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Your early warning system

REAGENT BASED URINALYSIS TEST
 For the rapid determination of Blood traces in urine.
PRODUCT NAME: IcleTest

INTENDED USE AND DESCRIPTION OF DEVICE

IcleTest is a DIY at home self test for In Vitro Diagnostic use only to identify blood in urine. Test result may provide information regarding the status of kidney infections, kidney stones, urethritis, cystitis, enlarged prostate gland, prostate / bladder / kidney cancers. It is measured by a reagent test paper attached to a plastic strip and gives a Yes / No test result. The test strip is read visually. Your IcleTest contains a reagent strip for testing for blood in the urine, a plastic arm for attaching the strip and placing over the toilet so it is not contaminated, and Instructions for Use.

It is recommended to use IcleTest at the first passing of urine in the morning.

WARNING AND PRECAUTIONS

If you are using any form of medication while intending to use this test, please seek further medical advice as the medication being used may affect test results.

The vacuum packaging of the IcleTest reagent strip will contain a desiccant to sustain a state of dryness. **It is not intended for any part of IcleTest or its packaging to be ingested. If you do so, please seek immediate medical advice.**

TEST PROCEDURE

Please Note: Do not touch the yellow test pad area of the test strip when attaching the test strip to the test arm. Attach the test strip via the white area of the test strip only.

The procedure must be followed exactly to achieve reliable results.

- 1) Open up the outer packaging of the box.
- 2) Remove the vacuum packed test strip and test arm from packaging (Image 1).
- 3) Please wash hands thoroughly before proceeding (Image 2).
- 4) Open vacuum packed test strip immediately before use where indicated, then remove test strip from vacuum pack. DO NOT touch the yellow test pad when doing so, as this could corrupt test results (Image 3).

IMPORTANT NOTICE

Icle Test Limited does not practice medicine or provide medical services or advice. The contents of this package (The IcleTest DIY Men's Health Blood in Urine Test) are not intended to be a substitute or replacement for medical advice or for a medical examination by a qualified healthcare professional. The IcleTest DIY Men's Health Blood in Urine Test is intended to be an aid to early diagnosis of Men's health issues only and is not intended to provide a diagnosis of any specific medical condition; It is intended only to detect blood in urine. A negative result should not be relied on in substitution for medical advice or for a medical examination by a qualified healthcare professional. If the test is positive please arrange to see a qualified healthcare professional.

- 5) Remove adhesive protection from reverse of test strip (Image 4).
- 6) Attach test strip to front of test arm by pressing (white part only) firmly together to ensure proper adhesion. DO NOT touch yellow test pad when doing so (Image 5).
- 7) Flush toilet prior to applying test to ensure toilet bowl is urine free (Image 6).
- 8) Open extendable part of test arm and attach to side of toilet bowl immediately (Image 6 & 7). Please Note: No part of IcleTest should be in touch with toilet water when in position (Image 7).
- 9) Once attached to the toilet bowl pass urine over the (yellow) test pad, ensuring the best coverage of test pad as possible (Image 8).
- 10) **Wait a minimum of 20 seconds and a maximum of 60 seconds for the test result. Test pad remains YELLOW = NO traces of blood present. Test pad changes to GREEN/BLUE = YES traces of blood detected. If YES please seek further medical advice (Image 8).**
- 11) After use remove test from toilet bowl and dispose of via household waste (Image 9).
- 12) Please wash hands thoroughly once all previous steps have been completed (Image 10).

Q&A - BEFORE TEST

How should I store the device?

Store in a cool, dry place at temperatures between 2° to 30°. Do not store IcleTest in a refrigerator or freezer. Store away from moisture and light.

What should I do if the package is damaged?

For best performance and consistent result of reagent test strip it should be in its sealed, unopened vacuum packaging prior to test being carried out.

How does the test work?

The test is based on the Pseudo-peroxidase activity of the haem moiety of haemoglobin and myoglobin in blood. The chromogen on the test strip (yellow part) is oxidized by a hydroperoxide in the presence of haem and changes colour from Yellow to Green/Blue. Ingredients; Cumene Hydroperoxide 12mg, o-Tolidine 35mg

Q&A - SETTING UP ICLETEST

What should I do if reagent strip is discoloured (green / blue) when removed from packaging?

