Fusion SARS-CoV-2 Assay. There was 100% concordance between the IntelliPlex SARS-CoV-2 Detection Kit and the Hologic EUA authorized assay. As a condition of authorization, PlexBio is conducting a clinical study in partnership with the US based company, DiaCarta, Inc. (Richmond, CA). The clinical study will include testing of at least 30 positive and 30 negative clinical specimens with both the DiaCarta assay (QuantiVirus SARS-CoV-2 Test Kit, FDA authorized) and the IntelliPlex SARS CoV-2 Detection Kit, to demonstrate the clinical performance of PlexBio's Kit. Once the data are available, PlexBio will submit to FDA for review and if data are acceptable, the labeling/IFU will be updated accordingly.

PlexBio customer service immediately for further assistance.

- Specimens may be retested using the previously extracted nucleic acid if stored according to requirements. In the event re-extraction of viral RNA is required, access the original, properly stored sample and repeat the full assay procedure. If the repeat testing still results in a failure, it is recommended to obtain a new patient specimen.
- In the event of a Positive Control failure, the sample may be re-tested using the previously extracted nucleic acid and stored according to requirements. In the event of a Negative Control failure due to contamination, it is recommended to re-extract the original properly stored sample and repeat the full assay procedure. If the Negative Control failed because of πCode MicroDiscs failure, retesting using residual extracted specimen RNA is accepted. If the Reference Gene Control or Extraction Control has failed, extract new nucleic acid before testing. If testing is affected by specimen quality, a new specimen is required. If a πCode MicroDiscs control failed, retesting using residual extracted specimen RNA is accepted.

| Problem | Possible Cause | Recommendations |
|-------------------------|--|---|
| No Valid Assay Assigned | 1. No plate inserted. 2. Plate inserted in wrong orientation. 3. No assay APP installed. 4. No ENC file imported. 5. Two or more lots of reagent used. | 1. Confirm plate is inserted and repeat reading. 2. Confirm orientation of plate and repeat reading. 3. Install assay APP and repeat reading. 4. Import ENC file and repeat reading. 5. One reagent lot used at a time. |

17. TROUBLESHOOTING

- The troubleshooting steps listed below address possible problem causes and solutions that could be experienced during the assay procedures. If the problem persists after completing the recommended steps in the table provided below, please contact

| Problem | Possible Cause | Recommendations | Problem | Possible Cause | Recommendations |
|--|---|--|------------------------------|---|---|
| Positive Control Fail | <p>1. No Positive Control added.</p> <p>2. RNase contamination.</p> <p>3. Assay did not work.</p> <p>4. Wrong PC well selected.</p> <p>5. “πCode MicroDiscs Combination”, “Blank Control”, “πCode MicroDiscs Count”, or “SAPE Monitor Control” failed</p> | <p>1. Ensure Controls are added. Ensure proper reconstitution of Positive Control as described. Repeat testing using residual extracted sample for RT-PCR.</p> <p>2. Ensure all operating procedures are followed correctly and work environment is free of RNase. Repeat testing using newly extracted sample.</p> <p>3. Make sure all the assay procedures are followed correctly. Ensure all components are stored at required storage conditions. Repeat testing using residual extracted sample for RT-PCR. If there is a general problem with assay performance, obtain new assay kit.</p> <p>4. Choose the correct PC well and repeat reading.</p> <p>5. See section below for more details. Repeat testing using residual extracted sample for RT-PCR.</p> | Negative Control Fail | <p>1. Cross-contamination between samples</p> <p>2. Wrong NC well selected.</p> <p>3. “πCode MicroDiscs Combination”, “Blank Control”, “Reference Gene Control”, “πCode MicroDiscs Count”, or “SAPE Monitor Control” failed</p> | <p>1. Clean all surfaces and equipment. Instruction in Package Insert on utilizing different rooms and unidirectional workflow must be followed. Repeat testing using newly extracted sample.</p> <p>2. Choose the correct NC well and repeat reading.</p> <p>3. See section below for more details. Repeat testing using residual extracted sample for RT-PCR.</p> |
| πCode MicroDiscs Combination Fail | <p>1. πCode MicroDiscs from a different assay/ lot are used.</p> <p>2. Missing π Code MicroDiscs due to wrong operation</p> | <p>1. Use πCode MicroDiscs provided with the <i>IntelliPlex™ SARS-CoV-2 Detection Kit</i> and ensure the lot-ENC is available.</p> <p>2. Refer to “πCode MicroDiscs Count Fail” below.</p> | | | |
| πCode MicroDiscs Count Fail | <p>1. πCode MicroDiscs are not properly dispersed in the well.</p> <p>2. Not enough πCode MicroDiscs added to well.</p> <p>3. Microbes exist in Wash buffers.</p> <p>4. Instruments error or malfunction.</p> | <p>1. Re-disperse the microplate using IntelliPlex 1000 Processor, and repeat reading.</p> <p>2. Ensure πCode MicroDiscs are well-mixed with proper amount added. Repeat using residual extracted sample for RT-PCR.</p> <p>3. Use freshly prepared wash buffer and ddH₂O for hybridization to reduce πCode MicroDiscs loss rate. Repeat using residual extracted sample for RT-PCR.</p> <p>4. Contact PlexBio Customer Service.</p> | | | |

| Problem | Possible Cause | Recommendations | Problem | Possible Cause | Recommendations |
|---------------------------|---|---|-----------------------------|---|---|
| SAPE Monitor Control Fail | 1. No SA-PE was added or insufficient SA-PE solution for dispensing. | 1. Make sure all the assay procedures are followed correctly. Calculate sufficient SA-PE solution volume for dispensing. Repeat testing using residual extracted sample for RT-PCR. | Extraction Control Fail | 1. The Extraction Control was not correctly added to the specimen | 1. Follow the instruction provided in the Package Insert. Repeat testing using newly extracted sample. |
| | 2. SA-PE solution deactivated. | 2. Ensure correct storage condition and minimize the light exposure. Do not use SA-PE past its expiration date. | | 2. Problem during nucleic acid purification/extraction. | 2. Follow the instruction provided by the manufacturer of the nucleic acid purification kit. Ensure all buffers are freshly prepared. Repeat testing using newly extracted sample. |
| | 3. Incorrect tested lanes of microplate selected for SA-PE solution dispensing. | 3. Repeat assay using residual extracted sample for RT-PCR and make sure lanes are selected correctly. | | | |
| Blank Control Fail | 1. Wrong hybridization conditions. | 1. Ensure correct hybridization program is selected. Repeat testing using residual extracted sample for RT-PCR. | Reference Gene Control Fail | 1. Poor specimen sample quality | 1. Specimen was not collected, transported, or stored according to requirements. |
| | 2. Residues of SA-PE solution in wells after hybridization. | 2. Ensure all buffers (Wash buffer and ddH ₂ O) on IntelliPlex 1000 Processor are fresh-made and sufficient for washing procedures. Repeat testing using residual extracted sample for RT-PCR. | | 2. RNA purification failed or PCR inhibitors existed. | 2. Follow instructions of sample extraction carefully. Ensure required temperature ranges and centrifugation needs are complied. Ensure complete removal of ethanol. Repeat testing using newly extracted sample. |
| | 3. PlexBio 100 Fluorescent Analyzer is not calibrated. | 3. Perform calibration on PlexBio 100 Fluorescent Analyzer. Repeat testing using residual extracted sample for RT-PCR. | | 3. PCR procedures are not performed correctly. | 3. Make sure all PCR procedures are followed correctly. Do not use expired materials or mixed lots of reagents. Ensure storage conditions are correct. Repeat testing with residual extracted sample for RT-PCR. |
| | 4. Markings on plates. | 4. Do not make any marking on the plate. Repeat testing using residual extracted sample for RT-PCR. | | 4. RNase contamination. | 4. Ensure all the operating procedures are followed correctly. Ensure work environment is free of RNase. Repeat testing using newly extracted sample. |
| | | | | 5. Hybridization did not work. | 5. Make sure all the assay procedures are followed correctly. Ensure samples are freshly heat-denatured. Repeat testing using residual extracted sample for RT-PCR. |

18. SYMBOLS

| Symbol | Explanation | Symbol | Explanation |
|--------|-----------------------------------|--------|------------------------------|
| | In-vitro diagnostic use | | Catalog number |
| | Batch number | | Consult instructions for use |
| | Manufacturer | | Use by Date |
| | Temperature limitation | | Caution |
| | Contains sufficient for <n> tests | | Date of Manufacture |

19. CONTACT INFORMATION AND PRODUCT SUPPORT

For technical and product support, contact:
service@plexbio.com

Service hotline:
+886-2627-5878
Office hour: 09:00-18:00 (GMT+8)

U.S. Technical and Product Support:
+1 415-310-6025

Product support website:
www.plexbio.com

Notice to User

The use of this product and the associated PlexBio instrumentation is covered by one or more issued (US10302640B2, US10436778B2, US10436776B2, US9063044B2, US10019815B2) and pending US and foreign patents owned by PlexBio Co., Ltd. The purchase of this product includes nontransferable rights to use this amount of the product to practice the methods described therein. No general patent or other license of any kind other than this specific right of use from purchase is granted. Further information on purchasing licenses for other applications can be obtained from PlexBio Co., Ltd. 6F-1, No. 351, Yangguang St., Neihu District, Taipei City 11491, Taiwan.

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PlexBio™ 100 Fluorescent Analyzer

User Manual

PlexBio Co., Ltd.



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A01-150 V05 (RUO)_US

For IVD Use ONLY, For Emergency Use Authorization ONLY

- This product has not been FDA cleared or approved; the product has been authorized by FDA for use with the IntelliPlex SARS-CoV-2 Detection Kit under an Emergency Use Authorization (EUA) for use by laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, 42 U.S.C. §263a, that meet requirements to perform high complexity tests.
- This test has been authorized only for use with IntelliPlex SARS-CoV-2 Detection Kit for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
- 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 Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Standard Terms and Conditions for the Use of Products

Contract

The terms and conditions herein (hereinafter referred to as the “Standard Terms”) apply to all of the products and services provided or will be provided by **PlexBio Co., Ltd.** (hereinafter referred to as “**PlexBio**”). Any changes to the Standard Terms shall have no binding effect on **PlexBio** unless the same has been agreed upon by an authorized representative of **PlexBio** in writing. The “Dealer” referred to herein represents **PlexBio** (if the products are purchased from **PlexBio** directly), or the distributor licensed by **PlexBio**. **PlexBio** expressly disagrees with any terms or conditions made by the buyer in the purchase order or any of such which is different from or not included in this Standard Terms.

The buyer's acceptance, unpacking, or use of the products or services shall constitute his/her acknowledgment and acceptance of the Standard Terms unconditionally. Once the buyer opens the packaging of PlexBio products or uses the products or services in any manner, the buyer acknowledges and accepts the Standard Terms unconditionally, and also agrees that the Standard Terms constitute the contract which has binding effect on the buyer under law. Where the buyer disagrees with the Standard Terms, he/she shall contact PlexBio immediately to return the products before using the products or services in any manner, and he/she shall not use the products or services in any manner. **PlexBio** has the right to amend the terms and conditions regarding specification and service without notifying the buyer in advance if no specification or service has been specified and identified in writing before.

Warranty

The warranty terms and conditions in this Standard Terms (the "Warranty") apply to any instruments, spare parts and services (collectively, the "Products") purchased by the buyer from **PlexBio** directly and situated in the territory of Taiwan. The Warranty excludes any activities other than calibration, certification and maintenance. **PlexBio** will not provide any Warranty toward the sale and use of the Products outside the territory of Taiwan. The Products distributed outside the territory of Taiwan will be sold "As is". **PlexBio** will provide the buyer with quality assurance toward the spare parts purchased from **PlexBio** and that are used to maintain **PlexBio** instruments under the same terms and conditions herein in any countries/territories other than Taiwan around the world.

Particularly, the Warranty provided herein excludes any products, software or hardware provided not by **PlexBio**. If the product is purchased from a **PlexBio**'s distributor, the Warranty shall be provided by the distributor to the buyer in writing directly.

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Products: Regardless of whether or not the buyer accepts said terms and conditions, for any Products purchased from **PlexBio** directly, **PlexBio** will ensure that the performance of all the Products meets the product specifications provided by **PlexBio** within 12 months from the delivery date on (hereinafter referred to as the quality assurance period). **PlexBio** is entitled to take one of the following actions against any defects found and reported during the quality assurance period: (1) payment refund, or (2) defect repairs or spare parts replacements. The expenses derived from said actions shall be borne by **PlexBio**.

Software: **PlexBio** ensures that all the installed software substantially meets the functions described in the software documentation provided by **PlexBio**. Notwithstanding, **PlexBio** does not guarantee that the software is error-free or may not be attacked by hackers or viruses. The quality assurance period of the software is identical with that of the **PlexBio** product in which the software is installed.

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General clauses: The Warranty and quality assurance provided are subject to the following limitations, including (1) the said quality assurance does not apply to consumable materials,

accessories, normal wear and tear, damageable parts and fragile parts; (2) when the buyer asks **PlexBio** to provide quality assurance work beyond normal working hours, **PlexBio** shall be entitled to charge the buyer additional expenses; (3) the said quality assurance does not apply to the following circumstances: accidents, modifications, unfair use, abuse, destruction, or disassembly without authorization, or if the buyer fails to keep or operate in the manner as required, and(or) do unauthorized maintenance, installation or service, and(or) incorporates or integrates any product without permission from **PlexBio** into the **PlexBio** Products, or integrates the **PlexBio** Products into the buyer's environment or products, and(or) uses other software or user interface provided by the buyer/vendor without **PlexBio**'s permission; (4) for the Products sold by **PlexBio** but produced by another manufacturer, the quality assurance provided by **PlexBio** is only valid in the residual period in which the manufacturer provides its quality assurance; (5) once any Products is maintained and repaired by **PlexBio**, the buyer acknowledges that the maintenance work will not extend the quality assurance period or derive any new quality assurance period. Other than the Warranties and quality assurance explicitly provided in writing in this Standard Terms, **PlexBio** does not provide any other warranties, including but not limited to the warranty toward fitness for a specific purpose, explicitly or implicitly. If the dealer determines, on the basis of its own judgment, that the buyer has misused the Products or failed to follow the instructions to use the Products, the warranty provided by the dealer toward the sale of the Products shall be invalid.

PlexBio shall not be liable for any direct or incidental damage caused by the use of or failure to use the Products, including but not limited to, the loss in the process of operation, shutdown, loss of revenue or profit, loss of the buyer's product or other products, in addition to the liability to be borne by the buyer to the supplier, or by the supplier due to such loss, and the labor or other expenses, damages or losses caused by such Products, including personal injury or loss of property, unless the personal injury or loss of property is caused by the PlexBio's willful conduct or gross negligence.

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For any Products situated outside the territories of Taiwan for which maintenance is required:

- (i) The buyer shall notify **PlexBio** in writing of the issue of the Products immediately and also provide the details about the issue verified.
- (ii) The buyer shall contact **PlexBio** or the service maintenance engineers trained and qualified by

- PlexBio** to evaluate the problems and verify the issues, and might need to bear the related expenses derived from the maintenance or transportation of the Products.
- (iii) The buyer shall return the Products at issue to **PlexBio** or the distributor as per **PlexBio**'s request. **PlexBio** might analyze the Products returned. Upon verifying that no defects exist, **PlexBio** will send the Products back to the buyer and the buyer shall bear the related expenses and freight. Notwithstanding, if **PlexBio** verifies that some issues exist, **PlexBio** will bear the freight. The buyer is not entitled to return the Products without **PlexBio**'s prior written consent.

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The use of this instrumentation and its associated software is covered by one or more pending US and foreign patents owned by PlexBio Co., Ltd. The purchase of this instrument and software includes nontransferable rights to use the instrument and software to practice the methods described therein. No general patent or other license of any kind other than this specific right of use from purchase is granted. For further information on purchasing licenses for other applications can be obtained from PlexBio Co., Ltd. 6F-1, No. 351, Yangguang St., Neihu District, Taipei City 11491, Taiwan.

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Chapter 1: Introduction

1.1 Instructions

Before using PlexBio™ 100 Fluorescent Analyzer, please read this manual carefully. It provides essential hardware and software information regarding of PlexBio™ 100 Fluorescent Analyzer, information such as follows:

- Safety information
- Symbols
- System overview
- Hardware installation
- DeXipher™ software overview
- Starting DeXipher™
- Troubleshooting
- Maintenance

1.2 Symbols and Regulatory Labels

There are important symbols throughout this manual with different meanings, including identification, conditions, and safety warnings.

| | | |
|---|---|---|
|  |  |  |
| General cautions and warnings | Caution: pinch point | Warning: Biohazard |
|  |  |  |
| Consult instructions for use | Manufacturer | Date of Manufacture |
|  |  |  |
| Batch code | Serial number | Federal Communications Commission (FCC) Mark |
|  |  |  |
| UL Mark | Waste Electrical and Electronic Equipment | For Research Use Only |

Table 1. List of labels



General cautions and warnings

This symbol indicates a need for caution, as incorrect handling through disregard of the sign may result in death, personal injury, or possible damage to property or equipment. Read and understand all warning and cautionary safety instructions below before proceeding with use or operation of this system.

- Inspect all components prior to use and immediately report any damage or defects observed to PlexBio Co., Ltd. or your local distributors.
- Contact PlexBio Co., Ltd. or your local distributors for scheduling installation and repairs of the system.
- PlexBio™ 100 Fluorescent Analyzer contains optical and electronics modules. Please handle with extreme care when moving or relocating system as mishandling can damage the system.

- Lift the unit from the base only. DO NOT lift by or put excessive force on the plastic case.
- DO NOT put excessive force on the stage or it may become tilted or bent. This will severely interfere with the performance of the system.
- To avoid electric shock or possible damage to the system:
 - ✧ DO NOT open or remove the covers on the analyzer or system peripherals.
 - ✧ Use only power cords supplied with the system or cords with grounded outlets properly rated for the system.
 - ✧ Ensure the power cord is connected to properly grounded AC outlets only.
 - ✧ Users should not perform any maintenance or cleaning of the electrical components in the system.
- If any malfunction happens, please turn off the power button and then disconnect the power cable.
- DO NOT look directly at the green LED light. The LED shutter is automatically on when users open the lid. If malfunction occurs, please contact PlexBio Co., Ltd. or your local distributors for servicing.



*** Caution: Pinch point**

Please do not put your hands under the sides of the lid when closing the lid.



***Warning: Biohazard**

Human and animal samples in the 96-well plate may contain biohazardous, infectious agents. To prevent spilling, please wear gloves and handle with extreme care when loading the plate onto the stage.



Figure 1. The position of warning labels



Waste Electrical and Electronic Equipment

Within the European Union, the Waste Electrical and Electronic Equipment Directive 2002/96/EC requires that you properly dispose of electrical and electronic equipment when it reaches the end of its lifecycle.

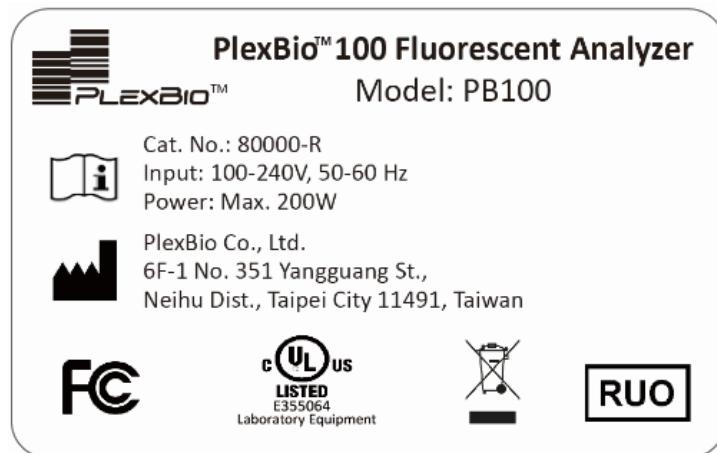


Figure 2. PlexBio™ 100 Fluorescent Analyzer label on the backside of the instrument

Chapter 2: PlexBio™ 100 Fluorescent Analyzer System Overview

2.1 Intended Use

PlexBio™ 100 Fluorescent Analyzer is a digital microscope system intended for fluorescence detection applications. It captures images from microscope and analyzes them to identify image patterns of πCode™ MicroDisc and fluorescence signals. This system combines a CCD camera, LED, and microscope. The system is composed of a fluorescence detection unit, an image-identification mechanism, an automation mechanism, a data-acquisition and -storage system, and software to process the resulting data.

2.2 πCode™ MicroDisc Technology

PlexBio's Precision Image Code (πCode™) MicroDiscs are manufactured by using a photo lithography fabrication process and able to generate over 16,000 distinct circular image codes for multiplexing applications. To be used in biological applications, each circular disc is encapsulated in a highly stable biocompatible polymer with an added paramagnetic property, which allows it to be suitable for bio-conjugation, washing, and automation applications.

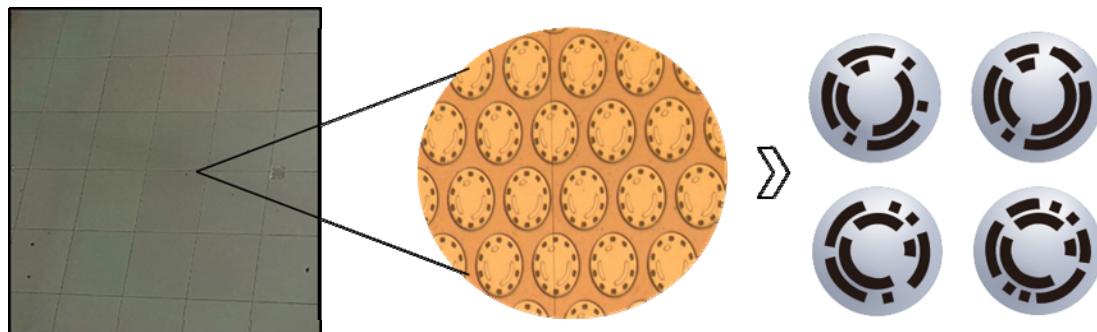


Figure 3. Photo lithography fabrication process of πCode™ MicroDisc

Each πCode™ MicroDisc has a distinct circular image pattern, which corresponds to the specific capture agents conjugated to the disc surface, thus allowing the capture and detection of specific analytes from a sample. Virtually any probe used in research diagnostics can be conjugated to πCode™ MicroDiscs, including DNA, RNA, antigens, antibodies, proteins, or chemical compounds.

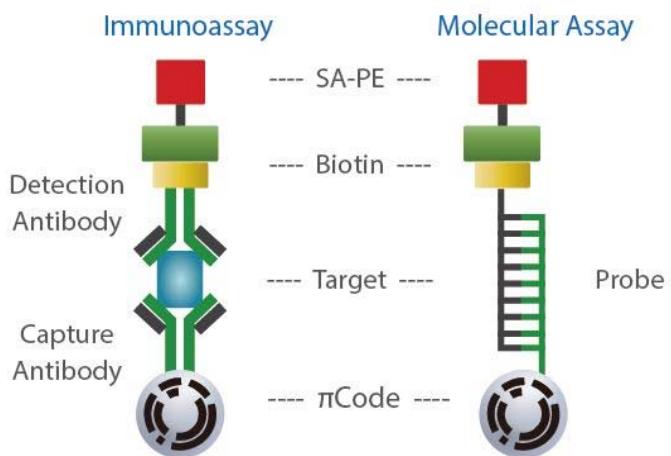


Figure 4. Application of πCode™ MicroDisc for immunoassay and molecular assay

In order to perform a biological test, πCode™ MicroDiscs with desired detection probes were pooled together in a single well and reacted with patient sample, followed by hybridization and fluorescent labeling. The assay detection was done by optical imaging through the PlexBio™ 100 Fluorescent Analyzer, which uses the CCD camera to read the distinct image patterns under bright field and quantifies the analyte by reading the fluorescence signal intensity under dark field, reporting the reactions occurring at each πCode™ MicroDisc in a user-friendly interface.

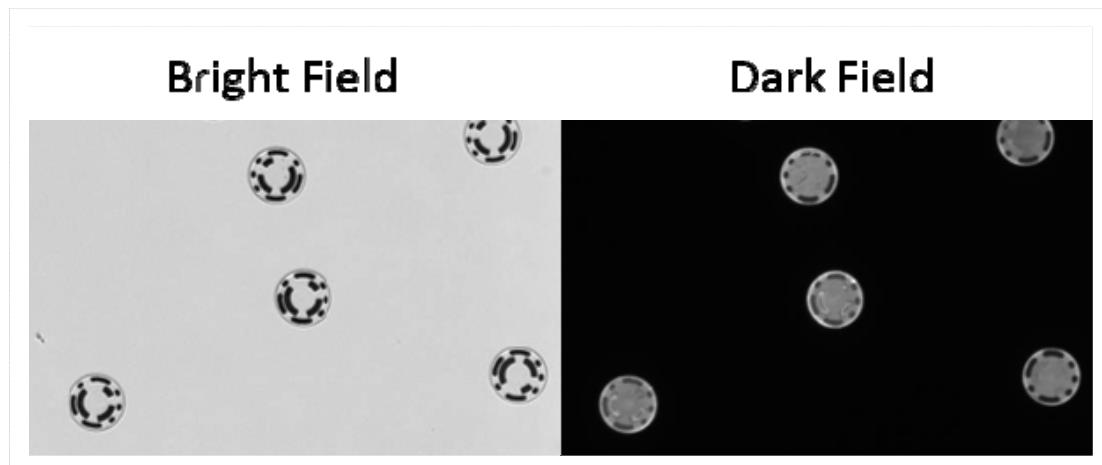


Figure 5. Bright and dark field images after reporting

2.3 Instrument Specifications

| Model | PB100 |
|---|---|
| OPTICS | |
| Coding | Image Pattern |
| Optics (Excitation) | LED |
| Optics (Detection) | CCD imager |
| A/D resolution | 14 bits |
| Focus Lens | 10x magnification |
| OPERATION ENVIRONMENT | |
| Temperature | 15~35 °C |
| Humidity | 20~80%RH, non-condensing |
| Altitude | Up to 3,000 meters above mean sea level |
| STORAGE CONDITIONS | |
| Temperature | -10~70 °C |
| Humidity | 10~80% RH non-condensing |
| PERFORMANCE | |
| πCode Classification Accuracy | ≥ 98% |
| πCode Recognition Precision (CV) | ≤ 2.5% |
| MFI Precision (CV) | ≤ 1.5% |
| Daily Start-Up | ≤ 15 min |
| Reading Time | 1 well ≤ 50 sec |
| PHYSICAL CHARACTERISTICS | |
| Power | 100-240V, 50-60Hz |
| Dimensions | 27.3 cm W x 54 cm D x 44.1 cm H |
| Weight | 25 kg (55.0 lbs) |
| Connection | USB and Ethernet |

Table 2. PlexBio™ 100 Fluorescent Analyzer specifications

2.4 Advantages of PlexBio™ 100 Fluorescent Analyzer

The PlexBio™ 100 Fluorescent Analyzer is a robust optical imaging system that is both highly effective and easy to use. The compact machine is simple to maintain – no wash or waste fluid management required – and it accurately decodes πCode™ through high-contrast imaging. The system is compatible with any protein- or DNA-based assays using PlexBio’s multiplex πCode™ MicroDisc.

Advantages

- Ease of use: intuitive, user-friendly interface with a 15-minute startup
- Robustness: no-fuss maintenance due to simplicity of instrument; no probes or fluids necessary
- Accuracy: πCode™ image pattern classification of only non-overlapping πCode™ MicroDisc means virtually no misread πCode™ MicroDiscs; πCode™ MicroDisc read on well bottom eliminates cross-over
- Efficiency: run multiple tests with one sample by multiplexing your assays in a compact machine
- Flexibility: use PlexBio’s commercial assays or develop your own, with up to 16,000 unique πCode™ MicroDisc to mix and match
- Traceability: original data can be traced back to individual πCode™ MicroDisc post-assay

Chapter 3: Hardware Installation

3.1 Components

Note that the PlexBio™ 100 Fluorescent Analyzer is to be installed and serviced by PlexBio's qualified service engineers only. Please contact PlexBio Co., Ltd. or your local distributors to schedule an installation or any repairs of the system. Refer to the Pre-Installation Guide for site and installation requirements.

The PlexBio™ 100 Fluorescent Analyzer includes:

- ✓ 1 PlexBio™ 100 system
- ✓ 1 USB 2.0 cable (A, B head)
- ✓ 1 Ethernet cable
- ✓ 2 AC power cords (110V, 220V)
- ✓ 1 Installation USB: includes DeXipher™ Basic software.
- ✓ 1 User Manual
- ✓ Optional items: Industrial All-in-one PC

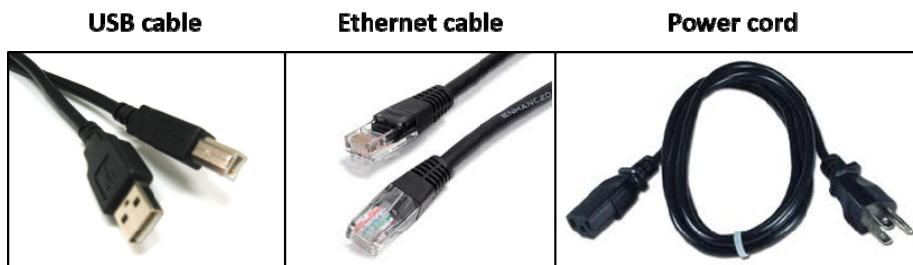


Figure 6. Connecting accessories

Please lift PlexBio™ 100 Fluorescent Analyzer from the bottom if you want to move the system. Do not pull, push, or bend the case from the side. The PlexBio™ 100 system needs an operation area of 0.20 square meters. Please keep the operation bench flat. The system also needs to be placed at least 10 centimeters away from the wall for cable connection with PC and for efficient cooling.

3.2 Minimum PC Requirements

| Component | Minimum | Recommended |
|---------------------|--|--|
| Operation System | Microsoft Windows 7 Professional SP1 64bit | Microsoft Windows 7 Professional SP1 64bit |
| CPU | Intel core i7 | Intel core i7 or above |
| Main Memory | 4 GB DDR2 SDRAM | 8 GB DDR2 SDRAM |
| Hard Drive | 500GB 7500RPM SATA HDD | 1TB 7500RPM SATA HDD |
| Port for connection | 1 USB and 1 Ethernet port | 1 USB and 1 Ethernet port or more |
| Network: | 100MB Ethernet | 100MB Ethernet or above |
| .NET Framework | 4.0 | 4.0 or above |
| PDF Viewer | Adobe Reader 10.0 | Adobe Reader 10.0 or above |
| Office Tools | - | Microsoft Office Compatible |

Table 2. PC requirements

3.3 Cable Connection

Please turn off the PC before connecting the cables.

1. Please make sure the PC has been turned off.
2. Connect USB cable and Ethernet cable between PlexBio™ 100 Fluorescent Analyzer and PC.
3. Connect PlexBio™ 100 Fluorescent Analyzer power cable.
4. Turn on PC. Wait until the PC is ready.
5. Turn on PlexBio™ 100 Fluorescent Analyzer. The indicator light on the front will be steady pink.
6. Warm up for about 15 minutes. Once the indicator light is white, the PlexBio™ 100 Fluorescent Analyzer is ready to use.

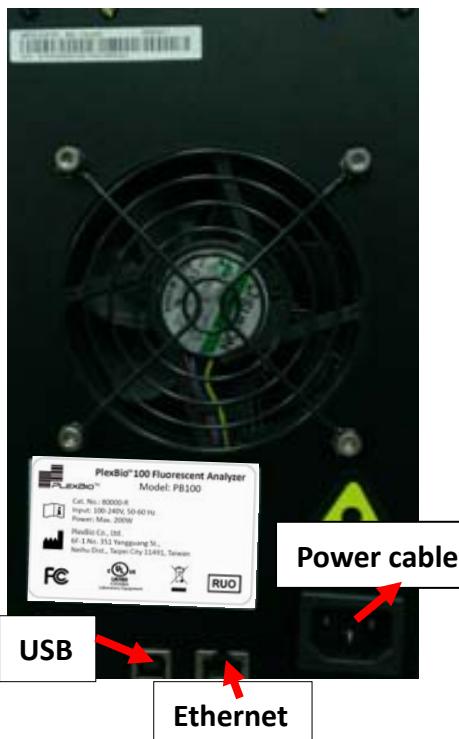


Figure 7. PlexBio™ 100 Fluorescent Analyzer ports



※Caution

- ❖ Under the following situations, please contact PlexBio Co., Ltd. or local distributors for reading position recalibration.
 - First time instrument installation.
 - Industrial Computer replacement.
 - Instrument relocation, or any components are renewed.
- ❖ After turning off the power, please unplug the power cable to **fully disconnect PlexBio™ 100 Fluorescent Analyzer from the main circuit.**
- ❖ Please make sure the electrical socket is easily accessible for plugging.
- ❖ **Do not** position the equipment so that it is difficult to disconnect the plugs.

3.4 Indicator Light Signals



| Mode | Signals |
|----------------------------|---|
| Warm up | Steady Pink |
| Standby / finished reading | Steady White |
| Reading | Alternating Flashing Pink and White |
| Lid open before reading | Flashing Pink |
| Lid open during reading | Alternating Flashing Pink and White with warning message |
| Error | Flashing Red |

Table 4. Indicator light signals

Chapter 4: DeXipher™ Software Overview

4.1 Software Versions

DeXipher™ Basic is included with every PlexBio™ 100 Fluorescent Analyzer delivered. DeXipher™ Basic has all the required functions for users to decode πCode™ and get data reports. All raw data can be exported for further analysis.

For advanced functions such as data analysis, kit applications, account management, please contact PlexBio Co., Ltd. or local distributors for DeXipher™ RU version. Please see Table 5 for a feature comparison of DeXipher™ Basic and RU versions.

| Key Features | Basic | RU |
|--|-------|----|
| Number of Accounts # | 1 | >1 |
| Account Management | | ✓ |
| Quick Read | ✓ | ✓ |
| Export Raw Data | ✓ | ✓ |
| Identify Kit ID and Lot ID | | ✓ |
| Calibration (Stage and Fluorescence) | ✓ | ✓ |
| Data and Results (Check Previous Data/ Summary Data) | ✓ | ✓ |
| Define Standard, Control, and Sample Well | | ✓ |
| Create your own protocol/ assay | | ✓ |
| Data Analysis and Reports (Standard Curve Calculation and Charts) | | ✓ |
| Kit Reports (e.g. IntelliPlex™-branded Assays) | | ✓ |

Table 5. Software version comparison

4.2 Installation

Users can run “Install.exe” and follow the guideline to install DeXipher™. There are components to be installed:

1. Microsoft .NET Framework 4.5
2. Microsoft VC++ 2005
3. Microsoft VC++ 2012
4. Remove Previous Database
5. Sql Server Express
6. Create Database
7. AVT Vimba SDK
8. DeXipher™

Please ensure all components are installed before using PlexBio™ 100 Fluorescent Analyzer.

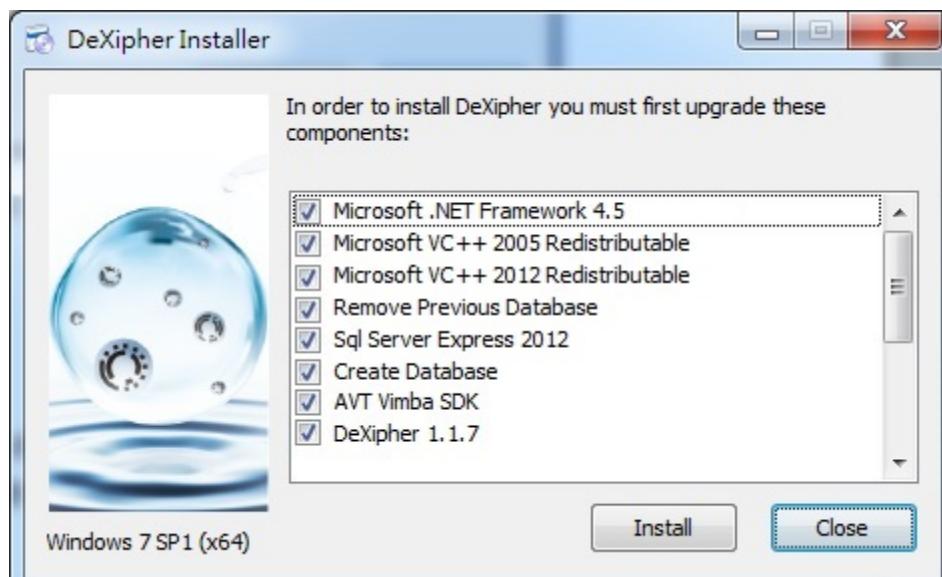


Figure 8. Installation of DeXipher™

4.3 Uninstallation

To uninstall DeXipher™, user can go to Windows “Control Panel/Programs”. There are 3 programs to uninstall to fully remove DeXipher™ from PC: DeXipher™, AVT Vimba, and Microsoft SQL server. If you have any issues for uninstallation, please contact PlexBio Co., Ltd. or your local distributors for further help.

Chapter 5: Starting DeXipher™

Before decoding by PlexBio™ 100 Fluorescent Analyzer, warm up the system with the lid in the closed position for approximately 15 minutes and ensure that the indicator light has changed to white light.

***Do not open the lid when the system is warming up or the system will repeat the initialization step when the lid is being closed again.**

Starting DeXipher™

To start DeXipher™, click on the application icon on your desktop or select DeXipher™ from the Programs directory on your Windows Start menu.



Figure 9. DeXipher™ icon

Required Screen Resolution

Your computer screen resolution must be set to at least **1024 x 768** pixels for correct display of DeXipher™ user interface. Dialog boxes and system status bar may not display properly at lower resolution.

DeXipher™ Login

Once the computer has completed booting, desktop with icons should be displayed. Double-click on the DeXipher™ icon, and the following login window will be displayed as shown in Figure 10. Type the **User ID** and the **Password** to log into DeXipher™.



Figure 10. Login screen

After logging in, the DeXipher™ homepage will be displayed as shown in Figure 11.



Figure 11. DeXipher™ homepage

Please see Table 6 below for details on DeXipher™ icons and corresponding descriptions.

Table 6. Icons in DeXipher™

| Icon | Description |
|------|--|
| | View DeXipher™ version and license information |
| | Check imported kits |
| | Import kits |
| | Assign well numbers from left to right |
| | Assign well numbers from up to down |
| | Set well type as Standard |
| | Set well type as Control |
| | Set well type as Sample |

| | |
|--|--|
| | Clear well type setting of a single well |
| | Reset current well type settings |
| | Add |
| | Remove |
| | Save |
| | Delete |
| | Confirm |
| | Backward |
| | Forward |
| | Search reports |
| | Bar chart function |
| | View well images |
| | Export reports as PDF files |
| | Export Raw Data as Excel files |
| | Set up report contents |
| | Modify report settings |
| | View report settings |
| | Conceal well info in "Summary Data" |
| | Disclose well info in "Summary Data" |

| | |
|---|--|
|  | Conceal πCode™ info in “Summary Data” |
|  | Disclose πCode™ info in “Summary Data” |
|  | View System Log |
|  | Add new accounts |

5.1 Quick Read

Quick Read is for users to check or read wells first without defining control or standard wells. All well types will be seen as sample wells in DeXipher™. There are two main applications for Quick Read:

1. Quickly check distribution of πCode™ MicroDiscs in the well, πCode™ Microdisc counts per well, and fluorescence intensity of πCode™ MicroDisc.
2. Conduct reading/scanning first to define well info and/or panel info for later data analysis.

5.1.1 Quick Read Screen

When click on the  Quick Read button on DeXipher™ homepage, user will enter the main Quick Read screen as follows. The system will automatically begin hardware initialization and check the status of functional modules. Please see Figure 12 for screen description.

※Caution: Do not open the lid when the system is initializing. The indicator lights of both the camera and stage in the system status bar will be shown in red. Please wait until they are green to open the lid.

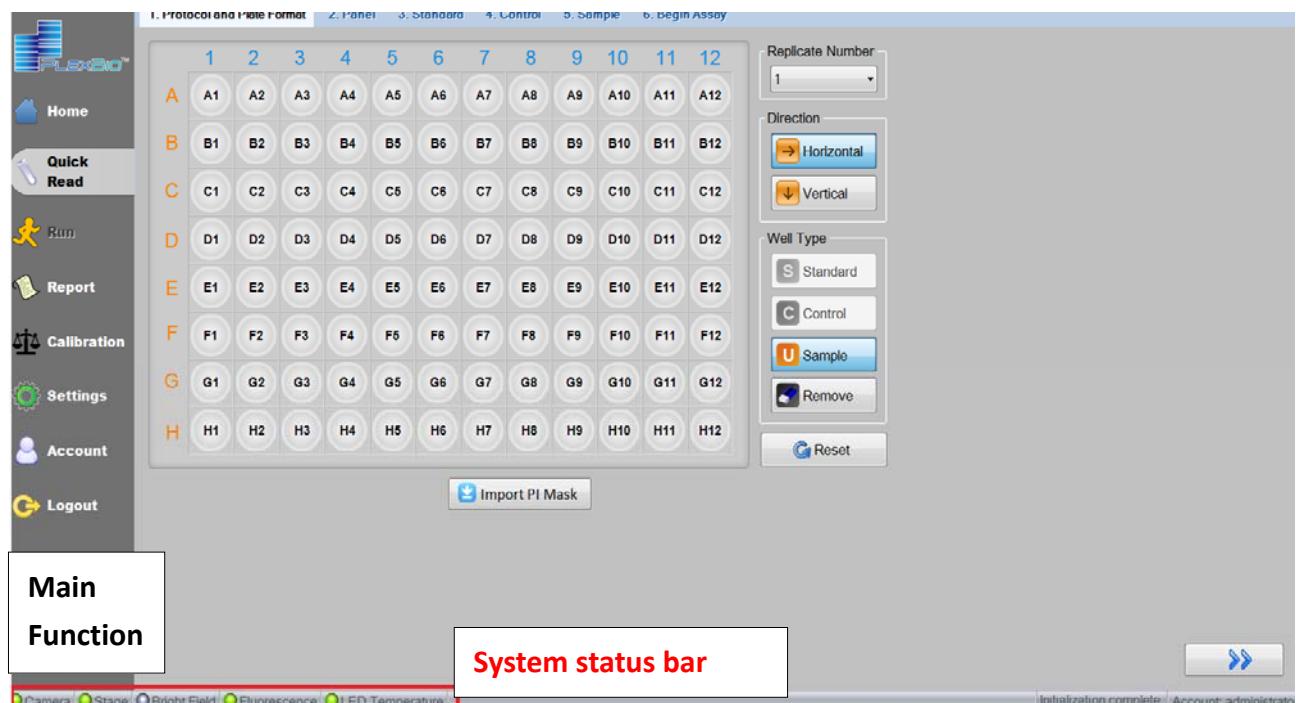


Figure 12. Quick Read screen

1. **Main functions:** there are 7 main functions in DeXipher™:

- Home: Go back to DeXipher™ homepage
- Quick Read: Select sample wells for quick scanning
- Run: Display the reading status
- Report: Check previous data and reports of completed tests
- Settings: Decide what parameters to be shown in Data Report
- Account: Set account information
- Logout: Log out of DeXipher™

2. **System status bar:** Displays system status, please see Fig.



Figure 13. System status bar

- Camera: Green indicates the CCD is ready and normal; red indicates the CCD is warming up or malfunctioning.
- Stage: Green indicates the stage is ready and normal; red indicates the stage is warming up or malfunctioning.
- Bright Field: Gray indicates the bright field lighting LED is off; green indicates the LED is on; red indicates the LED is malfunctioning.
- Fluorescence: Green indicates the fluorescence LED is ready and normal; red indicates the fluorescence LED is malfunctioning.
- LED Temperature: Green indicates the temperature of fluorescence LED is normal; red indicates the temperature is over 70°C. If the indicator light is red, please restart the PlexBio™ 100 system. If the light keeps red for LED Temperate after the system restarts, please contact PlexBio service engineers.
- The system will automatically shut down when the system temperature is over 70°C.

3. **Sub-functions and sub-function screen:**

For each main function, there are associated sub-functions which will be described in the following chapter.

