

# Urinalysis Strips



## SUMMARY AND INTENDED USE

The content of the instruction includes usage, reaction principle, and notification. Urinalysis strips are intended for qualitative and semi-quantitative urinalysis and for *in vitro* diagnostics use. The strips are for professional use only. The strips may be read visually or instrumentally. Please read the instruction carefully before use. There are the test items of every products type.

Products type	Packaging	Test item
URS 14	25/50/100 strips per canister	Urobilinogen, Bilirubin, Ketone (acetoacetic acid), Blood, Protein, Nitrite, Leukocytes, Glucose, Specific Gravity, pH, and Ascorbic Acid, Microalbumin, Creatinine, Calcium
URS 13, URS 12, URS 11, URS 10, URS 9, URS 8, URS 7, URS 6, URS 5, URS 4, URS 3, URS 2, URS 1	25/50/100 strips per canister	The items of product type from URS 2 to URS 13 can be combined randomly from URS 14 test items mentioned above. US1 item can be any item from URS 14.

## SPECIMEN COLLECTION AND PREPARATION

Collect fresh urine in a clean dry container. Use uncentrifuged urine and mix the sample before testing. The sample should not be more than 2 hours old at the time of testing. Always handle specimens under sanitary conditions.

**Note:** Water should not be used as negative control. Preservatives will not prevent the deterioration of ketones, bilirubin or urobilinogen. Bacterial growth from contaminating organisms may affect glucose, pH, nitrite and blood test results.

## VISUAL READING TECHNIQUE

1. Immerse all reagent areas in specimen and remove strip immediately.
2. Run edge of strip against the rim of the container to remove excess urine.
3. Hold strip horizontally and compare test areas closely with color chart on bottle label. Record the results.

For a semi-quantitative result read the reagent areas at the time specified on the color chart. The pH and Protein areas may also be read immediately or at any time up to 60 seconds after dipping. For a qualitative result read the reagent areas between 1 and 2 minutes. If a positive result is obtained, repeat the test, reading each reagent at the time specified on the color chart.

Color changes after 2 minutes are of no diagnostic value.



## INSTRUMENT READING TECHNIQUE

Follow the directions given in the appropriate instrument-operating manual.

## STORAGE AND HANDLING PROCEDURES

Store only in original bottle. Do not use after expiry date. Every strip can be used only once. Do not remove desiccant(s). Do not remove strip from the bottle until immediately before it is to be used for testing. Replace cap immediately and tightly after removing reagent strip. Shelf life: 24 months. Stability period after opening: 3 months

Store at temperatures between 2°C-30°C. Don't store in refrigerator. Keep away from direct sunlight.

Do not touch test areas of reagent strips. PROTECTION AGAINST AMBIENT MOISTURE, LIGHT AND HEAT IS ESSENTIAL TO GUARD AGAINST ALTERED REAGENT REACTIVITY. Deterioration may result in discoloration or darkening of the reagent areas. If this is evident or if test results are questionable or inconsistent with expected results, confirm that strips are within the expiry dates and compare with control urine. Please deal with the waste strips according to "Treatment Regulations of Lab Biohazard Materials".

## LIMITATIONS OF PROCEDURES

As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be made or based on any single result or method.

## TEST PRINCIPLES

**Glucose:** One enzyme, glucose oxidase catalyzes the formation of gluconic acid and hydrogen peroxide from the oxidation of glucose. Hydrogen peroxide releases neo-ecotypes oxide [O] under the function of peroxidase, [O] oxidates potassium iodides chromogen, so that it makes the color change.

**Bilirubin:** This test is based on coupling the direct bilirubin with diazotized dichloroaniline in a strongly acid medium, which produce the diazotizing colors.

**Ketone:** This test is based on that acetoacetate acid react with sodium nitroprusside in an alkaline medium, producing violet color.

**Specific gravity:** Electrolyte (M+X-) in the form of salt in urine reacts with poly (methyl vinyl ether/maleic anhydride (-COOH), which is weakly acid ionic exchanger. And then hydrogenous ion is replaced from it and reacts with pH indicator in order to make the color change.

**Blood:** This test is based on the peroxidase activity of hemoglobin and myoglobin, which makes peroxide release neo-ecotypic Oxide [O]. Indicator is oxidized by [O] and shows color change subsequently.

