



IntelliPlex™ ALK Rearrangement Kit User Manual

REF 82023 24 Reactions

RUO For Research Use Only



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IMPORTANT:
Read the instructions carefully prior to use

1. INTENDED USE

The IntelliPlex ALK Rearrangement Kit, based on π Code™ technology and PlexBio's instrument platform, is an in vitro RT-PCR assay intended for qualitative detection of 24 gene rearrangements in *ALK* gene from a variety of suitable samples, including RNA samples derived from formalin-fixed paraffin-embedded non-small cell lung cancer (NSCLC) tissue. This product is for research use only, and not for use in diagnostic procedures.

2. INTRODUCTION

The *anaplastic lymphoma kinase (ALK)* gene is an oncogene in NSCLC and other cancers. Chimeric proteins, such as EML4-ALK, contain an N-terminus derived from EML4 fused to the C-terminal kinase domain of ALK, which permits the ligand-independent dimerization and constitutive activation of ALK. Other fusion partners of ALK include KIF5B and TFG. The IntelliPlex ALK Rearrangement kit combines one step RT-PCR with π Code technology to enable multiplex, single-well detection of gene rearrangements from RNA specimens containing large amounts of wild-type RNA. The IntelliPlex ALK Rearrangement Kit identifies 24 rearrangements of the *ALK* gene (Table 1).

Table 1. Variants Detected

Gene	Fusion Variant	Inferred Breakpoint	
ALK	EML4-ALK A19	E6;A19	
	EML4-ALK V1	E13;A20	
	EML4-ALK V2	E20;A20	
	EML4-ALK V3a	E6;A20	
	EML4-ALK V3b	E6ins33;A20	
	EML4-ALK V3c	E6ins18;A20	
	EML4-ALK V4	E14;ins11del49A20	
	EML4-ALK V"4"	E15del60;del71A20	
	EML4-ALK V5a	E2b;A20	
	EML4-ALK V5b	E2;ins117A20	
	EML4-ALK V"5"	E18;A20	
	EML4-ALK V6	E13;ins69A20	
	EML4-ALK V7	E14;del12A20	
	EML4-ALK V8a	E17;isn30A20	
	EML4-ALK V8b	E17ins61;ins34A20	
	EML4-ALK i2	E14isn2;isn56A20	
	EML4-ALK i18	E20;isn18A20	
	EML4-ALK i53	E3;ins53A20	
	EML4-ALK i68	E17;isn68A20	
	KIF5B-ALK	KIF5B-ALK	K24;A20
			K15;A20
	TFG-ALK	TFG-ALK	T4;A20
			T5;A20
			T6;A20

3. TECHNOLOGICAL PRINCIPLES

The IntelliPlex ALK Rearrangement Kit utilizes two technologies, one-step RT-PCR and π Code, to achieve high sensitivity multiplex variant detection.

One-step RT-PCR

One-step RT-PCR combines cDNA synthesis and PCR amplification in a single tube, reducing operation time and contamination risk while yielding highly sensitive results.

π Code MicroDisc

π Code MicroDisc are manufactured to generate up to 16,000 distinct circular image patterns for multiplexing applications. Each π Code MicroDisc 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 a one-well reaction.

Detection Principle

The test is based on five processes:

1. RNA extraction from specimens
2. Multiplex one step RT-PCR amplification
3. Hybridization of PCR amplicons with variant-specific probe tagged π Code in a one-well reaction
4. Fluorescent labeling with streptavidin-phycoerythrin
5. Image pattern decoding and fluorescent signal detection by the PlexBio™ 100 Fluorescent Analyzer

4. WARNINGS AND PRECAUTIONS

- For research use only. Not for use in diagnostic procedures.
- This assay kit should only be used by qualified laboratory personnel.
- **Do not repeatedly freeze-thaw the reconstituted positive control. Use within one freeze-thaw cycle.**
- Separate, dedicated rooms and equipment for pre- and post- PCR process with unidirectional manner to avoid any contaminations are required.
- Pre-PCR process preparation should be operated in laminar flow hood to avoid contamination.
- Do not use a kit or reagent past its expiration date.
- Note that tumor samples are non-homogeneous in terms of genotype, and may contain non-tumor sections, which can cause false negative results.
- Reagent components have been diluted optimally. Further dilution of the component reagents is not recommended.
- Specimens should be handled as infectious material. Please follow universal precautions for safe use.
- 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 may interfere with decoding and signal acquisition.

