WHO Prequalification of In Vitro Diagnostics
PUBLIC ASSESSMENT REPORT

Product: BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH)
WHO reference number: PQDx 13194-160-00

BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH) with product codes C61RHG25 and C61RHH25, manufactured by Rapigen, Inc., Rest-of-World, was accepted for the WHO list of prequalified in vitro diagnostics and was listed on 13 April 2026.

Summary of the WHO Prequalification Assessment for the BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH)

	Date	Outcome
Prequalification listing	13 April 2026	listed
Dossier assessment	7 April 2026	MR
Product performance evaluation	4 August 2020[1]	MR

MR: Meets Requirements

Intended use

According to the intended use claim from Rapigen, Inc., *"The BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH) is an in-vitro diagnostic immunochromatographic assay designed for the qualitative detection of Plasmodium falciparum and Plasmodium vivax infections using P. falciparum-specific pLDH antigens and P. vivax- specific pLDH antigens in both human capillary and venous whole blood. For venous whole-blood specimens, only blood collected in tubes containing validated anticoagulants (EDTA, heparin or citrate) is acceptable. This assay is intended to aid the diagnosis of individuals aged 5 years and older who present with signs and symptoms consistent with Plasmodium infection and to differentiate P. falciparum (Pf) and/or P. vivax (Pv) infections. Its performance has not been validated in pregnant women or neonates (within 28 days of birth), and use in these populations is therefore restricted.*

This Rapid Diagnostic Test (RDT) is not intended for self-testing. The diagnosis of malaria caused by P. falciparum and/or P. vivax should be made based on medical history, clinical signs and symptoms, exposure likelihood, and other laboratory test results, in conjunction with this assay. The test is not automated and does not require any additional instrument.

Note: This test detects parasite lactate dehydrogenase (pLDH) from Plasmodium falciparum and Plasmodium vivax, which is associated with viable parasites. Following effective anti-

[1] This evaluation was carried out prior to submission of application PQDx 13194-160-00. However, based on the declaration from the manufacturer that the product in the previous submission is identical to the product submitted in this application, these results were considered for this application.

malarial treatment, pLDH levels generally decline and test results typically become negative within a relatively short period. However, positive results may still be observed shortly after treatment. Therefore, this test is not intended for monitoring the response to anti-malarial treatment.
The test is intended to be performed only by qualified healthcare professionals or trained laboratory personnel."

Test kit contents

Component	25 tests (product code C61RHG25)	25 tests (product code C61RHH25)
Test device (Foil pouch with desiccant)	25	25
Buffer Bottle (6 mL)	1	1
Specimen transfer device (Inverted cup)	Pack of 25	Pack of 25
Sterile lancet	25	25
Alcohol swab	25	25
Pair of disposable gloves	/	25
Instructions for use	1	1

Items required but not provided

- Latex gloves (Except for C61RHH25)
- Pen or pencil
- Timer
- Lancing device
- General waste bin
- Extra lancets and alcohol swabs (if needed, for instances such as lancet misfires, insufficient blood volume, dried-out alcohol swabs, etc.)
- Sterile gauze or cotton wool (to stop bleeding at the punctured area)
- Micropipette and tip (for collecting venous whole blood from venipuncture)
- Materials to collect venous whole blood
- Biosafety sharps container
- Biohazard waste container (for potentially infectious waste)

Storage Temperature and Stability

Parameter	Condition
Storage Temperature	2 to 40 ℃
Shelf Life (from manufacture)[2]	24 months.

[2] The assigned device shelf-life is based on stability data generated from the date of manufacture. The finished goods shelf-life, calculated from the date of packaging

Dossier review

The manufacturer submitted a product dossier as per the "Instructions for compilation of a product dossier" (PQDx_018). The information (data and documentation) submitted in the product dossier was reviewed by WHO staff and external technical experts (assessors) appointed by WHO.

The manufacturer's responses to the discrepancies found during dossier screening and assessment findings were accepted on 7 April 2026.

Based on the product dossier screening and assessment findings, the product dossier for BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH) meets WHO prequalification requirements.

Manufacturing site inspection

The inspection of the manufacturing site(s) was conducted to assess whether the manufacturer's quality management system (QMS) and manufacturing practices are in alignment with:
(i) applicable international standards, such as ISO 13485 (Medical devices – Quality management systems – Requirements for regulatory purposes);
(ii) the manufacturer's own documented procedures and quality requirements; and
(iii) other relevant international standards and guidelines applicable to in vitro diagnostic (IVD) medical devices. The WHO's Public Inspection Reports are accessible at:

https://extranet.who.int/pqweb/vitro-diagnostics/who-public-inspection-reports

Product performance evaluation

BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH) was evaluated in the 2nd quarter of 2020 at Centers for Disease Control and Prevention on behalf of WHO according to protocol PQDx_317, version 2.1.

Performance evaluation
BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH) was evaluated against a *Plasmodium falciparum* cultured line panel, *P. falciparum wild type* parasite panel, *P. vivax* wild type parasite panel,

completion, may be shorter depending on the time elapsed between manufacture and final packaging of the device.

HRP-2 deletion panel (wild-type and cultured parasites), WHO International Standard for *P. falciparum* antigens and a *P. falciparum* and *P.vivax* negative panel.

Performance characteristics			
	P. falciparum	***P. vivax***	**Pf *-hrp2* deletion panel**
Panel detection score (PDS)[a] at 200 parasites/µL	99/100, 99.0%	35/35, 100%	59/60, 98.3%
Proportion reactive lines at 200 parasites/µL	Pf-pLDH line: 397/400, 99.3%	Pv-pLDH line: 140/140, 100%	Pf-pLDH line: 239/240, 99.6%
False positive results %	All negative specimens: 3/200, 1.5% Of which, clean negative specimens: 3/104, 2.9% No false Pf-positive result with the *P. vivax* specimens at 200 and 2000 parasites/µL (N=210). False Pv-positive results with the *P. falciparum* specimens at 200 and 2000 parasites/µL: 6/600, 1.0%.		
Invalid rate % (N= 1050)	0%		
Inter-reader variability on the wild-type and negative panels% (N= 1010)	Pf-pLDH test line: 0.5% Pv-pLDH test line: 0.5%		
Lowest concentration of Pf-pLDH detected using the 1st WHO International standard for Pf antigens (NIBSC code: 16/376)	3.9 IU/mL with both lots		

[a]*The panel detection score is the proportion of specimens at a specified concentration that gave positive results in all four tests performed with this specimen (two tests on each of two lots).*

Operational characteristics and ease of use

This assay does not require laboratory equipment and can be performed in laboratories with limited facilities or in non-laboratory settings.

The assay was found easy to use by the operators performing the evaluation.

However, the operators noted that 283/1010 (28.0%) of the tests performed on the wild-type and negative panels showed anomalies (27.8% with incomplete clearing and 0.2% with red background).

Key operational characteristics	
Validated specimen types and volume	5 µL of capillary whole blood or venous whole blood collected in tubes with validated anticoagulants (EDTA, heparin, or citrate)
Number of steps*	2 steps in total 1 step with precision pipetting (for venous whole blood only)
Time to result	25 minutes
Endpoint stability (interval)	10 minutes (the test can be read between 25 and 35 minutes after addition of diluent)
Internal QC	Yes, reagent addition control

Based on these results, the performance evaluation for BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH) meets the WHO prequalification requirements.

Labelling review

The labelling submitted for BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH) was reviewed by WHO staff and external technical experts appointed by WHO. The review evaluated the labelling for clarity and consistency with the information submitted in the product dossier, alignment with international guidance and standards, and suitability for the intended users and settings in WHO Member States, including low- and middle-income countries.

The table below provides traceability of the labelling documents reviewed during the assessment, including document titles, version numbers, approval dates, and control identifiers.

Controlled Labelling References

Document Type	Document Title	Version / Revision	Date Approved	Controlled Document No.
Outer box artwork	Kit box-C61RHG25_EN	0	2026-05-22	2010558
	Kit box-C61RHG25_4A	0	2026-05-22	2010559
	Kit box-C61RHH25_EN	0	2026-05-22	2010566
Pouch / Device label	Test device pouch	0	2023-12-28	2020109

Reagent bottle labels	Assay buffer label	0	2025-12-04	3010292
Accessory labelling	Inverted cup	2	2026-04-16	1090071
		0	2023-05-29	1090020
	Sterile lancet	1	2026-04-16	1100015
	Alcohol swab	0	2020-04-00	1100008
		0	2024-02-29	1100012
	Gloves (Included for C61RHH25)	0	2023-09-01	1100009
Instructions for Use (IFU)	IFU	0	2026-05-22	2030937

Labels

Rapigen	디자인 사양서					
제품명	BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH)_C61RHG25			요청부서	RA 배샛별 과장님	
사이즈	150×92×70mm	인쇄색상	K	사용색상	PANTONE 186C	Pantone 7734C
재질/코팅						
변경사항	1. Diluent ->Buffer로 변경 WHO PQ에 의한 BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH) 제품의 판매용					

Rapigen

BIOCREDIT

Malaria Ag Pf/Pv (pLDH/pLDH)

One step, rapid, immunochromatographic assay for the qualitative detection of malaria *Plasmodium falciparum* and/or *Plasmodium vivax* specific lactate dehydrogenase (pLDH) in human whole blood

One Step Rapid Test
25
Tests/Kit

- **Intended purpose**
  For the qualitative detection of malaria *Plasmodium falciparum* and/or *Plasmodium vivax* specific lactate dehydrogenase (pLDH) in human whole blood
- **Package** 25 Tests/Kit
- **Storage** Store at 2-40 ℃ (36–104 °F)
- **Contents**
  Test device (Foil pouched with desiccant)×25, Assay buffer bottle (6 mL)×1, Specimen transfer device (Inverted cup)×25, Alcohol swab×25, Sterile lancet×25, Instructions for use×1
- **Do not reuse**
- **For professional *in vitro* diagnostic use only**