**pH:** This test is based on a double indicator principle.

**Protein:** The test is based on the protein-error-of-indicators principle. Anion on the specific pH indicator is absorbed by cation on protein molecule, which make the indicator ionize and present color change at critical point of color.

**Urobilinogen:** This test is based on coupling the urobilinogen with diazotized salt in a strongly acid medium, which produce the pink-red azo dye.

**Nitrite:** This test depends upon the nitrite diazotize with aromatic amino sulphanilamide to form a diazonium compound. This diazonium compound in turn couples with 1,2,3,4-tetrahydro-benzo(h)quinolin-3-phenol to produce a pink color.

**Leucocytes:** Granulocytic leukocytes in urine contain esterase's that catalyze the hydrolysis of the privatized pyrrole amino acid ester to liberate 3-hydroxy-5-pheny pyrrole. This pyrrole then reacts with a diazonium salt to form a purple color.

**Ascorbic acid:** Ascorbic acid, with 1,2-dihydroxy alkenes, under alkaline condition, deoxidizes blue 2,6-dichloroindophenolate form into colorless N-(P-phenol)-2,6-dichloro-P- amine phenol.

**Microalbumin:** Based on the protein deviation method, utilizing the sulfone phthalein dyestuff only specific to Microalbumin.

**Creatinine:** Creatinine can act with 3, 5-2 nitro benzoic acid in strong alkalinity, generating colored compound.

**Calcium:** Calcium can with o-Cresol phthalein complex one in an alkaline medium, producing violet color.

### Note:

**GLUCOSE:** The test is specific for glucose, no substance excreted in urine other than glucose is known to give a positive result. In dilute urine containing less than 0.28 mmol/L ascorbic acid, as little as 2.2 mmol/L glucose may produce a color change that might be interpreted as positive. Ascorbic acid concentrations of 2.8 mmol/L or greater and/or high acetoacetic concentrations (1.0 mmol/L) may influence test. Small amounts of glucose may normally be excreted by the kidney. These amounts are usually below the sensitivity of this test.

**BILIRUBIN:** Normally no bilirubin is detectable in urine by even the most sensitive methods. Even trace amounts of bilirubin are sufficiently abnormal to require further investigation. Medicines that color the urine red or that are themselves red in an acid medium, e.g., phenazopyridine may influence the test. Large ascorbic acid concentration may cause false negatives.

**KETONES:** The test reacts with acetoacetic acid in urine. It does not react with acetone or  $\beta$ -hydroxybutyric acid. Normal urine specimens usually yield negative results with this reagent. False positive results may occur with highly pigmented urine specimens or those containing large amounts or levodopa metabolites.

**SPECIFIC GRAVITY:** The specific gravity permits determination of urine specific gravity between 1.000 and 1.030. In general, it correlates within 0.005 with values obtained with the refractive index method. For increased accuracy, 0.005 may be added to readings from urines with pH equal to or greater than 6.5. Strips read instrumentally are automatically adjusted for pH by the instrument. The SG test is not affected by certain nonionic urine constituents such as glucose or by the presence of radiopaque dye. Highly buffered alkaline urines may cause low readings relative to other methods. Elevated specific gravity readings may be obtained in the presence of moderate quantities (1-7.5 g/L) of protein.

**BLOOD:** The significance of the 'Trace' reaction may vary among patients, and clinical judgment is required for assessment in an individual case. Development of green spots (intact erythrocytes) or green color (free hemoglobin/ myoglobin) on the reagent area within 60 seconds indicates the need for further investigation. Blood is often found in the urine of menstruating females. Hemoglobin concentration of 150-620  $\mu$ g/L is approximately equivalent to 5-15/ $\mu$ L intact red blood cells per microlite.

This test is highly sensitive to hemoglobin and thus complements the microscopic examination. The sensitivity of this test may be reduced in urines with high specific gravity. This test is equally sensitive to myoglobin as to hemoglobin. Certain oxidizing contaminants, such as hypochlorite, may produce false positive results. Microbial peroxidase associated with urinary tract infection may cause a false positive reaction. Levels of 5.0 mmol/L ascorbic acid normally found in urine do not interfere with this test.

**pH:** The pH test area measures pH values generally to within 1 unit in the range of 5.0-8.5 visually and 5.0-9.0 instrumentally.

