# Just Fitter 10 Parameter Test Strips Instructional Guide

## Product

**Product Codes:** JF10PARA100, JF10PARA150
**Product Name:** 10 Parameter Test Strips
**Product Description:** Just Fitter 10 Parameter Test Strips are dip-and-read test strips for in vitro diagnostic to help detect the presence of Leukocytes, Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, and Glucose in urine. Test results may provide information regarding the status of carbohydrate metabolism, kidney and liver function, acid-base balance, and urinary tract infection. It is measured by comparing the colored reactants attached to a plastic strip with the color chart blocks printed on the bottle label.

## Intended Use

The Just Fitter 10 Parameter Test Strips are used for qualitative and semi-quantitative detection of Leukocytes, Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, and Glucose presence in urine. Urine undergoes many changes during state of disease or body dysfunction before blood composition is altered to a significant extent. Testing urine is used as an indicator of health or disease, and as such, is a part of routine health screening. The Just Fitter 10 Parameter Test Strips can be used in general evaluation of health, and aids in the diagnosis and monitoring of metabolic or systemic diseases that affect kidney function, endocrine disorders, and diseases or disorders of the urinary tract. For in vitro diagnostic use only.

## Materials Provided

•Strips
•Package insert

Product Variations:
Just Fitter 10 Parameter Test Strips 100 strips per bottle
Just Fitter 10 Parameter Test Strips 150 strips per bottle

## Materials Needed But Not Provided

Container to collect urine
Timer or watch

## Specimen Collection and Preparation

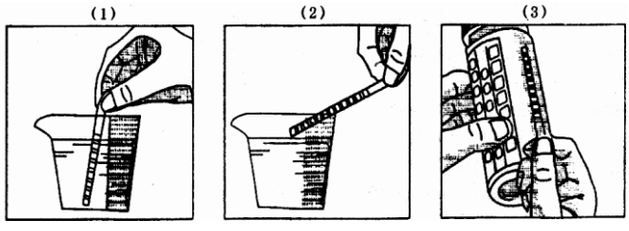
Use only clean dry container to collect urine. Shake the collected urine before testing and test within 2 hours of being collected. Any operations must be in a sanitary environment. The use of urine preservatives is not recommended. Prolonged storage of unpreserved urine at room temperature may result in microbial proliferation.

## Caution ⚠

Water cannot be used as negative quality control liquid. Antiseptic properties of urine cannot prevent the ketone, bilirubin, and urobilinogen from deteriorating. For stale urine specimen, the test results of glucose, pH, nitrite, and blood can be affected because of bacterial growth.
•Do not use after the expiration date.
•Do not touch the reagent areas of the strip.
•Discard any discolored strips that may have deteriorated.
•The strips should remain in the closed bottle until use.
•All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
•Used strips should be discarded after testing.

## Test Procedure

1. Remove one strip from the bottle and replace the cap immediately. Immerse the reagent area of the strip in the urine specimen and take it out quickly.
2. Wipe off excess urine against the rim of the specimen container.
3. Read the test results carefully within 30-120 seconds in a good light and with the test area held near the appropriate color chart on the bottle label. Changes in color that appear along the edges of the test pads or after more than 2 minutes have passed are of no diagnostic significance. Results with Leukocytes test portion can be read within 120 seconds. Nitrate, Urobilinogen, Protein, pH and Blood can be read in 60 seconds. Specific Gravity in 45 seconds, Ketones in 40 seconds and Bilirubin and Glucose in 30 seconds.




## Test Conditions

Ambient temperature: 20°C—30°C
Relative humidity: ≤80%
Best test temperature: 23°C—27°C

## Storage

Store between 2°C—30°C in dry condition. Do not refrigerate, and keep away from direct sunlight. Isolate from damp, light, and high temperature in order to preserve the reactivity of the reagent.

## Limitation of Procedures

Just like all laboratory tests, the diagnosis results and therapeutic decisions should not be based on any single result or method and must be considered with other clinical information available to a physician.

## How to Read Results

**Leukocytes:** Usually not present in urine. The detection of white blood cells in the urine suggests a possible kidney infection, bladder infections, or a blockage in the urinary tract.
Expected result: Negative

**Nitrite:** Usually not present in urine. The presence of infections caused by nitrate-reducing bacteria suggests a possible urinary tract infection.
Expected result: Negative
*Note: Leukocytes and Nitrite are commonly used to screen for possible Urinary Tract Infection (UTI).*

**Urobilinogen:** Usually not present in urine. The presence of excreted urobilinogen suggests a possible deterioration of liver functions. Urobilinogen is the breakdown product of bilirubin.
Expected result: less than 17 µmol/l (< 1mg/dl)

