



Manufacturer's Declaration of Conformity

We, OraSure Technologies Inc., 220 East First Street, Bethlehem, Pennsylvania 18015, United States, hereby declare under our sole responsibility that the product

OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test
OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test Kit Controls

meets the provisions of the European Directive 98/79/EC for *in vitro* Diagnostic Medical Devices.

Variants:

- 1001-0284 OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test, 25 Count
- 1001-0285 OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test, 100 Count
- 1001-0288 OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test Kit Controls
- 1001-0513 OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test, 25 Count, Algeria
- 1001-0514 OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test, 100 Count, Algeria
- 1001-0515 OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test, 100 Count, Egypt,
Dept. of Health
- 1001-0516 OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test, 100 Count, Egypt,
Dept. of Defense
- 3001-1347 OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test, Single Unit

The conformity with the requirements of the Directive has been assessed following the procedures outlined in the following annexes of the Directive: Annex IV

(EC) Certificate numbers DGM-585 and DGM-586 have been issued by:

Presafe
Tuborg Parkvej 8
2900 Hellerup
Denmark
Notified Body ID Number 0543

Technical documentation demonstrating compliance is kept by the manufacturer and can be made available by the authorized representative in Europe:

QARAD BV
Cipalstraat 3
2440 GEEL, Belgium


Rebecca Rader
Sr. Manager, Regulatory Affairs


Date



Certificate

No. Q5 058921 0009 Rev. 02

Holder of Certificate: **Pacific Biotech Co., Ltd.**
6 (Sonthiwattana 3)
Ladprao 110
Plubpla
Wangthonglang
Bangkok 10310
THAILAND

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution of Rapid Diagnostic Immunochemical Test Kits for the Detection of Infectious Diseases, Drug Abuse and Fertility**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 058921 0009 Rev. 02

Report No.: TH0161021T008

Valid from: 2021-12-01
Valid until: 2024-05-30

Date, 2021-11-09

Christoph Dicks
Head of Certification/Notified Body

Certificate

No. Q5 058921 0009 Rev. 02

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Pacific Biotech Co., Ltd.
6 (Sonthiwattana 3), Ladprao 110, Plubpla, Wangthonglang,
Bangkok 10310, THAILAND

Distribution including warehousing and administrative activities
(purchasing, customer related process, document control and
resource management) of Rapid Diagnostic Immunochemical Test
Kits for the Detection of Infectious Diseases, Drug Abuse and
Fertility.

Pacific Biotech Co., Ltd.
42 Moo 4, Petchaboon-Chalianglub Road, Napa, Muang,
Petchaboon 67000, THAILAND

Design and Development, Production and Distribution including
warehousing of Rapid Diagnostic Immunochemical Test Kits for
the Detection of Infectious Diseases, Drug Abuse and Fertility.

Pacific Biotech Co., Ltd.
177 Moo 9, Saraburi-Lomsak Road, Huai Sakae, Muang,
Petchaboon 67210, THAILAND

Distribution including warehousing of Rapid Diagnostic
Immunochemical Test Kits for the Detection of Infectious
Diseases, Drug Abuse and Fertility.

Pacific Biotech Co., Ltd.
172/1 Petcharoen Road, Nai Muang, Muang, Petchaboon 67000,
THAILAND

Distribution including warehousing of Rapid Diagnostic
Immunochemical Test Kits for the Detection of Infectious
Diseases, Drug Abuse and Fertility.

Pacific Biotech Co., Ltd.
Hi-Tech Industrial Estate 137 Moo 1, Tambol Baanlane, Amphur
Bangpa-In, Ayutthaya Province 13160, THAILAND

Design and Development, Production and Distribution including
warehousing of Rapid Diagnostic Immunochemical Test Kits for
the Detection of Infectious Diseases, Drug Abuse and Fertility.

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-Test²

	Date	Outcome
PQ listing	8 April 2016	listed
Dossier review	26 January 2016	MR
Site inspection(s) of quality management system	3 -5 November 2014	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

¹Country specific variations are documented through a suffix “###” to the product code.

²Dossier assessment 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://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-rdts/public_report/en/

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

Report amendments and/or product changes

This public report has since been amended. Amendments may have arisen because of changes to the prequalified product for which 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 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 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 double-sided single page to a single-sided single page. Added a limitation of the test in the IFU as follows “ <i>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</i> ”. 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 outer packaging (i.e. 5X4-1001.001, .002, ...). Change on product labelling due to minor revisions.	17 December 2021

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

7.0	1. Edits to 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
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Intended use⁵

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 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”.

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.

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)
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	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 instructions for use • 1 disposal bag	• 1 disposal bag
Each kit contains the same pouched device configuration as the community version, except the contents are contained in a carton.	
OraQuaick HIV-Self-Test (individual unit product code 5x4-0004.###)	
• 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	

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 temperatures in the range of 15 to 37 °C (59 ° - 99 °F).

Shelf-life upon manufacture:

30 months.

Warnings:

- Refer to current version of manufacturer's instructions for use (IFU).

Limitations:

- Refer to current version of manufacturer's instructions for use.

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.

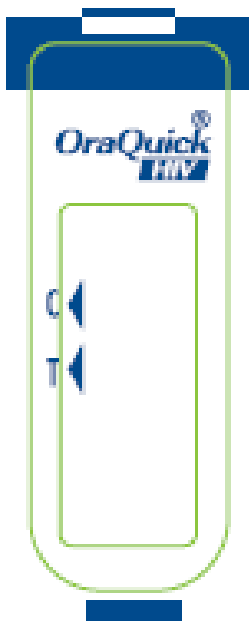
Labelling

1. Labels

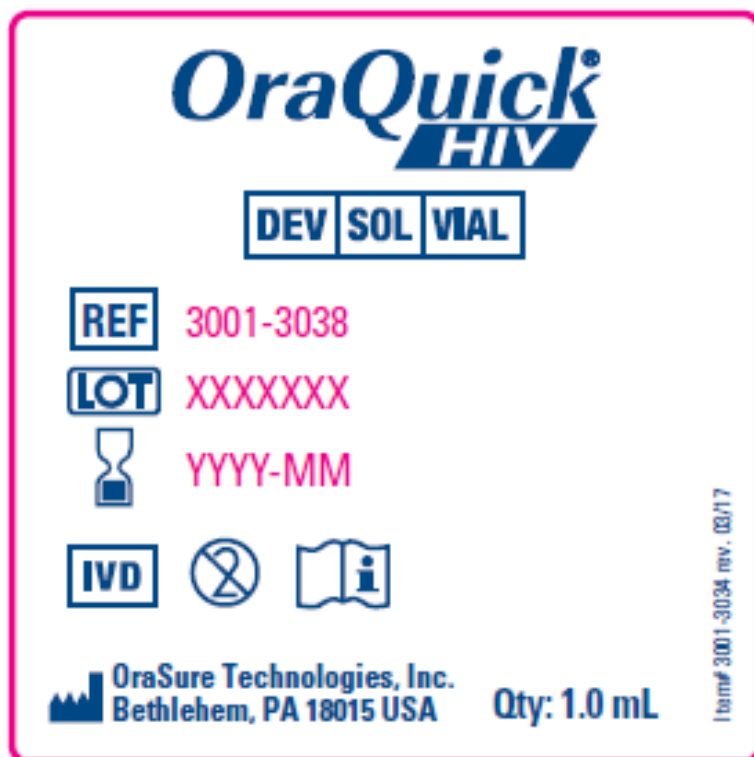
2. Instructions for use

I. Community version

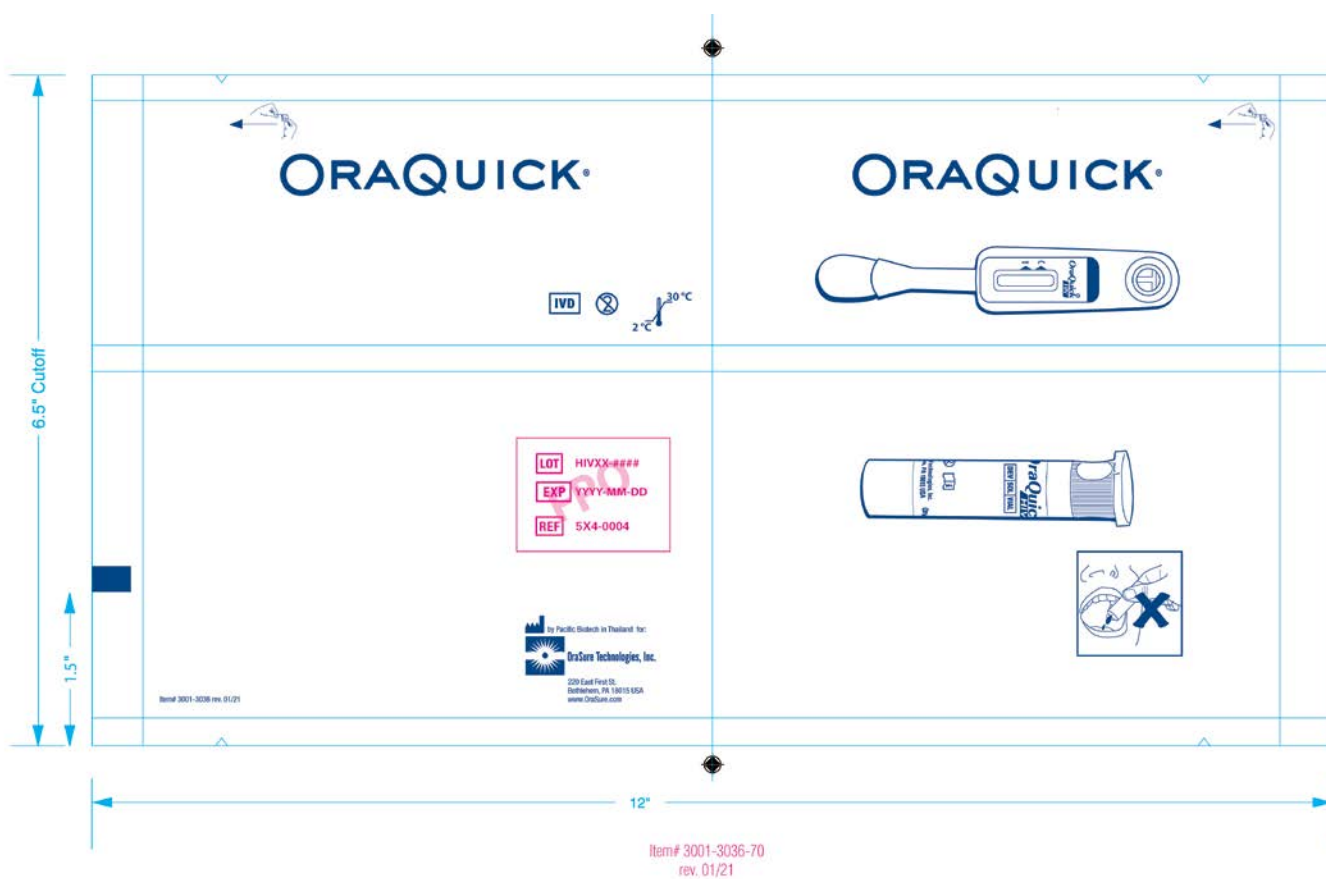
1. Device Label 3001-3035 rev 03/17

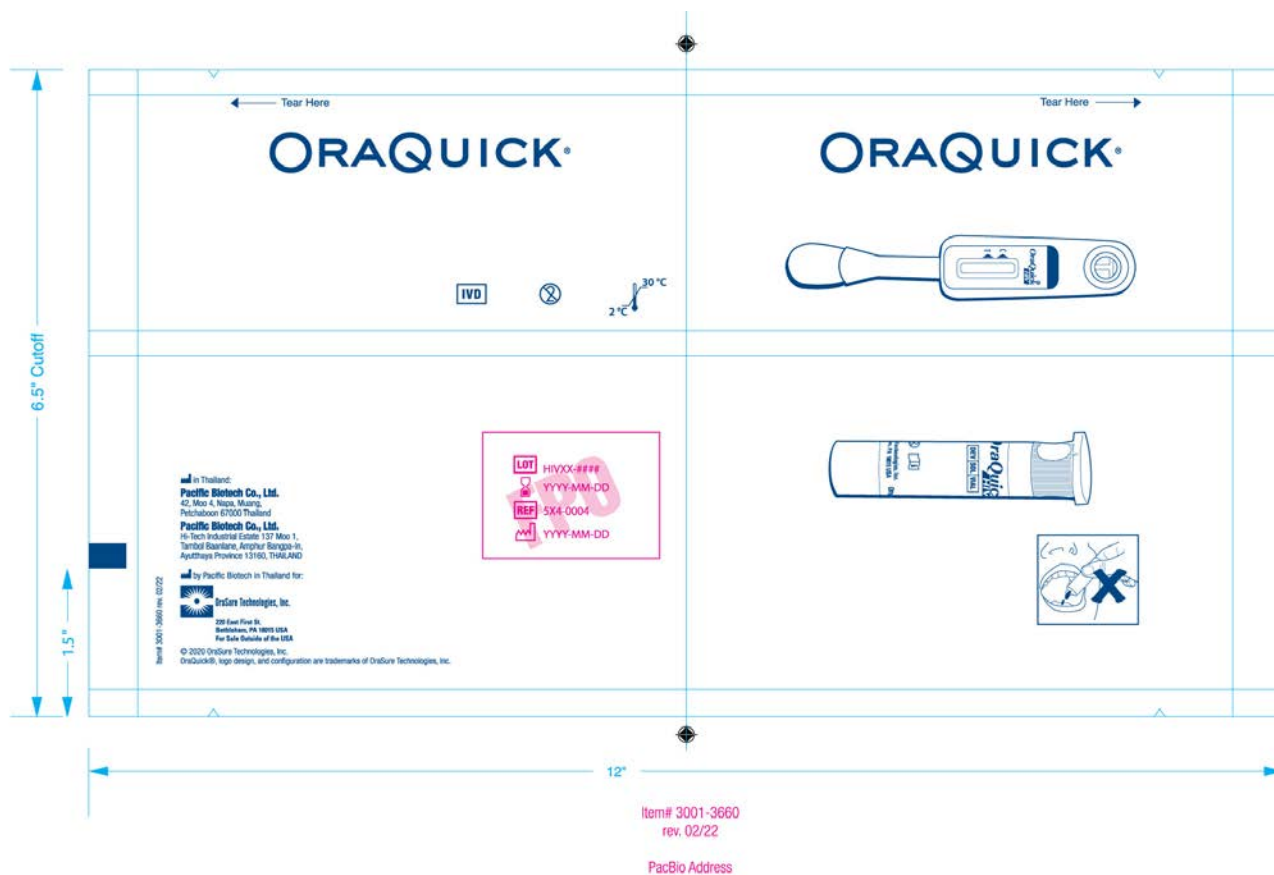


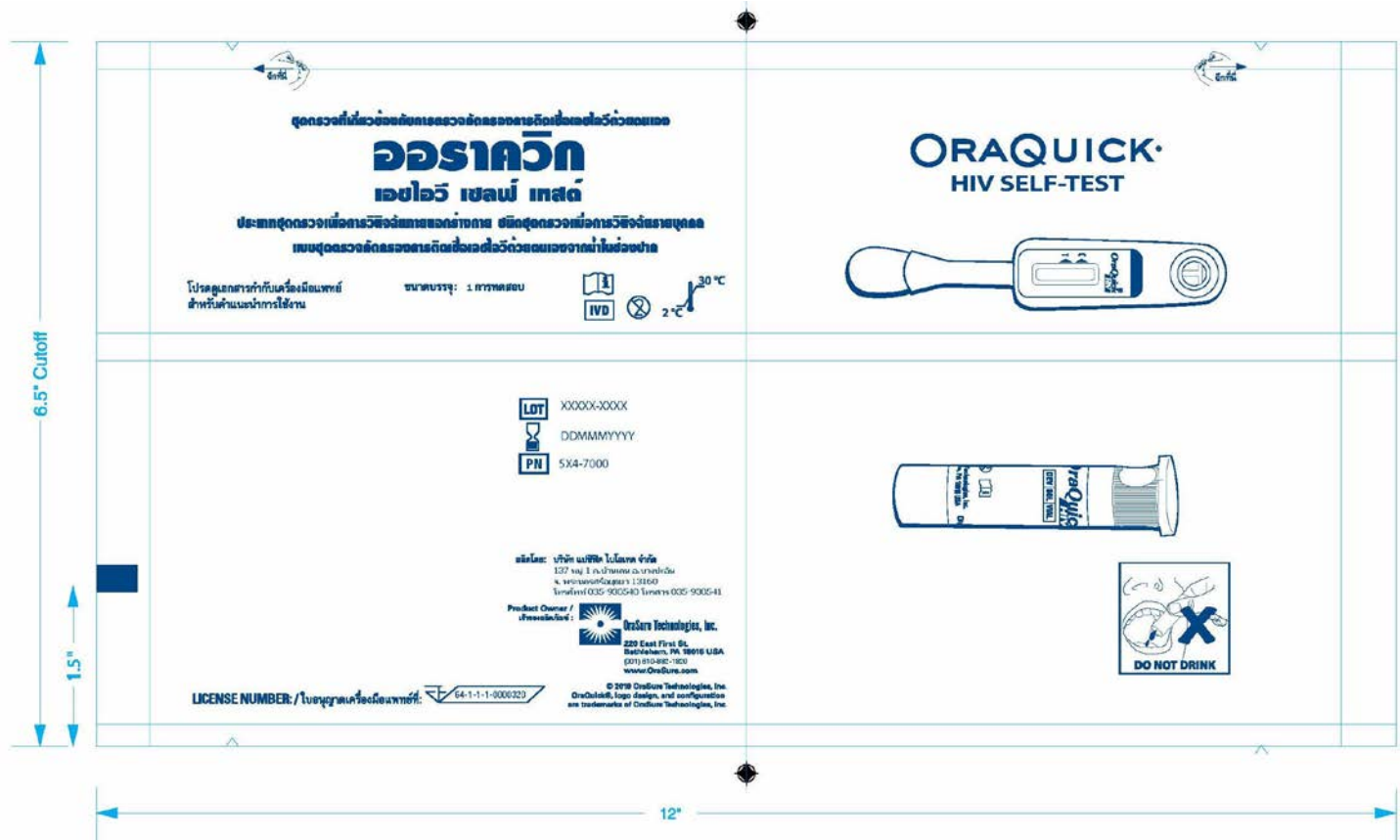
2. Developer Vial Label 3001-3034 rev 03/17

