WHO Prequalification of In Vitro Diagnostics
PUBLIC REPORT

Product: STANDARD G6PD Test
WHO reference number: PQDx 0581-117-00

STANDARD G6PD Test with product codes 02G6S11 and 02G6S11A, manufactured by SD Biosensor, Inc., Rest of World regulatory version was accepted for the WHO list of prequalified in vitro diagnostics and was listed on 18 December 2024.

Summary of WHO prequalification assessment for the STANDARD G6PD Test

	Date	Outcome
Prequalification listing	18 December 2024	listed
Dossier assessment	16 December 2024	MR
Site inspection(s) of quality management system	24-26 May 2023	MR
Product performance evaluation	21 March 2023	MR

MR: Meets Requirements

Intended use

According to the intended use claim from SD Biosensor, Inc., "*The STANDARD G6PD System is an enzymatic colorimetric assay intended for the semi-quantitative measurement of G6PD activity in nonanticoagulated capillary (finger-stick) whole blood or venous whole blood (K2-EDTA, sodium heparin, or acid citrate dextrose [ACD]). The STANDARD G6PD Test System is indicated for differentiating normal, intermediate, and deficient G6PD activity levels to aid in the detection of G6PD deficiency in individuals. The test will provide results expressed as the ratio of units of G6PD activity per gram of hemoglobin (G6PD U/g Hb) which can be used to determine G6PD status. Samples which generate a G6PD deficient or intermediate result should be assayed using a quantitative G6PD test to verify a deficiency. T-Hb results are measured in grams per deciliter (g/dL); however, the results are only for internal use for the calculation of G6PD activity in units per gram of hemoglobin. T-Hb results are not displayed on the analyzer screen. The STANDARD G6PD Test System is intended for use by health care professionals in a laboratory or point-of-care environment. The system is for in vitro diagnostic use only. This product has been validated for use with individuals aged two years of age and older (children and adults). The STANDARD G6PD Test has not been validated for use with neonatal samples. The STANDARD G6PD Analyzer must be used exclusively with the STANDARD G6PD Test Device, STANDARD G6PD Control, and STANDARD G6PD Check strip manufactured by SD BIOSENSOR."*

Assay description

According to the claim of assay description from SD Biosensor, Inc., *"The STANDARD G6PD Test contains a flow through STANDARD G6PD Test Device with treated membrane and mesh. The test is based on a colorimetric detection system for the automatic calculation of G6PD activity on the codechip for each test device. G6PD catalyzes the first step in the PPP, oxidizing G6P (glucose-6-phosphate) to 6-phosphogluconolactone and reducing NADP (nicotinamide adenine dinucleotide phosphate) to NADPH. When NADPH is generated by G6PD, the BCIP (5-bromo-4-chloro-3-indolyl-phosphate) and NBT (nitro blue tetrazolium) are reduced by the diaphorase reaction to yield a violet color. The rate of the color production is directly proportional to the concentration of G6PD present in the specimen (see schematic below). The color intensity can be measured through reflectance photometry of the reduced BCIP and NBT. The T-Hb concentration is also measured by reflectance on a separate location on the test device. The STANDARD G6PD Analyzer's screen displays the G6PD enzyme activity in U/g Hb. When the T-Hb is "Lo" or "HI", the test result of the G6PD enzyme activity will be displayed as "N-A". The Analyzer has a temperature monitor and a pre-programmed algorithm corrects the values for temperature as long as the test was run within the operating temperature range of the test (15°C to 40°C / 59°F to 104°F)."*

Test kit contents:

Component	25 tests/kit (product code 02G6S11)	10 tests/kit (product code 02G6S11A)
STANDARD G6PD Test Device	25	10
Extraction buffer	25	10
STANDARD Ezi tube+ (10 µl)	50	20
Codechip	1	1
Instructions for Use (IFU)	1	1

Items required but not provided:

- STANDARD G6PD Analyzer(product code 02GA11).
- STANDARD G6PD Control (Level 1: 1 x 10 ea, Level 2: 1 x 10 ea)(product code 02G6C11).
- Standard blood drawing equipment or lancet, lancing device, alcohol swab.

Storage:

The test kit should be stored at 2-30 °C.

Shelf-life upon manufacture:

18 months.

Warnings/limitations:
NOTE: The WHO-prequalified product version is the STANDARD G6PD Test with product codes 02G6S11 and 02G6S11A, used in conjunction with the STANDARD G6PD Analyzer (product code 02GA11). This analyzer does not display Total Haemoglobin values, and any other version of the product that includes the display of Total Haemoglobin values is not WHO-prequalified.

Please refer to the current version of the manufacturer's instructions for use attached to this public report.

Prioritization for prequalification
Based on the established eligibility criteria, the STANDARD G6PD Test was given priority for the WHO prequalification assessment.

Product dossier assessment

SD Biosensor, Inc. submitted a product dossier for the STANDARD G6PD Test 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 nonconformities found during dossier screening and assessment findings were accepted on 16 December 2024.

Based on the product dossier screening and assessment findings, the product dossier for the STANDARD G6PD Test meets WHO prequalification requirements.

Manufacturing site inspection

An inspection of SD Biosensor Inc., located at 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea was conducted between 24-26 May 2023. At the time of considering the product application for Prequalification, the Manufacturer of the product had a well-established quality management system and manufacturing practices in place that would support the manufacture of a product of consistent quality. Routine inspections of the Manufacturing site will be conducted with copies of the WHO Public Inspection Report (WHOPIR) published on the WHO Prequalification web page as per Resolution WHA57.14 of the World Health Assembly. Note that a WHOPIR reflects the information on the most current assessment performed at a manufacturing site for in vitro diagnostic products and summarises the assessment findings.

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

All published WHOPIRs are with the manufacturer's agreement.

Based on the site inspection and corrective action plan review, the quality management system for the STANDARD G6PD Test meets WHO prequalification requirements.

Product performance evaluation

STANDARD G6PD Test (SD Biosensor Inc.) was evaluated by the Emerging Infections and Parasitology Laboratory, International Centre for Diarrhoeal Disease Research, Bangladesh on behalf of WHO in the 3rd quarter of 2021, according to protocol PQDx_366, version 1.

