WHO Prequalification of In Vitro Diagnostics
PUBLIC REPORT
Product: OraQuick HIV Self-Test
WHO reference number: PQDx 0159-055-01

OraQuick HIV Self-Test with product codes **5X4-1000.###[1], 5X4-1001.###[1], 5X4-2001.###[1], 5X4-7000.050, 5X4-7000.250, 5X4-7000.200, and 5X4-0004.###** manufactured in Thailand for **OraSure Technologies, Inc.**, **rest-of-world regulatory version**, was accepted for the WHO list of prequalified in vitro diagnostics and was listed 20 July 2017.

Summary of WHO prequalification assessment for OraQuick HIV Self-Test[2]

	Date	Outcome
PQ listing	8 April 2016	listed
Dossier review	26 January 2016	MR
Site inspection(s) of the quality management system	22-26 July 2019	MR
Laboratory evaluation of performance and operational characteristics	28 January 2016	MR

MR: Meets requirements

OraSure Technologies, Inc submitted a change notification for their prequalified product OraQuick HIV 1/2 Rapid Antibody Test to introduce a new configuration with an intended use specific for HIV self-testing (OraQuick HIV Self-Test). The new configuration was adapted from the corresponding professional use product (OraQuick HIV 1/2 Rapid Antibody Test), for which a WHO prequalification assessment has already taken place. Additional data was generated to meet particular requirements for self-testing as set out in the WHO Technical Specifications Series document TSS-1 Human Immunodeficiency Virus (HIV) rapid diagnostic tests for professional use and/or self-testing. [3]

[1] Country specific variations are documented through a suffix "###" to the product code.

[2] Dossier assessment, manufacturing site inspection and laboratory evaluation for the OraQuick HIV Self-Test were adapted from the professional use product, OraQuick HIV 1/2 Rapid Antibody Test prequalified in 2016. Please refer to the WHO Prequalification of Diagnostics Programme PUBLIC REPORT for OraQuick HIV 1/2 Rapid Antibody Test https://extranet.who.int/pqweb/content/public-report-oraquick-hiv-12-rapid-antibody-test-pqdx-0159-055-00

[3] https://apps.who.int/iris/bitstream/handle/10665/251857/9789241511742-eng.pdf;jsessionid=153ABC9D88E7623A1AD1DF946A22B4C8?sequence=1

Report amendments and product changes

This public report has since been amended. Amendments may have arisen because of changes to the prequalified product for which the WHO has been notified and has undertaken a review. Amendments to the report are summarized in the following table, and details of each amendment are provided below.

Public report amendment	Summary of amendment	Date of report amendment
2.0	Introduction of a new configuration with an intended use specific for HIV self-testing (OraQuick HIV Self-Test). The new configuration (OraQuick HIV Self-Test) was adapted from their professional use product (OraQuick HIV 1/2 Rapid Antibody Test), for which a WHO prequalification assessment had already taken place. Additional data was generated to meet requirements in the WHO Technical Specifications Series document TSS-1 Human Immunodeficiency Virus (HIV) rapid diagnostic tests for professional use and/or self-testing[4].	14 June 2016
3.0	Inclusion of a pharmacy distribution variant (5X4-2001) in addition to the existing community version (5X4-1000 and 5X4-1001)	8 May 2018
4.0	Inclusion of latest labelling and Correction of a typographical error.	20 June 2018
5.0	1. Add 1 IFU to the labelling on the pouched device and implement the use of a blank inner and outer pouch to allow for customization of country-specific information on the pouch. Added a statement to the Public Report for PQDx-0159-055-01 indicating that country-specific variations are documented through a suffix "###" to the product code. 2. Revision of the IFU from a single double-sided page to a single-sided single page. Added a limitation of the test in the IFU as follows "*This product has not been evaluated for use in self-testing for individuals younger than 12 years of age. For children ages 2-11, testing must be performed by a trained health care worker*". Revision of the inner pouch to utilize ISO 15223 compliant symbols and addition of a disposal bag to both the community and pharmacy versions of the test kit.	29 November 2019
6.0	Correction of product codes to reflect country-specific variations documented through a suffix "###" to the product code on the	17 December 2021

[4] http://apps.who.int/iris/bitstream/handle/10665/251857/9789241511742-eng.pdf;jsessionid=E2718EC36EFD314EFE87E902244528E1?sequence=1

	outer packaging (i.e. 5X4-1001.001, .002, …). Change on product labelling due to minor revisions.	
7.0	1. Edits on notes on page 4 of the public report from "inner pouch" to pouch only to address procurers' concerns. Updating of the pouch label to align with country-specific configurations. 2. Addition of product codes 5X4-7000.050, 5X4-7000.250, 5X4-7000.200, and 5X4-0004.###.	16 August 2022
8.0	1. Increasing warehousing capacity to meet the ongoing increase in demand for the OraQuick HIV Self-Test. The new facility will be used for raw material storage, warehousing and distribution. 2. Addition of the manufacturing site inspection assessment in the footnote on pages 1 and 6 of the public report so that users of the public report can refer to the OraQuick HIV 1/2 Rapid Antibody Test public report for more details. 3. Updated the date of the manufacturing site inspection with the most recent inspection.	18 May 2023

Intended use[5]

According to the claim of the manufacturer, "*OraQuick HIV Self-Test is an in-vitro diagnostic medical device (IVD) that is used for self-testing of antibodies for HIV-1 and HIV-2 in oral fluid. This test is intended as an aid to detect antibodies to HIV-1 and HIV-2 from infected individuals".*

Assay description

According to the claim of manufacturer, "*OraQuick HIV Self-Test is a visually read, qualitative immunochromatographic test for the detection of IgG antibodies to HIV-1 and HIV-2. The flat pad that contacts the gums is treated with a mild surfactant, and no materials of viral origin are used in the manufacture of the test. One cannot become infected with HIV by taking this test. The device is placed into the subject's mouth, so that the flat pad is between the cheek and the outer gums, then swabbed across the outer gum line. The device is then placed into a vial containing a premeasured amount of developer solution, and allowed to develop. Use only the stand provided to hold the developer vial. Fluid from the surface of the gums enters the device through the flat pad, then flows onto a test strip. As it migrates across the strip, it hydrates and mixes with a red-colored reagent (protein A bound to colloidal gold). IgG antibodies in the specimen bind to the reagent. If in turn the bound IgG antibody*

[5] This product is one that uses Protein A to detect human IgG antibodies. Protein A is also able to detect other classes of human antibody (IgA, IgD, IgE and IgM) but not as reliably as it does IgG. This product has been prequalified with respect to its ability to detect human IgG antibodies. Any claim to detect other types of antibodies on this kind of product has not been validated based on WHO prequalification requirements.

recognizes synthetic HIV-1 or HIV-2 antigen immobilized on the strip enclosed in the housing, a colored line forms in the 'T' (test) area of the result window. If not, no line forms there.

Further up the strip, the colored reagent encounters an immobilized biochemical that recognizes human antibodies. The line that forms in this 'C' area of the result window is the control line. It demonstrates assay validity, indicating that the oral fluid contains IgG, that the strip is functioning properly, and that fluid is migrating appropriately through the device".

Test kit contents:

OraQuick HIV Self-Test (community version)	
Product code 5X4-1000.### - 50 pouched kits	**Product code 5X4-1001.### - 250 pouched kits**
Each pouched kit (5X4-0004.xxx) contains: • **1 divided pouch** with - a **single use test device**; and - a **desiccant**; and - a **developer solution vial** containing 1ml of phosphate buffer saline solution containing polymers and an antimicrobial agent • **1 test stand** • **1 instructions for use** • **1 disposal bag**	Each pouched kit (5X4-0004.xxx) contains: • **1 divided pouch** with - a **single use test device**; and - a **desiccant**; and - a **developer solution vial** containing 1ml of phosphate buffer saline solution containing polymers and an antimicrobial agent • **1 test stand** • **1 instructions for use (IFU)** • **1 disposal bag**
50 pouched kits (product code 5X4-7000.050)	**250 pouched kits (product code 5X4-7000.250)**
Each pouched kit (5X4-7000) contains: • **1 divided pouch** with - a **single use test device**; and - a **desiccant**; and - a **developer solution vial** containing 1ml of phosphate buffer saline solution containing polymers and an antimicrobial agent • **1 test stand** • **1 instructions for use** • **1 disposal bag**	Each pouched kit (5X4-7000) contains: • **1 divided pouch** with - a **single use test device**; and - a **desiccant**; and - a **developer solution vial** containing 1ml of phosphate buffer saline solution containing polymers and an antimicrobial agent • **1 test stand** • **1 instructions for use (IFU)** • **1 disposal bag**
OraQuick HIV Self-Test (pharmacy version)	
Product code 5X4-2001.### - 200 boxed kits (5X4-2001U.###)	**Product code 5X4-7000.200) - 200 Boxed kits (5X4-7000P)**

<table>
<tr>
<td>Each boxed kit (5X4-2001U.###) contains:
• 1 divided pouch with
- a single use test device; and
- a desiccant; and
- a developer solution vial containing 1ml of phosphate buffer saline solution containing polymers and an antimicrobial agent
• 1 test stand
• 1 instructions for use
• 1 disposal bag</td>
<td>Each boxed kit (5X4-7000P) contains:
• 1 divided pouch with
- a single use test device; and
- a desiccant; and
- a developer solution vial containing 1ml of phosphate buffer saline solution containing polymers and an antimicrobial agent
• 1 test stand
• 1 instructions for use
• 1 disposal bag</td>
</tr>
<tr>
<td colspan="2">Each kit contains the same pouched device configuration as the community version, except the contents are contained in a carton.</td>
</tr>
<tr>
<td colspan="2">OraQuaick HIV-Self-Test (individual unit product code 5x4-0004.###)</td>
</tr>
<tr>
<td colspan="2">• 1 divided pouch with
- a single use test device; and
- a desiccant; and
- a developer solution vial
containing 1ml of phosphate buffer saline solution containing polymers and an antimicrobial agent
• 1 test stand
• 1 instructions for use
• 1 disposal bag</td>
</tr>
</table>

NOTE:
Country-specific variations are documented through a suffix "###" to the product code on the outer packaging (i.e. 5X4-1001.001, .002, …). Therefore, product codes 5X4-1000.###, 5X4-1001.### and 5X4-2001.### are prequalified product codes. The country-specific product code relates to the language of the IFU provided within the product.

The single pouch product code REF 5X4-0004.### and the single box product code REF 5X4-2001U.###, where the suffix .### is the country-specific/language designation, are prequalified products.

Items required but not provided:

Item
Clock, watch or timing device

Storage:

- Store and perform this test in a cool area.
- DO NOT use this test if it has been stored outside the acceptable temperature of 2 to 30 °C (36 °- 86 °F).
- This test should be performed at 15 to 37 °C (59 °- 99 °F).

Shelf-life upon manufacture:

30 months.

Warnings/Limitations

Please refer to the current version of the manufacturer's instructions for use (IFU).

Prequalification assessments:

Dossier assessment, manufacturing site inspection and laboratory evaluation for the OraQuick HIV Self-Test were adapted from the professional use product, OraQuick HIV 1/2 Rapid Antibody Test, prequalified in 2016. Please refer to the WHO Prequalification of Diagnostics Programme PUBLIC REPORT for OraQuick HIV 1/2 Rapid Antibody Test https://extranet.who.int/pqweb/content/public-report-oraquick-hiv-12-rapid-antibody-test-pqdx-0159-055-00

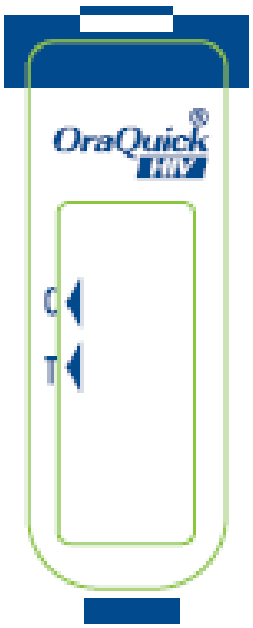
Commitments:
Final report of shipping stability to demonstrate the acceptable performance of the unit box and the device after shipping stressors, report due 31 March 2018. The commitment was closed.