LOT LOT No. :
Buffer :
EXP. Date :

Manufactured by
Rapigen, Inc.
161, Saneop-ro 155beon-gil, Gwonseon-gu, Suwon-si, Gyeonggi-do, 16648, Republic of Korea
TEL : +82-31-427-4677 FAX : +82-31-427-4678 E-mail : info@rapigen.com www.rapigen.com

IVD 2℃ 40℃ Σ 25

REF C61RHG25 B-H016G-EN03 (2026.05.22)

Dual Color System

BIOCREDIT

Malaria Ag Pf/Pv (pLDH/pLDH)

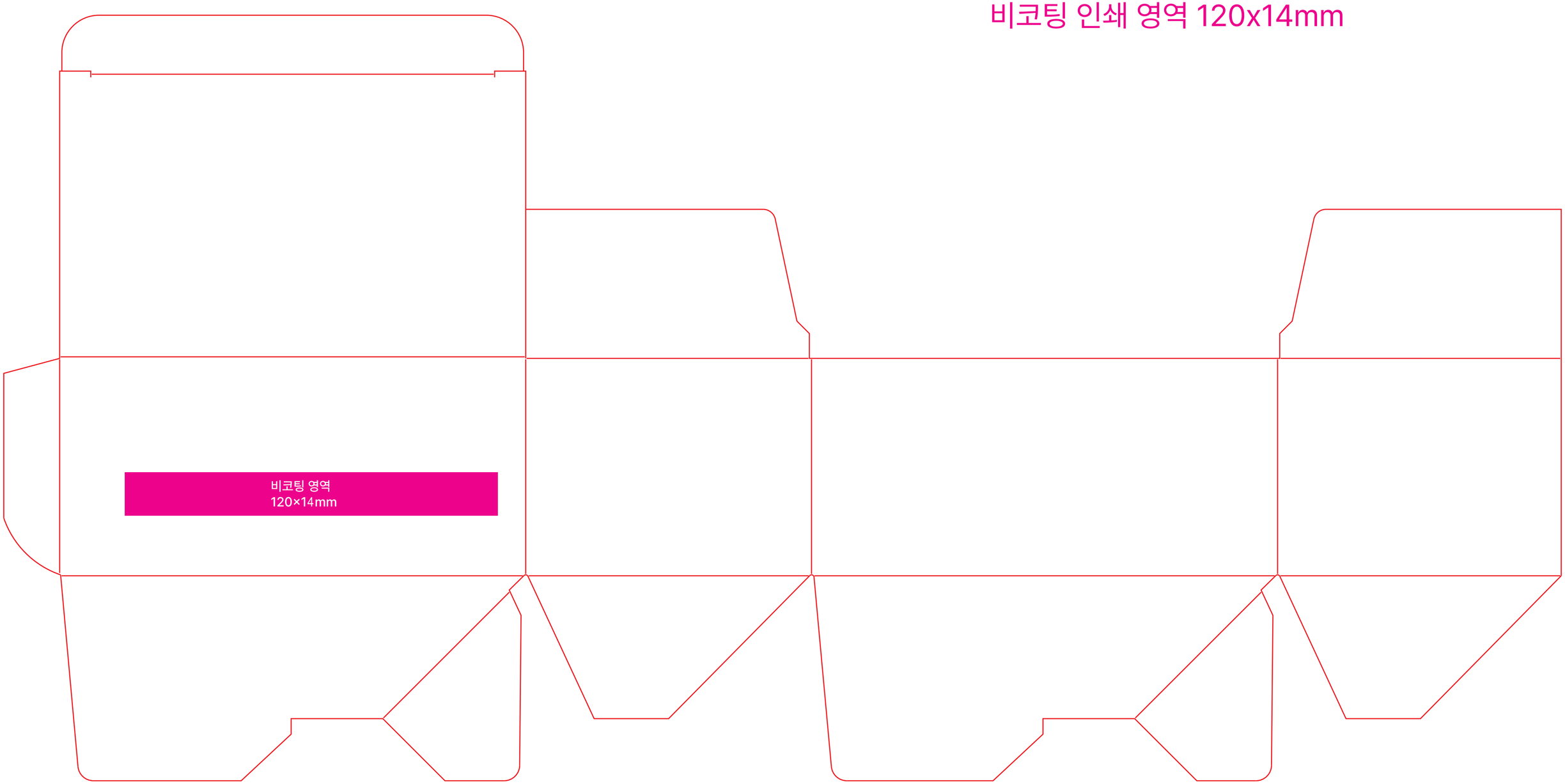
Simple, Accurate and Convenient

Dual Color System

Rapigen

150×92×70mm 박스

비코팅 인쇄 영역 120x14mm



Rapigen	디자인 사양서				
제품명	BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH)_C61RHG25		요청부서	RA 배샛별 과장님	
사이즈	150×92×70mm	인쇄색상	K	사용색상	PANTONE 186C / Pantone 7734C
재질/코팅					
변경사항	1. WHO PQ에 의한 BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH) 제품의 판매용				

Rapigen

BIOCREDIT

Malaria Ag Pf/Pv (pLDH/pLDH)

One step, rapid, immunochromatographic assay for the qualitative detection of malaria *Plasmodium falciparum* and/or *Plasmodium vivax* specific lactate dehydrogenase (pLDH) in human whole blood

One Step Rapid Test
25
Tests/Kit

EN • **Intended purpose** For the qualitative detection of malaria *Plasmodium falciparum* and/or *Plasmodium vivax* specific lactate dehydrogenase (pLDH) in human whole blood • **Package** 25 Tests/Kit • **Storage** Store at 2-40 °C (36-104 °F) • **Contents** Test device (Foil pouched with desiccant)×25, Assay buffer bottle (6 mL)×1, Specimen transfer device (Inverted cup)×25, Alcohol swab×25, Sterile lancet×25, Instructions for use×1 • **Do not reuse** • **For professional *in vitro* diagnostic use only**

FR • **Utilisation prévue** Test immunochromatographique rapide à une étape pour la détection qualitative de la lactate déshydrogénase (pLDH) spécifique de *Plasmodium falciparum* et/ou *Plasmodium vivax*, responsables du paludisme, dans le sang total humain • **Package** 25 Tests/Kit • **Stockage** Conserver à 2-40 °C (36-104 °F) • **Composants** Dispositif de test (Emballage en aluminium avec dessiccant)×25, Flacon de tampon d'essai (6 mL)×1, Dispositif de transfert d'échantillon (Applicateur inversé)×25, Compresses d'alcool×25, Lancette stérile×25, Instructions d'utilisation×1 • **Ne pas réutiliser** • **Uniquement à un usage professionnel en diagnostic *in vitro***

ES • **Uso previsto** Ensayo inmunocromatográfico rápido de un paso para la detección cualitativa de la lactato deshidrogenasa (pLDH) específica del *Plasmodium falciparum* y/o *Plasmodium vivax*, causantes de la malaria, en sangre entera humana • **Empaque** 25 Pruebas/Kit • **Almacenamiento** Conservar a 2-40 °C (36-104 °F) • **Componentes** Dispositivo de prueba (Empaque de aluminio con desecante)×25 , Frasco de tampón de ensayo (6 mL)×1, Dispositivo de transferencia de muestra (Aplicador invertido)×25, Paño con alcohol×25, Lanceta estéril×25, Instrucciones de uso×1 • **No reutilizar** • **Solo para uso profesional de diagnóstico *in vitro***

PT • **Uso pretendido** Ensaio imunocromatográfico rápido de um passo para a detecção qualitativa da lactato desidrogenase (pLDH) específica do *Plasmodium falciparum* e/ou *Plasmodium vivax*, causadores da malária, em sangue total humano • **Embalagem** 25 Testes/Kit • **Armazenamento** Conservar entre 2-40 °C (36-104 °F) • **Componentes** Dispositivo de teste (Embalagem de alumínio com dessecante)×25, Frasco de tampão de ensaio (6 mL)×1, Dispositivo de transferência de espécime (Aplicador invertido)×25, Zaragatoas com álcool×25, Lanceta estéril×25, Instruções de uso×1 • **Não reutilizar** • **Apenas para uso profissional de diagnóstico *in vitro***

LOT LOT No. :
Buffer :
EXP. Date :

Manufactured by
Rapigen, Inc.
161, Saneop-ro 155beon-gil, Gwonseon-gu, Suwon-si, Gyeonggi-do, 16648, Republic of Korea
TEL : +82-31-427-4677 FAX : +82-31-427-4678 E-mail : info@rapigen.com www.rapigen.com

IVD 2°C 40°C Σ 25

REF C61RHG25 B-H016G-4A03 (2026.05.22)

Dual Color System

BIOCREDIT

Malaria Ag Pf/Pv (pLDH/pLDH)