Clinical performance evaluation

In this limited laboratory-based evaluation of clinical performance characteristics, a panel of 310 venous whole blood specimens was used. Although the sample size according to the protocol included 80 G6PD-deficient, 80 G6PD-intermediate and 150 G6PD-normal specimens, due to reconsideration of reference results during analysis, the final sample size included 79 G6PD-deficient, 69 G6PD-intermediate and 162 G6PD-normal specimens (using thresholds at 30% and 80% of the average male median (AMM)). The specimens were characterized using the Glucose-6-Phosphate Dehydrogenase Reagent Set (Pointe Scientific) performed on Shimadzu UV-1800 (Shimadzu, Japan), performed in duplicate. Haemoglobin levels were determined using Sysmex XT-1800i Hematology Analyzer.

Clinical performance characteristics in comparison with an agreed reference standard		
	Positive percent agreement % (95% CI)	Negative percent agreement % (95% CI)
G6PD-Deficient (<30% AMM) (N=79)	100.0 (95% CI: 95.4 - 100.0)	92.6 (95% CI: 88.5 – 95.7)
G6PD-Intermediate (30-80% AMM) (N=69)	37.7 (95% CI: 26.3 – 50.2)	98.3 (95% CI: 95.8 – 99.5)
G6PD-Normal (>80% AMM) (N=162)	96.9 (95% CI: 92.9 – 99.0)	81.8 (95% CI: 74.6 – 87.6)
With threshold at 70% AMM		
Intermediate (30-70% AMM) (N=43)	53.5 (95% CI: 37.7 - 68.8)	97.4 (95% CI: 94.7 - 98.9)
Normal (>70% AMM) (N=188)	95.2 (95% CI: 91.1 – 97.8)	95.1 (95% CI: 89.6 – 98.2)
Kappa coefficient	0.74	
Bias Limits of agreement	G6PD: 0.49 U/g Hb (95% limit of agreement: -2.14 to 3.13)	
	Haemoglobin: 2.18 g/dL (95% limit of agreement: 0.04 to 4.32)	
Invalid rate (N= 310)	There were no invalid results in the clinical evaluation	

Analytical performance evaluation

Analytical performance characteristics	
Within-run precision (repeatability)	%CV ranged from 7.6 to 19.5 for G6PD results %CV ranged from 4.3 to 7.5 for haemoglobin results
Within-laboratory precision (reproducibility)	%CV ranged from 11.5 to 22.1 for G6PD results %CV ranged from 7.5 to 10.7 for haemoglobin results
Influence of temperature	A significant influence of temperature on G6PD level was found for 2 of 6 specimens (both normal specimens) and a significant difference in Hb results was found in 4 of 6 specimens.
Carry-over	The mean carry-over (k) over 5 pairs of specimens (normal/deficient) was 0.016 IU/g Hb.
Comparison between results using capillary and venous whole blood	65/75 (86.7%) specimens showed concordant results using capillary versus venous whole blood. The kappa coefficient was 0.77.

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.

Key operational characteristics	
Specimen type(s) and volume	10 µL of capillary whole blood or venous whole blood
Number of steps for one specimen*	5 steps in total 2 steps using the STANDARD Ezi tube+(10µL) provided in the kit
Number of steps for instrument management**	3 steps per day
Time to result for one test	5 minutes
Operator hands-on time for one test	2 minutes
Quality controls	QC are provided by the manufacturer and should be purchased separately. Level-1 (Deficient) & Level-2 (Normal)
Operating temperature	15- 40 °C.
Result display and connectivity	Results are displayed on screen
Power sources	Battery
Biosafety *(outside of infectious specimen handling)*	Operators reported no biosafety concerns for the user.
Waste	The volume of liquid waste is approx. 210 µL per test. The volume of solid waste is approx. 20 g per test. Standard biohazard waste disposal measures in addition to usual laboratory biohazard waste disposal procedures. Only a small biohazard bag and sharp container can be used and need hypochloride treatment before disposal.
Calibration	No calibration needed.
Maintenance	Weekly maintenance (cleaning) is required.
Other specific requirements	NA

** Steps for one specimen: each action required to obtain a result for one specimen (excluding specimen collection, instrument management, maintenance/calibration*
*** Steps for instrument management: each action required daily or per run to set up and shut down the instrument*

Based on these results, the following deficiencies were identified:

1. An important bias was identified in hemoglobin result, when compared to a reference method, albeit the study was not designed to measure hemoglobin performance over the full clinically relevant hemoglobin dynamic range and critical threshold values.
2. The operating temperature had a significant impact on the G6PD and haemoglobin results.

The manufacturer was requested to remove the display of haemoglobin results from the device and to review the operating temperature range.
The manufacturer agreed to remove the display of haemoglobin results from the device and provided additional data regarding operating temperature that were reviewed as part of the dossier review and found acceptable to support the operating temperature claim.

As a result, the performance evaluation of the STANDARD G6PD Test meets the WHO prequalification requirements.

Labelling

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

1. Labels

1.1 Standard G6PD Test Packaging Box (02G6S11)

STANDARD
G6PD Test

25 TESTS KIT

ES -25 PRUEBAS/KIT-
CONTENIDO
1) Dispositivo de prueba x 25
2) Buffer de extracción x 25
3) STANDARD™ Ezi Tube+ (10µl) x 50
4) Chip de código x 1
5) Instrucciones de uso x 1

FR -25 TESTS/KIT-
CONTENU
1) Dispositif de test x 25
2) Solution tampon d'extraction x 25
3) STANDARD™ Ezi Tube+ (10µl) x 50
4) Puce à code x 1
5) Instrucciones de uso x 1

PT -25 TESTES/KIT-
COMPONENTES
1) Dispositivo de teste x 25
2) Buffer de extração x 25
3) STANDARD™ Ezi Tube+ (10µl) x 50
4) Chip de código x 1
5) Instruções de uso x 1

DE -25 TESTES/KIT-
INHALT
1) Testgerät x 25
2) Extraktionspuffer x 25
3) STANDARD™ Ezi Tube+ (10µl) x 50
4) Code Chip x 1
5) Gebrauchsanweisung x 1

IT -25 TESTES/KIT-
CONTENUTO
1) Dispositivo di test x 25
2) Buffer di estrazione x 25
3) STANDARD™ Ezi Tube+ (10µl) x 50
4) Chip del codice x 1
5) Istruzioni per l'uso x 1