Labelling

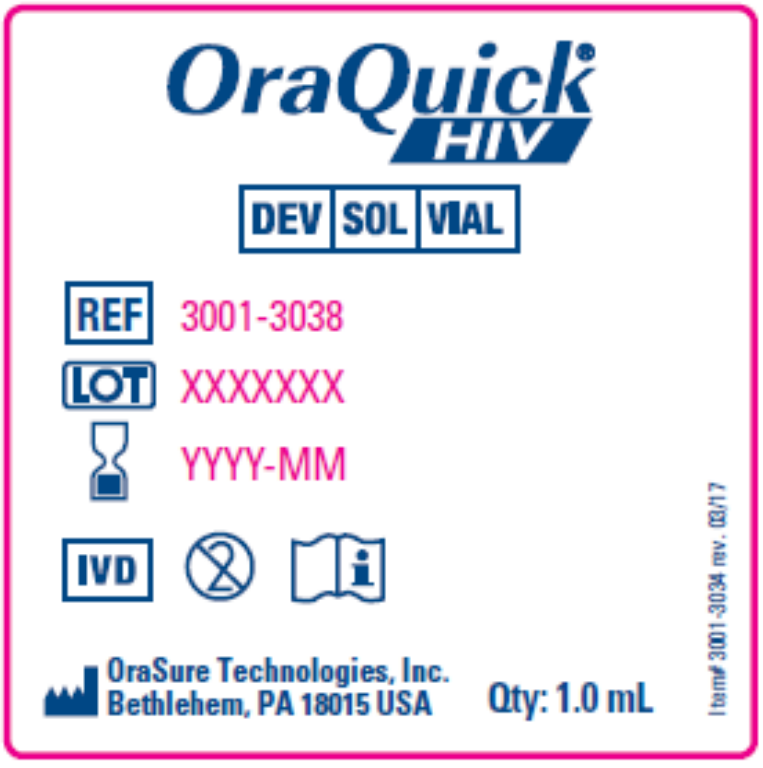
1. **Labels**
2. **Instructions for use**

I. Community version

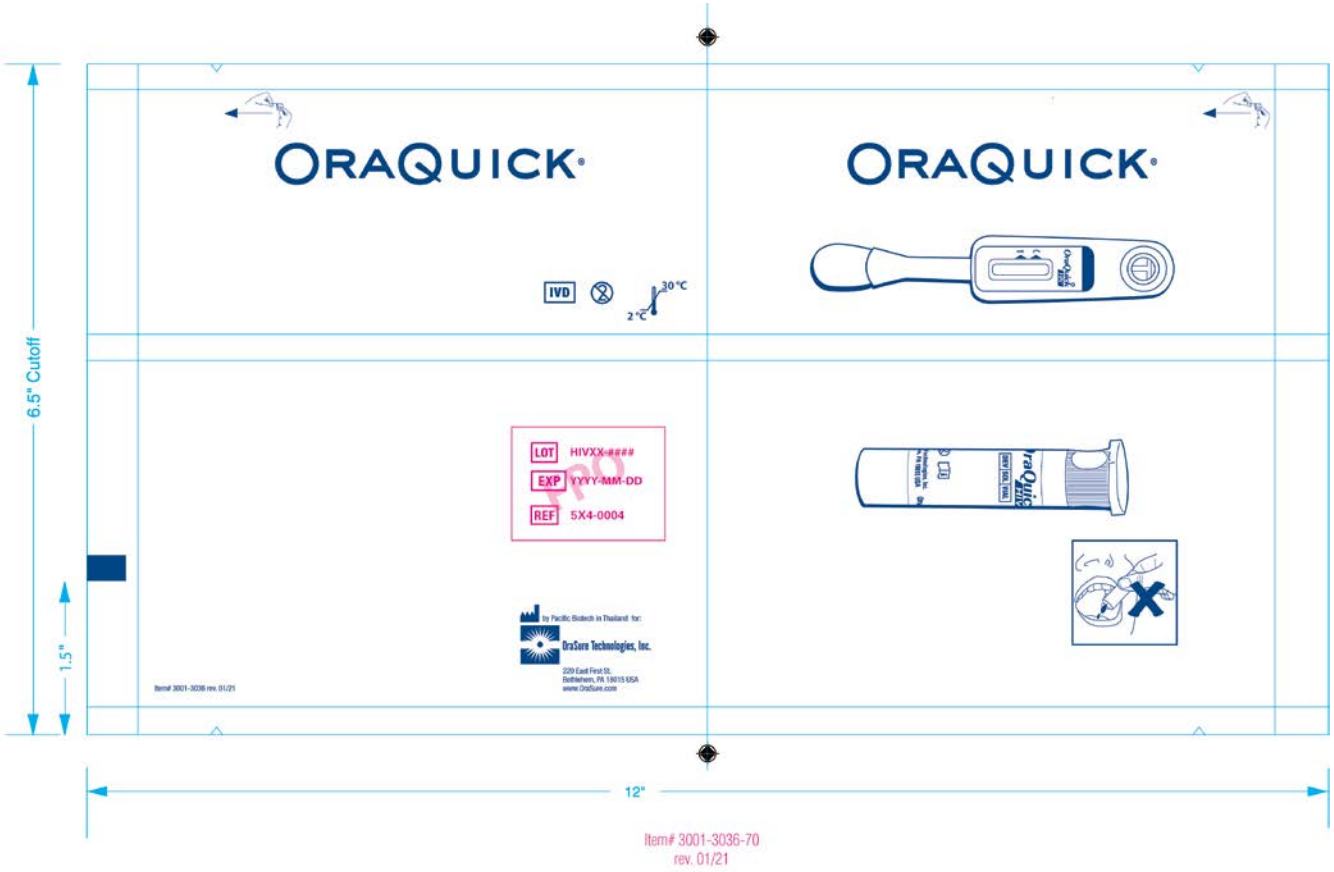
1. Device Label 3001-3035 rev 03/17

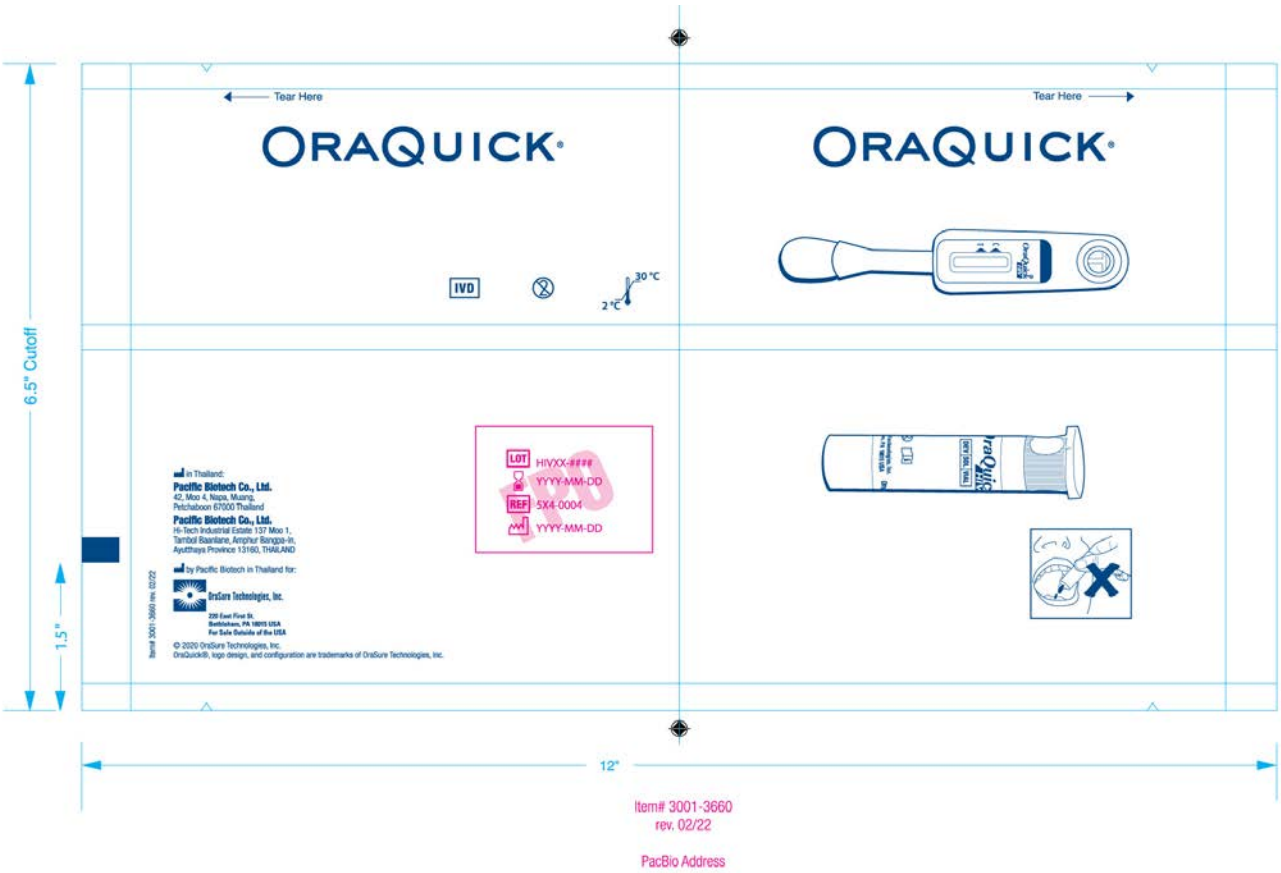


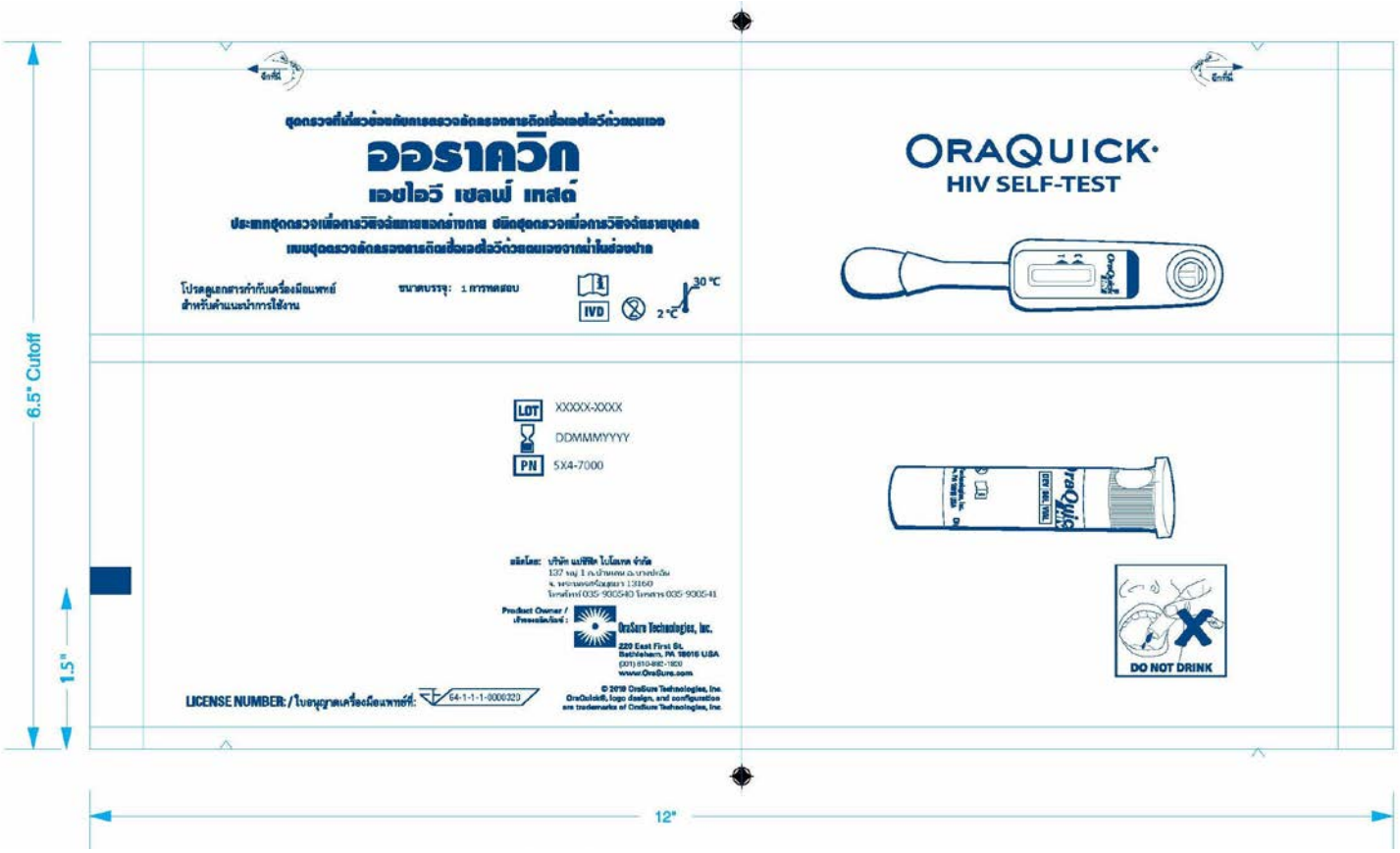
2. Developer Vial Label 3001-3034 rev 03/17



