



DIP UTI

Home Based 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?
Call 0800 170 7776

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 healthcare 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 urinalysis reagent stick, a Colour-Board 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 infections (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 healthcare professional to decide on further care.

Precautions

- For in vitro use only.
- The stick 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, stick and Colour-Board are for single use only.
- Do not use the cup if it is contaminated by dirt or foreign substances.
- Dip the stick so that all the 10 patches are immersed in the urine.

- Keep the stick 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 stick that is provided with the kit.
- Do not use a soiled stick or Colour-Board.
- Do not use a bent or broken stick 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.
- If the smartphone battery is very low, 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 (2–30°C, 35–85°F). The package should be kept out of direct sunlight.
- 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.
- Open the cup.
- Collect mid-stream urine – After 1 or 2 seconds of passing urine, place the cup underneath the urine stream and begin collecting urine.
- Place the cup in the designated cup holder.
- The urine test should be conducted not more than 10 minutes after collecting the urine.
- Immerse the stick in the urine and follow the app instructions.

Phone and Operating System Limitations

Please visit www.healthy.io/download/dip-uti to verify your phone is compatible with the DIP UTI test.

Materials Provided

- 1 Cup and lid
- 1 Colour-Board
- 1 User manual
- 1 Urinalysis 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 open it to its full length. Fill it with midstream urine up to the full marked line. Following the app instructions, immerse the stick 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 healthcare 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 Urinalysis Reagent Strips

The performance characteristics of the Urinalysis Reagent Strips (urine) have been determined in both laboratory and clinical tests. The following table indicates possible range of results for each parameter.

Reagents

Urinalysis 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 urine dipstick analysis test 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

Urine samples from 500 subjects were tested using the DIP UTI system. The same samples were tested on another commercially marketed urine analyser and the results were compared:

DIP UTI - Home Based Dipstick Analyser Reading vs. Predicate Device Reading		
Analyte	% Agreement \pm 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.
Miss-placed stick	The dipstick was not placed in its designated place at the centre of the Colour-Board.	Make sure that the stick 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.healthy.io/download/dip-uti to verify your phone is compatible with the DIP UTI test.

Factors That May Interfere With the Test Results

Note: The test sticks may be affected by substances that cause abnormal urine colour, such as drugs containing azo dyes, nitrofurantoin and riboflavin. The colour development on the stick 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

Or call to:
0800 170 7776

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	Store between 2°-30°C
	Keep dry
	Use by
	Keep away from sunlight
	For in vitro diagnostic use only
	Consult instructions for use
	Authorised Representative
	Manufactured by



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



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

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