5.2 Run Quick Read

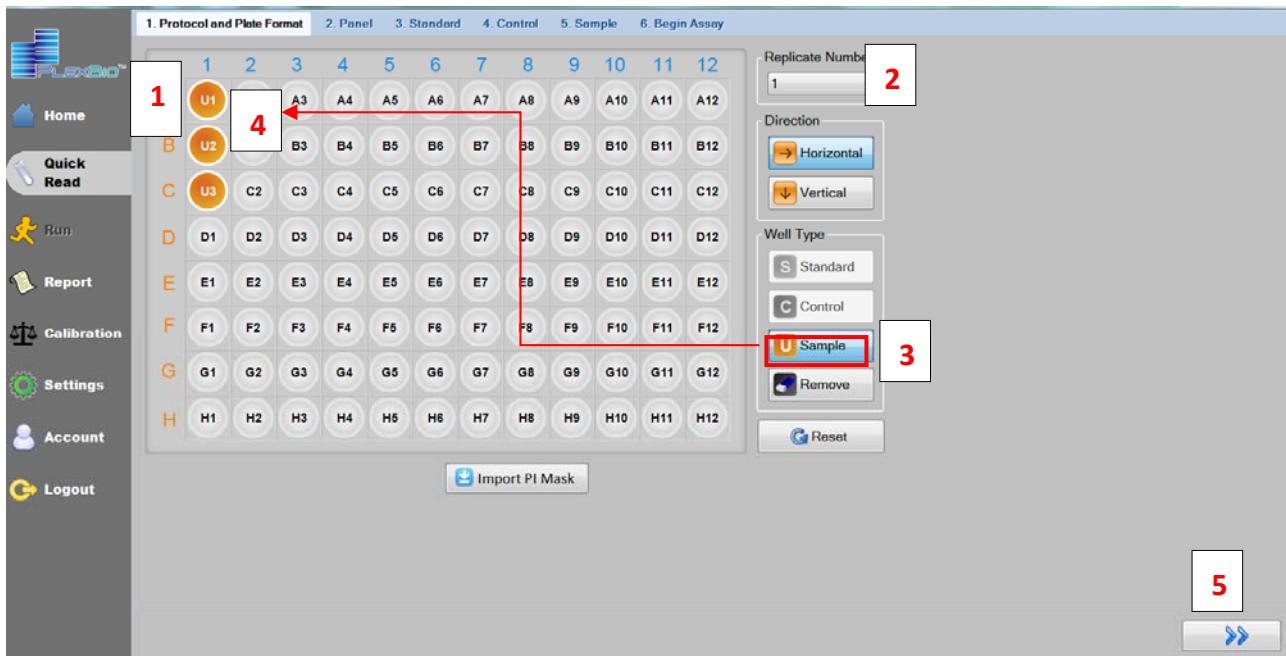


Figure 14. Quick Read / Protocol and Plate Format

Please see Fig. 14 for Quick Read steps 1~5.

- Step 1. Under Quick Read, user will see the plate format.
- Step 2. Select the number of replicates. In this case, the replicate number is 1.
- Step 3. Select samples as well type by clicking **U** (sample well).
- Step 4. Select wells by clicking or dragging. In this case, wells A1, B1, and C1 have been selected.

If users select the wrong wells, they can select **Remove** and then click on the well to remove. Users can also remove all settings by clicking on **Reset** to remove settings of all selected wells.

- Step 5. Click on **>>** to go to the next page.

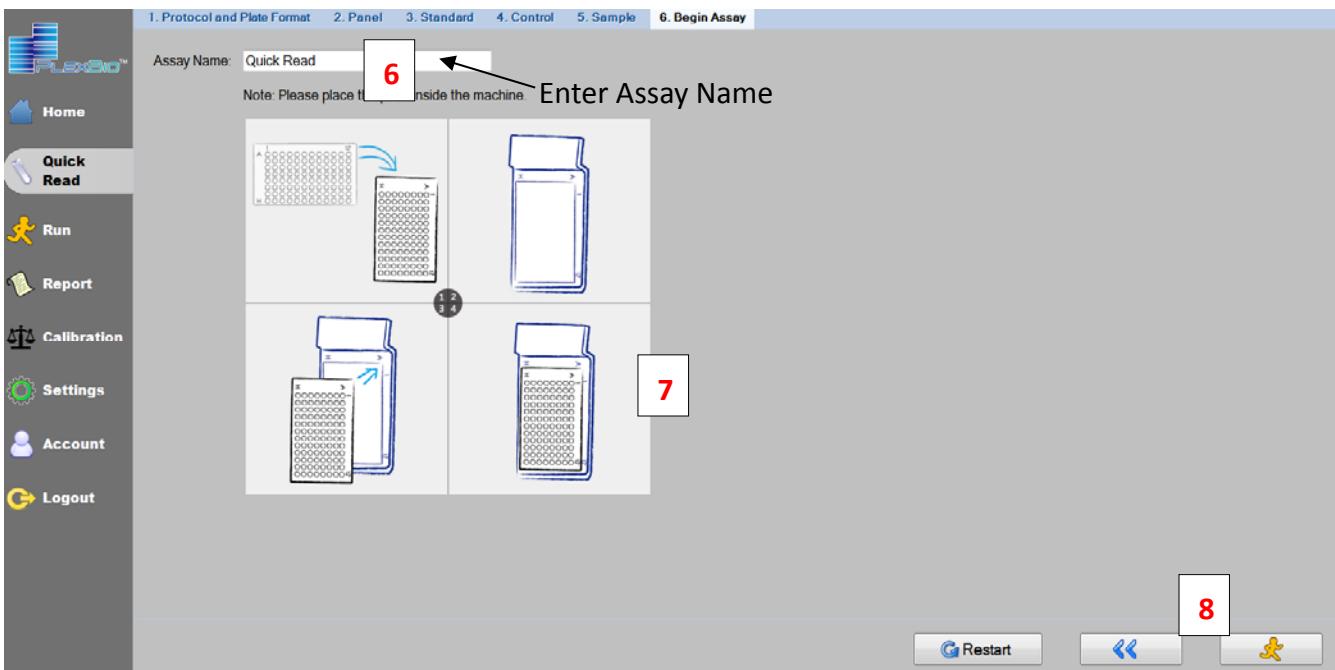


Figure 15. Quick Read/Begin Assay

Please see Figure 15 for Quick Read steps 6~8.

- Step 6. Enter assay name. In this case, the assay name is “Quick Read”.
- Step 7. Follow the drawing to put the 96-well plate onto the stage with the correct orientation.
- Step 8. Click on to start reading. DeXipher™ will ask users to confirm that the plate is in PlexBio™ 100 system. Click “OK” to begin reading.

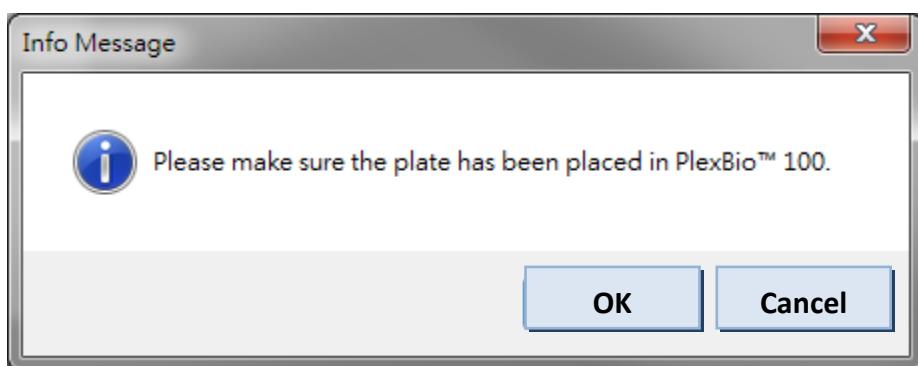


Figure 16. Quick Read/Begin Assay/Info Message

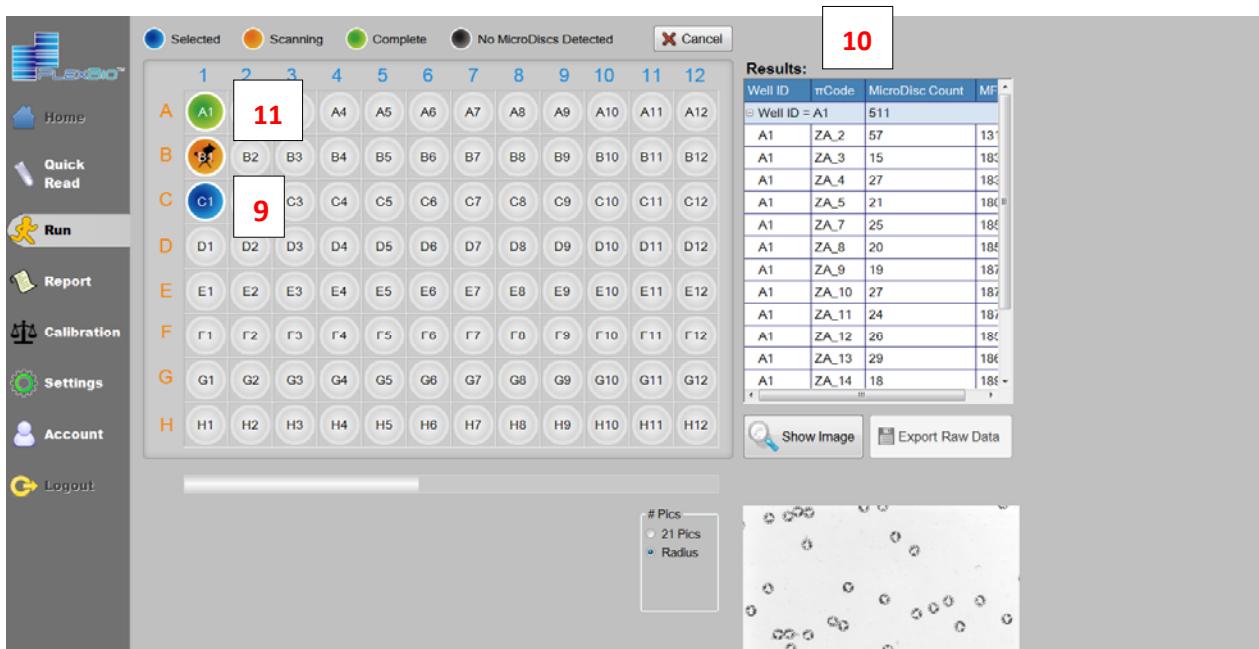


Figure 17. Run screen during reading

- Step 9. During reading/scanning, the active function will become “Run”, which indicates decoding progress and results. Please note the following color codes for wells:
- : Selected- The well has been selected for decoding and has not been scanned.
 - : Scanning- The well is being scanned.
 - : Complete- The well has been scanned.
 - : No πCode™ - The well scanning is complete but no πCode™ MicroDiscs were found in the well.
- Step 10. When scanning is complete, πCode™ Count and MFI (Median Fluorescence Intensity) of each completed well will be shown in the “Results” section.
- There are three functions to use during reading/scanning: Cancel, Show Image, and Export Data.
- Cancel:** Cancel current scanning/reading. The data will not be saved for further analysis
- Show Image:** Check well images for πCode™ distribution
- Export Raw Data:** Export raw data of completed wells to Excel files
- Step 11. After scanning is complete, users can check well images by double-clicking on the completed wells.

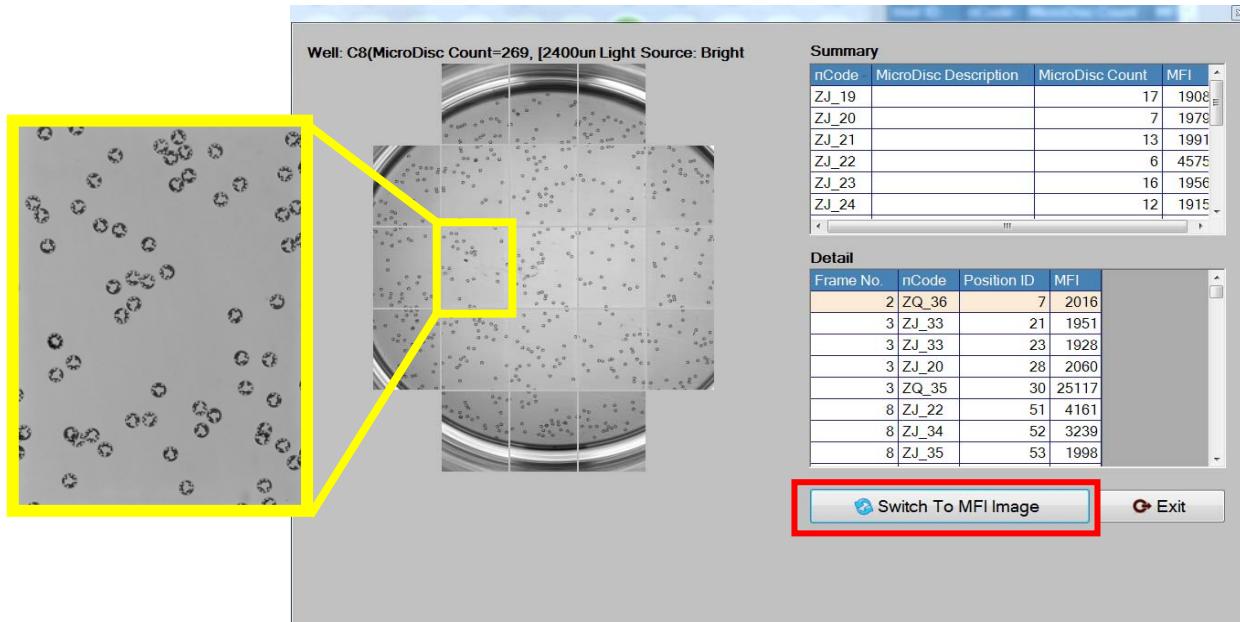


Figure 18. Bright field image of the selected well

Step 12. Click **Switch To MFI Image** to check fluorescence images

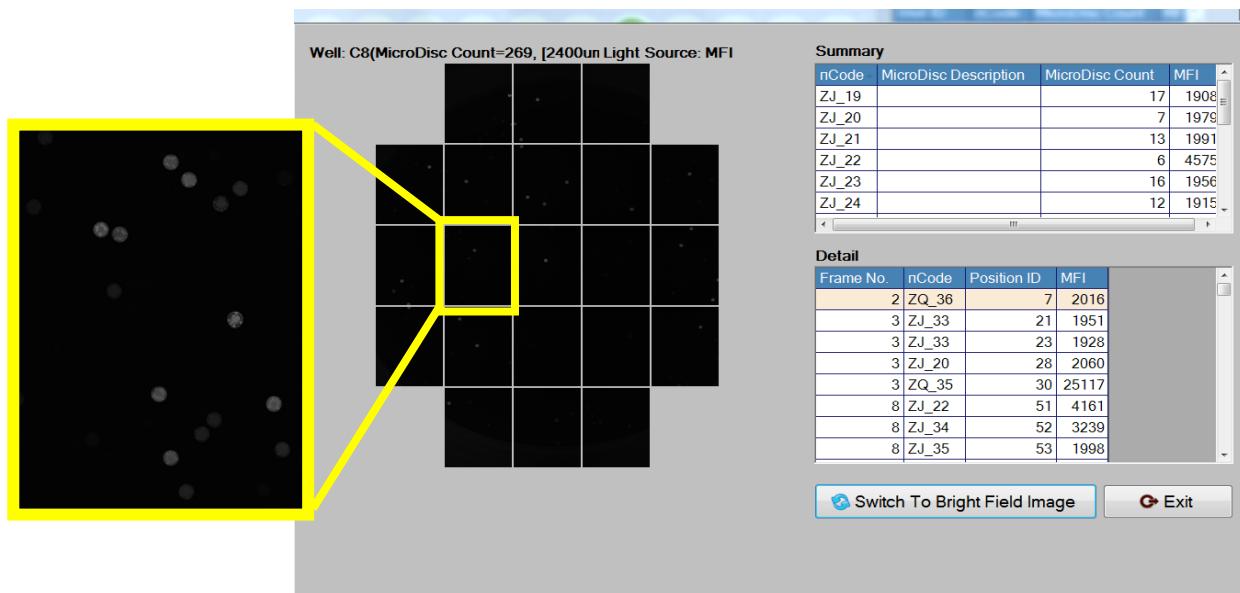


Figure 19. Fluorescent image of the selected well

Step 13. Click on **Switch To Bright Field Image** to go back to bright field images

Step 14. Click on **Exit** to leave this function.

5.3 Report

Every completed reading/scanning will generate data in computer database. The Report function is used to view previous data, create reports, and/or export data for further analysis.

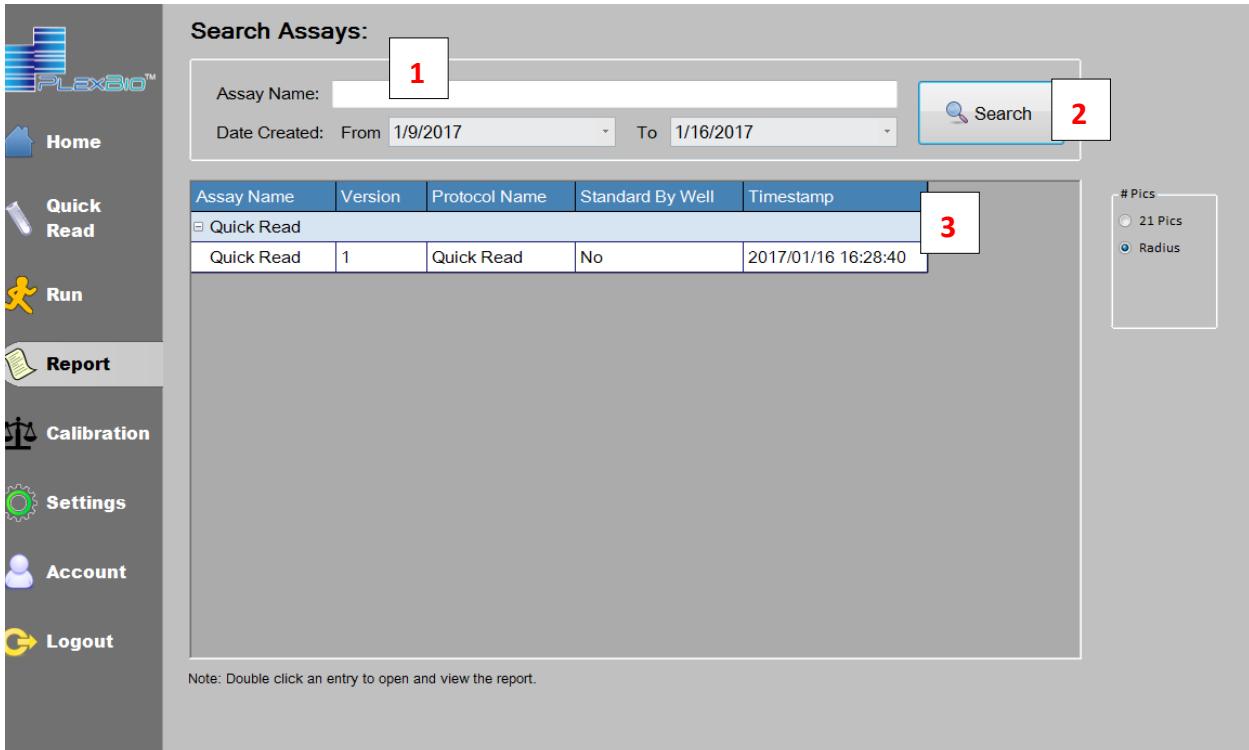


Figure 20. Data report

1. **Search Assays**: User can use this function to find previous assay data.

Step 1. User can use “From” and “To” to search previous assay data reports based on the time at which the assay was decoded.

Step 2. Click on to get previous results.

Step 3. Previous data will be listed based on time.

5.4 Settings

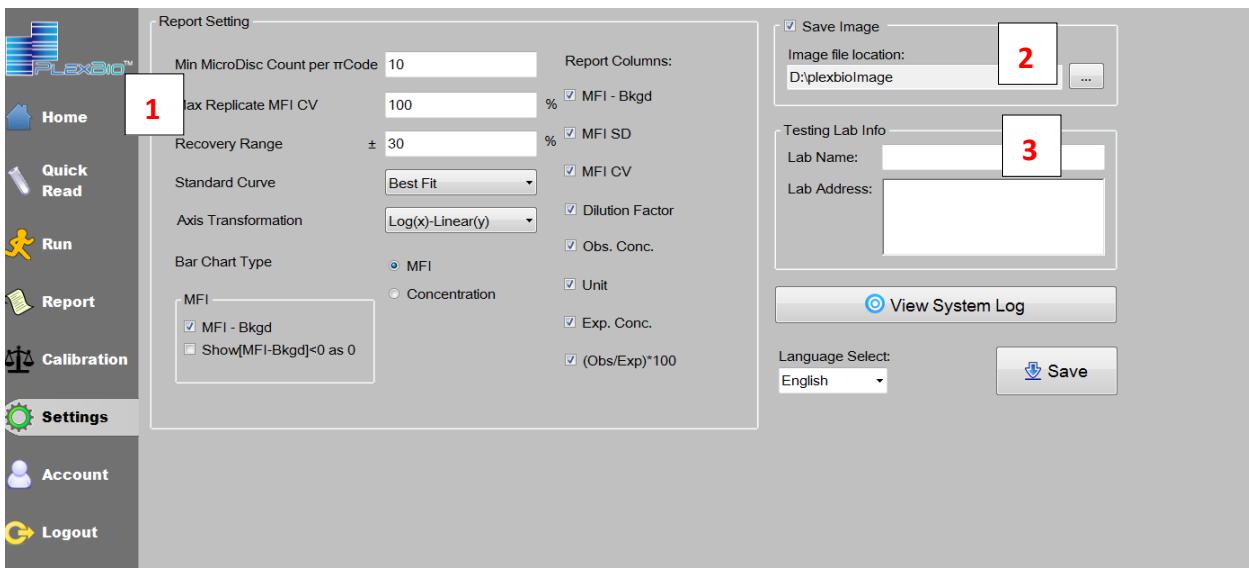


Figure 21. Settings

The Settings function is for users to configure report contents and image storage pathway. Please see Figure 21.

1. Report settings:

- *Min πCode™ Count per πCode*: Define the minimum πCode™ count to be noted in the report.
- *Max Replicate MFI CV*: Define the maximum replicate fluorescence CV to be noted in the report.
- *Recovery Range*: Define recovery range to be noted in the report.
- **MFI-Bkgd**: Select whether the background value is subtracted.
- *Show [MFI-Bkgd]<0 as 0*: Select whether negative values are shown as zero.
- *Report Columns*: Select information to be shown in the report.
 - i. **MFI**: Median Fluorescent Intensity
 - ii. **MFI-Bkgd**: FL value minus the background
 - iii. **MFI SD**: Standard deviation of fluorescence signals
 - iv. **MFI CV**: CV (coefficient of variance) of fluorescence signals
 - v. **Dilution Factor**: Dilutions of sample or analytes
 - vi. **Obs. Conc.**: Observed concentration
 - vii. **Unit**: Concentration unit of sample or analytes
 - viii. **Exp. Conc.**: Expected concentration
 - ix. **[Obs./Exp.]*100**: The ratio of Observed concentration and Expected concentration

2. **Image file location**: Define image storage pathway.

3. **Testing Lab info**: Edit Lab Name and Lab Info (shown in kit reports).

4. **Save** all inputs by clicking on

5.5 IntelliPlex™ Assay Kit

The IntelliPlex™ Assay Kit function is for commercial kits developed for IntelliPlex™ platform. DeXipher™ will identify kit contents and lot number based on classified πCode™ image pattern. In addition, DeXipher™ will also generate associated kit reports for research purposes.

In this chapter, the IntelliPlex™ KRAS G12/13 Mutation Kit will be used as an example.

Note: Before using an IntelliPlex™ Assay Kit on DeXipher™, please import the related kits. See 5.6 for more details.

Note: DeXipher™ Basic will not support IntelliPlex™ Assay Kit. Please contact PlexBio Co., Ltd. or your local distributors for DeXipher™ RU version.

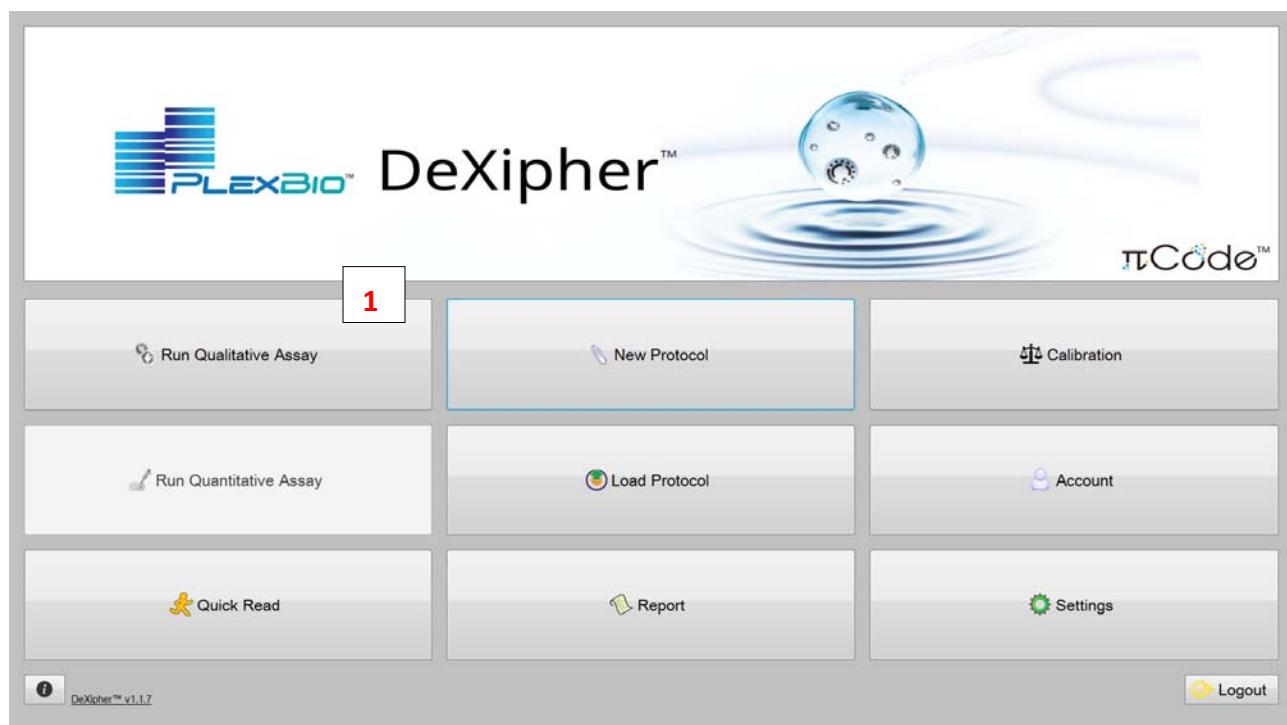
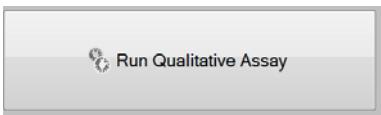


Figure 22. DeXipher™ homepage

Step 1. Click on  on the DeXipher™ homepage.

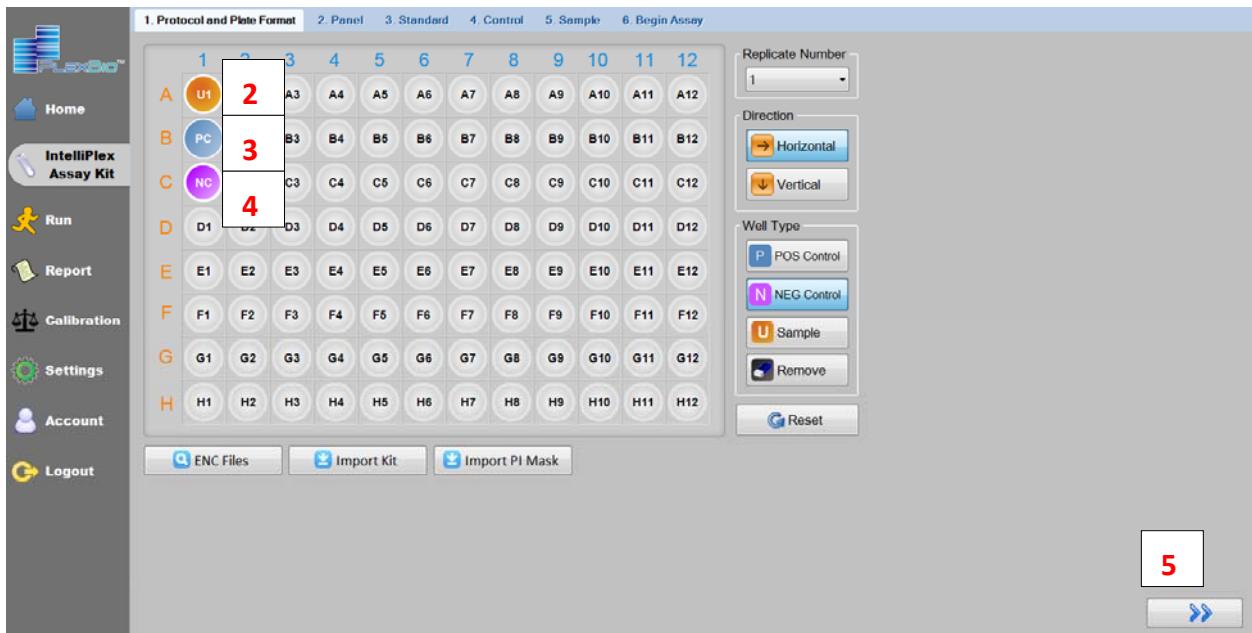


Figure 23. IntelliPlex™ Assay Kit/ Protocol and Plate Format

- Step 2. Select A1 as Sample well
- Step 3. Select B1 as POS Control
- Step 4. Select C1 as NEG Control
- Step 5. Click on to go to the next page

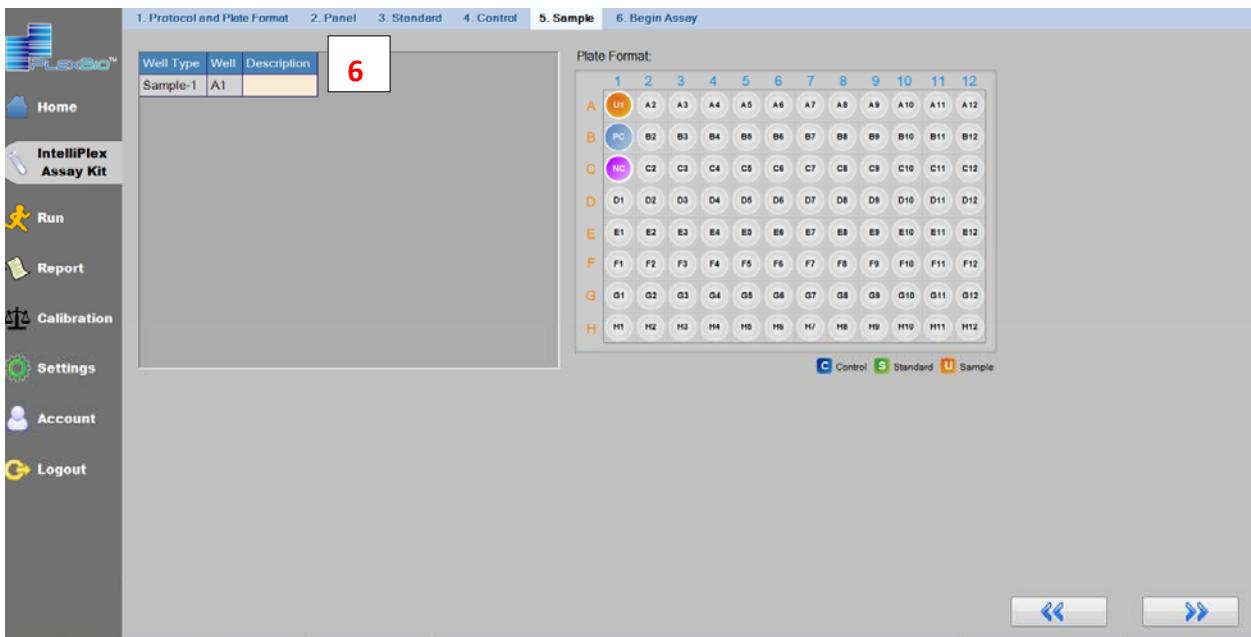


Figure 24. IntelliPlex™ Assay Kit/ Sample

- Step 6. Enter sample descriptions. The plate format is available as reference.
- Step 7. If sample descriptions are left blank, DeXipher™ will display a **warning message** and **user must enter the information in order to proceed to the next step.**

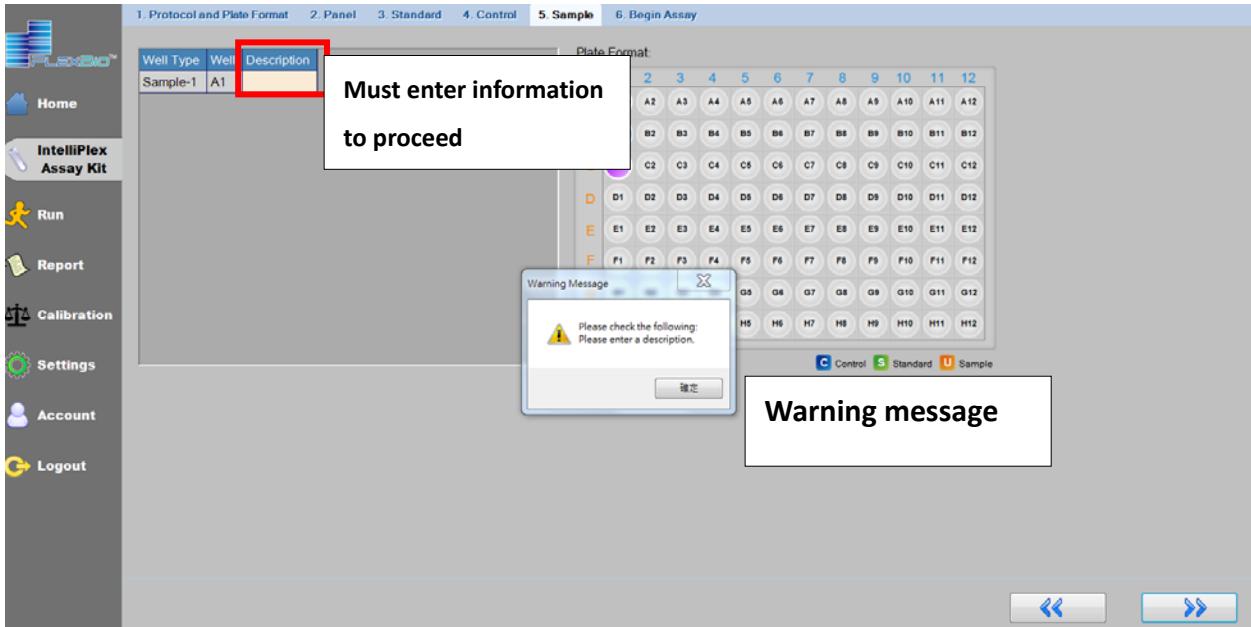


Figure 25. IntelliPlex™ Assay Kit/ Sample

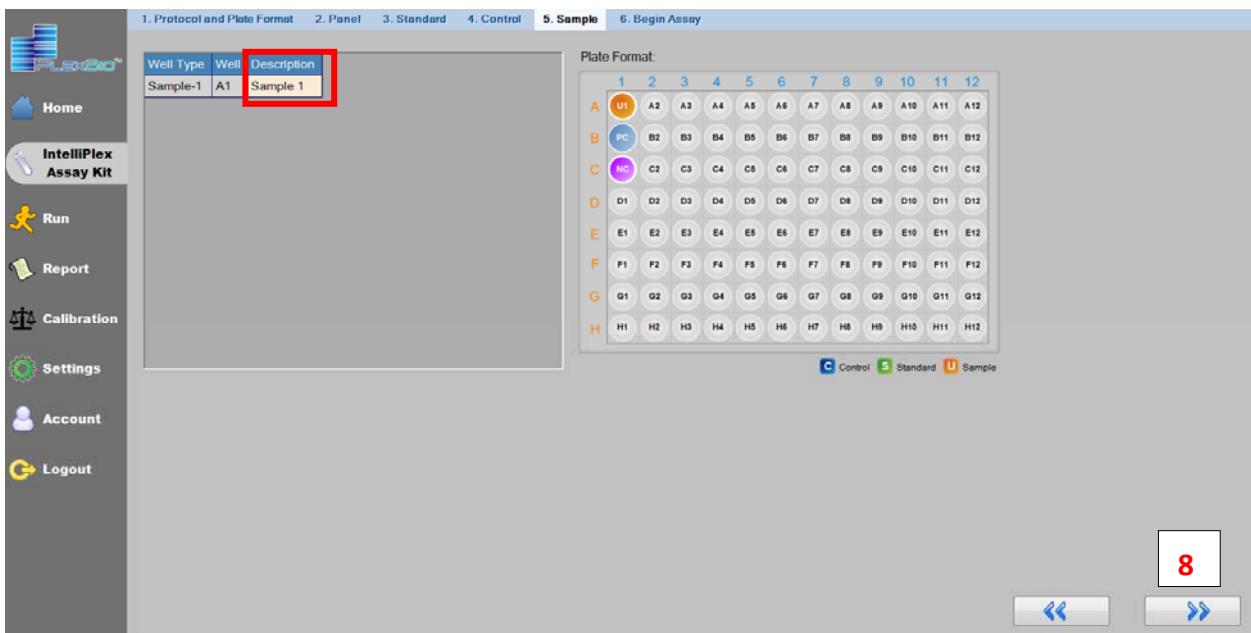


Figure 26. IntelliPlex™ Assay Kit/ Sample

Step 8. After entering sample descriptions, click on

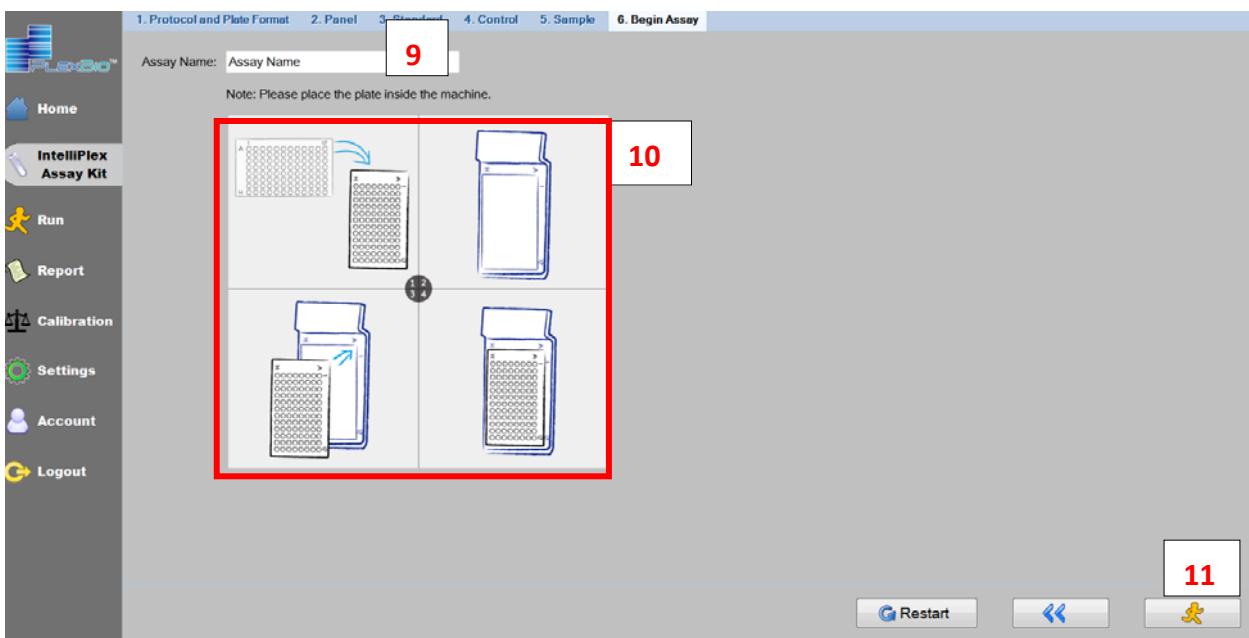


Figure 27. IntelliPlex™ Assay Kit/ Begin Assay

Step 9. Enter Assay Name.

Step 10. Follow the drawing to put the 96-well plate onto the stage with the correct orientation.

Step 11. Click on  to start reading.

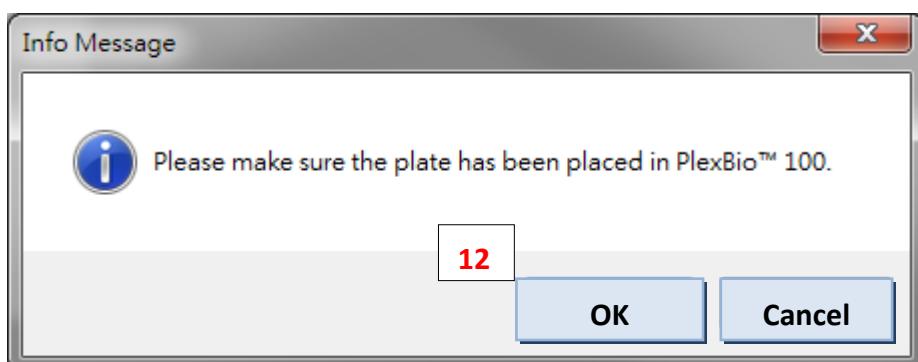


Figure 28. IntelliPlex™ Assay Kit/Begin Assay/Info Message

Step 12. DeCipher™ will ask users to confirm that the plate is in PlexBio™ 100 system. Click "OK" to begin reading.

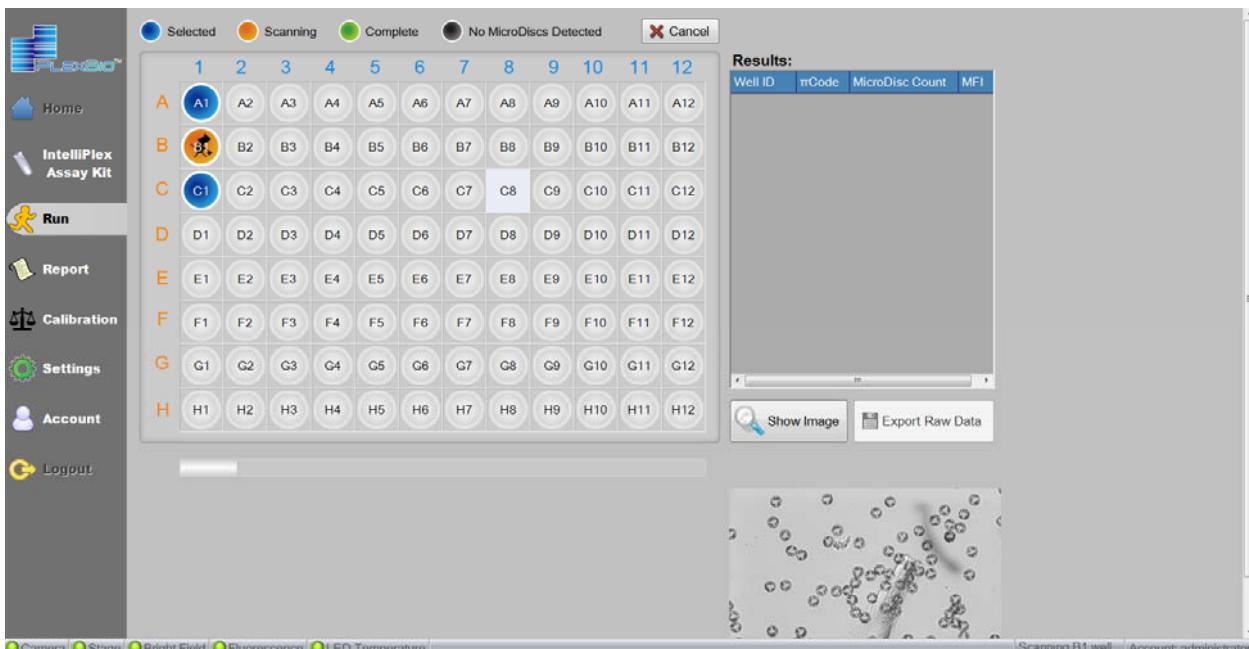


Figure 29. Run Screen

Step 13. PlexBio™ 100 Fluorescent Analyzer starts to read selected wells. It takes approximately 50 sec to read one well.