3. Inner Pouch 3001-3036 revision 01/21
Or 3001-3660 revision 02/22


ORAQUICK
ORAQUICK
IVD
30°C
2°C
LOT HIVXX-####
EXP YYYY-MM-DD
REF 5X4-0004
6.5" Cutoff
1.5"
12"
Item# 3001-3036-70
rev. 01/21


Tear Here
ORAQUICK
IVD
30 °C
2 °C
Tear Here
ORAQUICK
6.5" Cutoff
1.5"
LOT
HIVXX-####
YYYY-MM-DD
REF
5X4-0004
YYYY-MM-DD
12"
Item# 3001-3660
rev. 02/22
PacBio Address


6.5" Cutoff
1.5"
12"
ชุดตรวจที่เก็บตัวอย่างด้วยตนเองสำหรับการตรวจคัดกรองสารภูมิคุ้มกันเชื้อเอชไอวีด้วยตนเอง
ออราควิก
เอชไอวี เซลฟ์ เทสต์
ประเภทชุดตรวจเพื่อการวินิจฉัยภายนอกร่างกาย ชนิดชุดตรวจเพื่อการวินิจฉัยสำหรับบุคคล
แบบชุดตรวจคัดกรองสารภูมิคุ้มกันเชื้อเอชไอวีด้วยตนเองจากน้ำในช่องปาก
โปรดดูเอกสารกำกับเครื่องมือแพทย์ สำหรับคำแนะนำการใช้งาน
ขนาดบรรจุ: 1 การทดสอบ
IVD
2°C
30°C
LOT XXXX-XXXX
DDMMMYYYY
PN 5X4-7000
ผลิตโดย: บริษัท แม็กซิส ไบโอเทค จำกัด
137 หมู่ 1 ต.บ้านเพ อ.นาเกลือ
จ. พระนครศรีอยุธยา 13160
โทรศัพท์ 035-900540 โทรสาร 035-900541
Product Owner / เจ้าของผลิตภัณฑ์:
OraSure Technologies, Inc.
220 East First St.
Bethlehem, PA 18015 USA
(001) 610-882-1820
www.OraSure.com
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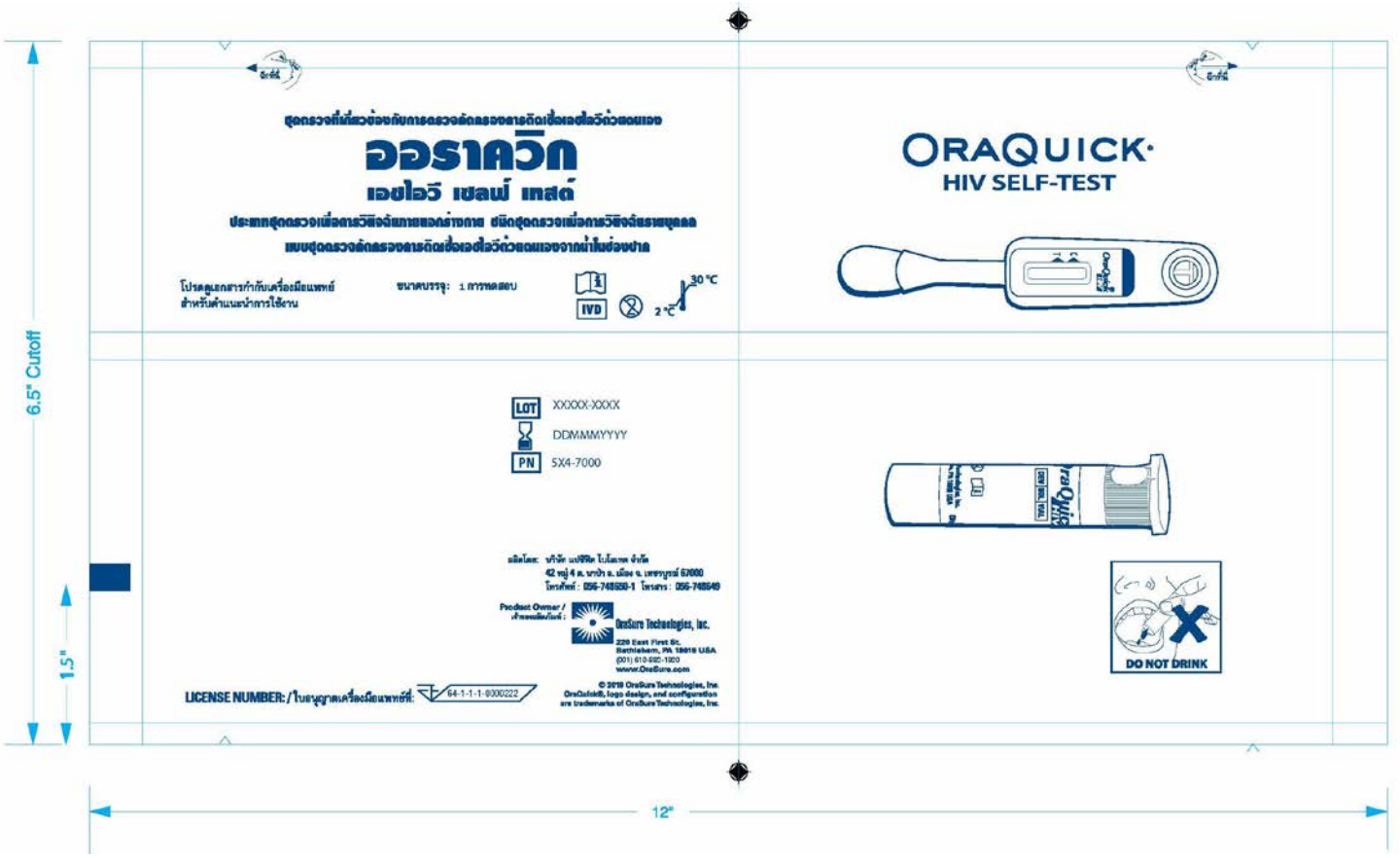
LICENSE NUMBER: /ใบอนุญาตเครื่องมือแพทย์ที่:
64-1-1-1-0000320
ORAQUICK·
HIV SELF-TEST
DO NOT DRINK


6.5" Cutoff
1.5"
12"
ชุดตรวจที่ใช้ด้วยตัวเองสำหรับการตรวจคัดกรองการติดเชื้อเอชไอวีด้วยตัวอย่างน้ำลาย
ออราควิก
เอชไอวี เซลฟ์ เทสต์
ประเภทชุดตรวจเพื่อการวินิจฉัยภายนอกร่างกาย ชนิดชุดตรวจเพื่อการวินิจฉัยระดับบุคคล
แบบชุดตรวจคัดกรองการติดเชื้อเอชไอวีด้วยตัวอย่างน้ำลายจากน้ำในช่องปาก
โปรดดูเอกสารกำกับเครื่องมือแพทย์ สำหรับคำแนะนำการใช้งาน
ขนาดบรรจุ: 1 การทดสอบ
IVD
2 °C
30 °C
LOT XXXXX-XXXX
DDMMMYYYY
PN SX4-7000
ผลิตโดย: บริษัท แบริฟิค โปรดักส์ จำกัด
42 หมู่ 4 ต. หาบำ อ. เมือง จ. เพชรบูรณ์ 67000
โทรศัพท์: 056-748558-1 โทรสาร: 056-748549
Product Owner / เจ้าของผลิตภัณฑ์:
OraSure Technologies, Inc.
220 East First St.
Bethlehem, PA 18015 USA
(001) 610-882-1820
www.OraSure.com
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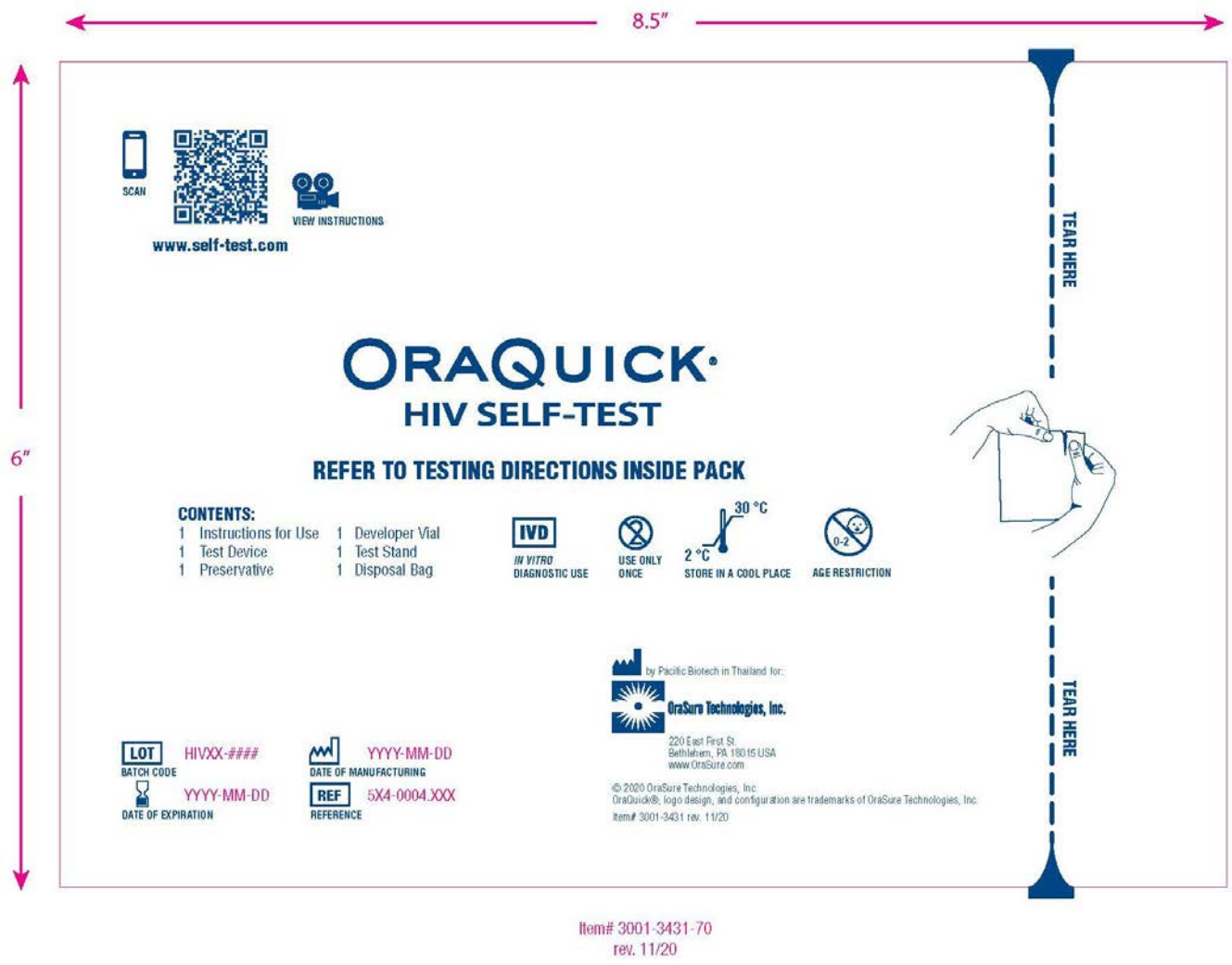
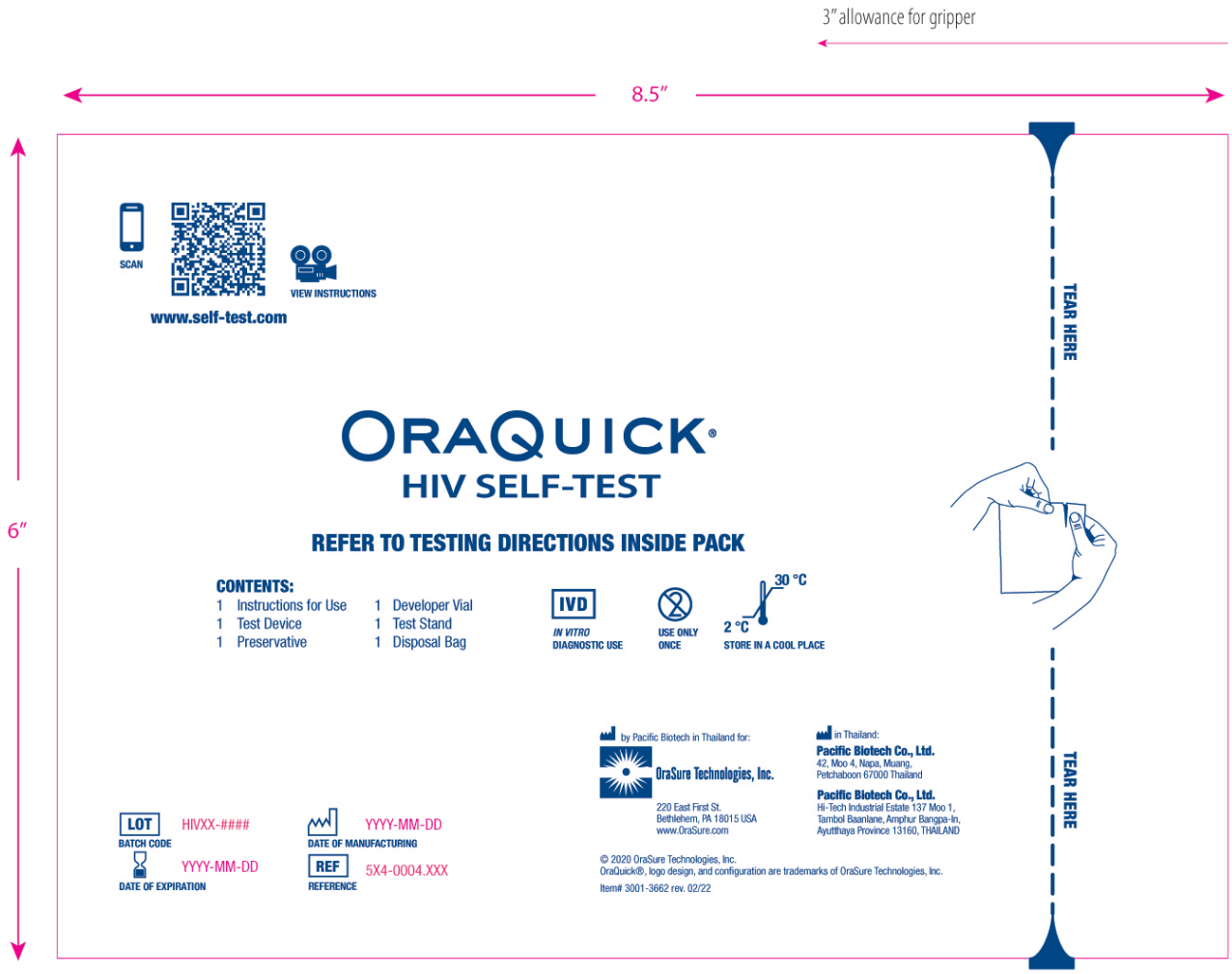
LICENSE NUMBER: / ใบอนุญาตเครื่องมือแพทย์ที่:
64-1-1-1-0000222
ORAQUICK·
HIV SELF-TEST
DO NOT DRINK