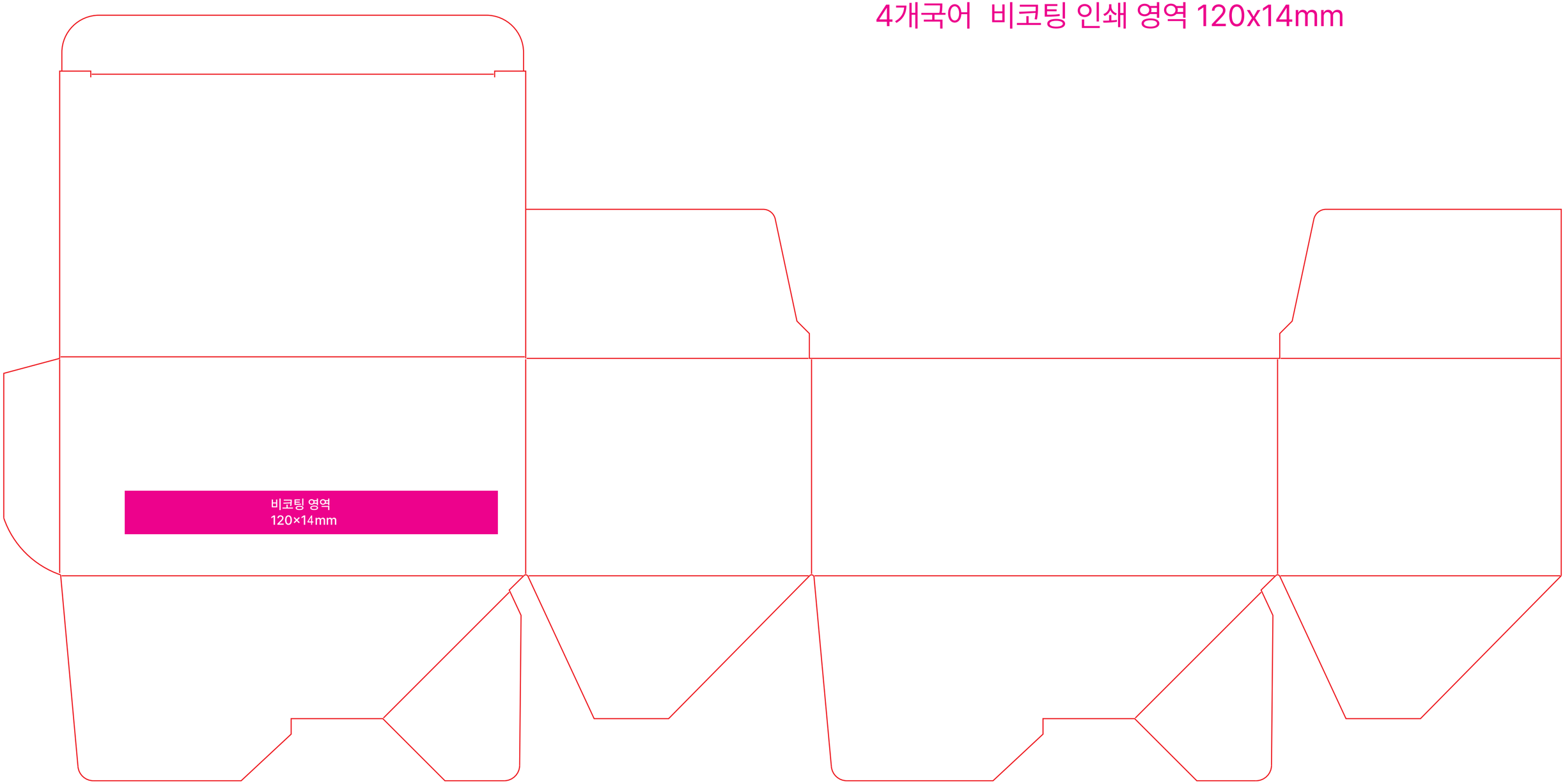
Simple, Accurate and Convenient

Dual Color System

Rapigen

말라리아 GE타입 4개국어 150×92×70mm

4개국어 비코팅 인쇄 영역 120x14mm



Rapigen	디자인 사양서			
제품명	Malaria Ag Pf/Pv (pLDH/pLDH)_C61RHH25 BOX		요청부서	RA 배샛별 과장님
사이즈	210×115×100mm	인쇄색상	K PANTONE 186C Pantone 7734C	
재질/코팅				
변경사항	1. WHO PQ에 의한 BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH) 제품의 판매용			

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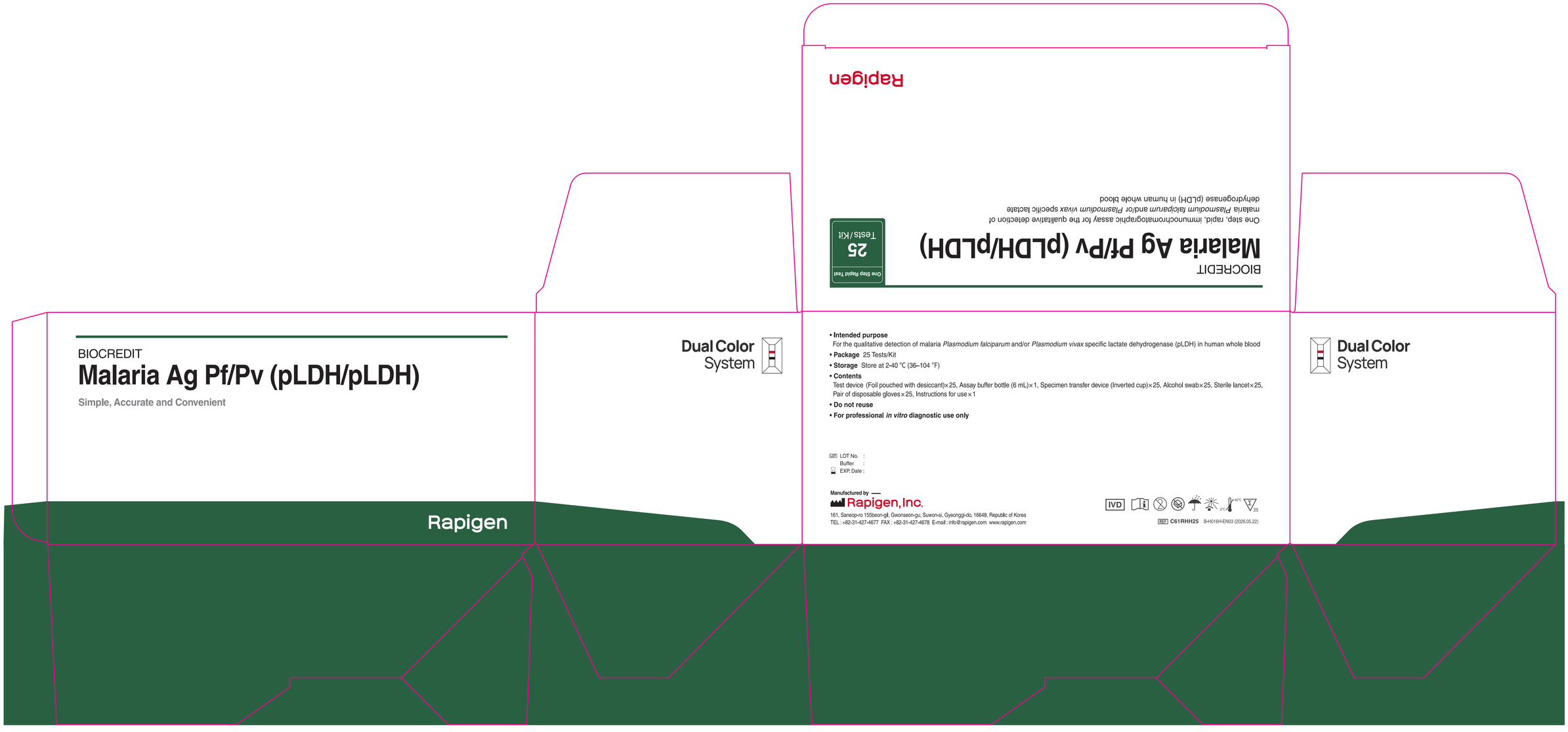