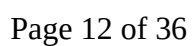


01/21

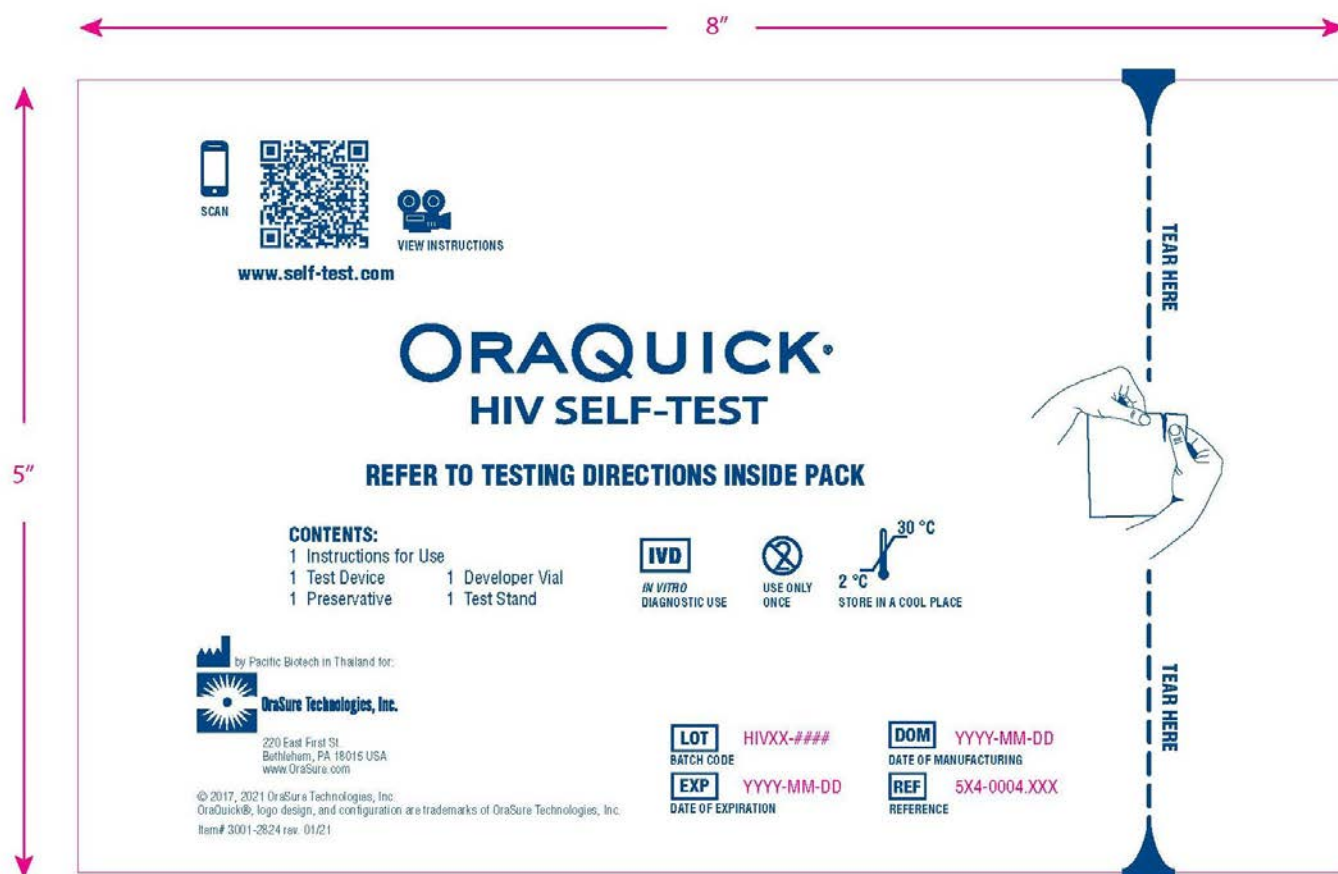








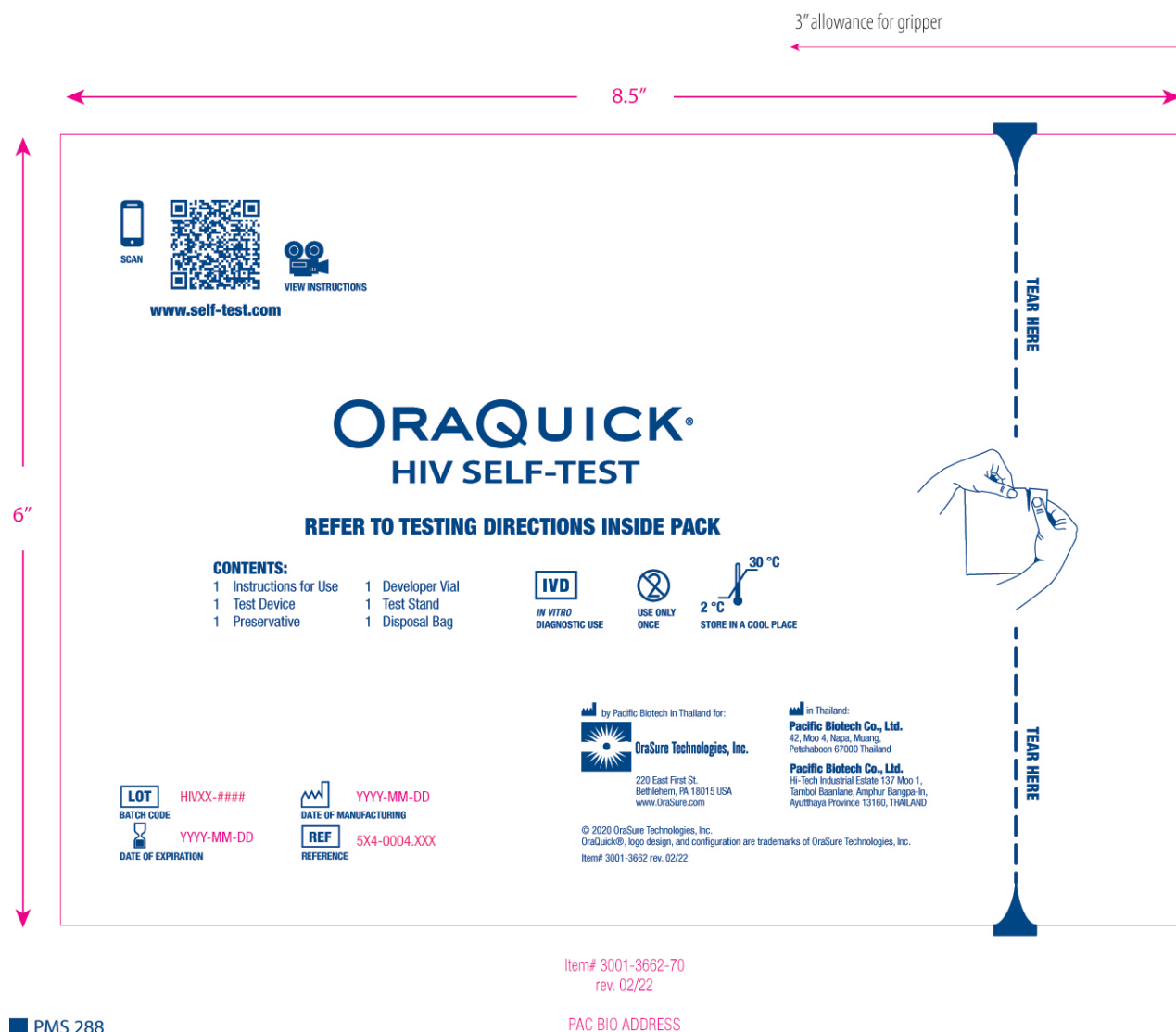
**4. Outer Pouch 3001-2824, revision 01/21
or 3001-3431 revision 11/20
or 3001-3662, revision 02/22**



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



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





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

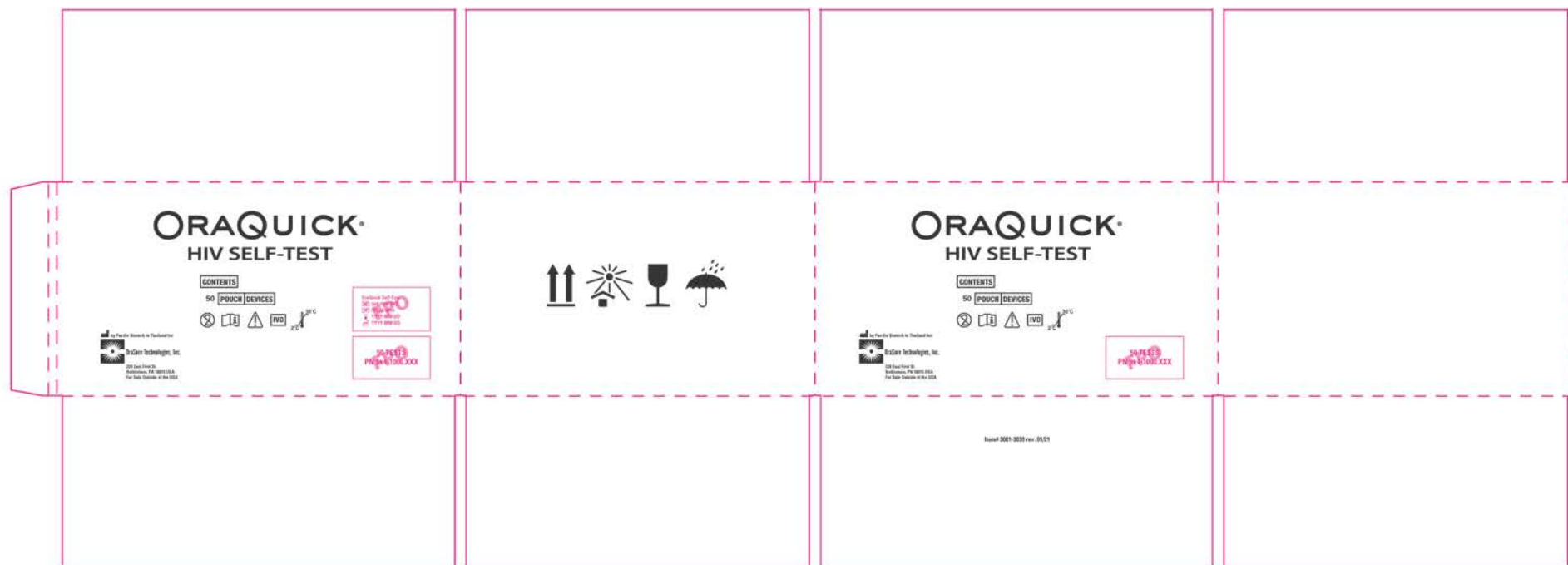


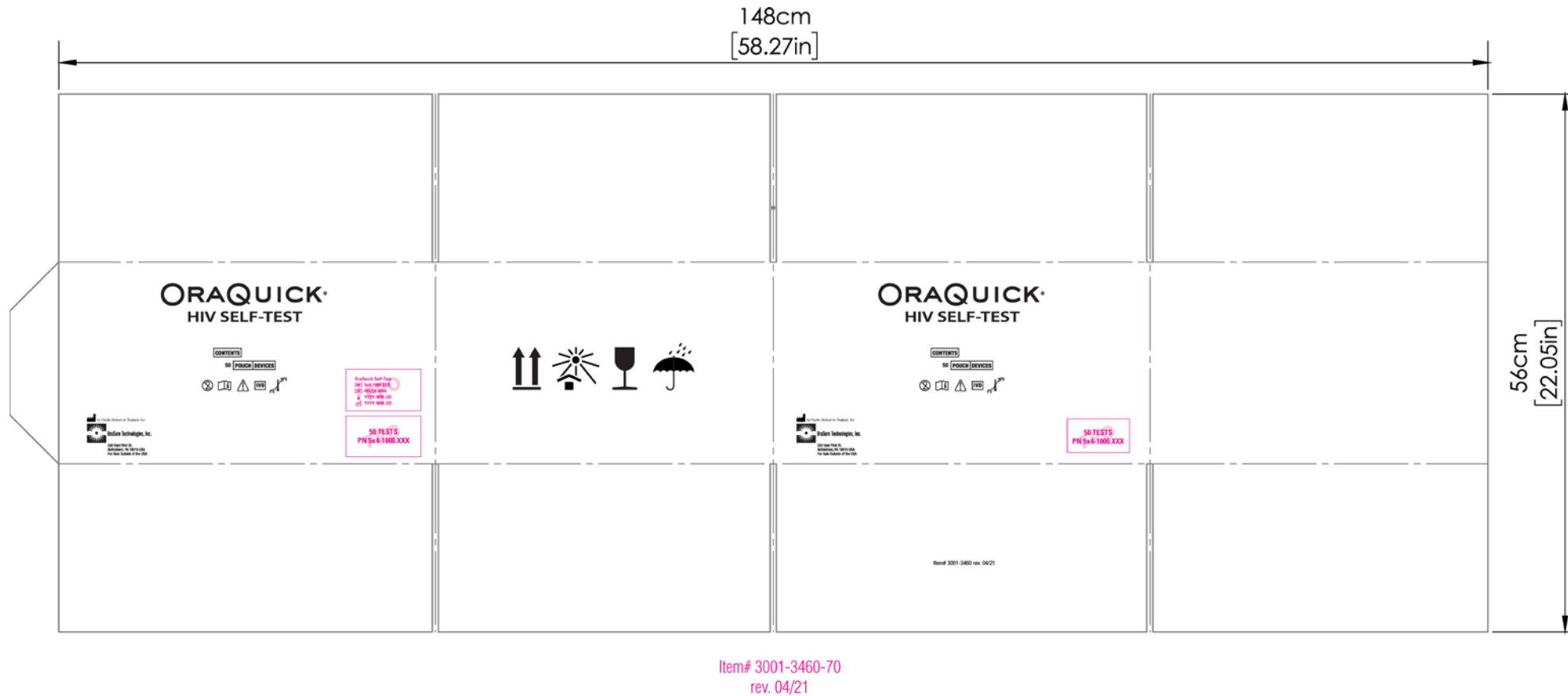
5X4-7000C Outer Pouch , Front

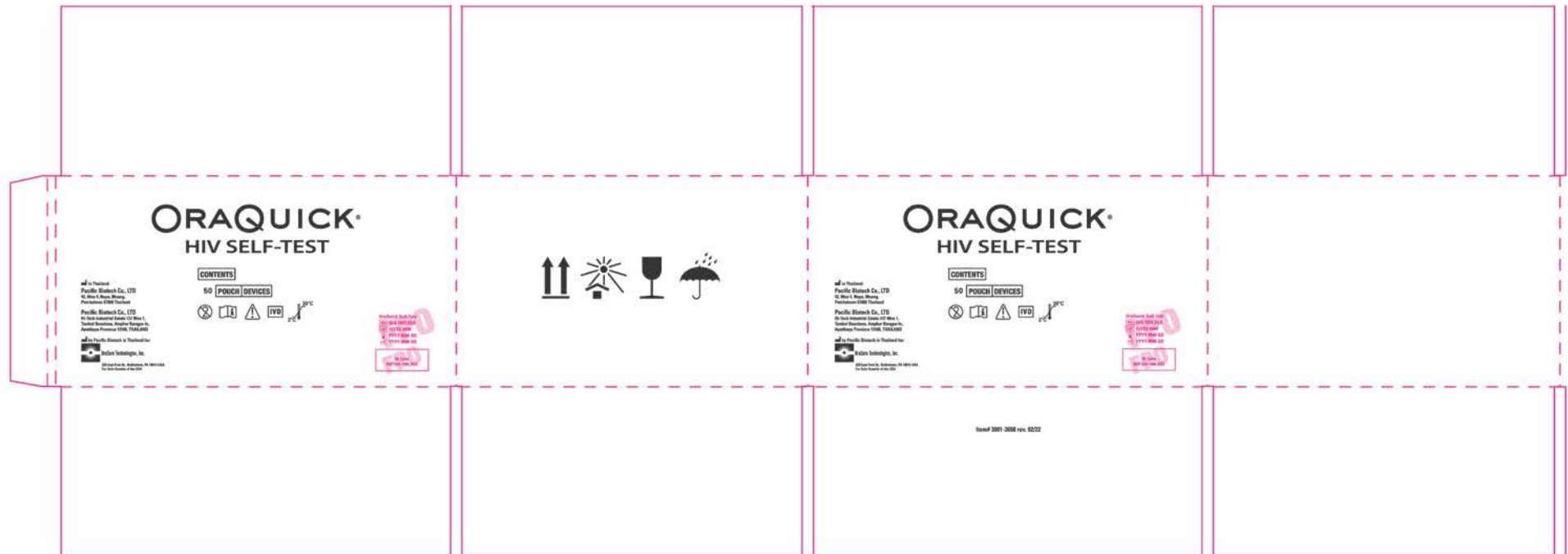


5X4-7000C Outer Pouch , Front



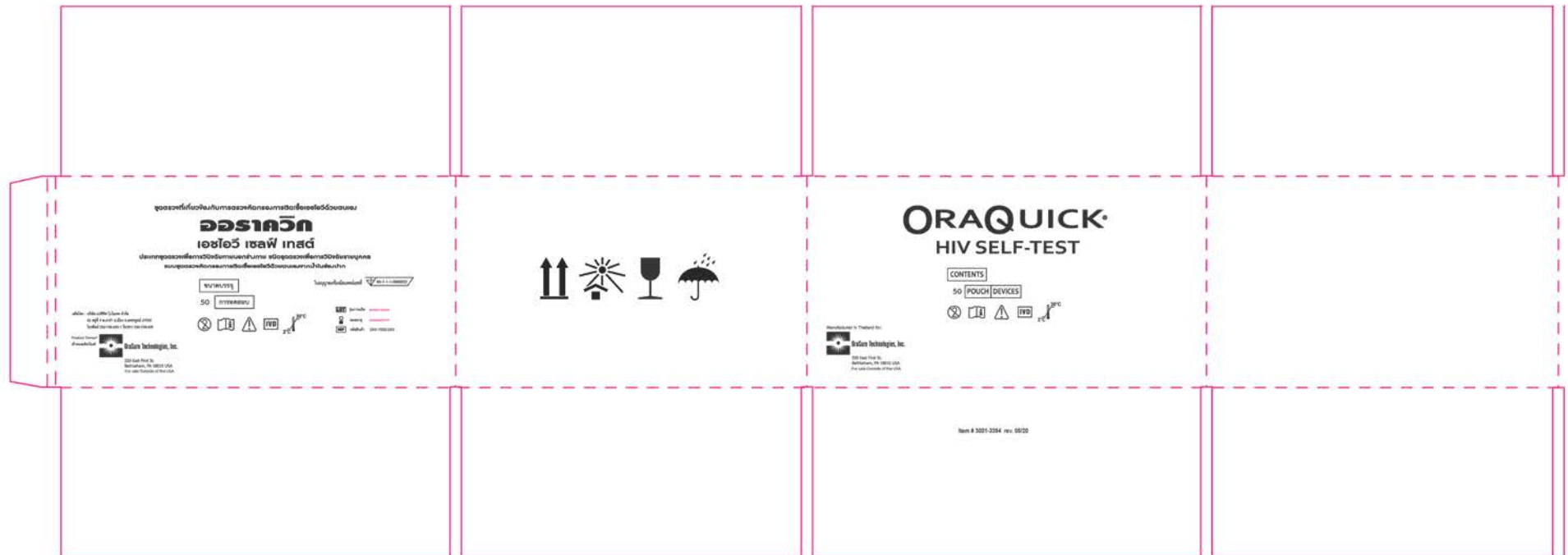
5. 50 Count Shipper Box 3001-3039 revision 01/21**Or 3001-3460 revision 04/21****Or 3001-3658 revision 02/22****Or 3001-3655 revision 05/20****Or 3001-3394 revision 05/20**Item# 3001-3039-70
rev. 01/21