4. Outer Pouch 3001-2824, revision 01/21
or 3001-3431 revision 11/20
or 3001-3662, revision 02/22

Item# 3001-2824-70
rev. 01/21



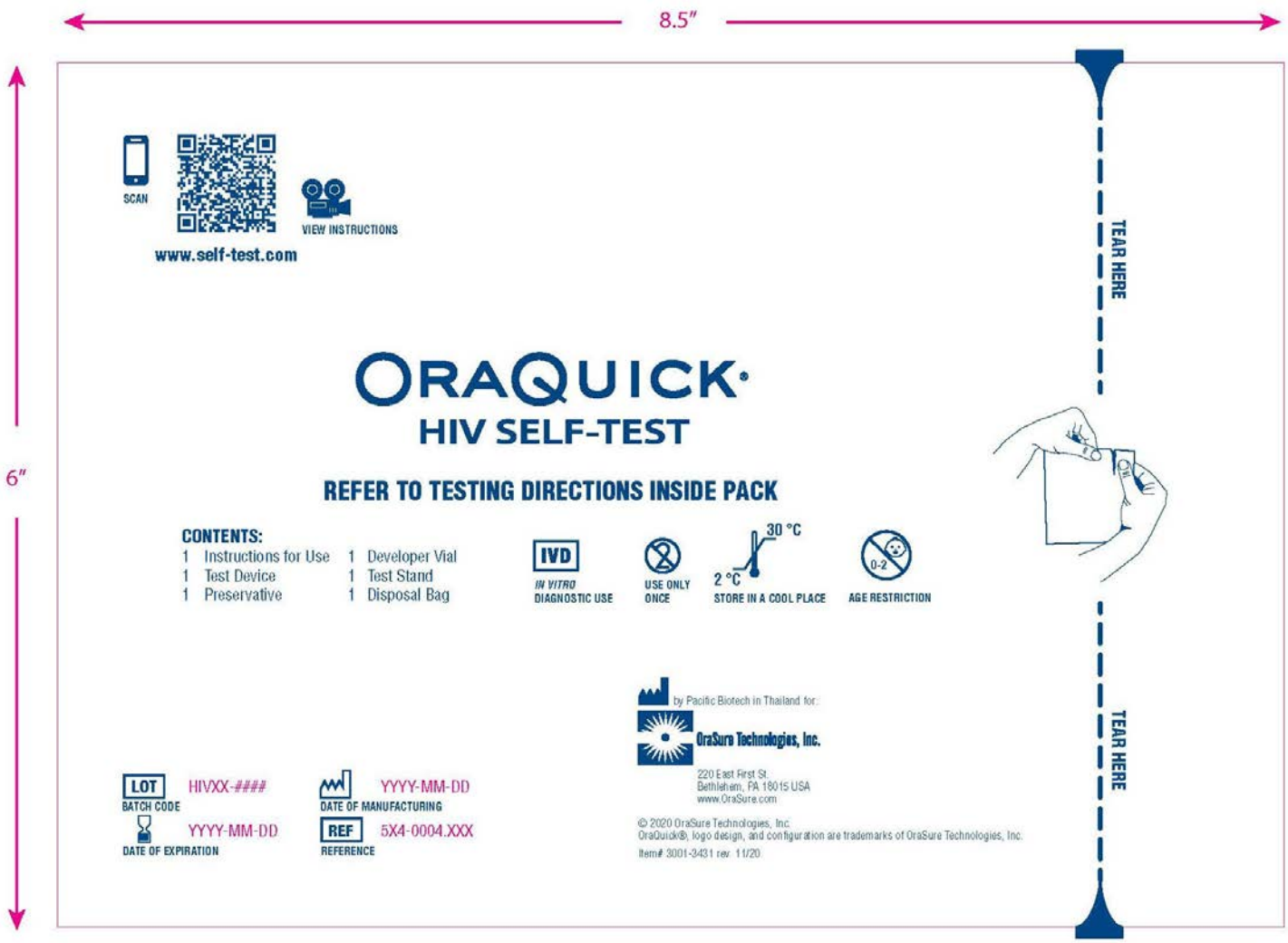
Item# 3001-3431-70
rev. 11/20



Item# 3001-3662-70
rev. 02/22

PMS 288

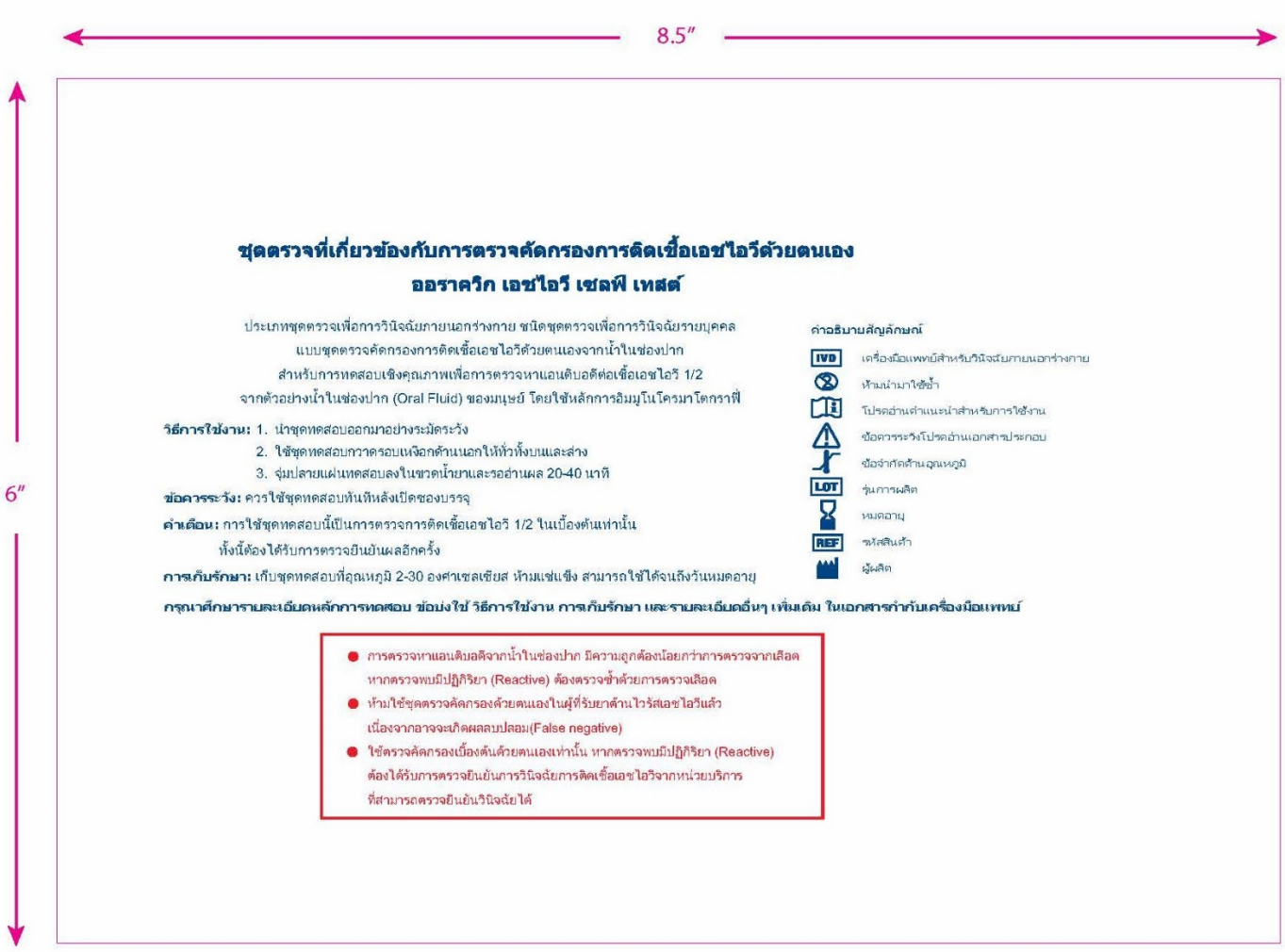
PAC BIO ADDRESS



Item# 3001-3431-70
rev. 11/20

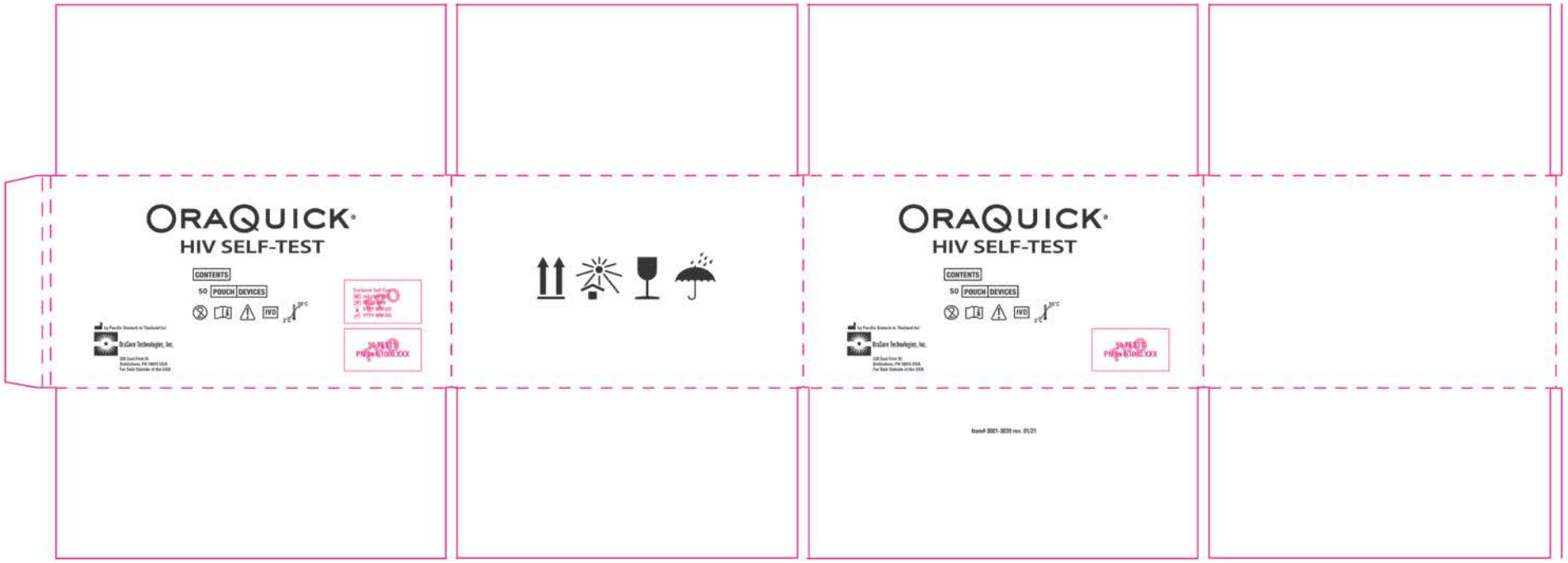
5X4-7000C Outer Pouch , Front

5X4-7000C Outer Pouch , Front



5X4-7000C Outer Pouch , Back

5. 50 Count Shipper Box 3001-3039 revision 01/21