REF 02GS11
Cat. No.: 02GS11

STANDARD
G6PD test

CONTENTS
1) Test Device x 25
2) Extraction buffer x 25
3) STANDARD™ Ezi Tube+ (10µL) x 50
4) Code Chip x 1
5) Instructions for use x 1

IVD

25

www.sdbiosensor.com

SD BIOSENSOR

STANDARD
G6PD test

UDI Label
Placeholder Example
Do not print

STANDARD
G6PD test

STANDARD™ G6PD test

www.sdbiosensor.com

SD BIOSENSOR

B07G6S11ML4R0
Issue date: 2025.01

25 TESTS KIT

STANDARD
G6PD test

STANDARD™

Manufactured by:
SD Biosensor, Inc.
Head office
C-4th&5th, 16, Deogyeong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, REPUBLIC OF KOREA
Manufacturing site
74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, REPUBLIC OF KOREA

1.2 Standard G6PD Test Packaging Box (02G6S11A)

www.sdbiosensor.com
SD BIOSENSOR
IVD
2℃ ~ 30℃ (36~86°F)
10
CONTENTS
1) Test Device x 10
2) Extraction buffer x 10
3) STANDARD™ Ezi Tube+ (10μl) x 20
4) Code Chip x 1
5) Instructions for Use x 1
STANDARD
G6PD test
REF 02GS11
Cat. No.: 02GS11A
STANDARD
G6PD test
10 TESTS KIT
ES -10 PRUEBAS/KIT-
CONTENIDO
1) Dispositivo de prueba x 10
2) Buffer de extracción x 10
3) STANDARD™ Ezi Tube+ (10μl) x 20
4) Chip de código x 1
5) Instrucciones de uso x 1
FR -10 TESTS/KIT-
CONTENU
1) Dispositif de test x 10
2) Solution tampon d'extraction x 10
3) STANDARD™ Ezi Tube+ (10μl) x 20
4) Puce à code x 1
5) Instructions de uso x 1
PT -10 TESTES/KIT-
COMPONENTES
1) Dispositivo de teste x 10
2) Buffer de extração x 10
3) STANDARD™ Ezi Tube+ (10μl) x 20
4) Chip de código x 1
5) Instruções de uso x 1
STANDARD
G6PD test
UDI Label
Placeholder Example
Do not print
STANDARD
G6PD test
STANDARD™ G6PD test
10 TESTS KIT
www.sdbiosensor.com
SD BIOSENSOR
B08G6S11MLR0
Issue date: 2025.01
STANDARD
G6PD test
Manufactured by
SD Biosensor, Inc.
Head office
C-4th&5th, 16, Deogyeong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, REPUBLIC OF KOREA
Manufacturing site
74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, REPUBLIC OF KOREA
STANDARD™

1.3 STANDARD G6PD Test Device Pouch

STANDARD

G6PD Test Device

Σ 1

1Test

IVD

30°C (86°F)

2°C (36°F)

STANDARD™

LOT / LOT No.

/ MFG DATE

/ EXP DATE

/ CODE

L25G6S11R0

Issue date : 2024.12

Manufactured by

SD BIOSENSOR 에스디 바이오센서(주)

www.sdbiosensor.com

1.4 Extraction buffer label (25 ea)

*Zipper bag must be tightly closed after use to avoid evaporation

Extraction buffer

L36GA1ENR1
Issue date : 2017.10

IVD

VOLUME : 200µl/1ea
QUANTITY : 25ea

LOT NO. :
MFG DATE :
EXP DATE :

SD BIOSENSOR

STANDARD™

1.5 Extraction buffer label (10 ea)

*Zipper bag must be tightly closed after use to avoid evaporation

Extraction buffer

L36GA2ENR0
Issue date : 2022.07

IVD

VOLUME : 200 µl/1 ea
QUANTITY : 10 ea

LOT NO. :
MFG DATE :
EXP DATE :

www.sdbiosensor.com

SD BIOSENSOR

1.6 STANDARD Ezi Tube+ (10µL) for 20 ea and 25 ea

STANDARD™

Ezi Tube+ 10㎕

Σ 20 PCS

1. 사용목적 : 모세관 현상을 이용하여 혈액을 채취하는 가는 튜브 모양의 기구

2. 사용방법

(1) 사용 전 준비사항

① 사용 전 포장 개봉여부를 확인한다.
개봉 및 파손 되었을 경우 사용하지 않는다.

② 사용 전 제품 외관에 이상이 없는 지 확인 후 사용한다.

(2) 사용방법

① 채혈침을 이용하여 손가락 끝에 검체를 모아준다.

② 모세관 튜브의 채혈부를 검체에 가져다 대고 표시선까지 검체를 채취한다.

③ 튜브의 끝부분을 살짝 눌러서 검체를 점적한다.

(3) 사용 후 관리방법 : 사용 후 지정된 곳에 폐기한다.

3. 사용 시 주의사항

(1) 사용한 제품은 감염 위험이 있으니 관련 법규에 따라 안전한 곳에 폐기하여 주십시오.

(2) 검체를 채취한 경우 기포가 생기지 않도록 주의하여 주십시오. 기포가 생길 경우, 정확한 양의 혈액을 채취할 수 없습니다.

(3) 사용 후 남은 제품은 밀폐하여 보관하여 주십시오.

(4) 혈액 채취 후, 튜브 끝을 천천히 눌러 주십시오.

품목명, 모델명 : 모세관채혈튜브, STANDARD™ Ezi Tube+ 10uL

품목신고번호 : 경인 수신 13-271 호

수입업자: 에이치엘비생명과학㈜

경기도 안성시 공도읍 용머리큰길 104

제조자 상호 및 주소 : Jiangsu Kehua Medical Instrument Technology Co., Ltd.
West Industrial Park, Wulie Town, Dongtai City, Jiangsu Province, China

부작용 보고 관련 문의처 : 한국의료기기안전정보원, 080-080-4183

일회용 의료기기/재사용 금지

STANDARD™

Ezi Tube+ 10㎕

Σ 20 PCS

1. How to use

A. Before usage

1) Check the amount of blood sample needed.
2) Check the length of capillary tube for sample amount.
3) Check the condition of STANDARD Ezi Tube+.