PacBio Address
Item# 3001-3658
rev. 02/22





3001-3394
 Petchaboon
 Rev. 05/20

6. 250 Count Shipper 3001-3040 revision 01/21

Or 3001-3461 revision 04/21

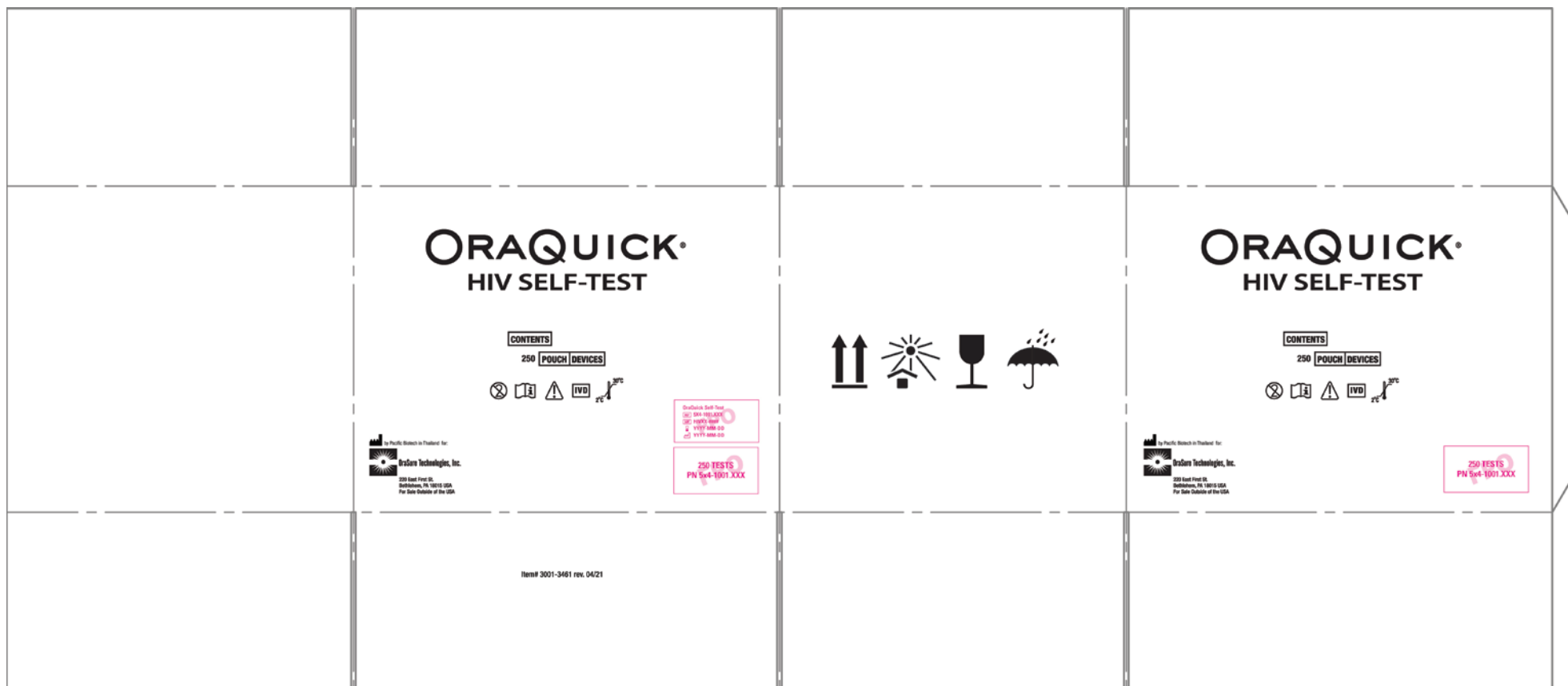
Or 3001-3659 revision 02/22

Or 3001-3395 revision 05/20

Or 3001-3656 revision 05/20



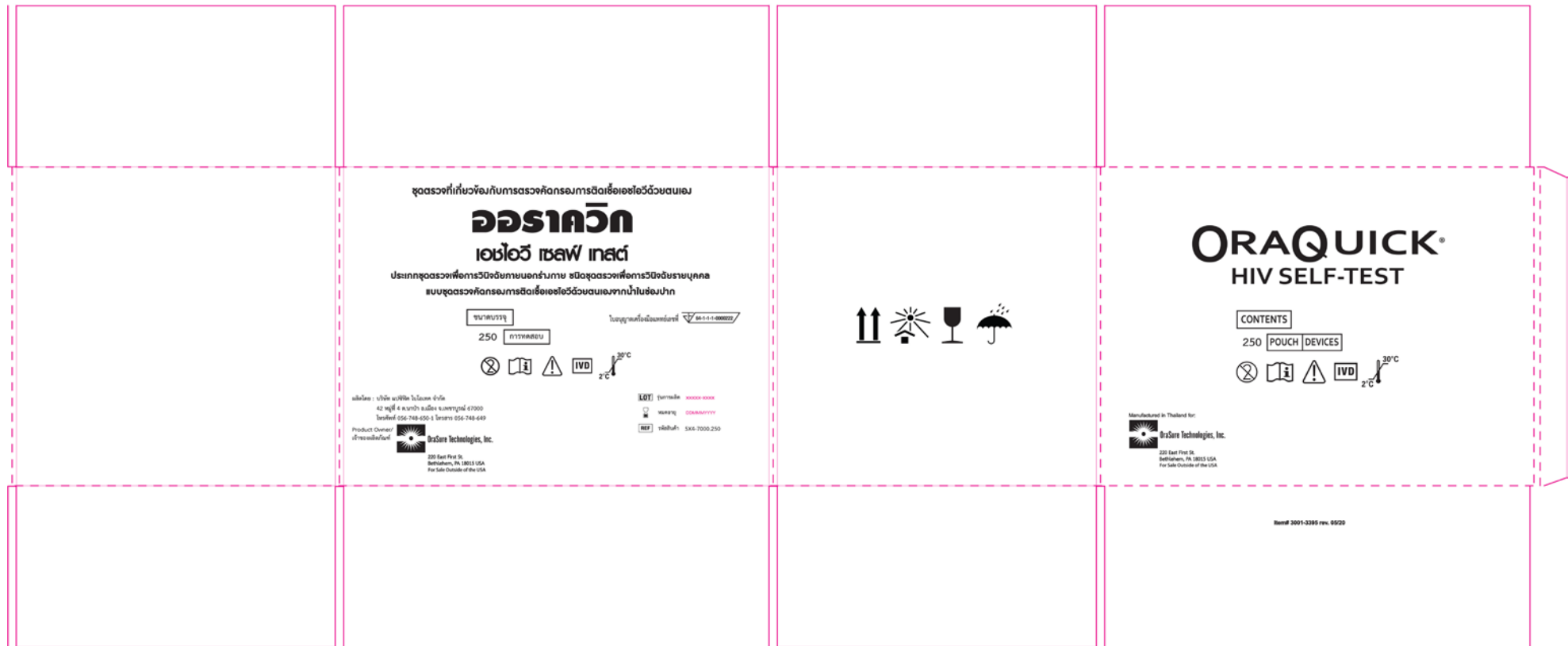
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rev. 01/21



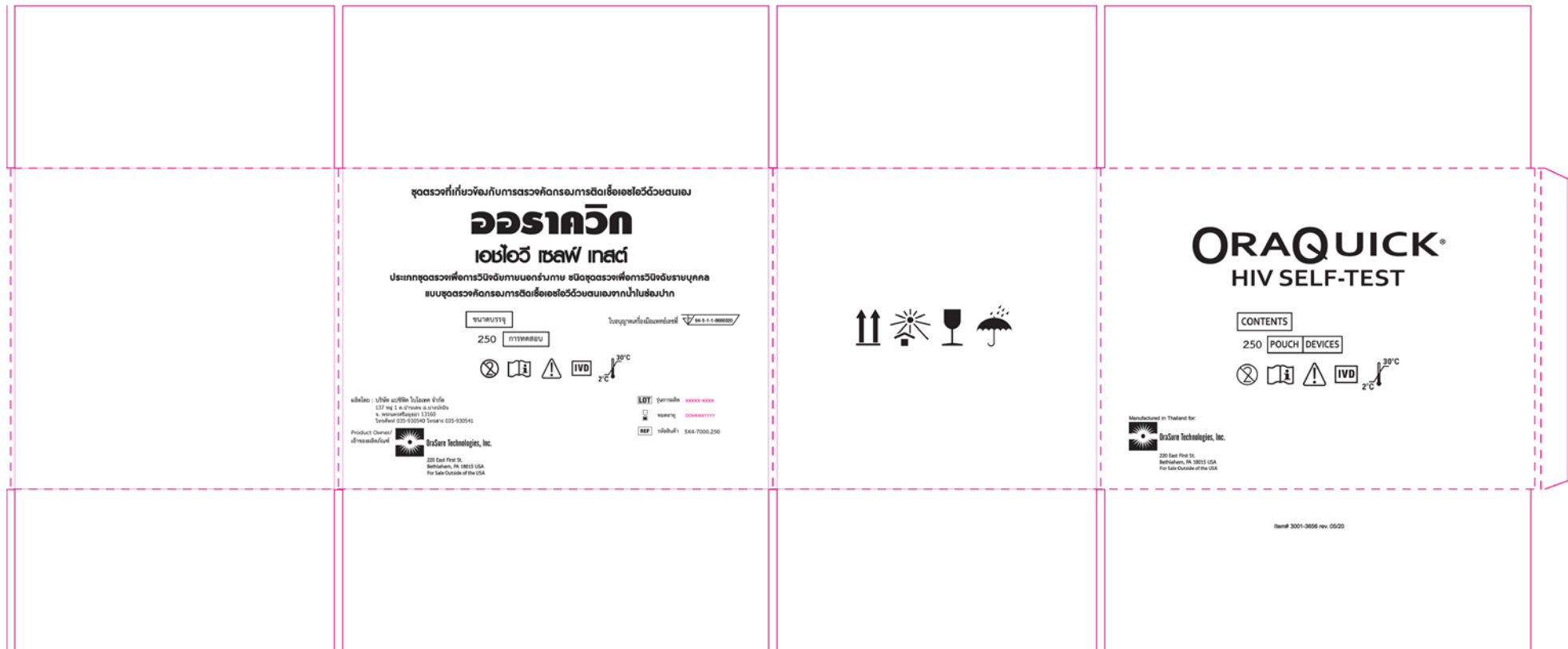
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rev. 04/21