Or 3001-3460 revision 04/21
Or 3001-3658 revision 02/22
Or 3001-3655 revision 05/20
Or 3001-3394 revision 05/20



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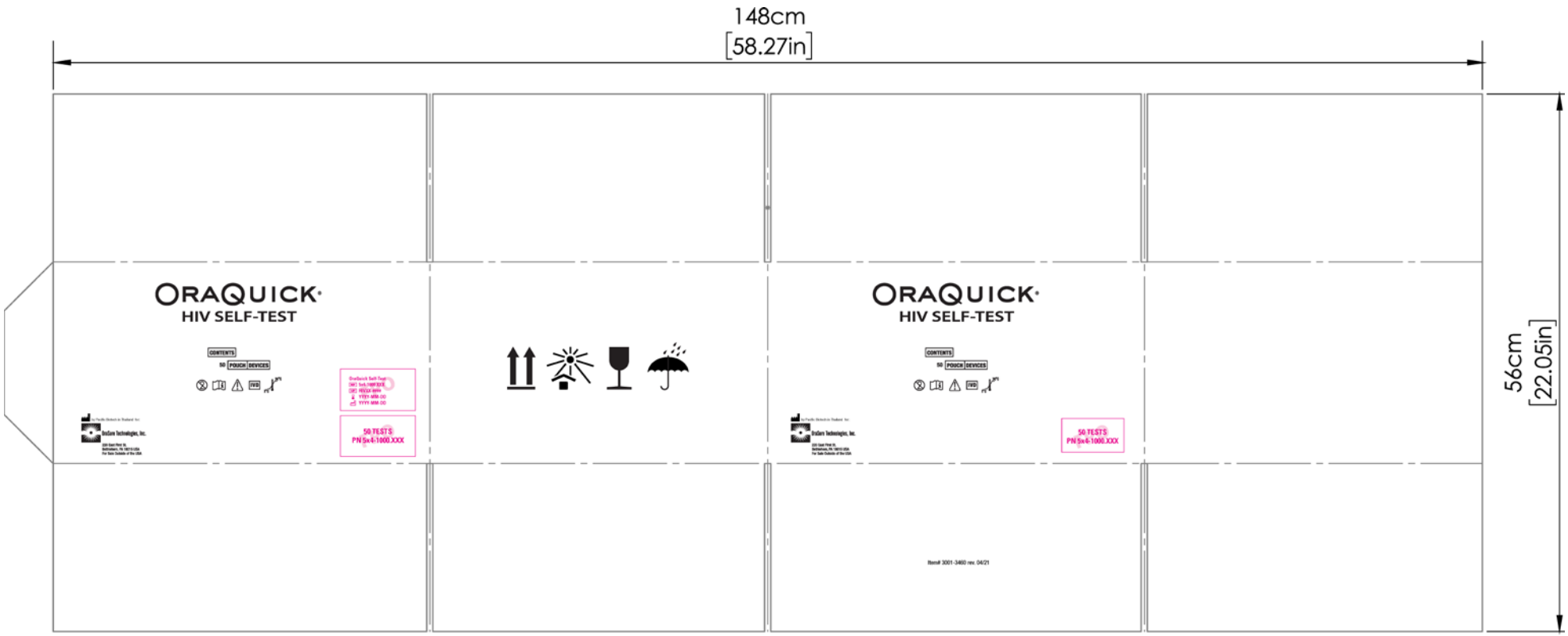
rev. 01/21



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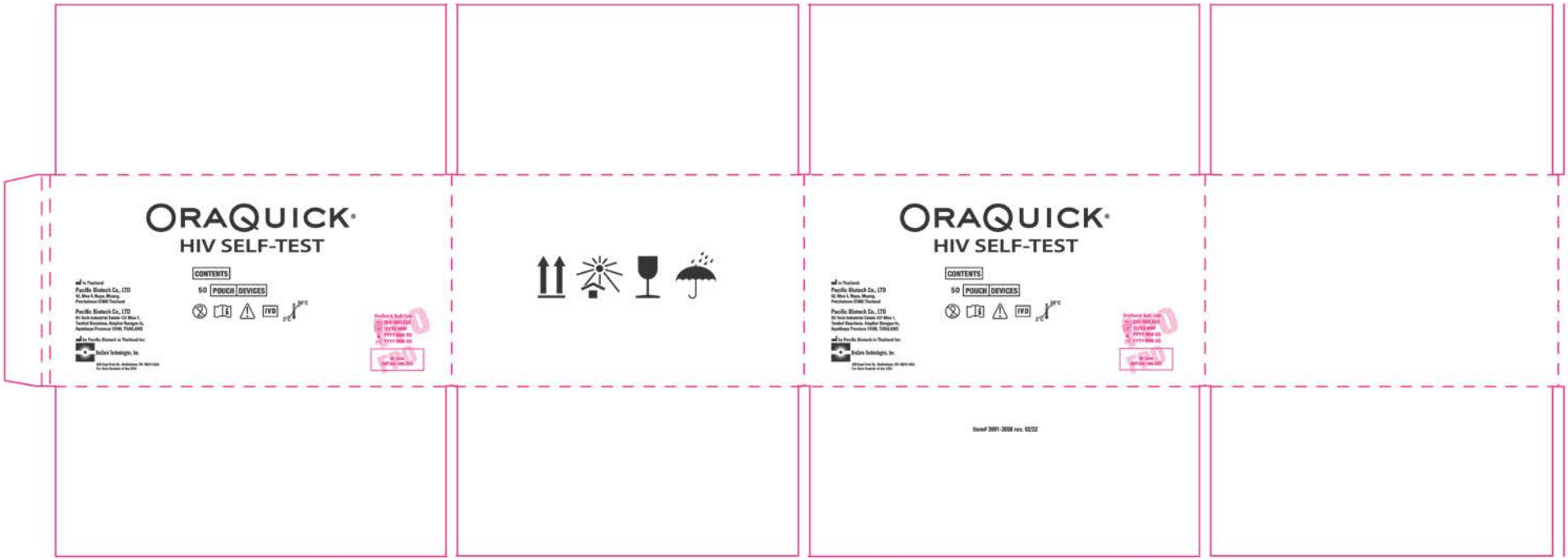
rev. 04/21



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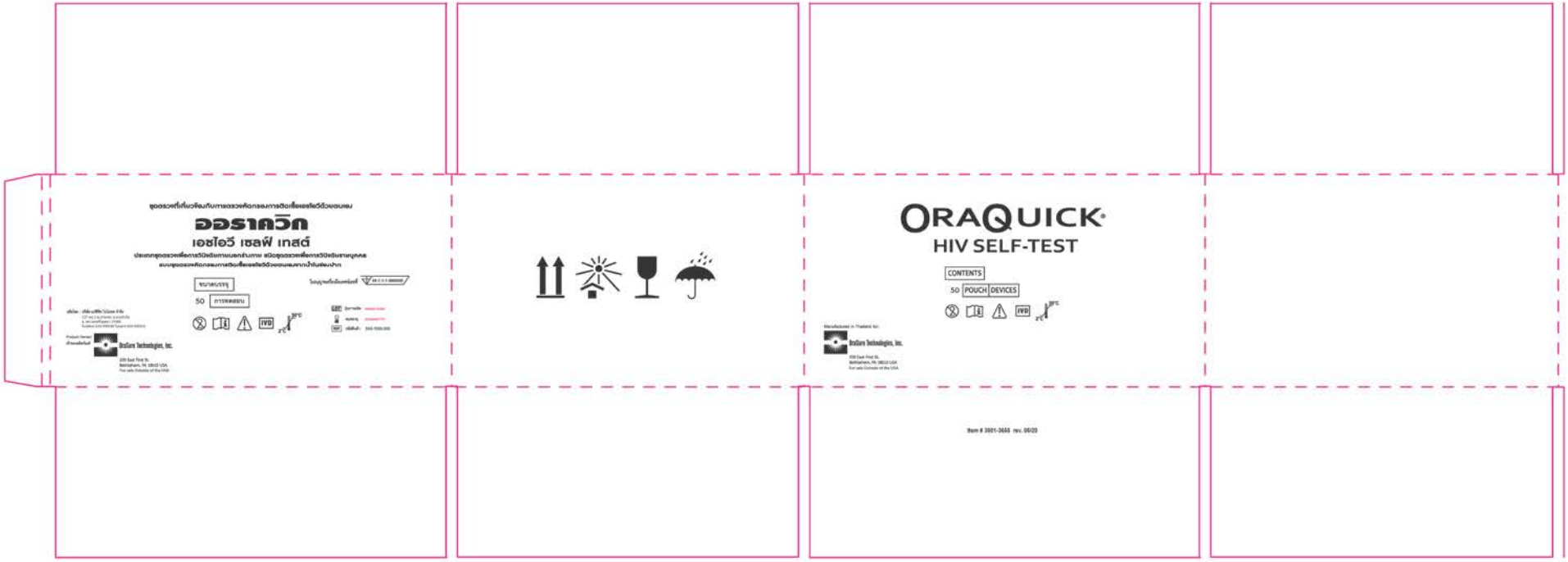
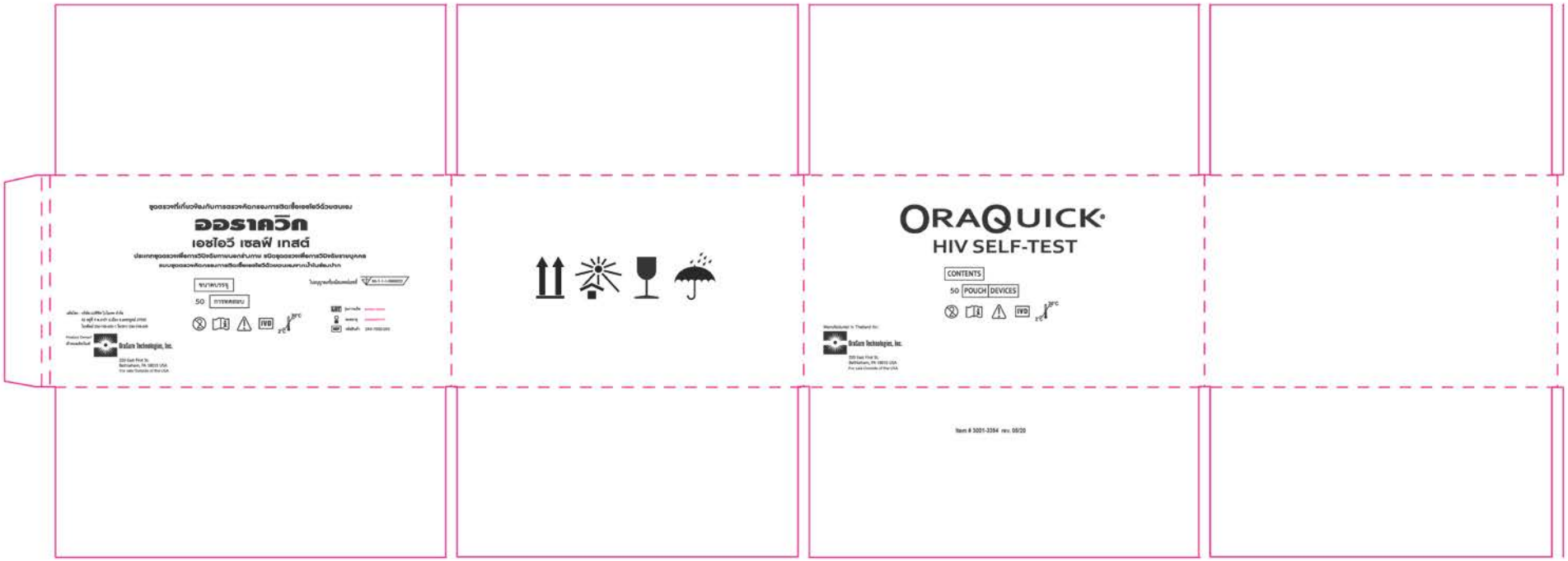
rev. 02/22