### PROTEIN and MICROALBUMIN:

The Protein reagent area can detect albumin in urine and has low sensitivity to mucoprotein, generally up to 0.6 g/L concentration.

The Microalbumin reagent area is to detect the microalbumin. Beyond 0.15 g/L indicate albuminuria clinically. The Microalbumin reagent can detect specifically microalbumin, and 9 times more sensitive than other protein.

Visible blood urine ( $\geq 0.05$  g/L) can be false negative action.

**UROBILINOGEN:** This test area will detect urobilinogen in concentrations as low as 3  $\mu\text{mol/L}$  (approximately 0.2 Ehrlich unit/dL) in urine. The normal range with this test is 3-16  $\mu\text{mol/L}$ . a result of 33  $\mu\text{mol/L}$  represents the transition from normal to abnormal, and the patient and/or urine specimen should be evaluated further. The absence of urobilinogen cannot be determined with this test.

**NITRITE:** This test depends upon the conversion of nitrate (derived from the diet) to nitrite by the action of principally Gram-negative bacteria in the urine. The test is specific for nitrite and will not react with any other substance normally excreted in urine. Pink spots or pink edges should not be interpreted as a positive result. Any degree of uniform pink color development should be interpreted as a positive nitrite test suggesting the presence of  $10^5$  or more organisms per mL, but color development is not proportional to the number of bacteria present. A negative result does not prove that there is no significant bacteriuria. Negative results may occur ① when urinary tract infections are caused by organisms which do not contain reductase to convert nitrate to nitrite; ② when urine has not been retained in the bladder long enough (four hours or more) for reduction of nitrate to occur, ③ or when dietary nitrate is absent. Sensitivity of the nitrite test is reduced for urines with high specific gravity. It may resist 2.8mmol/L Ascorbic Acid.

**LEUKOCYTES:** Test area react with esterase in leucocytes (granulocytic leukocytes). Normal urine specimens generally yield negative result; positive results (+ or greater) are clinically significant. Individually observed 'Trace' results may be of questionable clinical significance; however, 'Trace' results observed repeatedly may be clinically significant. 'Positive' results may occasionally be found with random specimens from females due to contamination of the specimen by vaginal discharge. Elevated glucose concentrations (160 mmol/L) or high specific gravity may cause decreased test results.

**ASCORBIC ACID:** The test area can detect the ascorbic acid in urine. Through the ascorbic acid detection, we will know the level of ascorbic acid in the body and the effect degree that the ascorbic acid brings to the test on glucose, bilirubin, blood and nitrite. It will reduce the sensitivity when the oxidant (such as potassium permanganate, hypochlorite) in the urine.

**Creatinine:** Adult normal urine creatinine is 0.6-2.0 g/24 hour (the Creatinine reagent area results is about 50-200 mg/dL). Result of random urine sample differ largely, from 10 mg/dL to 300 mg/dL. Concentrated urine and morning urine have high concentration (possibly over 200 mg/dL). Because of diuresis, excessive drinking water, or other urine dilution, resulting in testing analyte concentration decrease (result can be less than 50 mg/dL).

### SPECIFIC PERFORMANCE CHARACTERISTICS

Specific performance characteristics are based on clinical and analytical studies. In clinical specimens, the sensitivity depends upon several factors; the variability of color perception, the presence or absence of inhibitory factors typically found in urine, specific gravity, pH, and the lighting conditions when the product is read visually. Each color block or instrumental display value represents a range of values. Because of specimen and reading variability, specimens with analyte concentrations that fall between nominal levels may give results at either level. Results at levels greater than the second positive level for the Protein, Glucose, Ketone, and Urobilinogen tests will usually be within one level of the true concentration. Exact agreement between visual results and instrumental results might not be found because of the inherent differences between the perception of the human eye and the optical system of the instruments.