- 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 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.**
- 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. A 1:10 dilution of household bleach will produce a 0.5% sodium hypochlorite solution.
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.
- Material Safety Data Sheets (MSDS) are available upon request from PlexBio Customer Service.

5. KIT COMPONENTS

The IntelliPlex ALK Rearrangement Kit contains sufficient reagents for up to 24 tests. Kit components include:

1. **ALK KIT RT-PCR Buffer**
Ref. No.: 20171-R
Quantity & Volume: 1 vial, 300 uL/vial
Description: For RT-PCR amplification
Contents: 2X Reaction Mix, MgSO₄ and dNTPs
2. **ALK KIT RT-PCR Enzyme**
Ref. No.: 20172-R
Quantity & Volume: 1 vial, 14.4 uL/vial
Description: For RT-PCR amplification
Contents: RT/Hot-Start Taq MIX, RNase Inhibitor

- 3. ALK KIT RT-PCR Primer Mix**
Ref. No.: 20170-R
Quantity & Volume: 1 vial, 165.6 uL/vial
Description: For RT-PCR amplification
Contents: <20 % Forward Primer,
 <10 % Reverse Primer (biotin labeled)
- 4. ALK KIT π Code MicroDisc**
Ref. No.: 20174-R
Quantity & Volume: 1 vial, 480 μ L/vial
Description: For PCR amplicon capture
Contents: π Code MicroDisc, Glycerol,
 Phosphate buffered saline,
 0.1% Albumin- from bovine (Biological),
 <0.1% EDTA and <0.1% Sodium azide
- 5. ALK KIT POS Control**
Ref. No.: 20168-R
Quantity & Volume: 3 vials, lyophilized
Description: Assay positive control; reconstituted
 25 μ L ddH₂O per vial prior to use.
Contents: 20% EML4-ALK v1 RNA,
 80% RNastable[®] LD
- 6. NEG Control**
Ref. No.: 20549-R
Quantity & Volume: 1 vial, 120 μ L/vial
Description: Assay negative control
Contents: ddH₂O
- 7. SA-PE Solution**
Ref. No.: 20302
Quantity & Volume: 1 bottle, 7 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
- 8. ALK KIT Hy Buffer**
Ref. No.: 20166-R
Quantity & Volume: 1 bottle, 2.4 mL/bottle
Description: For hybridization
Contents: ALK Detector,
 Saline-Sodium Phosphate-EDTA
- 9. 10X Wash Buffer**
Ref. No.: 20546-R
Quantity & Volume: 1 bottle, 50 mL/bottle
Description: For π Code washing
Contents: Phosphate buffered saline,
 1% Tween-20 and <0.1% Sodium azide

- 10. ddH₂O**
Ref. No.: 20548-R
Quantity & Volume: 1 vial, 1.5 mL/vial
Description: For reconstitution of ALK POS Control
Contents: Nuclease-free water

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

6. MATERIALS AND EQUIPMENT REQUIRED BUT NOT SUPPLIED

Required products for compatibility with IntelliPlex kits:

- 96-well plate (PlexBio; Cat. No. 80025 or Greiner Bio-one; Cat. No. 655101)
- IntelliPlex™ 1000 π Code Processor (PlexBio; Cat. No. 80033)
- PlexBio 100 Fluorescent Analyzer (PlexBio; Cat. No. 80000)
- U Tray (PlexBio; Cat. No. 80023)
- V Tray (PlexBio; Cat. No. 80024)
- DeXipher™ RUO (Required: PlexBio; Cat. No. 80050)

Required components:

- Qubit™ Fluorometer with dedicated quantitative reagents (Invitrogen; any models) or equivalent
- Clean tubes for PCR reaction (Gunster; Cat. No. MB-P08A or equivalent)
- Dedicated micropipette
- Filter tips for micropipette
- ddH₂O for dilution of 10X Wash Buffer
- Nucleic acid sample purification kit compatible with downstream PCR amplification.
- For FFPE samples: FFPE RNA extraction kit (Recommended: RNeasy[®] FFPE Kit; Qiagen; Cat. No. 73504 or equivalent)
- Vortex mixer
- Micro-centrifuge
- Thermocycler (Recommended: DigiPlex™ Thermocycler, PlexBio; Cat. No. 80018/ MiniAmp™ Thermal Cycler, Applied Biosystems™; Cat. No. A37834 or equivalent)
- Industrial Computer (Recommended: PlexBio; Cat. No. 80002)

7. STORAGE, STABILITY AND TRANSPORTATION

Storage

All kit components should be stored at 2-8°C.

