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Rev #:00

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

PUBLIC ASSESSMENT REPORT FOR JUSCHEK HCG PREGNANCY RAPID TEST DIPSTICK

Version number 2.0, 26.05.2026

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1. Introduction

JusCheck is a class B in-vitro diagnostic device belonging to the immunology specialty category. It is approved in Tanzania as a single invitro diagnostic device for use in women in reproductive age by healthcare professionals only.

1.1. Administrative Information

Registration number	TAN 23 MDR 0200
Brand Name (if relevant)	JusCheck
Common name	HCG Pregnancy Rapid Test Dipstick (Urine)
Class of the device and rule applied	B according to rule 4 of In vitro diagnostics classification
GMDN code and term	33819, Total human chorionic gonadotropin IVD, kit, rapid ICT, clinical
Name and complete address of the Market Authorization Holder	Hangzhou Alltest Biotech Co., LTD 550, Yinhai Street, Hangzhou Economy and Technology Development Area Hangzhou, P.R. China
Name and address(es) of local responsible person (LRP).	BB Pharma Consultancy Limited, P.O. Box 31338, Mabibo External, EPZA, Dar es Salaam, Tanzania.

1.2. Assessment Procedure

The application for registration of JusCheck was submitted 03.07.2023. The product underwent full assessment. Assessment was completed in 1 round of evaluation. JusCheck was registered on 23.08.2023.

2. Technical information

2.1. Intended use

The intended use of JusCheck as declared by the manufacturer and approved by TMDA is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin in urine to aid in the early detection of pregnancy. JusCheck is approved for use in healthcare settings and point of care by trained personnel.

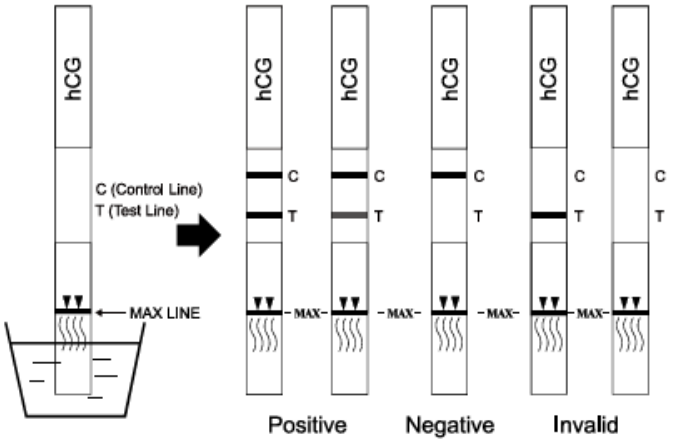
2.2. Device details and features

JusCheck has been registered as a single invitro diagnostic device.

JusCheck is a manually operated device. It is used for screening of early pregnancy. JusCheck operates by rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin in urine to aid in the early detection of pregnancy. The test uses two lines to indicate results. The test utilizes a combination of antibodies including a monoclonal hCG antibody to selectively detect elevated levels of hCG. The control line is composed of goat polyclonal antibodies and colloidal gold particles. The assay is conducted by immersing the test dipstick in a urine specimen and observing the formation of colored lines. The specimen migrates via capillary action along the membrane to react with the colored conjugate. Positive specimens react with the specific antibody-hCG-colored conjugate to form a colored line at the test line region of the membrane. Absence of this colored line suggests a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred. The test out-put is qualitative.

The type of specimen used is urine and is collected by urinating in a dry and clean container.

(T) after an extended period of time. Do not interpret the **result after 10 minutes.**



2.3. Commercial presentation

There is one approved commercial presentation as follows: 1 strip in the primary foil pouch as primary package. 50 foil pouches in secondary pack are placed in carton box.

Additional contents include Instructions for Use document.

2.4. Items required but not submitted

Sample collection container and timer.

3. Storage instructions

3.1.1. Shelf-life

The approved shelf-life is 24 months.

3.1.2. Storage conditions

The recommended storage conditions are 2°C to 30°C

3.1.3. Shipping conditions

The recommended shipping conditions is 30% to >=80%relative humidity, -20 to 55°C temperature conditions for 36 months.

4. Manufacturing site audit

The manufacturer of the device is Hangzhou All Test Biotech Co., LTD,550, Yinhai Street, Hangzhou Economy and Technology Development Area Hangzhou, Hangzhou, P.R. China.

5. Performance Evaluation

5.1. Analytical Performance

The analytical performance characteristics of the device was established through the following test parameters: Precision (repeatability and reproducibility), analytical sensitivity, analytical specificity, High-Dose Hook Effect (Prozone Effect) and interference study.

5.2. Clinical Performance

Clinical performance was conducted at Guangxi Zhuang Autonomous Region Institute of Skin Disease Prevention and Control. The following parameters were tested clinical sensitivity and clinical specificity.