#### Sensitivity and test range of urinalysis strips

Item	Sensitivity	Instrumental test range	Visual test range
Glucose (mmol/L)	2.8-5.5	Neg-55	
Protein (g/L)	0.15-0.3	Neg -3.0	Neg - 20.0
Microalbumin (g/L)	0.08-0.15	0-0.15	
Ketone (acetoacetic acid) (mmol/L)	0.5-1.0	Neg-7.8	Neg-16
Blood (Ery/uL)	5-15	Neg.- 200	
Bilirubin ( $\mu\text{mol/L}$ )	3.3-8.6	Neg.-100	
Nitrite ( $\mu\text{mol/L}$ )	13-22	Neg. or Pos.	
Leukocytes (cells/ $\mu\text{L}$ )	5-15	Neg. - 500	
Urobilinogen ( $\mu\text{mol/L}$ )	3.3-16	3.3-131	
Ascorbic acid (mmol/L)	0.3-0.6	0-5.0	
Creatinine (mg/dL)	25-75	10-300	
pH	---	5.0-9.0	5.0-8.5
Specific Gravity	---	1.005-1.030	1.000-1.030
Calcium (mmol/L)	2.5-3.5	2.5-10.0	2.5-10.0

### REACTIVE INGREDIENTS (based on dry weight at time of impregnation)

**Protein:** 0.1% m/m tetrabromophenol blue; 97.4% w/w buffer; 2.5% w/w nonreactive ingredients

**Blood:** 26.0% w/w diisopropylbenzene dihydro peroxide; 1.5% w/w tetramethylbenzidine; 35.3% w/w buffer; 37.2 % nonreactive ingredients.

**Glucose:** 1.7% w/w glucose oxidase (microbial.123U); 0.2 % w/w peroxidase (horseradish. 203 IU); 0.1% w/w potassium iodide; 71.8% w/w buffer; 26.2% w/w nonreactive ingredients.

**Ketone:** 5.7% w/w sodium nitroprusside; 29.9% w/w nonreactive ingredients; 64.4% w/w buffer;

**Leukocytes:** 4.3% w/w pyrrole amino acid ester; 0.4% w/w diazonium salt; 92.6% w/w buffer; 2.7% w/w nonreactive ingredients.

**Nitrite:** 1.3% w/w 1,2,3,4-Tetrahydrobenzo(h)quinolin-3-ol; 89.6% w/w buffer; 9.1% w/w nonreactive ingredients.

**Specific Gravity:** 4.8% w/w bromothymol blue; 90.2% w/w poly (methyl vinyl ether co maleic anhydride); 5.0% w/w sodium hydroxide.

**pH:** 3.3% w/w bromocresol green; 55.0% w/w bromothymol blue; 41.7% w/w nonreactive ingredients.

**Bilirubin:** 0.6% w/w 2,4-dichlorobenzene amine diazonium salt; 57.3% w/w buffer; 42.1% w/w nonreactive ingredients.

**Urobilinogen:** 0.2% w/w fast B blue; 98.0% w/w buffer; 1.8% w/w nonreactive ingredients.

**Ascorbic acid:** 0.8% w/w 2,6-dichloroindophenolate hydrate; 40.7% w/w buffer; 58.5% w/w nonreactive ingredients.

**Microalbumin:** 2.2% w/w sulfone phthalein dyestuff; 96.0% w/w buffer; 1.8 w/w nonreactive ingredients.

**Creatinine:** 4.8% w/w 3, 5-2 nitro benzoic acid; 85.2% w/w buffer; 10% w/w nonreactive ingredients.

**Calcium:** 2.5% W/W o-Cresol phthalein Complex one; 87.5% w/w buffer; 10% w/w nonreactive ingredients.

### INDEX OF SYMBOLS

	Consult instructions for use		Tests per kit		Authorized Representative
	For <i>in vitro</i> diagnostic use only		Use by		Do not reuse
	Store between 2~30°C		Lot Number		Catalog#

 Zhejiang Orient Gene Biotech Co.,Ltd  
Address: 3787#, East Yangguang Avenue, Dipu Street,  
Anji 313300, Huzhou, Zhejiang, China  
Tel: +86-572-5226111 Fax: +86-572-5226222  
Website: www.orientgene.com

 Shanghai International Holding Corp. GmbH (Europe)  
Add: Eiffestrasse 80, 20537 Hamburg, Germany