OZ-243 래피젠- (2) 210X115X100

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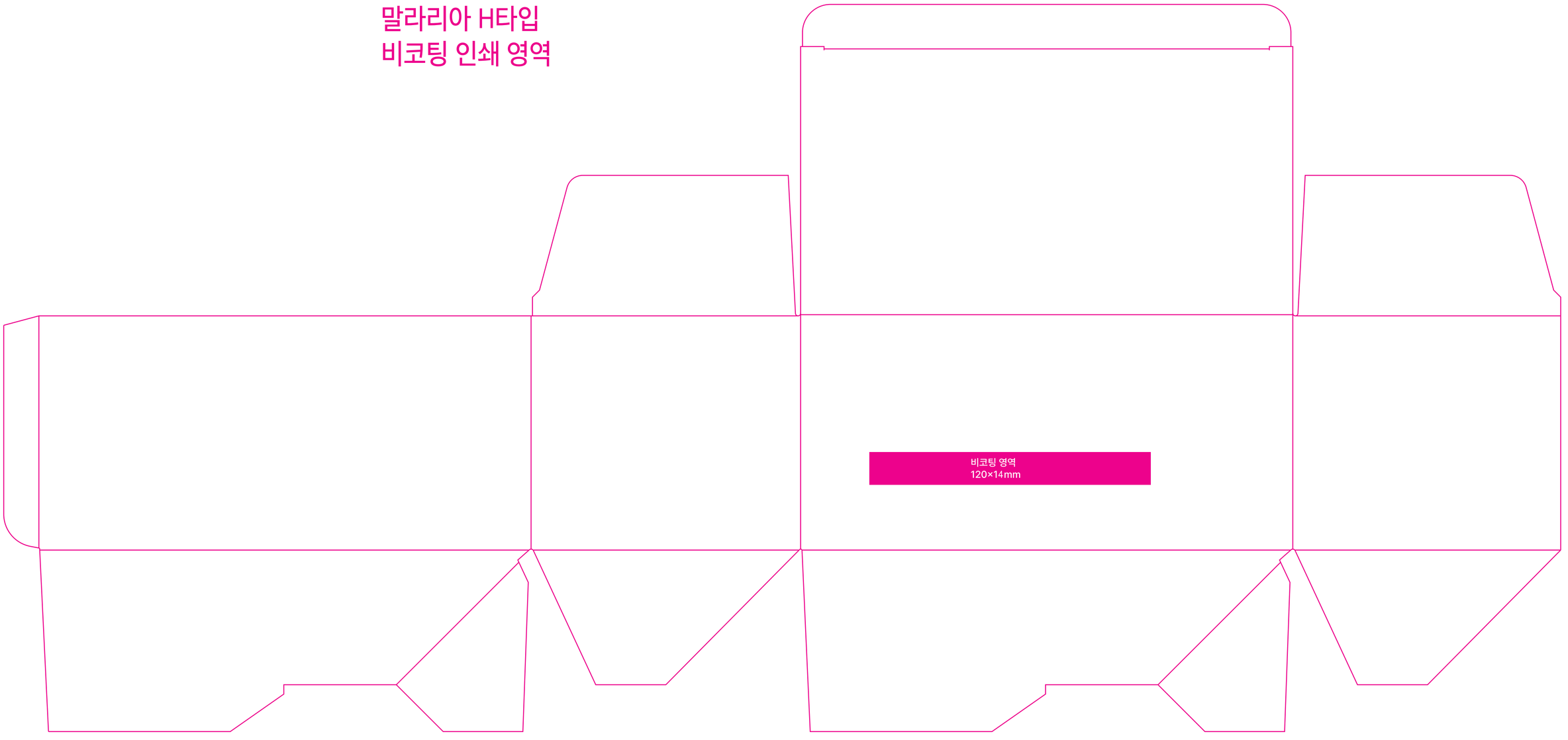
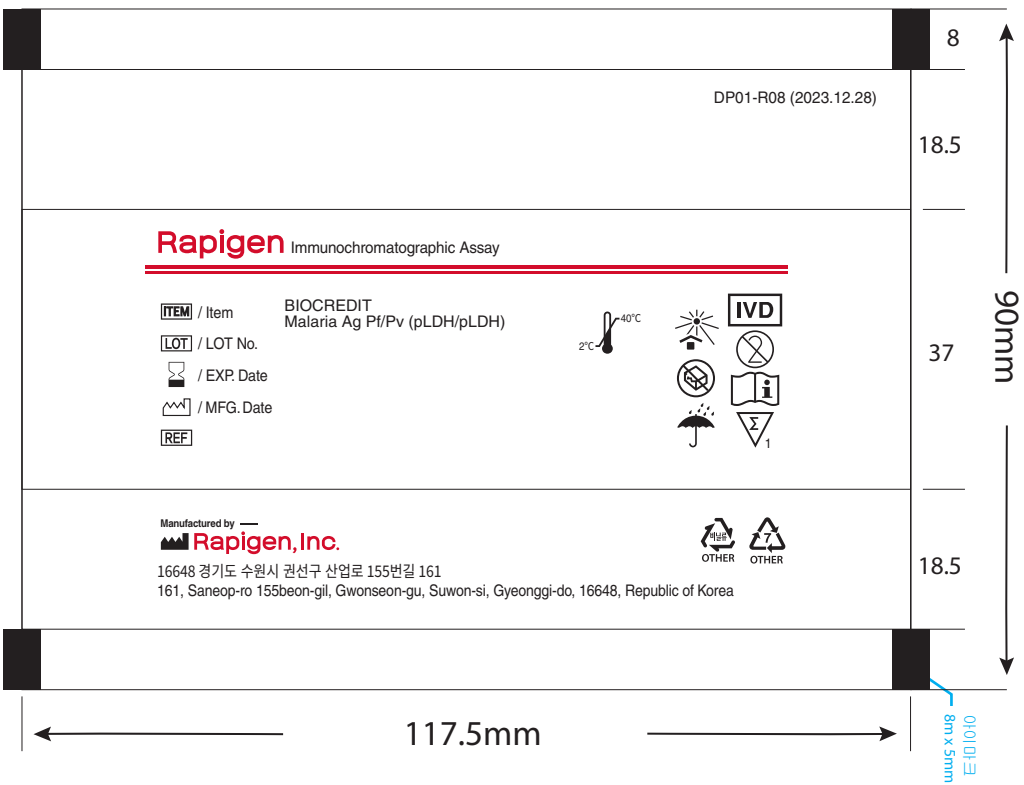
비코팅 인쇄 영역

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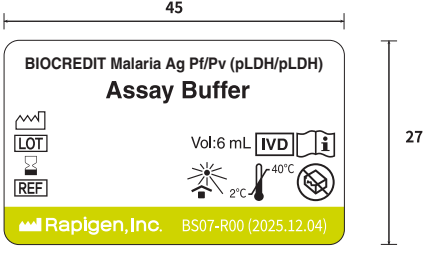
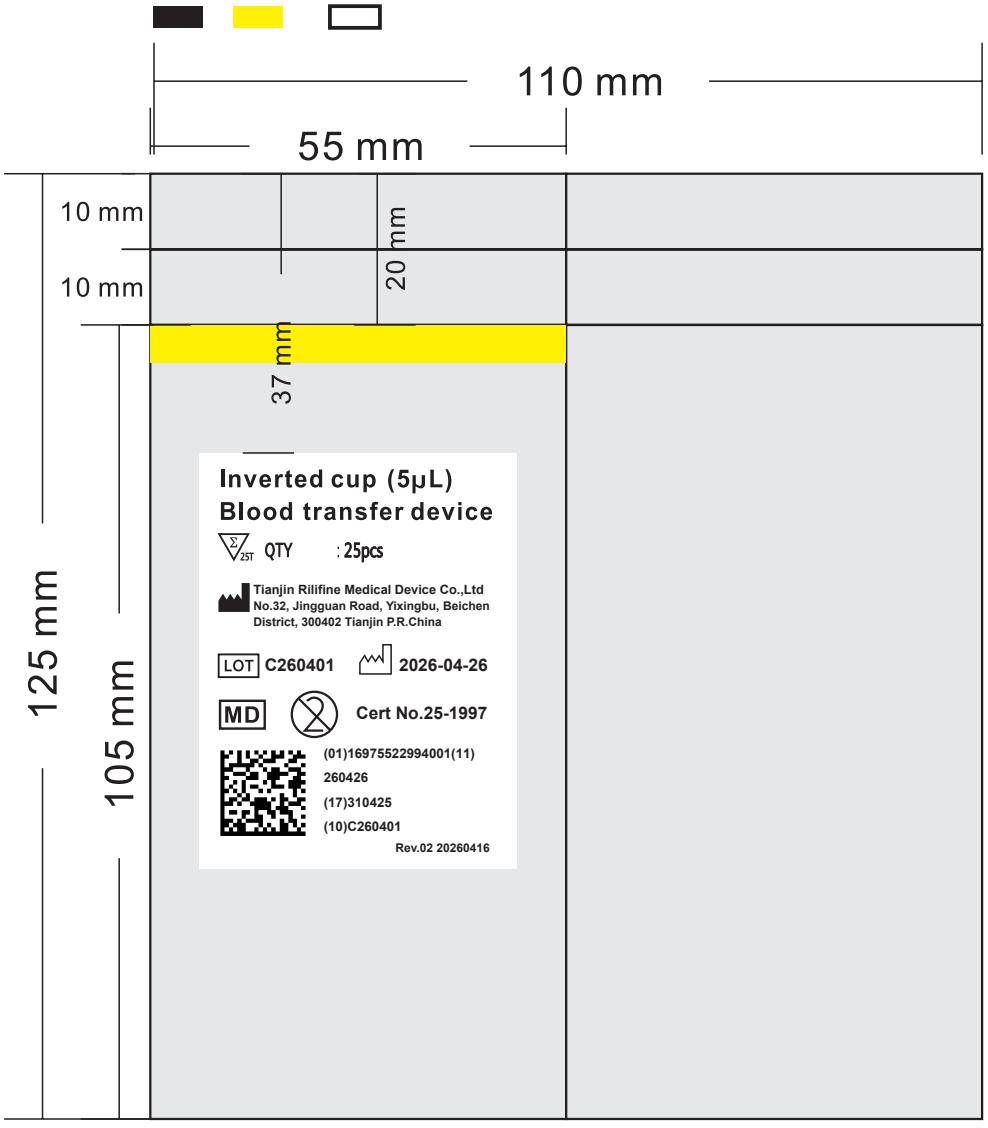
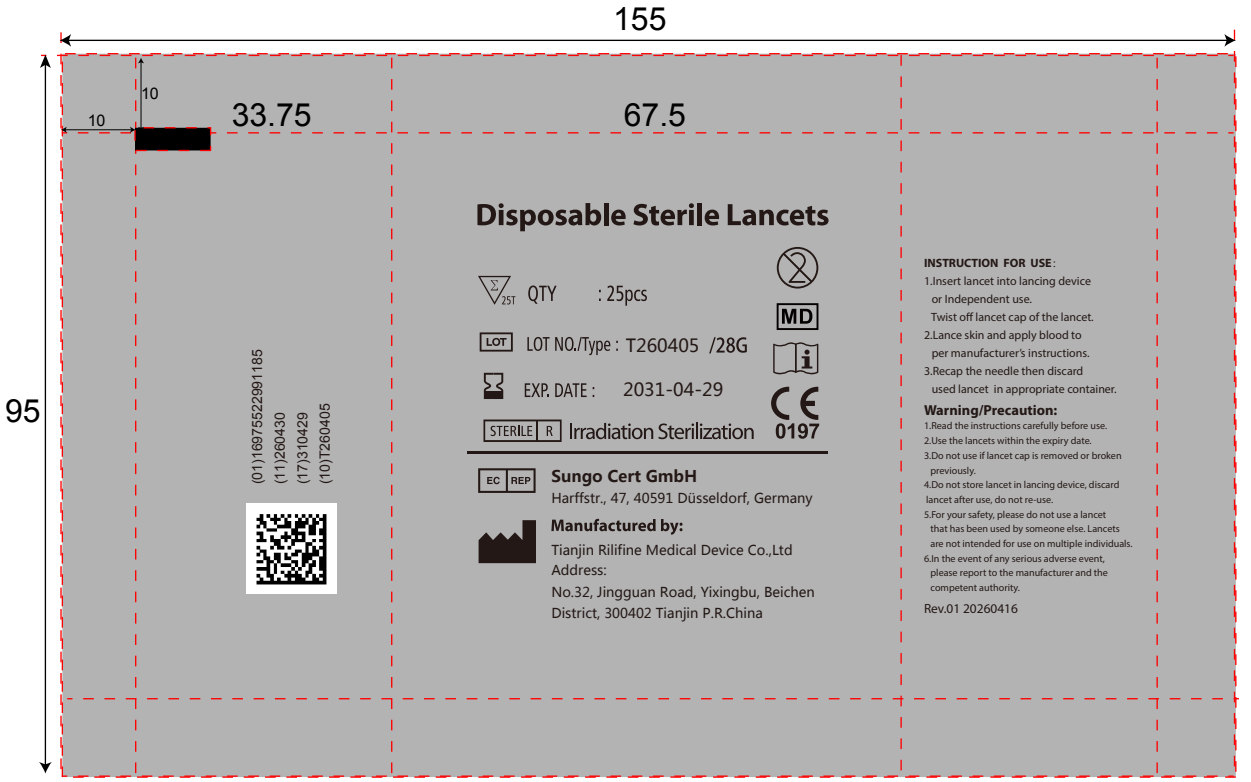
DP01-R08 (2023.12.28)
18.5
Rapigen Immunochromatographic Assay
ITEM / Item
LOT / LOT No.
/ EXP. Date
/ MFG. Date
REF
BIOCREDIT
Malaria Ag Pf/Pv (pLDH/pLDH)
2°C
40°C
IVD
37
90mm
Manufactured by
Rapigen, Inc.
16648 경기도 수원시 권선구 산업로 155번길 161
161, Saneop-ro 155beon-gil, Gwonseon-gu, Suwon-si, Gyeonggi-do, 16648, Republic of Korea
OTHER
OTHER
18.5
117.5mm
8m x 5mm