B. How to use

1) Make the blood drop on tip of finger by using lancing device.
2) Put the tip of capillary tube to blood drop and collect the sample.
3) Apply the sample to the testing spot by carefully pushing the head.
4) Discard the used STANDARD Ezi Tube+ at designated place.

2. Caution

1) Used STANDARD Ezi Tube+ can cause infection. Please discard used one at designated place.
2) Be careful not to collect air bubble while sampling. Air bubble can affect the test result due to incorrect amount of sample.
3) If STANDARD Ezi Tube+ is open to room temperature for long time, please use the new STANDARD Ezi Tube+.
4) Make sure to cover the hole on feeder when applying the specimen.

IVD CE REF 90CT15

EC REP **Sungo Cert GmbH .,**
Harffstr47 40591 Düsseldorf, Germany (01)08809899620991

Manufactured by **Jiangsu Kehua Medical Instrument Technology Co., LTD.**
West Industrial Park, Wulie Town, Dongtai City,
Jiangsu Province, China

Marketed by **SD Biosensor, Inc.**
C-4th&5th, 16, Deogyeong-daero 1556beon-gil, Yeongtong-gu,
Suwon-si, Gyeonggi-do, 16690, REPUBLIC OF KOREA

LOT / LOT. NO. | 제조번호 :

/ MFG | 제조년월일 :

S002602002REV.2

STANDARD™

Ezi Tube+ 10㎕

Σ 25PCS

1. 사용목적 : 모세관 현상을 이용하여 혈액을 채취하는 가는 튜브 모양의 기구

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(2) 검체를 채취한 경우 기포가 생기지 않도록 주의하여 주십시오. 기포가 생길 경우, 정확한 양의 혈액을 채취할 수 없습니다

(3) 사용 후 남은 제품은 밀폐하여 보관하여 주십시오.

(4) 혈액 채취 후, 튜브 끝을 천천히 눌러 주십시오.

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품목신고번호 : 경인 수신 13-271 호

수입업자: 에이치엘비생명과학㈜

경기도 안성시 공도읍 용머리큰길 104

제조자 상호 및 주소 : Jiangsu Kehua Medical Instrument Technology Co., Ltd.

West Industrial Park, Wulie Town, Dongtai City, Jiangsu Province, China

부작용 보고 관련 문의처 : 한국의료기기안전정보원, 080-080-4183

일회용 의료기기/재사용 금지

STANDARD™

Ezi Tube+ 10㎕

Σ 25PCS

1. How to use

A. Before usage

1) Check the amount of blood sample needed.
2) Check the length of capillary tube for sample amount.
3) Check the condition of STANDARD Ezi Tube+.

B. How to use

1) Make the blood drop on tip of finger by using lancing device.
2) Put the tip of capillary tube to blood drop and collect the sample.
3) Apply the sample to the testing spot by carefully pushing the head.
4) Discard the used STANDARD Ezi Tube+ at designated place.

2. Caution

1) Used STANDARD Ezi Tube+ can cause infection. Please discard used one at designated place.
2) Be careful not to collect air bubble while sampling. Air bubble can affect the test result due to incorrect amount of sample.
3) If STANDARD Ezi Tube+ is open to room temperature for long time, please use the new STANDARD Ezi Tube+.
4) Make sure to cover the hole on feeder when applying the sample.

IVD CE REF 90CT15

EC REP **Sungo Cert GmbH .,**
Harffstr 47 40591 Düsseldorf, Germany (01)08809899621219

Manufactured by **Jiangsu Kehua Medical Instrument Technology Co., LTD.**
West Industrial Park, Wulie Town, Dongtai City,
Jiangsu Province, China

Marketed by **SD Biosensor, Inc.**
C-4th&5th, 16, Deogyeong-daero 1556beon-gil, Yeongtong-gu,
Suwon-si, Gyeonggi-do, 16690, REPUBLIC OF KOREA

LOT / LOT. NO. | 제조번호 :

/ MFG | 제조년월일 :

S002602502REV.2

2. Instructions for use[1]

[1] 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.

EN REF 02GS11

Cat. No.: 02G6S11, 02G6S11A

STANDARD

G6PD Test

STANDARD™ G6PD Test

PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST

SD BIOSENSOR

EXPLANATION AND SUMMARY

■ Introduction

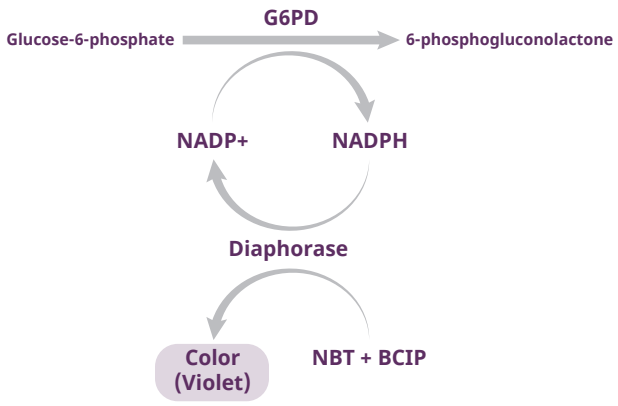
G6PD (glucose-6-phosphate dehydrogenase) deficiency is one of the most common enzymopathological diseases, described as a widespread, heritable, X-chromosome linked abnormality. It is estimated that it aff ects approximately 400 million people worldwide and the prevalence can be as high as 25 percent in ethnic populations originating from Africa, the Middle East, Asia, and the Mediterranean.[1,2] The G6PD enzyme plays an important role in survival of erythrocytes. The G6PD enzyme is involved in the PPP (pentose phosphate pathway) and provides the NADPH (reduced nicotinamide adenine dinucleotide phosphate) and GSH (reduced glutathione). GSH produced by PPP can react with H_20_2 and reduce H_20_2 to H_20. This helps protect erythrocytes from certain generation of oxidative stress.[3,4] The most common medical problem associated with G6PD deficiency is hemolytic anemia, which can lead to paleness, yellowing of the skin and whites of the eyes, dark urine, fatigue, shortness of breath, and a rapid heart rate. The STANDARD G6PD Test is a fast, simple and reliable test system that provides results in 2 minutes and point-of-care diagnosis of G6PD deficiency.