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



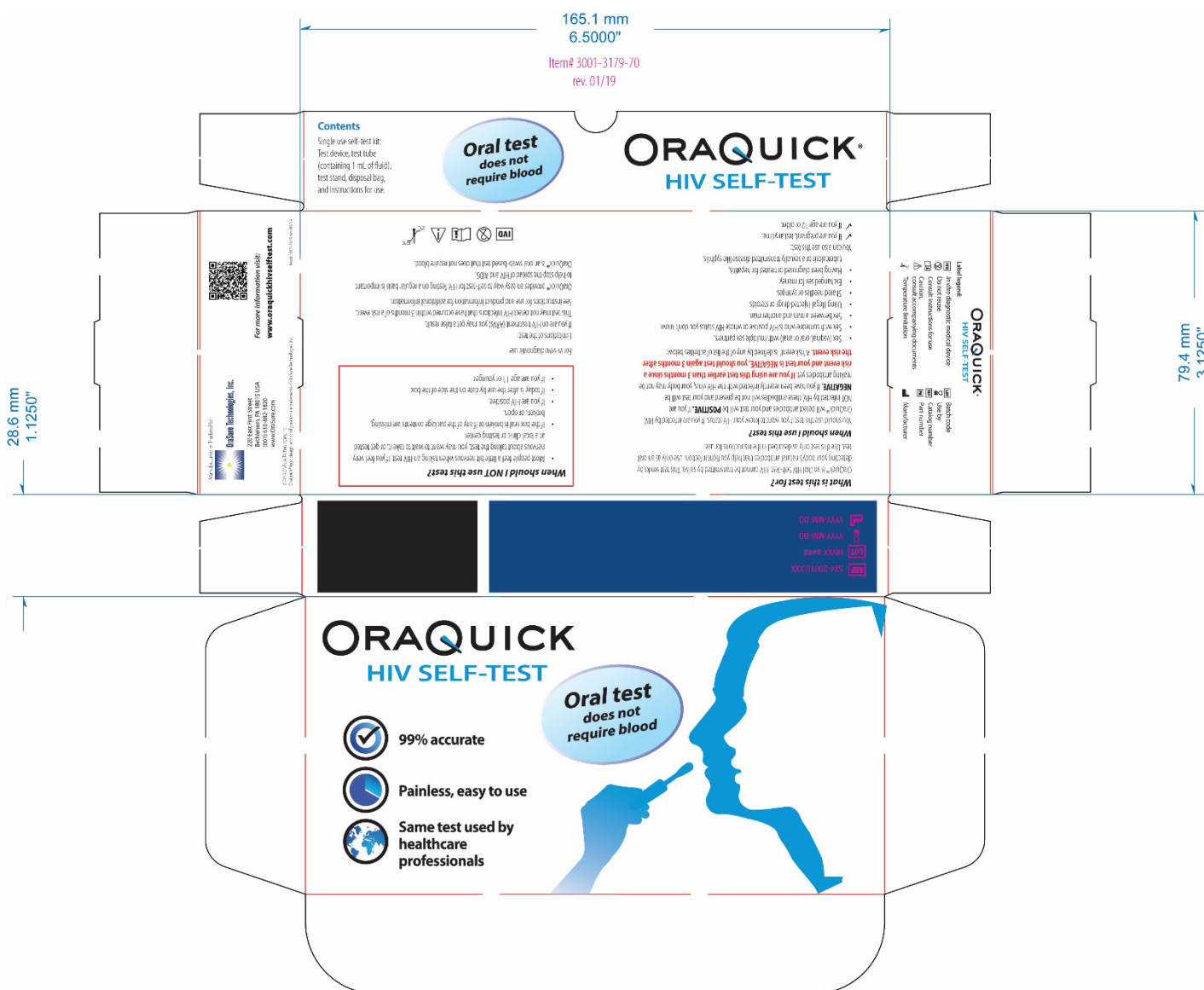
3001-3395
Petchaboon
Rev. 05/20

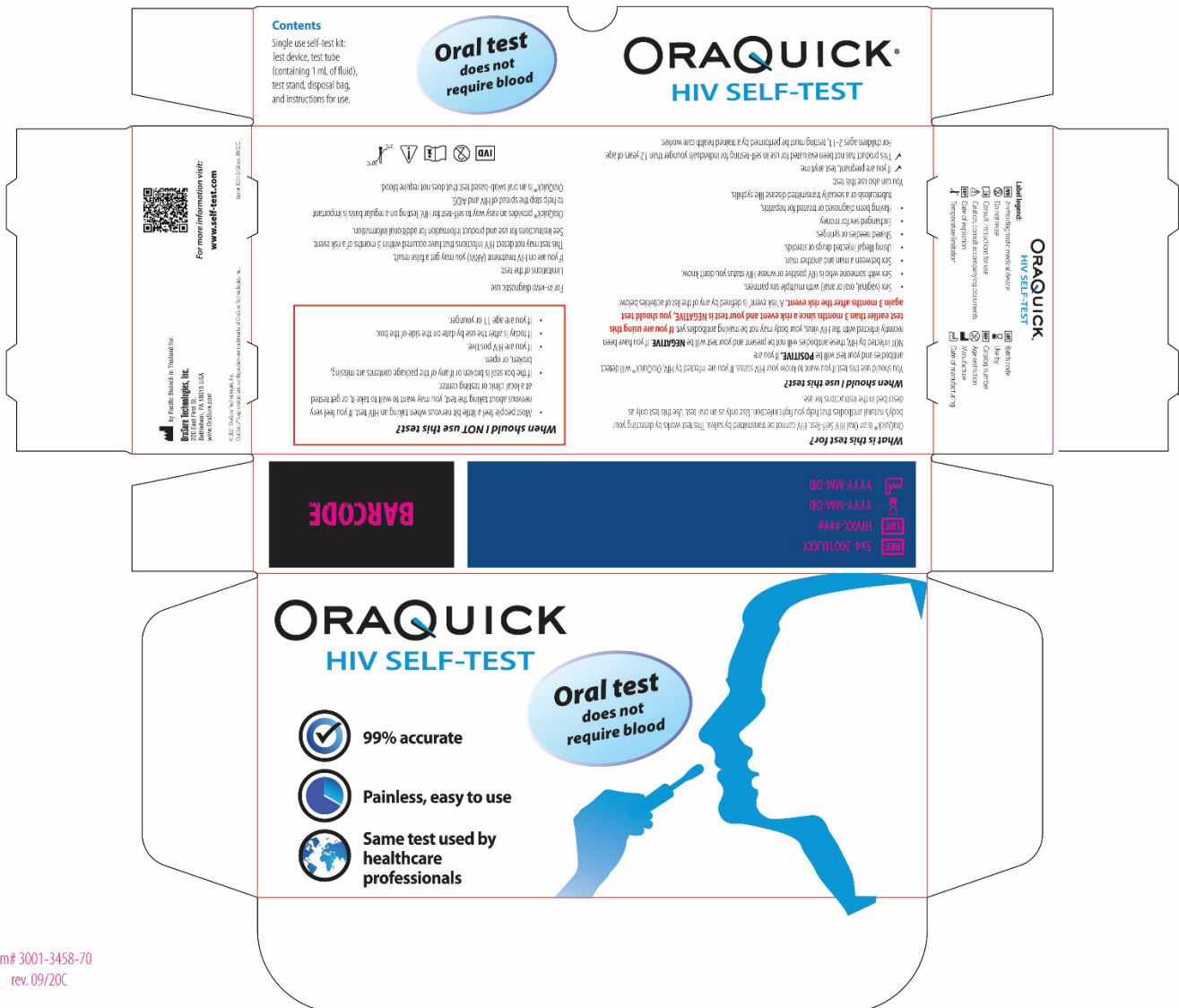


Ayutthaya
Item# 3001-3656
rev. 05/20

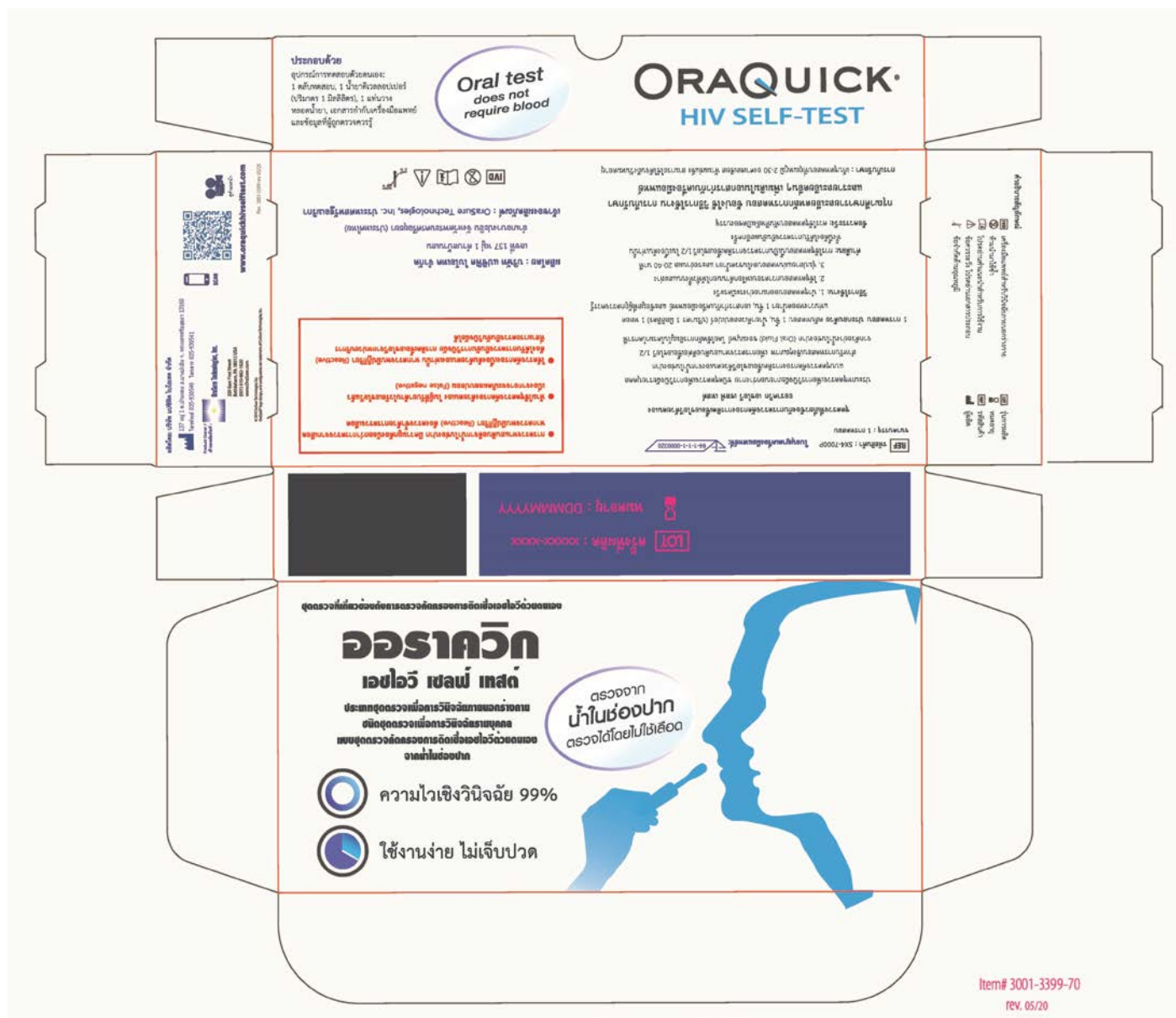
II. Pharmacy version

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

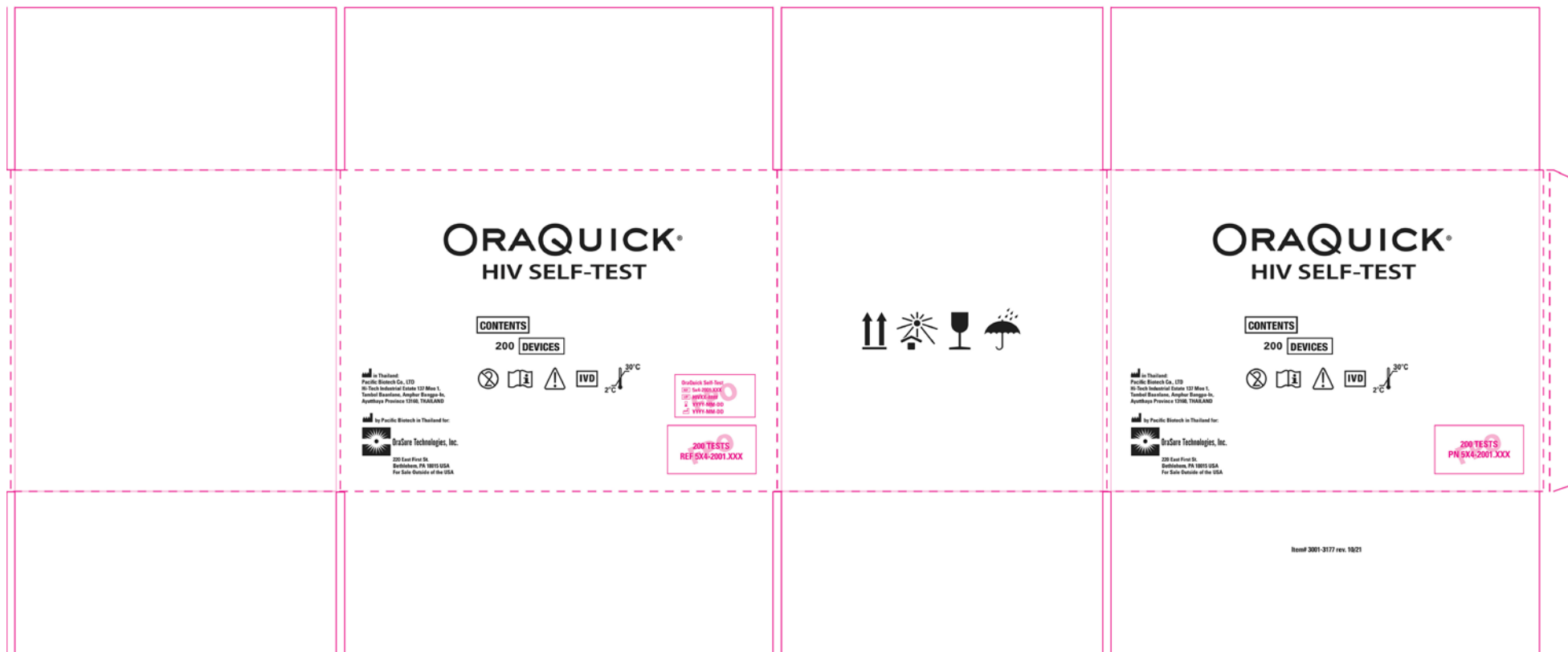




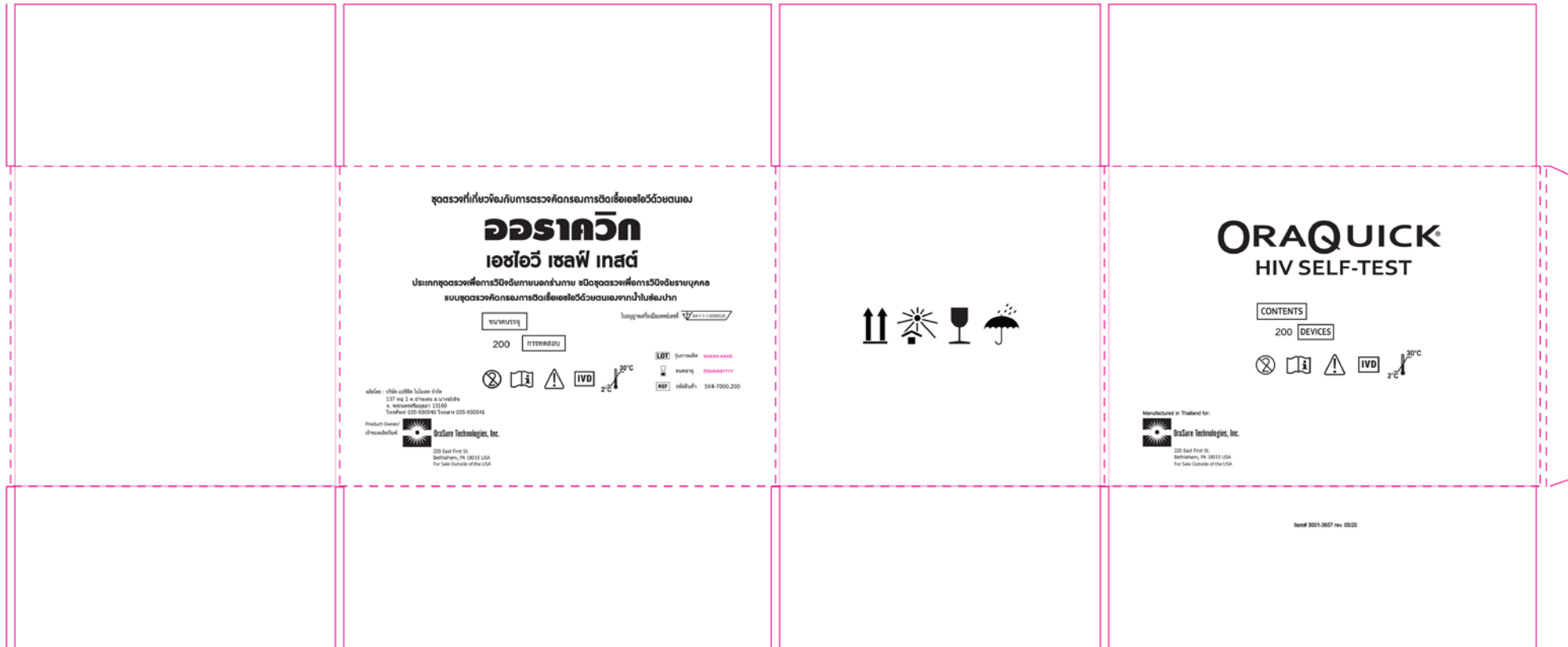
Item# 3001-3458-70
rev. 09/20C



**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



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

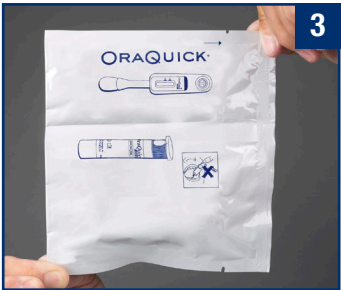
HOW TO USE THE ORAQUICK® HIV SELF-TEST KIT



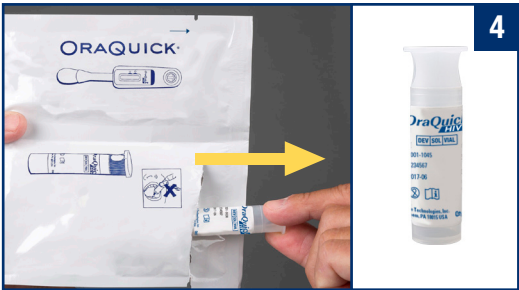
YOU WILL NEED A WAY TO TIME THE TEST



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



Your test kit contains two pouches.



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



Remove the cap.



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



Slide the tube into the **stand**.



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.



Preservative
THROW AWAY.
Not needed for the test.
DO NOT EAT.



fig. 1



fig. 2

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).



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



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

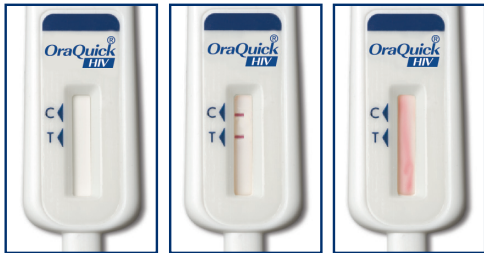


ONE LINE next to the "C" and NO line next to the "T", your result is HIV NEGATIVE.

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		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 :



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(+1) 610-882-1820 • www.OraSure.com

ROMANIAN

Citiți în întregime acest prospect înainte de a utiliza produsul. Respectați instrucțiunile cu atenție la efectuarea testelor, în caz contrar, se pot produce rezultate de test incorecte.

IVD Pentru utilizare în scopuri de diagnostic *in vitro*.

A se utiliza exclusiv de către cadre medicale.

DESTINAȚIA DE UTILIZARE

Testul rapid de detectare a anticorpilor anti-HIV-1/2 OraQuick *ADVANCE*® este un test de imunodotare calitativ de unică folosință pentru detectarea anticorpilor la virusul imunodeficienței umane de tip 1 (HIV-1) și tip 2 (HIV-2) în probe de salivă, sânge capilar, sânge integral venos și plasmă. Testul HIV-1/2 OraQuick *ADVANCE*® este destinat utilizării ca test efectuat la punctul de îngrijire pentru diagnosticarea infecției cu HIV-1 și HIV-2.

RESTRIȚII

- Testul HIV-1/2 OraQuick *ADVANCE*® nu este aprobat în vederea utilizării la selecția donatorilor de sânge sau țesuturi.
- Testul HIV-1/2 OraQuick *ADVANCE*® nu este destinat utilizării pentru monitorizarea persoanelor care urmează terapie antiretrovirală extrem de activă (HAART).

REZUMATUL ȘI EXPLICAREA TESTULUI

Sindromul imunodeficienței dobândite (SIDA), complexul asociat SIDA (ARC) și pre-SIDA sunt considerate a fi cauzate de virusul imunodeficienței umane (HIV). Testarea în vederea depistării prezenței anticorpilor anti-HIV în fluidele organice (de exemplu, sânge, salivă) reprezintă un ajutor de precizie în diagnosticarea infecției cu HIV.

PRINCIPIILE BIOLOGICE ALE TESTULUI

Testul HIV-1/2 OraQuick *ADVANCE*® este o imunoanaliză de 20 de minute realizată manual, cu citire vizuală, pentru detectarea calitativă a anticorpilor împotriva HIV-1 și HIV-2. Banda de test pentru efectuarea analizei, conține peptide sintetice reprezentând regiunea capsulară a virusului HIV și un ser de control procedural pe bază de IgG anti-umană de capră imobilizat pe o membrană de nitroceluloză în zona de Test (T) și, respectiv, în zona de Control (C).

MATERIALE FURNIZATE (REF 1001-0284 25 TESTE, REF 1001-0285 100 TESTE)

- Punga compartimentată conține Testul HIV-1/2 OraQuick *ADVANCE*® plus agent deshidratant și Soluția revelatoare HIV-1/2 OraQuick *ADVANCE*®: flacon cu 1 mL soluție salină tamponată cu fosfat conținând polimeri și un agent antimicrobian.
- Suporturi de test reutilizabile
- Anse de recoltare
- Prospect

MATERIALE NECESARE, DISPONIBILE CA ACCESORII ALE KIT-ULUI

Seruri de control pentru kit-ul testului rapid de detectare a anticorpilor HIV-1/2 OraQuick *ADVANCE*®

MATERIALE NECESARE, DAR NEFURNIZATE

Cronometru cu posibilitate de cronometrare a 20 până la 40 de minute

Recipient pentru deșuri care prezintă pericol biologic

Articole suplimentare necesare pentru recoltarea probelor de sânge din deget și din venă

Șervețel antiseptic, lanțetă sterilă sau materiale pentru puncție venoasă, mănuși de unică folosință (opțional pentru analiza salivei), tamponate de tifon sterile, centrifugă

AVERTISMENTE

Pentru utilizare în scopuri de diagnostic *in vitro*. A se utiliza exclusiv de către cadre medicale.

- Citiți în întregime prospectul înainte de a utiliza produsul.
- Acest kit a fost aprobat pentru utilizare doar cu probe de salivă, sânge integral din deget, sânge integral din venă și plasmă.
- Acest test trebuie efectuat la temperaturi în intervalul 15°-37°C. În cazul în care se păstrează la frigider, asigurați-vă că punga compartimentată este adusă la temperatura de funcționare (15°-37°C) înainte de a efectua testarea.
- În cazul în care kit-ul de test este păstrat la temperaturi în afara limitelor de temperatură ambiantă (2°-27°C) sau este utilizat în afara limitelor de temperatură de funcționare (15°-37°C), utilizați serurile de control ale kit-ului pentru a asigura performanța testului.
- Persoanele infectate cu HIV-1 și/sau HIV-2 care urmează terapie antiretrovirală extrem de activă (HAART) pot înregistra rezultate fals negative.

PRECAUȚII

- Manevrați speciile și materialele care intră în contact cu speciile ca și cum ar putea transmite agenți infecțioși.
- Purtați mănuși la unică folosință în timpul manevrării și testării speciilor de sânge. Schimbați mănușile și spălați-vă bine pe mâini după efectuarea fiecărui test. Eliminați mănușile utilizate într-un recipient pentru deșuri care prezintă pericol biologic.
- Se recomandă utilizarea de mănuși pentru testarea salive deoarece orice specimen biologic trebuie tratat ca fiind potențial infecțios. Administratorii de test care prezintă răni la nivelul pielii (tăieturi, escoriații sau dermatită) trebuie să poarte mănuși la efectuarea testării asupra probei de salivă. Spălați-vă bine pe mâini după efectuarea fiecărui test asupra probei de salivă și după contactul cu saliva.
- Nu reutilizați ansele de recoltare a probelor, dispozitivele de test sau soluția de reacție. Eliminați aceste componente în mod corespunzător. Reutilizarea acestor componente poate cauza transmiterea de agenți infecțioși.
- Nu utilizați testul după data de expirare imprimată pe pungă.

DEPOZITAREA

- Păstrați testele HIV-1/2 OraQuick *ADVANCE*® neutilizate la 2°-27°C fără a le deschide.
- Nu deschideți punga până când nu sunteți pregătit să efectuați un test.
- În cazul în care se păstrează la frigider, asigurați-vă că punga este adusă la temperatura de funcționare (15°-37°C) înainte de deschidere.

MANEVRAREA SPECIMENELOR

- Salivă: Asigurați-vă înainte de testare că subiectul nu a consumat niciun fel de alimente, băuturi și nu a mestecat gumă timp de cel puțin 15 minute. Spuneți subiectului să aștepte cel puțin 30 de minute înainte de testare în cazul în care a utilizat produse de igienă orală. Colectați specimenul și introduceți-l imediat în soluție revelatoare.
- Sânge integral sau plasmă: introduceți dispozitivul de test în soluția revelatoare în decurs de 60 de minute de la adăugarea probei.
- Specimenele de sânge integral sau de plasmă colectate în eprubete cu heparină sodică și litiu heparină sau citrat de sodiu pot fi păstrate la 2°-30°C timp de până la 24 de ore. Specimenele de plasmă pentru care se utilizează o eprubetă cu EDTA pot fi păstrate timp de până la 7 zile la 2°-8°C. Răsturnați eprubeta de mai multe ori pentru omogenizare.
- Plasmă: Centrifugați la 1000-1300 x g timp de aproximativ 5 minute.

INDICAȚII DE UTILIZARE

PREGĂTIREA GENERALĂ A TESTULUI

- Lăsați toate componentele să atingă temperatura de funcționare (15°-37°C).
- Așezați suportul de test reutilizabil pe suprafața dumneavoastră de lucru. Utilizați doar suportul furnizat împreună cu kit-ul de test HIV-1/2 OraQuick *ADVANCE*®.
- Introduceți flaconul cu soluție revelatoare pentru testul HIV-1/2 OraQuick *ADVANCE*® în suportul de test. Țineți flaconul nemişcat în suport și scoateți capacul clătindu-l înainte și înapoi în timp ce trageți de acesta.
- Nu deschideți punga până când nu sunteți pregătit să efectuați un test. Verificați punga pentru a detecta eventuale deteriorări sau perforații. Aruncați-o dacă este deteriorată.
- Căutați în pungă un pachet cu agent deshidratant. Dacă acesta nu este prezent sau pare deteriorat, aruncați punga și deschideți una nouă.
- NU acoperiți cele 2 orificii de pe partea din spate a dispozitivului cu etichete. Blocarea orificiilor poate genera un rezultat invalid.

1. RECOLTAREA PROBELOR

1a. Salivă

- Asigurați-vă înainte de testare că subiectul nu a consumat niciun fel de alimente, băuturi și nu a mestecat gumă timp de cel puțin 15 minute. Spuneți subiectului să aștepte cel puțin 30 de minute înainte de testare în cazul în care a utilizat produse de igienă orală.
- Scoateți din pungă Testul HIV-1/2 OraQuick *ADVANCE*®. NU atingeți suprafața plată de prelevare.
- Tamponați complet în jurul gingiilor exterioare de jos și de sus **O SINGURĂ DATĂ**. NU tamponați bolta palatină, obrații sau limba.

1b. Sânge integral din deget

- Dezinfectați degetul. Lăsați să se usuce la aer.
- Înțepați degetul cu o lanțetă sterilă. Ștergeți prima picătură de sânge cu un tampon de tifon steril. Țineți degetul în jos și exercitați o presiune ușoară lângă punctul de înțepare. Nu strângeți degetul pentru a-l face să sângereze.
- Umpleți ansa de recoltare. Introduceți imediat ansa în soluția revelatoare. Amestecați cu ajutorul ansei.
- Dacă ansa este scăpată sau intră în contact cu orice altă suprafață, aruncați-o. Utilizați o nouă ansă pentru recoltarea sângelui.

1c. Sânge integral din venă

- Colectați proba utilizând proceduri de flebotomie standard într-o eprubetă ce conține EDTA, heparină sodică, litu heparină sau citrat de sodiu. Nu au fost testați alți anticoagulanți, astfel încât aceștia pot genera un rezultat incorect.
- Omogenizați sângele prin răsturnare. Umpleți ansa de recoltare. Introduceți imediat ansa în soluția revelatoare. Amestecați cu ajutorul ansei.

1d. Plasmă

- Plasmă: Colectați proba utilizând proceduri de flebotomie standard într-o eprubetă ce conține EDTA, heparină sodică, litu heparină sau citrat de sodiu.
- Centrifugați la 1000-1300 x g timp de aproximativ 5 minute.
- Umpleți ansa de recoltare. Introduceți imediat ansa în soluția revelatoare. Amestecați cu ajutorul ansei.

2. EFECTUAREA TESTULUI

- Introduceți dispozitivul de test în soluția revelatoare.
- Setați cronometrul la 20 - 40 de minute.



REZULTATUL TESTULUI ȘI INTERPRETAREA

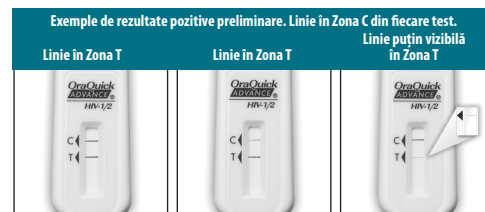
Observați vizorul de afișare a rezultatelor de pe dispozitivul de test.

NON-REACTIV

Un test este non-reactiv dacă apare o linie în Zona C și NU apare NICIO linie în Zona T. Un rezultat de test non-reactiv înseamnă că în specimen nu au fost detectați anticorpi HIV. Se presupune că pacientul nu este infectat cu HIV.

REACTIV

Un test este reactiv dacă o linie apare în Zona C și o alta apare în Zona T. Intensitatea liniilor poate varia. Testul este reactiv indiferent de cât de puțin vizibile sunt aceste linii. Un rezultat de test reactiv înseamnă că în specimen au fost detectați anticorpi HIV. Rezultatul de test este interpretat ca fiind PRELIMINAR POZITIV pentru anticorpii HIV-1 și/sau HIV-2. Se recomandă confirmarea unui rezultat reactiv printr-una sau mai multe metode de test.



INVALID

Nu apare nicio linie în Zona C	Nu apare nicio linie în Zona C	Fundalul roșu ocultează rezultatele	Liniile se află în afara Zonei C sau T
			SAU

Un test este invalid dacă:

Un rezultat de test invalid înseamnă că a survenit o problemă în efectuarea testului, fie în legătură cu specimenul, fie în legătură cu dispozitivul. Un rezultat invalid nu poate fi interpretat. Repetați testul cu o nouă pungă și un nou specimen. Contactați Serviciul pentru clienți al OraSure Technologies dacă nu puteți obține un rezultat de test valid în urma testării repetate.

CURĂȚAREA GENERALĂ DUPĂ EFECTUAREA TESTULUI

- Eliminați materialele de test utilizate și mănușile într-un recipient pentru deșeurile care prezintă pericol biologic.
- Când utilizați mănuși, schimbați-vă mănușile după fiecare test pentru a preveni contaminarea.
- Utilizați o soluție de înălbitor de 10% proaspăt preparată pentru curățarea oricărui deversări.

CONTROLUL CALITĂȚII

Testul HIV-1/2 OraQuick *ADVANCE*® are încorporat un ser de control procedural. O linie în Zona C după 20 de minute indică validitatea analizei. Seruri de control externe sunt disponibile separat. Utilizați serurile de control din kit-ul Testului rapid de detectare a anticorpilor HIV-1/2 OraQuick *ADVANCE*® în conformitate cu politica unității de asigurare a calității.

LIMITĂRILE TESTULUI

- 1. Testul HIV-1/2 OraQuick *ADVANCE*® este aprobat pentru utilizare doar cu probe de salivă, sânge integral din deget, sânge integral din venă și plasmă. Este posibil ca utilizarea altor lichide organice să nu producă rezultate corecte.
- 2. Citirea rezultatelor de test mai devreme de 20 de minute sau mai târziu de 40 de minute poate conduce la rezultate eronate.
- 3. Testarea de sânge integral din venă sau testarea de probe de plasmă recoltate utilizând o eprubetă care conține un alt anticoagulant decât EDTA, heparină sodică și litiu heparină sau citrat de sodiu poate să nu producă rezultate corecte.
- 4. Un rezultat negativ la acest test nu exclude posibilitatea infectării cu HIV. Se pot produce rezultate fals negative în următoarele situații.
 - Persoane infectate cu HIV-1 sau HIV-2 care urmează terapie antiretrovirală extrem de activă (HAART).
 - Niveluri scăzute de anticorpi datorate expunerii recente.
- 5. Testul HIV-1/2 OraQuick *ADVANCE*® Test este conceput să ajute la diagnosticarea infecției cu HIV-1 și/sau HIV-2. SIDA și afecțiunile asociate SIDA reprezintă sindroame clinice, iar diagnosticarea acestora poate fi determinată doar clinic.
- 6. Nu au fost colectate date clinice care să demonstreze efectuarea testului HIV-1/2 OraQuick *ADVANCE*® la persoane cu vârste mai mici de 12 ani.