Stability

Do not use any kit that has expired. All components are

stable up to the expiration date on the label if handled and stored under the recommended conditions.

Transportation

The shipping temperature for the kit is 2-8°C. If the kit package or components are incomplete, please contact PlexBio customer service (service@plexbio.com).

8. INSTRUMENT AND SOFTWARE

Instrument

Please refer to the instrument user manual for complete operation instructions (Thermocycler, IntelliPlex 1000 π Code Processor and PlexBio 100 Fluorescent Analyzer).

Software Installation

The ALK Rearrangement Kit has a designated Kit App and ENC file. The Kit App contains the π Code 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 **ALK Kit App**.
2. Click on the "Installer" in the APP folder and follow the instructions to complete 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 **ALK 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 RUO kit.
2. Save the ENC file to your computer.
3. Follow the PlexBio 100 Fluorescent Analyzer User Manual to import the ENC file.

9. SAMPLES

The IntelliPlex ALK Rearrangement Kit supports a variety of samples, including formalin-fixed paraffin embedded tissues (FFPET) from NSCLC. The nucleic acid of all samples must be extracted with a purification procedure supporting downstream RT-PCR amplification.

NOTE FOR USE OF FFPET:

- FFPET specimens may be stored $\leq 30^{\circ}\text{C}$ for up to 12 months after the date of tissue collection and processing. The optimal tissue fixation time for test should be less than 72 hr.
- Only FFPET sections of 10- μm thickness containing at least 10% tumor content are to be used in the ALK Rearrangement Test. Any specimen containing less than 10% tumor content should be macro-dissected prior to deparaffinization.
- Do not use stained FFPE specimens which could generate invalid and/or incorrect results.

Storage of Extracted RNA

Extracted RNA can be stored at -20°C for immediate use (≤ 24 hours), or at -80°C for long-term (1 – 14 days) storage. Do not subject the extracted RNA to repeated freeze/thaw cycles.

10. BEFORE YOU START

1. Check that the Kit App has been installed and the lot specific ENC file has been imported to DeXipher.
2. Check that you have 5 μL of extracted RNA (≥ 10 ng/ μL) ready for analysis.

11. ASSAY PROCEDURE

Warning:

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

11.1 RNA Quantification

1. Quantify the extracted RNA using a Qubit Fluorometer (or equivalent) according to the manufacturer's protocol.
2. The RNA Stock concentration should be ≥ 10 ng/ μL to ensure optimal performance. Each RT-PCR reaction uses 5 μL of a ≥ 10 ng/ μL RNA Stock (at least 50 ng of total RNA input are recommended).

11.2 Multiplex one-step RT-PCR Amplification

1. Briefly centrifuge the POS Control tube and reconstitute with 25 μL ddH₂O per vial by pipetting up and down. Keep reconstituted POS control on ice prior to use.

NOTE: Do not repeatedly freeze-thaw the reconstituted POS control. Use within one freeze-thaw cycle and store the leftover at -20°C if needed.

2. Vortex to mix each sample before use.
3. Spin down and keep samples on ice.

4. Prepare the one-step RT-PCR Reaction:

For each RT-PCR reaction:

ALK RT-PCR Buffer	12.5 μ L
ALK RT-PCR Enzyme	0.6 μ L
ALK RT-PCR Primer Mix	6.9 μ L
Sample/POS Control/NEG Control	5 μ L
Total volume	25 μL

NOTE:

- The amount of one-step RT-PCR reagent 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.

5. Mix by tapping the tubes and spin down before placing the tubes on the thermocycler. Set up the one-step RT-PCR program conditions as below:

PCR Program Conditions*

Temp. ($^{\circ}$ C)	Time	Cycles
45	15 min	-
95	2 min	-
95	15 sec	50
60	30 sec	
72	30 sec	
4	Hold	-

NOTE: Ramp rate: 100% (PlexBio; Cat. No. 80018).
3.0 $^{\circ}$ C/sec (ABI MiniAmpTM; Cat. No. A37834).