■ Intended use

The STANDARD G6PD System is an enzymatic colorimetric assay intended for the semi-quantitative measurement of G6PD activity in non-anticoagulated capillary (finger-stick) whole blood or venous whole blood (K2-EDTA, sodium heparin, or acid citrate dextrose [ACD]). The STANDARD G6PD Test System is indicated for differentiating normal, intermediate, and deficient G6PD activity levels to aid in the detection of G6PD deficiency in individuals. The test will provide results expressed as the ratio of units of G6PD activity per gram of hemoglobin (G6PD U/g Hb) which can be used to determine G6PD status. Samples which generate a G6PD deficient or intermediate result should be assayed using a quantitative G6PD test to verify a deficiency. T-Hb results are measured in grams per deciliter (g/dL); however, the results are only for internal use for the calculation of G6PD activity in units per gram of hemoglobin. T-Hb results are not displayed on the analyzer screen. The STANDARD G6PD Test System is intended for use by health care professionals in a laboratory or point-of-care environment. The system is for *in vitro* diagnostic use only. This product has been validated for use with individuals aged two years of age and older (children and adults). The STANDARD G6PD Test has not been validated for use with neonatal samples. The STANDARD G6PD Analyzer must be used exclusively with the STANDARD G6PD Test Device, STANDARD G6PD Control, and STANDARD G6PD Check strip manufactured by SD BIOSENSOR.

■ Test principle

The STANDARD G6PD Test contains a flow through STANDARD G6PD Test Device with treated membrane and mesh. The test is based on a colorimetric detection system for the automatic calculation of G6PD activity on the codechip for each test device. G6PD catalyzes the first step in the PPP, oxidizing G6P (glucose-6-phosphate) to 6-phosphogluconolactone and reducing NADP (nicotinamide adenine dinucleotide phosphate) to NADPH. When NADPH is generated by G6PD, the BCIP (5-bromo-4-chloro-3-indolyl-phosphate) and NBT (nitro blue tetrazolium) are reduced by the diaphorase reaction to yield a violet color. The rate of the color production is directly proportional to the concentration of G6PD present in the specimen (see schematic below). The color intensity can be measured through reflectance photometry of the reduced BCIP and NBT. The T-Hb concentration is also measured by reflectance on a separate location on the test device. The STANDARD G6PD Analyzer's screen displays the G6PD enzyme activity in U/g Hb. When the T-Hb is "Lo" or "HI", the test result of the G6PD enzyme activity will be displayed as "N-A". The Analyzer has a temperature monitor and a pre-programmed algorithm corrects the values for temperature as long as the test was run within the operating temperature range of the test (15°C to 40°C / 59°F to 104°F).



MATERIALS PROVIDED

For Cat. No.: 02G6S11	For Cat. No.: 02G6S11A
1. STANDARD G6PD Test Device x 25	1. STANDARD G6PD Test Device x 10
2. Extraction buffer x 25	2. Extraction buffer x 10
3. STANDARD Ezi tube+ (10 µl) x 50	3. STANDARD Ezi tube+ (10 µl) x 20
4. Codechip x 1	4. Codechip x 1
5. Instructions for use x 1	5. Instructions for use x 1

MATERIALS REQUIRED BUT NOT PROVIDED

1. STANDARD G6PD Analyzer
2. STANDARD G6PD Control (Level 1: 1 x 10 ea, Level 2: 1 x 10 ea)
3. Standard blood drawing equipment or lancet, lancing device, alcohol swab

WARNING

1. The test device should not be used beyond the printed expiration date.
2. A test device is for single use only. Do not reuse.
3. Ensure the proper specimen volume for the test device is used. The specimen volume should be at least 10 µl.
4. Do not ingest.
5. Dispose of all specimens and materials used to perform the test as biohazardous waste. Laboratory chemical and biohazardous waste must be handled and discarded in accordance with all local, state, and national regulations.
6. The extraction buffer contains Triton X-100 (3.0%) which can cause serious eye irritation. Follow proper steps for disposal according to applicable regulations for hazardous waste disposal.
7. If exposed to Triton X-100, immediately wash the affected area thoroughly with soap and water for at least 15 minutes. If irritation persists, seek medical attention. In case of eye exposure, rinse thoroughly with running water for at least 15 minutes and consult a doctor.

PRECAUTIONS

1. The STANDARD G6PD Test device should only be used with the STANDARD G6PD Analyzer.
2. Make sure the codechip and the code number printed on the test device pouch match.
3. The test should be performed at 15°C to 40°C / 59°F to 104°F (10-93% RH, Relative Humidity).
4. Reagents should be brought to room temperature (15 ~25°C) when stored at 2 ~ 8°C.
5. Components from different lots and reagent kits should not be exchanged. Reagents should not be pooled.
6. Insert a test device and codechip into the test device slot and the codechip slot of the analyzer, respectively.
   - Insert a test device into the test device slot with blood application chamber facing up and toward the analyzer.
   - Insert a codechip into the codechip slot with the surface printed with the code number facing up and toward the analyzer.
   - Insert a test device into the analyzer gently until it will go no further.
7. Do not apply mixed specimen on another site except blood application area of a test device.
8. Quality control values outside of acceptable ranges indicate potential instability or deterioration. In such cases, users should:
   - Verify that the test was performed accurately according to the user guide.
   - Check the code number on the test strip matches the number on the code chip.
   - Confirm the expiration dates of both the test strip and the quality control.
   - Retest the quality control using a new test strip.
   - If the retest result is still invalid, discontinue use and contact SD BIOSENSOR or your local representative of SD BIOSENSOR.

KIT STORAGE AND STABILITY

1. The sealed pouch containing the test device may be stored at 2°C to 30°C / 36°F to 86°F out of direct sunlight for the duration of its shelf life.
2. The test device and buffer must remain in the sealed pouch until use and should be used immediately after removal from the device pouch and opening the buffer lid (within 5 minutes).
3. DO NOT FREEZE, but test device may be stored in a refrigerator at 2°C to 8°C / 36°F to 46°F.
4. Do not use beyond the expiration date.
5. Keep the codechip either in the analyzer or the test device package.
6. Allow the test device to be at room temperature (15 ~ 25°C) at least 1 hour before starting the test.