CARACTERISTICI DE PERFORMANȚĂ

SENSIBILITATE

Detectarea anticorpilor anti-HIV-1 în specimene prelevate de la indivizi infectați cu HIV-1.

Salivă

Un studiu de sensibilitate a fost efectuat asupra unor specimene de salivă obținute proaspăt, recoltate de la 597 de persoane raportate a fi infectate cu HIV-1. Din cele 597 de specimene care au fost identificate ca fiind seropozitive în urma unor teste de confirmare autorizate, 597 au produs un rezultat reactiv la testul HIV-1/2 OraQuick *ADVANCE*®. Sensibilitatea testului rapid de detectare a anticorpilor HIV-1/2 OraQuick *ADVANCE*® în specimene de salivă a fost calculată ca fiind 597/597= 100%.

Sânge integral

Un studiu de sensibilitate a fost efectuat asupra unor probe de sânge integral obținute proaspăt prin înțepătură în deget și/sau din eprubetă de la 543 persoane cunoscute a fi infectate cu HIV-1. Din cele 543 de probe care au fost determinate ca fiind confirmat pozitive în urma unui test autorizat EIA și Western blot/analiză imunofluorescentă (IFA), 543 au produs un rezultat reactiv la Testul HIV-1/2 OraQuick *ADVANCE*®.

Plasmă

Un studiu de sensibilitate a fost efectuat în unsprezece centre de studiu clinic asupra unor specimene de plasmă în EDTA recoltate de la 728 de persoane raportate a fi infectate cu HIV-1. Din cele 728 de specimene care au fost identificate ca fiind seropozitive prin analiză imunoenzimatică (EIA) și teste de confirmare autorizate, 728 au produs un rezultat reactiv la Testul HIV-1/2 OraQuick *ADVANCE*®.

TABELUL 1. Rezumatul studiilor de sensibilitate

Specimen	Reactiv	N total	Sensibilitate
Salivă	597	597	100,0%
Sânge integral	543	543	100,0%
Plasmă	728	728	100,0%

Reactivitate cu specimene care conțin HIV-1 din diferite regiuni geografice

Pentru a evalua sensibilitatea Testului HIV-1/2 OraQuick *ADVANCE*® pentru specimene care conțin HIV-1 din diferite regiuni geografice, 119 de specimene reprezentând subtipurile de HIV-1 A, B, C, D, E, F, G, H, J și Grupa O au fost testate și toate au fost reactive la testul HIV-1/2 OraQuick *ADVANCE*®.

Reactivitate cu bilanțuri de seroconversie HIV-1

Au fost testate treizeci de bilanțuri de seroconversie HIV-1 comparativ cu testele EIA anti-HIV cu marcaj CE. Fiecare bilanț era format din specimene secvențiale de ser/plasmă obținute de la un singur individ în timpul seroconversiei. Cele treizeci de bilanțuri de seroconversie erau formate din 235 de specimene. Rezultatele acestui studiu sunt indicate în Tabelul 2. În acest studiu, Testul HIV-1/2 OraQuick *ADVANCE*® a detectat seroconversie, în medie, în aproximativ același timp ca și testul EIA cu marcaj CE.

TABELUL 2. Comparație între Testul HIV-1/2 OraQuick *ADVANCE*® și testele EIA anti-HIV autorizate prin utilizarea bilanțurilor de seroconversie

Nr. de bilanțuri	Reactiv
17	OraQuick® = Test EIA de referință
13	OraQuick® < Test EIA de referință

Diferența medie a fost de 2,5 zile (intervale de încredere de 95%: 1,2 - 3,8 zile) mai târziu pentru Testul HIV-1/2 OraQuick *ADVANCE*®.

Detectarea anticorpilor anti-HIV-2 în specimene prelevate de la indivizi infectați cu HIV-2

Un total de 104 de specimene depozitate confirmate a fi pozitive pentru anticorpii anti-HIV-2 prin test anti-HIV-2 EIA autorizat și metode de test suplimentare, inclusiv Western blot și teste de radio-imunoprecipitare (RIPA), au fost obținute din diverse surse. Testul OraQuick *ADVANCE*® a detectat 104/104 (100%) din specimene de la indivizi confirmate a fi pozitive pentru anticorpii anti-HIV-2. Alte două studii au fost efectuate pentru a evalua sensibilitatea testului OraQuick *ADVANCE*® în rândul unei populații cunoscute a fi infectate cu HIV-2. Trei persoane infectate cu HIV-2 din SUA și 13 persoane infectate cu HIV-2 din Guinea-Bissau, Africa, au fost testate prin metodele OraQuick *ADVANCE*® de testare a sângelui integral din deget și a salivei. Probele de sânge integral din deget și de salivă de la toți subiecții au fost reactive la testul OraQuick *ADVANCE*®. Combinând numărul de rezultate reactive la testele OraQuick *ADVANCE*® obținute din toate studiile, sensibilitatea Testului HIV-1/2 OraQuick *ADVANCE*® pentru detectarea anticorpilor anti-HIV-2 a fost calculată ca fiind 120/120= 100%.

SPECIFICITATE

Salivă

Un studiu de specificitate a fost efectuat în patru centre de studiu clinic asupra unor specimene de salivă obținute proaspăt, recoltate de la 606 persoane neselectate în prealabil cu risc scăzut de infectare cu HIV-1. Toate cele 606 de specimene au fost, așa cum era și corect, non-reactive în urma Testului HIV-1/2 OraQuick *ADVANCE*®. Din cele 106 specimene negative pentru anticorpii anti-HIV de la cele patru centre de studiu care au examinat populații cu risc crescut de infectare cu HIV-1, testul OraQuick *ADVANCE*® a fost non-reactiv în cazul a 105.

Un studiu separat realizat de Centrele pentru Controlul și Prevenirea Bolilor (Centers for Disease Control and Prevention - CDC) a evaluat probele de salivă colectate de la 1679 de persoane cu situație HIV necunoscută. Testul HIV-1/2 OraQuick *ADVANCE*® a produs rezultate non-reactive în cazul a 1662 din cele 1666 de specimene identificate drept probe confirmat negative.

Combinând numărul de rezultate non-reactive obținute din ambele studii, specificitatea Testului HIV-1/2 OraQuick *ADVANCE*® din aceste studii a fost calculată ca fiind 2373/2378= 99,8%.

Sânge integral din deget

Un studiu de specificitate a fost efectuat asupra unor probe de sânge integral din deget obținute proaspăt de la 2189 de persoane neselectate în prealabil cu risc scăzut și crescut de infectare cu HIV-1. Din cele 2189, 2166 au fost determinate ca fiind probe negative în urma testelor EIA și suplimentare. Toate speci-menele confirmat negative au produs rezultate non-reactive în urma Testului HIV-1/2 OraQuick *ADVANCE*® pentru un grad de specificitate de 100%.

Plasmă

Un studiu de specificitate a fost efectuat în șapte centre de studiu clinic asupra unor specimene de plasmă în EDTA recoltate de la 1657 persoane neselectate în prealabil cu risc scăzut și crescut de infectare cu HIV. Din cele 1657 de specimene, 1642 au fost determinate ca fiind negative pentru HIV pe baza rezultatelor testelor EIA autorizate și suplimentare. Toate cele 1642 de specimene au produs rezultate non-reactive în urma Testului HIV-1/2 OraQuick *ADVANCE*®.

Combinând numărul de rezultate non-reactive la testele OraQuick *ADVANCE*® obținute din toate studiile, specificitatea Testului HIV-1/2 OraQuick *ADVANCE*® din aceste studii a fost calculată ca fiind 1642/1642= 100%.

TABELUL 3. Rezumatul studiilor de specificitate

Specimen	N total	OraQuick® non-reactiv	Confirmat negativ	Specificitate
Salivă	2378	2373	2378	99,8%
Sânge integral din deget	2189	2166	2166	100,0%
Plasmă	1657	1642	1642	100,0%

SUBSTANȚELE INTERFERENTE ȘI AFECȚIUNILE MEDICALE NEASOCIATE

Pentru a evalua impactul afecțiunilor medicale neasociate sau al substanțelor interferente asupra sensibilității Testului HIV-1/2 OraQuick *ADVANCE*®, 200 de specimene de ser/plasmă atestând o varietate de afecțiuni medicale neasociate infecției cu HIV-1 și 100 de specimene cu substanțe interferente au fost amestecate cu un specimen pozitiv pentru HIV-1 pentru a indica un nivel de reactivitate în intervalul pozitiv inferior. Toate speci-
menele amestecate au produs rezultate reactive.

Pentru a evalua impactul afecțiunilor medicale neasociate sau al substanțelor interferente asupra specificității Testului rapid de detectare a anticorpilor HIV-1/2 OraQuick *ADVANCE*®, au fost analizate 321 de specimene de ser/plasmă atestând o varietate de afecțiuni medicale neasociate infecției HIV și 119 de specimene cu substanțe interferente. Un specimen de la subiecți cunoscuți a fi pozitivi pentru virusul Epstein-Barr (EBV), VHB sau factorul reumatoid, unul de la o femeie multipară și trei specimene de la subiecți cunoscuți a fi infectați cu VHA au indicat rezultate false pozitive.

Tabelul 4. Afecțiuni medicale neasociate infecției HIV

Afecțiune medicală (n = 321)	OraQuick® reactiv	OraQuick® non-reactiv
Femei multipare	1	14
Anticorp antinuclear (ANA)	0	17
Lupus	0	15
Factor reumatoid	1	17
Citomegalovirus (CMV)	0	15
Virusul Epstein Barr (EBV)	1	14
Virusul hepatitei A (VHA)	3	17
Virusul hepatitei B (VHB)	1	16
Virusul hepatitei C (VHC)	0	15
Virusul limfotrop T uman de tip I (HTLV-I)	0	15
Virusul limfotrop T uman de tip II (HTLV-II)	0	15
Rubeolă	0	15
Gamopatii IgG	0	13
Gamopatii IgM	0	12
Sifilis	0	15
Toxoplasmoză	0	15
Tuberculoză	0	15
Gripă	0	10
Transfuzii multiple	0	10
Bolnavii de hemofilie	0	10
Virusul herpes simplex	0	5
Ciroză	0	5
Pacient dializat	0	4
Cancer de colon	0	4
HTLV I/II	0	2
Chlamydia	0	3
Anticorp anti-scl sau anti-rnp	0	3
Cancer mamar	0	1
Anticorp anti-ADN	0	1
Gonoree	0	1
Substanțe interferente (n = 119)		
Valoare crescută a bilirubinei	0	20
Valoare crescută a hemoglobinei	0	20
Valori crescute ale trigliceridelor	0	20
Valori crescute ale proteinelor	0	20
Contaminare bacteriană	0	25
Hemoliză vizuală (hemolitic)	0	5
Icteric	0	5
Lipemic	0	4

OraSure Technologies realizează un scurt sondaj privind satisfacția în rândul clienților pentru a afla ce este important pentru aceștia. Am aprecia foarte mult dacă ați putea completa sondajul aflat pe site-ul nostru: <http://www.orasuresurvey.com>

Explicarea simbolurilor

 Perioada de valabilitate	HIV CONTROL - Ser de control negativ HIV	TEST Dispozitiv de test
REF Număr de catalog	HIV-1 CONTROL + Ser de control pozitiv HIV-1	TESTS Dispozitive de test
LOT Cod de lot	HIV-2 CONTROL + Ser de control pozitiv HIV-2	TEST STANDS Suporturi de test
 Producător	PACK INSERT Prospect	IVD Dispozitiv medical pentru diagnostic <i>in vitro</i>
 Consultați Instrucțiunile de utilizare	LOOPS 5μL 5 μL Anse	 Limită de temperatură
 Atenție, consultați documentele însoțitoare	ABS PACK Material absorbant	 A nu se reutiliza
CONTENTS Conținut	DEV SOL VIAL Flacon cu soluție revelatoare	EC REP Reprezentant autorizat în Comunitatea Europeană
KIT CTRLS Seruri de control ale kit-ului	 A nu se comercializa în SUA	
5μL SPEC COLLECT LOOP Ansa de recoltare a probelor de 5 μL	 Nu este destinat comerțului cu amănuntul	

CE
0543



OraSure Technologies, Inc.

220 East First Street
Bethlehem, PA 18015 U.S.A.
(001) 610.882.1820 • www.orasure.com



QARAD bvba
Cipalstraat 3
B-2440 GEEL
BELGIUM

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-Test²

	Date	Outcome
PQ listing	8 April 2016	listed
Dossier review	26 January 2016	MR
Site inspection(s) of quality management system	3 -5 November 2014	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

¹Country specific variations are documented through a suffix “###” to the product code.

²Dossier assessment 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://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-rdts/public_report/en/

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

Report amendments and/or product changes

This public report has since been amended. Amendments may have arisen because of changes to the prequalified product for which 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 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 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 double-sided single page to a single-sided single page. Added a limitation of the test in the IFU as follows “ <i>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</i> ”. 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 outer packaging (i.e. 5X4-1001.001, .002, ...). Change on product labelling due to minor revisions.	17 December 2021

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

7.0	1. Edits to 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
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Intended use⁵

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 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”.

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.

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)
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	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 instructions for use • 1 disposal bag	• 1 disposal bag
Each kit contains the same pouched device configuration as the community version, except the contents are contained in a carton.	
OraQuaick HIV-Self-Test (individual unit product code 5x4-0004.###)	
• 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	

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 temperatures in the range of 15 to 37 °C (59 ° - 99 °F).

Shelf-life upon manufacture:

30 months.

Warnings:

- Refer to current version of manufacturer's instructions for use (IFU).

Limitations:

- Refer to current version of manufacturer's instructions for use.

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.