45
BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH)
Assay Buffer
LOT
REF
Vol:6 mL
IVD
2℃
40℃
Rapigen, Inc.
BS07-R00 (2025.12.04)
27


110 mm
55 mm
10 mm
10 mm
20 mm
37 mm
125 mm
105 mm
Inverted cup (5μL)
Blood transfer device
QTY : 25pcs
Tianjin Rilifine Medical Device Co.,Ltd
No.32, Jingguan Road, Yixingbu, Beichen
District, 300402 Tianjin P.R.China
LOT C260401
2026-04-26
MD
Cert No.25-1997
(01)16975522994001(11)
260426
(17)310425
(10)C260401
Rev.02 20260416

P65-003_Inverted cup(80mm)25PCS_45×45


155
95
10
10
33.75
67.5
(01)16975522991185
(11)260430
(17)310429
(10)T260405
Disposable Sterile Lancets
QTY : 25pcs
LOT NO./Type : T260405 /28G
EXP. DATE : 2031-04-29
STERILE R Irradiation Sterilization
0197
MD
EC REP
Sungo Cert GmbH
Harffstr., 47, 40591 Düsseldorf, Germany
Manufactured by:
Tianjin Rilifine Medical Device Co.,Ltd
Address:
No.32, Jingguan Road, Yixingbu, Beichen District, 300402 Tianjin P.R.China
INSTRUCTION FOR USE:
1.Insert lancet into lancing device or Independent use.
Twist off lancet cap of the lancet.
2.Lance skin and apply blood to per manufacturer's instructions.
3.Recap the needle then discard used lancet in appropriate container.
Warning/Precaution:
1.Read the instructions carefully before use.
2.Use the lancets within the expiry date.
3.Do not use if lancet cap is removed or broken previously.
4.Do not store lancet in lancing device, discard lancet after use, do not re-use.
5.For your safety, please do not use a lancet that has been used by someone else. Lancets are not intended for use on multiple individuals.
6.In the event of any serious adverse event, please report to the manufacturer and the competent authority.
Rev.01 20260416

Antiseptic Alcohol Swab

IDO SWAB A

Isopropyl Alcohol 70%

Multi-purpose (Prep/Clean)

FOR EXTERNAL USE ONLY

1 Single Use Swab 1.2 in x 1.4 in (3 cm x 3.5 cm)

Dist. by: IDO PHARM **Made in Korea**

■ E-mail : idopharm@idopharm.com ■ Call +82-31-493-6545

Drug Facts

Active ingredient	***Purpose***
Isopropyl alcohol 70%	Antiseptic

Uses ■ for preparation of the skin prior to an injection ■ to decrease bacteria on skin without soap and water

Warnings **For external use only.**

Flammable. Keep away from fire or flame.

Do not use ■ in the eyes. In case of contact with eyes, rinse eyes thoroughly with water ■ on irritated skin

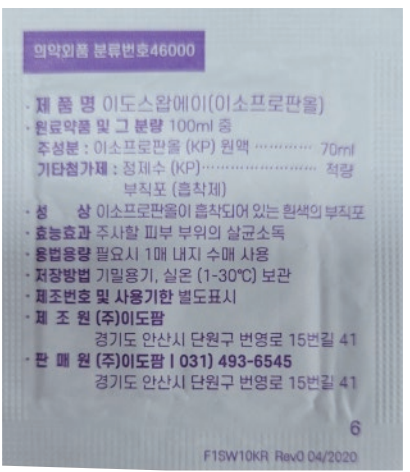
Stop use and ask a doctor if ■ skin irritation or redness develops ■ condition persists for more than 72 hours

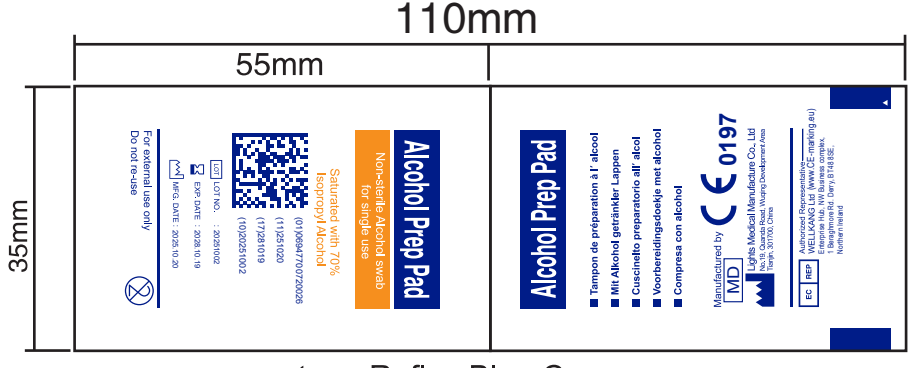
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions ■ tear open packet and remove swab (pad)
■ apply to skin as needed to clean intended area
■ apply to cut, scrape or burn and discard after single use

Inactive ingredients Purified water


소독용 이소프로필 스왑
이도스왑 A
IDO SWAB
Isopropyl Alcohol 70%
· FOR EXTERNAL USE ONLY
· DO NOT USE OPENED or DAMAGED


의약외품 분류번호46000
· 제 품 명 이도스왑에이(이소프로판올)
· 원료약품 및 그 분량 100ml 중
주성분 : 이소프로판올 (KP) 원액 ····· 70ml
기타첨가제 : 정제수 (KP)····· 적량
부직포 (흡착제)
· 성 상 이소프로판올이 흡착되어 있는 흰색의 부직포
· 효능효과 주사할 피부 부위의 살균소독
· 용법용량 필요시 1매 내지 수매 사용
· 저장방법 기밀용기, 실온 (1-30℃) 보관
· 제조번호 및 사용기한 별도표시
· 제 조 원 (주)이도팜
경기도 안산시 단원구 번영로 15번길 41
· 판 매 원 (주)이도팜 I 031) 493-6545
경기도 안산시 단원구 번영로 15번길 41
6
F1SW10KR Rev0 04/2020



pantone Reflex Blue C

pantone Hexachrome Orange C

光标：6x8mm
边距：2mm

479D−2

LABNARA

by consumers for consumers

LATEX GLOVE

POWDER-FREE LATEX GLOVES

REF LBN-LG 50 gloves

"Labnara Glove is one of the cheapest items for customer.
we can supply without margin as supplier."

☐ X-Small ☐ Small ☐ Medium

☐ Large ☐ X-Large

LABNARA

by consumers for consumers

Product Name	LBN LATEX GLOVE
Raw Material	LATEX
Manufacturer	A1 GLOBE Sdn Bhd A1-2, Block A, Jalan Haruan 5/9, Pusat Komersial Oakland II, Seremban, Negeri Sembilan, Malaysia.
Distributor	WONKANGBIO Co.,Ltd. (Tel : +82 2-382-7440) #445, 4F, ITECO B/D, Deokpung-dong, Hanam-si, Gyeonggi-do, Republic of Korea
Storage	Room temperature
MFG	On the box
EXP	3 years from MFG
License Number	SUSIN 23-2060 HO
Origin	Malaysia
Unit	50 gloves/pk
Single Use only (Non-Sterile)	

LOT NO

LBN-LG-RL001 (2023.09.01)

LABNARA

by consumers for consumers

제품명	LBN LATEX GLOVE
원료약품	LATEX
제조원	A1 GLOBE Sdn Bhd A1-2, Block A, Jalan Haruan 5/9, Pusat Komersial Oakland II, Seremban, Negeri Sembilan, Malaysia.
수입원	(주)원강바이오 (T.02-382-7440/F.031-790-4491) 경기도 하남시 조정대로 150, 445호(아이테크)
저장방법	실온보관
제조년월	박스포장의 후면에 기재
유효기간	제조일로부터 3년
품목허가	수신 23-2060 호
원산지	말레이시아
포장단위(중량)	박스포장의 전면에 표시
본 제품은 "비멸균" "일회용 의료기기"임 (재사용금지)	

☐ X-Small ☐ Small ☐ Medium

☐ Large ☐ X-Large

50 gloves

#Powder-Free #Excellent Chemical Resistance
#Surface Texture Treatment #Affordable Price Good Quality
#Wonkangbio

REF LBN-LG

LATEX GLOVE

POWDER-FREE LATEX GLOVES

Instructions for Use[3]

[3] 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.