Revision Date: 2023-02-28  
B20952-05

Reference number	Measured parameters	Reference number	Measured parameters
URS-1T-ASC	ASC	URS-4T-004	GLU-01, PH-01, SG-01, PRO-01
URS-1T-BIL	BIL	URS-4T-005	LEU-01, NIT-01, BLO-01, PH-01
URS-1T- BLO	BLO	URS-4T-006	LEU-01, NIT-01,BLO-01,PRO-01
URS-1T- CA	CA	URS-5T-001	PRO/PH/BLO/KET/GLU
URS-1T-CRE	CRE	URS-5T-002	GLU/PRO/BLO/LEU/NIT
URS-1T-GLU	GLU	URS-5T-003	GLU/KET/MA/PH/SG
URS-1T-KET	KET	URS-5T-004	GLU/PRO/PH/BLO/KET
URS-1T-LEU	LEU	URS-5T-005	MA/BLO/ASC/CRE/CA
URS-1T-MA	MA	URS-6T-001	LEU/NIT/PRO/BLO/GLU/KET
URS-1T- NIT	NIT	URS-6T-002	OXI/SG/PH/NIT/GLUT/CRE
URS-1T- PH	PH	URS-8T-001	LEU/NIT/PRO/PH/BLO/SG/KET/GLU
URS-1T-PRO	PRO	URS-9T-001	LEU/NIT/URO/PRO/PH/BLO/KET/BIL/GLU
URS-1T- SG	SG	URS-9T-002	BLO/BIL/URO/KET/PRO/NIT/GLU/PH/SG
URS-1T- URO	URO	URS-10T-001	LEU/NIT/URO/PRO/PH/BLO/SG/KET/BIL/GLU
URS-1T-ASC	ASC	URS-10T-002	LEU/NIT/URO/PRO/PH/BLO/SG/KET/BIL/GLU
URS-1T-BIL	BIL	URS-10T-003	URO/GLU/BIL/KET/SG/BLO/PH/PRO/NIT/LEU
URS-1T- BLO	BLO	URS-10T-004	LEU/NIT/URO/PRO/PH/BLO/SG/KET/BIL/GLU
URS-1T- CA	CA	URS-11T-001	LEU/NIT/URO/PRO/PH/BLO/SG/ASC/KET/BIL/GLU
URS-1T-CRE	CRE	URS-11T-002	URO/BLO/BIL/KET/LEU/GLU/PRO/PH/NIT/SG/MA
URS-2T-001	GLU/PRO	URS-11T-003	LEU/NIT/URO/PRO/PH/BLO/SG/ASC/KET/BIL/GLU
URS-2T-002	LEU/NIT	URS-11T-004	URO/BIL/KET/BLO/PRO/NIT/LEU/GLU/SG/PH/ASC
URS-2T-003	GLU/KET	URS-11T-005	31ET/URO/GLU/BIL/KET/SG/BLD/pH/PRO/NIT/LEU
URS-2T-004	pH/pH	URS-12T-001	(LEU/NIT/URO/MA/PRO/PH/BLO/SG/ASC/KET/BIL/GLU)
URS-3T-001	GLU/PRO/PH	URS-12T-002	URO/BIL/KET/BLO/PRO/MA/NIT/LEU/GLU/SG/PH/ASC
URS-3T-002	GLU/KET/PRO	URS-13T-001	LEU/NIT/URO/MA/PRO/PH/BLO/SG/ASC/CRE/KET/BIL/GLU
URS-4T-001	GLU-01, PRO-01, pH-01, BLO-01	URS-14T-001	LEU/NIT/URO/MA/PRO/PH/BLO/SG/ASC/CRE/KET/BIL/GLU/CA
URS-4T-002	PRO-01, GLU-01, pH-01, SG-01b	URS-14T-002	URO/BIL/KET/CRE/BLO/PRO/MA/NIT/LEU/GLU/SG/PH/ASC/CA
URS-4T-003	KET-01, BLO-01, BIL-01, NIT-01		

# Fecal Occult Blood Rapid Test Cassette (Feces)



## INTENDED USE

Fecal Occult Blood Rapid Test Cassette (Feces) is a rapid chromatographic immunoassay for the qualitative detection of human occult blood in feces by professional laboratories or physician's offices. It is useful to detect bleeding caused by a number of gastrointestinal disorders, e.g., diverticulitis, colitis, polyps, and colorectal cancer.

Fecal Occult Blood Rapid Test Cassette (Feces) is recommended for use in 1) routine physical examinations, 2) hospital monitoring for bleeding in patients, and 3) screening for colorectal cancer or gastrointestinal bleeding from any source.