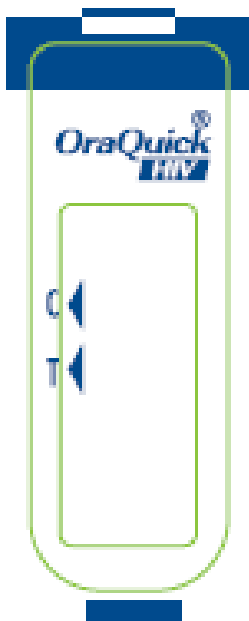
Labelling

1. Labels

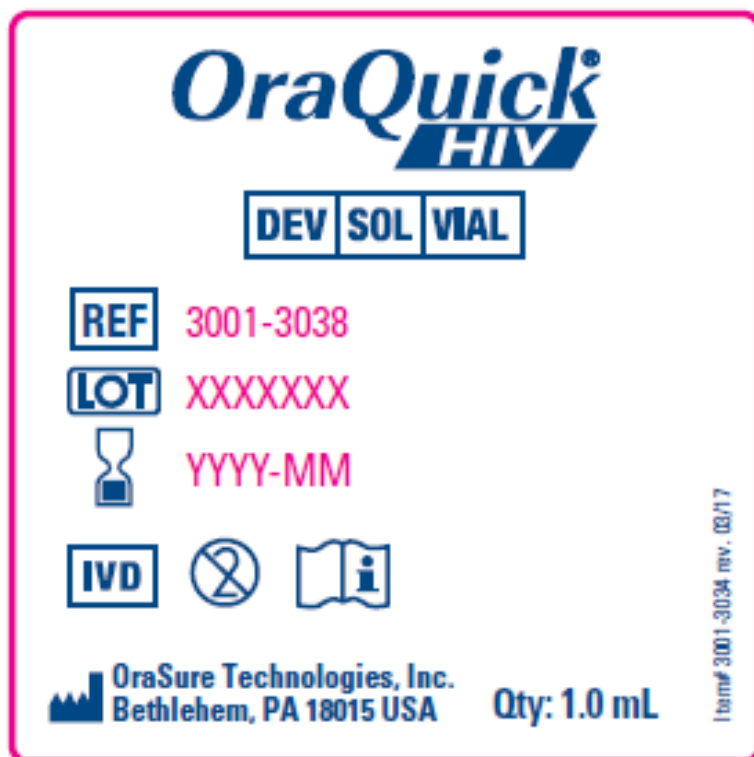
2. Instructions for use

I. Community version

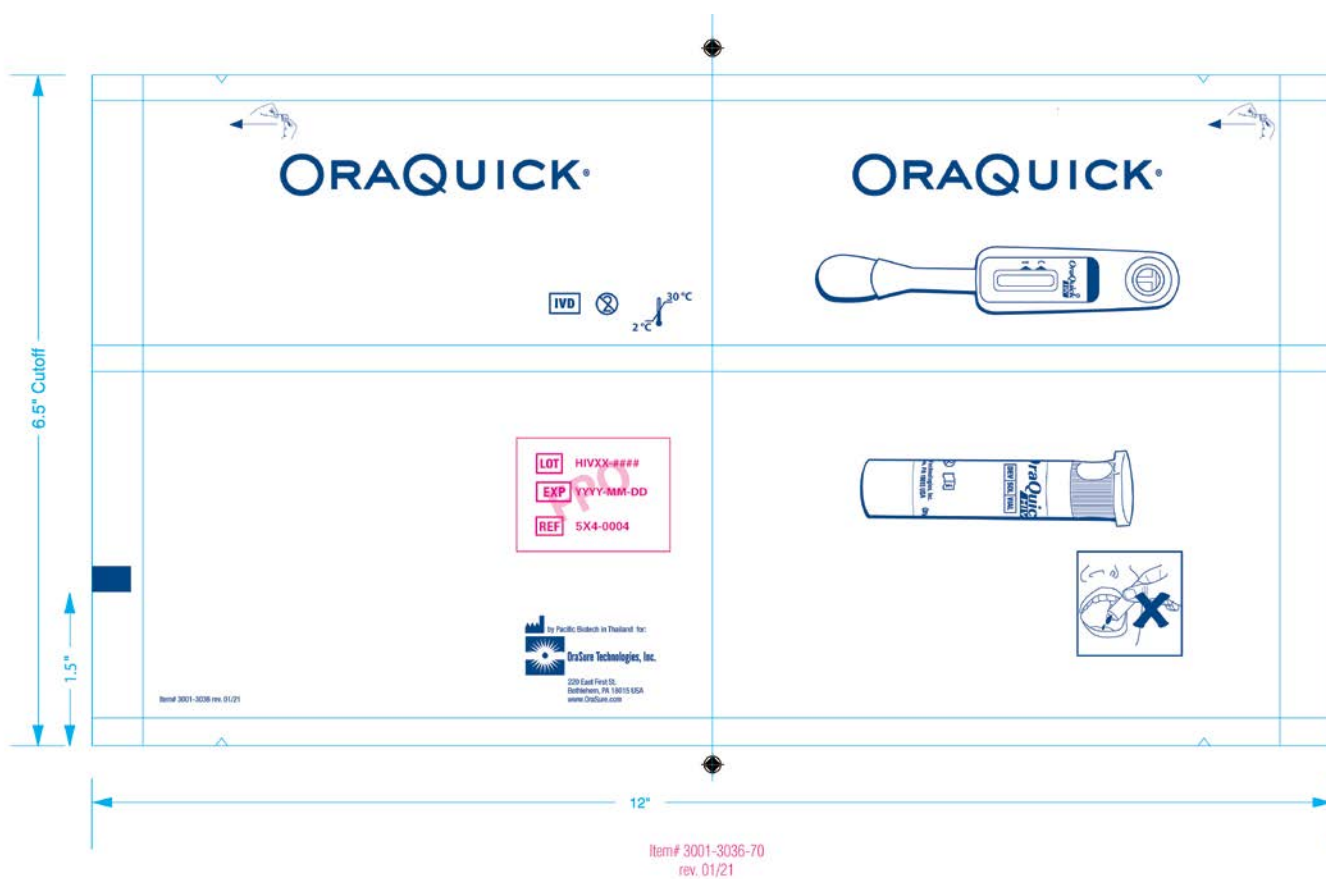
1. Device Label 3001-3035 rev 03/17

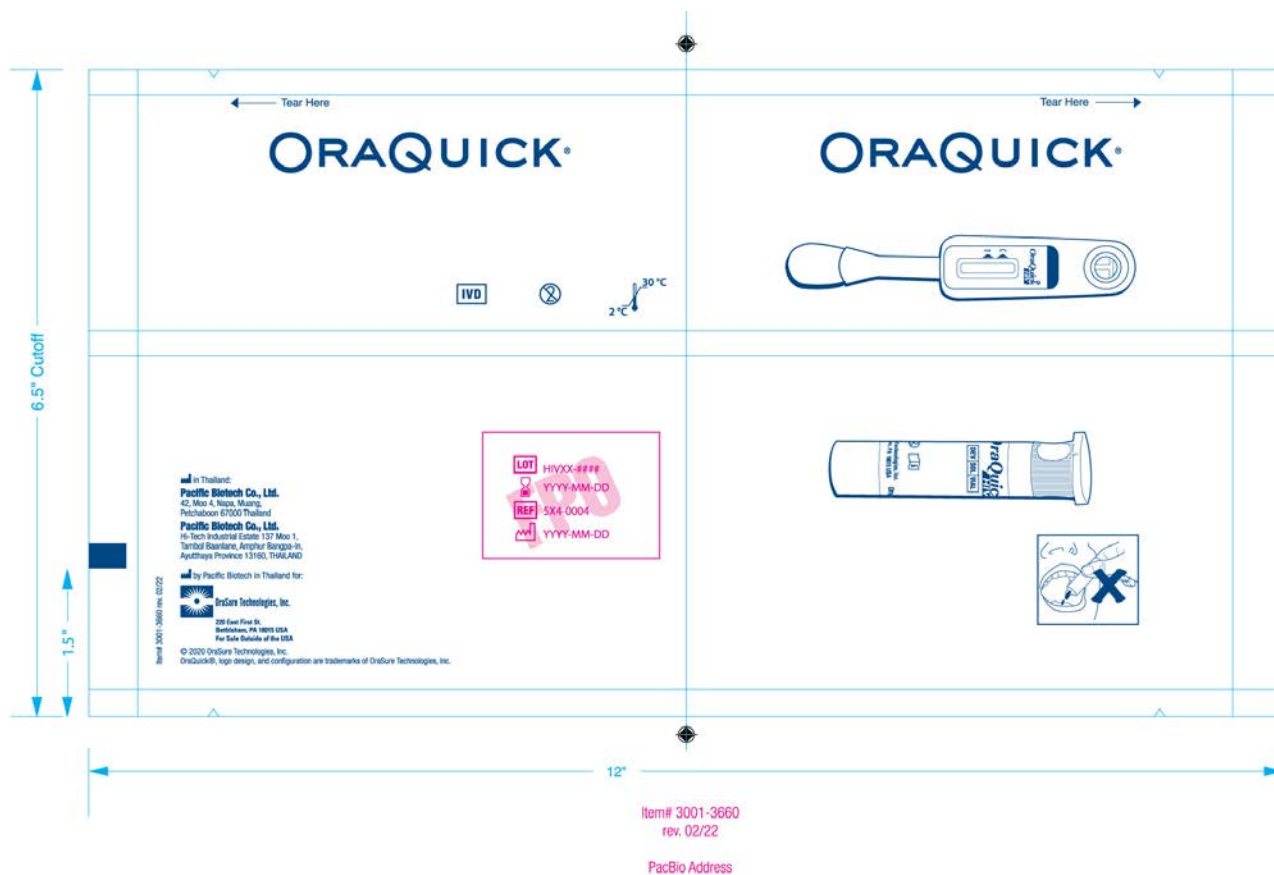


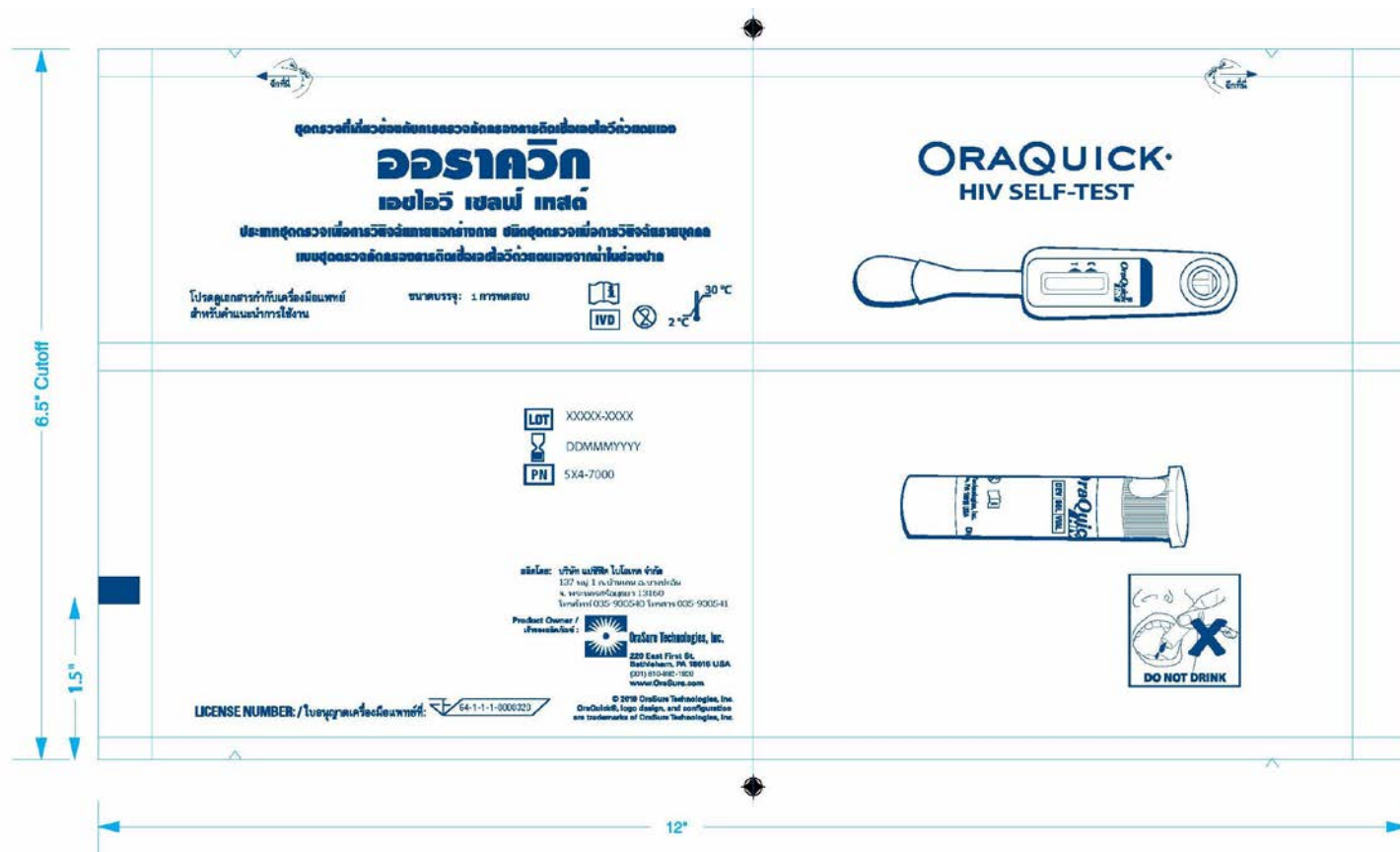
2. Developer Vial Label 3001-3034 rev 03/17

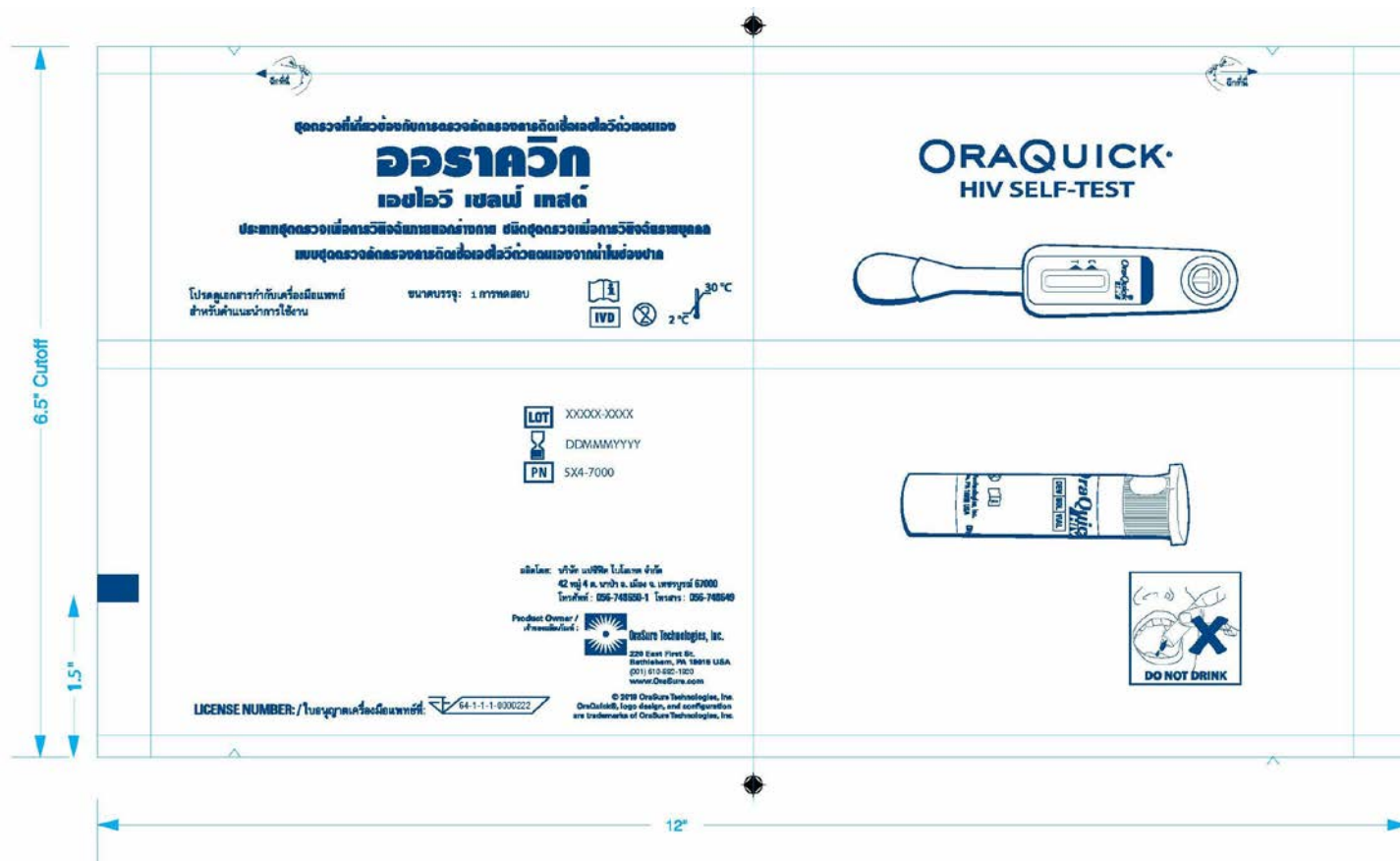


01/21

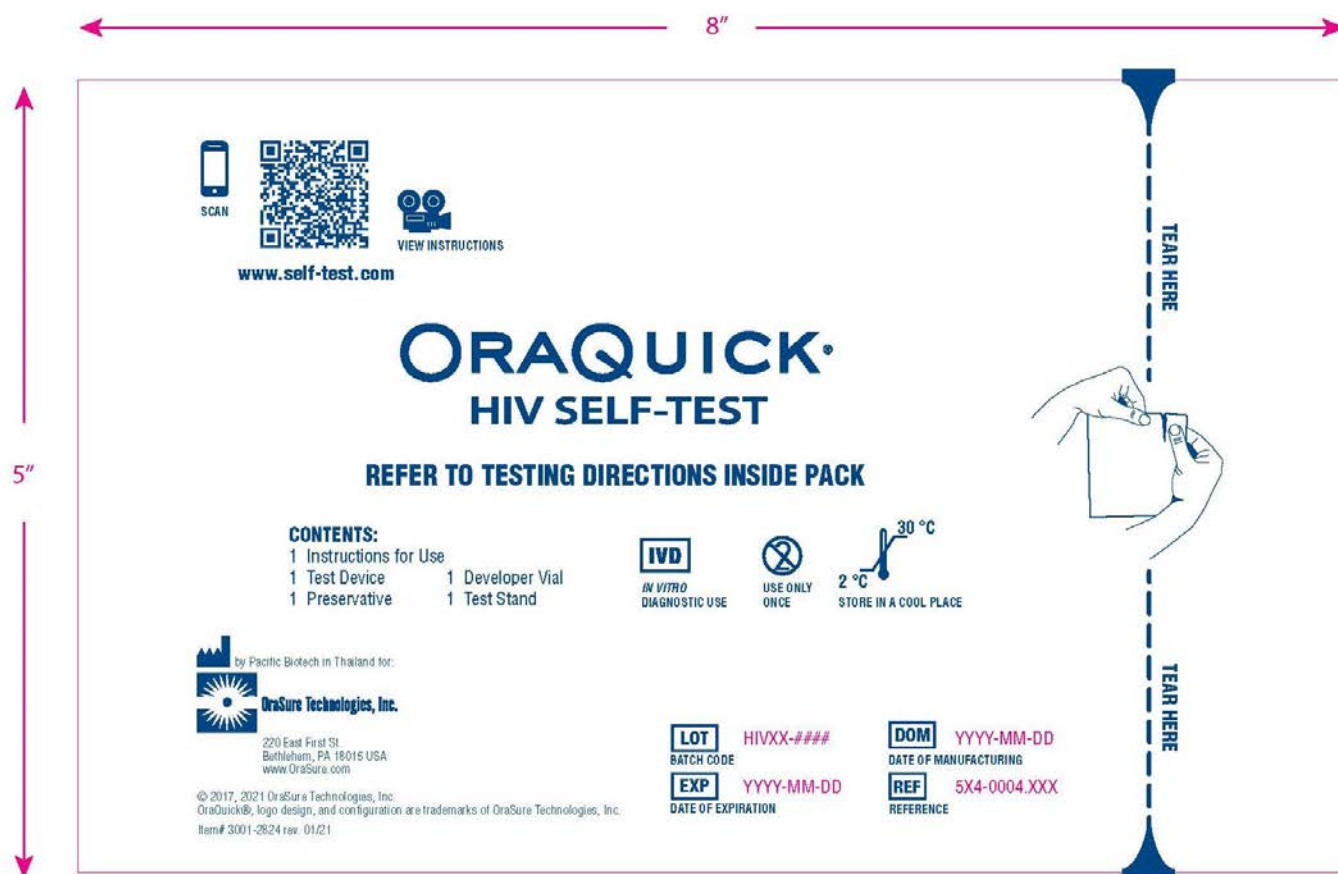








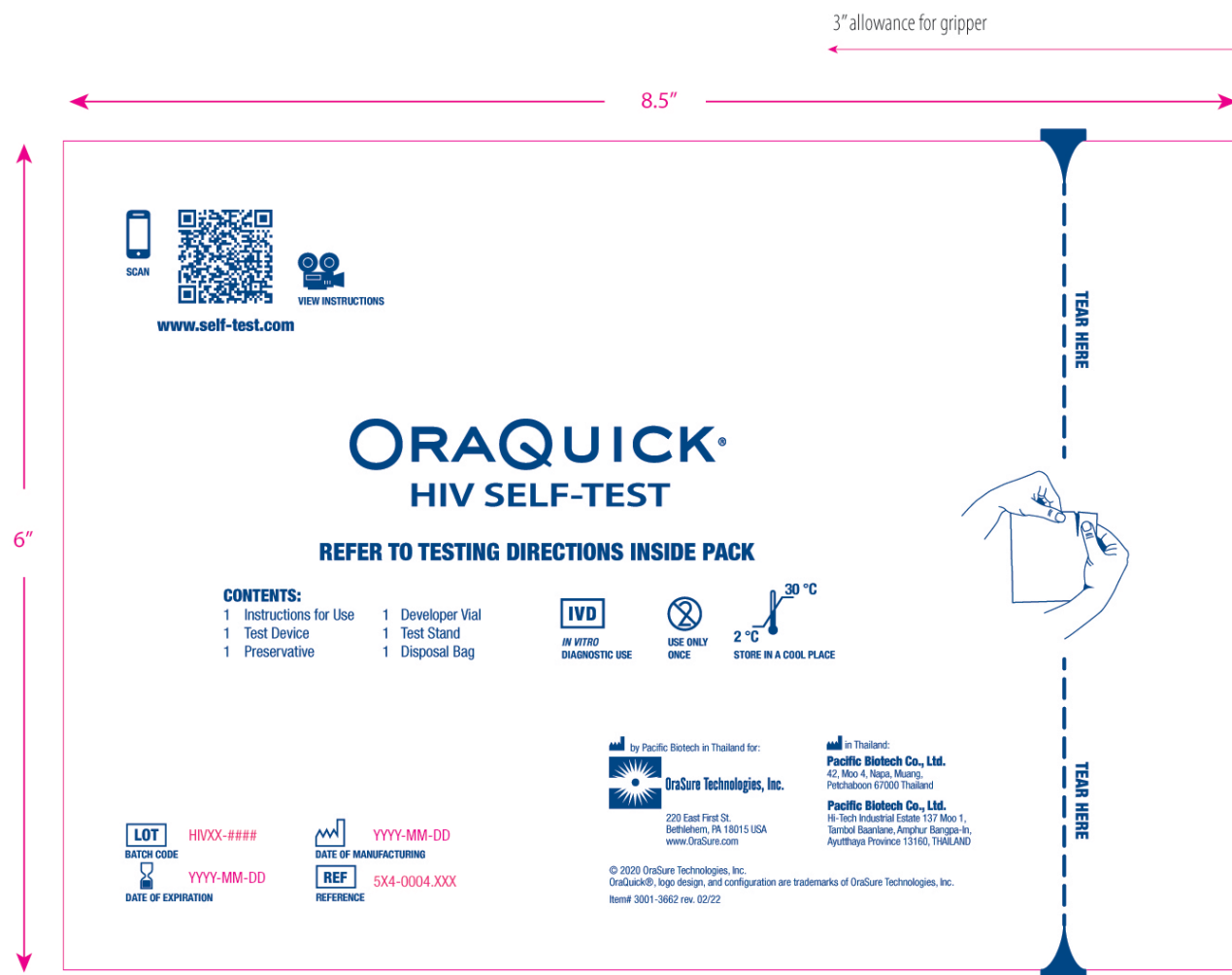
**4. Outer Pouch 3001-2824, revision 01/21
or 3001-3431 revision 11/20
or 3001-3662, revision 02/22**