Figure 30. Reading completed.

Step 14. The report can be opened once the reading is completed.

The screenshot displays the summary data page of the IntelliPlex™ KRAS G12/13 Mutation Kit. At the top left is the PlexBio logo. The title "IntelliPlex™ KRAS G12/13 Mutation Kit" is centered. Below the title, there is a table with assay details:

| | | | |
|----------------------|------------------|-------------------|---------------------|
| Assay Name: | 20161222 CC FFPE | Kit Lot No.: | 04010294 |
| Testing Lab: | | Test Date & Time: | 12/22/2016 14:11:59 |
| Testing Lab Address: | | | |

A red box highlights the "Report info" button. Below this, the "Control Well Result" section shows the following table:

| Well ID | Controls | Result |
|---------|------------------|--------|
| G1 | Positive Control | Pass |
| H1 | Negative Control | Pass |

Below the control results, another red box highlights the "Summary data" button. The "Summary" section contains a table of sample detection results:

| Well ID | Sample ID | Mutation Detected |
|---------|-----------|-------------------|
| A3 | G12V | G12V |
| B3 | G12A | G12A |
| C3 | G13D | G13D |
| D3 | G12S | G12S |

Figure 31. Summary data page of IntelliPlex™ KRAS G12/13 Mutation Kit

There are two main sections on the summary data page of IntelliPlex™ kit report.

1. **Report Info:** includes Assay Name, Kit Lot No., Testing Lab Name, Testing Lab Address, and Test Date & Time.
2. **Summary Data:** includes sample info and detection results.

Step 15. Users can export the report as a PDF by clicking and as an Excel spreadsheet by

clicking .



| IntelliPlex™ KRAS G12/13 Mutation Kit | | | | |
|---------------------------------------|---|----------|-----------------------|--------|
| Sample ID: G12V | | Well: A3 | | |
| Control | 1 | Result | Control | Result |
| πCode MicroDisc Count | | Pass | ReferenceGene Control | Pass |
| SAPE Monitor Control | 2 | Pass | | |
| Blank Control | | Pass | | |
| Mutation Detected: G12V | 3 | | | |

Figure 32. Sample in well A3 of IntelliPlex™ KRAS G12/13 Mutation Kit report

Each sample has its own test report.

In the sample result page of IntelliPlex™ Kit report, there will be three main sections:

1. **Report Info:** includes Sample ID and Well position.
2. **Validity:** includes control results which will decide the test is valid or not. In this case for IntelliPlex™ KRAS G12/13 Mutation Kit, validity results include MicroDisc Count, SAPE Monitor Control, Reference Gene Control, and Blank Control.
3. **Final result** for individual sample: For IntelliPlex™ KRAS G12/13 Mutation Kit, it shows mutation detected for each sample (see Fig. 32).

5.6 Import IntelliPlex™ Assay Kit

Before using IntelliPlex™ Assay Kit, users should import related kit information into DeXipher™.

Note: DeXipher™ Basic will not support IntelliPlex™ Assay Kit. Please contact PlexBio Co., Ltd. or your local distributors for DeXipher™ RU.

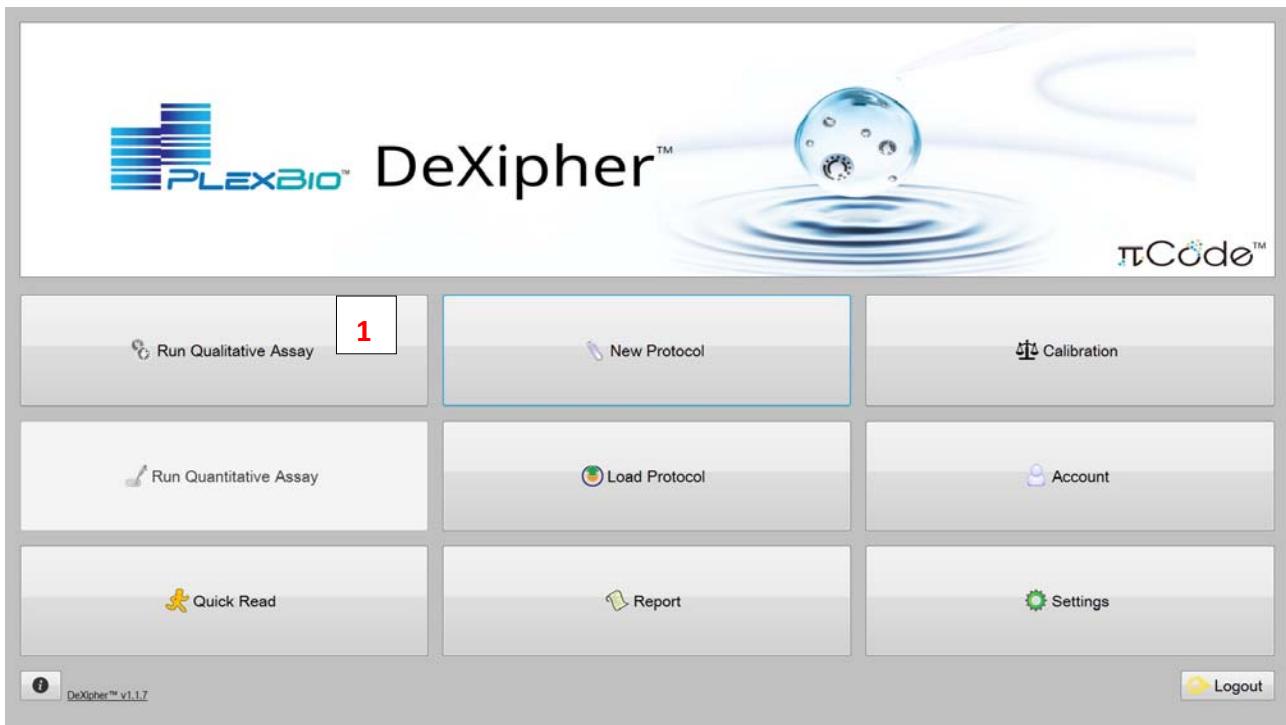
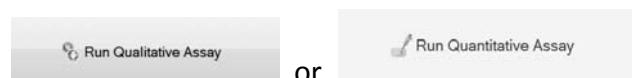


Figure 33. DeXipher™ homepage

Step 1. According to assay type, click on either shown in Figure 33. DeXipher™ homepage.



or

Step 2. Click on Import Kit to import kits.

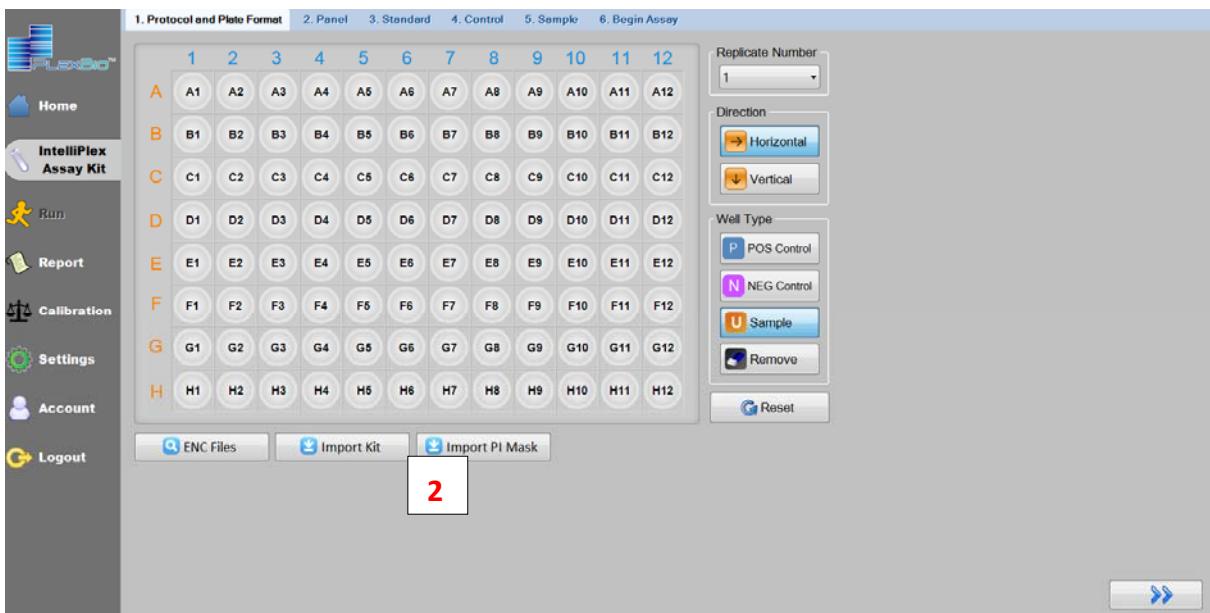


Figure 34. Import IntelliPlex™ Assay Kit

Step 3. Select the ENC file obtained from PlexBio Co., Ltd. or local distributor. In this case, the file is named “KRAS17041901.enc”.

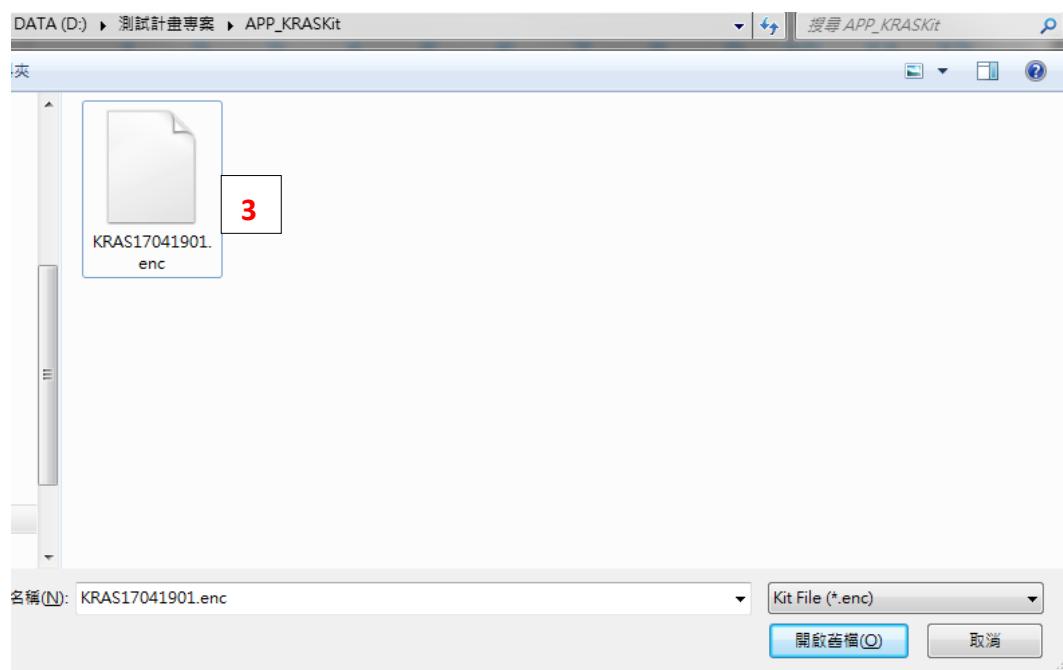


Figure 35. Selection of .enc file to import kit

Step 4. Click on **ENC Files** to check all imported kits.

Note. **Import PI Mask** will be used for future software upgrade given by PlexBio Co., Ltd. Or local distributors.

5.7 New Protocol

New Protocol is for users to generate and to test new assays. Users need to follow steps to set up required assay information before reading.

Note: DeXipher™ Basic does not support the protocol function. Please contact PlexBio or your local distributors for DeXipher™ RU.

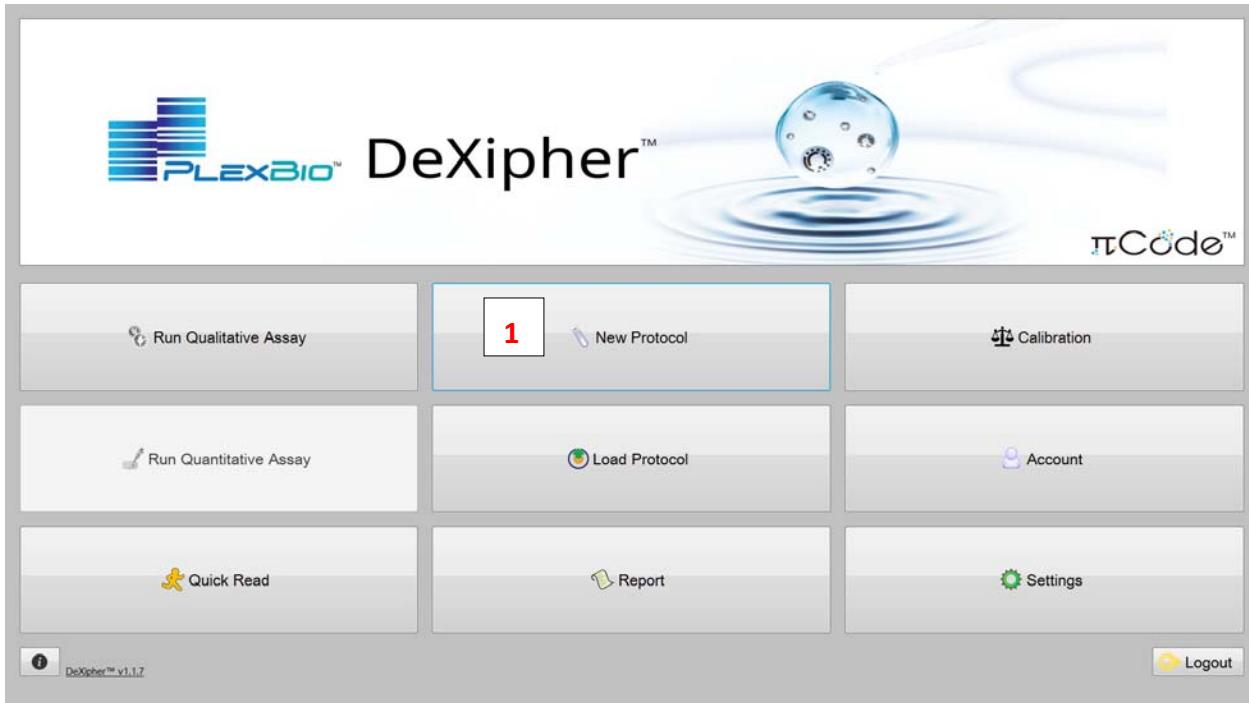


Figure 36. DeXipher™ homepage

Step 1. Click on **New Protocol** on the DeXipher™ homepage.

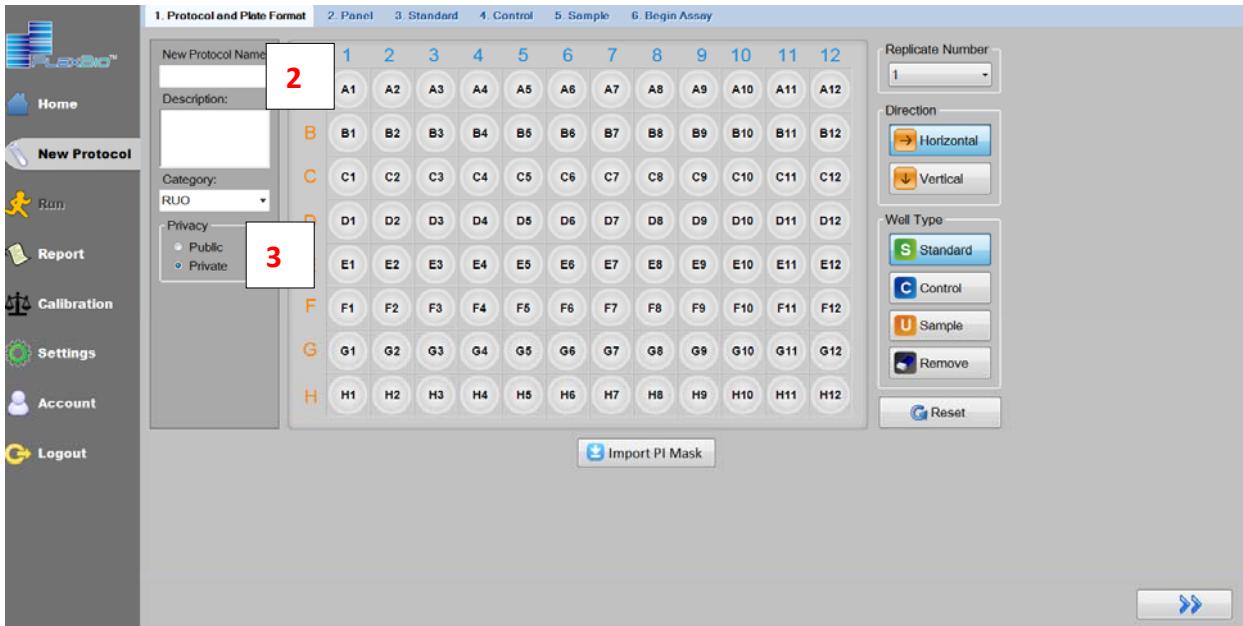


Figure 37. New Protocol/ Protocols and Plate Format

- Step 2. Type in **Protocol Name**, **Description**, and **Category**. The Category function can be used to organize protocols.
- Step 3. Users can also set protocols as **Public** or **Private**.

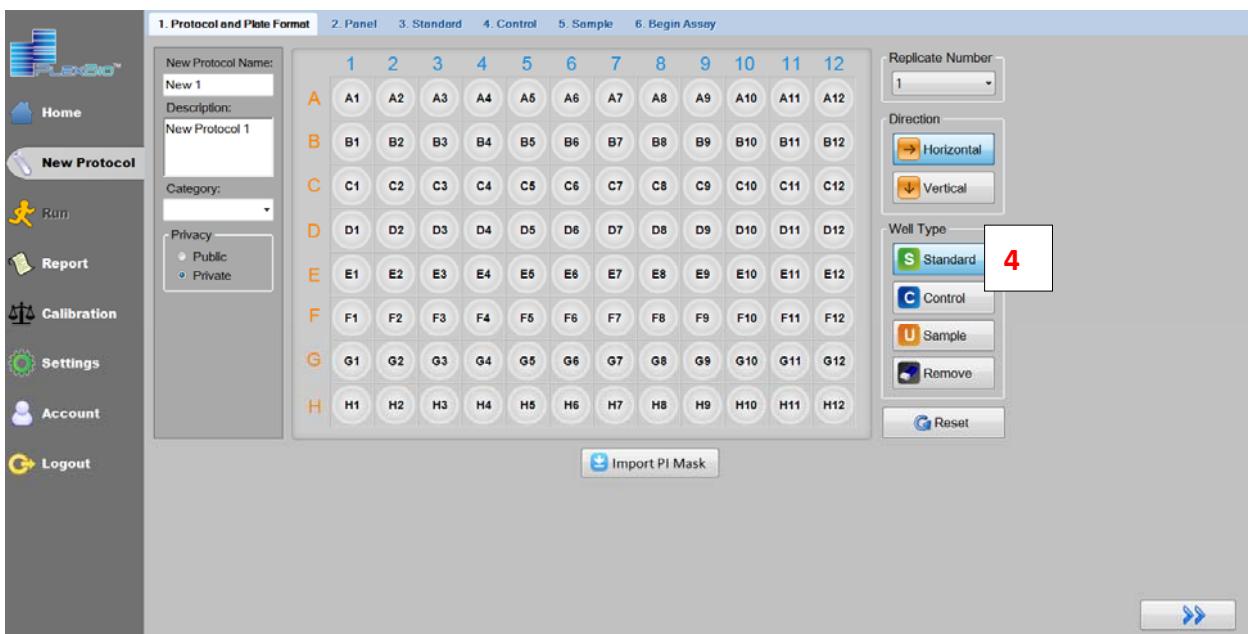


Figure 38. New Protocol/Protocols and Plate Format/Selection of Standard wells

- Step 4. Click on **S Standard**.
- Step 5. Select the wells by clicking and dragging. In this case, wells A1-E1 have been selected. Users can also choose a replicate number. In the example, the replicate number is 1 and the standards are displayed as S1-S5 from A1-E1.

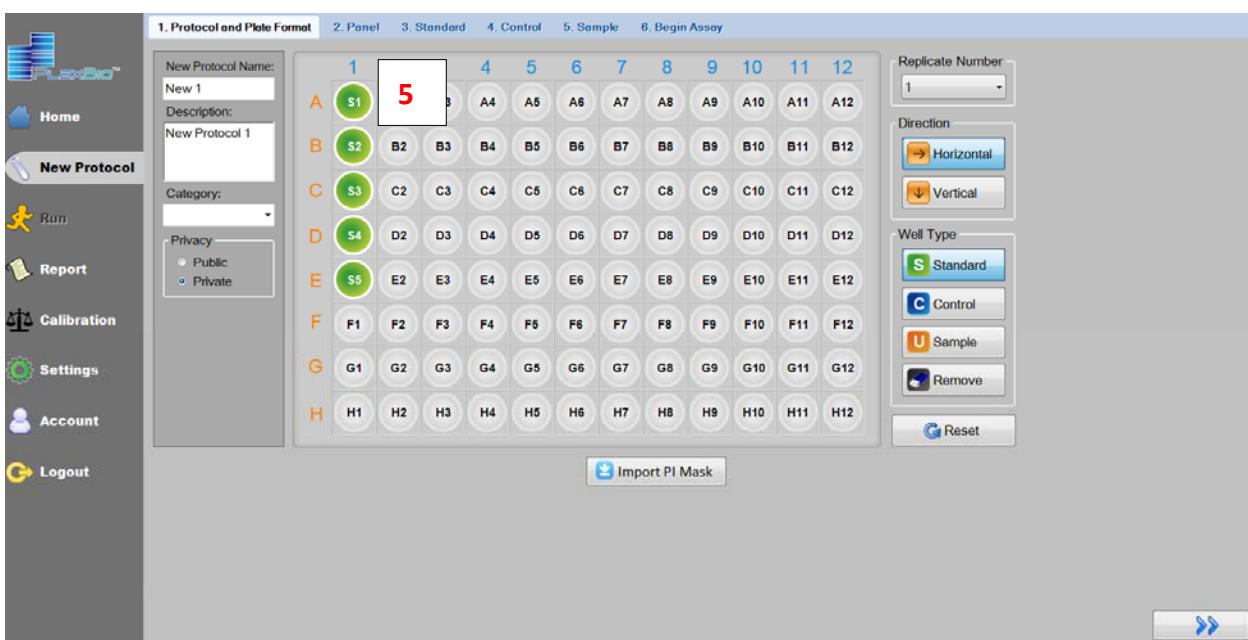


Figure 39. New Protocol/ Protocols and Plate Format/Selection of Standard wells

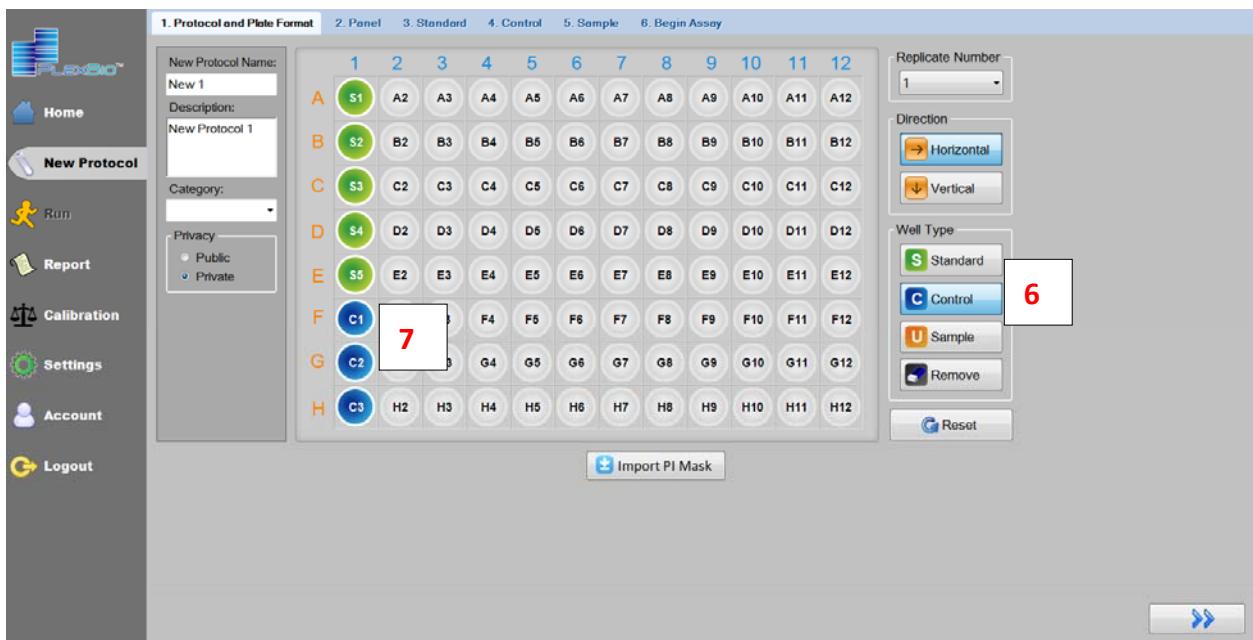


Figure 40. New Protocol/ Protocols and Plate Format/Selection of Control wells

Step 6. Click on **C Control**.

Step 7. Select the wells by clicking and dragging. In this example, wells F1-H1 have been selected. The replicate number is 1 and the controls are displayed as C1-C3 from F1-H1.

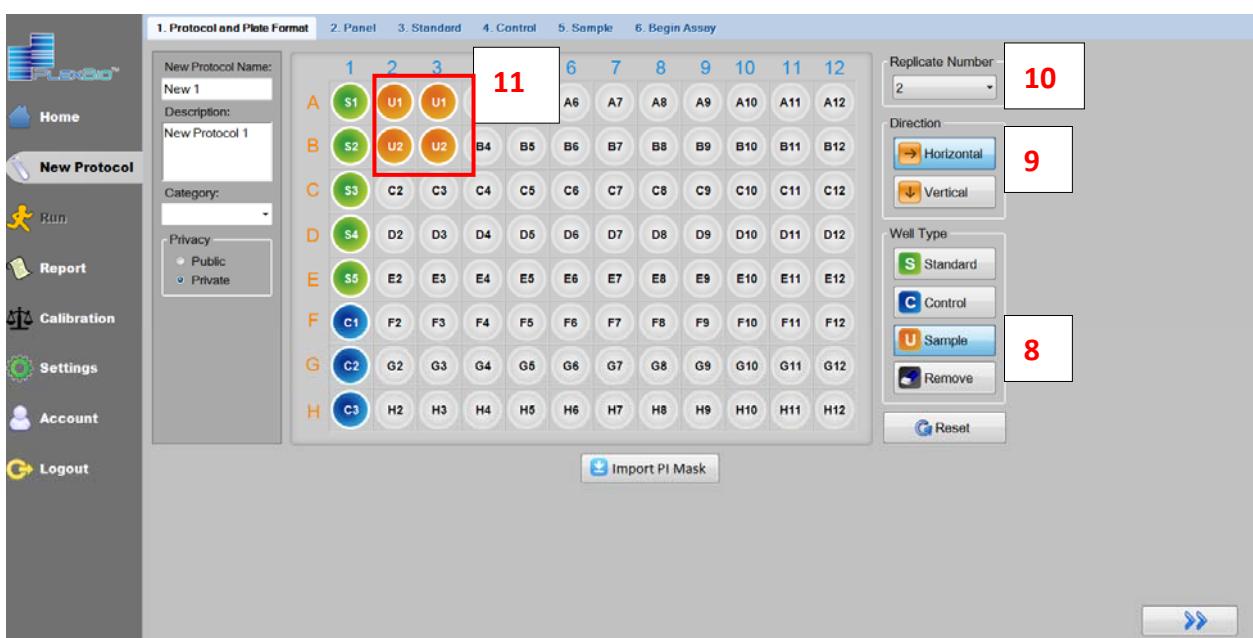


Figure 41. New Protocol/ Protocols and Plate Format/Selection of Sample wells using “Horizontal”

Step 8. Click on **U Sample**.

Step 9. Click on **Horizontal** in Direction.

Step 10. In the example, the replicate number is changed to 2.

Step 11. Select wells from A2 to B3. Because of  Horizontal, wells A2 and A3 will be labeled as Sample 1 (U1) and wells B2 and B3 as Sample 2 (U2).

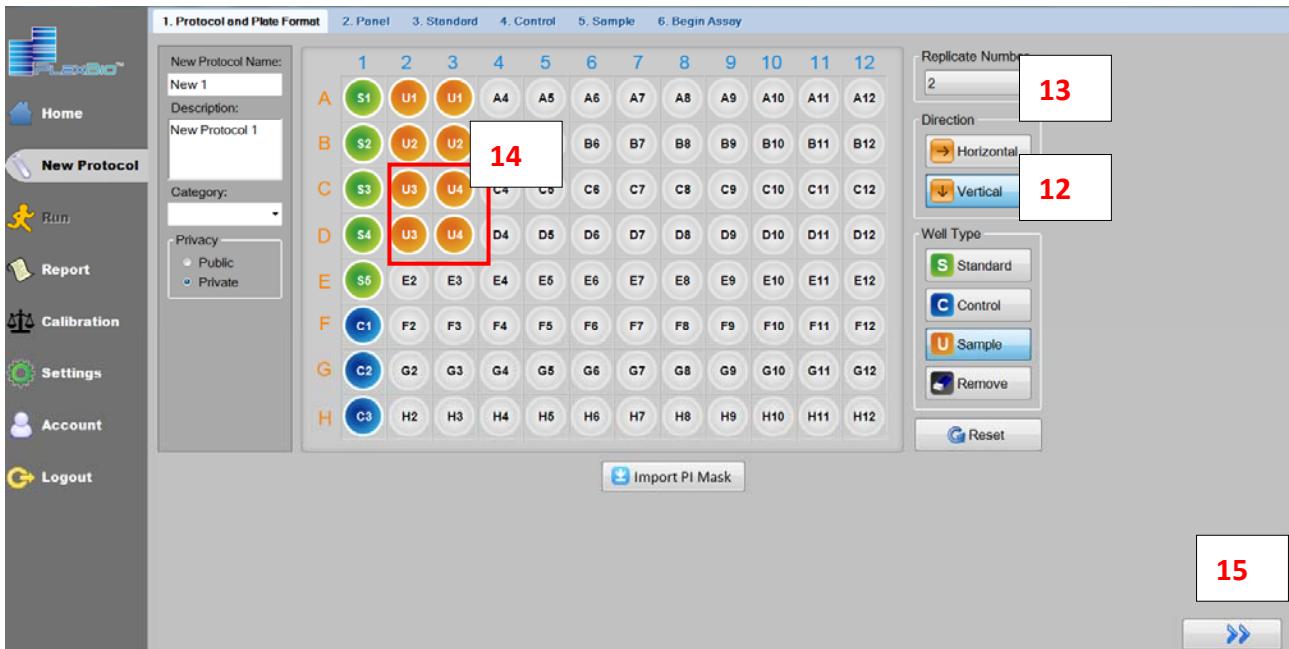
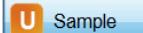


Figure 42. New Protocol/ Protocols and Plate Format/Selection of Sample wells using “Vertical”

Step 12. Under  Sample, click on  Vertical.

Step 13. Make sure “Replicate Number” is 2.

Step 14. Drag from C2 to D3. Because of  Vertical, wells C2 and D2 will be labeled Sample 3 (U3) and wells C3 and D3 will be labeled Sample 4 (U4).

Step 15. Click on  to go to the next page.

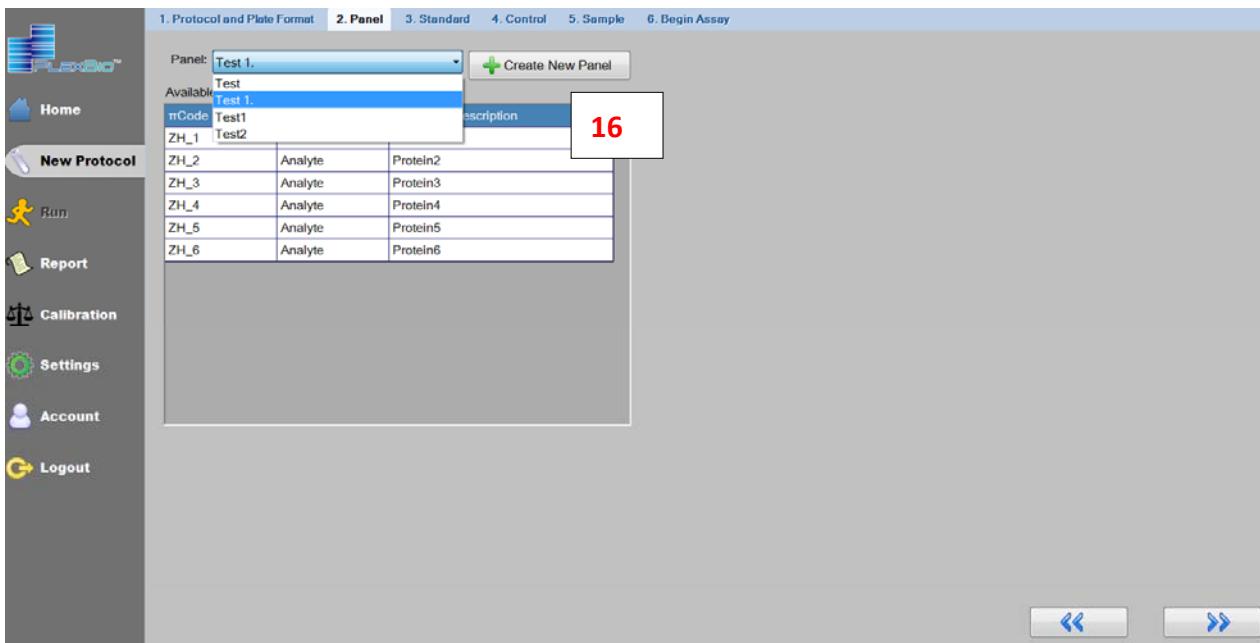


Figure 43. New Protocol/ Panel/Selection of previous panels

- Step 16. Users can select previous panels by clicking on the blank part of “Panel”. Please see Figure 43. In this case, the panel “Test1” was previously saved or used. Therefore, “Test 1” can be selected for use.

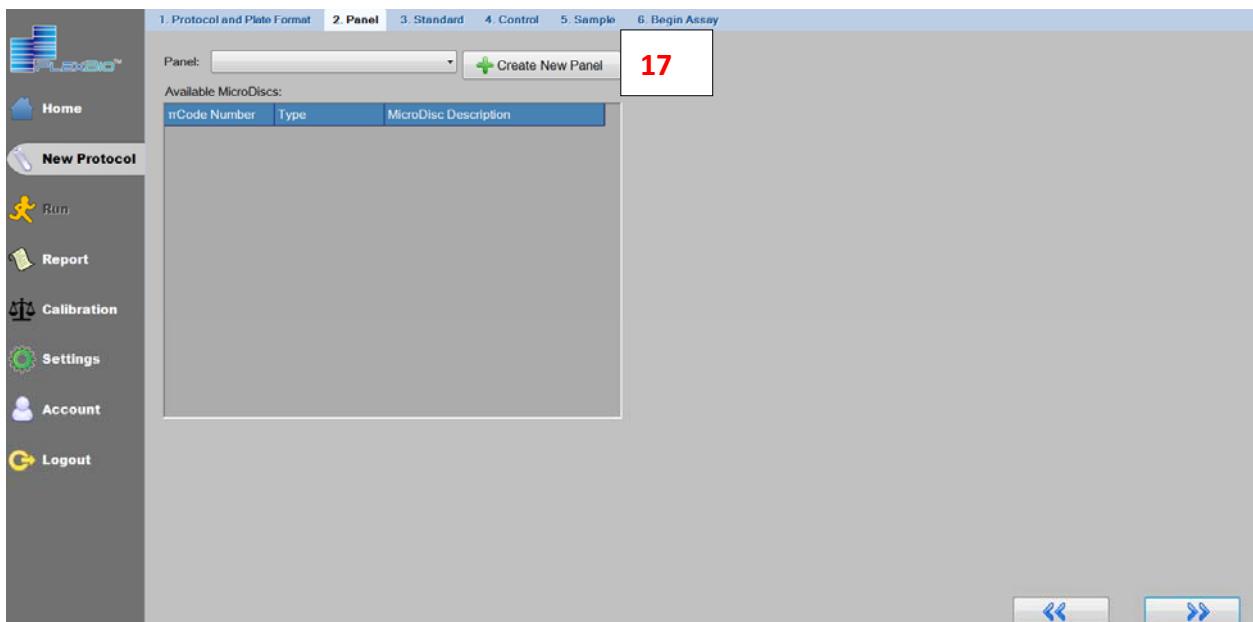


Figure 44. New Protocol/ Panel

- Step 17. Click on if user wants to create a new panel, panel setting window will be shown as Fig. 45.

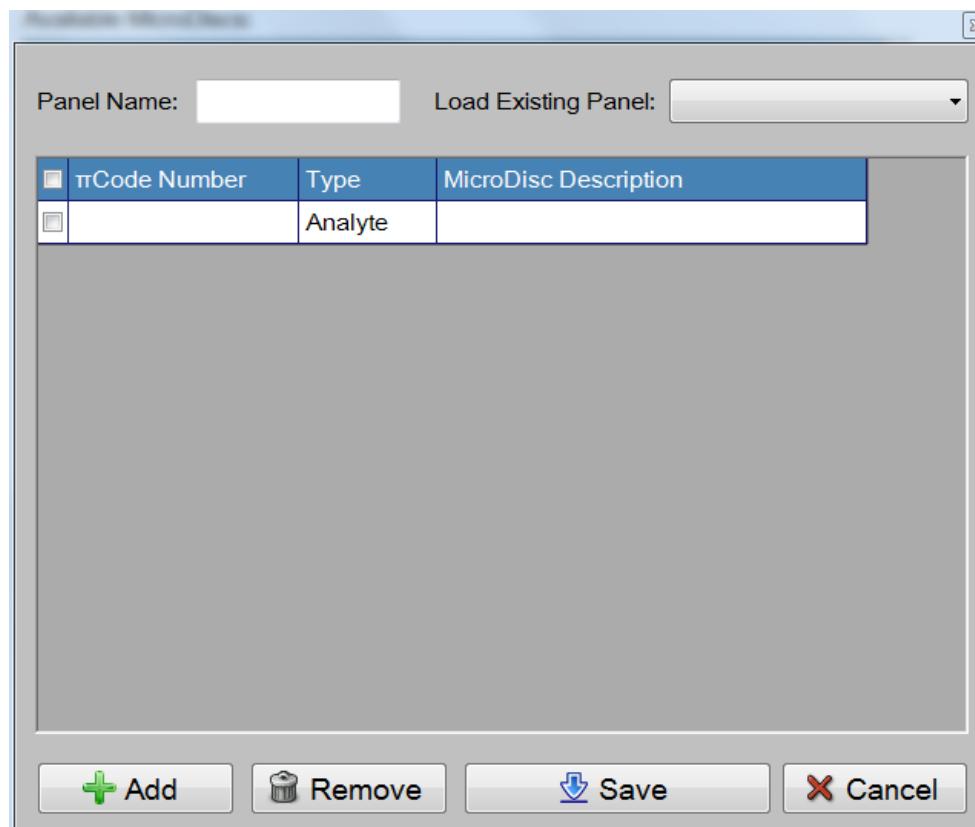


Figure 45. Create New Panel

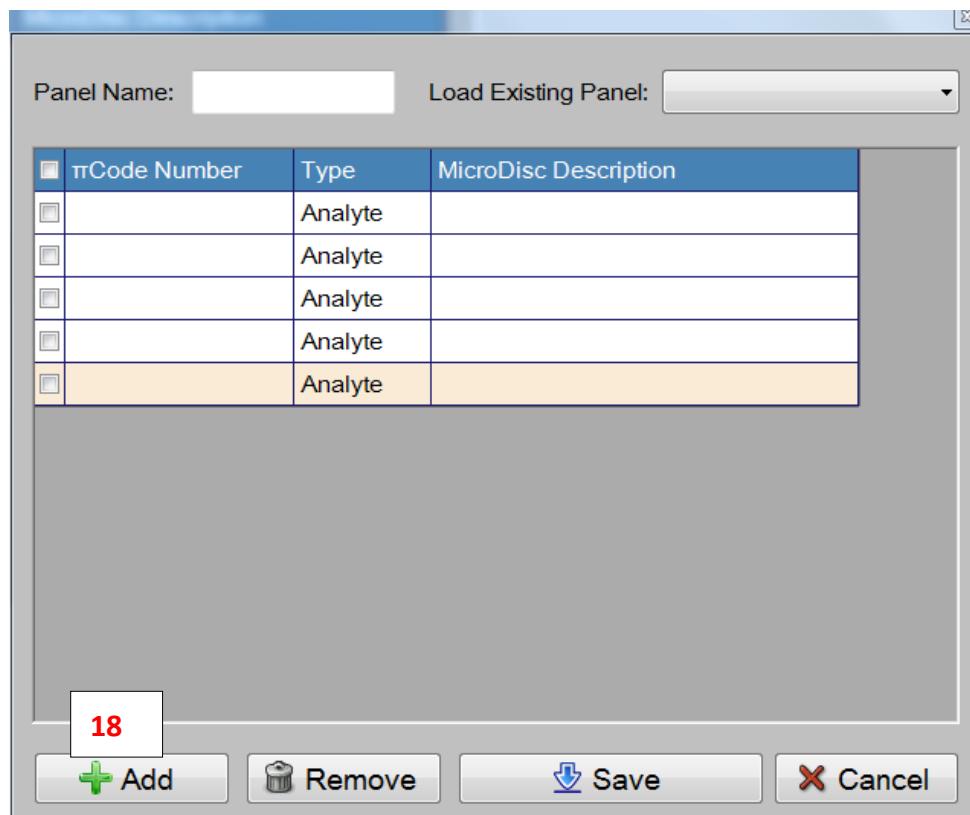


Figure 46. Create New Panel

Step 18. Clicking on to add a new row .

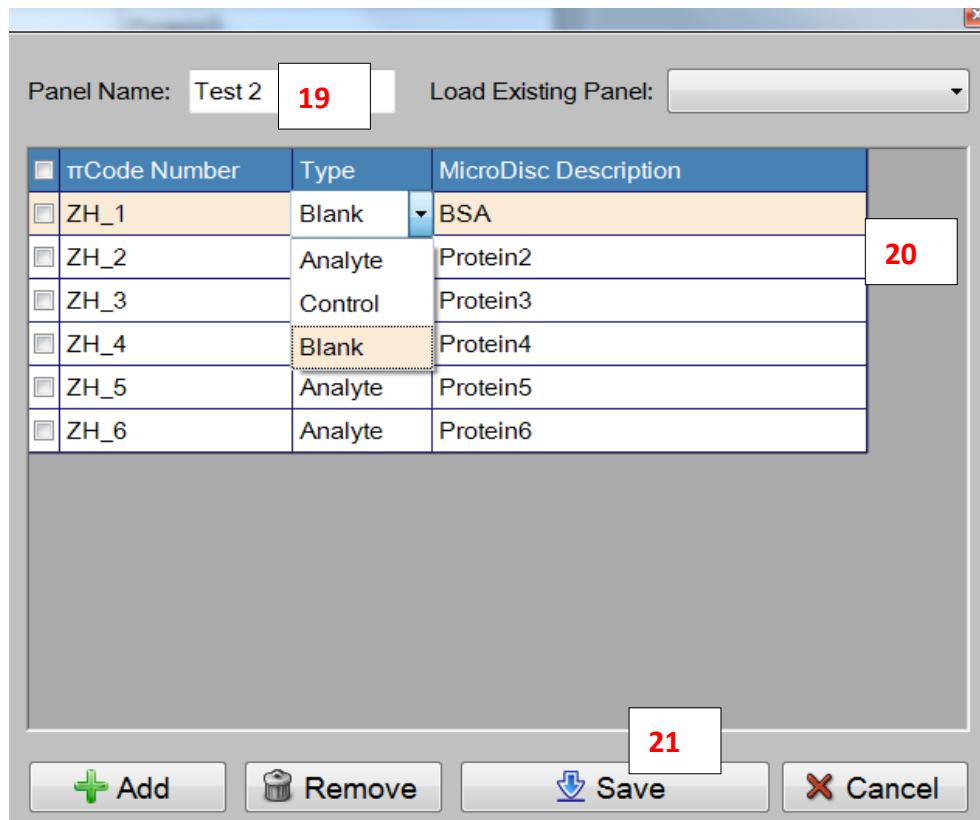


Figure 47. Create New Panel/ Type in panel info

Step 19. Enter **Panel name**. In this case, the panel name is “Test 2”.