**Protein:** A protein test is usually run to screen for kidney diseases. Protein in the urine is called Proteinuria. Low protein levels in urine is normal, larger amounts may be a cause for concern.
Expected result: Negative to Low

**pH:** Used to help measure acidity or alkalinity in the body through urine.
Expected result: 6.5 – 7.5

**Blood:** Usually not present in urine. Blood in the urine is called hematuria. A number of things can cause hematuria including UTI, kidney infection, medication, menstruation, and strenuous exercise.
Expected result: Negative

**Specific Gravity:** Evaluates the body's water balance (hydration) and urine concentration and helps evaluate kidney functions and possible kidney diseases.
Expected Results: low at 1,000 but normal ranges from 1.020 to 1.030

**Ketone:** Usually not present in urine. Ketones are the result of your body being in ketosis, indicating your body is burning fat for fuel rather than carbohydrates. For diabetics, ketones in the urine is a sign there is not enough insulin available to use glucose for energy. For nutritional dieters, this helps indicate the level of fat burning according to the type of diet you're on.
Expected Results: Negative for people with Type 1 diabetes. Positive for nutritional dieters.

**Bilirubin:** Usually not present in urine. Bilirubin in the urine is an early indication of liver disease. Even trace amounts of bilirubin are sufficiently abnormal to require further investigation.
Expected Result: Negative
*Note: Urobilinogen and Bilirubin are commonly used to screen for possible liver disease.*

**Glucose:** Usually not present in urine. Glucose in the urine could indicate diabetes or renal glycosuria.
Expected Results: Negative

⚠ **Urine and Ascorbic Acid**
People taking vitamin C may have large amounts of ascorbic acid in their urine. Ascorbic acid is known to interfere with the accuracy of some chemical test strips, causing them to be falsely low or falsely negative. Examples of tests that may be affected include tests for blood, bilirubin, nitrite, and glucose.

## Quality Control Procedure

For best results, performance of reagent strips should be confirmed by testing known positive and negative control samples.
•Test Quality Control according to laboratory policies and local or state regulations.
•Test commercially available positive and negative quality controls with each new lot, each new shipment of strips, and when you open a new bottle of reagent strips.
•Test the strips monthly that are stored for more than 30 days.

## Test Principle

**Leukocytes:** This test reveals the presence of granulocyte esterases. The esterases cleave a derivatized pyrazole amino acid ester to liberate derivatized hydroxy pyrazole. This pyrazole then reacts with a diazonium salt to produce a beige-pink to purple color. 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 from the same patient. Repeated trace and positive results are of clinical significance.

**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 color. 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.

**Urobilinogen:** This test is based on a modified Ehrlich reaction between p-diethylaminobenzaldehyde and urobilinogen in strongly acidic medium to produce a pink color. Urobilinogen is one of the major compounds produced in heme synthesis and is a normal substance in urine. The expected range for normal urine with this test is 0.2-1.0 mg/dL (3.5-17 µmol/L). A result of 2.0 mg/dL (35 µmol/L) may be of clinical significance, and the patient specimen should be further evaluated.

**Protein:** This reaction is based on the phenomenon known as the "protein error" of pH indicators where an indicator that is highly buffered will change color in the presence of proteins (anions) as the indicator releases hydrogen ions to the protein. At a constant pH, the development of any green color is due to the presence of protein. Colors range from yellow to yellow-green for negative results and green to green-blue for positive
results. 1-14 mg/dL of protein may be excreted by a normal kidney. A color equal or greater than 30 mg/dL indicates significant proteinuria. Clinical judgment is required to evaluate the significance of trace results.

**pH:** This test is based on a double indicator system which gives a broad range of colors covering the entire urinary pH range. Colors range from orange to yellow and green to blue. The expected range for normal urine specimens from newborns is pH 5-7. The expected range for other normal urine specimens is pH 4.5-8, with an average result of pH 6.

**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. The resulting color ranges from light orange to dark green. The significance of a trace results, or a 5 – 10 non-hemolyzed result, varies among patients, and clinical judgment is required for these specimens on an individual basis. Small amounts of blood with a strip result of 1+ hemolyzed, or a 50 Ery/µL

non-hemolyzed result, within 60 seconds are sufficiently abnormal to request a further investigation. Blood is often, but not invariably, found in the urine of menstruating females.

**Specific Gravity:** This test is based on the apparent pKa change of certain pretreated polyelectrolytes in relation to ionic concentration. In the presence of an indicator, colors range from deep blue-green in urine of low ionic concentration to green and yellow-green in urine of increasing ionic concentration. Randomly collected urine may vary in specific gravity from 1.003-1.035. Twenty-four hour urine from healthy adults with normal diets and fluid intake will have a specific gravity of 1.016-1.022. In cases of severe renal damage, the specific gravity is fixed at 1.010, the value of the glomerular filtrate.

