Dip UTI

Clinical home UTI test

User Guide

How to use your Dip UTI Test

STEP 1

Download the "Dip UTI" app for iOS or Android

Download on the App Store

GET IT ON Google Play

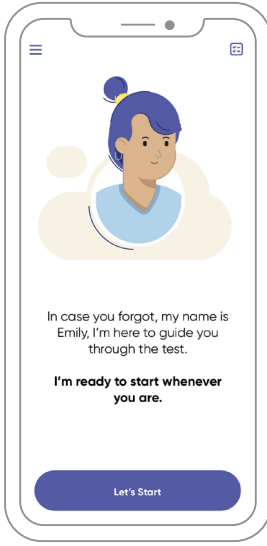
Or scan the QR code:

Need help installing the app?

Contact us at support@diputi.com

STEP 2

Open the Dip UTI app and follow the in-app instructions. It will guide you through the test process.



STEP 3

Once you complete the test, results will be securely stored on your device, and available for sharing with a health-care professional.

Intended Use

The Dip UTI urine dipstick analysis test system is intended for home-use in vitro analysis. The kit includes all standard equipment required to perform the test: a single-wrapped UTI urine reagent strip, a Colour-Board, an absorbing pad and a biocompatible urine collection cup and lid. The system allows for standard semi-quantitative detection of Leucocytes and Blood, as well as the qualitative detection of Nitrite in urine.

Indication for Use

The system measurements can be used for screening and monitoring of urinary tract infection (UTI). Healthcare professional interpretation of the results should be made in conjunction with the patient's other clinical information to decide on further care.

Summary

The device is a mobile application that in conjunction with the Dip UTI kit effectively turns a smartphone into a UTI urine dipstick analyser. The smartphone app guides the user through the process of the test, performs the scan and securely stores the test results on the device . The results will be available for sharing with a health-care professional to decide on further care.

Who is Dip UTI for?

Women aged 16-64 who have an iOS or Android powered smartphone who are not pregnant. For full eligibility criteria go to www.diputi.com/boots/eligibility

UTI symptoms may include

passing urine more often than usual, burning pain when passing urine, feeling the need to pass urine immediately, blood in your urine, needing to pass urine at night, pain in your lower tummy.

Please note

See your doctor or pharmacist straight away if you have flu-like symptoms or are vomiting, have a raised temperature, are confused or very drowsy, have kidney pain in your back just under the ribs or have any other unusual symptoms as these could be signs of a more serious infection.

Precautions

- For in vitro use only.
- The strip can only be read by the application.
- Do not touch the reagent area of the strip.
- The used strip should be discarded according to local regulations after testing.
- Wash your hands before and after performing a test.
- The cup, strip and Colour-Board are for single use only.
- Do not use the cup if it is contaminated by dirt or foreign substances.
- Dip the strip so that all the 3 patches are immersed in the urine.
- Keep the strip and Colour-Board in the original packaging until used.
- Do not use a kit that is past the expiration date or one that has deteriorated.
- Use only the strip that is provided with the kit.
- Do not use a soiled strip or Colour-Board.
- Do not use a bent or broken strip or Colour-Board.
- Make sure the smartphone camera is working before performing a urine test.
- Make sure the lens of the smartphone camera is clean before use.
- Make sure that your smartphone battery is at least 10% charged. If the smartphone battery is below this level, the test may not complete successfully.
- Make sure that the smartphone is connected to the Internet before performing the test.
- Make sure you have at least 50MB of available disk space on your smartphone before performing the test.

Storage and Stability

- Store in a packed container at room temperature or refrigerated (2-30°C, 35-85°F).
- Keep out of direct sunlight and high humidity.
- The strip is stable up to the expiration date. It should not be used beyond the expiration date.
- The package should not be frozen.
- Stability may be reduced in high humidity

Specimen Collection and Preparation

- Wash your hands.
- Remove the cup and its lid from the kit.
- Collect mid-stream urine – After 1 or 2 seconds of passing urine, place the cup underneath the urine stream and begin collecting urine, until you reach the 'FULL' marked line.
- Place the cup in the designated cup holder.
- The urine test should be conducted not more than 10 minutes after collecting the urine.
- Perform the test at room temperature (15-30°C or 59-86°F)
- Follow the app instructions.

Phone and Operating System Limitations

Please visit www.diputi.com/download to verify your phone is compatible with the Dip UTI test.