Step 20. Enter **πCode™ Number**, **Type**, and **πCode™ Description**. There are three types to choose from: Analyte, Control, and Blank.

NOTE: Please follow the πCode™ number on the label provided to enter **the πCode™ Number** information. If it is labelled as ZH-01, please enter ZH_1 ; If it is labelled as ZA-10, please enter ZA_10, and so on.

Step 21. Click on **Save**. The “Information Message” window will appear.

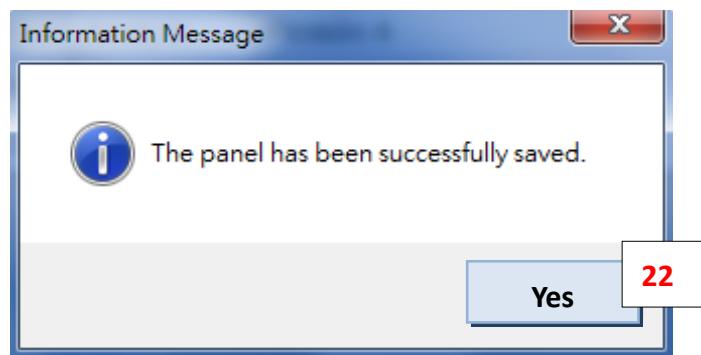


Figure 48. Information Message

Step 22. Click on “Yes” to exit the “Create New Panel” window.

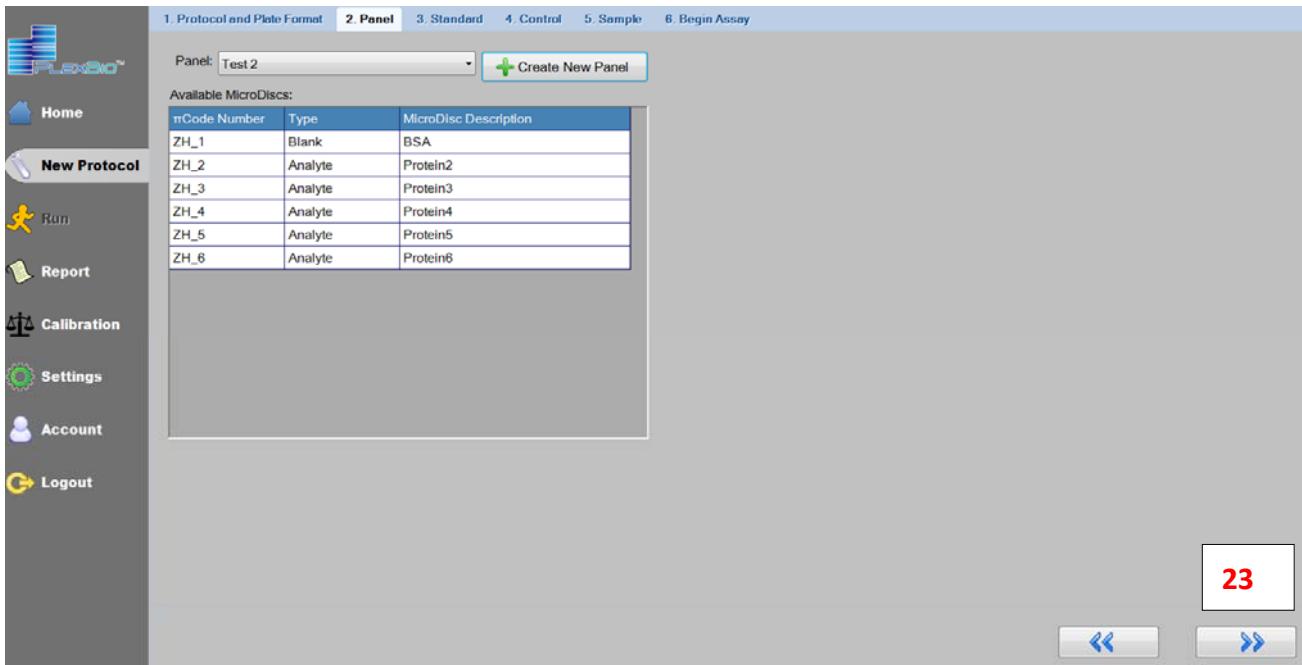


Figure 49. New Protocol/ Panel

Step 23. The newly created panel will be displayed on this screen. Click on to go to the next page.

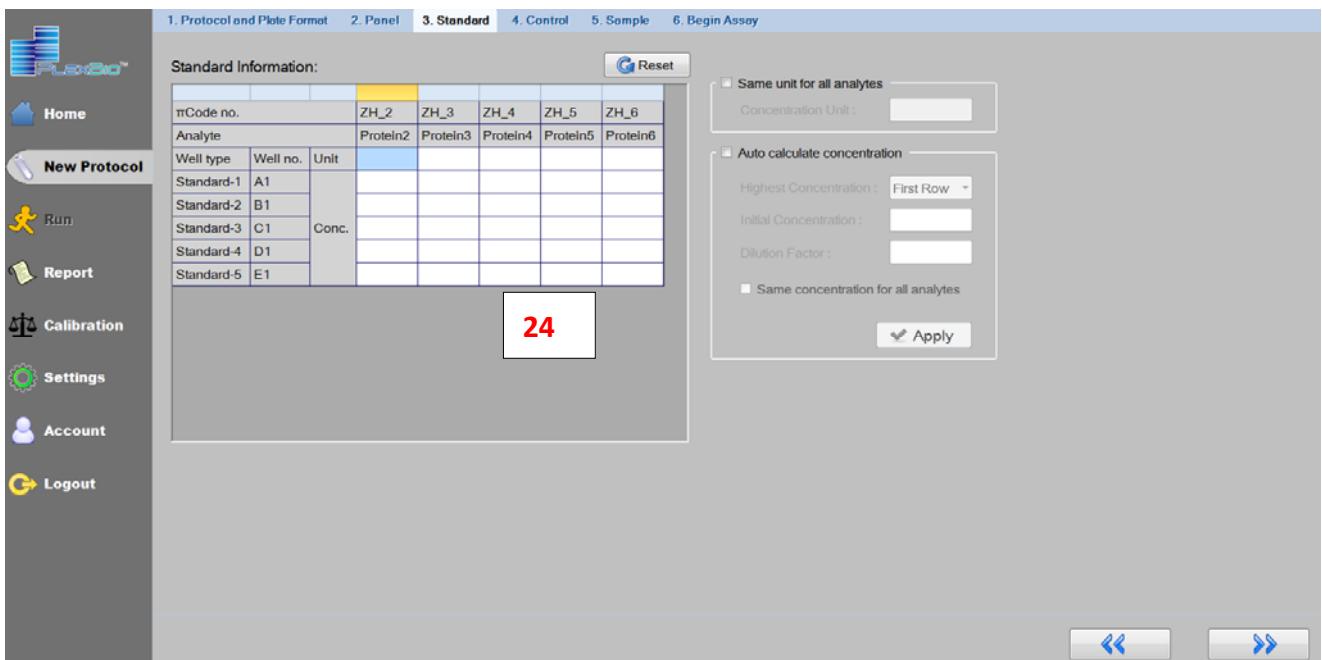


Figure 50. New Protocol/ Standard

Step 24. Units and concentrations for each analyte can be typed directly in the table or applied to multiple analytes using the tool on the right side of the screen. Please see Step 26 and Figure 51.

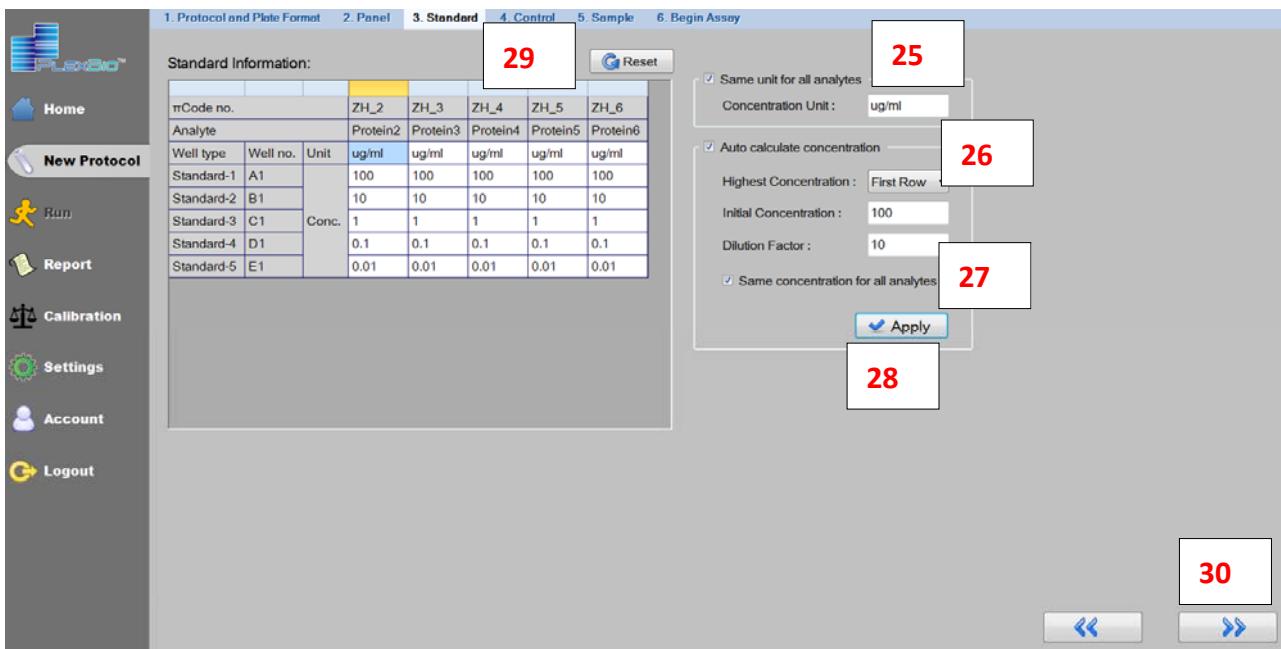


Figure 51. New Protocol/ Standard

Step 25. Click on Same unit for all analytes and type in Concentration Unit. In this example, the unit is “ug/ml”.

Step 26. Click on Auto calculate concentration. In this case, we select “Highest Concentration: First Row”, and enter Initial Concentration and Dilution Factor.

Step 27. If all analytes have the same concentration, check Same concentration for all analytes.

Step 28. Click on Apply to apply all settings.

Step 29. The settings will appear in the table on the left and can be edited if necessary. Click on Reset to reset all standard settings.

Step 30. Click on to go to the next page.

Control Information: **31**

| mCode no. | ZH_2 | ZH_3 | ZH_4 | ZH_5 | ZH_6 |
|-----------|----------|----------|----------|----------|----------|
| Analyte | Protein2 | Protein3 | Protein4 | Protein5 | Protein6 |
| Well type | Well no. | Unit | | | |
| Control-1 | F1 | | | | |
| Control-2 | G1 | Conc. | | | |
| Control-3 | H1 | | | | |

Same unit for all analytes
Concentration Unit :

Auto calculate concentration
Highest Concentration : First Row
Initial Concentration :
Dilution Factor :
 Same concentration for all analytes
 Apply

Save Protocol | << | >>

Figure 52. New Protocol/ Control

Step 31. **Control Information** can be entered similarly to **Standard Information** (see Steps 24-30).

Control Information: **32**

| mCode no. | ZH_2 | ZH_3 | ZH_4 | ZH_5 | ZH_6 |
|-----------|----------|----------|----------|----------|----------|
| Analyte | Protein2 | Protein3 | Protein4 | Protein5 | Protein6 |
| Well type | Well no. | Unit | ug/ml | ug/ml | ug/ml |
| Control-1 | F1 | | 100 | 100 | 100 |
| Control-2 | G1 | Conc. | 10 | 10 | 10 |
| Control-3 | H1 | | 1 | 1 | 1 |

Same unit for all analytes
Concentration Unit : ug/ml

Auto calculate concentration
Highest Concentration : First Row
Initial Concentration : 100
Dilution Factor : 10
 Same concentration for all analytes
 Apply

Save Protocol | << | >>

Figure 53. New Protocol/ Control/After typed in Control Information

Step 32. Click on Save Protocol and confirm when the dialog appears.

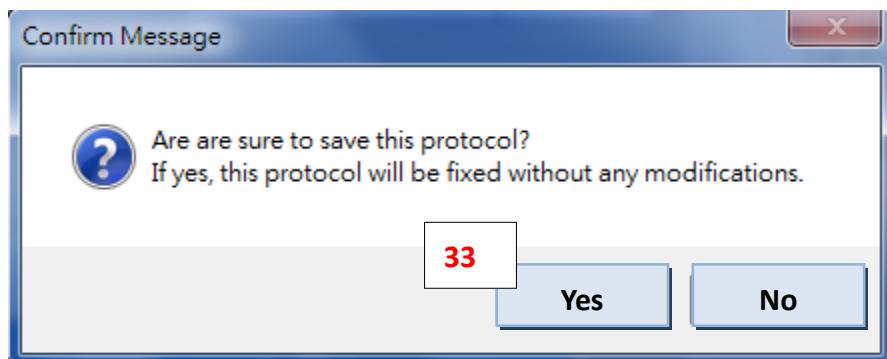
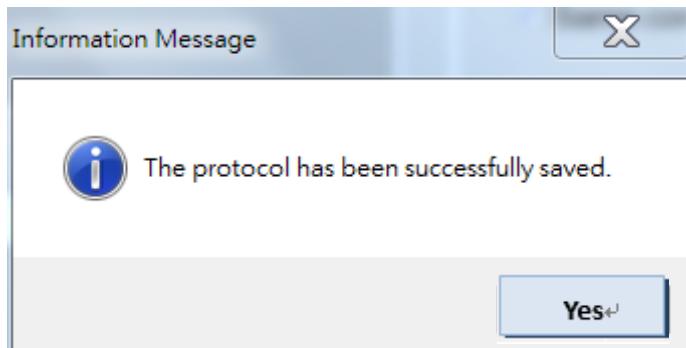


Figure 54. "Confirm Message" window

Step 33. Click "Yes" to save this protocol.



Note: Saved protocols will be kept in the database and can be loaded to run again or modified into a new protocol.

Note: The protocol info includes Standard Information and Control Information.

A screenshot of the PlexBio software interface. On the left is a vertical menu bar with icons for Home, New Protocol, Run, Report, Calibration, Settings, Account, and Logout. The main workspace is titled 'Control Information:' and contains a table for 'Control MicroDiscs Setting:'. The top navigation bar includes tabs for 1. Protocol and Plate Format, 2. Panel, 3. Standard, 4. Control (which is selected), 5. Sample, and 6. Begin Assay. A red rectangular callout box labeled '34' is positioned in the bottom right corner of the main window.

Figure 55. New Protocol/ Control

Step 34. Click on to go to the next page.

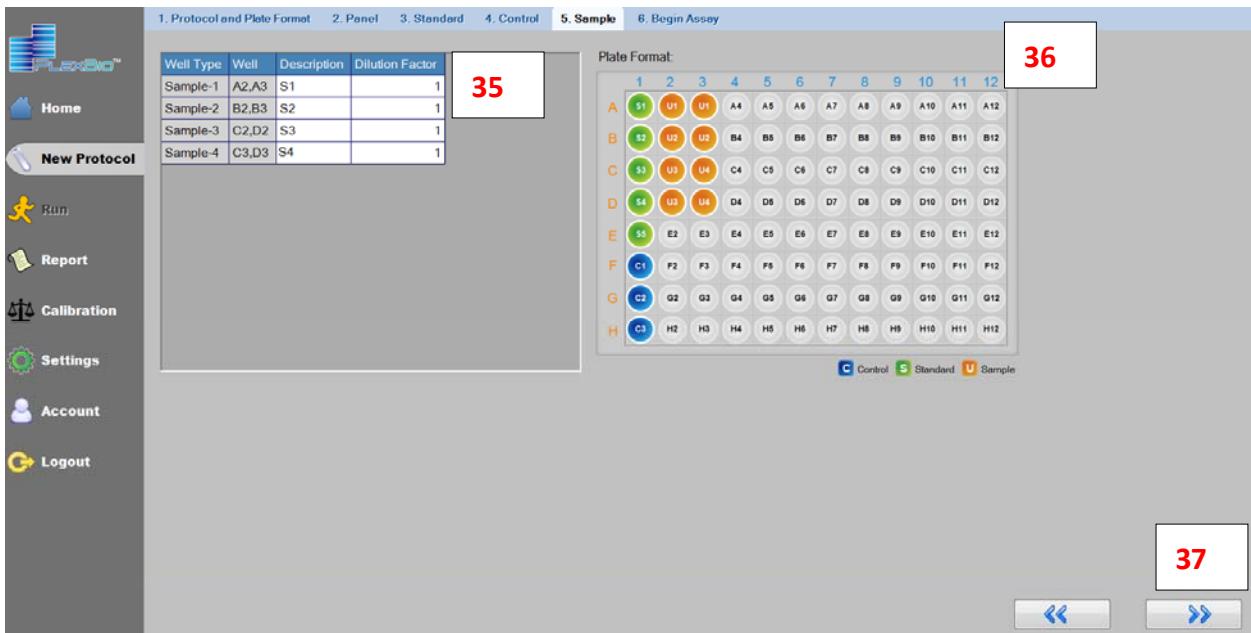


Figure 56. New Protocol/ Sample

Step 35. Type in sample **Description** and **Dilution Factor**.

Step 36. Confirm the plate format.

Step 37. Click on to go to the next page.

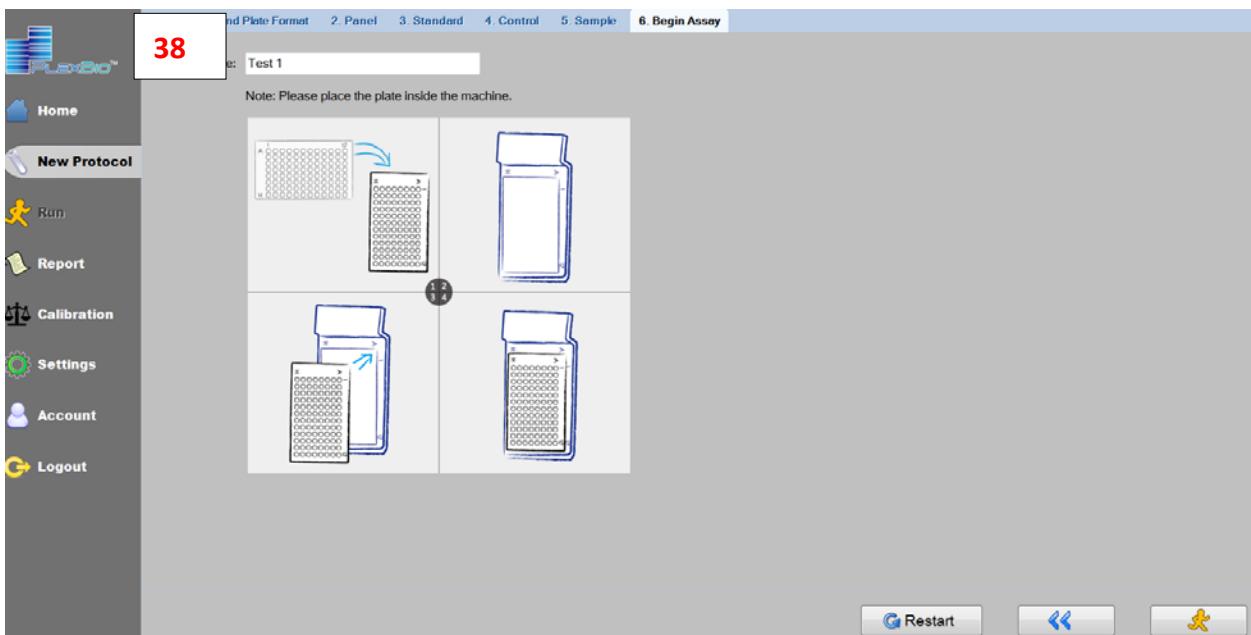


Figure 57. New Protocol/ Begin Assay

Step 38. “New Protocol/Begin Assay” will be the same as “Quick Read/Begin Assay”. Follow the steps in the “Quick Read” section to begin reading.

5.8 Load Protocol

The Load Protocol function allows users to use previously created protocols or modify existing protocols.

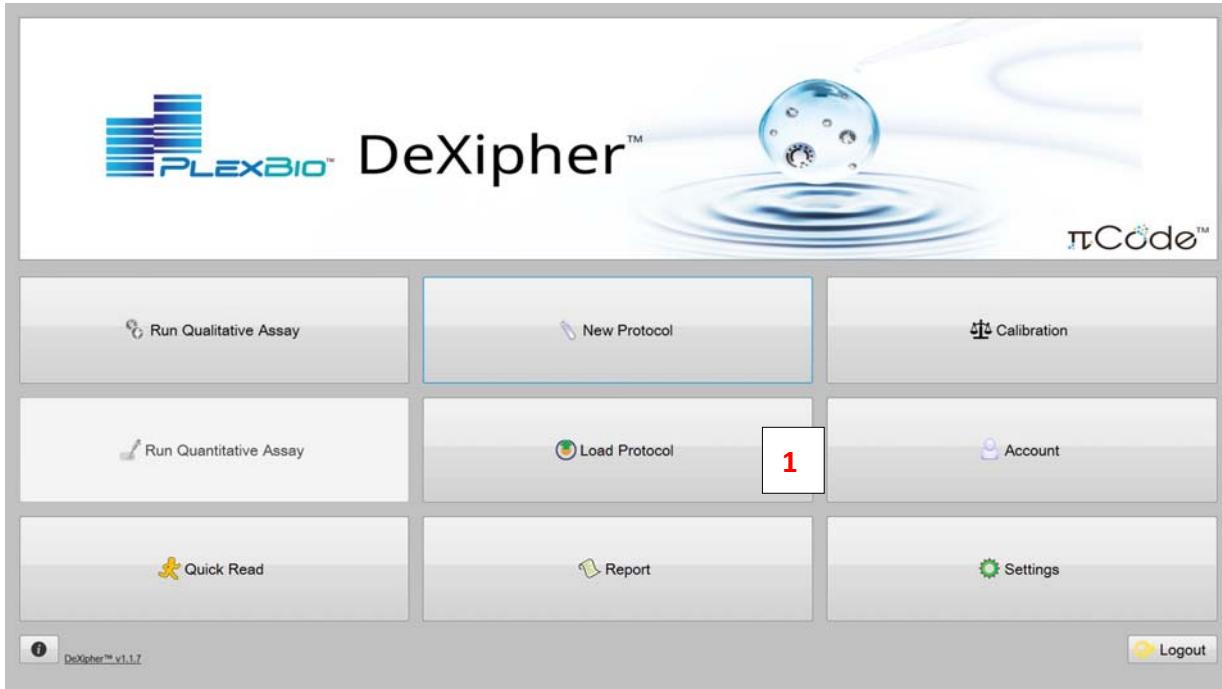


Figure 58. DeXipher™ homepage

Step 1. Click on **Load Protocol** on the DeXipher™ homepage.

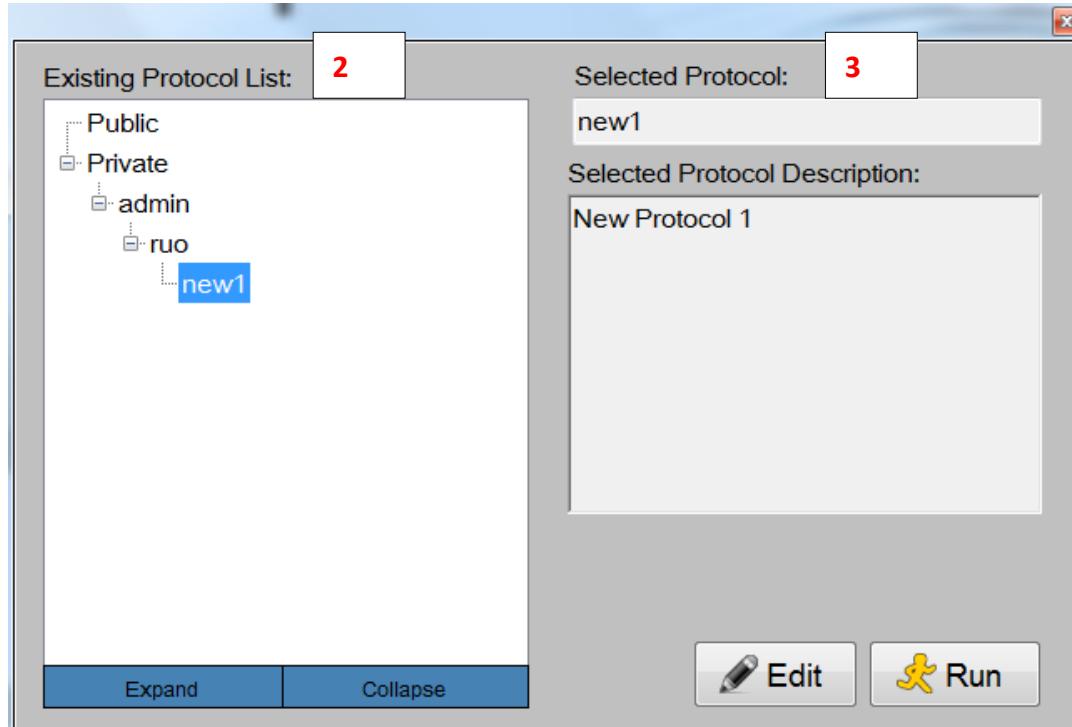


Figure 59. "Load Existing Protocol" window

- Step 2. Select the existing protocol in “Existing Protocol List”. In this case, “new 1” is selected.
Step 3. Protocol name and description of the selected protocol will be displayed on the right.
Step 4. Users can click on  to edit existing protocols (see 5.8.1) or click on  to run the existing protocols (see 5.8.2).

5.8.1 Load Protocol/Edit Existing Protocol

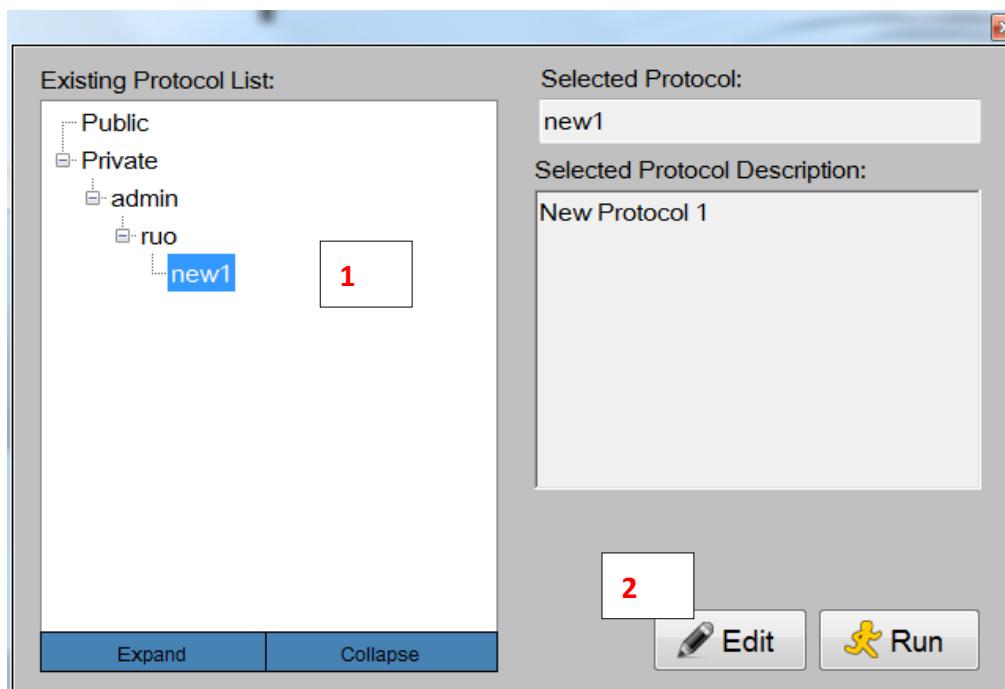


Figure 60. “Load Existing Protocol” window/Edit Protocol

Step 1. Click on the existing protocol. In this case, “new 1” is selected.

Step 2. Click on .

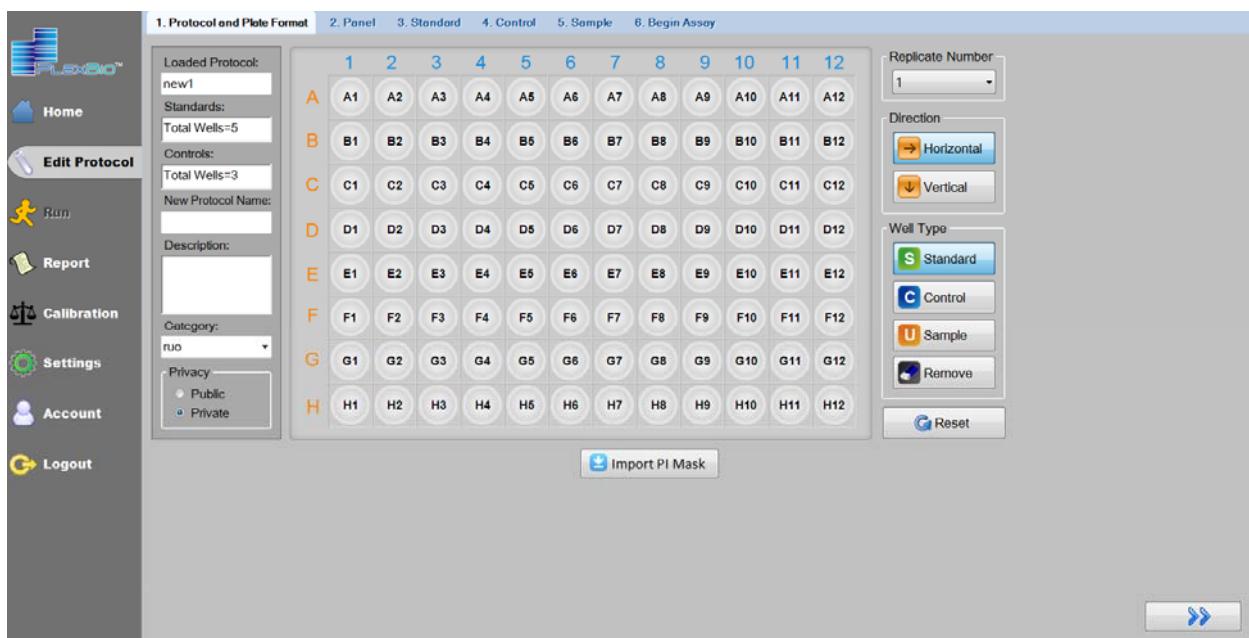


Figure 61. Edit Protocol/ Protocol and Plate Format

- Step 3. DeXipher™ displays the standard and control information of the loaded protocol. In this case, the loaded protocol is “new 1” and it has 5 standard wells and 3 control wells.
- Step 4. “**New Protocol Name**” must be entered before going to the next step.

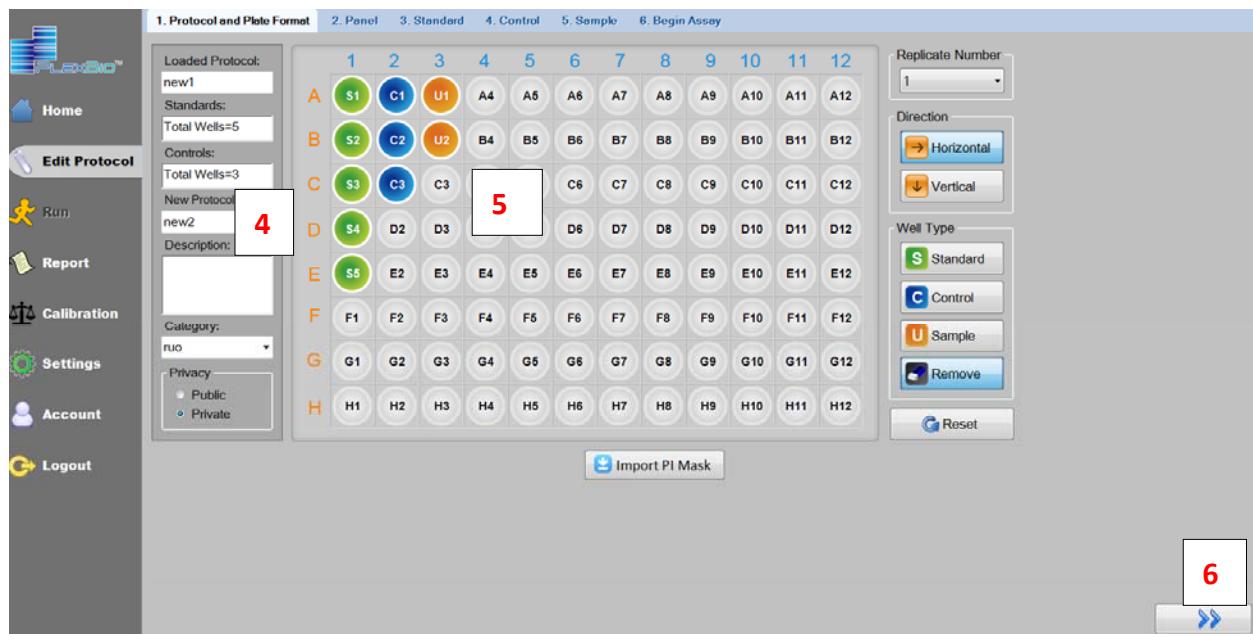


Figure 62. Edit Protocol/ Protocol and Plate Format/ Select wells

- Step 5. Users can format the well according to the loaded protocol or modify the protocol as needed.

Step 6. Click on to go to the next page.

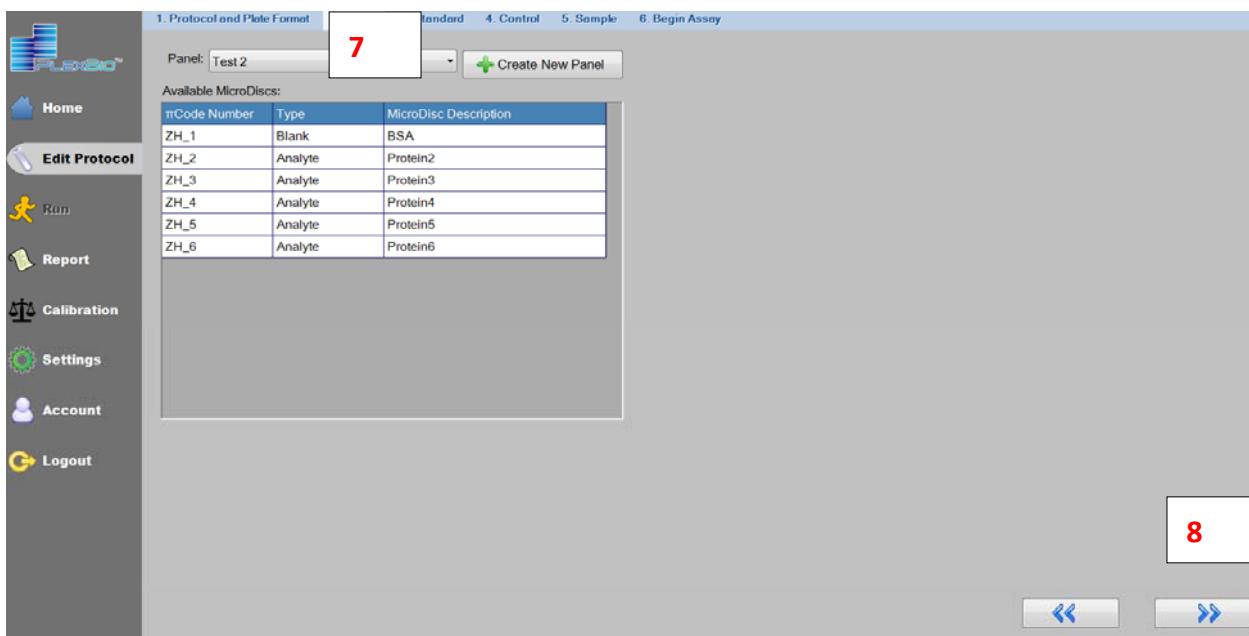


Figure 63. Edit Protocol/ Panel

Step 7. Users can use the same panel as the original protocol or modify the panel by loading a different panel or creating a new panel with . The process is similar to “New Protocol. Panel”.

Step 8. Click on to go to the next page.

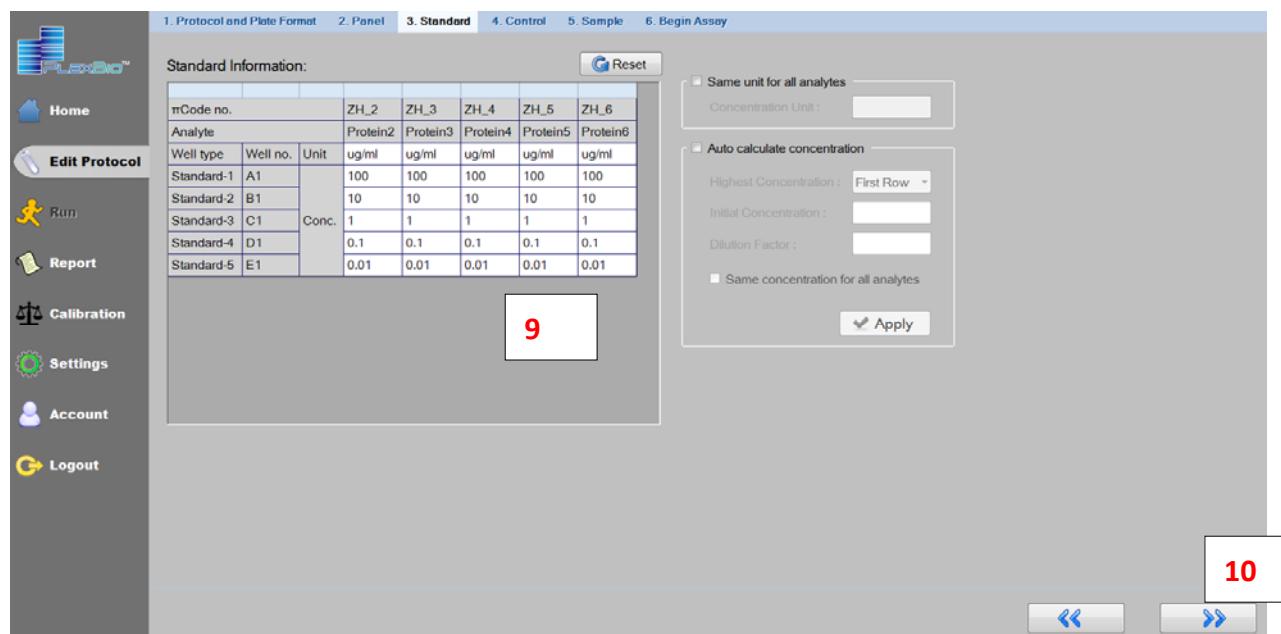


Figure 64. Edit Protocol/ Standard

Step 9. Users can keep the information from the original protocol or modify the Standard information.

Step 10. Click on to go to the next page.

| mCode no. | ZH_2 | ZH_3 | ZH_4 | ZH_5 | ZH_6 |
|-----------|----------|----------|----------|----------|----------|
| Analyte | Protein2 | Protein3 | Protein4 | Protein5 | Protein6 |
| Well type | A2 | | | | |
| Control-1 | A2 | 100 | 100 | 100 | 100 |
| Control-2 | B2 | 10 | 10 | 10 | 10 |
| Control-3 | C2 | 1 | 1 | 1 | 1 |

Control MicroDiscs Setting:

| mCode No. | MicroDisc Descrip | Condition | MFI |
|-----------|-------------------|-----------|-----|
|-----------|-------------------|-----------|-----|

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Figure 65. Edit Protocol/ Control

Step 11. Users can keep the information of the loaded protocol or modify the Control Information.

Step 12. Click on to go to the next page.

| Well Type | Well | Description | Dilution Factor |
|-----------|------|-------------|-----------------|
| Sample-1 | A3 | | 1 |
| Sample-2 | B3 | | 1 |

Type in Sample
Description

Type in Dilution
Factor

Plate Format:

| | | | | | | | | | | | | | | |
|---|----|----|----|----|----|----|----|----|-----|-----|-----|-----|-----|-----|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | | | |
| A | S1 | C1 | U1 | A2 | A3 | A4 | A5 | A6 | A7 | A8 | A9 | A10 | A11 | A12 |
| B | S2 | C2 | U2 | B4 | B5 | B6 | B7 | B8 | B9 | B10 | B11 | B12 | | |
| C | S3 | C3 | C4 | C5 | C6 | C7 | C8 | C9 | C10 | C11 | C12 | | | |
| D | S4 | D2 | D3 | D4 | D5 | D6 | D7 | D8 | D9 | D10 | D11 | D12 | | |
| E | S5 | E2 | E3 | E4 | E5 | E6 | E7 | E8 | E9 | E10 | E11 | E12 | | |
| F | F1 | F2 | F3 | F4 | F5 | F6 | F7 | F8 | F9 | F10 | F11 | F12 | | |
| G | G1 | G2 | G3 | G4 | G5 | G6 | G7 | G8 | G9 | G10 | G11 | G12 | | |
| H | H1 | H2 | H3 | H4 | H5 | H6 | H7 | H8 | H9 | H10 | H11 | H12 | | |

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Figure 66. Edit Protocol/ Sample

Step 13. Type in sample **Descriptions** and **Dilution Factors**.

Step 14. Confirm the plate format.

Step 15. Click on to go to the next page.

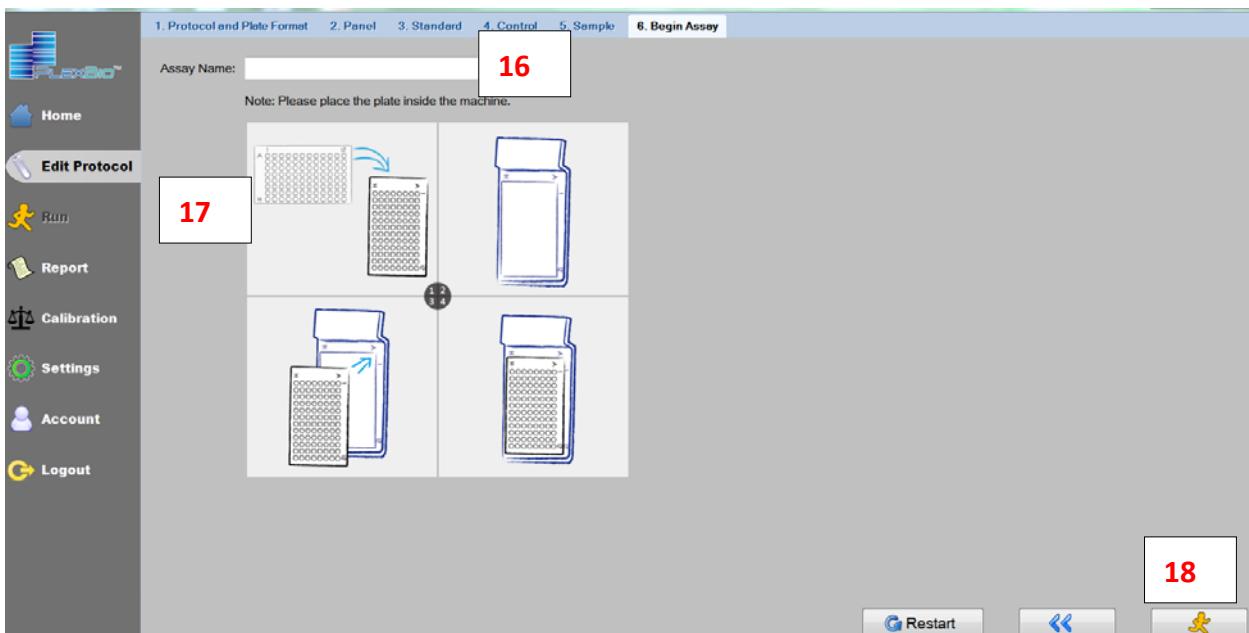


Figure 67. Edit Protocol/ Begin Assay

Step 16. Enter Assay Name. The process is the same as “Quick Read/BEGIN ASSAY”.