REF C61RHA25, C61RHG25, C61RHH25, C61RHF25

Rapigen

BIOCREDIT

Malaria Ag Pf/Pv (pLDH/pLDH)

Intended Purpose

The BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH) is an *in-vitro* diagnostic immunochromatographic assay designed for the qualitative detection of *Plasmodium falciparum* and *Plasmodium vivax* infections using *P. falciparum*-specific pLDH antigens and *P. vivax*-specific pLDH antigens in both human capillary and venous whole blood. For venous whole-blood specimens, only blood collected in tubes containing validated anticoagulants (EDTA, heparin or citrate) is acceptable. This assay is intended to aid the diagnosis of individuals aged 5 years and older who present with signs and symptoms consistent with *Plasmodium* infection and to differentiate *P. falciparum* (Pf) and/or *P. vivax* (Pv) infections. Its performance has not been validated in pregnant women or neonates (within 28 days of birth), and use in these populations is therefore restricted.This Rapid Diagnostic Test (RDT) is not intended for self-testing.

The diagnosis of malaria caused by *P. falciparum* and/or *P. vivax* should be made based on medical history, clinical signs and symptoms, exposure likelihood, and other laboratory test results, in conjunction with this assay. The test is not automated and does not require any additional instrument.

Note: This test detects parasite lactate dehydrogenase (pLDH) from *Plasmodium falciparum* and *Plasmodium vivax*, which is associated with viable parasites [1,2]. Following effective anti-malarial treatment, pLDH levels generally decline and test results typically become negative within a relatively short period [2]. However, positive results may still be observed shortly after treatment [3]. Therefore, this test is not intended for monitoring the response to anti-malarial treatment.

Intended User

The test is intended to be performed only by qualified healthcare professionals or trained laboratory personnel.

Principle of Test

The following *Plasmodium* antigens are detected in this test:

- *Plasmodium* lactate dehydrogenase specific for *P. falciparum* (Pf-pLDH)
- *Plasmodium* lactate dehydrogenase specific for *P. vivax* (Pv-pLDH)

The sequence of events is as follows:

1. **5 µL** whole blood is applied to the specimen well (Marked with 'S').
2. Next, add **3 drops** of the assay buffer into the buffer well (marked with "B").
3. The specimen–buffer mixture migrates along the membrane by capillary action.
4. As the mixture passes through the conjugate pad, colloidal-gold–conjugated detection antibodies specific for malaria pLDH are released. If Pf-pLDH or Pv-pLDH antigens are present, they bind to the gold-labeled detection antibodies to form antigen–antibody–gold complexes.
5. The complexes continue to migrate and reach two separate test lines, each coated with species-specific capture antibodies:
   - Pf Test Line (Pf): coated with *P. falciparum*-specific capture antibodies
   - Pv Test Line (Pv): coated with *P. vivax*-specific capture antibodies

   The complexes bind only to the test line corresponding to the matching species epitope.
6. Because the capture antibodies are applied in narrow areas of the membrane, accumulation of the gold-conjugated complexes generates visible colored lines:
   - Pf antigen present → visible line at Pf
   - Pv antigen present → visible line at Pv
   - Both antigens present → visible lines at both Pf and Pv
7. Unbound control-conjugates (Rabbit IgG- Gold conjugated (Red)) continue to migrate and bind to goat anti-rabbit antibodies at the control line, forming a red line. The appearance of the control line indicates successful reagent flow but does not confirm the presence of *Plasmodium* antigens.

   This species-differentiating mechanism fulfills the requirement for dual-target detection of Pf-pLDH and Pv-pLDH and enables clear interpretation of Pf, Pv, and mixed infections.

Main components of the test:

Test device:

- Detection antibodies conjugated to colloidal gold (in the conjugate pad):
  - Anti-Malaria pLDH gold conjugate
  - Rabbit IgG gold conjugate
- Test lines (on the nitrocellulose membrane):
  - *Plasmodium falciparum* line (Pf) : Monoclonal antibodies specific to Pf-pLDH
  - *Plasmodium vivax* line (Pv): Monoclonal antibodies specific to Pv-pLDH
- Control line (on the nitrocellulose membrane):
  - Goat anti-rabbit IgG

Assay buffer bottle:

- Tris-HCl Buffer, Sodium Azide

Specimen Collection and Storage

- Capillary whole blood or venous whole blood with the following anticoagulants: EDTA, heparin or citrate
- Time between specimen collection and specimen testing:
  - **Capillary :** Immediately, After capillary blood collection, users should stop the bleeding at the puncture site by applying sterile gauze or cotton wool.
  - **Venous :** Immediately. If immediate testing is not possible, store the whole blood specimen at 5±3 °C for up to 8 hours. Whole blood specimens frozen up to, and including, 30 days at -20±3 °C can be used for the product. Do not use specimens subjected to more than 2 freeze-thaw cycles.

Precautions

1. For professional *in vitro* diagnostic use only.
2. Read the instructions carefully before performing the test. Follow the test procedure and instructions strictly. Failure to do so can cause improper test functioning and inaccurate test results.
3. Apply standard biosafety precautions for handling and disposing of potentially infectious material.
   - Handle all specimens as potentially infectious.
   - Wear latex gloves while handling specimens and performing the test.
   - Avoid splashing and aerosol formation.
   - Thoroughly clean up spills using an appropriate disinfectant.
4. Dispose of all specimens, reaction kits, and potentially contaminated materials as if they were infectious waste, in a biohazard container with biosafety.
5. The assay buffer contains less than 0.1% Sodium Azide as a preservative, which may be toxic if ingested. In case of dermal or eye exposure, wash out thoroughly with running water and seek medical attention if necessary. When disposing of assay buffer in the sink, flush with large quantities of water.
6. Do not use any other assay buffer than the one provided within this kit.
7. Do not exchange components from different lots or reagent kits, or pooling reagents (e.g., buffer bottles from different lots should not be exchanged across lots).
8. Do not use the kit beyond its expiration date.
9. Do not use the kit if the packaging is damaged.
10. Do not use any other specimen than capillary and venous whole blood (EDTA, heparin or citrate).
11. Do not use if the unpackaged device has been exposed to excessive heat or humidity.
12. Perform the test immediately after opening the device packaging.
13. The assay buffer cap should be kept firmly sealed between each use.
14. Do not reuse the IVD test kit. All components, excluding this buffer, are disposable.
15. Do not wear sunglasses when interpreting the results.
16. The assay buffer is stable within its expiration date if stored at 2-40 °C with the lid closed even after opening.
17. If the desiccant's color indicator has changed from yellow to green, do not use the test device.
18. Do not use the lancet if it has expired or the protective cap is peeled off.
19. Avoid milking the fingertip when collecting finger-stick capillary blood.
20. Do not use clotted or lysed whole blood specimens.
21. Do not disassemble the test device for biological safety.
22. Do not place the test device on a sloped surface when performing the test.
23. If the test kit, components, or specimens have been stored in a refrigerator, allow them to equilibrate to room temperature (15-40 °C) for 30 minutes before use.
24. Add the specimen or reagents in the correct order to obtain accurate results.
25. The number of freeze-thaw cycles for frozen specimens must not exceed two for specimens that can be tested without compromising specimen integrity.
26. Do not expose the IVD to excessively high or low temperatures and humidity.
27. A faint band is considered positive, but if it is very faint and doubts exist, repeat the test.
28. Note that the control line only controls the flow of reagents, but not whether a sufficient volume of specimens has been added.

Kit Components

Components / Cat.No.	C61RHA25	C61RHG25*	C61RHH25*	C61RHF25
Test device (Foil pouched with desiccant)	25	25	25	25
Assay buffer bottle (6 mL)	1	1	1	1
Specimen transfer device (Inverted cup)	25	25	25	25
Sterile lancet	-	25	25	25
Alcohol swab	-	25	25	50
Pair of disposable gloves	-	-	25	25
Instructions for use	1	1	1	1

* Only product codes C61RHG25 and C61RHH25 are prequalified by WHO, while C61RHA25 and C61RHF25 are not.

Materials Required but not Provided

- Latex gloves (Except for C61RHH25, C61RHF25)
- Pen or pencil • Timer • Lancing device • General waste bin
- Extra lancets and alcohol swabs (if needed, for instances such as lancet misfires, insufficient blood volume, dried-out alcohol swabs, etc.)
- Sterile gauze or cotton wool (to stop bleeding at the punctured area)
- Micropipette and tip (for collecting venous whole blood from venipuncture)
- Materials to collect venous whole blood
- Biosafety sharps container
- Biohazard waste container (for potentially infectious waste)

Storage and Shelf life

1. Store the kit between 2-40 °C.
2. Do not store the kit in the freezer.
3. Protect the kit from humidity and direct sunlight.
4. The kit has a shelf life of 24 months from the date of manufacture. It remains stable until the expiration date that is marked on the RDT box and/or the packaging of individual components when stored as specified.

	Storage	Test Device (Disposable)	Assay Buffer
Open	2-40 °C	Use within 1 hour after opening	24 months from manufactured date
Not Open	2-40 °C	24 months from manufactured date	24 months from manufactured date

Assay Procedure

Before Testing

1. Prepare all necessary materials :
   - When stored in the refrigerator, bring the kit to room temperature (15-40 °C) at least 15 minutes before use.
   - Prepare the materials (Refer to the section on kit components).
2. Check the expiration date of the kit (Including assay buffer). If expired, do not use it; instead, use another unexpired kit.
3. Check if the device packaging is not damaged. If damaged, discard it and use another test.
4. Open the device packaging and check the desiccant's condition. If there is a color change in the desiccant pouch from yellow to green, do not use the test device. Dispose of the desiccant in the general waste bin.
   - Perform the test immediately after opening the device packaging.
   - Do not reuse the test device.
5. Take the device and place it on a flat surface, horizontally. You will see:
   - A result window marked with "C", "Pv", "Pf"
   - A small square well marked with "S" (for specimen)
   - A large square well marked with "B" (for assay buffer)
6. Write the patient name or identifier on the device.