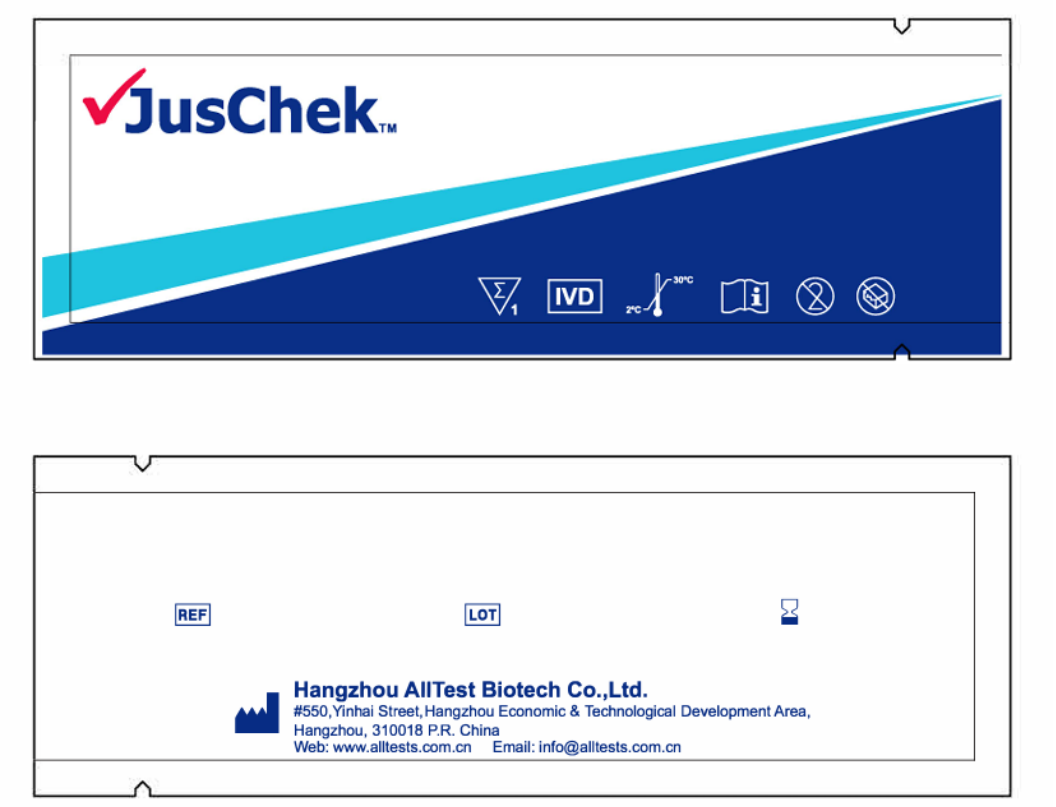
Based on results of the performance studies, it was concluded that the test clinical sensitivity and clinical specificity is 99.9% and 99.9% respectively. The studies further concluded that JusCheck is capable of consistently producing accurate and reliable test output.

6. Product label and instructions for use

The content of the primary and secondary labels is in line with TMDA labeling requirements in terms of content, layout and design. The label contains sufficient information for proper identification of the device and post marketing follow up of the product in the market.

The package insert includes all the relevant information to ensure correct and safe use of the device by intended user.

6.1. Primary pack



6.2. Secondary pack



6.3 Instructions for use/Package insert

See on last page

7. Risk – Benefit Analysis

On basis of the data submitted, the current state of knowledge and compliance of the manufacturer to ISO 13485, the benefit of the product outweighs the risks associated with its use when used in accordance to the manufacturer instruction. JusCheck is recommended for registration.

8. Post-approval updates

8.1 Variation applications

Reference number	Date submitted	Change requested	Recommendation	Granting date
None	None	None	None	None

8.2 Feedback from pharmacovigilance, post marketing surveillance and enforcement activities

Type of feedback	Impact	Response
None recorded	None recorded	None recorded

8.3 Re-registration applications

Not applicable.

JusChek

hCG Pregnancy Rapid Test Dipstick (Urine) Package Insert

REF FHC-101/111	English

A rapid test for the qualitative detection of human chorionic gonadotropin (hCG) in human urine.

For professional in vitro diagnostic use only.

INTENDED USE

The hCG Pregnancy Rapid Test Dipstick is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin in human urine to aid in the early detection of pregnancy.