Step 17. Follow the drawing to put the 96-well plate onto the stage with correct orientation.

Step 18. Click on to start reading.



Figure 68. Edit Protocol/ Begin Assay/Info Message

Step 19. DeXipher™ will ask you to confirm that the plate is in PlexBio™ 100 system. Click on “OK” to begin reading.

5.8.2 Load Protocol/Run Existing Protocol

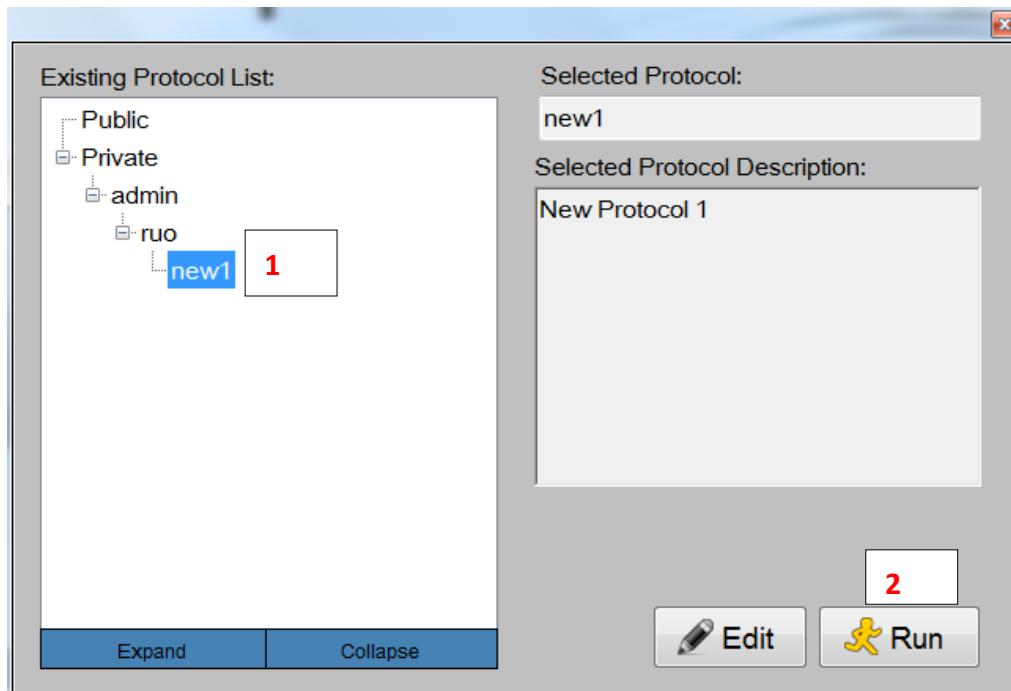


Figure 69. “Load Existing Protocol” window/ Run Protocol

Step 1. Click on the existing protocol. In this case, “new 1” is selected.

Step 2. Click on .

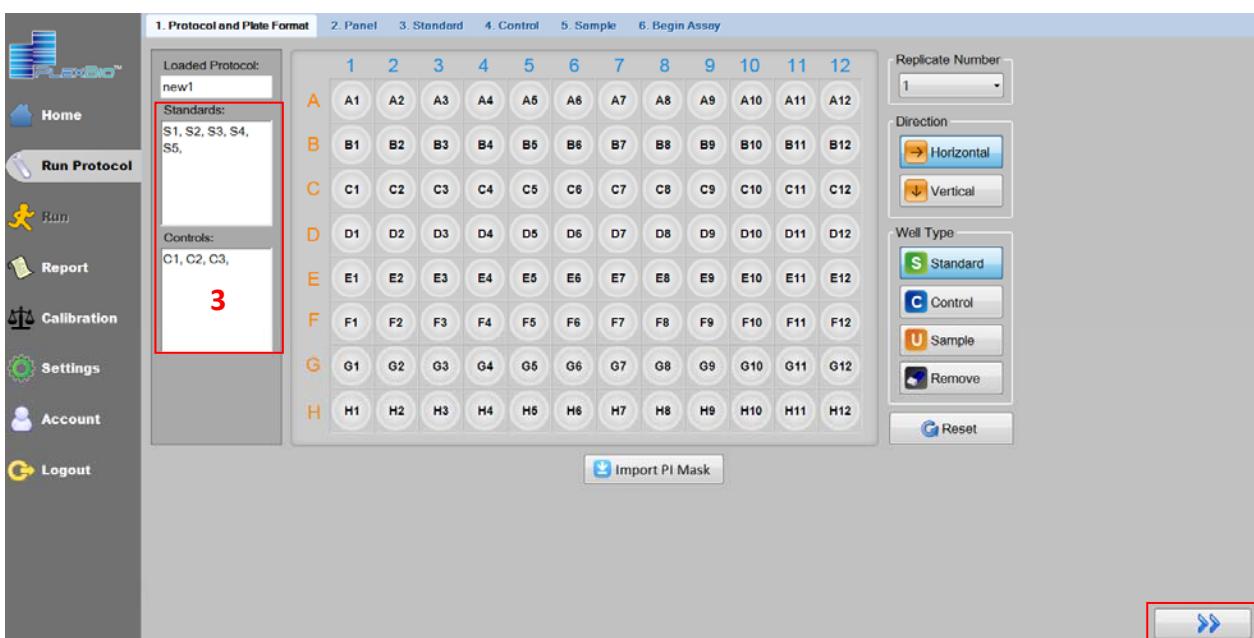


Figure 70. Run Protocol/ Protocol and Plate Format

- Step 3. DeXipher™ will display the details of the loaded protocol (See Figure 70).
- Step 4. Users are required to follow the settings of the loaded protocol when formatting the standards and controls. If the number of standard and control wells in the plate format does not match that of the loaded protocol, a pop-up “Warning Message” window (see Figure 71) will show up asking users to match the format of the loaded protocol.

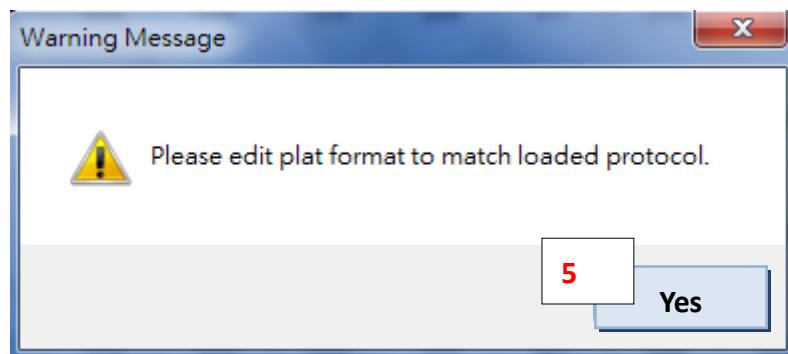


Figure 71. “Warning Message” window

- Step 5. If the warning appears, click on “Yes” to go back to the previous page.

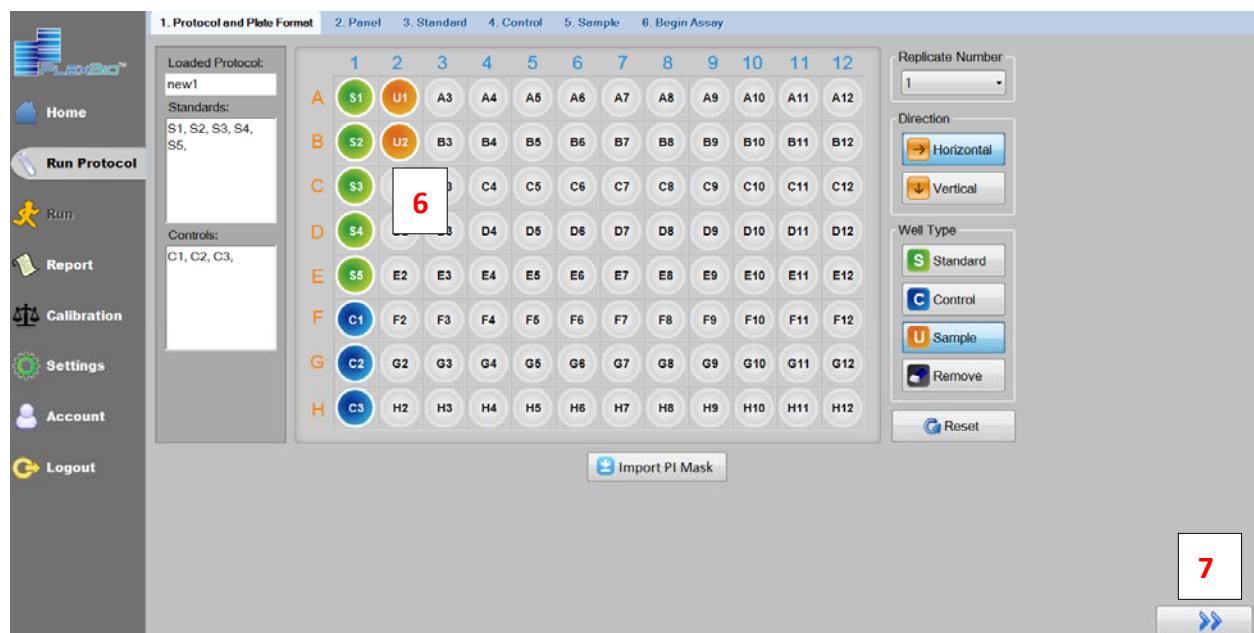


Figure 72. Run Protocol/ Select Standards and Controls as Loaded Protocol

- Step 6. Select standards and controls according to the loaded protocol. In this case, loaded protocol “new 1” has 5 standards and 3 controls. Therefore, 5 standard wells and 3 control wells have been selected. There is no restriction for the location of those wells or for the number of samples. In this example, 2 samples have been selected.

Step 7. Click on  to go to the next page.

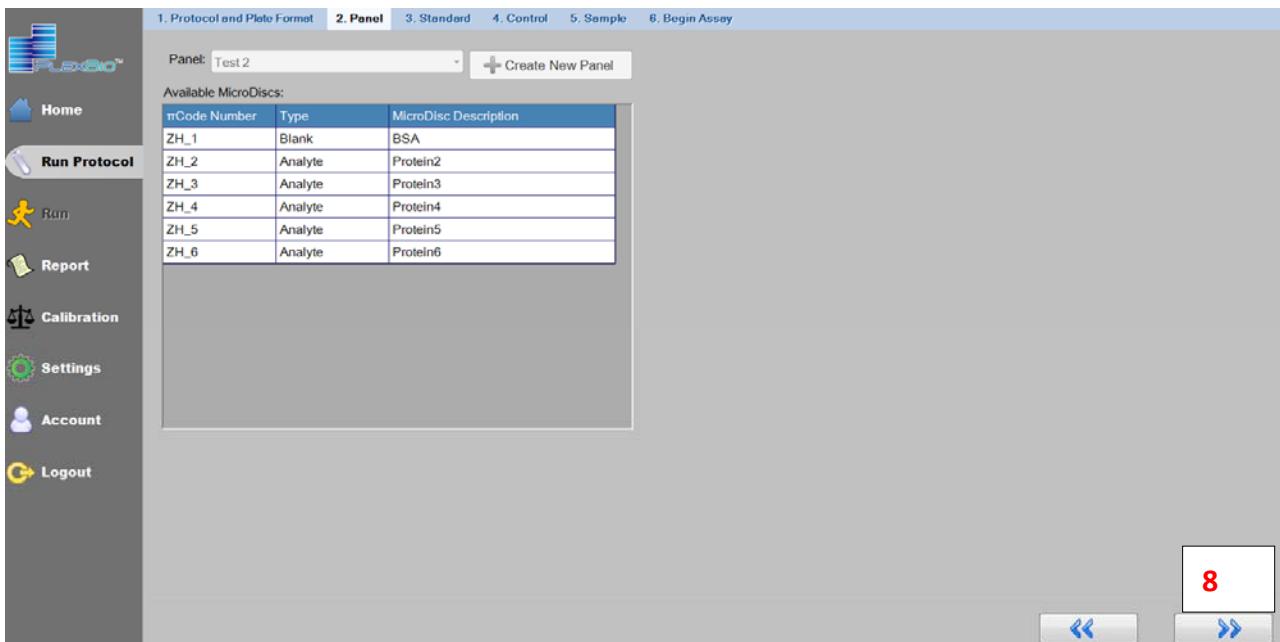


Figure 73. Run Protocol/ Panel

Step 8. Check Panel Information and click on  to go to the next page.

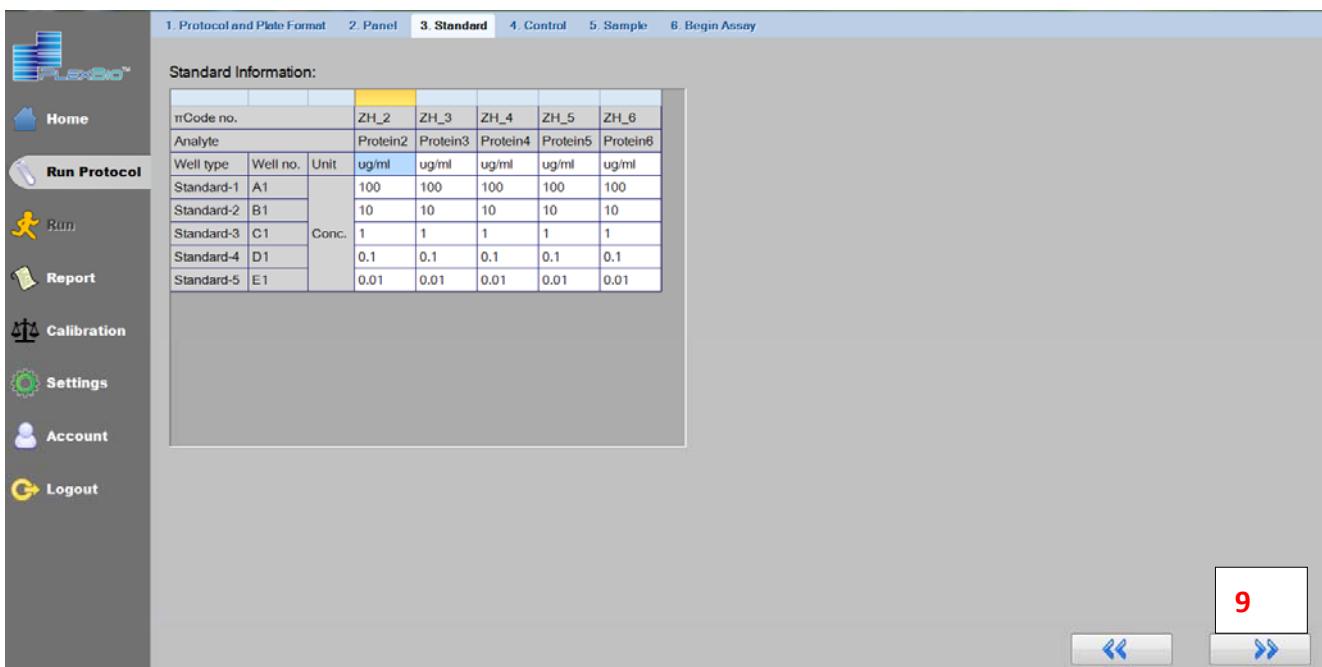


Figure74. Run Protocol/ Standard

Step 9. Check Standard Information and click on  to go to the next page.

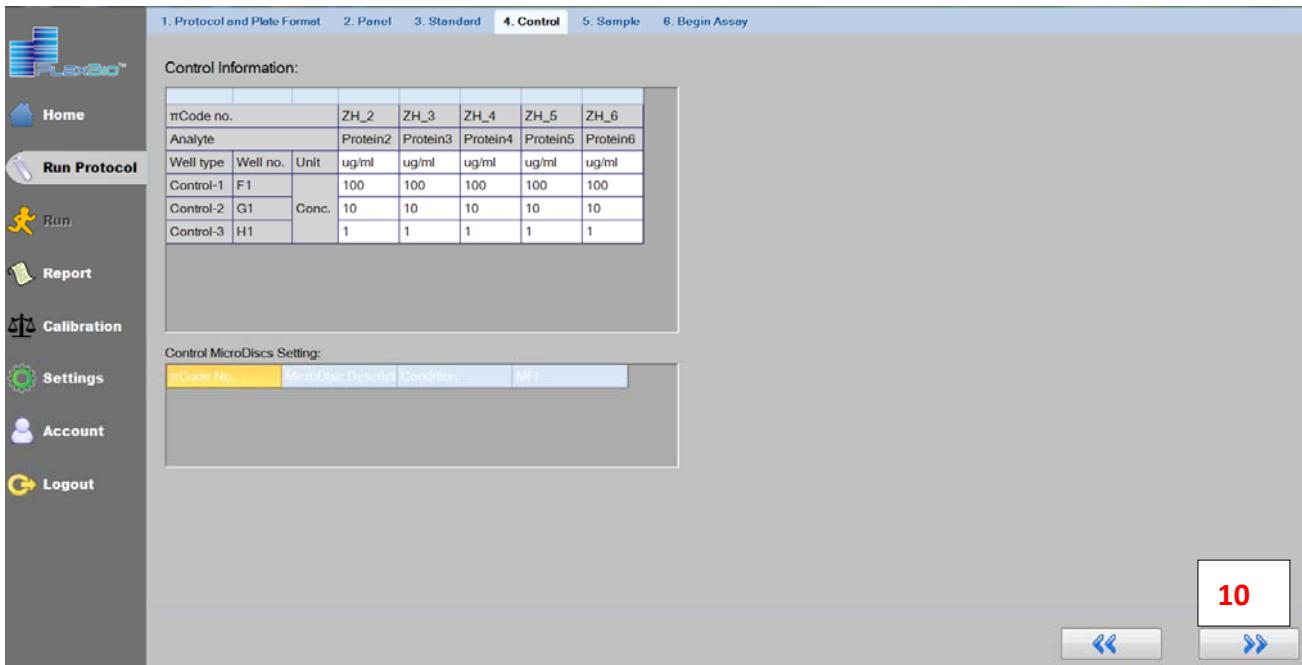


Figure 75. Run Protocol/ Control

Step 10. Check Control Information and click on to go to the next page.

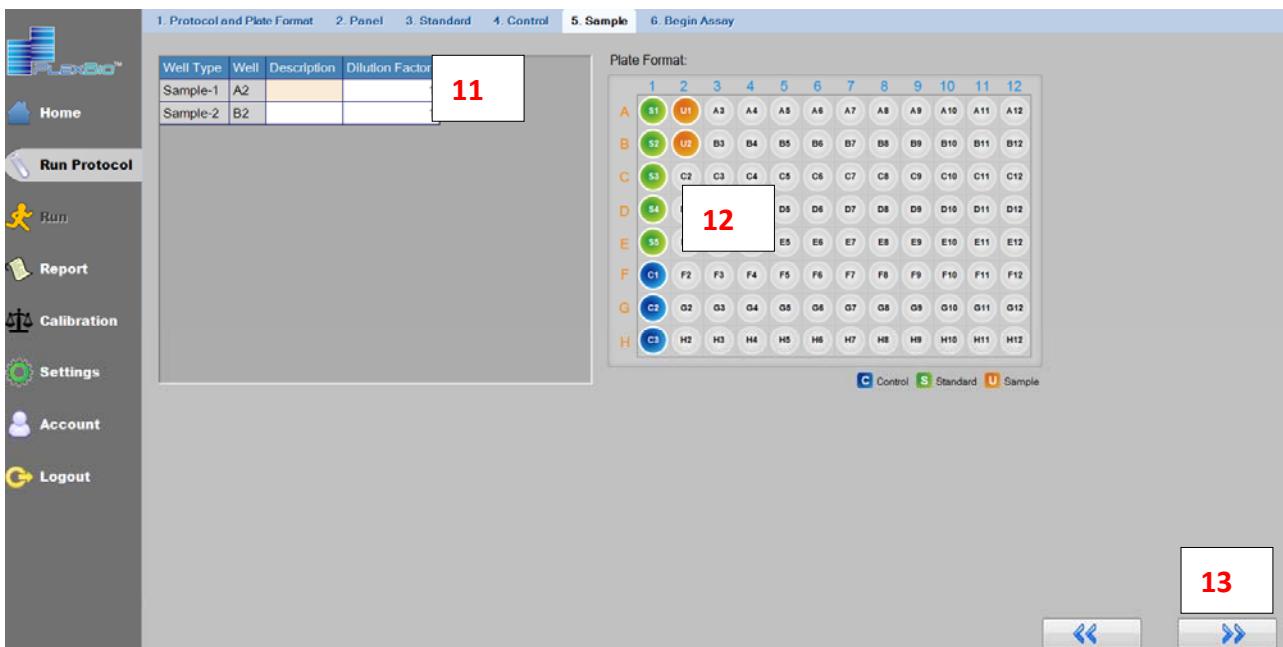


Figure 76. Run Protocol/ Sample

Step 11. Type in Sample Description and Dilution Factor.

Step 12. Confirm Plate Format.

Step 13. Click on to go to the next page

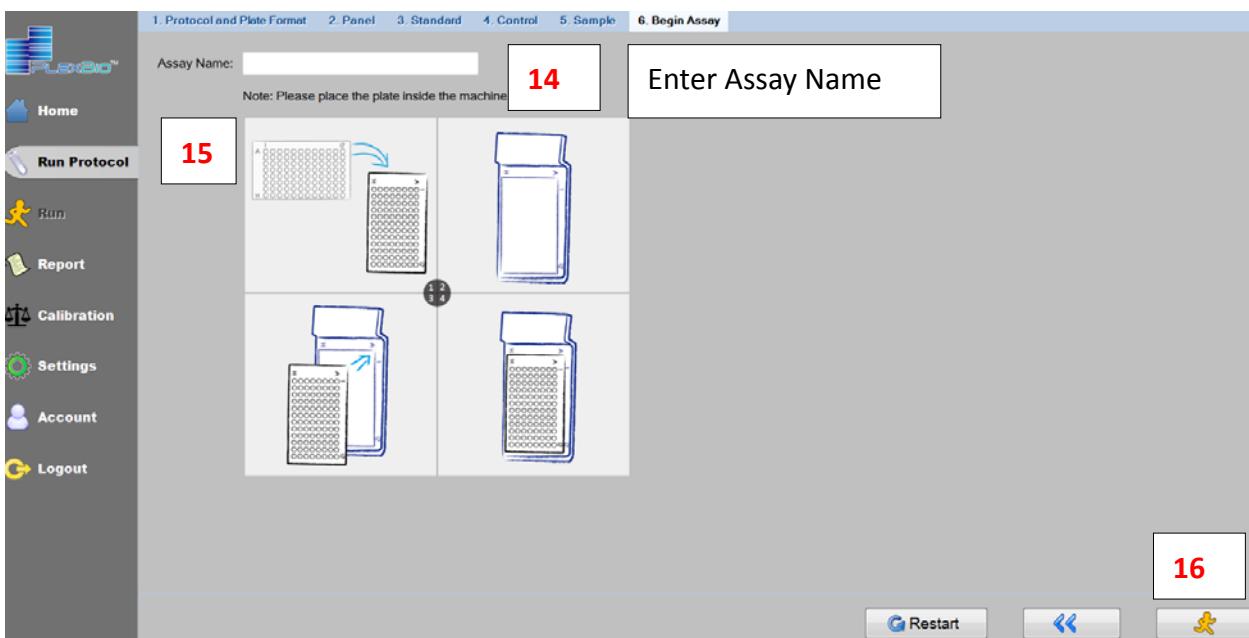


Figure77. Run Protocol/ Begin Assay

Step 14. Enter assay name.

Step 15. Follow the drawing to place the 96-well plate onto the stage with correct orientation.

Step 16. Click on to start reading.



Figure 78. Run Protocol/Begin Assay/Info Message

Step 17. DeXipher™ will ask you to confirm that the plate is in PlexBio™ 100 system. Click on "OK" to begin reading.

5.9 Calibration

Before using PlexBio™ 100 Fluorescent Analyzer for the first time, it is important to calibrate the system. Calibration once per month is highly recommended for the best results.

Step 1. Take out the Calibration Plate and place in the PlexBio™ 100 Fluorescent Analyzer.

Step 2. Click on

Calibration

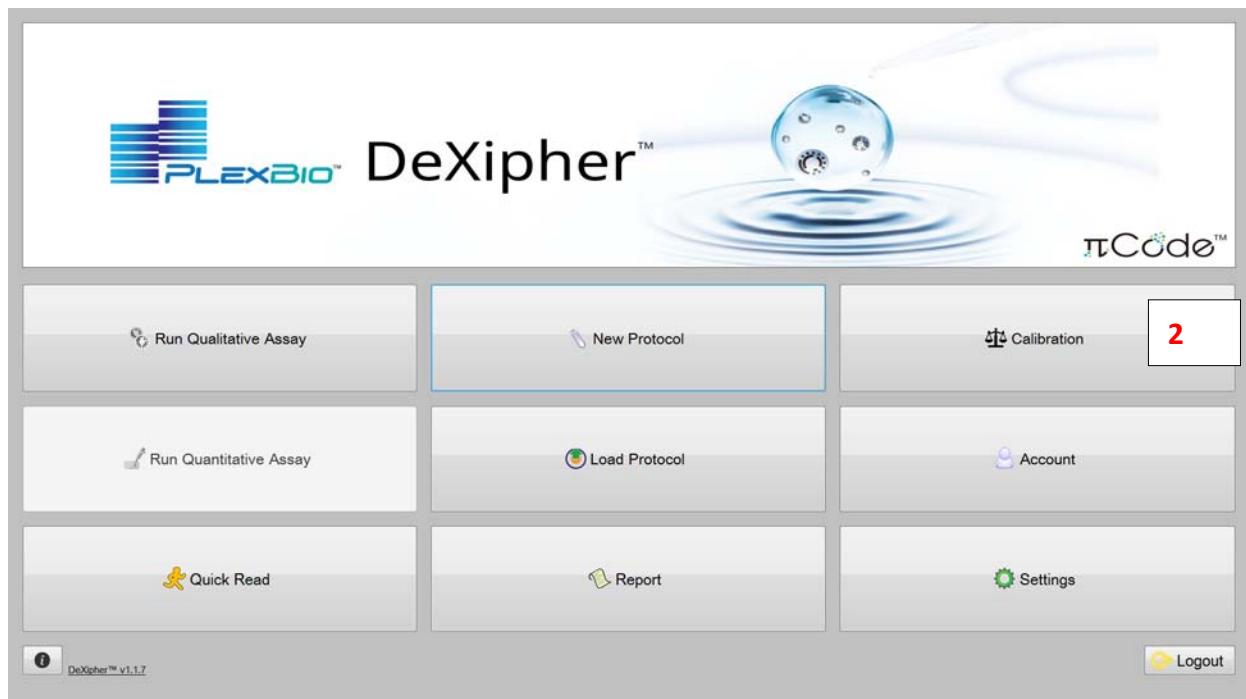


Figure 79. DeXipher™ homepage

Step 3. Click on

Import Calibration Kit

Step 4. Select both two of downloaded calibration ENC files from computer with the files named in “CAL-#####-0.enc” and “CAL-#####-1.enc”.

NOTE:

1. The “#####” are followed by the serial number provided on the calibration plate.
2. Users can only import one ENC file at one time.

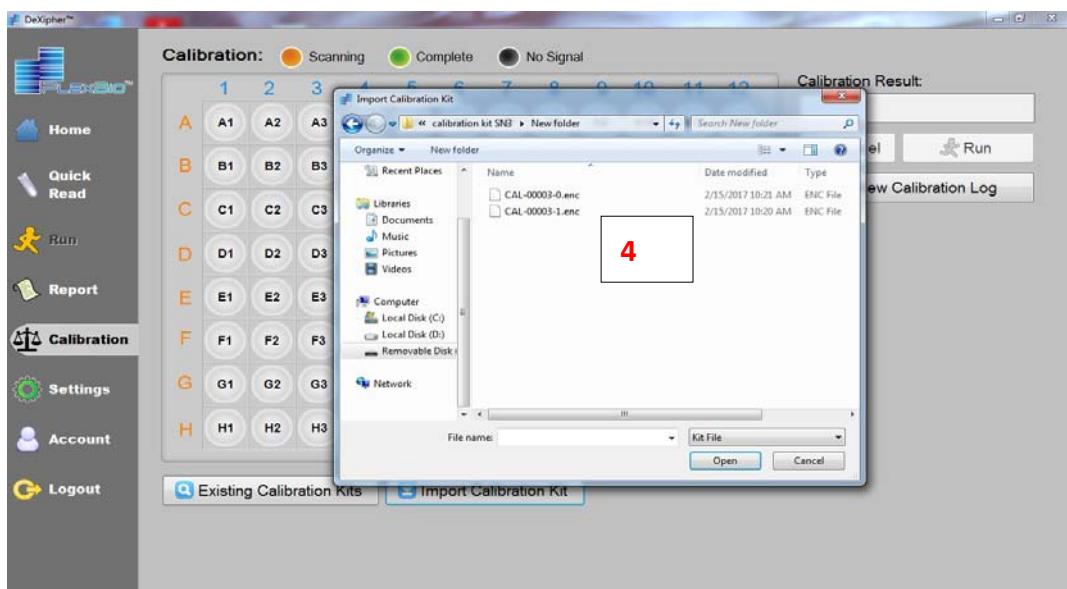


Figure 80. Selection of enc files to import for kit applications

Step 5. Click on  to start reading.

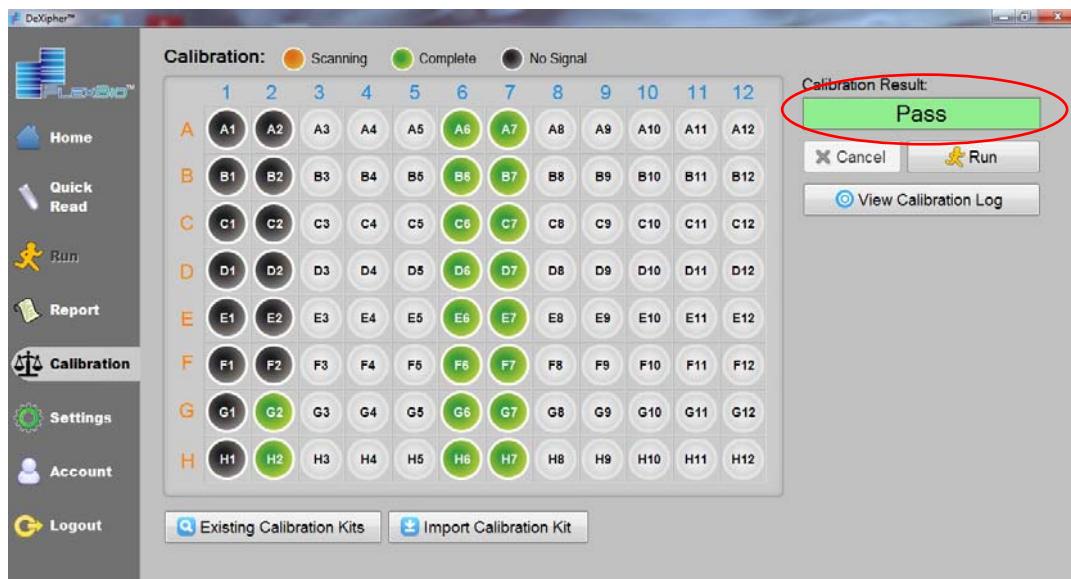


Figure 81. Calibration/Results

Step 6. When reading is completed, calibration results will be displayed on the right side.

Step 7. Click on  to check existing calibration kits.

5.10 Account Management

There are three types of accounts: Admin, Manager, and User.

Admin: can modify all established protocols and accounts.

Manager: can modify all established protocols.

User: can only modify protocols created under user's account.

Note: DeXipher™ Basic will not support the account function. Please contact PlexBio Co., Ltd. or your local distributors for DeXipher™ RU.

5.10.1 Add New Accounts



Figure 82. DeXipher™ Login

Step 1. Log in with the admin account.

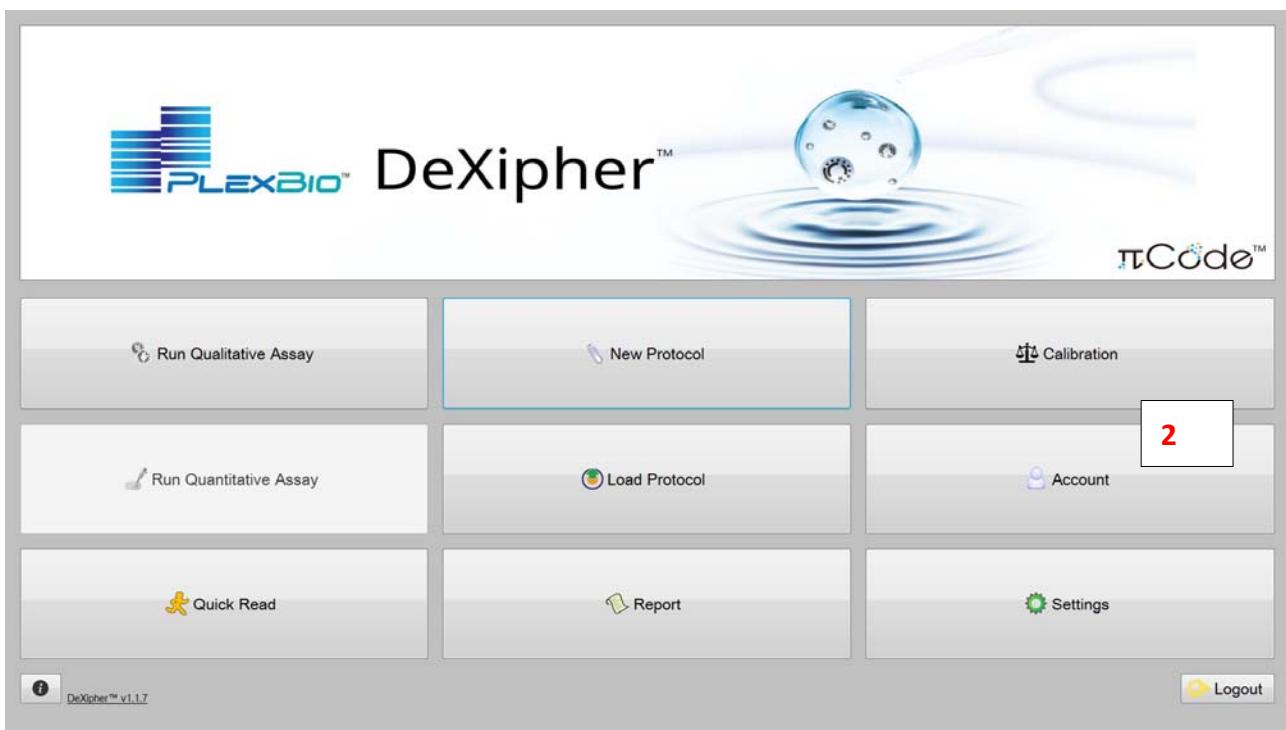


Figure 83. DeXipher™ homepage

Step 2. Click on Account

The screenshot shows the "Account" management screen. On the left is a vertical navigation menu with icons for Home, Quick Read, Run, Report, Calibration, Settings, Account (selected and highlighted in dark grey), and Logout. The main area has a title "Account". It contains several sections: "Change My Password" with fields for Account ID (admin), New Password, Current Password, Confirm Password, and an "Apply" button; "Manage Protocols" with a "Existing Protocol List" showing "Public" and "Private" options, and a "Selected Protocol Name" dropdown; "Manage Account" with fields for ID, Name, and a "Search" button, plus a "Role" dropdown and a "Create New" button (marked with a red number "3"); and "Database Backup" with "Export Database" and "Import and Replace Database" buttons. There are also "Refresh", "Expand", and "Collapse" buttons at the bottom of the protocol list.

Figure 84. Account

Step 3. Click on to access the Create Account window.

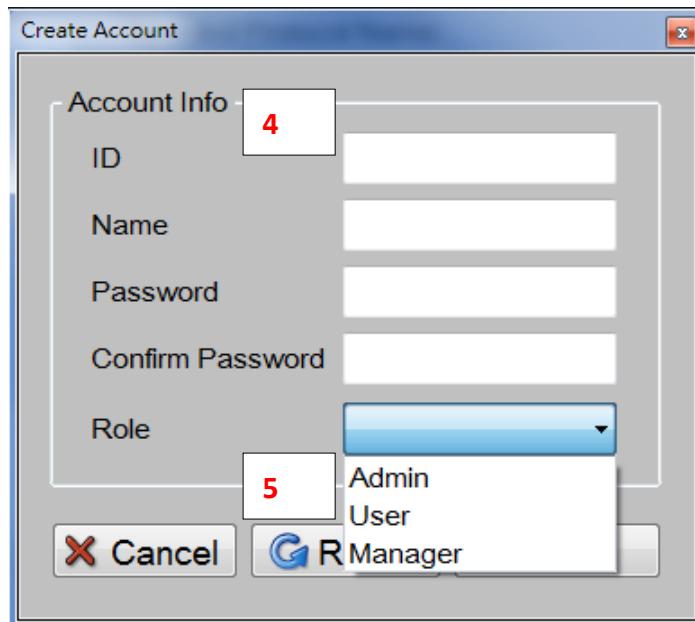


Figure 85. "Create Account" Window

Step 4. Enter **Account Info**.

Step 5. Select the role of the new account. Limits of authority of these three roles are listed at the beginning of this chapter.

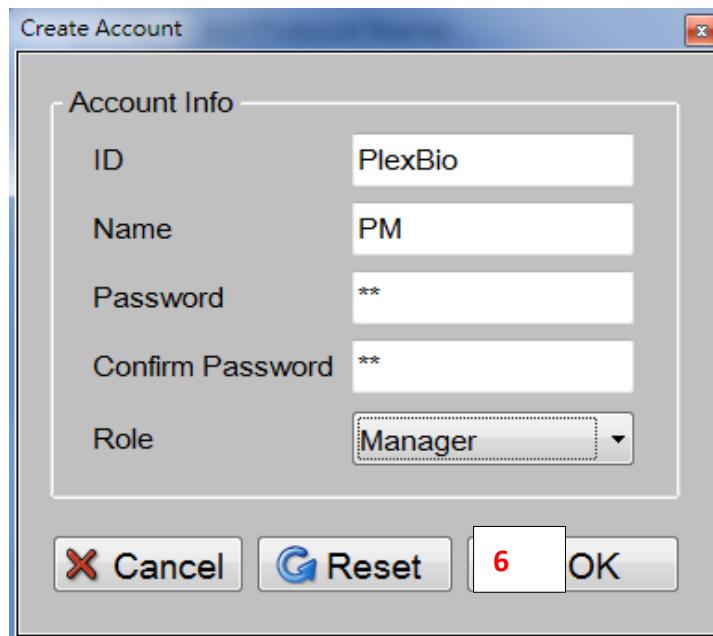


Figure 86. Create Account Window

Step 6. Click on to add the new account.

5.10.2 Edit Accounts

To edit accounts, please follow steps 1-5 of 5.10.1, and select current accounts to edit. After

finish editing, click on to confirm.

5.11 Database Management

Users can backup their DeXipher™ database through the Account screen. Users can also import database for recovery purposes.

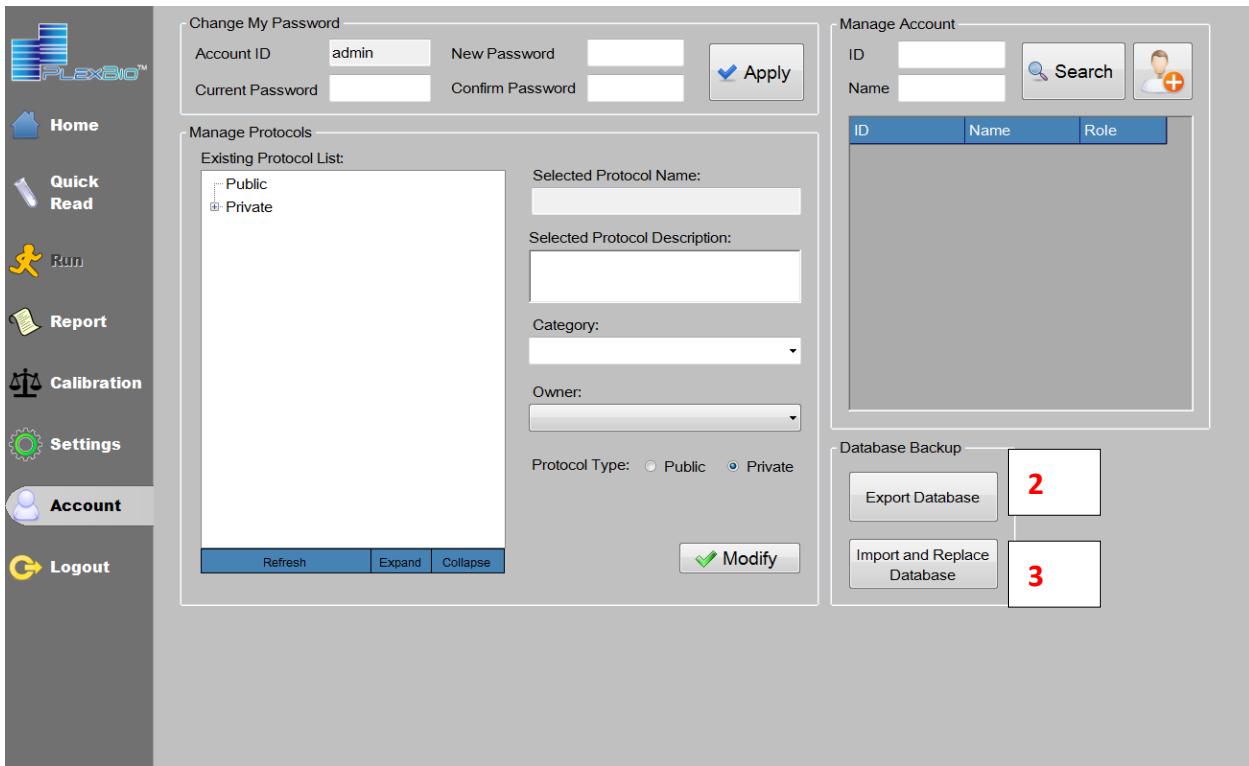


Figure 87. Account/ Database Backup

Step 1. Follow Chapter 5.10 and log in with admin account then proceed to the Account page.

Step 2. To export the DeXipher™ database, click on **Export Database** and then name and save the database as a SQL file.

Step 3. To import and replace database for recovery purposes, click on **Import and Replace Database** and then select the database (SQL file) to import.

Chapter 6: Operational and Maintenance Procedures

6.1 General Maintenance Precautions

Please read and follow the general maintenance precautions:

Personnel that use, maintain, or clean PlexBio™ 100 Fluorescent Analyzer should be trained in standard laboratory safety practices and should follow those practices when handling the instrument.

※Warning: Biohazard

Samples and waste fluid can contain biohazardous material. Where exposure to biohazardous material exists, follow appropriate bio-safety procedures, use personal protective equipment, and use ventilation devices.



※Caution

Users should not perform any maintenance or cleaning of the electrical components in the system.

6.2 Daily Procedures

- After using PlexBio™ 100 Fluorescent Analyzer, if there are stains on the instrument, users can wipe the surface of cover or stage with a soft cloth with mild soap solution or 70% alcohol.
- For cleaning of the objective, please use compressed air or gentle brush to remove particles first. If there are stains, use lens tissue with mild soap solution or 70% alcohol to wipe away.
- Shutdown the system after daily use to prolong the system service lifetime.

6.3 Annual Procedures

Please contact PlexBio Co., Ltd. or local distributors for annual maintenance.

Chapter 7: Troubleshooting

Troubleshooting procedures help users identify and remedy problems with the PlexBio™ 100 Fluorescent Analyzer. As outlined in the following table, users may identify the possible causes and take the corrective solution/ comment actions. If there is no user action stated in the table, please contact PlexBio Technical Support for further service.