Test Procedure

[Capillary Whole Blood from Finger Prick]

1. Put on latex gloves. Use new gloves for each patient.
2. Choose a finger for the finger prick:
   - Do not choose a finger that is swollen, bruised or scarred.
   - Preferably choose the 3rd or 4th finger of the hand the patient does not use to write.
3. Open the packaging of the alcohol swab. Take out the alcohol swab.
4. Wipe the complete fingertip with the alcohol swab. Wait until the finger has completely dried (Minimum 30 seconds).
5. Take the sterile lancet.
6. Detach the cap of the lancet. Puncture the side of the pulp (Ball) of the finger with the lancet. Dispose of the lancet immediately into the sharps box. **Avoid the tip or center of the finger.**
7. Ensure the presence of a well-formed drop of blood.
8. If there is no well-formed drop of blood, repeat the finger prick using a new lancet and choose a different puncture area.
9. Take the inverted cup and collect **5 µL** of blood by dipping the circular end of the inverted cup into the whole blood drop.
10. Place the circular end of the inverted cup in the small square well (S) to touch the strip (Pad at the bottom of the well). Press down lightly to transfer all the blood to the strip. Dispose of the used inverted cup into the non-sharps biohazard waste container.
11. Use sterile gauze or cotton wool to stop the bleeding. Ask the patient to press it to the finger prick to stop the bleeding.
12. Take the assay buffer bottle. Hold the open assay buffer bottle vertically above the large square well (B). In a vertical position, squeeze the buffer bottle gently and apply exactly **3 drops** into the large square well (B).
    - **Do not use water or any other buffer than the assay buffer provided within this kit.**
    - **Hold the assay buffer bottle vertically. This ensures that the drops contain the correct volume of assay buffer.**
    - **Do not place the test device on a sloped surface when testing.**
13. Start the timer immediately after adding the **3 drops** of buffer or write the time on the device.
14. Remove the used gloves and discard them into the non-sharps biohazard waste container.
15. **Read the result within 25-35 minutes.** Use a good light source when reading the test results.
    - **Do not read results before 25 minutes and after 35 minutes of adding assay buffer.**
16. Dispose of the used device into the non-sharps biosafety waste container.

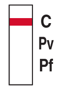
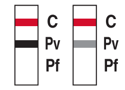
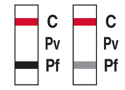
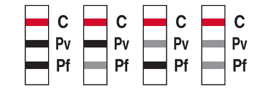
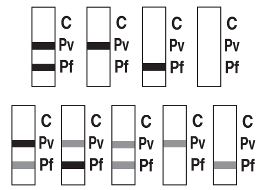
[Venous Whole Blood from Venipuncture]

1. Wear latex gloves.
2. Collect the blood by standard venipuncture procedure into a tube containing the correct anticoagulant (EDTA, heparin or citrate).
3. If the specimen has been stored under refrigerated conditions (2-8 °C for up to 8 hours) or frozen conditions (-23 to -17 °C for up to 30 days), it should be equilibrated to 15-25 °C for 30 minutes before testing.
4. Gently mix the tube before use.
5. Transfer **5 µL** of whole blood into the small square well (S) of the device using a micropipette.
6. Perform steps 12-16 of the previous section ("Capillary Whole Blood from Finger Prick").

Interpretation of Results

1. Within 25-35 minutes: compare the test lines with the demonstration in Table 1.
2. **Line intensities may vary from faint to strong intensity. Consider a faint test line as a positive result.**
3. Record the test results as noted in Table 1.

Table 1. Possible test results

Result	Representation	Interpretation
Negative		One red control line (C) in the result window. No antigen detected - does not rule out malaria (including early infection or low parasitaemia).
Positive		Two bands; **black** test line (Pv) and a red control line (C) in the result window. Positive for *Plasmodium vivax*
		Two bands; **black** test line (Pf) and a red control line (C) in the result window. Positive for *Plasmodium falciparum*
		Three bands; two **black** test lines (Pv), (Pf) and a red control line (C) in the result window. Positive for *Plasmodium falciparum* and *Plasmodium vivax*
Invalid		No control line (C) in the result window. * The test-line intensity may vary, but any result without a visible control line is invalid and must be repeated with a new device.

※ If an invalid result persists when retesting the specimen with new devices, please contact the manufacturer at info@rapigen.com. More information can be found on the back side of the IFU.

Limitations

As with most immunoassays, a few incidences of false results can occur.
If questionable results are obtained, other clinically available tests should be required. A clinical decision should not be based soley on the results of this test but should be made by a healthcare professional after evaluating all clinical and laboratory findings.

False-negative results (No test lines but the patient has malaria) can occur in the following conditions:

1. Very low antigen concentrations/parasite densities, for instance, < 100 parasites/µL.
   - Note that most clinical cases have higher parasite densities.
2. Very high parasite densities (Very exceptional, prozone or high-dose hook effect) for the pLDH antigen.
   - Note : No hook effect was observed in positive clinical specimens up to 1,245,000 parasites/µL for *Plasmodium falciparum* and 190,261 parasites/µL for *Plasmodium vivax*.
3. A high fraction of interstitial fluid due to the "milking" of fingertip.
4. Clotted specimens may cause false negative results.

False-positive results (Test lines visible but the patient does not have malaria) can occur among others in the following conditions:

1. Presence of human anti-mouse antibodies.
   - This product was found to give a false positive result at a concentration of HAMA serum (Type I) of 63 ng/mL.
2. Presence of *Plasmodium knowlesi*
   - This product was found to give a false positive result at a concentration of *Plasmodium knowlesi* of 125 parasites/µL.
3. Presence of infections with viruses or microorganisms that were not tested for cross-reactivity.

The presence of the control line only means that migration of added liquid occurred. It does not guarantee that:

1. The correct specimen has been used.
2. The specimen has been applied correctly.
3. The specimen and test have been correctly stored.
4. The test procedure was followed correctly.

* Not validated for use in pregnant women and neonates (within 28 days of birth).

Performance Characteristics

1. Clinical performance studies

Microscopy		Capillary			Venous		
Site (Study Type) [Study period]	Target	Study size (# positives)	Sensitivity [95% CI]	Specificity [95% CI]	Study size (# positives)	Sensitivity [95% CI]	Specificity [95% CI]
Indonesia (Pro.) [2021.12.~2023.05.]	Pf (pLDH)	399 (111)	98.2% [93.7-99.5]	83.68% [78.9-87.5]	399 (111)	97.3% [92.4-99.1]	73.96% [68.6-78.7]
	Pv (pLDH)	399 (81)	90.12% [81.7-94.9]	97.8% [95.5-98.9]	399 (81)	88.89% [80.2-94.0]	95.6% [92.8-97.4]
	Pf (pLDH) and/or Pv (pLDH)	399 (179)	97.21% [93.6-98.8]	83.64% [78.2-87.9]	399 (179)	96.09% [92.2-98.1]	78.64% [72.8-83.5]
Sudan (Pro.) [2022.01.~2023.05.]	Pf (pLDH)	280 (83)	98.8% [93.5-99.8]	97.46% [94.2-98.9]	280 (83)	97.59% [91.6-99.3]	97.97% [94.9-99.2]
	Pv (pLDH)	280 (28)	92.86% [77.4-98.0]	99.6% [97.8-99.9]	280 (28)	96.43% [82.3-99.4]	99.6% [97.8-99.9]
	Pf (pLDH) and/or Pv (pLDH)	280 (109)	100% [96.6-100]	99.42% [96.8-99.9]	280 (109)	99.08% [94.9-99.8]	99.42% [96.8-99.9]
Senegal (Pro.) [2021.11.~2022.02.]	Pf (pLDH)	181 (69)	97.1% [89.9-99.6]	78.6% [69.8-85.8]	183 (71)	98.6% [92.4-100]	78.6% [69.8-85.8]

Brazil (Retro.) [2019.07.~2019.12.]	Pf (pLDH)	N/A	979 (57)	94.7% [85.4-98.9]	95.8% [94.3-97.0]
	Pv (pLDH)	N/A	979 (280)	81.1% [76.0-85.5]	97.0% [95.4-98.1]
	Pf (pLDH) and/or Pv (pLDH)	N/A	979 (290)	97.6% [95.1-99.0]	95.5% [93.7-96.9]
Indonesia (Retro.) [2021.12.~2023.05.]	Pf (pLDH)	N/A	318 (81)	87.65% [78.7-93.2]	89.03% [84.4-92.4]
	Pv (pLDH)	N/A	318 (74)	89.19% [80.1-94.4]	98.77% [96.5-99.6]
	Pf (pLDH) and/or Pv (pLDH)	N/A	318 (145)	91.03% [85.3-94.69]	90.17% [84.83-93.8]

[Site 1. Indonesia] This was a prospective observational and retrospective diagnostic accuracy study conducted in primary healthcare facilities in Timika, Indonesia.

[Site 2. Sudan] This was a prospective observational diagnostic accuracy study conducted in primary healthcare facilities located in malaria-endemic areas of Sudan.

[Site 3. Senegal] This was a prospective cross-sectional diagnostic accuracy and usability study. Patients aged ≥6 months (and weighing at least 8 kg) presenting with febrile symptoms were recruited at five healthcare facilities in Kédougou, Senegal.

[Site 4. Brazil] This was a retrospective diagnostic accuracy study conducted in Porto Velho, Rondônia, Brazil, using stored frozen venous whole blood specimens collected under a completed cross-sectional study.

2. Analytical sensitivity (Limit of detection)

The analytical sensitivity of BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH) for the detection of *Plasmodium falciparum* is ≥ 3.91 IU/mL and for the detection of *Plasmodium vivax* is ≥ 0.98 IU/mL

3. Analytical specificity

[Cross reactivity]

No cross-reactivity was observed with 28 potential cross-reacting substances. However, weak cross-reactivity was observed with *Plasmodium knowlesi* at 125 parasites/μL on the Pv line.