Check packaging to confirm that the product is within its expiration date.

What happens if I touch the reagent test pad (yellow) area during assembly?

If you have washed your hands then proceed with test.
 If you have not washed your hands and have only touched part of the test pad then proceed with caution.
 If you have not washed your hands and have touched all of the test pad then do not proceed with test as possibility of false negative result.

RETURNS POLICY

As a customer, you have the right to return any unwanted items within 28 days of the receipt of purchase. You may receive a full refund providing the product is returned unopened, and in saleable condition. Please complete the provided returns note, stating reason for return and a full refund will be processed. Items that are dated after 28 days cannot be returned unless the item is proven to be faulty.

Faulty goods: Please contact returns@icletest.co.uk to report the fault and apply for a faulty goods returns envelope. Please Note: We do not refund shipping costs for returns, and any additional confirmation/insurance costs are the responsibility of the customer.

When should I attach the test strip to the test arm?

Once the reagent test strip has been removed from its individual packaging it should be attached to the test arm and used immediately.

Do I need to cover the entire test pad area with urine?

No, as any quantity of blood (above the detection limit) will cause reagent pad to change colour from yellow to green / blue.

Q&A – INTERPRETING THE RESULT

How long should I wait before reading the result?

As stated in step 8 you should wait a minimum of 20 seconds and a maximum of 60 seconds. Do not leave the test pad lying around for longer than this as it could cause discolouration and void the result.

What does it mean if the reagent pad fully or partially changes colour (green / blue)?

Blood is present in urine tested that is at or above 10-15 RBC/µl detection limit.

What does it mean if the reagent pad does not change colour (stays yellow)?

Blood is not present or below the detection limit of the test.

Can any medication / substances produce false positive results?

Yes, microbial peroxidase associated with urinary tract infection or high-buffered acidic urine, may increase the reactivity of the test.

Can any medication / substances produce false negative results?

Yes, ascorbic acid concentrations (>40 mg/dl), high-buffered alkaline urine, elevated specific gravity or protein in urine may reduce the reactivity of the test.

Is blood in urine normal?

No, hemoglobin is not normally detectable in urine.

If any change in colour is noticed having conducted the test then seek medical assistance to determine cause.

Are there any limitations of the procedure?

Yes, the variability of colour perception, the presence or absence of inhibitory and matrix factors typically found in urine, and the conditions in which the product is used (i.e. lighting, temperature, and humidity).

IF IN ANY DOUBT OR YOUR TEST IS POSITIVE PLEASE SEEK MEDICAL ASSISTANCE.

	Manufacturer		Do not re-use
	Use - by date		Temperature limits
	Batch Number		Keep away from sunlight
	IVD device		Do not use if damaged
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1 Remove vacuum packed test strip and test arm from outer packaging

Vacuum Pack
Test Arm

2 Please wash hands thoroughly before proceeding

3 Cut vacuum packed test strip open where indicated

Immediately before use remove test strip from vacuum pack. **Do not touch yellow test pad when doing so**

4 Remove adhesive protection from reverse of test strip

5 Attach test strip to test arm

White Test Strip
Yellow Test Pad

Attach test strip to front of test arm by pressing (white part only) firmly together to ensure proper adhesion. **Do not touch yellow test pad when doing so**

6 To apply, open test arm holder like so

Normal Position Extended Fitted to Toilet Bowl

Please note: Flush toilet prior to applying test to ensure toilet bowl is urine free

7 Attach test arm to side of toilet bowl like so

Please Note: No part of IceTest should be in touch with toilet water when in position

8 Once attached to the toilet bowl pass urine over the test pad without delay

Wait a minimum of 20 seconds and a maximum of 60 seconds for the test result.

Test pad remains YELLOW = NO traces of blood present. Test pad changes to GREEN/BLUE = YES traces of blood detected. If YES please seek further medical advice.

9 After use remove test from toilet bowl and dispose of in household waste

10 Please wash hands thoroughly once all previous steps have been completed

EXAMPLE TEST RESULTS

GREEN / BLUE = YES traces of blood detected

Images show YES examples of Full / Partial / Spot test pad urine coverage

Test pad remains YELLOW = NO traces of blood present

NO TRACE OF BLOOD SPOTS PARTIAL FULL