The following messages may as displayed by Indicator Light:

| Indicator Light Status | Cause | Solution/ Comment |
|--|---|--|
| Flashing in Red | 1. Disconnected from PC 2. System warm up failed | 1. Check PC is connected and restart PlexBio™ 100 system 2. Restart PlexBio™ 100 system and PC. Do not open the lid during warm up process |
| Alternating Flashing in Pink and White without system functioning | Lid opened during reading | Do not open the lid during system reading |
| Steady in Pink | System warming up | Do not open the lid and wait until system warm up complete (≤ 15 min) |

The following messages may as displayed by Status Bar on DeXipher:

| Status Bar Indicator | Cause | Solution/ Comment |
|---|--|--|
| Indicator turns into Red for more than 30 seconds (Refer to <u>section 5.1.1 Quick Read Screen</u> for status bar introduction) | Camera status error | Check Ethernet cable connection and restart DeXipher |
| | Stage status error | Check USB cable connection and restart DeXipher |
| | Bright/ Fluorescence status error | Restart PlexBio™ 100 system and PC |
| | LED Temperature status error | Restart PlexBio™ 100 system and PC |

The following error messages may as displayed on the DeXipher Software:

| Problem/Error | Cause | Solution/ Comment |
|---|---|--|
| The password entered is incorrect. Please try again. | Incorrect user ID or password. | Contact Plexbio or local distributors for password reset. |
| ➤ APP Name [XXXX] has more/less than 1 mappings. ➤ APP Install/Uninstall errors. | The corresponding KIT APP is not installed. | Refer to kit user manual or Contact Plexbio or local distributors for KIT APP installation. |
| Failed to save panel. Please try again. | 1. Insufficient storage available. 2. SQL server has been stopped. | 1. Free up disk space on your computer. 2. Activate SQL server. Please contact Plexbio or local distributors. |
| ➤ Failed to import kit. Please try again. ➤ Failed to import kit. The file may be corrupted. ➤ Failed to import kit. The file may be corrupted. This kit might be modified illegally. | 1. ENC file was altered or damaged. 2. SQL server has been stopped. | 1. Download the ENC file from website and import again. 2. Activate SQL server. Please contact Plexbio or local distributors. |
| Failed to initiate stage. | 1. Cable is disconnected or loose. 2. Improper operation or system error. | 1. Make sure all cables are well connected. 2. Restart PlexBio™ 100 system and PC |
| ➤ "Failed to export summary data. Please try again. ➤ Failed to export raw data. Please try again." | 1. Insufficient storage available. 2. SQL server has been stopped. 3. System error. | 1. Free up disk space on your computer. 2. Activate SQL server. Please contact Plexbio or local distributors. 3. Reinstall DeXipher. |
| Kit APP not responsive within 30 seconds. Errors possible. | 1. Adobe Reader was not installed (10.0 or above). 2. System error. | 1. Download and install Adobe Reader from website (10.0 or above). 2. Reinstall KIT APP. |
| Kit APP not responsive within 10 seconds. Errors possible. | System error. | Reinstall KIT APP. |
| Failed to init Kit APP thread. | System error. | Reinstall KIT APP. |
| ➤ Cannot find the image folder: ➤ Cannot find the image. | The image file/folder does not exist. | Check if the image database was altered. Analyze the microplate to obtain the image. |

Note:

This chapter does not troubleshoot problems with the PC. For help with PC problems, please contact PlexBio Technical Support or the technical service of your PC manufacturer.

Chapter 8: Getting Help

PlexBio Co., Ltd.

6F-1, No. 351, Yangguang St., Neihu District
Taipei City 11491, Taiwan

Contact Information

Web: <http://www.plexbio.com>

Phone: +886-2-2627-5878

Fax: +886-2-2627-5979

Order info. : order@plexbio.com

General info. : marketing@plexbio.com

Technical Support info. : service@plexbio.com

IntelliPlex™ 1000 πCode Processor

User Manual

PlexBio Co., Ltd.



PlexBio Co., Ltd.

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<http://www.plexbio.com>

A04-016 V05 (RUO)_US

For Research Use Only. Not For Use in Diagnostic Procedures.

For IVD Use ONLY, For Emergency Use Authorization ONLY

- This product has not been FDA cleared or approved; the product has been authorized by FDA for use with the IntelliPlex SARS-CoV-2 Detection Kit under an Emergency Use Authorization (EUA) for use by laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, 42 U.S.C. §263a, that meet requirements to perform high complexity tests.
- This test has been authorized only for use with IntelliPlex SARS-CoV-2 Detection Kit for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
- 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 Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

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Chapter 1. Instruction

1.1 Overview

Read this manual carefully before using IntelliPlex™ 1000 πCode Processor. It provides essential information about the following aspects of IntelliPlex 1000 πCode Processor:

- Safety and Regulatory Requirements
- Labeling
- Technical Information
- Installation
- Operation Procedures
- Settings
- Maintenance

1.2 Warnings



When operated in a safe environment according to the instructions in this user manual, there are no known hazards associated with the instrument. However, the operator should be aware of certain situations that could result in serious injury or possible damage of the instrument. The protection provided by the instrument may be impaired if it is used in a manner not specified in this instruction.

1.3 Symbols

The following symbols may appear throughout this manual with safety warnings, identification, conditions, instructions and regulatory agencies.

| | | |
|--|---|--|
|  General cautions and warnings |  Caution: pinch point |  Warning: Biohazard |
|  Warning: Hot Surface |  Manufacturer |  Date of Manufacture |
|  Consult instructions for use |  Batch code |  Serial number |
|  ETL Mark |  Federal Communications Commission (FCC) Mark |  Waste Electrical and Electronic Equipment |
|  For research use only | | |

Table 1. List of symbols

Chapter 2. Safety and Regulatory Requirements

Please read the safety information in this chapter before using IntelliPlex 1000 πCode Processor. The system contains electrical and mechanical components which may result in injury and damage of the instrument if handled improperly. Do not perform procedures on IntelliPlex 1000 πCode Processor that are not specifically described in the user manual.

2.1 Product Description

IntelliPlex 1000 πCode Processor is a 4-in-1 workstation and is intended to be used with dedicated 96-well plates for sample washing, shaking, incubation and automated fluorescence labeling. The workstation is specifically designed for the πCode™ MicroDisc hybridization, washing and labeling steps that precede fluorescent detection by the PlexBio™ 100 Fluorescent Analyzer. Additionally, this workstation can be utilized for ELISA assay washing if carried out in matching 96-well plates.

2.2 Regulatory Labels

The following label appears on the IntelliPlex 1000 πCode Processor. It displays the model, serial number, power requirements, regulatory status, electrical safety certification and manufacturer information.

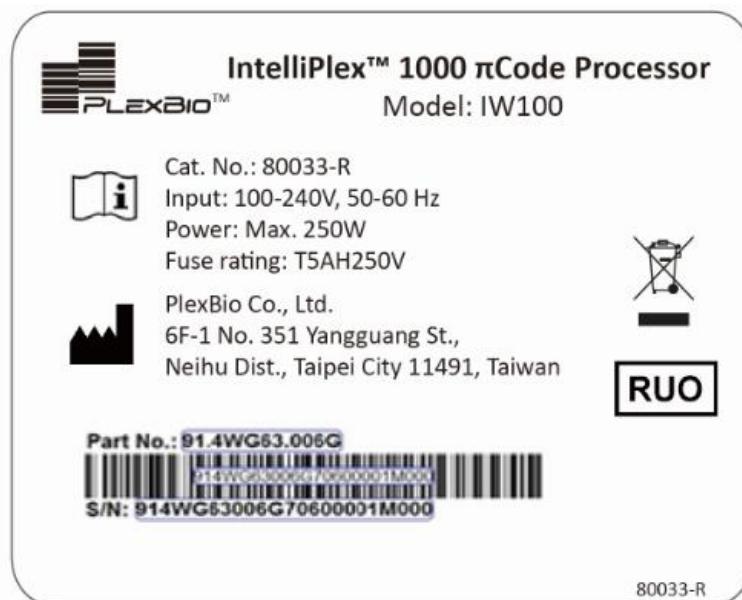


Fig. 1. Label of IntelliPlex 1000 πCode Processor

The following symbols may also appear on the instrument and user manual as necessary.

2.2.1 Testing and Certifications

The IntelliPlex 1000 πCode Processor has been tested and complies with the safety requirements.



Conforms to UL STD. 61010-1,
61010-2-010 and 61010-2-101;
Certified to CSA STD. C22.2 NO. 61010-1,
61010-2-010 and 61010-2-101

(ETL mark)



(FCC mark)

2.2.2 Safety Precautions

The following symbols indicated that safety precautions should be taken before and during system operation.



General Cautions

This message is used to indicate general caution.

- Please handle with extreme care when moving or relocating system as mishandling may damage the system.
- Lift the unit from the base only. **DO NOT** lift by or put excessive force on the plastic case.
- **DO NOT** put excessive force on the stage or it may become tilted or bent. This will severely interfere with the performance of the system.



Electrical Cautions

This message is provided to avoid electric shock or possible damage to the system.

- **DO NOT** open or remove the covers on the system peripherals.
- Use only power cords supplied with the system or cords with grounded outlets properly rated for the system. Ensure the power cord is connected to properly grounded AC outlets only.
- Use of surge protector is recommended.
- Users must not perform any maintenance or cleaning of the electrical components in the system.
- If any malfunction happens, please turn off the power button and then disconnect the power cable. The main plug is used as the main disconnection device; avoid positioning the equipment so that it is difficult to unplug.



**Pinch
Point**

- The IntelliPlex 1000 πCode Processor has modules that move during operation. To avoid any part of the body being caught by a moving part, please keep hands away from the moving part and do not put your hands under the moving part.



Hot Surface

- Please do not touch the heating plate surface until it has cooled.



Biohazard

- Human and animal samples in the 96-well plate may contain biohazardous, infectious materials. Please use personal protective equipment (PPE) including gloves and laboratory coats. Please handle with extreme care when loading the plate onto the stage to prevent spilling. Refer to Chapter 7 for cleaning instruction.



**Waste Electrical
And Electronic
Equipment
(WEEE)**

- Within the European Union, the Waste Electrical and Electronic Equipment Directive 2002/96/EC requires the proper disposal of electrical and electronic equipment when it reaches the end of its lifecycle.

If you are disposing an IntelliPlex 1000 πCode Processor, follow local regulations and requirements.

Chapter 3. IntelliPlex™ 1000 πCode Processor Technical Overview

This chapter introduces and describes the technology, module characteristics and technical specifications of the IntelliPlex 1000 πCode Processor.

3.1 Introduction

IntelliPlex 1000 πCode Processor is an automated workstation specifically designed for πCode MicroDiscs hybridization, washing and labeling steps that precede fluorescent detection by PlexBio 100 Fluorescent Analyzer. The IntelliPlex 1000 πCode Processor minimizes user's hands-on time and supports set up of up to six custom protocols (from hybridization to fluorescence labeling).

Features Include:

- User-friendly interface with embedded processing modes for PlexBio assays or customization.
- Multifunctional, automated operation that combines aspiration, buffer dispensing, shaking, rinsing, heating, with magnetic force application to minimize πCode MicroDiscs loss during washing steps.
- Cross-functional capability for both molecular and immunoassays.
- 7-inch industrial touchscreen panel.

3.2 Main Characteristics

The IntelliPlex 1000 πCode Processor automates the shaking, incubation, washing and fluorescence labeling steps for assays utilizing πCode MicroDiscs. The characteristics are provided as follows:

3.2.1 Shaking and Incubation

This function is designed for incubation of compatible 96-well microplates at different temperatures while shaking.

Features:

- Easy to control time and temperature for operation
- Simultaneous display of set and actual time, and temperature
- Heating and shaking platform for compatible 96-well microplates
- Ready to run built-in PlexBio assay programs

3.2.2 Washing

This function is designed to reduce hands-on time and human error during the πCode MicroDiscs washing process.

Features:

- Combines aspiration, buffer dispensing, shaking, automatic rinsing, and the use of magnetic forces to minimize πCode MicroDiscs loss during washing steps
- Simultaneous display of the current washing cycles and status
- Convenience: easy for operation and maintenance

3.2.3 Fluorescence Labeling

This function is designed to reduce hands-on time for the fluorescence labeling process. For compatibility with the PlexBio 100 Fluorescent Analyzer, use of Streptavidin-Phycoerythrin (SA-PE) conjugates for πCode MicroDiscs fluorescence labeling is recommended.

3.3 System Technical Specification

| | |
|-------------------------------------|---|
| Model | IW100 |
| PERFORMANCE | |
| Supported plates | 96-well plate (Plexbio; Cat. No. 80025 or Greiner Bio-one; Cat. No. 655101) |
| Processing time (full plate) | 3 ~ 6.5 min (one-time wash) |
| Shaking | Timing setting range: 1 sec ~ 23hr 59min 59sec Max. rate: 1200rpm |
| Incubator | Temperature range from RT+5°C to 60°C |
| Safety | Plate position sensor and door sensor |
| Temperature accuracy | ± 0.5°C |
| Temperature uniformity | 1°C |
| Shaking accuracy | ≤ 10% |
| Dispensing accuracy | ≤ ± 6% (Measured under following conditions: 8-way manifold, 150 µL, PlexBio Wash Buffer) |
| Dispensing uniformity | ≤ 4% CV (Measured under following conditions: 8-way manifold, 150 µL, PlexBio Wash Buffer) |
| MicroDisc loss | Around ≥ 75% of MicroDiscs retained after whole processes. (Measured under following condition: 500 ~ 1500 discs/well in 150 µL PlexBio Wash Buffer) |
| Residual volume | ≤ 5 µl/well (Measured under following conditions: 8-way manifold, 150 µL, PlexBio Wash Buffer) |
| OPERATION CONDITIONS | |
| Temperature/Humidity | 18°C ~ 32°C (64°F ~ 90°F)/20 ~ 80% RH, non-condensing |
| Altitude | Up to 2000 meters (6561 ft) above mean sea level |
| STORAGE CONDITIONS | |
| Temperature/Humidity | -10°C ~ 70°C (14°F ~ 158°F)/10 ~ 80% RH non-condensing |
| PHYSICAL CHARACTERISTICS | |
| Power | 100-240V, 50-60Hz, 250W |
| Dimensions | Without Bottle Carrier: (W)408mm*(D)540mm*(H)470mm With Bottle Carrier: (W)554mm*(D)540mm*(H)470mm |
| Weight | 38 kg (84 lbs) |
| Fuse rating | T 5A H 250V |
| OTHERS | |
| Pollution degree | 2 |
| Method of disposal | Electronic waste |

Table 2. System Technical Specification

Chapter 4. Receiving the Instrument

Note that IntelliPlex 1000 πCode Processor must be installed and serviced by PlexBio's qualified service engineers only. Before installation, please make sure the environmental conditions meet the operation requirements:

- Indoor use only
- Operating temperature: 18°C to 32°C (64°F ~ 90°F)
- Operating relative humidity: 20% to 80%, non-condensing
- Operating altitude: up to 2000m (6561 ft.) above mean sea level
- Storage temperature: -10°C to 70°C (14°F ~ 158°F)
- IntelliPlex 1000 πCode Processor needs an operation area of 0.36 square meters and needs to be placed at least 10 centimeters from the wall for components connection and efficient cooling.

4.1 Inspect the Instrument Package

IntelliPlex 1000 πCode Processor arrives in a large, corrugated cardboard overpack on skids.



Fig. 2. The IntelliPlex 1000 πCode Processor package

Inspect the shipping box and packaging for signs of damage. In case of damage, please contact your local distributor or PlexBio Technical Support at +886-2-2627-5878 or service@plexbio.com.

Do not open the box. Please schedule an installation appointment with your local distributor or PlexBio Technical Support.



Cautions

The package of IntelliPlex 1000 πCode Processor may be too heavy to lift. Please lift using adequate equipment. Please handle with care.

4.2 Inbox Accessories

The inbox accessories are listed below. All accessories will be inspected during installation process.

Do not open the box before installation.

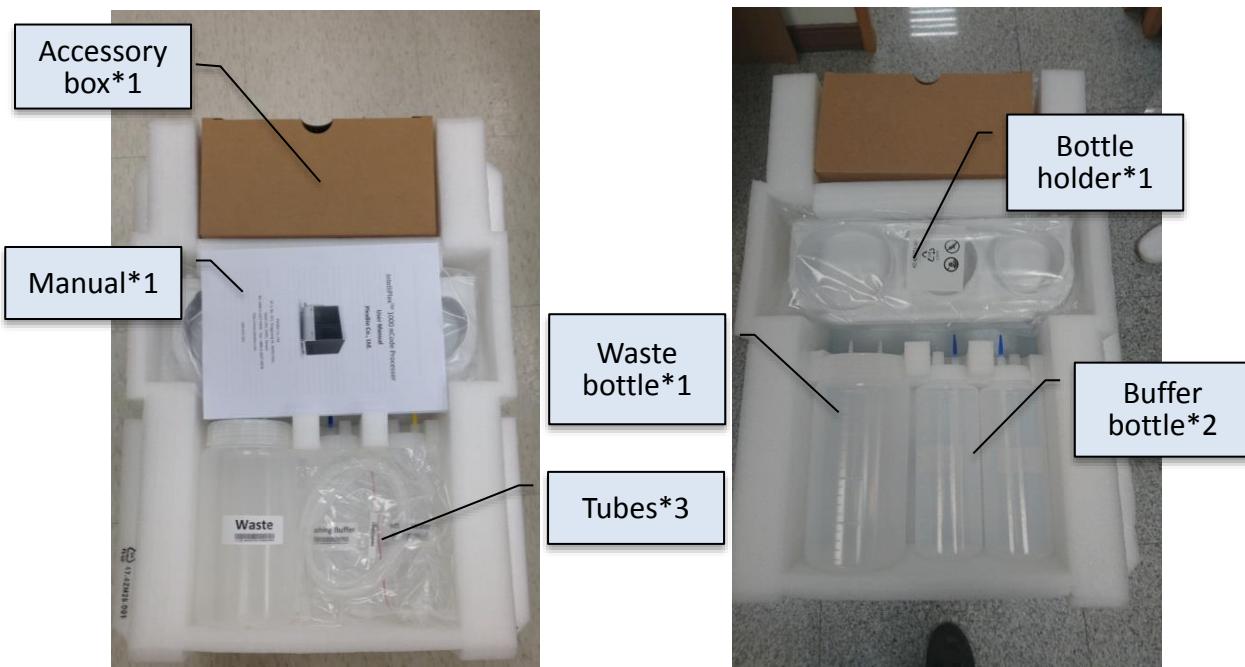


Fig. 3.1 Accessories in Top EPE foam packaging

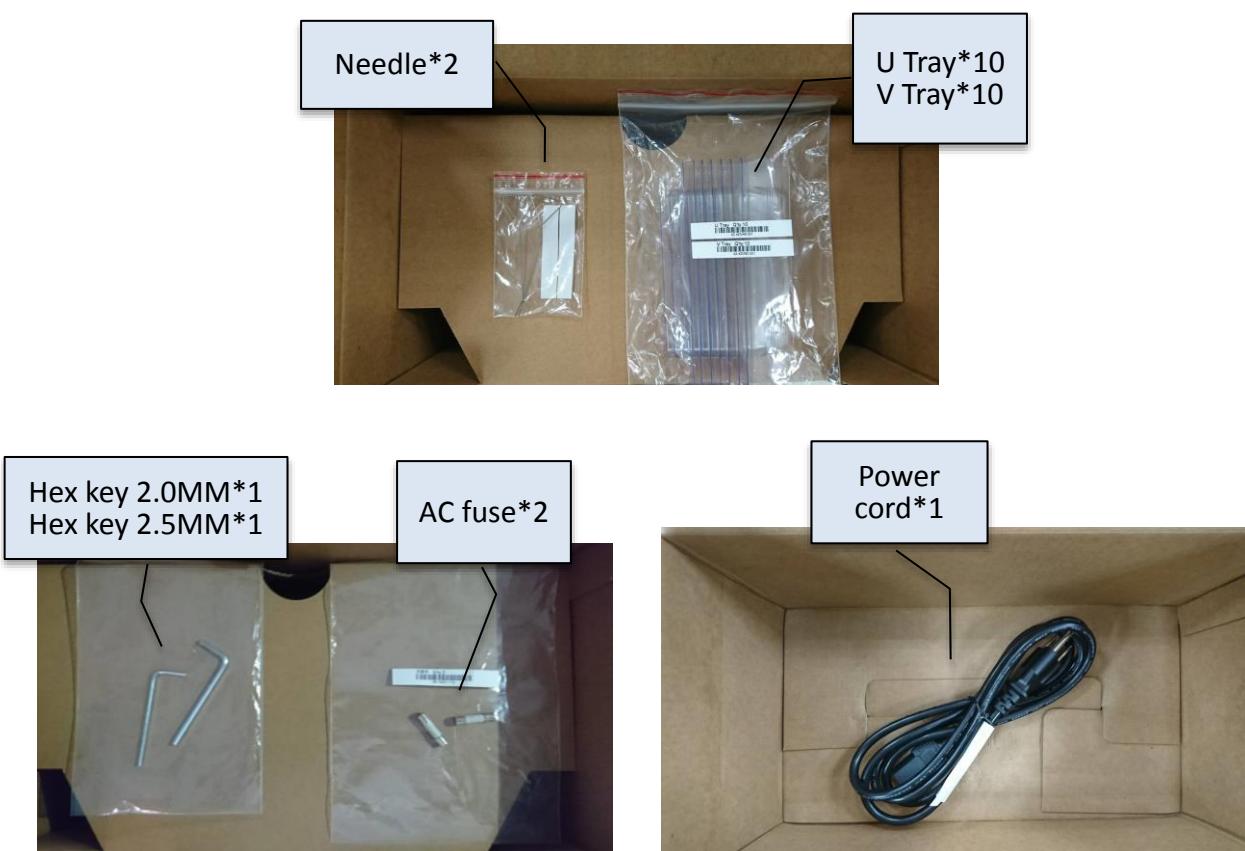


Fig. 3.2 Accessories in the box

Chapter 5. Operation Procedure

Only operate the IntelliPlex 1000 πCode Processor after installation. Do not operate IntelliPlex 1000 πCode Processor if annual maintenance is overdue.

Ensure all daily/weekly/monthly maintenance is performed (refer to Chapter 7. Maintenance for details). Not performing required maintenance will void the warranty. **Moving the IntelliPlex 1000 πCode Processor is not allowed.** If moving is required, please contact Customer Service of PlexBio Co., Ltd. or qualified local distributors.

Before operation, connect the power cord and the corresponding bottles and tubes (Fig. 4). Visually confirm that the U Tray is placed in washing tank (Fig. 5, please also refer to section 6.1.1). Make sure the bottles contain enough ddH₂O and enough wash buffer (refer to section 5.5.2), and the waste bottle is empty.

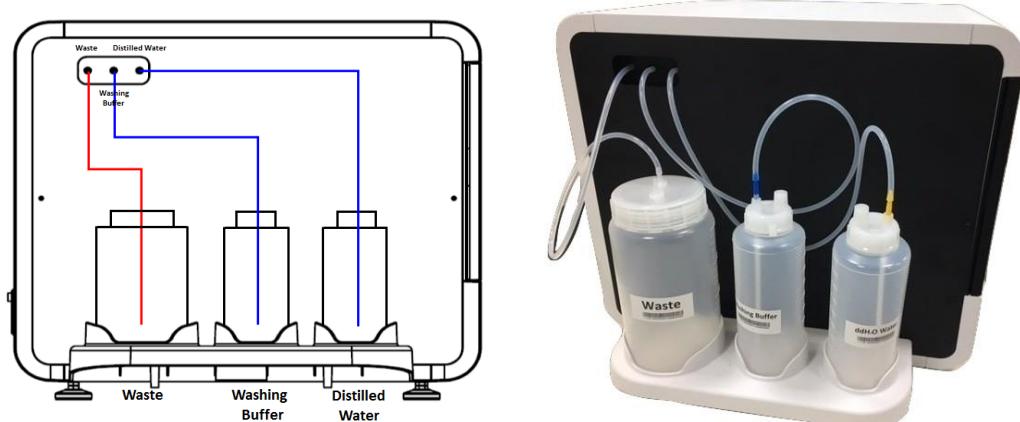


Fig. 4. Connected diagrams

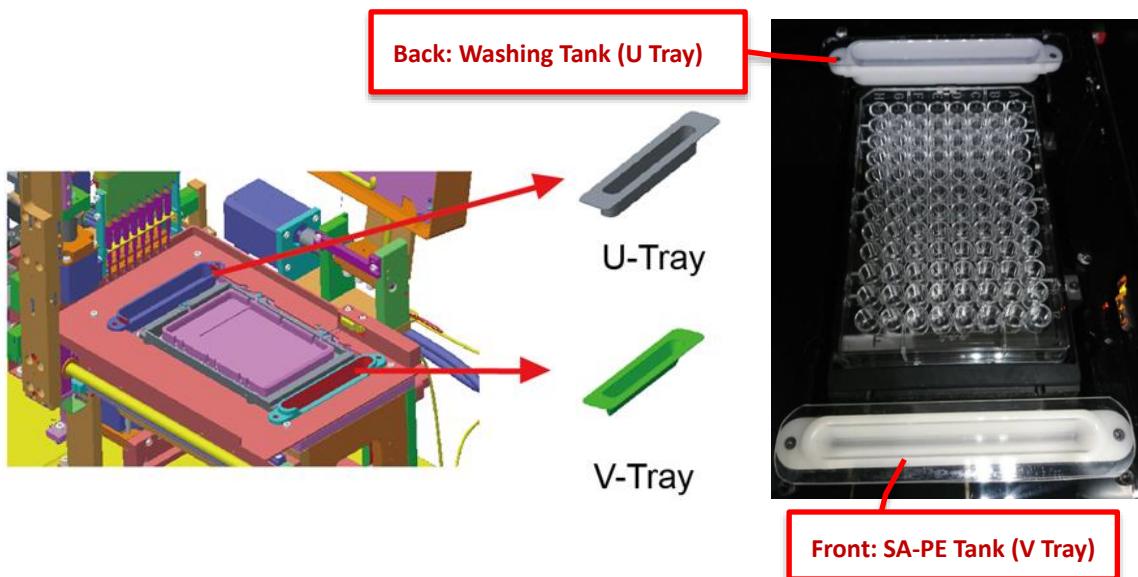


Fig. 5. Tray position

5.1 Startup

Turn on the power at the backside of the instrument. The system will run temperature check and system self-test every time the instrument is powered on. Make sure the ambient temperature is appropriate for instrument operation, the buffer/water bottles, and the waste bottle is empty. Click **OK** to complete **system self-test** process.

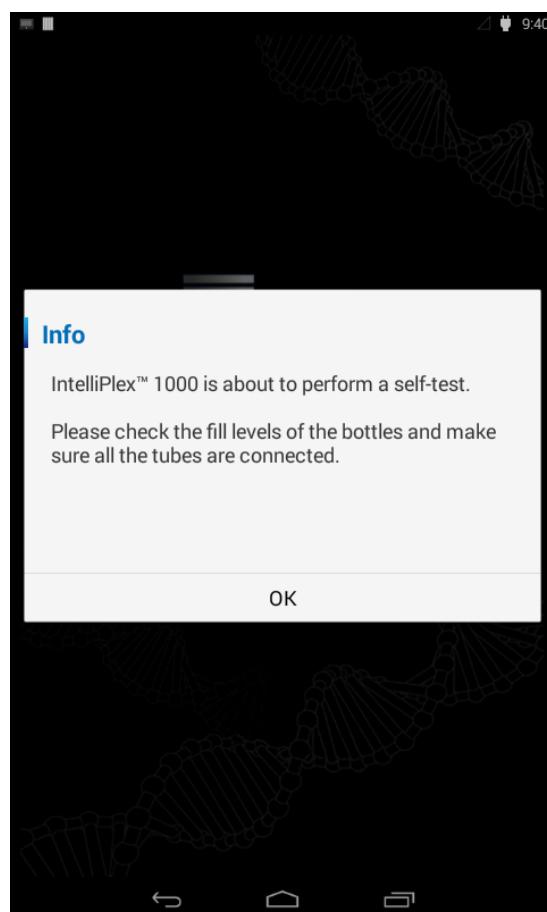


Fig. 6. Interface of system self-test

5.2 Touchscreen Introduction

Figure 7 below depicts the main home screen controls.

(1) Four main function buttons for different assay types.

- Built-in PlexBio Molecular Assay
- Built-in PlexBio Immunoassay
- Built-in PlexBio Applied Science
- Custom Program

(2) Menu button to access settings and maintenance procedures.

(3) Current date and time display.

(4) General information and software versions.



Fig. 7. IntelliPlex 1000 πCode Processor Home Screen

5.3 Predefined Assay Protocols

The IntelliPlex 1000 πCode Processor is installed with predefined assay protocols for the use with PlexBio's assay kits.

5.3.1 RUN the Built-in Assay Kit

For running a PlexBio assay kit, please follow step 1 to 6.

- Step 1. Fig. 8: Select built-in PlexBio assay type (Molecular Assay, Immunoassay or Applied Science).
- Step 2. Fig. 9: Select the desired lanes for processing and click **Next (➔)**.
- Step 3. Fig. 10: Select the corresponding assay to operate.
- Step 4. Fig. 11: Confirm the displayed procedure conditions are correct and click **START**.
- Step 5. Fig. 12: Make sure the pop-up window notices are followed and click **RUN** to start the assay.
- Step 6. Fig. 13: The touchscreen will display real-time operation status of the assay until the run is complete.



Fig. 8. Select the assay types

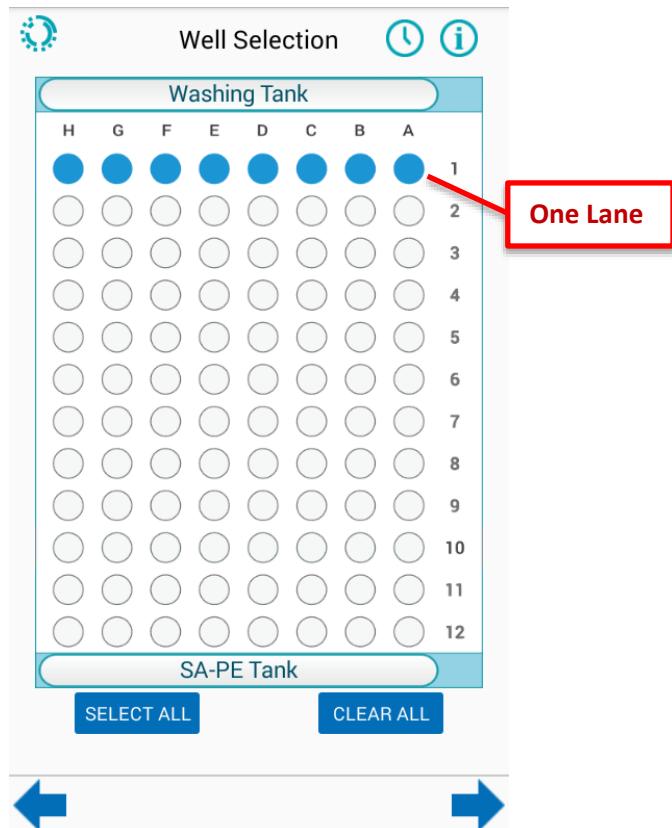


Fig. 9. Select the desired lanes for processing

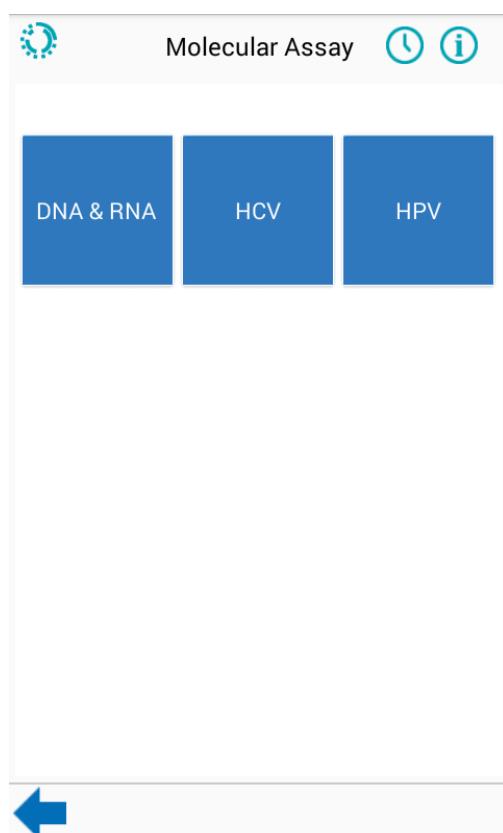


Fig. 10. Select the corresponding assay

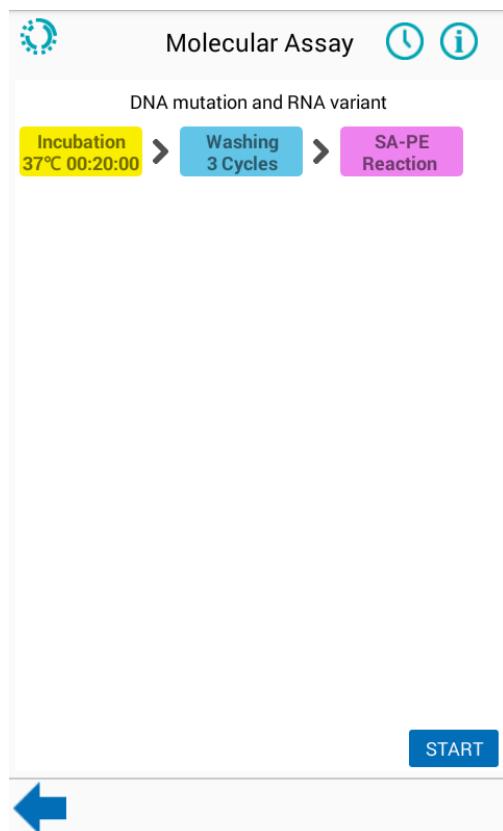


Fig. 11. Procedures confirmation

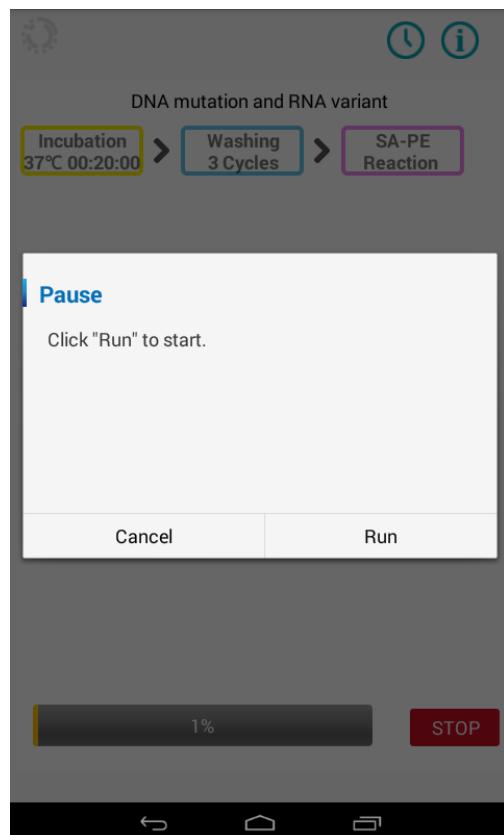


Fig. 12. Pop-up window confirmation

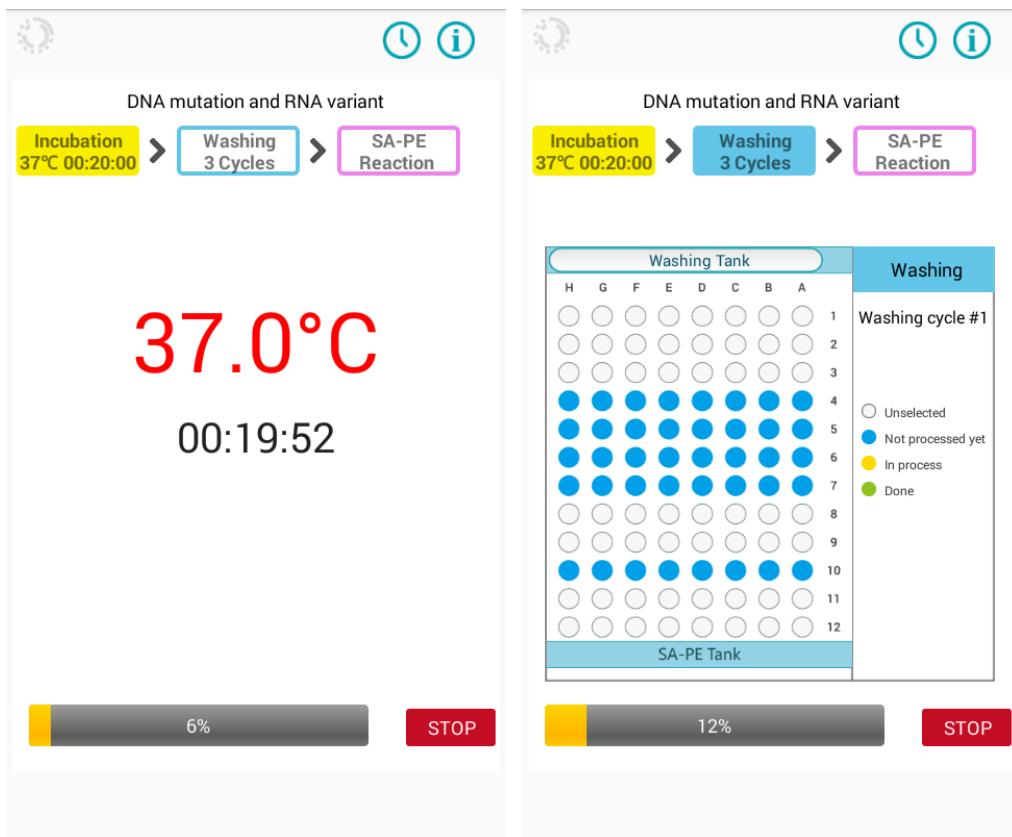


Fig. 13. Real-time display of the assay operation status

5.4 Create a Custom Program

The IntelliPlex 1000 πCode Processor also allows users to create and modify custom assay programs. The following section describes how to setup or edit a custom assay program (a total of six custom programs can be saved).

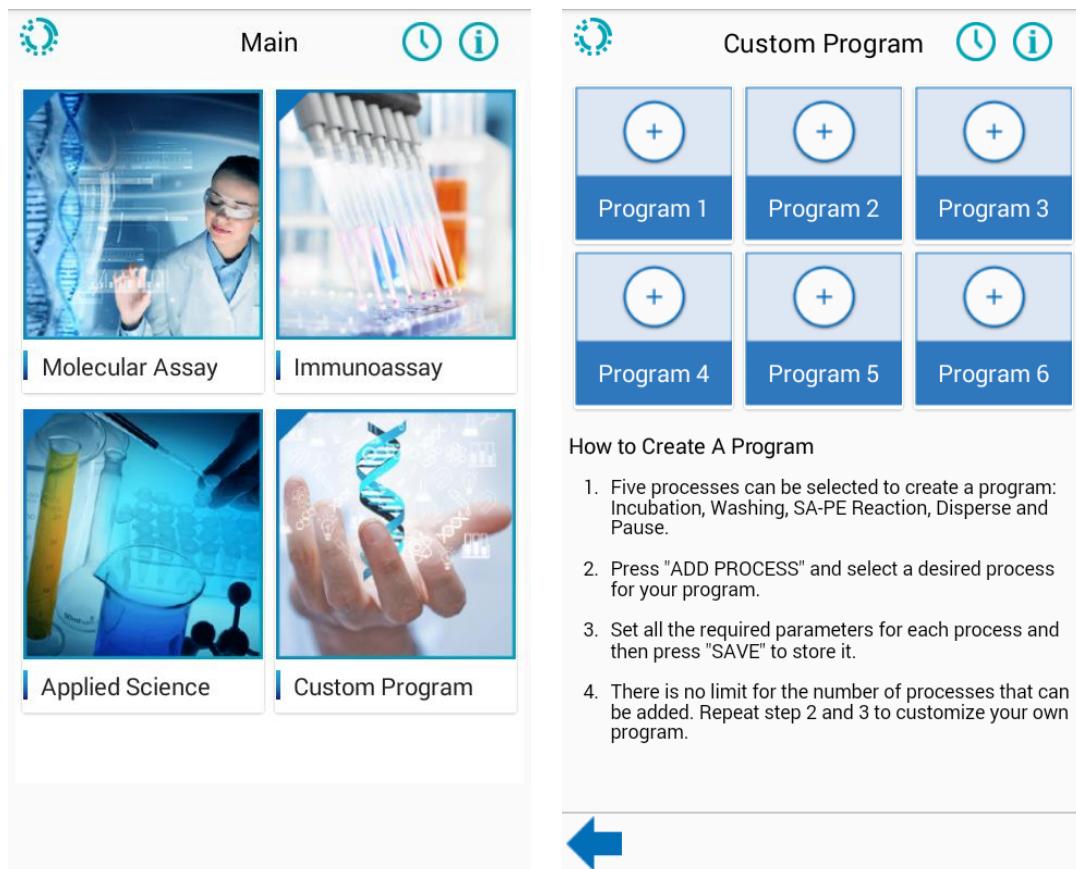


Fig. 14. Interface of custom program

5.4.1 Custom Assay Parameters

Incubation:

- (A) **Heater ON:** Setup the desired incubation temperature by either sliding the setting bar or by keying in the number into the gray box. The offered temperature range is 20°C to 60°C. It is important to highlight that the selected incubation temperature must be 5°C above the current temperature*. Please note that the IntelliPlex 1000 πCode Processor does not have active cooling system. If a new run follows a previous run, please wait until the heating plate has cooled down.

**Current temperature refers to the temperature of the heating plate. Note that the IntelliPlex 1000 πCode Processor measures environmental temperature using the temperature of the heating plate itself. The temperature inside the instrument can be a little higher. Thus, when the incubation temperature is too close to the environmental temperature, error may occur.*

For example, when the current temperature is 30°C, the incubation temperature must be at least 35°C or higher to successfully run the program. If the plate is still warm from the previous incubation process, please wait until the heating plate has cooled down. A pop-up will inform the user of any problems incubating at the selected incubation temperature. Please be aware that custom programs with multiple heating steps in a row may cause termination of the run if the previous temperature was significantly higher than the following temperature.

For example, if a first incubation is carried out at 50°C and immediately followed by a second incubation step at 30°C, an error occurs, and the program will be stopped. Including a wash step between two incubation at different temperatures may be enough to allow passive cool down of the heating plate.

- (B) **Incubation period:** Set up the desired incubation time by directly keying in the numbers into the hour (h), minute (m), and second (s) boxes. The time setting ranges from 1 sec to 23hr 59min 59sec.
- (C) **Close lid during incubation:** This function will decide if the lid is closed during incubation. The lid also includes a heating function. Closing lid during incubation helps in keeping samples more evenly heated. Please note that the lid does not seal the 96-well plate, thus does not prevent evaporation at elevated incubation temperatures.
- (D) **Shake before reaching temp.:** If activated, heating plate shaking and incubation time countdown start once the program has started, independent of the status of the incubation

temperature. If not activated, shaking and incubation time countdown will start once the incubation temperature has been reached.

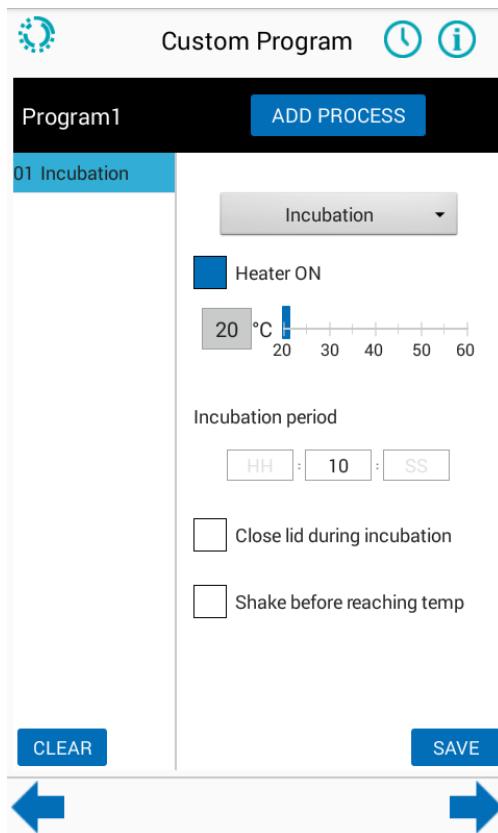


Fig. 15. Parameters of custom incubation procedure

Washing: Users can setup various conditions listed below during the washing process (Fig. 16).