SUMMARY

Human chorionic gonadotropin (hCG) is a glycoprotein hormone produced by the developing placenta shortly after fertilization. In normal pregnancy, hCG can be detected in both urine and serum or plasma as early as 7 to 10 days after conception.[1,2,3,4]hCG levels continue to rise very rapidly, frequently exceeding 100 mIU/mL by the first missed menstrual period[2,3,4] and peaking in the 100,000-200,000 mIU/mL range about 10-12 weeks into pregnancy. The appearance of hCG in both the urine and serum or plasma soon after conception, and its subsequent rapid rise in concentration during early gestational growth, make it an excellent marker for the early detection of pregnancy.

hCG Pregnancy Rapid Test Dipstick is a rapid test that qualitatively detects the presence of hCG in urine specimen at the sensitivity of 25 mIU/mL. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of hCG in urine. At the level of claimed sensitivity, hCG Pregnancy Rapid Test Dipstick shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH and hTSH at high physiological levels.

PRINCIPLE

The hCG Pregnancy Rapid Test Dipstick is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin in urine to aid in the early detection of pregnancy. The test uses two lines to indicate results. The test utilizes a combination of antibodies including a monoclonal hCG antibody to selectively detect elevated levels of hCG. The control line is composed of goat polyclonal antibodies and colloidal gold particles. The assay is conducted by immersing the test dipstick in a urine specimen and observing the formation of colored lines. The specimen migrates via capillary action along the membrane to react with the colored conjugate. Positive specimens react with the specific antibody-hCG-colored conjugate to form a colored line at the test line region of the membrane. Absence of this colored line suggests a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test contains anti-hCG particles and anti-hCG coated on the membrane.

PRECAUTIONS

Please read all the information in this package insert before performing the test.

- For professional *in vitro* diagnostic use only. Do not use after the expiration date
- The test should remain in the sealed pouch or closed canister until ready to use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test should be discarded according to local regulations.

STORAGE AND STABILITY

Store as packaged at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch or label of the closed canister. The test must remain in the sealed pouch or closed canister until use. **DO NOT FREEZE.** Do not uses beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Urine Assay

A urine specimen must be collected in a clean and dry container. A first morning urine specimen is preferred since it generally contains the highest concentration of hCG; however, urine specimens collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

Specimen Storage

Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

MATERIALS

Materials provided

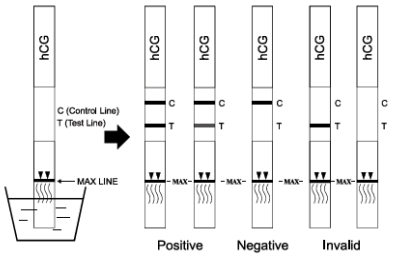
• Test dipsticks • Package insert

Materials required but not provided

• Specimen collection containers • Timer

DIRECTIONS FOR USE

1. Bring the pouch or canister to room temperature before opening it. Remove the test dipstick from the sealed pouch or closed canister and use it within one hour.
   NOTE: For canister packaging, immediately close the canister tightly after removing the required number of the test dipstick(s). Record the initial opening date on the canister. Once the canister has been opened, the remaining test dipstick(s) are stable for 90 days only.
2. With arrows pointing toward the urine specimen, immerse the test dipstick vertically in the urine specimen for **at least 15 seconds**. Do not pass the maximum line (MAX) on the test dipstick when immersing the dipstick. See illustration below.
3. Place the test dipstick on a non-absorbent flat surface, start the timer and wait for the colored line(s) to appear. The result should be read at 3 minutes.
   NOTE: A low hCG concentration might result in a weak line appearing in the test line region (T) after an extended period of time. Do not interpret the **result after 10 minutes.**



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE: Two colored lines appear. One colored line should be in the control line region (C) and another colored line should be in the test line region (T). One line may be lighter than the other; they do not have to match. This means that you are probably pregnant.

NEGATIVE: * One colored line appears in the control line region (C). No colored line appears in the test line region (T). This means that you are probably not pregnant.

INVALID: Control line fails to appear. The result is invalid if no colored line appears in the control line region (C), even if a line appears in the test line region (T). You should repeat the test with a new test dipstick.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative procedural control. If a background color appears in the result window and interferes with the ability to read the test result, the result may be invalid. It is recommended that a positive hCG control (containing 25-250 mIU/mL hCG) and a negative hCG control (containing "0" mIU/mL hCG) be evaluated to verify proper test performance when a new shipment of tests is received.