11.3 Hybridization and SA-PE Reaction

1. **Prepare 1X Wash Buffer:** Transfer 50mL of the 10X Wash Buffer to the IntelliPlex 1000 π Code 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 π Code Processor Wash Buffer consumption:

Procedure	Wash Buffer Consumption (mL)
Self-test	50 mL
DNA & RNA program (1 lane, up to 8 tests)	150 mL
DNA & RNA program (3 lanes, up to 24 tests)	220 mL

2. **Add 20 μ L π Code MicroDisc to 96 well plate:** Mix by vortexing the **ALK π Code** for 10 seconds, then, by pipetting, add 20 μ L of the π Code to each well directly. Vortex the tube of π Code every four wells in between dispensing to ensure homogeneous suspension.

NOTE : Each amplified PCR products (including samples, POS and NEG control) should be added into wells lane wise, in order of A1, B1...H1 and followed by A2, B2...H2 and so on.

3. **Add 100 μ L of ALK Hy Buffer** to each well.

4. Spin down the PCR products.

5. **Denature the PCR products** on the thermocycler by heating at 95 $^{\circ}$ C for 5 minutes, immediately cooled on ice/ cooler or thermocycler to ensure the denatured status. Spin down before use. Use immediately (within 1 hour after denaturation).

NOTE: Pay attention to the lid temperature of thermocycler while taking out the denatured PCR products.

6. **Add 10 μ L of the denatured PCR products** to each well.

7. **Pipet the desired volume of SA-PE solution** into the V Tray in SA-PE tank. Please note that the dead volume of the V Tray is **500 μ L** for up to 6 selected lanes or **800 μ L** if more than 6 lanes are selected. The minimum usage of SA-PE is **one lane (900 μ L)**.

Calculation Example:

For a 3-lane reaction, the required SA-PE solution volume is at least:

400 μ L x 3 lanes + 500 μ L (dead volume) = 1.7 mL
It is recommended to add extra solution volume into the V Tray to ensure sufficient dispensing volume.

NOTE:

Required SA-PE Solution by Lane(s):

Number of Processed Lane(s)	Required SA-PE Solution (μ L)
1	900
2	1300
3	1700
4	2100
5	2500
6	2900
7	3600

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

- SA-PE solution should be kept in the dark.
- Do not** reuse the leftover SA-PE solution and V Tray tank. Replace a new V Tray with every assay run.

8. **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 is finished.

NOTE:

- IntelliPlex 1000 πCode Processor must be maintained properly and regularly.
- Do not** open the door when the instrument is in operation.
- The kit contains sufficient reagents for 6 runs of tests (including POS and NEG controls) for a maximum of 24 tests. Please note that the included Wash Buffer is only sufficient for up to two independent runs. Additional Wash buffer can be ordered from PlexBio (Ref. No: 80210).

11.4 Image Decoding and Fluorescence Detection

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

NOTE:

- PlexBio 100 Fluorescent Analyzer must be calibrated regularly (once per month).
- 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 variant call report.

NOTE:

- A single run can include from 2 to 96 tests (including POS and NEG controls) per 96 well Microwell plate. When running more than 24 specimens, multiple IntelliPlex ALK Rearrangement Kits of the same lot will be required.
- The procedure described above must be followed to detect $\geq 5 \sim 1209$ RNA copies in a background of wild-type RNA for the ALK fusion variants in Table 1.

12. DISCLAIMERS

Negative Test Result

A negative test result means that the targeted variant was not detected by the kit. Experimental errors or other causes may lead to false negative results. Interpretation of the results should consider these possibilities.

Positive Test Result

A positive test result means that the targeted variant was detected by the kit. Experimental errors or other causes may lead to false positive results. Interpretation of the results should consider these possibilities.

13. INTERPRETATION OF RESULTS

Table 2. Interpretation of Results

Test Result	Reported Result	Interpretation
Fusion Detected	Refer to Table 1	Targeted fusion detected
Fusion Not Detected	None	Targeted fusion not detected
Invalid Assay	Invalid	Possible Causes: <ol style="list-style-type: none"> 1. PCR Inhibition (presence of inhibitor in the sample) 2. Improper stored reagents 3. Low sample RNA input or quality 4. Low πCode Disc Count (the πCode tube was not well-vortexed)

		before pipetting) 5. Reagent not added 6. Failed Blank π Code Control 7. Sample quality due to improper fixation process or storage condition
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NOTE:

In case of heterogeneity of samples or multiple fusion variants, only the dominantly detected fusion variant is reported. "Fusion Detected" indicates that the signal for at least one fusion site is greater than the cutoff value of the corresponding target. When multiple variants are detected in a sample, only the one that exhibits the highest signal is reported.