- (A) **Number of Washing Cycles:** Key in the desired number of washing cycles.
- (B) **Washing Volume:** Users can either select the 150 μ L washing volume (used for all π Code applications) or the ELISA wash function (which will dispense 200 μ L wash buffer).
- (C) **Last Dispense Volume:** If the function is activated, additional 150 μ L of wash buffer will be dispensed into each well at the end of the wash cycles followed by 10 sec shaking to spread out/disperse the π Code evenly. If the function is not activated, no liquid will be left in wells after washing process. It is recommended to only activate this function if the wash step ends the program and the plate is subsequently analyzed by the PlexBio 100 Fluorescence Analyzer.
- (D) **Magnetic:** Must be activated for all π Code assays. The magnet will collect and retain π Code at the bottom of the well and only the liquid waste will be aspirated during washing process. The magnetic function is not needed for ELISA assays.
- (E) **Clean Tip:** To prevent any carryover contamination between samples placed in different wells, click on this function and the tips will be cleaned before approaching to next set of wells. The tip cleaning will only be performed at the 1st cycle of each washing process.

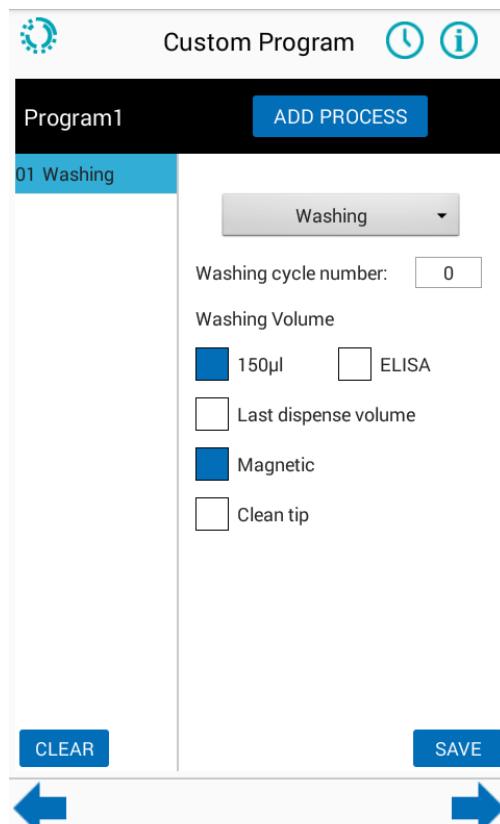


Fig. 16. Parameters of custom washing procedure

SA-PE Reaction: This process includes the fluorescence labeling step with automated SA-PE dispensing. A fixed volume of 50 µL SA-PE will be dispensed into each well, then incubate at 37°C for desired incubation period followed by 4 washing cycles. At the end, additional 150 µL of wash buffer will be dispensed into each well, followed by 10 sec. of shaking to spread πCode evenly. The plate will now be ready for fluorescence analysis using the PlexBio 100 Fluorescent Analyzer.

The incubation period can be adjusted from 1 sec to 23hr 59min 59sec.

Please ensure that enough SA-PE solution is added into V Tray before the program starts. See **Section 5.5 Special Applications** for more detail.

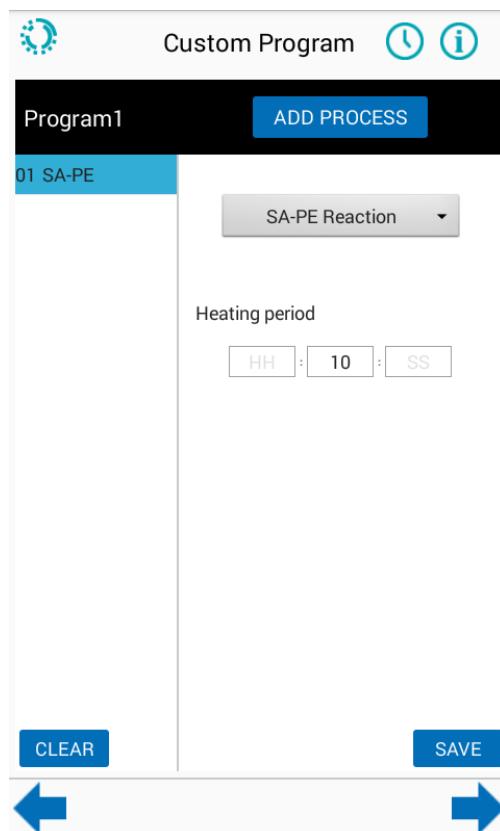


Fig. 17. Parameters of custom SA-PE procedure

Note: The IntelliPlex 1000 πCode Processor dispensing module will take up 50 µL of solution from the V Tray to dispense into selected wells. By default, the V Tray is used for SA-PE. Custom programs may also utilize the V Tray to dispense 50 µL of a solution of choice as long as the reaction is compatible with an incubation at 37°C. For example, immunoassays may dispense Phycoerythrin-labeled detection antibodies instead of SA-PE.

Disperse: This function is to minimize the πCode MicroDiscs aggregations before decoding with the PlexBio 100 Fluorescent Analyzer.

Pause: This function pauses a program to allow opening the front door without triggering the alarm. The ability to open the door without terminating the run provides a chance to check microplate status, add additional reagent manually or refill/ change the solution in the V Tray (we recommend using a new plastic V Tray for each solution).

Once the pause function is reached in an active program, the run will be stopped temporarily. It is only safe to open the door once instructed through a pop-up window in the User Interface. Before continuing the run, ensure that the plate is placed back onto the heating plate, the V Tray is inserted and filled, and the door is closed. The program will continue to the next process after the user clicks the confirm button.

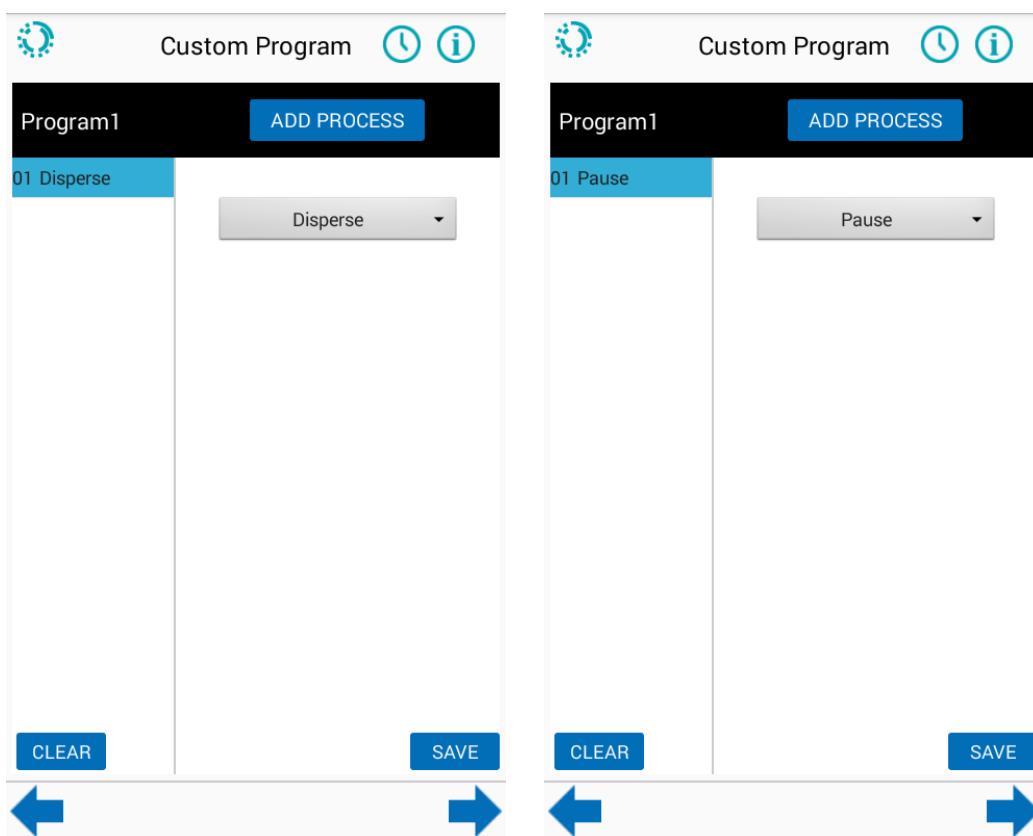


Fig. 18. Disperse and Pause Procedure

5.4.2 How to Create/Edit and Run a Customized New Program

Users can create and save a total of 6 customized programs. Note: Once all six programs have been created, users will need to edit one of the existing programs to create a different custom program.

To setup or edit a program, please follow steps 1 to 9:

- Step 1. Fig. 19: Click **Custom Program** on the home screen and select desired lanes for processing and click **Next**.
- Step 2. Fig. 20: Select one program to create/edit/run from Program 1 to 6 selection.
 - If the program already exists, go to step 9.
 - If the program needs editing, go to step 6.
 - If the program needs to be created, go to step 3.
- Step 3. Fig. 21: Click **ADD PROCESS** and choose the desired procedure from the drop-down menu on the right side.
- Step 4. Fig. 22: Set detailed parameters for each procedure like temperature, time, washing cycles, etc., and save the procedure (optional).
- Step 5. Repeat Step 3 and 4 to add all desired procedures to the custom program.
- Step 6. Click on any of processes on the left to edit its parameters.
- Step 7. Confirm all the procedures and the order are correct.
- Step 8. Click **SAVE** to save the program (optional).
- Step 9. Click ➔ to run the custom assay processes.

NOTE:

1. To delete a process that was added to the program, press on the appropriate process on the touchscreen for several seconds. A pop-up window will appear and confirmation to delete the process from the program is required.
2. Before running a custom program, make sure there is enough water and wash buffer (refer to section 5.5.2) and SA-PE solution (refer to section 5.5.1) in the dedicated containers, and the waste bottle is empty.
3. Once a custom program is started, the real-time operational status of the assay is displayed on the touchscreen until the run is completed (Fig. 23).

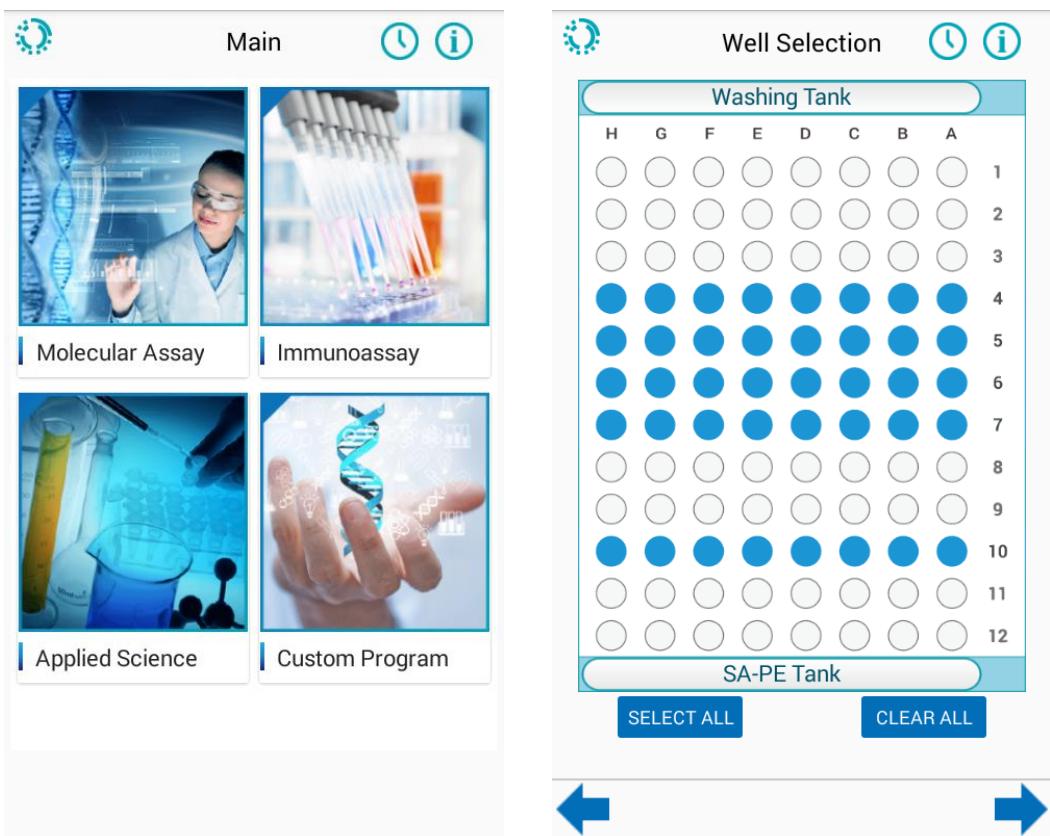


Fig. 19. Custom Program Home Screen and Well Selection

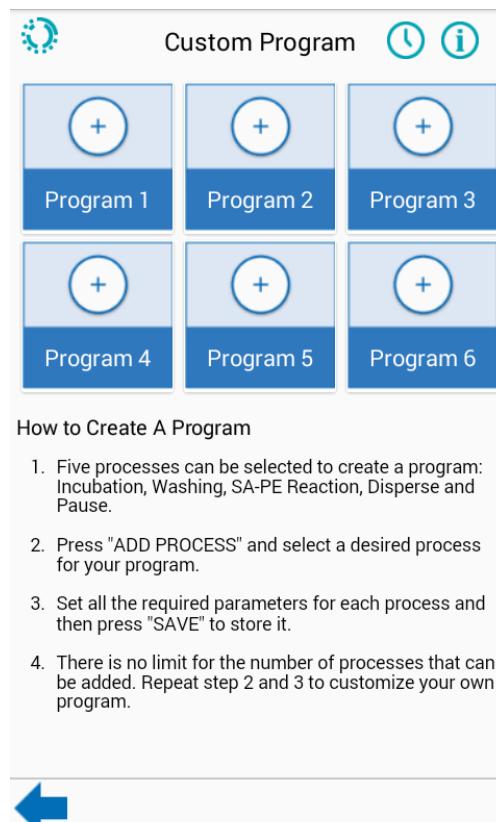


Fig. 20. Custom Program 1 to 6

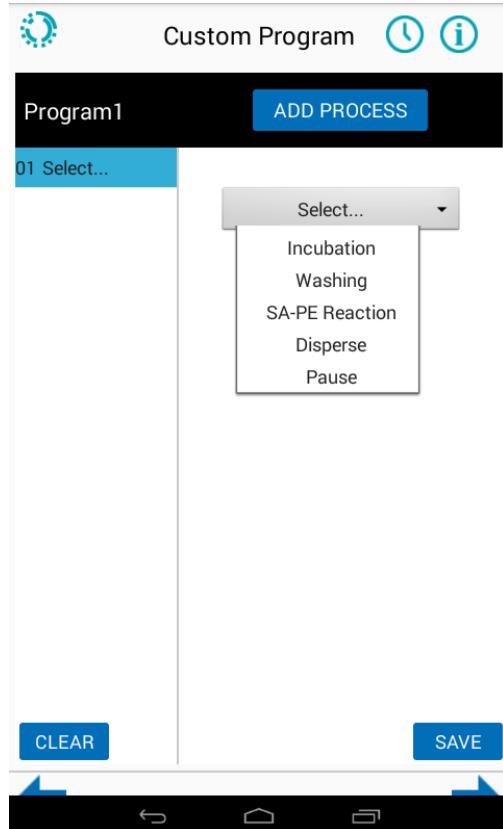


Fig. 21. Select desired procedures to set up a process

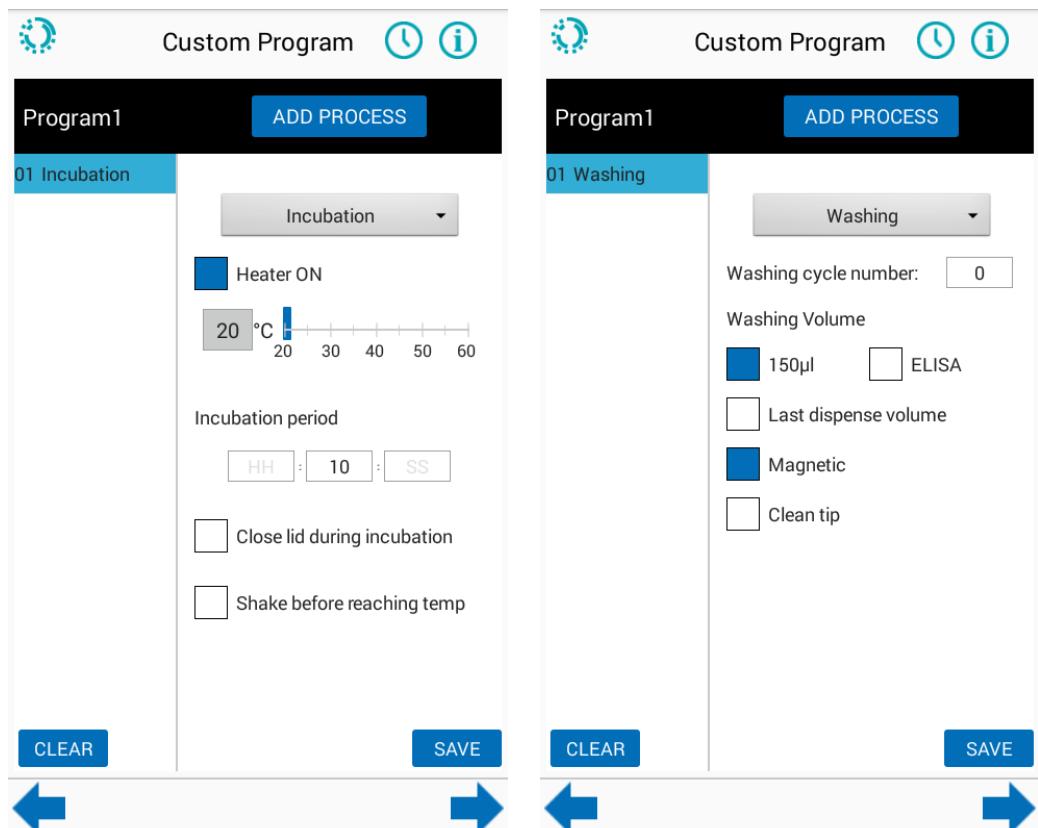


Fig. 22. Set detailed parameters for each process

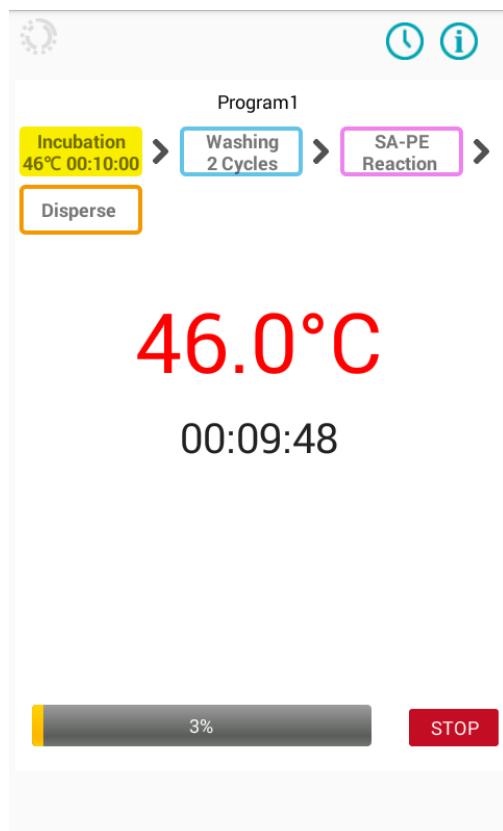


Fig. 23. Custom Program Process and Real-time Display

5.5 Special Applications

5.5.1 SA-PE Solution

This section describes the procedures for SA-PE solution preparation.

Preparation of SA-PE solution is required for all built-in PlexBio assays or any customized assays which utilizes πCode MicroDisc technology. Before starting any run, the appropriate amount of SA-PE solution must be added to the V Tray in the IntelliPlex 1000 πCode Processor.

The position of SA-PE tank is shown in Fig. 24. For each run, place a new clean plastic V Tray in the SA-PE tank and add enough SA-PE solution. The required volume of SA-PE solution per selected lane (8 wells, A to H; see schematic representation below) in an assay is **400 μL**. Please note that the dead volume of the V Tray is **500 μL** for up to 6 selected lanes or **800 μL** for more than 6 selected lanes (7-12 lanes). The minimum quantity of SA-PE solution required is **one lane = 400 μL + 500 μL = 900 μL**. Please refer to the overview table below for required SA-PE volumes based on numbers of lanes selected.

Calculation Example:

For a 3-lane reaction, the SA-PE solution needed is

$$400 \mu\text{L} \times 3 \text{ lanes} + 500 \mu\text{L} = 1.7 \text{ mL}$$

Required SA-PE Solution by Lane(s):

| Number of Processed Lane(s) | Required SA-PE Solution (μL) |
|-----------------------------|------------------------------|
| 1 | 900 |
| 2 | 1300 |
| 3 | 1700 |
| 4 | 2100 |
| 5 | 2500 |
| 6 | 2900 |

| Number of Processed Lane(s) | Required SA-PE Solution (μL) |
|-----------------------------|------------------------------|
| 7 | 3600 |
| 8 | 4000 |
| 9 | 4400 |
| 10 | 4800 |
| 11 | 5200 |
| 12 | 5600 |

Note: Do not reuse the leftover SA-PE solution. Replace a new V Tray with every assay run.

A-H is defined as a lane.

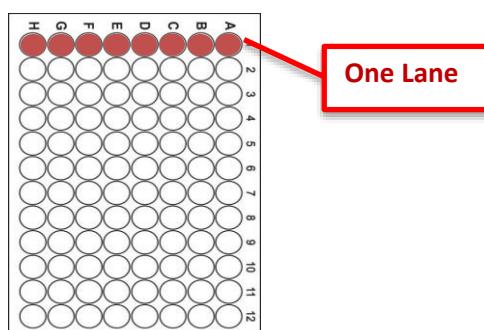




Fig. 24. Positions of the Washing and SA-PE Tanks

5.5.2 Wash Buffer

This section describes the procedures for Wash buffer preparation.

Preparation of Wash buffer is required for all built-in PlexBio assays. Before starting a run, sufficient amount of Wash buffer must be added to the Wash Buffer bottle connected to the IntelliPlex 1000 πCode Processor.

Wash buffer purchased from PlexBio is 10X concentrated. Preparation of 1X Wash Buffer (10-fold dilution of 10X Wash buffer with ddH₂O) is required before usage with the IntelliPlex 1000 πCode Processor. The prepared 1X Wash Buffer can be used for up to 1 week.

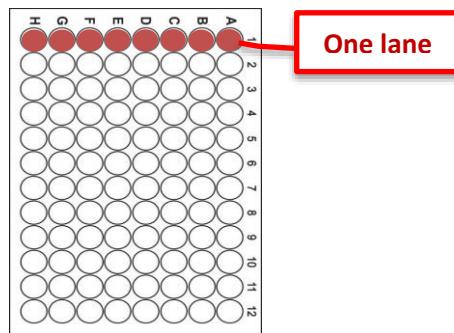
Do not use the buffer if visible contamination (e.g. fungus) occurs. Please discard of contaminated Wash Buffer according to local requirements and wash the fluid path and buffer bottles several times with 70% ethanol (refer to section 7.2.1).

In a custom program, the amount of wash buffer required per row depends on the selection of program parameters (such as number of wash cycle and selection of “clean tip” option). We recommend a fill level of at least 500 mL Wash Buffer for all assays with 7 or less wash cycles and a fill level of 1000 mL Wash Buffer for programs utilizing more than 7 wash cycles.

For PlexBio’s DNA/RNA program, the Wash Buffer consumption is as following:

| Procedure | Wash Buffer Consumption |
|---|-------------------------|
| Self-test | 50 mL |
| DNA/RNA program for 1 lane, up to 8 tests (3 wash cycles and 1 SAPE reaction) | 150 mL |
| DNA/RNA program for 3 lanes, up to 24 tests (3 wash cycles and 1 SAPE reaction) | 220 mL |
| DNA/RNA program for 6 lanes, up to 48 tests (3 wash cycles and 1 SAPE reaction) | 340 mL |
| DNA/RNA program for 12 lanes, up to 96 tests (3 wash cycles and 1 SAPE reaction) | 540mL |

A-H is defined as a lane.



Chapter 6. System Settings

To get to the **System Menu**, click on  (top left screen corner).

The Settings menu is shown in Fig. 25. Each section is described in detail below.

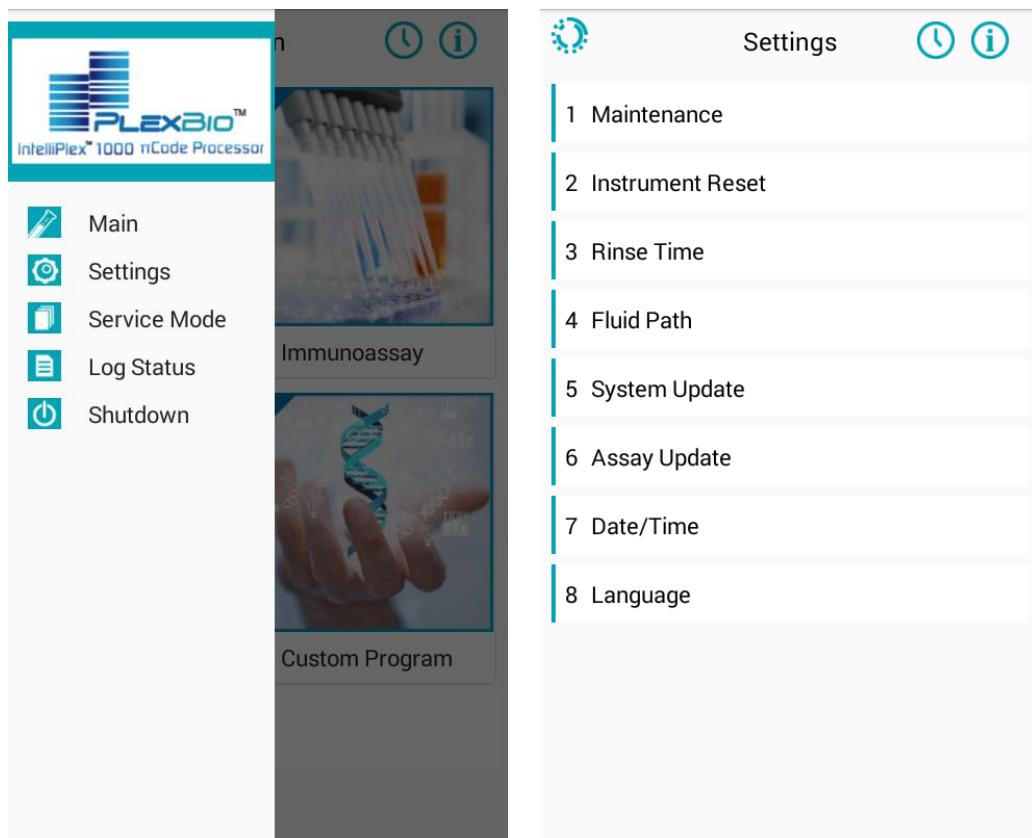


Fig. 25. The settings menu

6.1 Maintenance

This section describes how to renew the solution U Trays and clean the manifold (Fig. 26).

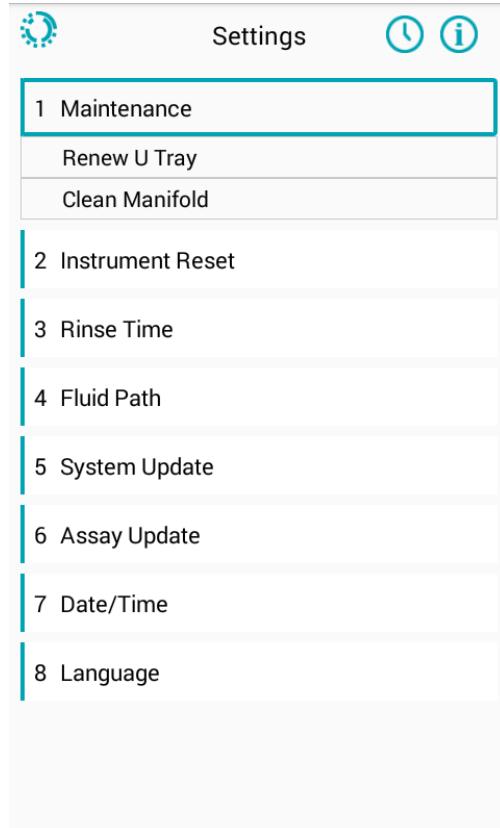


Fig. 26. Maintenance from tool menu

6.1.1 Renew U Tray

There are two tanks - the **washing tank (U Tray)** and the **SA-PE tank (V Tray)** (Fig. 27). Only the transparent U and V Tray is replaceable, do not tamper with the fixed white tank modules from the instrument. We recommend replacing the **U Tray** once a month to keep the tray clean and reduce the possibility of salts crystal formation or contamination. While the **V Tray** can be replaced directly (please dispose/replace after every run), replacing the **U Tray** requires the maintenance function in the settings menu.

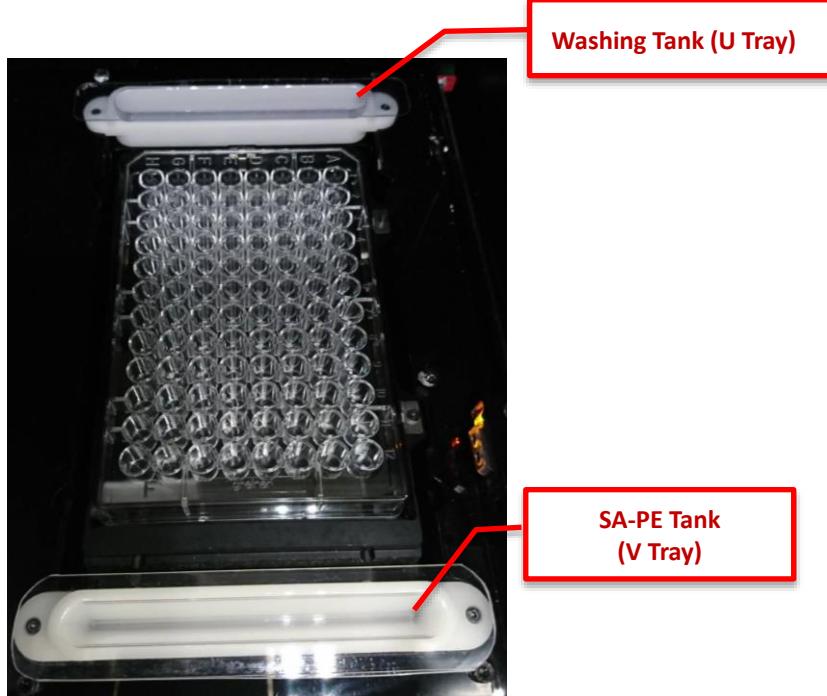


Fig. 27. Positions of the Washing and SA-PE Tanks

To renew the **U Tray**, please follow the steps below:

- Step 1. Open the **System Menu** 
- Step 2. Select **Setting** on the menu page.
- Step 3. Click on the **Maintenance** button.
- Step 4. Choose **Renew U Tray** (Fig. 28) and the manifold will move backwards to reveal the washing tank for replacing the U Tray.
- Step 5. Please remove the plastic U Tray carefully and avoid spilling of any liquid that might still be at the bottom of the tray.
- Step 6. Place a new tray into the white manifold. Ensure proper placement.

Note: It is recommended to renew U Tray once a month to reduce the possibility of contamination or crystal formation.

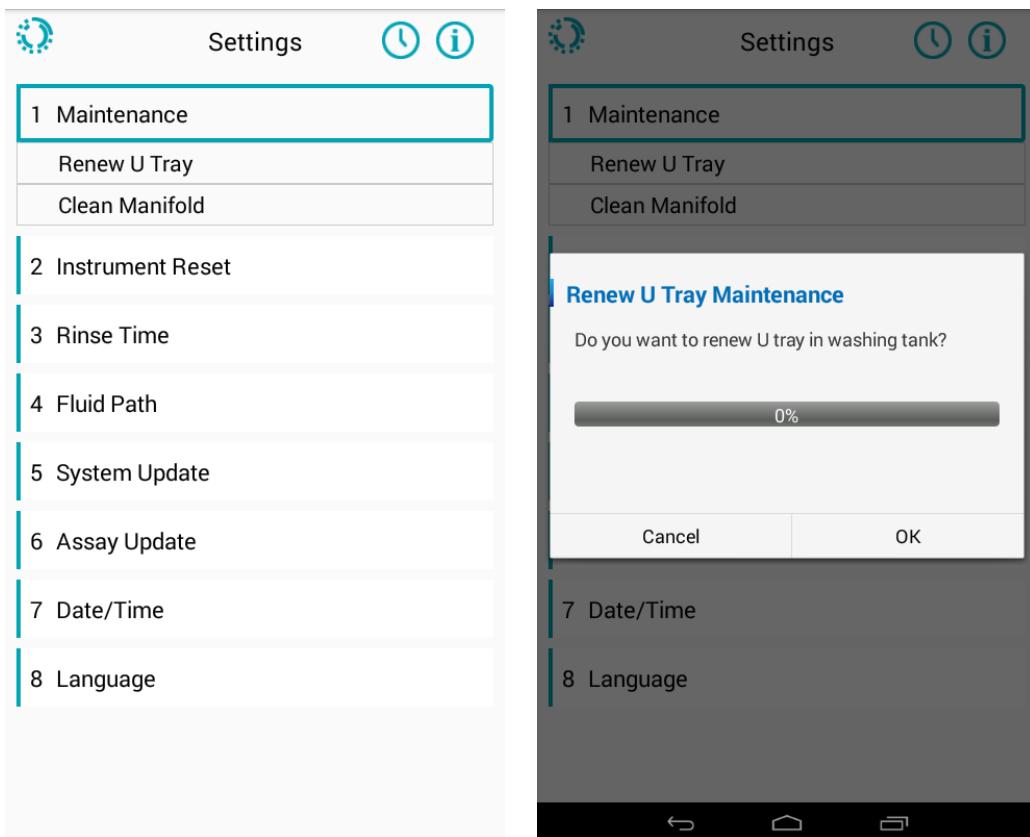


Fig. 28. Renew U Tray

Note: Never operate the IntelliPlex 1000 πCode Processor without the transparent U Tray placed in the white tank module. Operating the IntelliPlex 1000 πCode Processor without the plastic U Tray placed in the white module may damage the IntelliPlex 1000 πCode Processor. We recommend to visually confirm the presence of the plastic U Tray before operating the IntelliPlex 1000 πCode Processor.

6.1.2 Clean Manifold

Manifold cleaning helps to keep the manifold in good working order. If crystals do form and block the manifold tips, or visible dust develops on the manifold tips, follow the steps described below (Fig. 29), use the needles provided in the accessory box to clean the manifold tips.

Step 1. Remove V Tray from SA-PE tank.

Step 2. Open the **System Menu** 

Step 3. Select **Setting** on the menu page.

Step 4. Click on the **Maintenance** button.

Step 5. Select **Clean Manifold** and then click **OK** in the pop-up window. The dispensing module will move forward to allow access to the manifold.

Step 6. After manifold cleaning, perform **Instrument Reset** (see below).

Note: Manifold tips disassembly is restricted to qualified engineer only. If there is any precipitation or dust on manifold tips which cannot be cleaned away, contact **PlexBio Co., Ltd.** or local distributors for services.

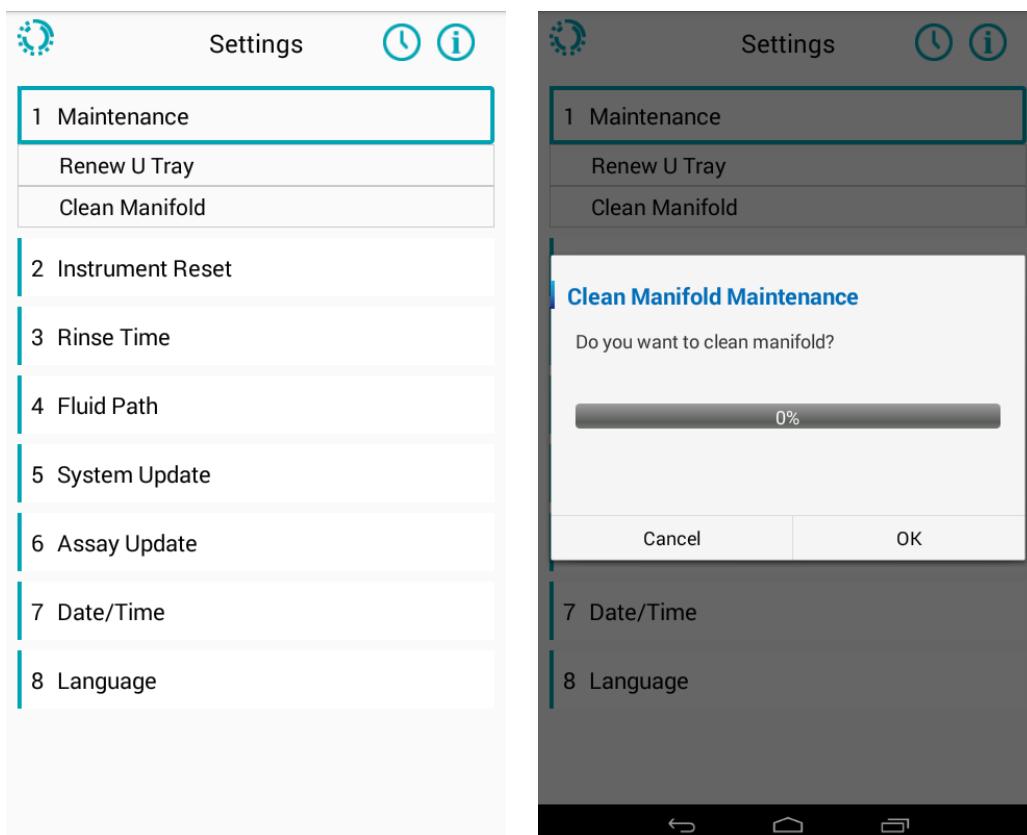


Fig. 29. Clean the manifold

6.2 Instrument Reset

This function returns the manifold, the thermal lid, and the magnetic plate back to their original positions.

- Step 1. Select **Setting** in the menu.
- Step 2. Choose **Instrument Reset** to reset all modules.
- Step 3. Click **OK** in the pop-up window.

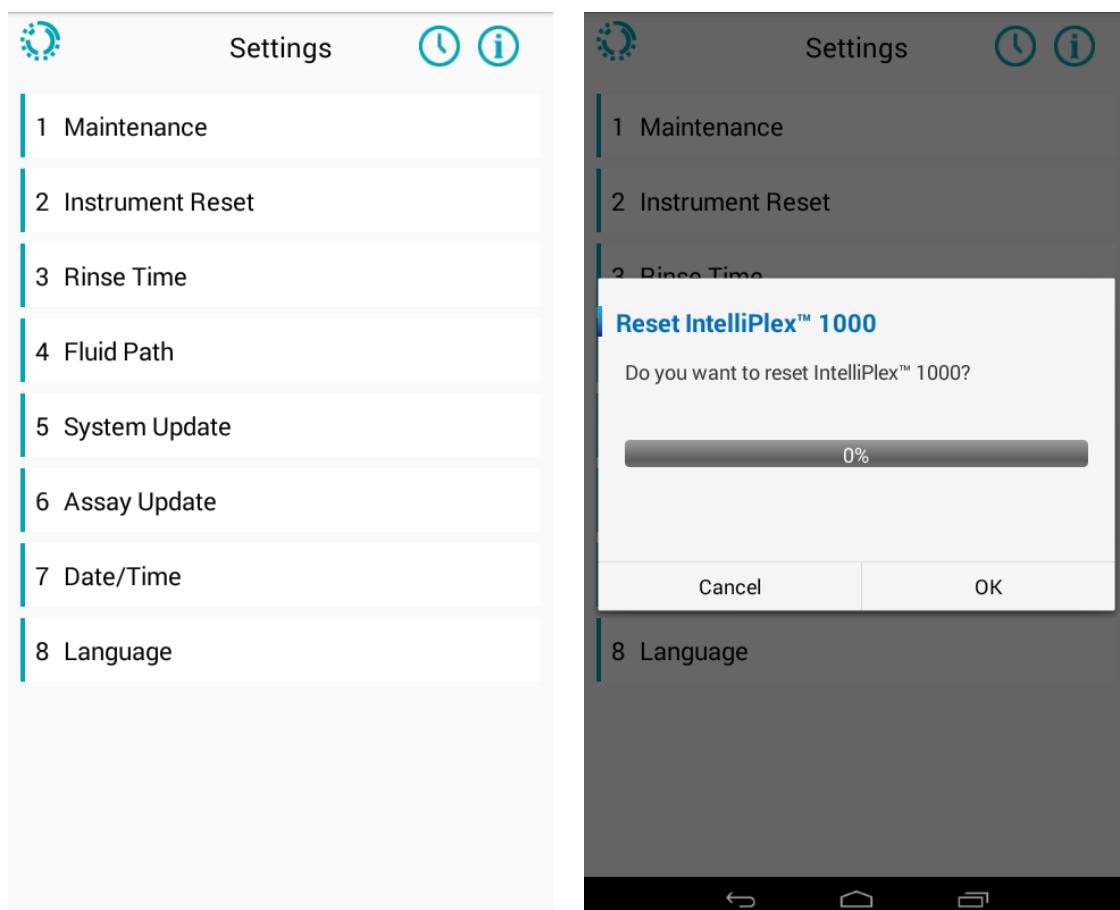


Fig. 30. IntelliPlex 1000 instrument reset

6.3 Rinse Time

The **RINSE** function is used to keep pumps and tubes wet and to prevent salt crystal formation which could lead to clogging of the fluid path and/or damage the pump.

By default, the **RINSE** function will execute after the IntelliPlex 1000 πCode Processor was idle for 2 hours, and as long as the instrument remains idle, the system will perform **RINSE** function repeatedly. The **RINSE** function will rinse the tubes with ddH₂O. Once the **RINSE** function is completed, a pop-up window will appear on the screen instructing to start the **PRIME** function, which will prime the tubing with Wash Buffer. The **PRIME** function can be performed immediately after the **RINSE** function or later but must be completed before performing the next run. Please make sure the wash buffer and waste bottle fill levels are adequate before running **PRIME**.

To adjust the idle time triggering the RINSE function follow the steps below:

- Step 1. Open the **System Menu** 
- Step 2. Select **Setting** on the menu page.
- Step 3. Select **Rinse Time** in the setting menu.
- Step 4. Set up the **Rinse Time**. The automated rinse can be set between 10 minutes or 24 hours.

Note: We recommend keeping the default settings. Please keep in mind that the instrument will perform another **RINSE** cycle if the instrument remains idle for 2 hours after the **PRIME** function was executed.

6.4 Fluid Path

There are three options: **RINSE** (ddH₂O), **PRIME** (wash buffer) or **RINSE/PRIME**. **RINSE** dispenses liquid from the ddH₂O inlet, while **PRIME** dispenses liquid from the wash buffer inlet. These functions are used during monthly maintenance and long-term shutdown procedure (see Chapter 7 for details)

- Step 1. Open the **System Menu** 
- Step 2. Select **Setting** on the menu page.
- Step 3. Select **Fluid Path** on the tool menu.
- Step 4. Choose **RINSE, PRIME or RINSE/PRIME**.
- Step 5. Press **OK** to start running.

Note: Before performing any of the function, please ensure that the ddH₂O and Wash Buffer bottles are adequately filled, and the Waste bottle is empty.