Materials Provided

- 1 Cup and lid
- 1 Colour-Board
- 1 Absorbent pad
- 1 User manual
- 1 UTI reagent strip

For Self-Testing

Directions for Use

Before starting the test, download the Dip UTI app and follow the app instructions. The app includes a dedicated instructional flow which will guide you through the test process step by step. Extract the cup and its lid, fill it with midstream urine up to the full marked line. According to the app instructions,

immerse the strip fully for about one second and then place it at the centre of the Colour-Board. Wait for 60 seconds and then use the in-app scanner to scan the Colour-Board. Your test results will be securely saved on your device to share with a health-care professional to decide on further care.

Blood: This test is based on the peroxidase-like activity of hemoglobin which catalyzes the reaction of diisopropylbenzene dihydroperoxide and 3,3',5,5'-tetramethylbenzidine. Blood is often, but not invariably, found in the urine of menstruating females. The significance of a trace reading varies among patients and clinical judgment is required in these specimens.

Nitrite: This test depends upon the conversion of nitrate to nitrite by the action of Gram negative bacteria in the urine. In an acidic medium, nitrite in the urine reacts with p-arsanilic acid to form a diazonium compound. The diazonium compound in turn couples with 1 N-(1-naphthyl)- ethylenediamine to produce a pink colour. Nitrite is not detectable in normal urine. The nitrite area will be positive in some cases of infection, depending on how long the urine specimens were retained in the bladder prior to collection. Retrieval of positive cases with the nitrite test ranges from as low as 40% in cases where little bladder incubation occurred, to as high as approximately 80% in cases where bladder incubation took place for at least 4 hours.

Leucocytes: This test reveals the presence of granulocyte esterases. The esterases cleave a derivatised pyrazole amino acid ester to liberate derivatised hydroxy pyrazole. This pyrazole then reacts with a diazonium salt to produce a beige-pink to purple colour. Normal urine specimens generally yield negative results. Trace results may be of questionable clinical significance. When trace results occur, it is recommended to retest using a fresh specimen. Repeated trace and positive results are of clinical significance.

Calibration and Maintenance

No calibration or maintenance is required.

Performance Characteristics of UTI Urine Reagent Strips

The performance characteristics of the UTI Urine Reagent Strip have been determined in both laboratory and clinical tests. The following table indicates possible range of results for each parameter.

Reagents

UTI Urine Reagent Strip Parameter Table

Parameter Name (Abbreviation)	Arbitrary	Conventional
Leucocytes (LEU)	- ± 1+ 2+ 3+	Neg 15 Leu/µL 70 Leu/µL 125 Leu/µL 500 Leu/µL
Nitrite (NIT)	- +	Neg Pos
Blood (BLO)	- ± 1+ 2+ 3+	Neg 10 Ery/µL 25 Ery/µL 80 Ery/µL 200 Ery/µL

Performance Characteristics of the Dip UTI System

The performance characteristics of Dip UTI system have been determined in both laboratory and clinical tests. The following table indicates performance characteristics for each parameter.

Reagent	Sensitivity – Dip UTI system
Leucocytes (LEU)	Detects leucocytes as low as 6 white blood cells (Leu/µL) in clinical urine.
Nitrite (NIT)	Detects sodium nitrite as low as 0.05 mg/dL.
Blood (BLO)	Detects free hemoglobin as low as 0.023 mg/dL or 6.5 Ery/µL.

Accuracy

The Dip UTI system was tested during extensive clinical trials with a variety of urine samples from different subjects. The same samples were tested on another commercially marketed urine analyser and the results were compared:

Dip UTI Reading vs. Predicate Device Reading		
Analyte	% Agreement ± 1 colour block	95% Confidence Interval
Leucocytes (LEU)	99.2%	98.0%- 99.8%
Nitrite (NIT)	100.0%	99.3%-100.0%
Blood (BLO)	99.8%	98.9%-100.0%

Troubleshooting

Error Message	Description	Patient Instructions
Bad lighting condition	Lighting condition doesn't enable accurate scanning.	Enhance the light or find a different room to perform the test.
Shadow on Colour-Board	Key parts of the Colour-Board are shared. Such conditions preclude accurate scanning.	Remove any objects that stand between the main light source and the Colour-Board. Make sure there's no strong shade covering the Colour-Board.