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



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



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

PAC BIO ADDRESS

■ PMS 288



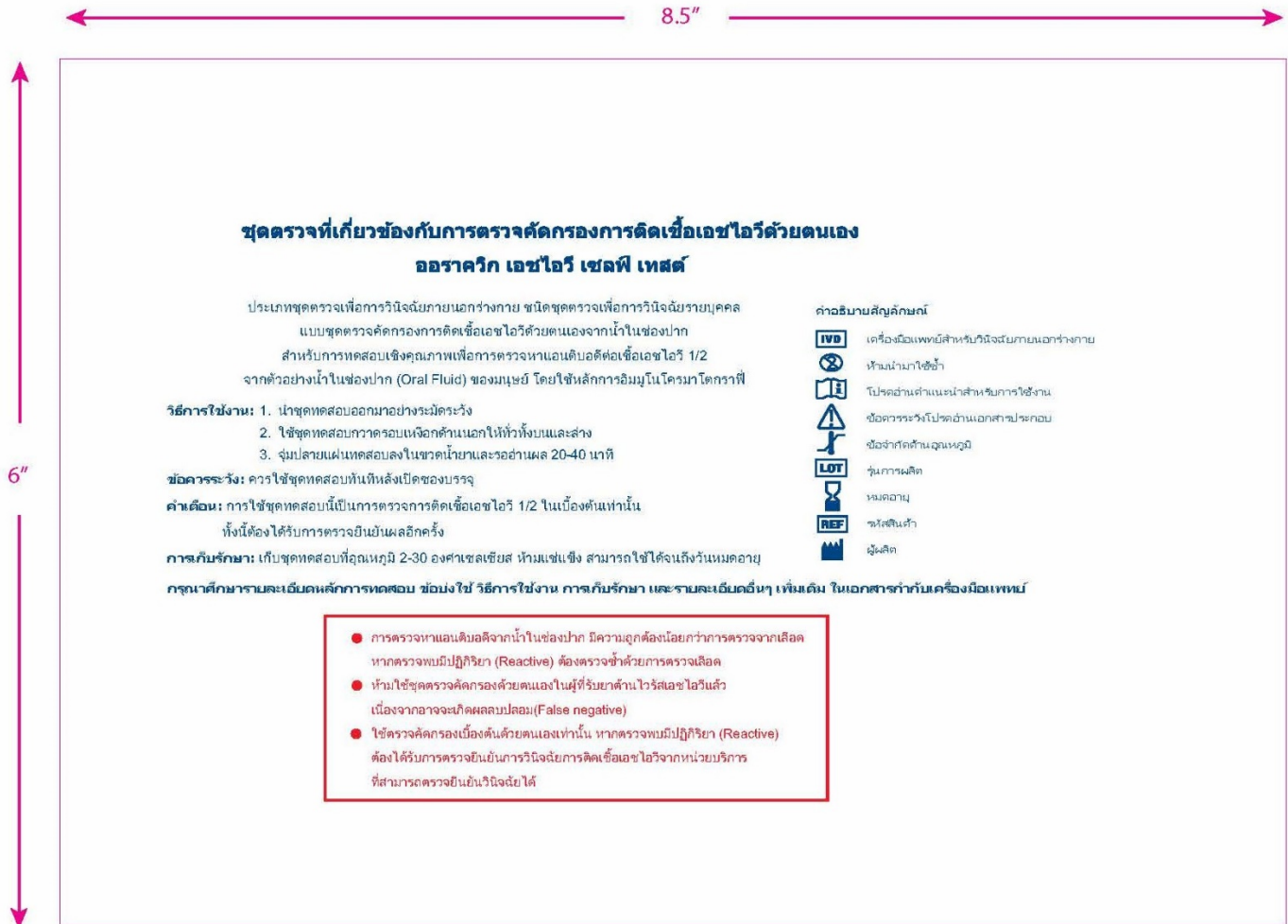
Item# 3001-3431-70
rev. 11/20



5X4-7000C Outer Pouch , Front

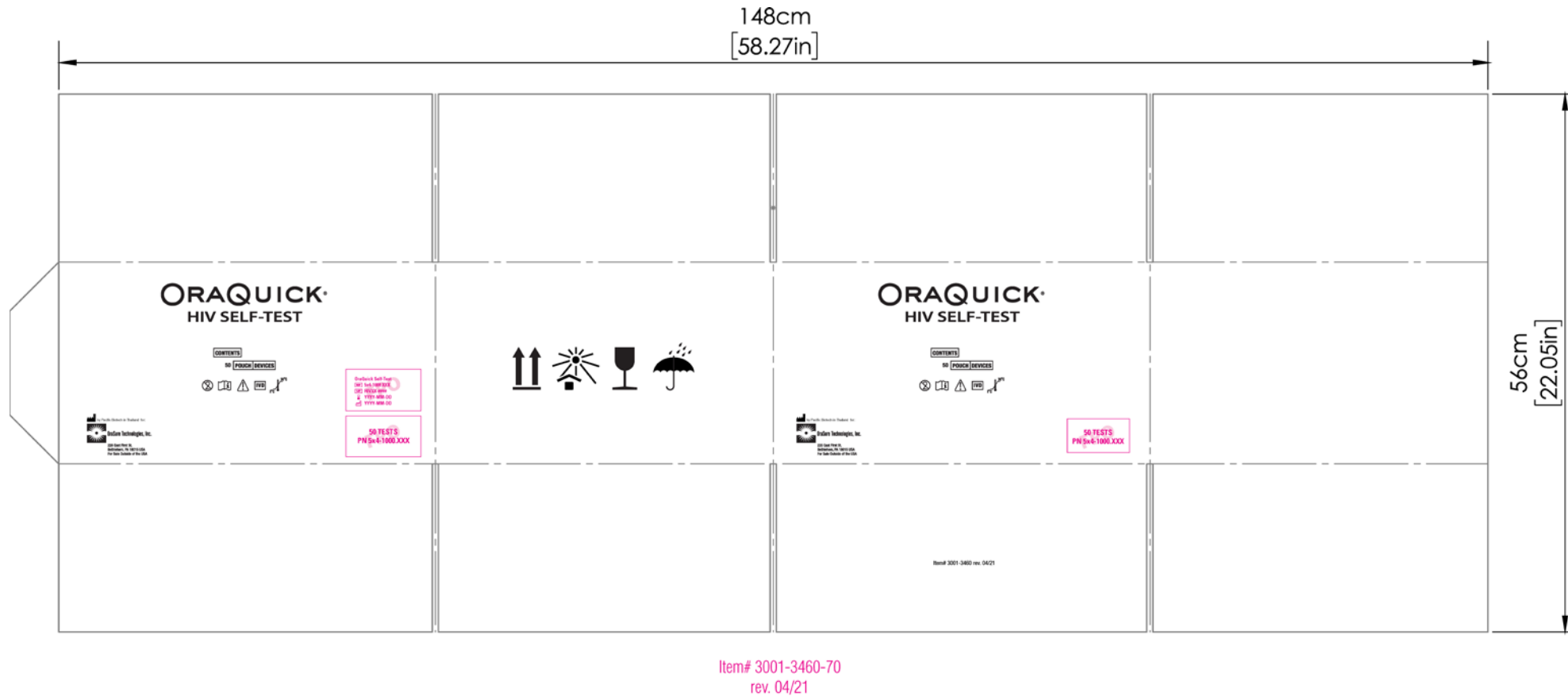


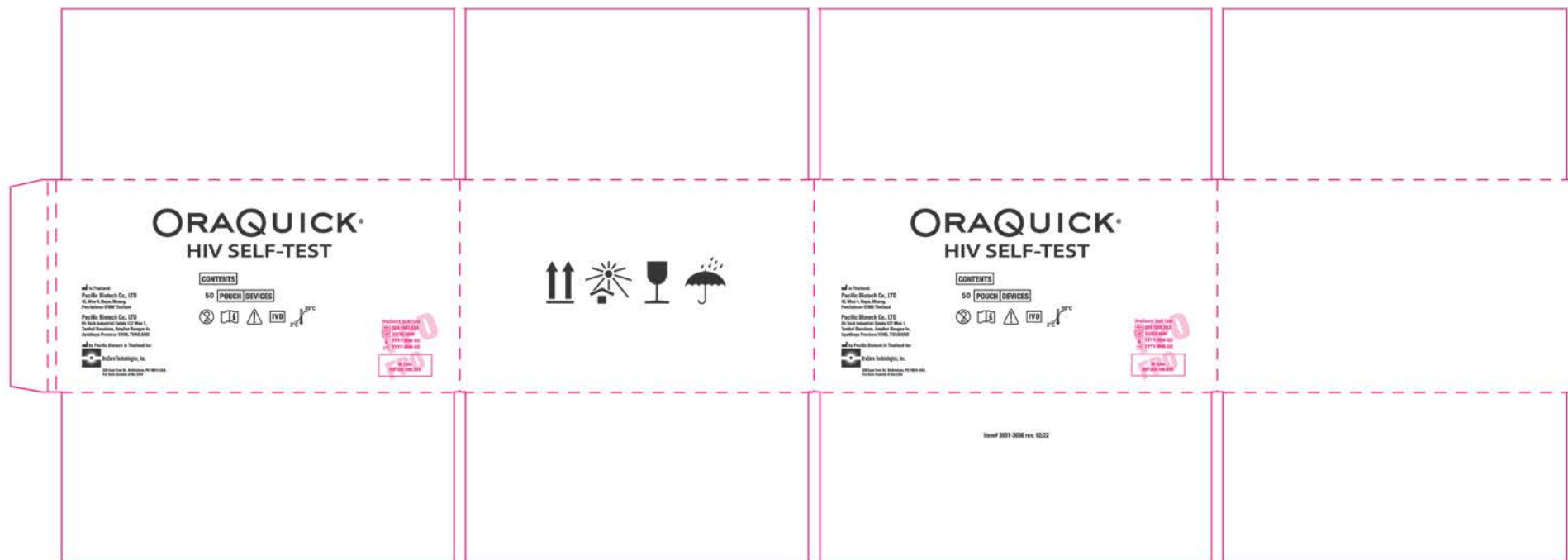
5X4-7000C Outer Pouch , Front



5X4-7000C Outer Pouch , Back

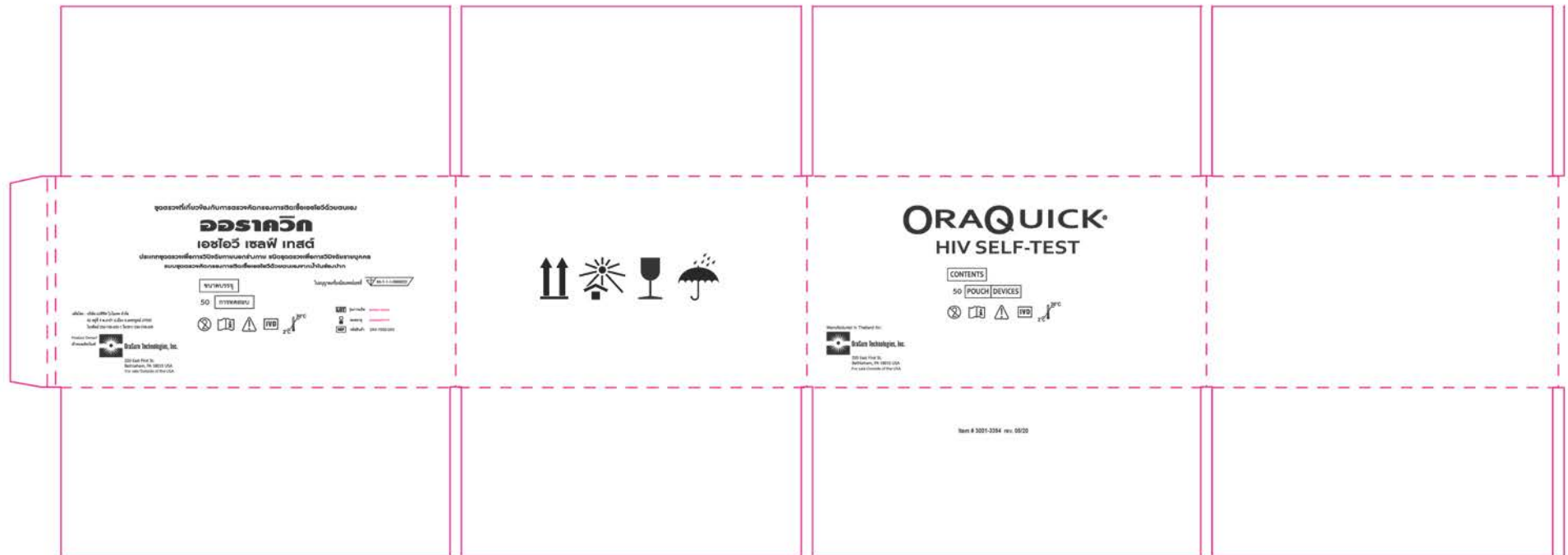
5. 50 Count Shipper Box 3001-3039 revision 01/21**Or 3001-3460 revision 04/21****Or 3001-3658 revision 02/22****Or 3001-3655 revision 05/20****Or 3001-3394 revision 05/20**Item# 3001-3039-70
rev. 01/21





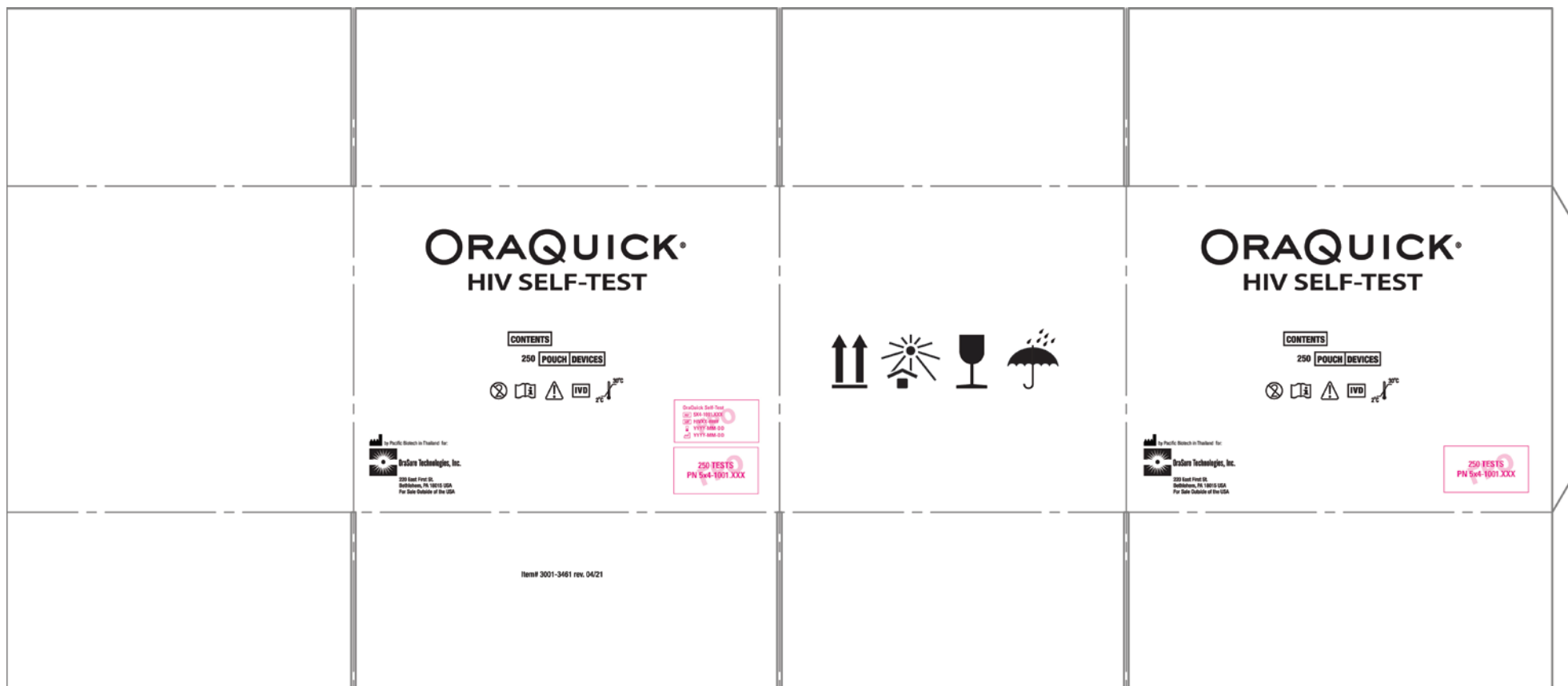
PacBio Address
Item# 3001-3658
rev. 02/22





3001-3394
Petchaboon
Rev. 05/20

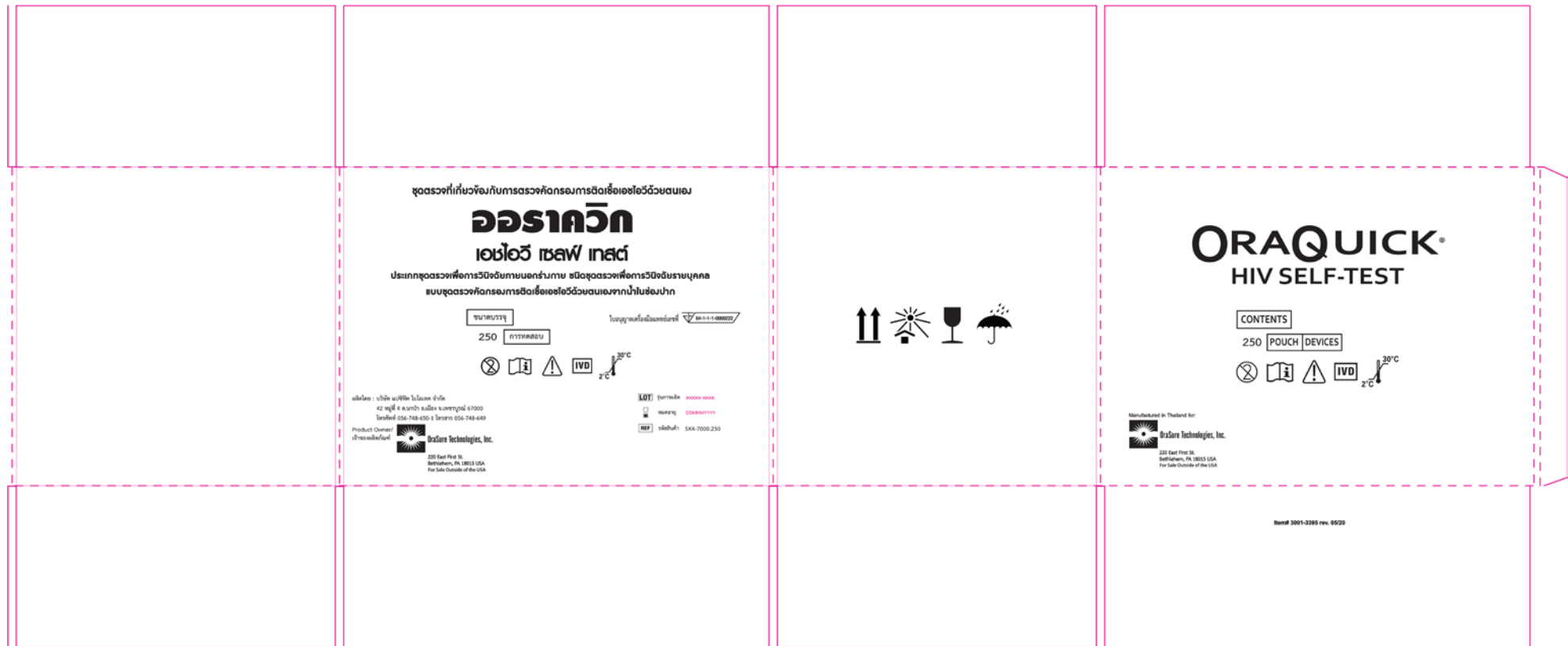
6. 250 Count Shipper 3001-3040 revision 01/21**Or 3001-3461 revision 04/21****Or 3001-3659 revision 02/22****Or 3001-3395 revision 05/20****Or 3001-3656 revision 05/20**Item# 3001-3040-70
rev. 01/21