## INTRODUCTION

Most of diseases can cause hidden blood in the stool. In the early stages, gastrointestinal problems such as colon cancer, ulcers, polyps, colitis, diverticulitis, and fissures may not show any visible symptoms, only occult blood. Traditional guaiac-based method lacks sensitivity and specificity, and has diet-restriction prior to the testing.

Fecal Occult Blood Rapid Test Cassette (Feces) is a rapid test to qualitatively detect low levels of fecal occult blood in feces. The test uses double antibody-sandwich assay to selectively detect as low as 50 ng/mL of hemoglobin or 6 µg hemoglobin/g feces. In addition, unlike the guaiac assays, the accuracy of the test is not affected by the diet of the patients.

## PRINCIPLE

Fecal Occult Blood Rapid Test Cassette (Feces) is a lateral flow chromatographic immunoassay based on the principle of the double antibody-sandwich technique. The membrane is pre-coated with anti-hemoglobin antibodies on the test line region of the device. During testing, the specimen reacts with the colloidal gold coated with anti-hemoglobin antibodies. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-hemoglobin antibodies on the membrane and generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence indicates 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.

## MATERIALS PROVIDED

- 20 Test cassettes
- 20 Specimen collection tubes with buffer
- 1 Package insert

## MATERIALS REQUIRED BUT NOT PROVIDED

1. Specimen collection containers
2. Clock or timer

## STORAGE AND STABILITY

All reagents are ready to use as supplied. Store unused test device unopened at 2°C-30°C. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test is not stable out of the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

## PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
3. Do not use it if the tube/pouch is damaged or broken.
4. Test is for single use only. Do not re-use under any circumstances.
5. **Do not use specimen with visible blood for the testing.**
6. Handle all specimens as if they contain infectious agents. Observe established standard procedure for proper disposal of specimens.
7. Specimen extraction buffer contains Sodium Azide (0.1%). Avoid contact with skin or eyes. Do not ingest.
8. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
9. Humidity and temperature can adversely affect results.
10. Do not perform the test in a room with strong air flow, ie. electric fan or strong air conditioning.

## PATIENT PREPARATION

1. A specimen should not be collected from a patient with following conditions that may interfere with the test results:

- Menstrual bleeding
  - Bleeding hemorrhoids
  - Constipating bleeding
  - Urinary bleeding.
2. Dietary restrictions are not necessary.
  3. Alcohol and certain medications such as aspirin, indomethacin, phenylbutazone, reserpine, cortocosteroids, and nonsteroidal anti-inflammatory drugs may cause gastrointestinal irritation and subsequent bleeding, thus gives positive reactions. On the advice of the physician, such substances should be discontinued at least 48 hours prior to testing.

## SPECIMEN COLLECTION AND PREPARATION

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

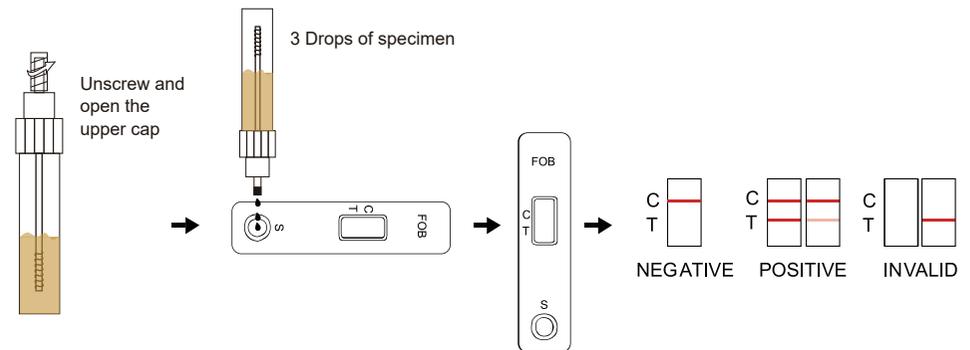
1. Collect a random sample of feces in a clean, dry receptacle.
2. Unscrew the top of the collection tube and remove the applicator stick.
3. Randomly pierce the fecal specimen in at least five (5) different sites.
4. Remove excess sample off the shaft and outer grooves. Be sure sample remains on inside grooves.
5. Replace the stick in the tube and tighten securely.
6. Shake the specimen collection bottle so that there is proper homogenisation of feces in buffer solution.