14. TROUBLESHOOTING

The troubleshooting listed below addresses possible problem causes and solutions provided during assay procedures.











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.

Problem	Possible Cause	Recommendations
Positive Control Fail / Negative Control Fail	1. No POS Control or NEG Control added. 2. RNase contamination. 3. Assay did not work. 4. Cross contamination between samples. 5. Wrong PC/NC wells chose.	1. Ensure POS Control and NEG Control are added. 2. Ensure all operating procedures are followed correctly. Ensure work environment is free of RNase. 3. Make sure all the assay procedures are followed correctly. 4. Clean all surfaces and equipment. Operate pre-PCR and post-PCR in the dedicated area and separate the equipment for use. 5. Choose the correct PC/NC wells and repeat reading.
π Code MicroDiscs Count Fail	DeXipher is unable to detect sufficient π Code MicroDiscs numbers for fusion variants determination.	
	1. π Code MicroDiscs are not proper dispersed in the well. 2. Not enough π Code MicroDiscs added to well. 3. Microbes exist in buffers. 4. Instruments error or malfunction.	1. Re-disperse the microplate using IntelliPlex 1000 Processor, and repeat reading. 2. Ensure π Code MicroDiscs are well-mixed with proper amount added. 3. Use freshly prepared wash buffer and ddH ₂ O for hybridization to reduce π Code MicroDiscs loss rate. 4. Contact PlexBio Customer Service.

Problem	Possible Cause	Recommendations
SA-PE Monitor Control Fail	Performance of SA-PE is assessed by the SAPE Monitor Control.	
	<ol style="list-style-type: none"> No SA-PE was added or insufficient SA-PE solution for dispensing. SA-PE solution inactivation. Incorrect tested lanes of microplate selected for SA-PE solution dispensing. 	<ol style="list-style-type: none"> Make sure all the assay procedures are followed correctly. Calculate sufficient SA-PE solution volume for dispensing. Repeat test. Ensure correct storage condition and minimize the light exposure. Do not use SA-PE past its expiration date. Repeat assay and make sure lanes selected correctly.
Blank Control Fail	“Background” is determined by measuring MFI of an internal control that should not give a signal.	
	<ol style="list-style-type: none"> Wrong hybridization conditions. Residues of SA-PE solution in wells after hybridization. PlexBio 100 Fluorescent Analyzer is not calibrated. Markings on plates. 	<ol style="list-style-type: none"> Check correct hybridization program is selected. Ensure all buffers (Wash buffer and ddH₂O) on IntelliPlex 1000 Processor are fresh-made and sufficient for washing procedures. Perform calibration on PlexBio 100 Fluorescent Analyzer. Do not make any marking on plate.

Problem	Possible Cause	Recommendations
Reference Gene Fail	Reference Gene monitors quality of tested sample and must be positive.	
	<ol style="list-style-type: none"> No Sample added or absence of human-derived RNA. Insufficient sample input for assays or poor sample quality. 	<ol style="list-style-type: none"> Ensure human-derived RNA samples are added. Do not use artificial RNA as samples which may generate invalid results. Quantify samples and check the sample input and RIN (RNA integrity number) value. If still remains failed, ensure the collected samples meet specimen requirements. Retest with new samples if needed.
	<ol style="list-style-type: none"> PCR inhibition exists. 	<ol style="list-style-type: none"> Follow sample extraction instructions carefully. Ensure required temperature ranges and centrifugation needs are complied. Ensure complete removal of ethanol.
	<ol style="list-style-type: none"> PCR procedures are not performed correctly. 	<ol style="list-style-type: none"> Make sure all PCR procedures are followed correctly. Do not to use expired materials or mixed lots of reagents. Ensure storage conditions are correct.



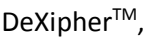

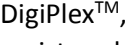
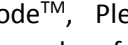
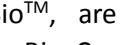
15. SYMBOLS

Symbol	Explanation	Symbol	Explanation
	For research use only		Catalog number
	Batch number		Consult instructions for use
	Manufacturer		Use by Date
	Temperature limitation		Caution
	Contains sufficient for <n> tests		Date of Manufacture

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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