LIMITATIONS

1. hCG Pregnancy Rapid Test Dipstick is a preliminary qualitative test, therefore, neither the quantitative value nor the rate of increase in hCG can be determined by this test.
2. Very dilute urine specimens, as indicated by a low specific gravity, may not contain representative levels of hCG. If pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested.
3. Very low levels of hCG (less than 50 mIU/mL) are present in urine specimens shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons, a test result that is weakly positive should be confirmed by retesting with a first morning urine specimen collected 48 hours later.[5]
4. This test may produce false positive results. A number of conditions other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasms including testicular tumors, prostate cancer, breast cancer, and lung cancer, cause elevated levels of hCG.[6,7] Therefore, the presence of hCG in urine should not be used to diagnose pregnancy unless these conditions have been ruled out.
5. This test may produce false negative results. False negative results may occur when the levels of hCG are below the sensitivity level of the test. When pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested. In case pregnancy is suspected and the test continues to produce negative results, see a physician for further diagnosis.
6. This test provides a presumptive diagnosis for pregnancy. A confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

EXPECT VALUE

Negative results are expected in healthy non-pregnant women and healthy men. Healthy pregnant women have hCG present in their urine and serum specimens. The amount of hCG will vary greatly with gestational age and between individuals. hCG Pregnancy Rapid Test Dipstick for Urine has a sensitivity of 25 mIU/mL, and is capable of detecting pregnancy as early as 1 day after the first missed menses.

PERFORMANCE CHARACTERISTICS

Accuracy

A multi-center clinical evaluation was conducted comparing the results obtained using the hCG Pregnancy Rapid Test Dipstick to another commercially available urine hCG Rapid test. The study included 608 urine specimens, and both assays identified 231 positive and 377 negative results. The results demonstrated >99% overall accuracy of hCG Pregnancy Rapid Test Dipstick when compared to the other hCG Rapid Test.

Method		Other hCG Rapid Test		Total Results
hCG Pregnancy Rapid Test Dipstick	Results	Positive	Negative	
	Positive	231	0	231
	Negative	0	377	377
Total Results		231	377	608

Sensitivity: ＞99.9% (98.7%~100%)* Specificity: ＞99.9% (99.2%~100%) *

Accuracy: ＞99.9% (99.5%~100%) * * 95% Confidence Intervals

Sensitivity and Cross-Reactivity

The hCG Pregnancy Rapid Test Dipstick detects hCG at a concentration of 25 mIU/mL or greater. The test has been standardized to the W.H.O. International Standard. The addition of LH (300 mIU/mL), FSH (1,000 mIU/mL), and TSH (1,000 μIU/mL) to negative (0 mIU/mL hCG)

and positive (25 mIU/mL hCG) specimens showed no cross-reactivity.

Precision

Intra-Assay

Within-run precision has been determined by using 10 replicates of four specimens containing 25 mIU/mL, 100 mIU/mL, 250 mIU/mL and 0 mIU/mL of hCG. The negative and positive values were correctly identified 100% of the time.

Inter-Assay

Between-run precision has been determined by using the same four specimens of 25 mIU/mL, 100 mIU/mL, 250 mIU/mL and 0 mIU/mL of hCG in 10 independent assays. Three different lots of the hCG Pregnancy Rapid Test Dipstick have been tested. The specimens were correctly identified 100% of the time.

Interfering Substance

The following potentially interfering substances were added to hCG negative and positive specimens.

Acetaminophen	20 mg/dL	Caffeine	20 mg/dL
Acetylsalicylic Acid	20 mg/dL	Gentisic Acid	20 mg/dL
Ascorbic Acid	20 mg/dL	Glucose	2 g/dL
Atropine	20 mg/dL	Hemoglobin	1 mg/dL
Bilirubin	2 mg/dL		

None of the substances at the concentration tested interfered in the assay.

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2. Catt KJ, ML Dufau, JL Vaitukaitis Appearance of hCG in pregnancy plasma following the initiation of implantation of the blastocyte, J. Clin. Endocrinol. Metab. 1975; 40(3): 537-540.
3. Braunstein GD, J Rasor, H. Danzer, D Adler, ME Wade Serum human chorionic gonadotropin levels throughout normal pregnancy, Am. J. Obstet. Gynecol. 1976; 126(6):678-681.
4. Lenton EA, LM Neal, R Sulaiman Plasma concentration of human chorionic gonadotropin from the time of implantation until the second week of pregnancy, Fertil. Steril. 1982;37(6): 773-778.
5. Steier JA, P Bergsjo, OL Myking Human chorionic gonadotropin in maternal plasma after induced abortion, spontaneous abortion and removed ectopic pregnancy, Obstet. Gynecol.1984; 64(3): 391-394.
6. Dawood MY, BB Saxena, R Landesman Human chorionic gonadotropin and its subunits in hydatidiform mole and choriocarcinoma, Obstet. Gynecol. 1977; 50(2): 172-181.
7. Braunstein GD, JL Vaitukaitis, PP Carbone, GT Ross Ectopic production of human chorionic gonadotropin by neoplasms", Ann. Intern Med. 1973; 78(1): 39-45.

Index of Symbols

	Caution		Tests per kit		Consult Instructions For Use
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C		Lot Number	REF	Catalog #
	Do not use if package is damaged		Manufacturer		

Hangzhou AllTest Biotech Co.,Ltd.
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