Picture is blurry	The scanning sequence took place while the patient moved the phone.	Retry the scanning sequence and hold the phone still while the picture sequence is starting.
Misplaced strip	The strip was not placed in its designated place at the centre of the Colour-Board.	Make sure that the strip is placed in the designated middle gap on the Colour-Board and retry the scanning sequence.
General	General problem.	Follow the app instructions and retry.
Image upload taking too long	The system recognises that the upload process is taking too long, or stuck due to bandwidth issues.	Keep the app running, the scan will be uploaded as soon as the bandwidth allows it and will notify accordingly.
No Internet connection	The system checks for stable Internet connection and notifies the patient about the status.	Make sure your device is connected to the Internet during the test.
Device / operating system is not supported	The system checks if the patient is using a compatible device / operating system and alerts if the system is incompatible.	Only supported devices and operating systems are valid for use. Please visit: www.diputi.com/download to verify your phone is compatible with the Dip UTI test.
Strip is no longer valid	The strip is valid for analysis between 60–120 seconds after it was dipped. The system measures the time and allows the user to scan only during this range.	Follow the app instructions and restart the test with a new kit.
Disk space	The system checks if there is enough disk space on the smartphone to perform the test.	Try to delete some data from your smartphone.
Low battery	The system checks if there is enough battery to perform the test.	Charge the smartphone above 10%.

Factors That May Interfere With the Test Results
Note: The test strips may be affected by substances that cause abnormal urine colour, such as drugs containing azo dyes, nitrofurantoin and riboflavin. The colour development on the strip may be masked or a colour reaction may be produced that could be interpreted as false results.

Blood: Positive results with this test are often seen with urine from menstruating females. Presence of unconjugated Bilirubin >75.44 mg/dL may cause false positives. Sodium Mercaptoethane (MESNA) at 13.25 mg/dL and Sodium Phosphate >275 mg/dL may also lead to false positives. The test is slightly more sensitive to free hemoglobin and myoglobin than to intact erythrocytes.

Nitrite: The test is specific for nitrite and will not react with any other substance normally excreted in urine. Any degree of uniform pink to red colour should be interpreted as a positive result, suggesting the presence of nitrite. Colour intensity is not proportional to the number of bacteria present in the urine specimen. Pink spots or pink edges should not be interpreted as a positive result. Unconjugated Bilirubin at 6.3 mg/dL or Hemoglobin at 178 mg/dL may cause false positives. A negative result does not at any time preclude the possibility of bacteriuria.

Leucocytes: High urinary protein may diminish the intensity of the reaction colour. Hemoglobin at 178 mg/dL may cause false positives. This test will not react with erythrocytes or bacteria common in urine.

Further Assistance

For further assistance please contact:
support@diputi.com

Bibliography

1. Free AH, Free HM. Urinalysis, Critical Discipline of Clinical Science, CRC Crit. Rev. Clin. Lab Sci 3(4): 481-531, 1972.

2. Yoder J, Adams EC, Free, AH. Simultaneous Screening for Urinary Occult Blood, Protein, Glucose, and pH. Amer. J. Med Tech. 31:285, 1965.

3. Shehersten B, Fritz H. Subnormal Levels of Glucose in Urine. JAMA. 201:129-132, 1967.

4. McGarry JD, Lilly. Lecture. 1978: New Perspectives in the Regulation of Ketogenesis. Diabetes 28:517-523 May, 1978.

5. Williamson DH. Physiological Ketoses, or Why Ketone Bodies? Postgrad. Med. J. (June Suppl.):372-375, 1971.

6. Paterson P, et al. Maternal and Fetal Ketone Concentrations in Plasma and Urine. Lancet: 862-865, April 22, 1967.

7. Fraser J, et al. Studies with a Simplified Nitroprusside Test for Ketone Bodies in Urine, Serum, Plasma and Milk. Clin. Chem. Acta II: 372-378, 1965.

8. Henry JB et al. Clinical Diagnosis and Management by Laboratory Methods, 20th Ed. Philadelphia. Saunders. 371-372, 375, 379, 382, 385, 2001.

9. Tietz NW. Clinical Guide to Laboratory Tests. W. B. Saunders Company, 1976.

10. Burtis CA, Ashwood ER. Tietz Textbook of Clinical Chemistry 2nd Ed. 2205, 1994.

	Do not reuse
	Store between 2°–30°C
	Keep dry
	Use by
	Keep away from sunlight
IVD	For in vitro diagnostic use only
	Consult instructions for use
EC REP	Authorised Representive
	Manufactured by

Healthy.io Ltd
2 Ibn Gabirol St. Tel Aviv
6407702, Israel

EC REP
Obelis
Bd General Wahis, 53
B-1030 Brussels, Belgium

Effective Date:
February 2020
Rev 1.4

CE 0483