SPECIMEN COLLECTION AND PREPARATION

■ Whole blood

[Capillary whole blood]

1. Capillary whole blood should be collected aseptically by fingertip.
2. Select the ring or index finger for sampling. Avoid calloused areas of the finger.
3. Clean the area to be lanced with an alcohol swab. Allow the area to air dry prior to sample collection.
4. Squeeze the end of the fingertip and pierce with a sterile lancet.
5. Wipe away the first drop of blood and allow a second drop to form.
6. Collect the capillary whole blood using the Ezi tube+ (10 uL); it must be tested immediately after collection.
7. Do not milk the finger during collection to avoid diluting the specimen.

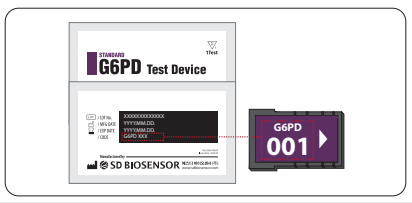
[Venous whole blood]

1. Collect the venous whole blood into a commercially available anticoagulant tube, such as K2-EDTA, sodium heparin, or ACD by venipuncture.
2. The venous blood treated by K2-EDTA, sodium heparin, or ACD should be tested within 4 hours at room temperature within the operating temperature range (15 ~ 40°C).
3. If stored venous blood treated by K2-EDTA, sodium heparin, or ACD is kept in a refrigerator (2 ~ 8°C), the specimen blood can be used for testing within 5 days (120 hours) after collection.

TEST PROCEDURE

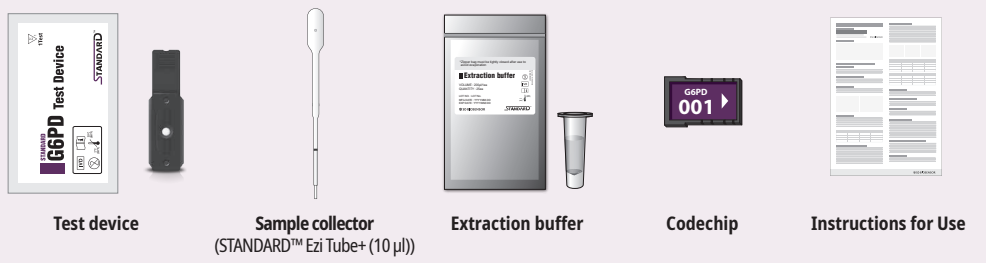
■ Preparation

1. Check the expiration date printed on a test device pouch.
2. Check the code number on the codechip matches the code number printed on the test device pouch.



Make sure the code number printed on the test device pouch and the codechip match.

■ Components

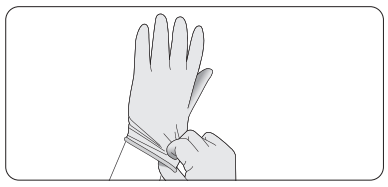


Test device	Sample collector (STANDARD™ Ezi Tube+ (10 µl))	Extraction buffer	Codechip	Instructions for Use

3. Insert a new codechip until it snaps into place.
4. Turn on the analyzer; the codechip number will appear on the screen.
5. Make sure the codechip number matches with the number on the screen.

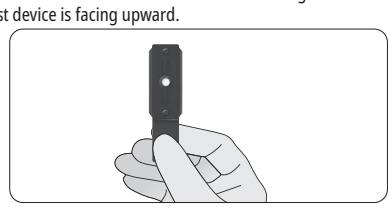
- Make sure the analyzer is turned off.
- Remove an old codechip if one is installed.
- Refer to the analyzer manual for detailed display information.

6. Put on gloves. Use new gloves for each patient.

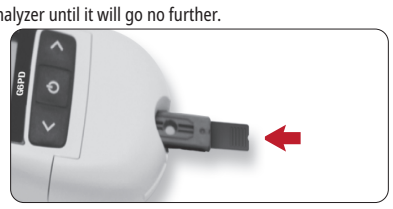


7. Open the test device pouch and take out a test device.
   ※ Use the test device within 5 minutes after opening the pouch.

8. Hold the test device with thumb and index finger so that the upper test device is facing upward.

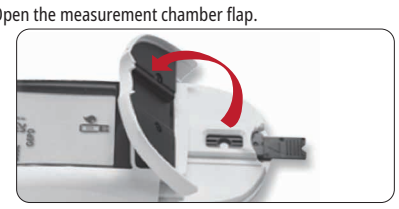


9. Insert the test device into the test device slot of a STANDARD G6PD Analyzer until it will go no further.



10. The screen will display 'OPE'.

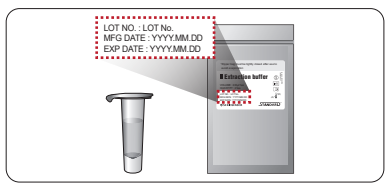
11. Open the measurement chamber flap.



※Make sure to check that the analyzer is in testing mode, not control mode. Performing the test in control mode can give an inaccurate result.

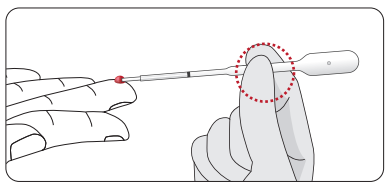
■ Specimen Collection

1. Open the extraction buffer pouch. Take out the extraction buffer and open the extraction buffer lid.
   ※An extraction buffer should not be used beyond the printed expiration date, EXP.
   ※Use the buffer within 5 minutes after opening buffer lid.

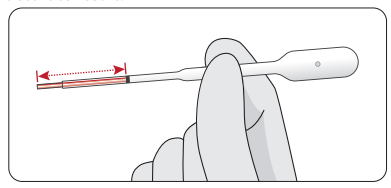


[Capillary whole blood]

2-a Hold the STANDARD Ezi tube+ (10 µl) horizontally, and touch the tip of STANDARD Ezi tube+ (10 µl) to the blood specimen (10 µl).

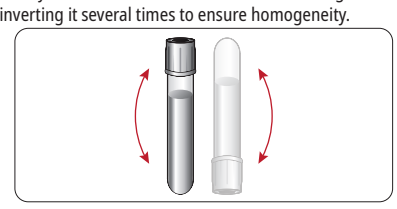


2-b. Capillary action will automatically draw the specimen to the black line and stop.
※Insufficient or excessive volume of specimen causes an inaccurate result.