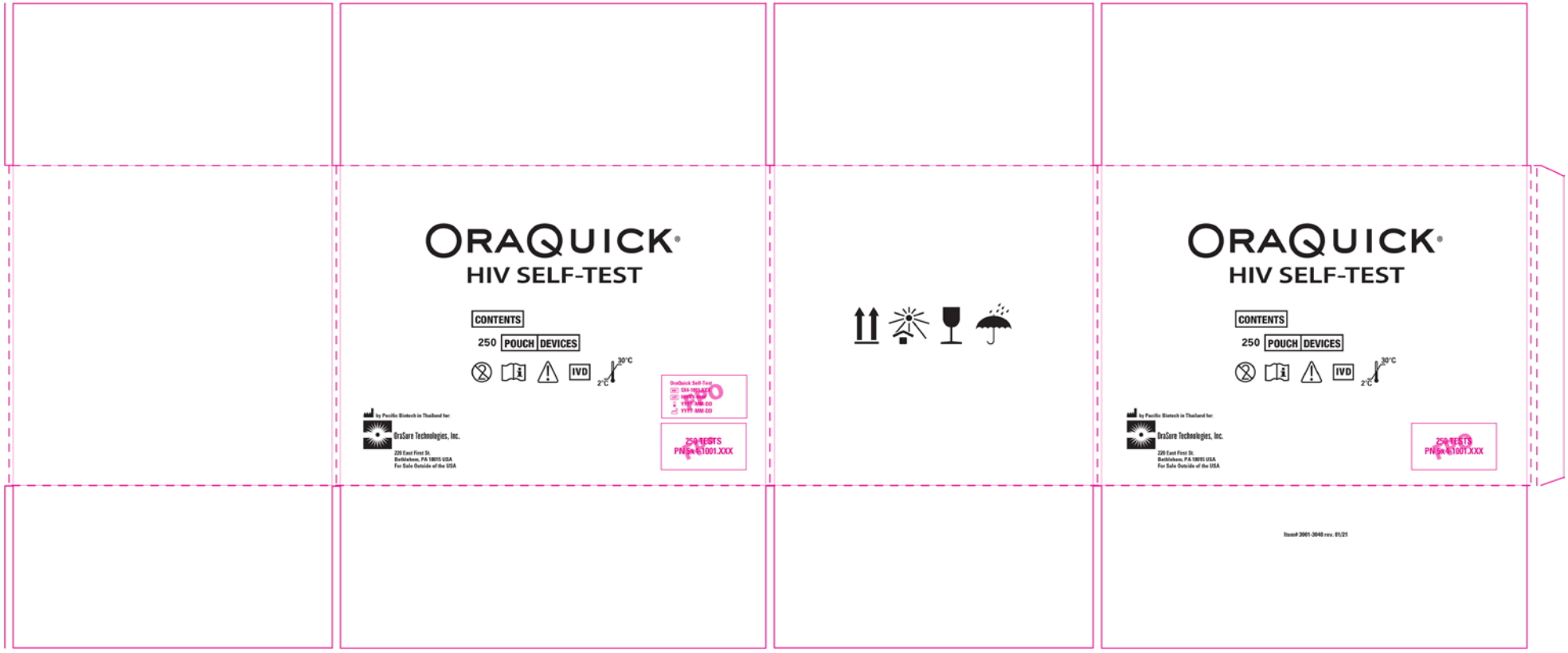


Ayutthaya
Item# 3001-3655
rev. 05/20



3001-3394
Petchaboon
Rev. 05/20

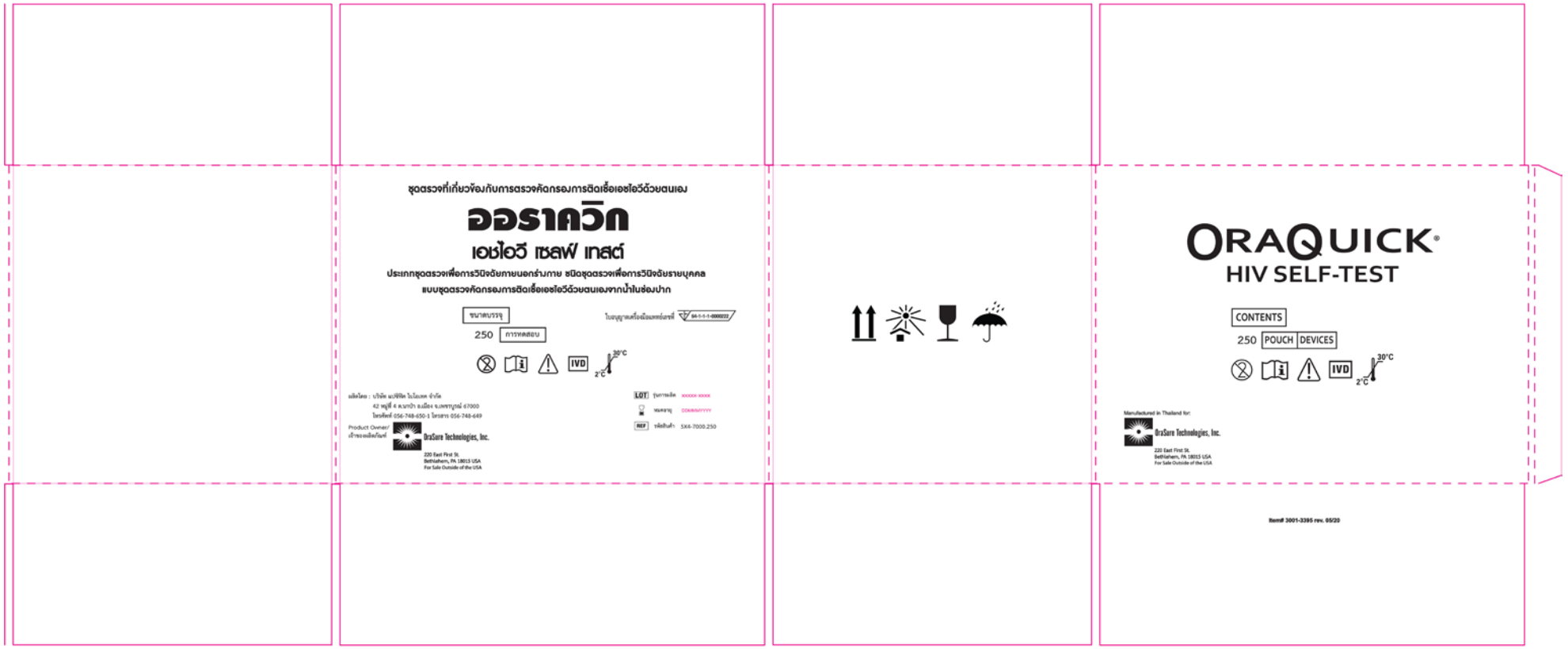
6. 250 Count Shipper 3001-3040 revision 01/21
Or 3001-3461 revision 04/21
Or 3001-3659 revision 02/22
Or 3001-3395 revision 05/20
Or 3001-3656 revision 05/20