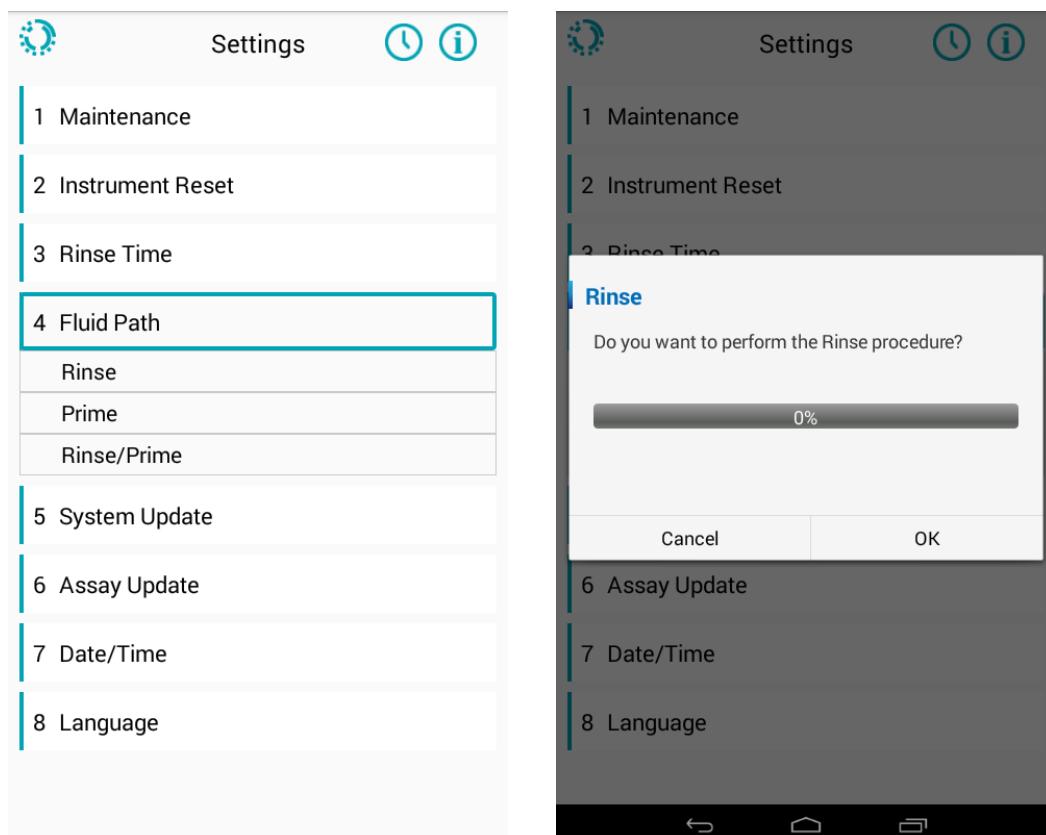


Fig. 31. Fluid path process

6.5 System Update

This function is restricted to qualified engineer only. The software version will be checked during maintenance by engineer. Contact PlexBio Co., Ltd. or local distributors for more information.

6.6 Assay Update

This function allows to update the built-in assay protocols.

PlexBio Co., Ltd or your local distributor will inform you once upgrades become available and provide further instruction. Updates are uploaded using the USB port below the touch screen of the IntelliPlex 1000 πCode Processor.

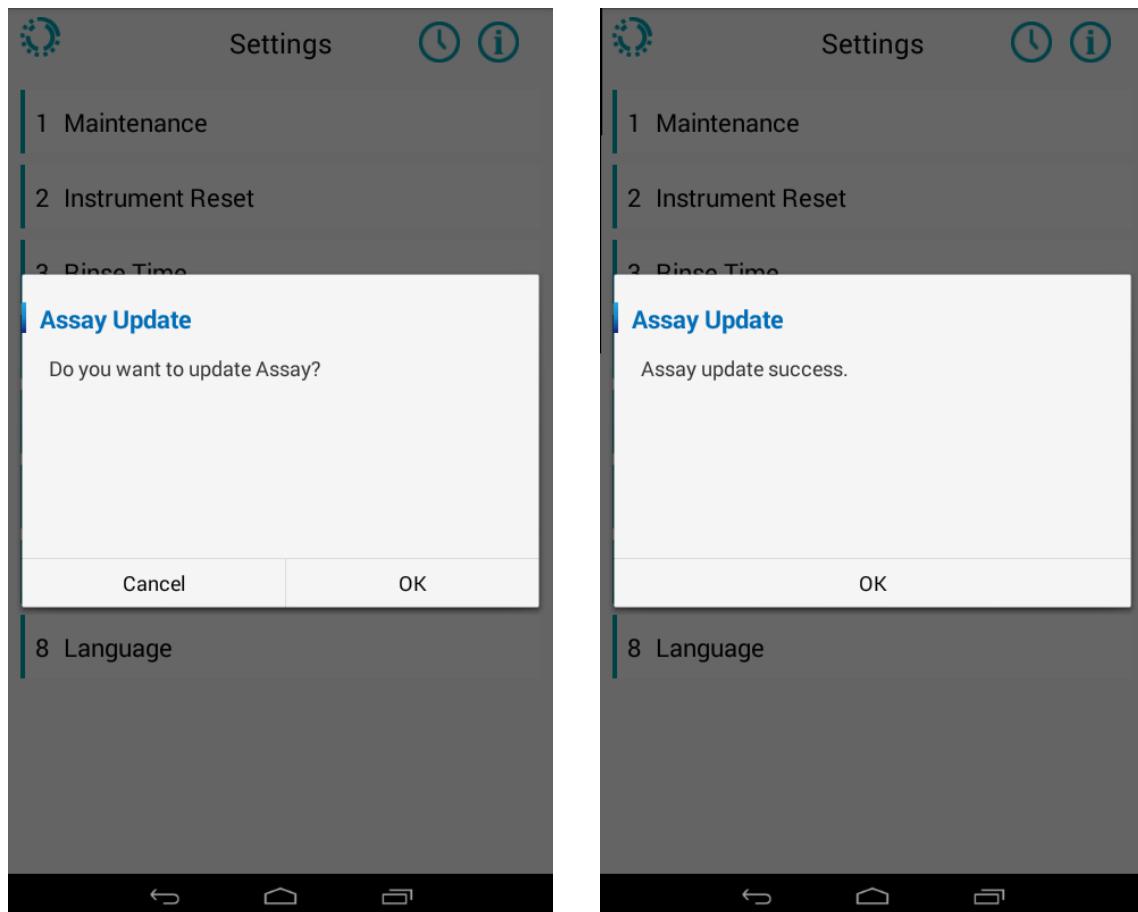


Fig. 32. Update Assay Protocols

6.7 Date/Time

Setup the current Date and Time for the instruments.

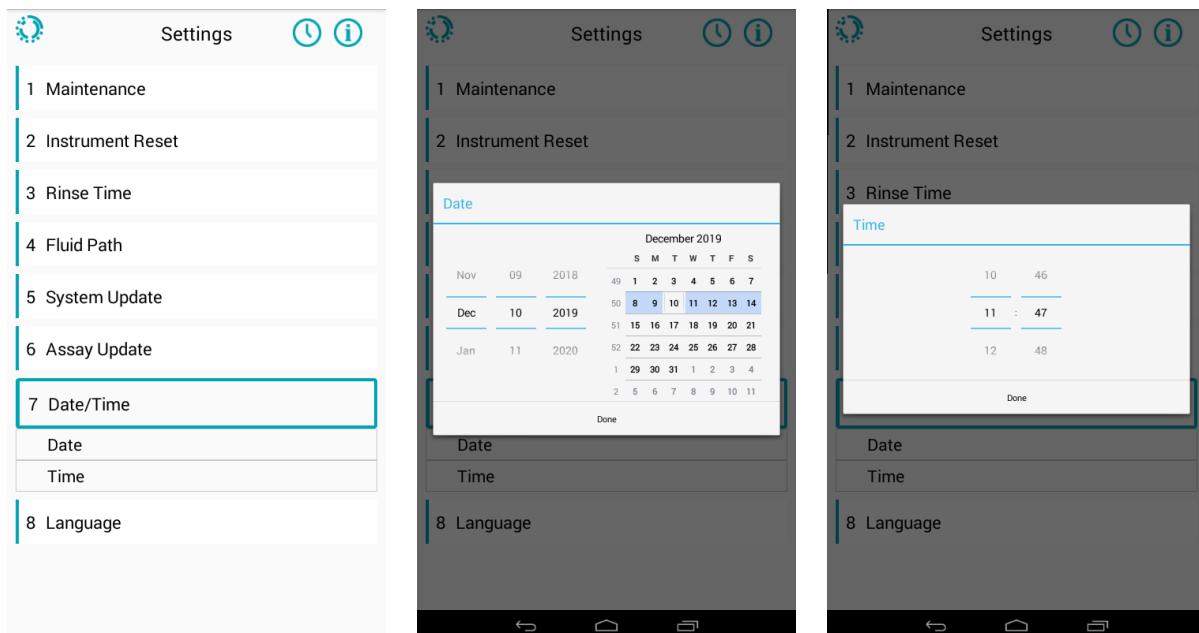


Fig. 33. Date and time setting

6.8 Language

Set the language to English or Simplified Chinese.

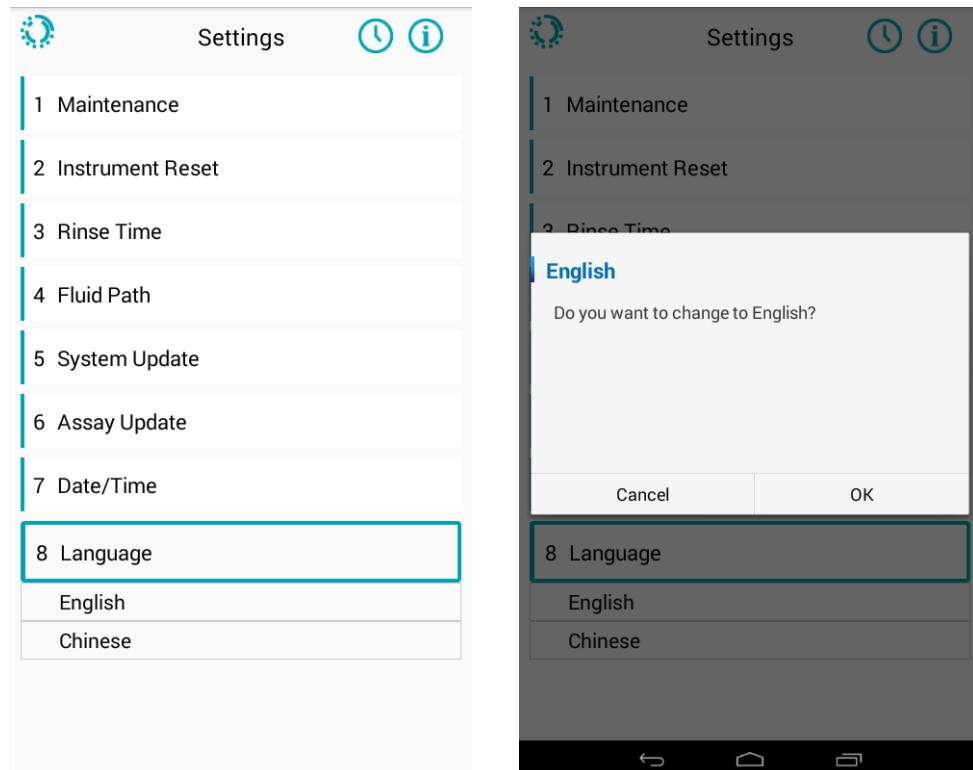


Fig. 34. Language setting

6.9 Service Mode

The Service Mode is intended for use by a qualified service engineer. Do not access the service mode unless specific instructions are given by PlexBio technical support.

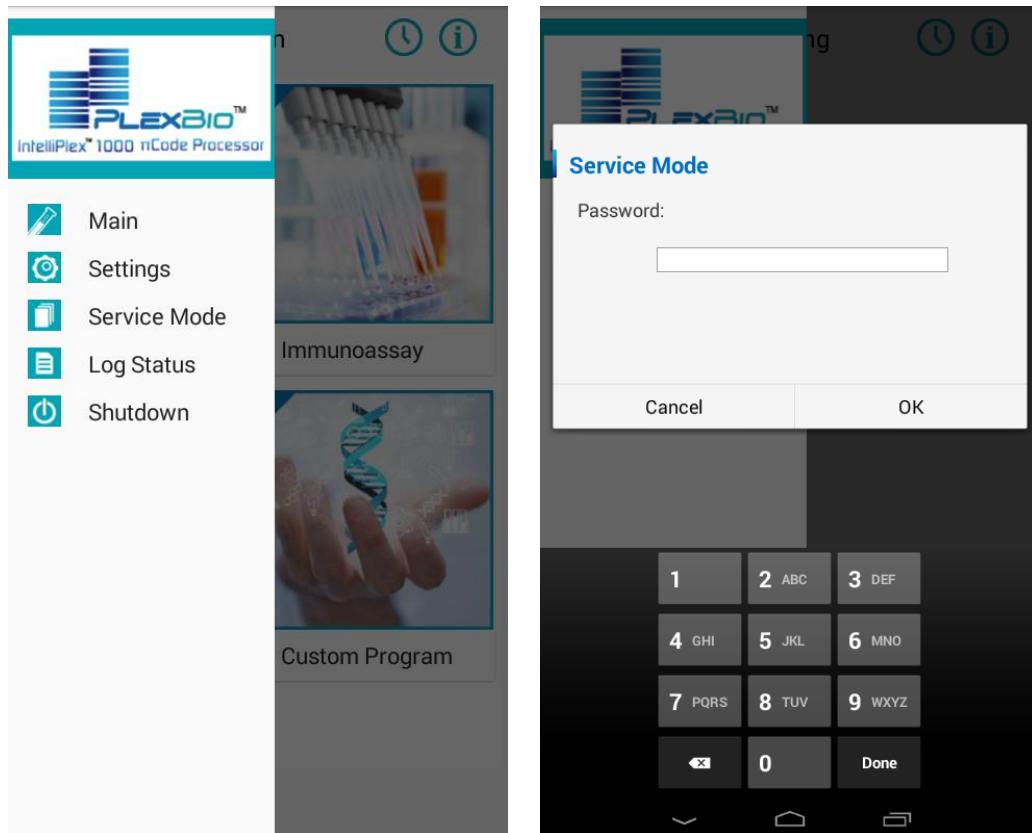


Fig. 35. Service Mode

6.10 Log Status

To view the system log history:

- Step 1. Select the **Log Status** on the home screen menu.
- Step 2. Choose the date and time to check the detailed log.
- Step 3. Click **DISPLAY** to check the detailed log.

To export log files:

Step 1. Prepare an USB drive with FAT32 format and at least 2GB capacity available.

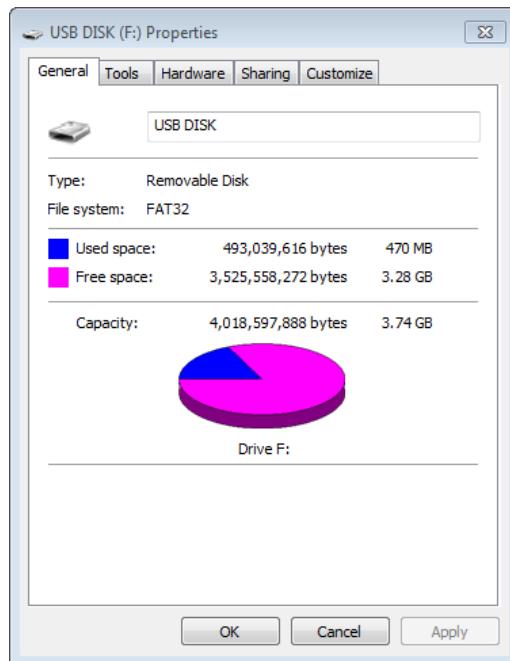


Fig. 36. USB drive requirements

Step 2. Create a new folder named “**PlexbioUpdate**”.

Step 3. Insert the USB drive into the USB port below the touch screen.

Step 4. Pull out the menu and select **Log Status**.

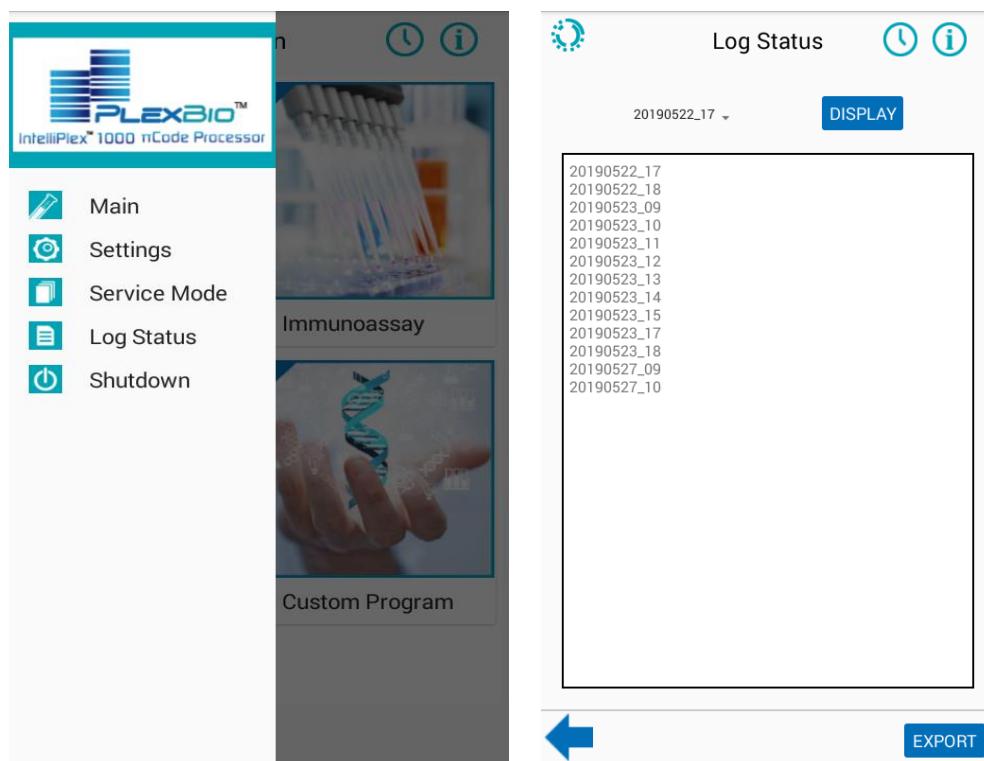


Fig. 37. Log status menu

Step 5. Click **EXPORT** on the bottom right to export log files.

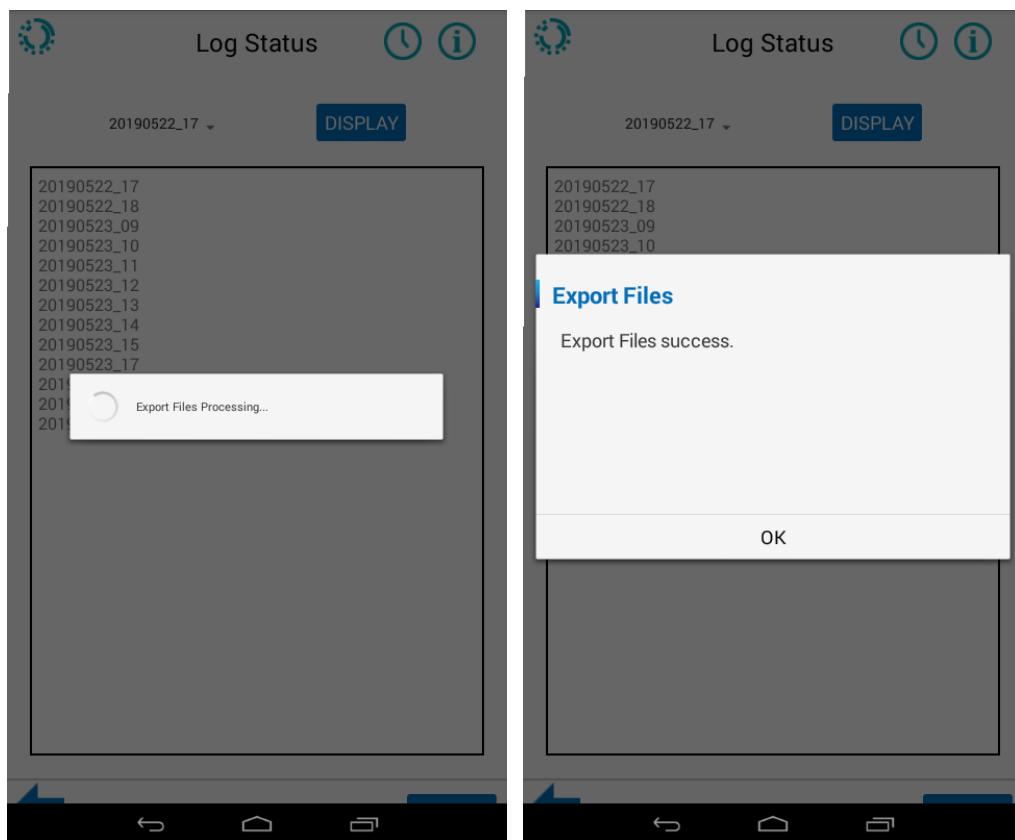


Fig. 38. Export log files

Step 6. Pull out the USB drive after the process is completed.

Step 7. Connect the USB drive to a computer to check the files saved in “Logs” file folder.

6.11 Shutdown

After finishing using the IntelliPlex 1000 Processor, it is important to shut down the system. To do so, run the **Shutdown** program. The **Shutdown** procedure will ensure that the pump and tubes are rinsed, and all modules are at their proper position. **Never** turn off the power on the backside of the instrument without running the **Shutdown** program first.

Step 1. Open the **System Menu** 

Step 2. Select **Shutdown** on the menu.

Step 3. Press **OK** to run the auto-rinse followed by the system turning off.

Step 4. After the system is off, switch the power button off.

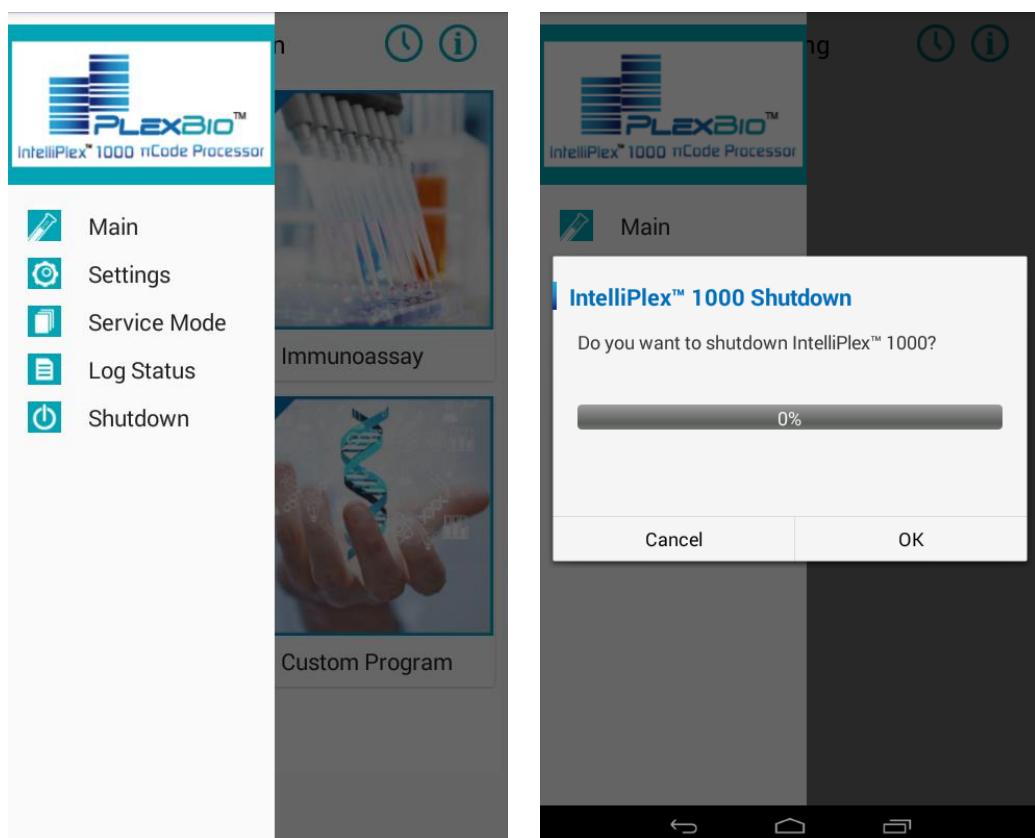


Fig. 39. System shutdown program

Chapter 7. Maintenance

Personnel that use, maintain, or clean IntelliPlex 1000 πCode Processor should be trained in standard laboratory safety practices and should follow those practices when handling the instrument.



Biohazard

Samples and waste fluid may contain biohazardous material. Where exposure to biohazardous material exists, follow appropriate bio-safety procedures, use personal protective equipment, and use ventilation devices.



General Cautions

Users should not perform any maintenance or cleaning of the electrical components in the system without training.

7.1 Recommended Maintenance Schedule

Regular care and maintenance of IntelliPlex 1000 πCode Processor will ensure optimal system performance. It is required to follow the schedule below. Operating the IntelliPlex 1000 πCode Processor without proper maintenance will void its warranty.

Please read and follow the section **7.2 As Needed Maintenance** below carefully. For more information on Preventive Maintenance or Extended Warranties, please contact Customer Service of PlexBio Co., Ltd. or qualified local distributors.

| Action | User | | Qualified Specialist |
|---|-------|---------|----------------------|
| | Daily | Monthly | Yearly |
| Check/Empty waste bottles | ✓ | | |
| Long-term Shutdown | | Varies | |
| Replace U Tray from Washing Tank | | ✓ | |
| Clean bottles | | ✓ | |
| Clean external surface | | ✓ | |
| Clean fluid path tubes with 70% ethanol | | ✓ | |
| Lubricate the stage guideway to prevent stage positioning error or motor failure. | | | ✓ |
| Replace the plastic tips | | | ✓ |
| Re-position all axes of moving modules | | | ✓ |
| Calibrate waterway performance | | | ✓ |
| Calibrate heater performance | | | ✓ |

Important: Depending on users' assays, some or all the maintenance procedures are more

frequently required than recommended in the schedule.

7.2 As Needed Maintenance

7.2.1 Clean Fluid Path Tubes with 70% Ethanol

It is required to clean the fluid path at least once a month:

- Step 1. Disconnect the ddH₂O and wash buffer bottle lids from their respective bottles.
- Step 2. Empty bottle by discarding all solutions. Rinse Wash Buffer bottle several times with water.
- Step 3. Use a bottle containing 800mL 70% ethanol (if not dedicated ethanol bottle is available, the ddH₂O bottle can be filled with 800mL 70% ethanol and used instead) and connect the ddH₂O bottle lid. Ensure the straw is submerged in ethanol.
- Step 4. Confirm that the Waste Bottle is connected and has sufficient space.
- Step 5. Run the **Rinse** cycle of the Fluid Path on the setting menu **four times** (refer to section 6.4).
- Step 6. Remove the ddH₂O bottle lid and place on clean paper towel. Connect the wash buffer lid to the bottle with 70% ethanol. Ensure the straw is submerged in ethanol.
- Step 7. Run the **Prime** cycle of the Fluid Path on the setting menu **four times** (refer to section 6.4).
- Step 8. Remove the wash buffer lid from the bottle and place on clean paper towel.
- Step 9. Run the **Rinse/Prime** cycle of the Fluid Path on the setting menu **four times**. This step will pump air through the tubing to displace any remaining liquid.
- Step 10. Disconnect the Waste Bottle Lid and empty the Waste Bottle, rinse several times with water.
- Step 11. Clean all lids with 70% ethanol and let air dry.
- Step 12. Clean all bottles with 70% ethanol and let air dry.
- Step 13. Assemble all bottle and lids with the IntelliPlex 1000 πCode Processor.
- Step 14. Fill the ddH₂O and Wash Buffer bottles with at least 500mL ddH₂O or Wash Buffer.
- Step 15. Perform **Rinse/Primer** two times (refer to section 6.4).
- Step 16. The IntelliPlex 1000 πCode Processor is operational.

Note: The “Clean Fluid Path Tubes” operation must be performed using 70% ethanol. The use of BLEACH and other chemicals is not permitted.

7.2.2 Clean and Disinfect Surfaces

We recommend cleaning the exterior surfaces of the IntelliPlex 1000 πCode Processor as needed. The surfaces can be cleaned with water, 70% ethanol or a mild detergent (followed by water wipe to remove any residual detergent).

To disinfect contaminated areas, remove all contaminant first. Disinfect the area using a 0.1% bleach solution for 5 minutes, then rinse well with water. Please note that interior spills must be handled with extreme care. Do not use excessive volumes, liquid must not gain access to the interior of the instrument. Caution: the heating plate and lid may be hot.

7.2.3 Renew U Tray

It is required to renew the U Tray at least once per month. Please refer to section 6.1.1.

7.2.4 Long-term Shutdown

We recommend performing **Long-term Shutdown** if the IntelliPlex 1000 πCode Processor will not be in operation for more than a week or if it cannot be switched on/off at least once a week.

The **Long-term Shutdown** procedure cleans the fluid path with water to remove all Wash Buffer followed by a 70% ethanol rinse to reduce the possibility of salt crystal formation and bacterial/fungal growth in the fluid path.

- Step 1. Remove the plastic V Tray.
- Step 2. Disconnect the ddH₂O and wash buffer bottle lids from their respective bottles
- Step 3. Empty bottle by discarding all solutions. Rinse Wash Buffer bottle several times with water.
- Step 4. Use a bottle containing 800mL 70% ethanol (if not dedicated alcohol bottle is available, the ddH₂O bottle can be filled with 800mL 70% ethanol and used instead) and connect the ddH₂O bottle lid. Ensure the straw is submerged in ethanol.
- Step 5. Confirm that the Waste Bottle is connected and has enough space.
- Step 6. Run the **Rinse** cycle of the Fluid Path on the setting menu **four times** (refer to section 6.4).
- Step 7. Remove the ddH₂O bottle lid and place on clean paper towel. Connect the wash buffer lid to the bottle with 70% ethanol. Ensure the straw is submerged in ethanol.
- Step 8. Run the **Prime** cycle of the Fluid Path on the setting menu **four times** (refer to section 6.4).

- Step 9. Remove the wash buffer lid from the bottle and place on clean paper towel.
- Step 10. Run the **Rinse/Prime** cycle of the Fluid Path on the setting menu **four times**. This step will pump air through the tubing to displace any remaining liquid.
- Step 11. Remove the plastic U Tray (refer to section 6.1.1).
- Step 12. Run the **Shutdown** program to turn off the instrument.
- Step 13. Switch the power off.
- Step 14. Disconnect the power cord from the power plug.
- Step 15. Disconnect the Waste Bottle Lid and empty the Waste Bottle, rinse several times with water.
- Step 16. Clean all lids with 70% ethanol and let air dry.
- Step 17. Clean all bottles with 70% ethanol and let air dry.
- Step 18. Assemble all bottle and lids with the IntelliPlex 1000 πCode Processor. Close the air valves of the ddH₂O and Wash Buffer lids.

7.2.5 Restarting after Long-term Shutdown

To initiate the IntelliPlex 1000 πCode Processor after Long-term Shutdown:

- Step 1. Open the air valves of the ddH₂O and Wash Buffer lids.
- Step 2. Do **not** fill the ddH₂O and Wash Buffer bottles.
- Step 3. Ensure that the on/off switch in the rear panel of the instrument is in the off position.
- Step 4. Plug the power cord into the back of the instrument and switch on the IntelliPlex 1000 πCode Processor.
- Step 5. Perform self-test (the system will pump air during self-test).
- Step 6. Place a new plastic U Tray (refer to section 6.1.1).
- Step 7. Fill the ddH₂O and Wash Buffer bottles with at least 500mL ddH₂O or Wash Buffer.
- Step 8. Perform **Rinse/Prime** two times (refer to section 6.4).
Visually confirm the uptake of ddH₂O or Wash Buffer and confirm discharge into waste bottle. If no ddH₂O or Wash Buffer uptake is observed, repeat **Rinse/Prime** up to four additional times. If still no uptake is observed, please contact Customer Service of PlexBio Co., Ltd. or qualified local distributors. If no ddH₂O or Wash Buffer uptake is observed but no discharge into waste bottle, perform system shutdown, switch the instrument and contact Customer Service of PlexBio Co., Ltd. or qualified local distributors.
- Step 9. The IntelliPlex 1000 πCode Processor is operational.

7.2.6 Connecting the Components

To connect the components:

- Step 1. Take out all the accessories including bottles, tubes and the AC power cord.
- Step 2. Plug the power cord into the back of the instrument.
- Step 3. Ensure that the on/off switch in the rear panel of the instrument is in the off position.
- Step 4. Fill up the wash buffer bottle with wash buffer and fill up the ddH₂O bottle with distilled water.
- Step 5. Connect the buffer tubes (Wash buffer and Distilled water) to the inlet connectors on the rear panel of the instrument and to the corresponding bottle as well. See the Fig. 4 for the connected diagrams.

7.2.7 Fuse Replacement

If the fuse in the instrument is broken, please follow these steps to replace it:

- Step 1. Pull out the fuse holder from the power socket.
- Step 2. Take out the broken fuse and replace it with a new one from the accessory box.
- Step 3. Push the fuse holder back to its original place.



Fig. 40. Fuse holder

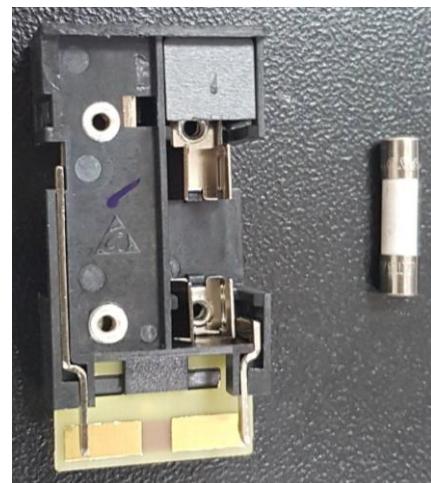


Fig. 41. Fuse and the fuse holder

Chapter 8. Troubleshooting

| Item | Error Code | Description | Solution |
|------|------------|--|---|
| 1 | 1001 | The temperature of bottom heater is higher than 65°C. The system will be locked. | Contact PLEXBIO or local distributors for service. |
| 2. | 1002 | The temperature of top heater is higher than 65°C. The system will be locked. | Contact PLEXBIO or local distributors for service. |
| 3. | 1003 | Abnormality is detected from the bottom heater sensor. The system will be locked. | Contact PLEXBIO or local distributors for service. |
| 4. | 1004 | Abnormality is detected from the top heater sensor. The system will be locked. | Contact PLEXBIO or local distributors for service. |
| 5 | 1005 | The temperature cannot reach $\pm 1.5^{\circ}\text{C}$ of configured temperature in 3 minutes during an incubation process. The system will be locked. | Contact PLEXBIO or local distributors for service. |
| 6 | 1103 | The temperature of bottom heater is detected to be higher than 95 °C. The system will be locked. | Contact PLEXBIO or local distributors for service. |
| 7 | 1104 | The temperature of top heater is detected to be higher than 95°C. The system will be locked. | Contact PLEXBIO or local distributors for service. |
| 8 | 2001 | The shaker motor does not return to the defined home position. | Reboot the machine and perform self-test. Contact PLEXBIO or local distributors for service if the error continues. |
| 9 | 2005 | The rpm of BLDC (shaking motor) is instable. | Reboot the machine and perform self-test. Contact PLEXBIO or local distributors for service if the error continues. |
| 10 | 3001 | Y axis moves abnormally. The system will be locked. | Contact PLEXBIO or local distributors for service. |
| 11 | 3101 | Z axis moves abnormally. The system will be locked. | Contact PLEXBIO or local distributors for service. |
| 12. | 3201 | Z_p axis moves abnormally. The system will be locked. | Contact PLEXBIO or local distributors for service. |
| 13. | 3301 | Z_M axis moves abnormally. The system will be locked. | Contact PLEXBIO or local distributors for service. |
| 14 | 3401 | The heat lid moves abnormally. The system will lock from further use. | Contact PLEXBIO or local distributors for service. |
| 15 | 6001 | The temperature of bottom heater is detected to be 1.5°C higher than the configured temperature during the period of 3 minutes after incubation process started to the end of incubation. The system will be locked. | Contact PLEXBIO or local distributors for service. |

| Item | Error Code | Description | Solution |
|-------------|-------------------|---|---|
| 16 | 6002 | The temperature of bottom heater is detected to be 1.5°C lower than the configured temperature during the period of 3 minutes after incubation process started to the end of incubation. The system will be locked. | Contact PLEXBIO or local distributors for service. |
| 17 | 6101 | The temperature of top heater is detected to be 1.5°C higher than the configured temperature during the period of 3 minutes after incubation process started to the end of incubation. The system will be locked. | Contact PLEXBIO or local distributors for service. |
| 18 | 6102 | The temperature of top heater is detected to be 1.5°C lower than the configured temperature during the period of 3 minutes after incubation process started to the end of incubation. The system will be locked. | Contact PLEXBIO or local distributors for service. |
| 19 | 6501 | The temperature appears to be lower than operation requirement (<18°C) during the temperature check when the instrument is turned on. | Wait until the temperature rises to requirement if the environmental temperature is within suitable range. |
| 20 | 6502 | The temperature does not reach the operation requirement within an hour after error 6501 occurs. The instrument should be operated under 18-32°C. | Shutdown the instrument. Make sure the environmental temperature rises to suitable range and reboot the instrument. |
| 21 | 6503 | The current temperature is too high. The configured temperature has to be at least 5 °C greater than current temperature to successfully start the program. | Wait until the heater cools down naturally, or check the environmental temperature and try again. |
| 22 | 5000 | Two or more error codes occurs at the same time. | Contact PLEXBIO or local distributors for service. |

Chapter 9. Contact Information

PlexBio Co., Ltd.

6F-1, No. 351, Yangguang St., Neihu Dist.,
Taipei City 11491, Taiwan

Customer Service and Sales

Web: <http://www.plexbio.com>

Phone: +886-2-2627-5878

Fax: +886-2-2627-5979

Order info: order@plexbio.com

Customer Service: service@plexbio.com

Chapter 10. Standard Terms and Conditions for the Use of Products

Contract

The terms and conditions herein (hereinafter referred to as the “Standard Terms”) apply to all of the products and services provided or will be provided by **PlexBio Co., Ltd.** (hereinafter referred to as “**PlexBio**”). Any changes to the Standard Terms shall have no binding effect on **PlexBio** unless the same has been agreed upon by an authorized representative of **PlexBio** in writing. The “Dealer” referred to herein represents **PlexBio** (if the products are purchased from **PlexBio** directly), or the distributor licensed by **PlexBio**. **PlexBio** expressly disagrees with any terms or conditions made by the buyer in the purchase order or any of such which is different from or not included in this Standard Terms.

The buyer's acceptance, unpacking, or use of the products or services shall constitute his/her acknowledgment and acceptance of the Standard Terms unconditionally. Once the buyer opens the packaging of PlexBio products or uses the products or services in any manner, the buyer acknowledges and accepts the Standard Terms unconditionally, and also agrees that the Standard Terms constitute the contract which has binding effect on the buyer under law. Where the buyer disagrees with the Standard Terms, he/she shall contact PlexBio immediately to return the products before using the products or services in any manner, and he/she shall not use the products or services in any manner. **PlexBio** has the right to amend the terms and conditions regarding specification and service without notifying the buyer in advance if no specification or service has been specified and identified in writing before.

Warranty

The warranty terms and conditions in this Standard Terms (the “Warranty”) apply to any instruments, spare parts and services (collectively, the “Products”) purchased by the buyer from **PlexBio** directly and situated in the territory of Taiwan. The Warranty excludes any activities other than calibration, certification and maintenance. **PlexBio** will not provide any Warranty toward the sale and use of the Products outside the territory of Taiwan. The Products distributed outside the territory of Taiwan will be sold “As is”. **PlexBio** will provide the buyer with quality assurance toward the spare parts purchased from **PlexBio** and that are used to maintain **PlexBio** instruments under the same terms and conditions herein in any countries/territories other than Taiwan around the world.

Particularly, the Warranty provided herein excludes any products, software or hardware provided

not by **PlexBio**. If the product is purchased from a **PlexBio**'s distributor, the Warranty shall be provided by the distributor to the buyer in writing directly.

Quality Assurance

Products: Regardless of whether or not the buyer accepts said terms and conditions, for any Products purchased from **PlexBio** directly, **PlexBio** will ensure that the performance of all the Products meets the product specifications provided by **PlexBio** within 12 months from the delivery date on (hereinafter referred to as the quality assurance period). **PlexBio** is entitled to take one of the following actions against any defects found and reported during the quality assurance period: (1) payment refund, or (2) defect repairs or spare parts replacements. The expenses derived from said actions shall be borne by **PlexBio**.

Software: **PlexBio** ensures that all the installed software substantially meets the functions described in the software documentation provided by **PlexBio**. Notwithstanding, **PlexBio** does not guarantee that the software is error-free or may not be attacked by hackers or viruses. The quality assurance period of the software is identical with that of the **PlexBio** product in which the software is installed.

Service: **PlexBio** ensures that, where the buyer finds any nonconformity of related services and notifies **PlexBio** of the same in writing within 30 days after the related services are performed; **PlexBio** shall be obligated to provide necessary services, assistance and consultation to correct the nonconformity.

General clauses: The Warranty and quality assurance provided are subject to the following limitations, including (1) the said quality assurance does not apply to consumable materials, accessories, normal wear and tear, damageable parts and fragile parts; (2) when the buyer asks **PlexBio** to provide quality assurance work beyond normal working hours, **PlexBio** shall be entitled to charge the buyer additional expenses; (3) the said quality assurance does not apply to the following circumstances: accidents, modifications, unfair use, abuse, destruction, or disassembly without authorization, or if the buyer fails to keep or operate in the manner as required, and(or) do unauthorized maintenance, installation or service, and(or) incorporates or integrates any product without permission from **PlexBio** into the **PlexBio** Products, or integrates the **PlexBio** Products into the buyer's environment or products, and(or) uses other software or user interface provided by the buyer/vendor without **PlexBio**'s permission; (4) for the Products sold by **PlexBio** but produced by another manufacturer, the quality assurance provided by **PlexBio** is only valid in the residual period in which the manufacturer provides its quality assurance; (5) once any Products is maintained and repaired by **PlexBio**, the buyer acknowledges that the maintenance

work will not extend the quality assurance period or derive any new quality assurance period. Other than the Warranties and quality assurance explicitly provided in writing in this Standard Terms, **PlexBio** does not provide any other warranties, including but not limited to the warranty toward fitness for a specific purpose, explicitly or implicitly. If the dealer determines, on the basis of its own judgment, that the buyer has misused the Products or failed to follow the instructions to use the Products, the warranty provided by the dealer toward the sale of the Products shall be invalid.

PlexBio shall not be liable for any direct or incidental damage caused by the use of or failure to use the Products, including but not limited to, the loss in the process of operation, shutdown, loss of revenue or profit, loss of the buyer's product or other products, in addition to the liability to be borne by the buyer to the supplier, or by the supplier due to such loss, and the labor or other expenses, damages or losses caused by such Products, including personal injury or loss of property, unless the personal injury or loss of property is caused by the PlexBio's willful conduct or gross negligence.

Maintenance: This maintenance clause applies to Products provided by **PlexBio** within the territory of Taiwan only. The maintenance includes correction, verification, and regular maintenance works only. **PlexBio** does not provide any warranty to the sales outside of Taiwan. The Products sold outside Taiwan shall be labeled "original manufactured" and provided "as-is". In regards of any spare parts placed outside Taiwan and used for the purpose of maintaining the **PlexBio** Products, **PlexBio** shall provide the quality assurance hereunder.

For any Products situated outside the territories of Taiwan for which maintenance is required:

- (i) The buyer shall notify **PlexBio** in writing of the issue of the Products immediately and also provide the details about the issue verified.
- (ii) The buyer shall contact **PlexBio** or the service maintenance engineers trained and qualified by **PlexBio** to evaluate the problems and verify the issues, and might need to bear the related expenses derived from the maintenance or transportation of the Products.
- (iii) The buyer shall return the Products at issue to **PlexBio** or the distributor as per **PlexBio**'s request. **PlexBio** might analyze the Products returned. Upon verifying that no defects exist, **PlexBio** will send the Products back to the buyer and the buyer shall bear the related expenses and freight. Notwithstanding, if **PlexBio** verifies that some issues exist, **PlexBio** will bear the freight. The buyer is not entitled to return the Products without **PlexBio**'s prior written consent.

Notice to User

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