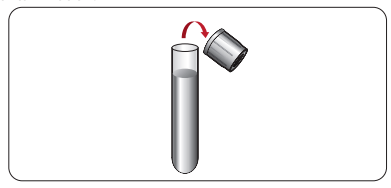


[Venous whole blood]

2-A. Gently mix the venous blood in the anticoagulant tube by inverting it several times to ensure homogeneity.



2-B. Open the anticoagulant tube carefully to avoid spillage or contamination.



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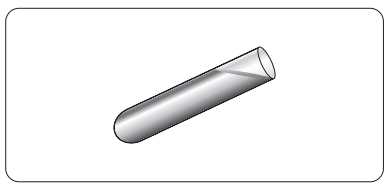
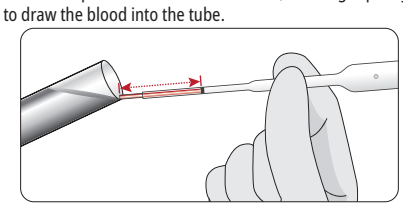
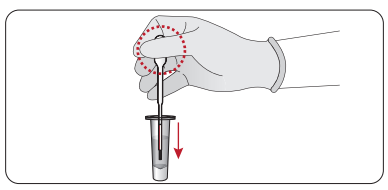
2-C. Tilt the tube slightly to allow the blood to pool near the opening.



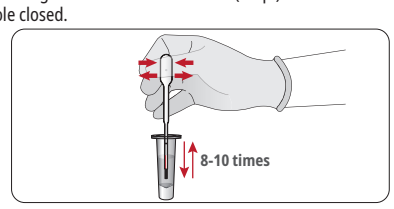
2-D. Hold the STANDARD Ezi-Tube+ (10 µl) at a slight angle and gently touch the open end to the blood surface, allowing capillary action to draw the blood into the tube.



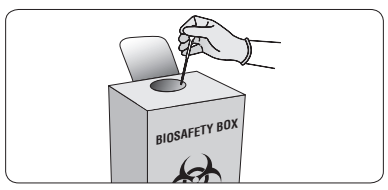
3. Place the STANDARD Ezi tube+ (10 µl) with the specimen into the extraction buffer.



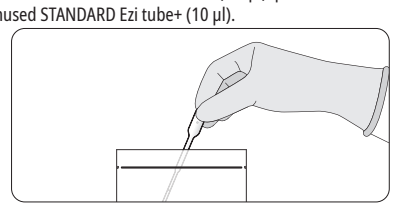
4. Mix the collected specimen with the extraction buffer, pressing and releasing the STANDARD Ezi tube+ (10 µl) 8 to 10 times with the hole closed.



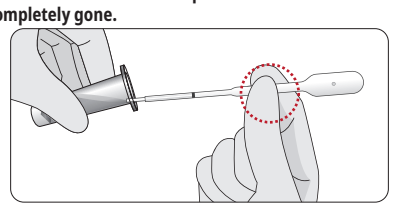
5. Discard the STANDARD Ezi tube+ (10 µl) in a biosafety box.



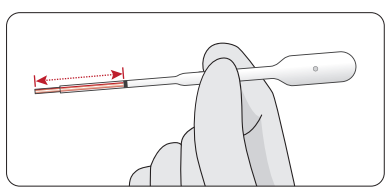
6. Open the STANDARD Ezi tube+ (10 µl) pouch and take out an unused STANDARD Ezi tube+ (10 µl).



7. Hold the STANDARD Ezi tube+ (10 µl) horizontally, and touch the tip of STANDARD Ezi tube+ (10 µl) to the mixed specimen.
※Do not collect mixed specimen until the bubbles are completely gone.



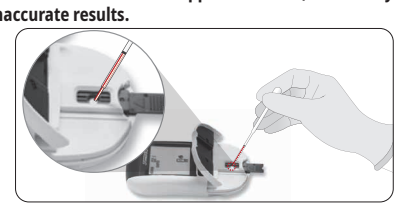
8. Capillary action will automatically draw the mixed specimen to the black line and stop.



※Insufficient or excessive volume of specimen causes an inaccurate result.
※Apply the sample mixture within 1 minute after mixing the blood sample and extraction buffer solution. Failure to apply the sample-extraction buffer within one minute will lead to an inaccurate result.

■ Operation

1. Apply the mixed specimen to the specimen application hole of the test device.
※When applying the specimen to the specimen application hole, gently press the bulb of the Ezi tube+(10µl). Do not touch the Ezi tube to the application hole, which may lead to inaccurate results.

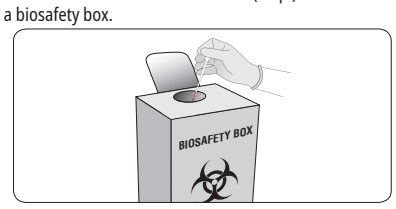


2. The screen will display 'Clo' to close.

3. Close the measurement chamber flap immediately after applying.
※Exposing the test device to direct and strong light may cause false results.

4. The analyzer will automatically count down from 2 minutes once the flap is closed.
※Do not open the chamber flap while it is counting down.

5. Discard the used STANDARD Ezi tube+ (10 µl) and extraction buffer in a biosafety box.



6. After 2 minutes of reaction time, the test result will be appear on the screen.

An E-7 error occurs if the flap is open for 20 seconds after applying the control material (specimen), or the flap is opened during measurement.

MEASURING RANGES

STANDARD G6PD Test measures G6PD activity of numerical values as the following ranges.

G6PD	0-20 U/g Hb

If the result is outside of the measuring range, the STANDARD G6PD Analyzer will display a "Lo" or "HI" message.

- STANDARD G6PD only displays the G6PD values. However, it measures T-Hb values internally as well which is not shown on the analyzer. If the T-hb values are lesser than 7 g/dL or higher than 25 g/dL, the test result of the G6PD enzyme activity will be displayed as "N-A".
- When G6PD activity is higher than 20, the test result of the G6PD enzyme activity will be displayed as "HI".
- When G6PD activity is lower than 0, the test result of the G6PD enzyme activity will be displayed as "Lo".