- Bacteria/ Parasites

Potential cross-reacting substances	Potential cross-reacting substances
Trypanosoma cruzi	*Toxoplasma gondii*
Leishmania sp	*Brucella* IgG
Leptospira IgG	*Brucella* IgM
Leptospira IgM	*Plasmodium ovale*
Treponema pallidum	*Plasmodium malariae*
M.tuberculosis	*Plasmodium knowlesi*
Schistosoma spp.	-

- Viral infection

Potential cross-reacting substances	Potential cross-reacting substances
Tick borne encephalitis	Dengue type 4
HIV	Yellow fever
HBV	Yellow Fever IgG positive plasma
HCV	Measles
HAV	Influenza A virus (H3N2)
Dengue type 1	Influenza A virus (H1N1)
Dengue type 2	Influenza B virus
Dengue type 3	SARS-CoV-2

[Interference]

No interference was observed with 22 potential interfering substances. However, weak interference was observed with HAMA serum Type 1 at 63 ng/mL on the Pf line.

- Endogenous

Potential interfering substances	Potential interfering substances
Bilirubin	Hemoglobin
Bilirubin conjugate	Immunoglobulin G
Cholesterol	Immunoglobulin M
HAMA Serum, Type 1	Pregnant whole blood
HAMA Serum, Type 2	Rheumatoid factor

- Exogenous

Potential interfering substances	Potential interfering substances
Acetaminophen	Isoniazid
Aspirin (Acetylsalicylic acid)	Ethanol
Ibuprofen	Caffeine
Chloroquine	EDTA
Primaquine	Sodium citrate
Ivermectin	Heparin
Tenofovir disoproxil fumarate	-

4. Precision of Measurement

[Repeatability]

The repeatability of the BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH) was confirmed that the results were 100% agreement at each test concentration.

[Reproducibility]

The reproducibility of the BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH) was confirmed across 3 sites, 2 lots, 2 operators, and 5 days, with 3 repetitions at each test concentration, demonstrating that all results were 100% consistent between operators, between days, between lots, and between sites.

■ Package

25 Tests/Kit

■ Bibliography

1. Mathison, B. A., & Pritt, B. S. (2017). Update on malaria diagnostics and test utilization. Journal of clinical microbiology, 55(7), 2009-2017.
2. Dalrymple, Ursula, et al. (2018). How long do rapid diagnostic tests remain positive after anti-malarial treatment?. Malaria journal, 17(1), 1-13.
3. Fitri, Loeki Enggar, et al. (2022). Malaria diagnostic update: From conventional to advanced method. Journal of Clinical Laboratory Analysis, 36(4), e24314.

■ Symbol Key

LOT Lot number
REF Catalog number
Temperature limitation
Do not reuse
Keep dry
Keep away from sunlight
Manufacturer
Manufacture date
Consult instructions for use
Expiration date (YYYY.MM.DD)
Content sufficient for <n> tests
IVD *In vitro* diagnostic medical device
Do not use if packaging is damaged

■ Revision History

Date	IFU ver.	Revision history
2017.08.23	I-H016A-E06 (C61RHA25)	In use on the market
2020.04.09	I-WG-H016A-E01 (C61RHG25), I-WH-H016A-E01 (C61RHH25)	Specially produced to meet WHO standards for content such as YouTube
2023.06.28	I-H016A-E00	Merged three catalogs (C61RHA25, C61RHG25, C61RHH25) into a unified English Market IFU. - Manufacturing address (Anyang to Suwon) - Authorized representative address (Altenhofstrasse 80 to Ernst-Heckel'- Straße 7, 66386 St.Ingbert, Germany) - New CI (Rapigen, INC. to Rapigen, Inc.)
2023.11.21	I-H016A-EN00	WHO IFU and Market IFU have been integrated. - Changed the language code of IF No. to EN according to WI-603 (Rev. 2, 2023.11.15). - Changed it to A4 size to reduce costs.
2024.03.20	I-H016A-EN01	Supplementation of clinical data in performance characteristics section
2025.01.20	I-H016A-EN02	Minor changes in the Intended User, Specimen Collection and Storage, Precautions, and Test Procedure in the Quick Guide. The Performance Characteristics section was updated. Changed from A4 to A3 to enhance visibility in addition to including the information in the IFU.
2026.05.22	I-H016A-EN03	Revised in accordance with WHO review comments.

Manufactured by
Rapigen, Inc.
161, Saneop-ro 155beon-gil, Gwonseon-gu, Suwon-si, Gyeonggi-do, 16648, Republic of Korea
TEL : +82-31-427-4677 FAX : +82-31-427-4678
E-mail : info@rapigen.com www.rapigen.com

I-H016A-EN03 (2026.05.22)

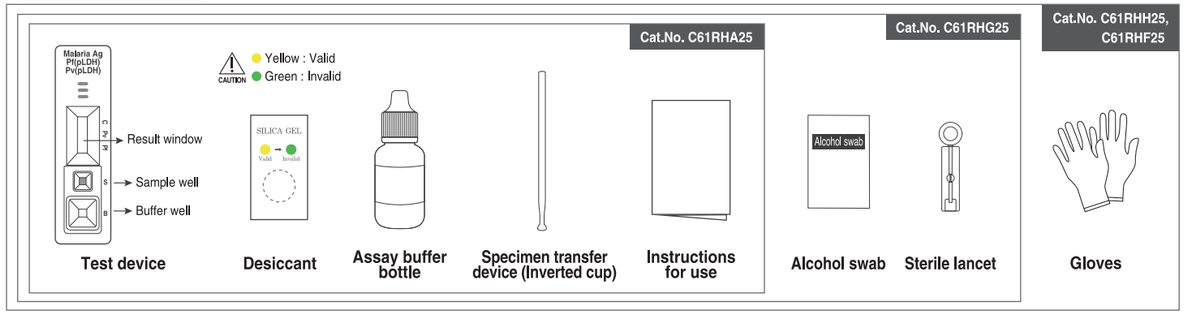
BIOCREDIT

Malaria Ag Pf/Pv (pLDH/pLDH)

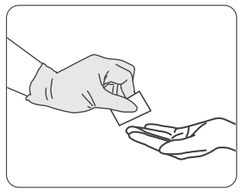
Quick Guide

How to use

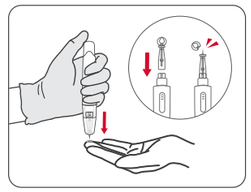
Kit Components



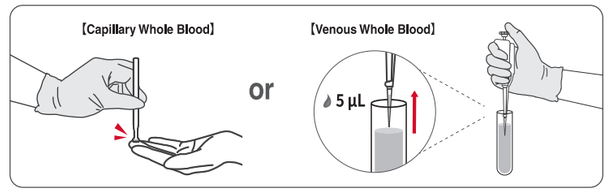
Test Procedure



1 Clean the finger with the alcohol swab. Wait until the finger has completely dried (Minimum 30 seconds).

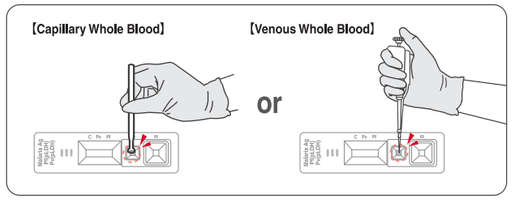


2 Open the lancet. Prick patient's finger to get a drop of blood.
*Lancing device is required but not provided.

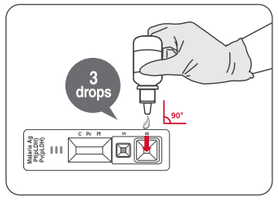


3 【Capillary Whole Blood】
Use the inverted cup to collect the drop of blood.

【Venous Whole Blood】
Collect the 5 μL of the venous whole blood specimen using a micropipette.



4 Add 5 μL of whole blood to the sample well (S) of the test device.
※ Do not place the test device on a sloped surface when testing.



5 Hold the bottle vertically. Add 3 drops of Assay buffer into the buffer well (B).

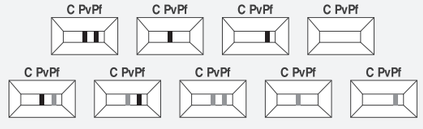
6 Read the result within 25-35 minutes.
* Do not read results before 25 minutes and after 35 minutes of adding assay buffer.

Interpretation of Results

Negative

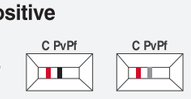
One **red** "C" (Control line) in the result window.
* No antigen detected - does not rule out malaria (including early infection or low parasitaemia).

Invalid



No **red** "C" (Control line) in the result window.
* The test-line intensity may vary, but any result without a visible control line is invalid and must be repeated with a new device.

Positive



① Two bands; **black** "Pv" (Test line) and **red** "C" (Control line) in the result window.
Positive for *Plasmodium vivax*

② Two bands; **black** "Pf" (Test line) and **red** "C" (Control line) in the result window.
Positive for *Plasmodium falciparum*

③ Three bands; two **black** "Pv" and "Pf" (Test lines) and one **red** "C" (Control line) in the result window.
Positive for *Plasmodium falciparum* and *Plasmodium vivax*

* Line intensities may vary from faint to strong intensity. Consider a faint test line as a positive result

Storage and Shelf life

	Storage	Test Device (Disposable)	Assay Buffer
Open	2-40 °C	Use within 1 hour after opening	24 months from manufactured date
Not Open	2-40 °C	24 months from manufactured date	24 months from manufactured date

1. Store the kit between 2-40 °C.
2. Do not store the kit in the freezer.
3. Protect the kit from humidity and direct sunlight.
4. The kit has a shelf life of 24 months from the date of manufacture. It remains stable until the expiration date that is marked on the RDT box and/or the packaging of individual components when stored as specified.