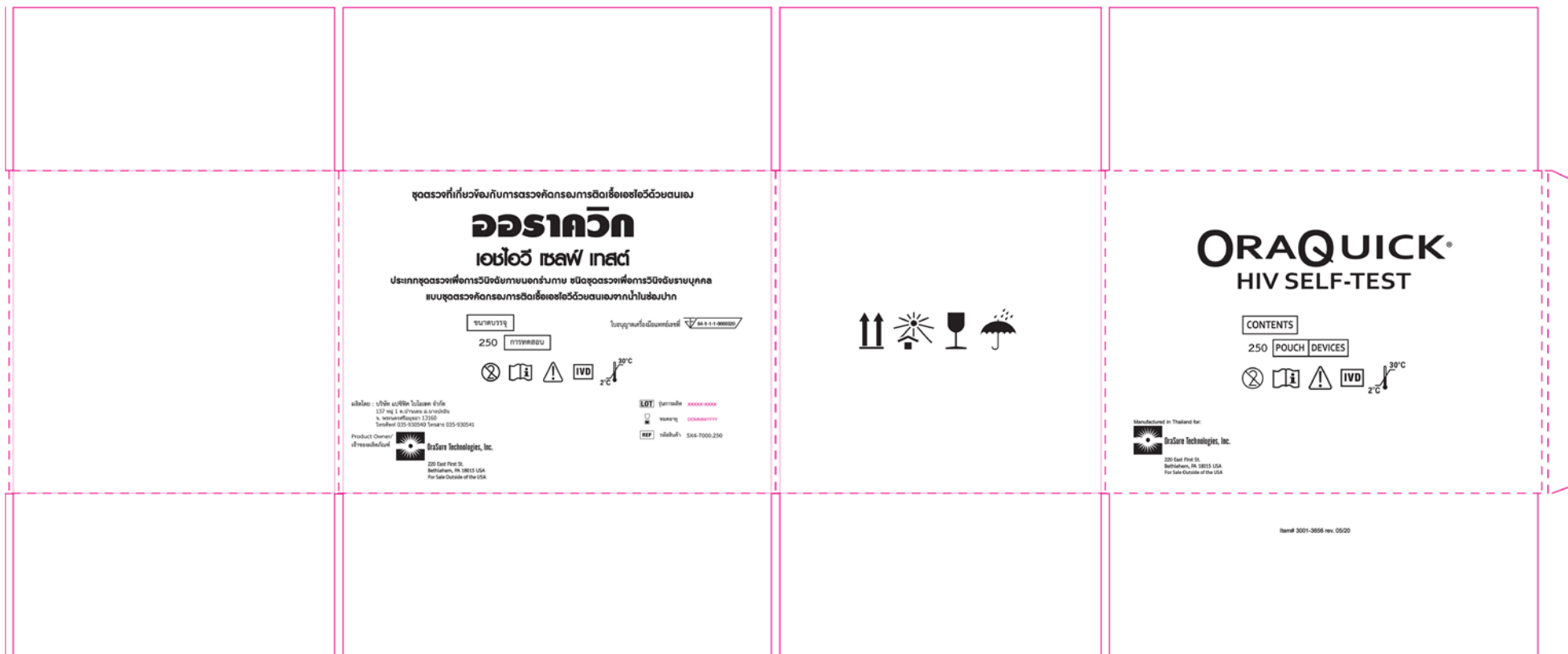
Item# 3001-3461-70
rev. 04/21



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



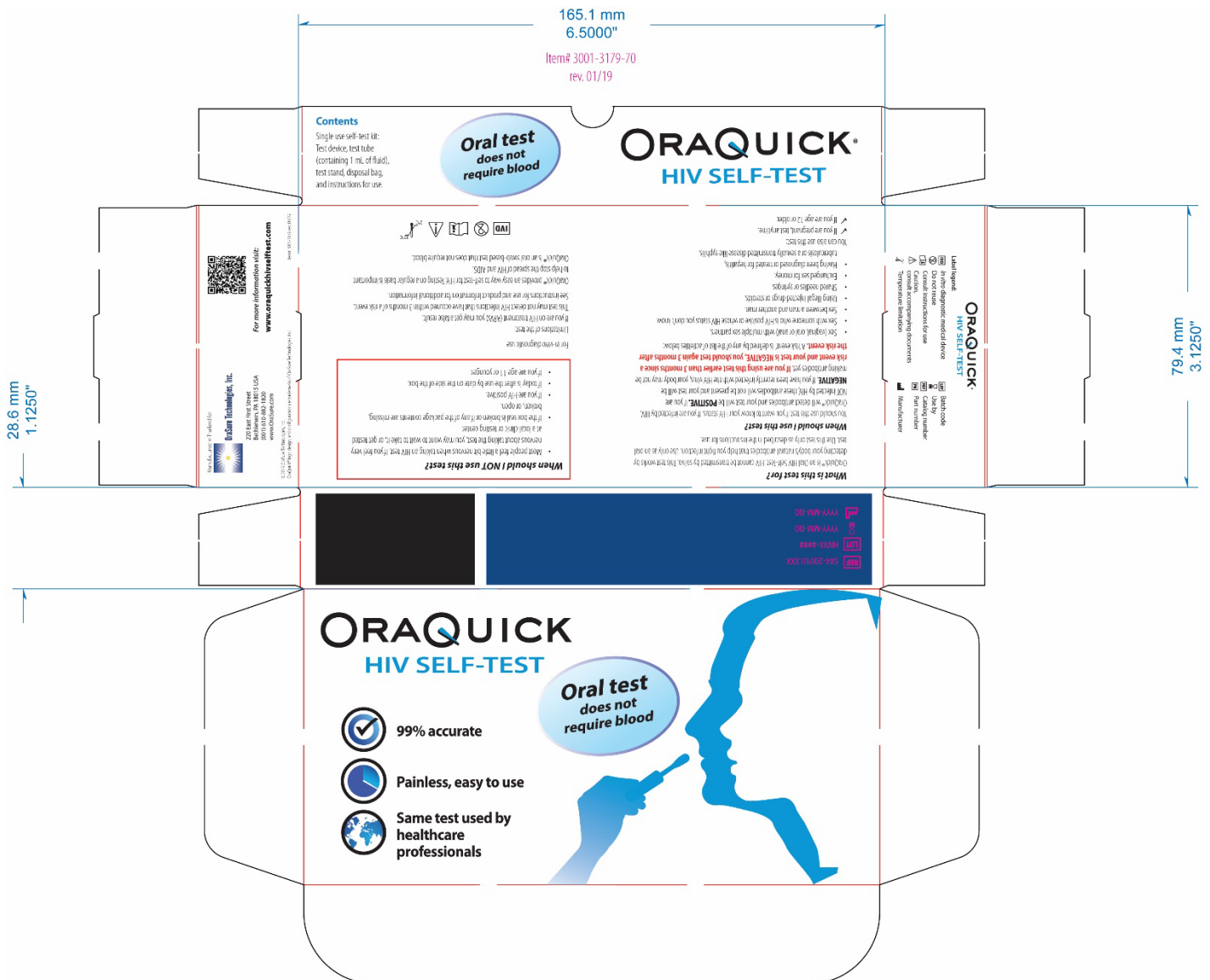
3001-3395
Petchaboon
Rev. 05/20

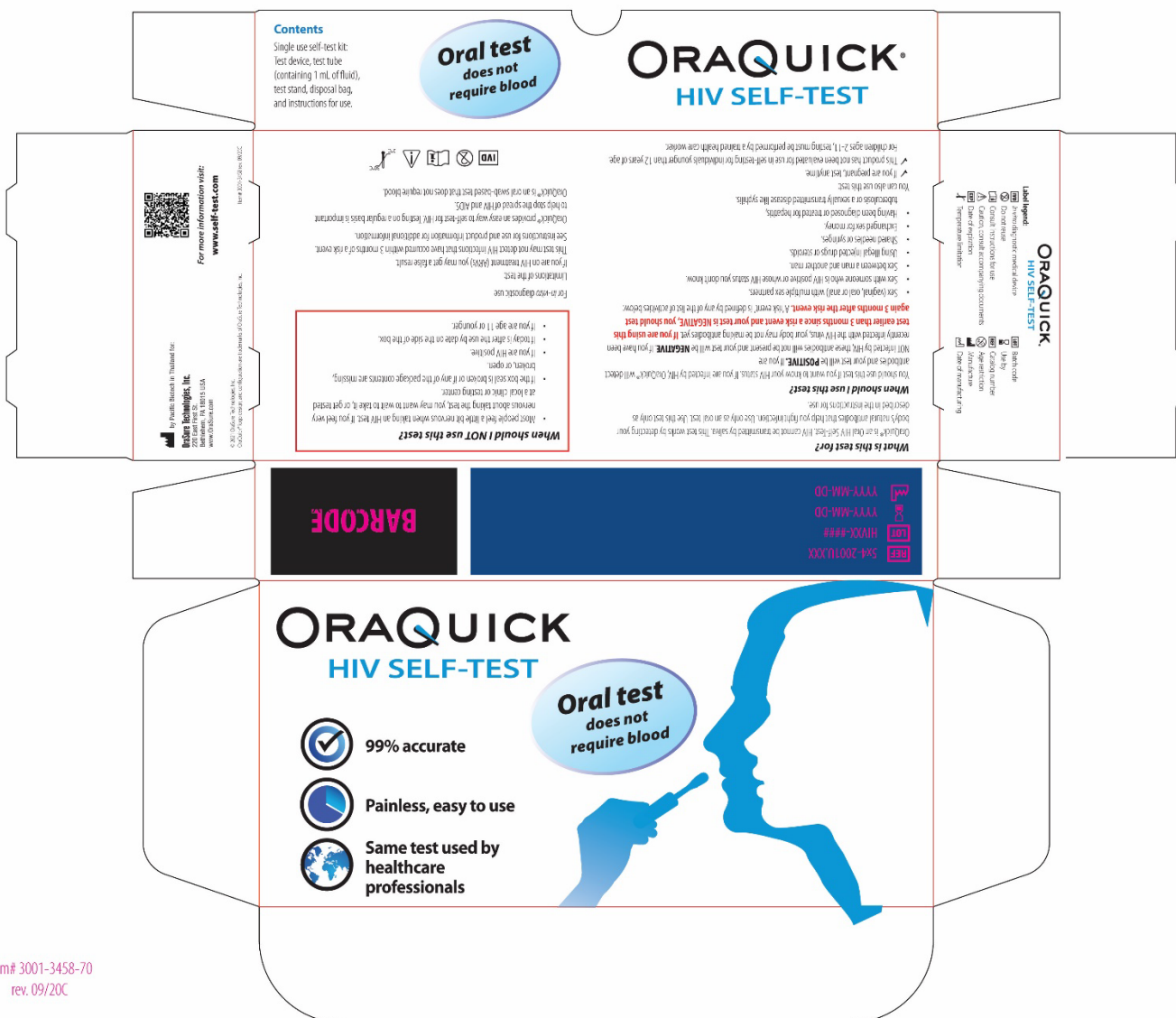


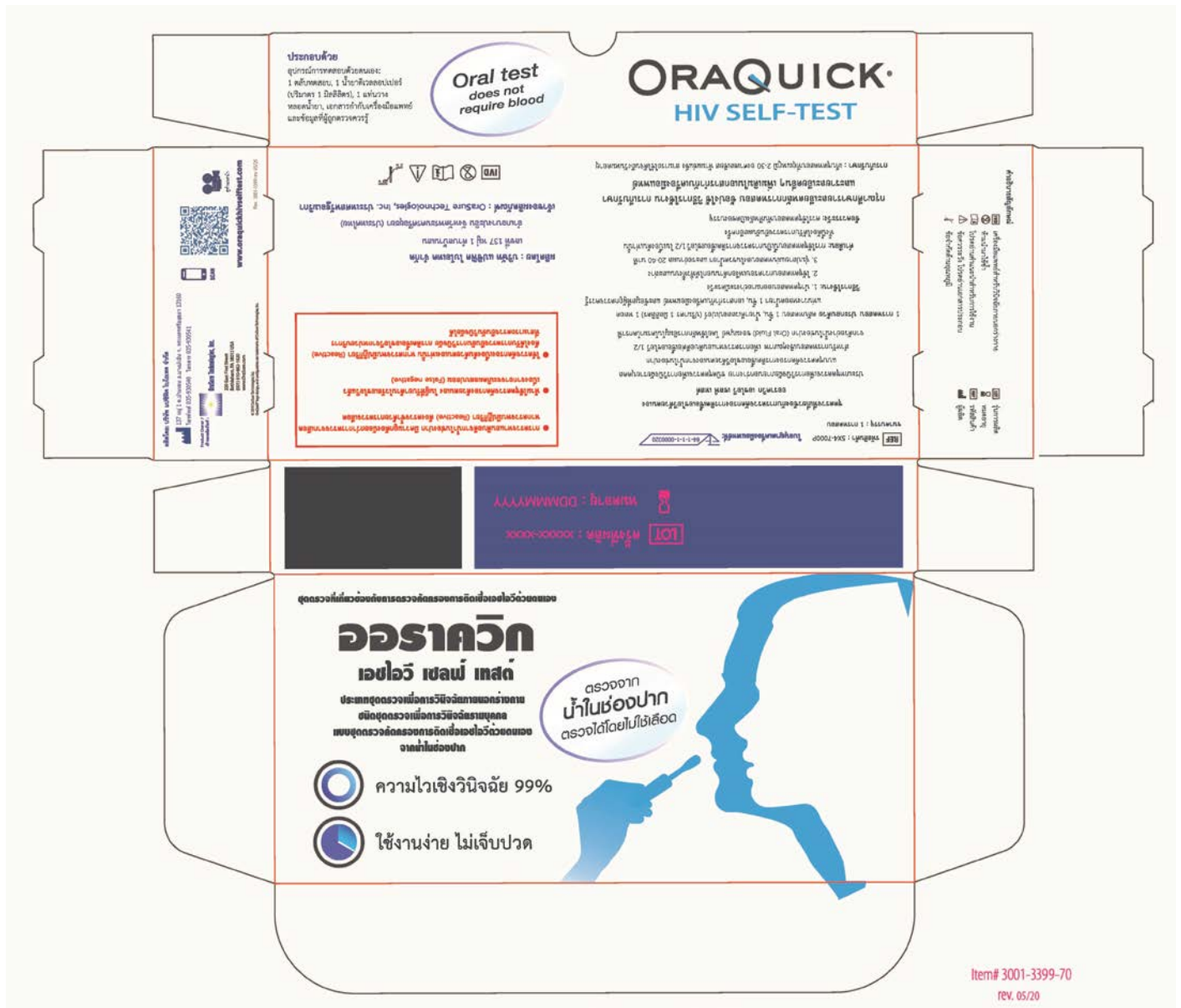
Ayutthaya
Item# 3001-3656
rev. 05/20

II. Pharmacy version

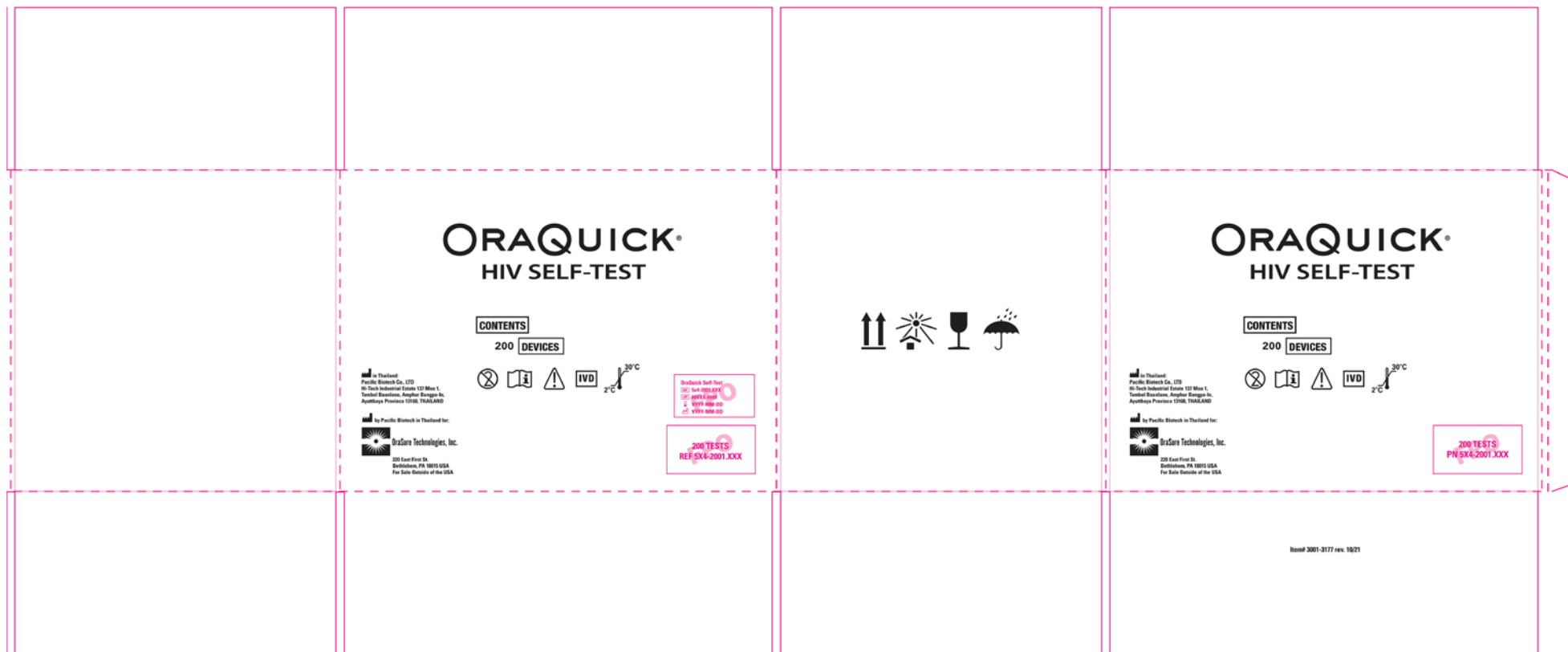
1. Outer carton 3001-3179 revision 01/19 Or 3001-3458 revision 09/20C Or 3001-3399 revision 05/20



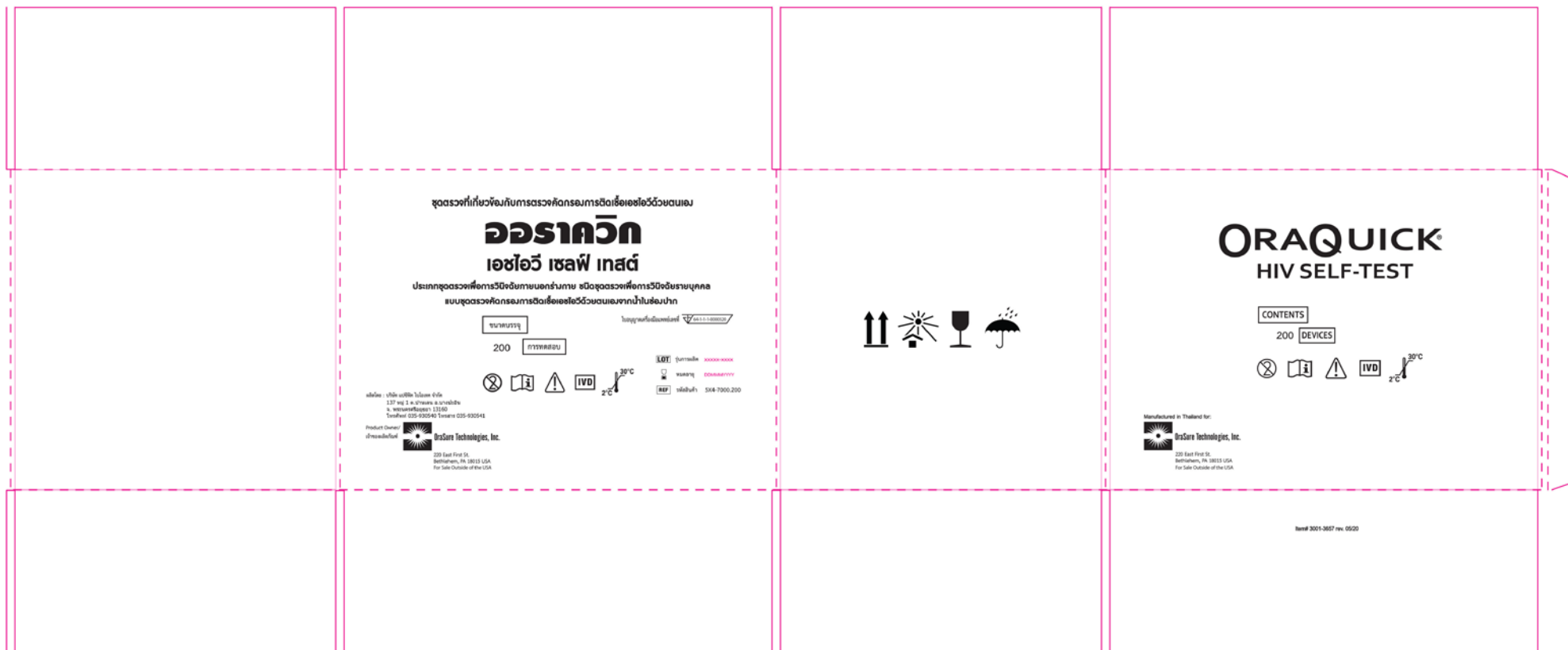




**2. 200 Count shipper box 3001-3177 revision 10/21
Or 3001-3657 revision 05/20**



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



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

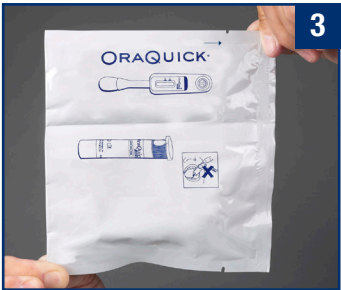
HOW TO USE THE ORAQUICK® HIV SELF-TEST KIT



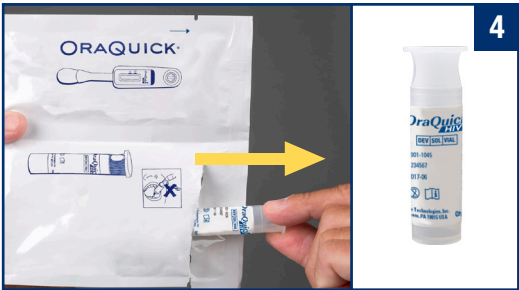
YOU WILL NEED A WAY TO TIME THE TEST



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



Your test kit contains two pouches.



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



Remove the cap.



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



Slide the tube into the **stand**.



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.



Preservative
THROW AWAY.
Not needed for the test.
DO NOT EAT.



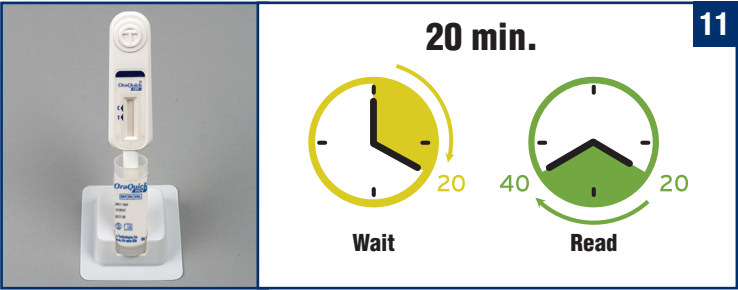
AND



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).



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



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

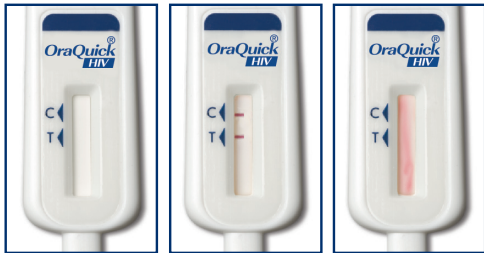


ONE LINE next to the "C" and NO line next to the "T", your result is HIV NEGATIVE.

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		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 :



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