Lo	Below the measuring range (Low)
HI	Above the measuring range (High)

INTERPRETATION OF TEST RESULT

Male		Female	
G6PD Deficient*	≤ 4.0 U/g Hb	G6PD Deficient*	≤ 4.0 U/g Hb
G6PD Normal	≥ 4.1 U/g Hb	G6PD Intermediate**	4.1-6.0 U/g Hb
		G6PD Normal	≥ 6.1 U/g Hb

* Deficient was determined during clinical evaluation as approximately 30% of the adjusted male median of specimens tested.
** Intermediate was determined during clinical evaluation as females with activity greater than 30% and less than or equal to 70% of the adjusted male median.

LIMITATIONS OF THE PROCEDURE

- In cases of severe anemia, extremely elevated white blood cell counts, or very low levels of red cell G6PD activity, the contribution of white blood cell G6PD activity to the total may be significant, and may result in false normal. White blood cell depletion may correct for this.[5]
- Specimens collected from patients who have haemolytic anaemia may give inaccurate results.

PERFORMANCE CHARACTERISTICS

1. Method comparison

To demonstrate the accuracy of the STANDARD G6PD Test System, fresh prospective venous and capillary whole blood was collected from participants at four (4) clinical sites and then tested on the STANDARD G6PD Test System in a point-of-care setting.[6] Performance of the G6PD result is shown in the tables below.

Venous G6PD Performance

		Reference			Total	Agreement (95% CI)
		Deficient	Intermediate	Normal		
SD Biosensor	Deficient	117	28	35	180	100.0% (96.9% - 100.0%)
	Intermediate*	0	33	84	117	42.3% (31.2% - 54.0%)
	Normal	0	17	3,646	3,663	96.8% (96.2% - 97.4%)
Total		117	78	3,765	3,960	95.9% (95.2% - 96.5%)

Capillary G6PD Performance

		Reference			Total	Agreement (95% CI)
		Deficient	Intermediate	Normal		
SD Biosensor	Deficient	120	24	45	189	100.0% (96.9% - 100.0%)
	Intermediate*	0	36	97	133	45.0% (33.8% - 56.5%)
	Normal	0	20	3,680	3,700	96.3% (95.6% - 96.9%)
Total		120	80	3,822	4,022	95.4% (94.7% - 96.0%)

*Intermediate only includes female participants.

Samples with an intermediate result may be overestimated using the STANDARD G6PD Test. Samples which generate a G6PD deficient or intermediate result should be assayed using a quantitative G6PD test to verify a deficiency.

2. Sensitivity

Limit of Blank (LoB) and Limit of Detection (LoD) studies were performed to determine the sensitivity of the assay. The sensitivity was determined as shown below.

G6PD (U/g Hb)	
LoB	LoD
0.06	0.44

3. Precision

Precision study was performed using 9 venous sample spanning the analytical ranges for G6PD.

Sample	N	Mean	Within-Run (SD, %CV)	Between-Run (SD, %CV)	Between-Day (SD, %CV)	Total (SD, %CV)
G6PD – L1	80	1.12	0.21, 18.7%	0.08, 6.9%		0.22, 19.9%
G6PD – L2	80	3.24	0.30, 9.4%	0.09, 2.6%		0.32, 9.8%
G6PD – L3	80	6.23	0.45, 7.2%		0.16, 2.6%	0.48, 7.6%
G6PD – L4	80	8.94	0.34, 3.9%		0.17, 1.9%	0.39, 4.3%

Capillary whole blood precision was determined by testing multiple capillary whole blood samples from individuals with varied G6PD concentrations. A total of 120 samples were tested from 15 participants resulting in a standard deviation of 0.64 U/g Hb G6PD.

4. Linearity

Linearity was determined for G6PD activity.

G6PD
0 - 20 U/g Hb

5. Interference

Interference studies have been conducted to determine the level of interference. Samples spiked with potentially interfering materials at the following concentrations were shown to have no effect on assay performance.

No.	Interfering Substance	Interfering Level	No.	Interfering Substance	Interfering Level
1	Total cholesterol	250 mg/dL addition	8	Ascorbic acid	3.0 mg/dL addition
2	Bilirubin	1.0 mg/dL addition	9	Dopamine	0.9 mg/dL addition
3	Protein	8.0 g/dL addition	10	Uric acid	9.0 mg/dL addition
4	Lactic acid	23.4 mg/dL addition	11	Aspirin	4.34 mM/L addition
5	Copper chloride	0.1 mM/dL addition	12	Paracetamol	3.0 mg/dL addition
6	Copper sulfate	0.1 mM/dL addition	13	Ibuprophen	50 mg/dL addition
7	Abnormally hemocrit	66%	14	Caffeine	5.15 mM/L addition

QUALITY CONTROL

[STANDARD G6PD Analyzer check strip test]

The STANDARD G6PD Check Strip test should be conducted according to STANDARD G6PD Analyzer's manual to check that analyzer is working properly. STANDARD G6PD Analyzer package contains a check strip and it is re-usable.

When to use :

1. Once for using your analyzer for the first time.
2. Once for your result does not agree with the test result you expected.
3. Once for replacing the batteries or cleaning the analyzer.
4. Once if the analyzer has been dropped.

EXTERNAL QUALITY CONTROL

[STADNARD G6PD Control]

Quality control testing can be optionally run to check the performance of STANDARD G6PD Test and STANDARD G6PD Analyzer. STANDARD G6PD Control (Cat. no.: 02G6C11) manufactured by SD BIOSENSOR should be used for quality control testing in accordance with the instructions of STANDARD G6PD Control.
External quality control test is recommended:

- Once for opening a new test device packaging (new lot number).
- Once for your result does not agree with the test result you expected.
- As required by test procedures in instructions STANDARD G6PD Control and in accordance with local, state and federal regulations or accreditation requirements.

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IVD

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REF Reference number | IVD *In vitro* Diagnostics | Consult Instructions for Use | Contains Sufficient for <n> Tests | Caution | Note | Do not re-use. | Use by | LOT Batch code | Manufacturer | Date of manufacture | Indicate that you should keep the product dry | Keep away from sunlight | Do not use if packaging is damaged | To indicate the temperature limitations in which the transport package has to be kept and handled.