**Note:** Specimens prepared in the specimen collection tube may be stored at room temperature (15-30°C) for 3 days maximum, at 2-8°C for 7 days maximum or at -20°C for 3 months maximum if not tested within 1 hour after preparation.

## TEST PROCEDURE

**Allow the test cassette, specimen, and/or controls to reach room temperature (15-30°C) prior to testing.**

1. Remove the test cassette from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test cassette on a clean, flat surface.
3. Shake the specimen collection tube several times.
4. Hold the specimen collection tube upright and then unscrew and open the upper cap.
5. Squeeze 3 drops (~90 µL) of the sample solution in the sample well of the cassette and start the timer.
6. Wait for the colored line(s) to appear. Read results in 5 minutes. Do not interpret the result after 5 minutes.



## INTERPRETATION OF RESULTS

(Please refer to the illustration above)

**Positive:** Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).

**Negative:** One colored line appears in the control line region (C). No line appears in the test line region (T).

**Invalid:** Control line fails to appear. The test should be repeated using a new cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

**NOTE:**

1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is a qualitative test only, and

# Fecal Occult Blood Rapid Test Cassette (Feces)

cannot determine the concentration of analytes in the specimen.

2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

## QUALITY CONTROL

An internal procedural control is included in the test. A colored line appearing in the control line region (C) is an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique. Control standards are not supplied with this kit; however it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

## LIMITATIONS

1. This test kit is to be used for the qualitative detection of human hemoglobin in fecal samples. A positive result suggests the presence of human hemoglobin in fecal samples. In addition to intestinal bleeding the presence of blood in stools may have other causes such as hemorrhoids, blood in urine etc.
2. Not all colorectal bleedings are due to precancerous or cancerous polyps. The information obtained by this test should be used in conjunction with other clinical findings and testing methods, such as colonoscopy gathered by the physician.
3. Negative results do not exclude bleeding since some polyps and colorectal region cancers can bleed intermittently or not at all. Additionally, blood may not be uniformly distributed in fecal samples. Colorectal polyps at an early stage may not bleed.
4. Urine and excessive dilution of sample with water from toilet bowl may cause erroneous test results. The use of a receptacle is recommended.
5. Feces specimens should not collect during the menstrual period and not three day before or afterwards, at bleeding due to constipation, bleeding haemorrhoids, or at taking rectally administered medication. It could cause false positive results.
6. This test may be less sensitive for detecting upper g.i. Bleeding because blood degrades as it passes through the g.i. Track.
7. The Fecal Occult Blood Rapid Test Cassette (Feces) is to aid in diagnosis and is not intended to replace other diagnostic procedures such as G.I. fibroscope, endoscopy, colonoscopy, or X-ray analysis. Test results should not be deemed conclusive with respect to the presence or absence of gastrointestinal bleeding or pathology. A positive result should be followed up with additional diagnostic procedures to determine the exact cause and source for the occult blood in the feces.

## PERFORMANCE CHARACTERISTICS

### 1. Sensitivity: 99.6%

Fecal Occult Blood Rapid Test Cassette (Feces) can detect the levels of human occult blood as low as 50 ng/mL hemoglobin or 6 µg hemoglobin/g feces.

### 2. Prozone Effect:

It is observed that this FOB test can detect 2 mg/mL hemoglobin.

### 3. Specificity: 99.9%

Fecal Occult Blood Rapid Test Cassette (Feces) is specific to human hemoglobin. Specimen containing the following substances at the standard concentration was tested on both positive and negative controls and showed no effects on test results at standard concentration.

Substances	Concentrations (Diluted with the extraction buffer)
Beef hemoglobin	2 mg/mL
Chicken hemoglobin	0.5 mg/mL
Pig hemoglobin	0.5 mg/mL
Goat hemoglobin	0.5 mg/mL
Horse hemoglobin	20 mg/mL
Rabbit hemoglobin	0.06 mg/mL

## REFERENCES

1. Simon J.B. Occult Blood Screening for Colorectal Carcinoma: A Critical Review, Gastroenterology, Vol. 1985;88:820.
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## INDEX OF SYMBOLS

	Consult instructions for use		Tests per kit		Authorized Representative
	For <i>in vitro</i> diagnostic use only		Use by		Do not reuse
	Store between 2~30°C		Lot Number		Catalog#

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 GEFOB-602b

# H. pylori Ag Rapid Test Cassette (Feces)



## INTENDED USE

H. pylori Ag Rapid Test Cassette (Feces) is a sandwich lateral flow chromatographic immunoassay for the qualitative detection of H. Pylori antigen in feces. It is for professional *in vitro* diagnostic use only.