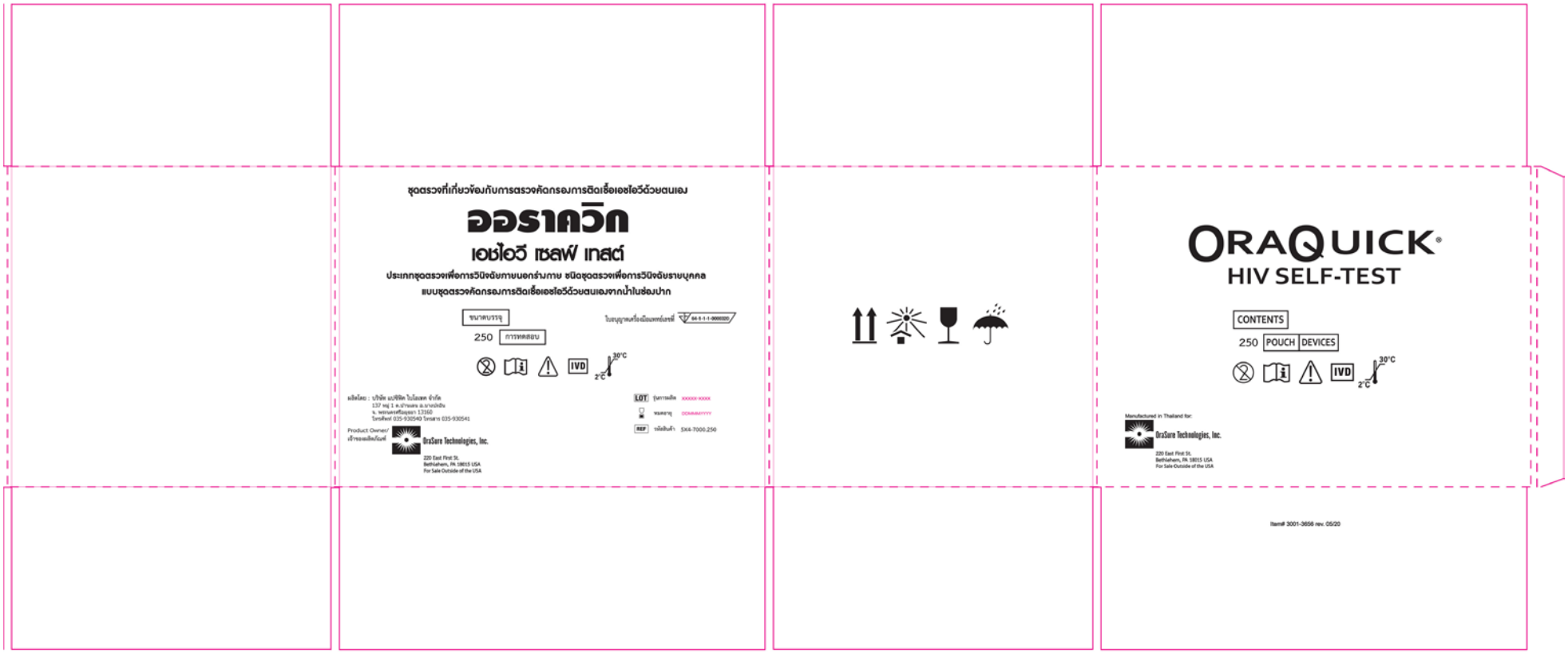
Item# 3001-3040-70
rev. 01/21

Item# 3001-3461-70
rev. 04/21

PacBio Address
Item# 3001-3659
rev. 02/22



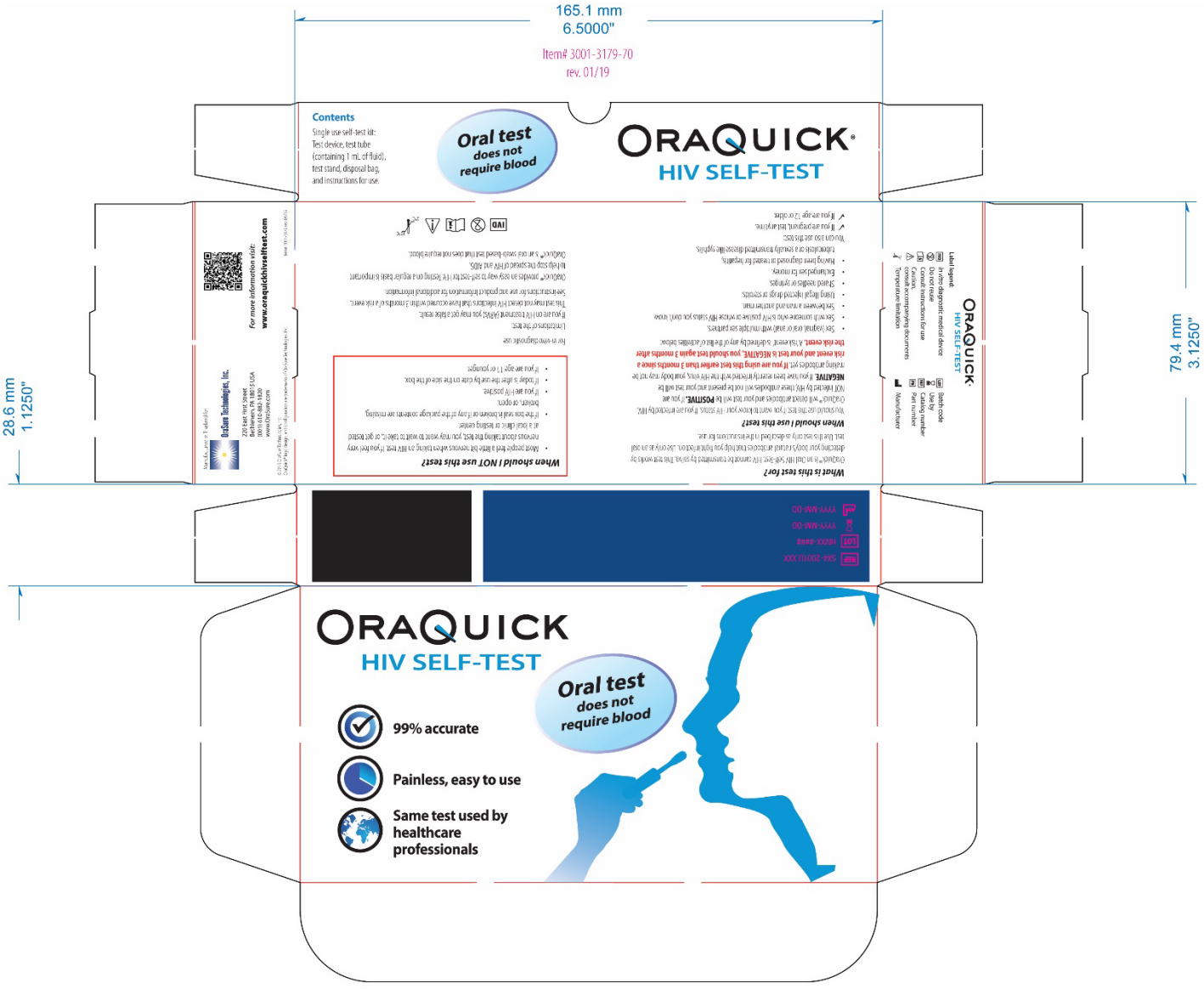
3001-3395
Petchaboon
Rev. 05/20

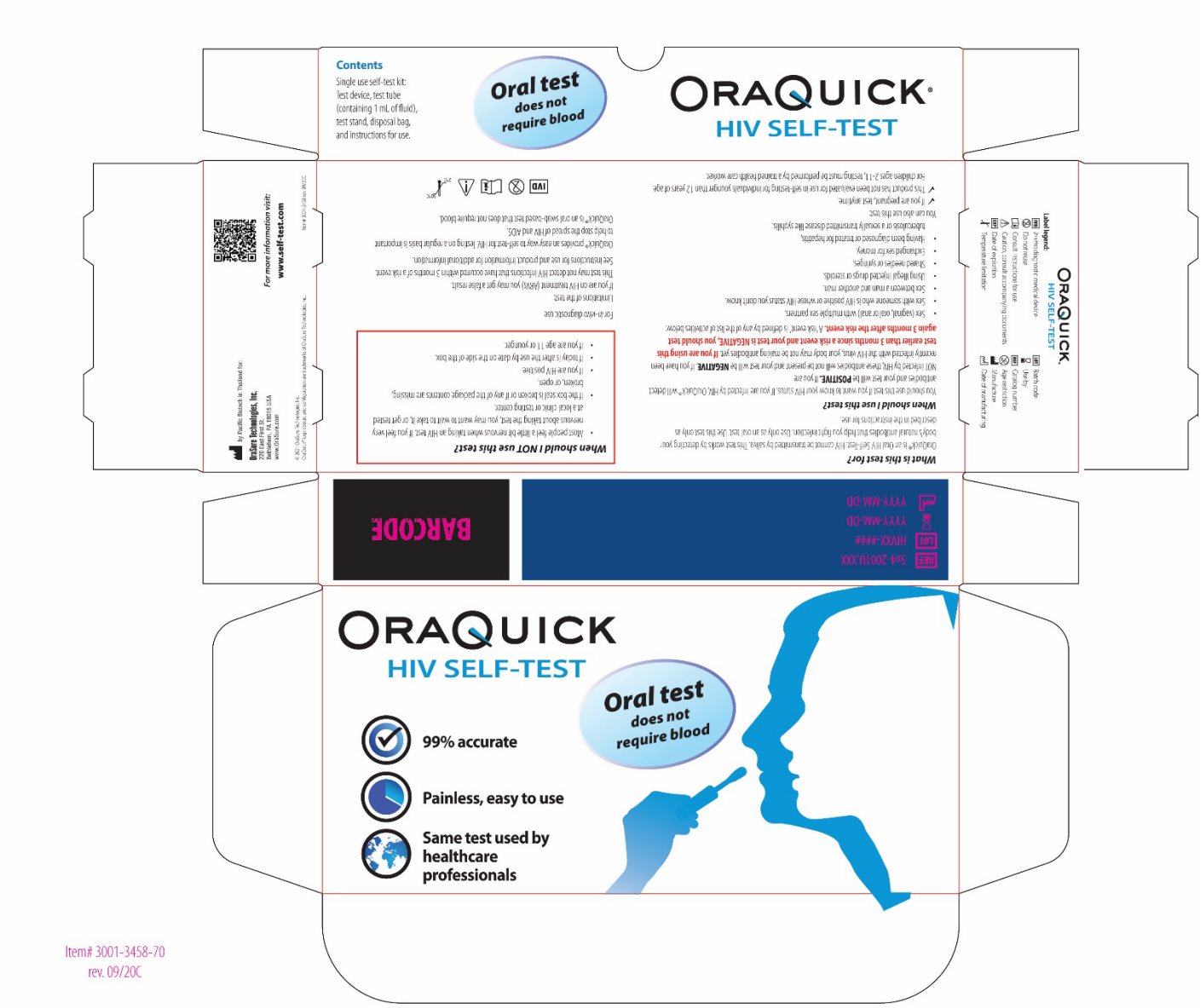


Ayutthaya
Item# 3001-3656
rev. 05/20

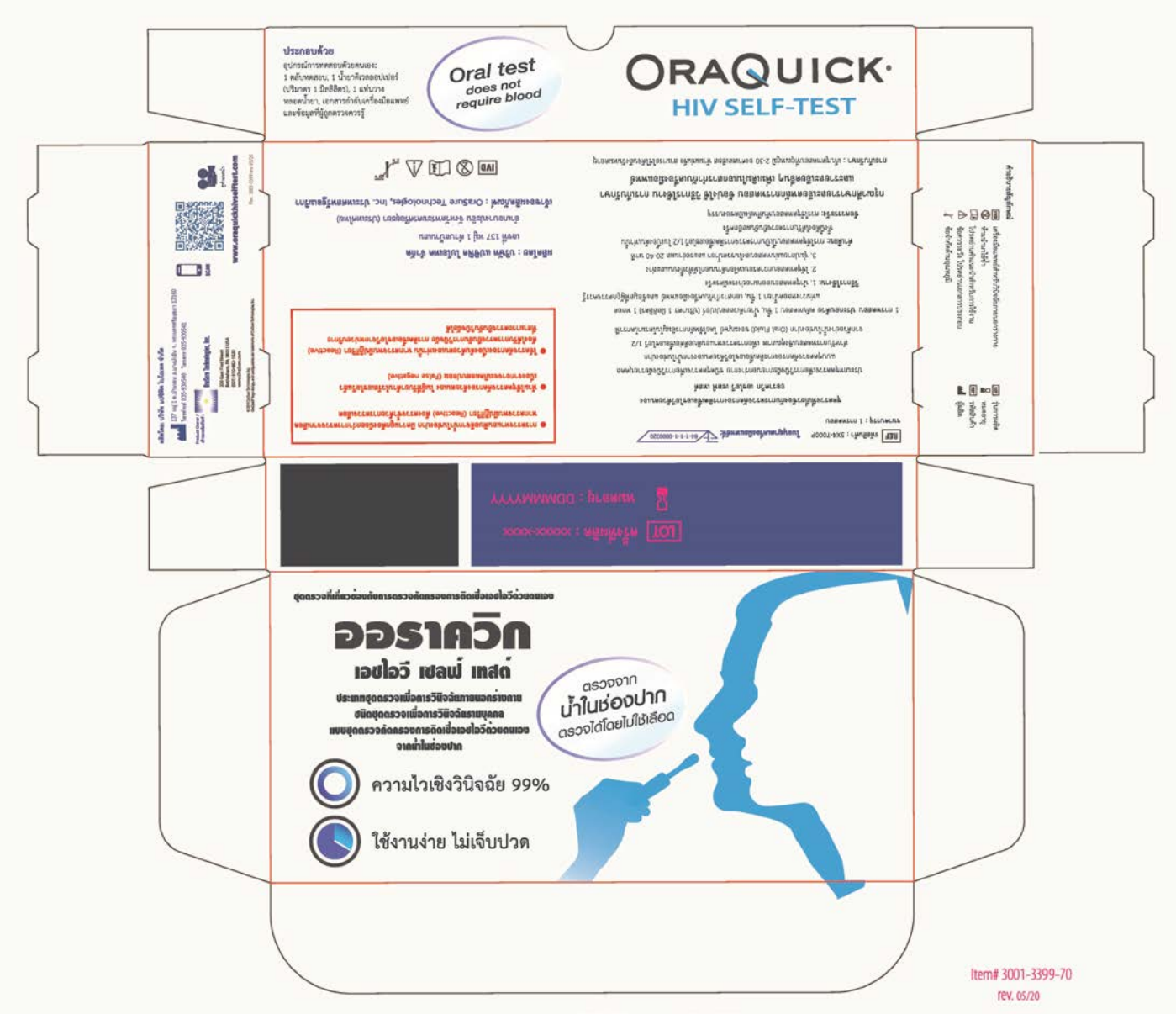
II. Pharmacy version

1. Outer carton 3001-3179 revision 01/19
Or 3001-3458 revision 09/20C
Or 3001-3399 revision 05/20

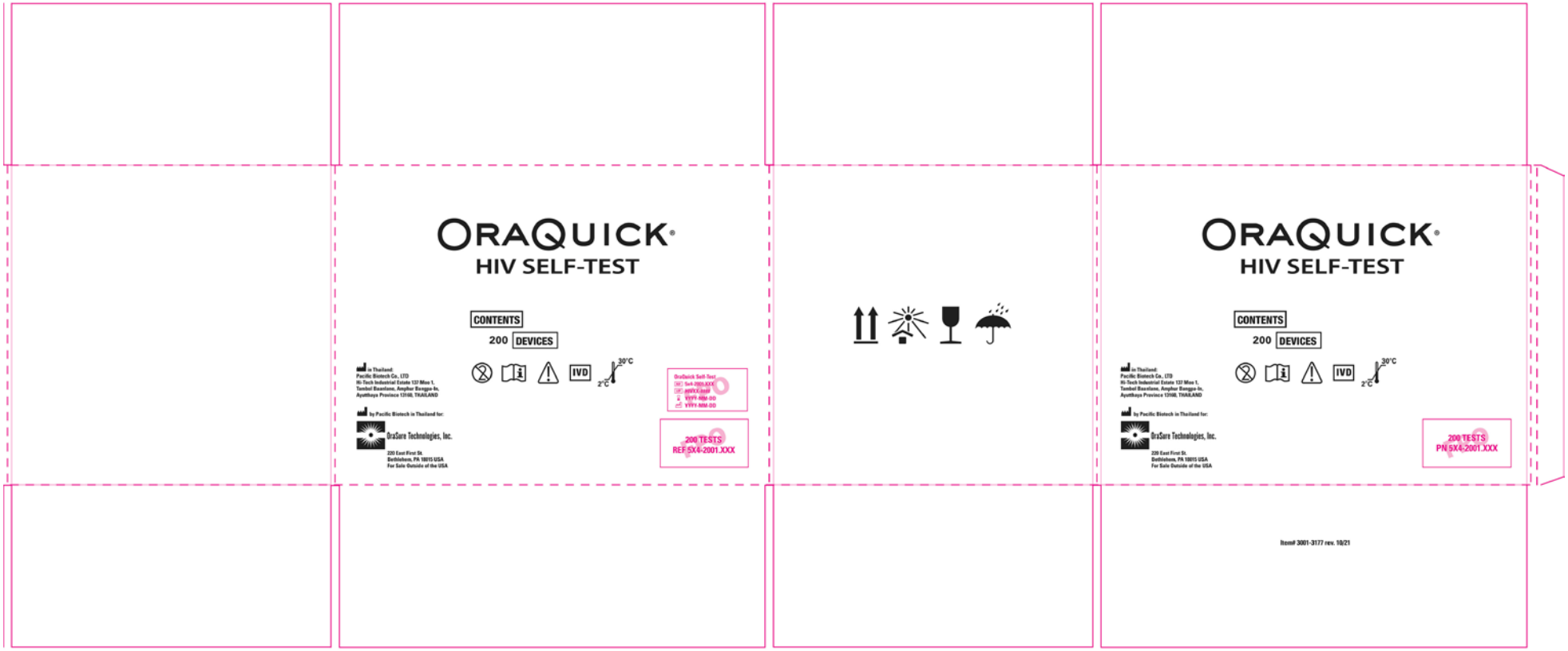




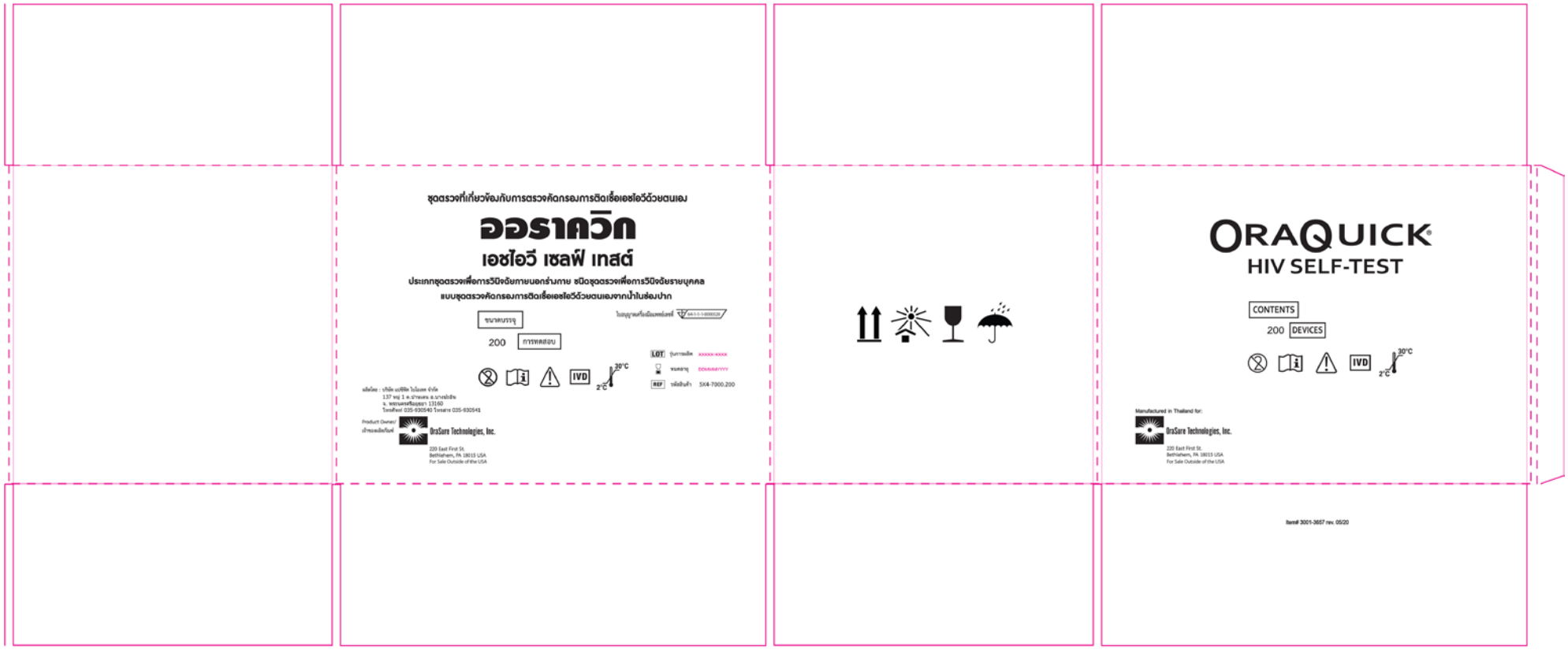
Item# 3001-3458-70
rev. 09/20C


ประกอบด้วย
Oral test does not require blood
ORAQUICK
HIV SELF-TEST
ออราควิก
เอชไอวี เซลฟ์ เทสต์
ตรวจจาก น้ำในช่องปาก ตรวจได้โดยไม่ใช้เลือด
ความไวเชิงวินิจฉัย 99%
ใช้งานง่าย ไม่เจ็บปวด
Item# 3001-3399-70
rev. 05/20

2. 200 Count shipper box 3001-3177 revision 10/21
Or 3001-3657 revision 05/20



Item# 3001-3177
rev. 10/21
Self Test Shipper Box - 200ct. ENG



Ayutthaya
Item# 3001-3657
rev. 05/20

7. Instructions for use [6]

[6] English version of the IFU was the one that was assessed by WHO. It is the responsibility of the manufacturer to ensure correct translation into other languages

For Outside USA Use Only • In Vitro Diagnostic Use • Do Not Reuse

INSTRUCTIONS FOR USE

The OraQuick® HIV Self-Test is an *in-vitro* diagnostic medical device (IVD) that is used for self-testing of antibodies for HIV-1 and HIV-2 in oral fluid. This test is intended as an aid to detect antibodies to HIV-1 and HIV-2 from infected individuals. **You must follow the test directions carefully to get an accurate result.**

WARNING: If you are on HIV treatment you may get a false result. Clinical data has not been collected to demonstrate the performance of OraQuick® HIV Self-Test in individuals that are undergoing PrEP. **Do not eat or drink for at least 15 minutes before you start the test or use mouth cleaning products 30 minutes before you start the test.**

VIEW INSTRUCTIONS
www.self-test.com

ENGLISH

ORAQUICK®
HIV SELF-TEST

HOW TO USE THE ORAQUICK® HIV SELF-TEST KIT

1

YOU WILL NEED A WAY TO TIME THE TEST

2

Kit contains: **test kit, test stand**, **instructions for use** and **disposal bag.** Remove these items to begin testing.

3

Your test kit contains two pouches.

4

Tear open the pouch containing the **tube.**

5

Remove the cap.

6

DO NOT pour out the liquid. **DO NOT** drink.

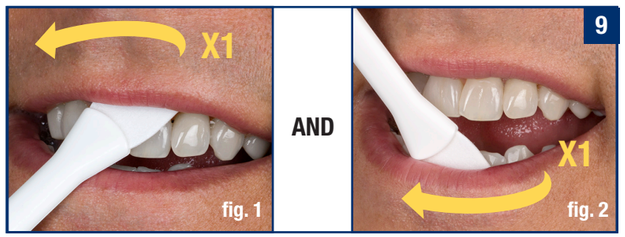
7

Slide the tube into the **stand.**

8

Tear open pouch containing the **test device** and remove. **DO NOT** touch the flat pad with your fingers. **DO NOT** eat or swallow the preservative.

9

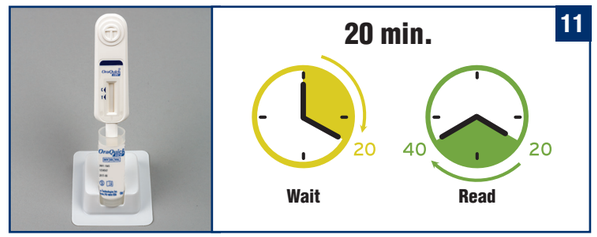


Press the **Flat Pad** firmly against your gum and swab it along your **upper gum once** (fig. 1) and **your lower gum once** (fig. 2).

10

Put the **flat pad** all the way into the tube until it touches the bottom.

11



LEAVE IT THERE for 20 MINUTES before reading the results. DO NOT read the result after 40 minutes.

INTERPRETING RESULTS Read test results in a well-lit area

HIV POSITIVE RESULT

Two complete lines, even if the line is faint, means you may be HIV POSITIVE and you need to seek additional testing by a trained professional to confirm an HIV diagnosis.

99.4% of people (152 out of 153) correctly reported their result as positive. This means that 1 out of 153 people infected with HIV reported a negative test result. This is called a false negative.