**Ketone:** This test is based on ketones reacting with nitroprusside and acetoacetic acid to produce a color change ranging from light pink for negative results to a darker pink or purple color for positive results. Ketones are normally not present in urine. Detectable ketone levels may occur in urine during physiological stress conditions such as fasting, pregnancy and frequent strenuous exercise. In starvation diets, or in other abnormal carbohydrate metabolism situations, ketones appear in the urine in excessively high concentration before serum ketones are elevated.

**Bilirubin:** This test is based on azo-coupling reaction of bilirubin with diazotized dichloroaniline in a strongly acidic medium. Varying bilirubin levels will produce a pinkish-tan color proportional to its concentration in urine. In normal urine, no bilirubin is detectable by even the most sensitive methods. Even trace amounts of bilirubin require further investigation. Atypical results (colors different from the negative or positive color blocks shown on the color chart) may indicate that bilirubin-derived bile pigments are present in the urine specimen, and are possibly masking the bilirubin reaction.

**Glucose:** This test is based on the enzymatic reaction that occurs between glucose oxidase, peroxidase and chromogen. Glucose is first oxidized to produce gluconic acid and hydrogen peroxide in the presence of glucose oxidase. The hydrogen peroxide reacts with potassium iodide chromogen in the presence of peroxidase. The extent to which the chromogen is oxidized determines the color which is produced, ranging from green to brown. Glucose should not be detected in normal urine. Small amounts of glucose may be excreted by the kidney. Glucose concentrations as low as 100 mg/dL may be considered abnormal if results are consistent.

## Performance Characteristics

The following table below indicates read times and performance characteristics for each parameter. (based on dry weight at time of impregnation)

| Reagent | Read Time | Composition | Description |
|---|---|---|---|
| Leukocytes (LEU) | 120 seconds | derivatized pyrrole amino acid ester; diazonium salt; buffer; nonreactive ingredients | Detects leukocytes as low as 9-15 white blood cells Leu/µL in clinical urine. |
| Nitrite (NIT) | 60 seconds | p-arsanilic acid; N-(1-naphthyl) ethylenediamine; non-reactive ingredients | Detects sodium nitrite as low as 0.05-0.1 mg/dL in urine with a low specific gravity and less than 30 mg/dL ascorbic acid. |
| Urobilinogen (URO) | 60 seconds | p-dethylaminobenzaldehyde; buffer and non-reactive ingredients | Detects urobilinogen as low as 0.2-1.0 mg/dL (3.5-17 mol/L). |
| Protein (PRO) | 60 seconds | tetrabromophenol blue; buffer and non-reactive ingredients | Detects albumin as low as 7.5-15 mg/dL (0.075-0.15 g/L). |
| pH | 60 seconds | methyl red sodium salt; bromothymol blue; non-reactive ingredients | Permits quantitative differentiation of pH values within the range of 5-9. |
| Blood (BLO) | 60 seconds | 3,3',5,5'-tetramethylbenzidine (TMB); diisopropylbenzene dihydroperoxide; buffer and nonreactive ingredients | Detects free hemoglobin as low as 0.018-0.060 mg/dL or 5-10 Ery/µL in urine specimens with ascorbic acid content of < 50 mg/dL |
| Specific Gravity (SG) | 45 seconds | bromothymol blue indicator; buffer and non-reactive ingredients; poly (methyl vinyl ether/maleic anhydride); sodium hydroxide | Determines urine specific gravity between 1.000 and 1.030. Results correlate with values obtained by refractive index method within ±0.005. |
| Ketone (KET) | 40 seconds | sodium nitroprusside; buffer | Detects acetoacetic acid as low as 2.5-5 mg/dL (0.25-0.5 mmol/L) |
| Bilirubin (BIL) | 30 seconds | 2, 4-dichloroaniline diazonium salt;buffer and non-reactive ingredients | Detects bilirubin as low as 0.4-1.0 mg/dL (6.8-17 µmol/L). |
| Glucose (GLU) | 30 seconds | glucose oxidase; peroxidase; potassium iodide; buffer; nonreactive ingredients | Detects glucose as low as 50-100 mg/dL (2.5-5 mmol/L). |

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## Legend and Symbols

| | | | | | |
|---|---|---|---|---|---|
| | Do not use if package is damaged | | Store between 2°C—30°C | IVD | For in vitro diagnostic use |
| | Do not re-use | Σ 100 | Contains sufficient for 100 tests | LOT | Batch code |
| | Keep dry | | Use-by date | | Consult instructions for use |
| | Keep away from sunlight | | Date of manufacture | | Dispose properly |

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