As soon as possible . . .

Visit your nearest HIV Testing Centre or Health Facility

HIV NEGATIVE RESULT

IF READ BEFORE 20 MINUTES, RESULT MAY NOT BE CORRECT

ONE LINE next to the “C” and NO line next to the “T”, your result is HIV NEGATIVE.

99.0% of people (717/724) correctly reported their result as negative. This means that 7 out of 724 people not infected with HIV reported a positive test result. This is called a false positive.

Seek regular testing. If you may have been exposed to HIV, test again in 3 months.

INVALID RESULT

If there is no line next to the “C” (even when there is a line next to the “T”), the test line or control line are not complete (all the way across the window), or a red background makes it impossible to read the test, the test is not working and should be repeated. **You will need to obtain another test.**

1.8% of study subjects (16 out of 900) failed to obtain a test result.

The test did not work properly.

Visit your nearest HIV Testing Centre or Health Facility to test again.

NOT SURE OF RESULT

You do not know your result or you are unsure of your result. Visit your nearest HIV Testing Centre or Health Facility to test again.

DISPOSE

Remove the test stick, put the cap on the test tube, place in the disposal bag provided and throw away all contents in the normal trash.

PRODUCT INFORMATION

REF **5X4-1000, 5X4-1001, 5X4-2001**

WARNINGS AND PRECAUTIONS

- **DO NOT** use the test if you are HIV positive.
- **DO NOT** use the test if it has been exposed to household cleaning products (i.e. bleach).
- Remove dental products such as dentures or any other products that cover your gums prior to the oral fluid collection.
- If you have participated in a HIV vaccine clinical trial, you may get a positive result using this test, but it may not mean that you are infected with HIV. You should seek follow-up with your health facility.
- **DO NOT** use if any of the package contents are missing, broken, or open.
- If today is after the ‘Use By’ on the outside of the pouch, do not use this test.

LIMITATIONS OF THE TEST

- Oral bleeding may result in an invalid result. If the test result is invalid, visit your nearest testing centre or healthcare facility.
- The OraQuick® HIV Self-Test may not detect HIV infections that have occurred within the last 3 months.
- For a positive result, the intensity of the test line does not necessarily equal the amount of antibody in the specimen.
- This product has not been evaluated for use in self-testing for individuals younger than 12 years of age. For children ages 2-11, testing must be performed by a trained health care worker.

INTERFERING SUBSTANCES AND UNRELATED MEDICAL CONDITIONS

If you are HBV, HCV or HTLV (I/II) positive, you may get a false result. It is recommended that users observe a 15 minute wait period after food and drink and a 30 minute wait period after using oral care products.

EXPLANATION OF SYMBOLS

LOT	Batch Code	IVD	*In Vitro* Diagnostic Medical Device	0+	Age Restriction	DOM	Date of Manufacturing
	Do Not Reuse		Use By		Consult Instructions for Use		
	Temperature Limitation		Caution, Consult Accompanying Documents	EXP	Date of Expiration		
REF	Catalog Number		Manufacture		Date of Manufacturing		

in Thailand for :

OraSure Technologies, Inc.
220 East First Street, Bethlehem, PA 18015 USA
(+1) 610-882-1820 • www.OraSure.com

Item# 3001-XXXX rev. XX/XX