## INTRODUCTION

H. Pylori is associated with a variety of gastrointestinal diseases included non-ulcer dyspepsia, duodenal and gastric ulcer and active, chronic gastritis.<sup>1,2</sup> The prevalence of H. pylori infection could exceed 90% in patients with signs and symptoms of gastrointestinal diseases. Recent studies indicate an association of H. Pylori infection with stomach cancer.<sup>3</sup> H. Pylori colonizing in the gastrointestinal system elicits specific antibody responses<sup>4,5,6</sup> which aids in the diagnosis of H. Pylori infection and in monitoring the prognosis of the treatment of H. Pylori related diseases. Antibiotics in combination with bismuth compounds have been shown to be effective in treating active H. Pylori infection. Successful eradication of H. pylori is associated with clinical improvement in patients with gastrointestinal diseases providing a further evidence.<sup>7</sup>

## PRINCIPLE

H. pylori Ag Rapid Test Cassette (Feces) is a lateral flow chromatographic immunoassay based on the principle of the double antibody–sandwich technique. The test cassette consists of: 1) a burgundy colored conjugate pad containing H. Pylori antibodies conjugated with color particles (H. Pylori conjugates). 2) a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). The T band is pre-coated with non-conjugated H. Pylori antibodies.

When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. The antigen of H. Pylori if present in the specimen will bind to the H. Pylori antibodies conjugates. The immunocomplex is then captured on the membrane by the pre-coated H. Pylori antibodies, forming a burgundy colored T band, indicating a H. Pylori antigen positive test 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. Otherwise, the test result is invalid and the specimen must be retested with another device.

## PRODUCT CONTENTS

H. pylori Ag Rapid Test Cassette (Feces) containing anti- H. pylori antibodies particles and anti-H. pylori antibodies coated on the membrane.

## MATERIALS SUPPLIED

- 20 Sealed pouches each containing a test cassette and a desiccant
- 20 Specimen collection tubes with extraction buffer, 2.0 mL
- 1 Package insert

## MATERIAL REQUIRED BUT NOT PROVIDED

1. Clock or timer
2. Specimen collection containers.

## STORAGE AND STABILITY

All reagents are ready to use as supplied. Store unused test device unopened at 2°C-30°C. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test is not stable out off the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

## WARNINGS AND PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. Do not use it if the tube/pouch is damaged or broken.
3. Test is for single use only. Do not re- use under any circumstances.
4. Handle all specimens as if they contain infectious agents. Observe established standard procedure for proper disposal of specimens
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assay.
6. Humidity and temperature can adversely affect results

## SPECIMEN COLLECTION

Collect sufficient quantity of feces (1-2 mL or 1-2 g) in a clean, dry specimen collection container to obtain maximum antigens (if present). Best results will be obtained if the assay is performed within 6 hours after collection. Specimen collected may be stored for 3 days at 2-8°C if not tested within 6 hours. For long term storage, specimens should be kept below -20°C.

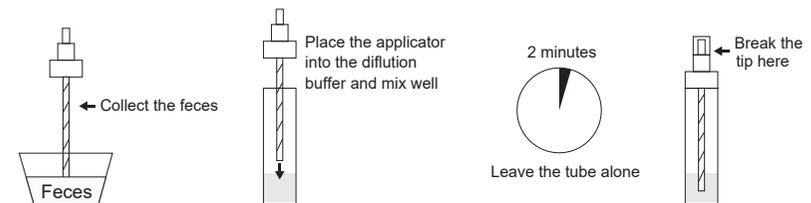
To process fecal specimens:

• For Solid Specimens:

Unscrew the cap of the specimen collection tube, then randomly stab the specimen collection applicator into the fecal specimen in at least 3 different sites to collect approximately 50 mg of feces (equivalent to 1/4 of a pea). Do not scoop the fecal specimen.

• For Liquid Specimens:

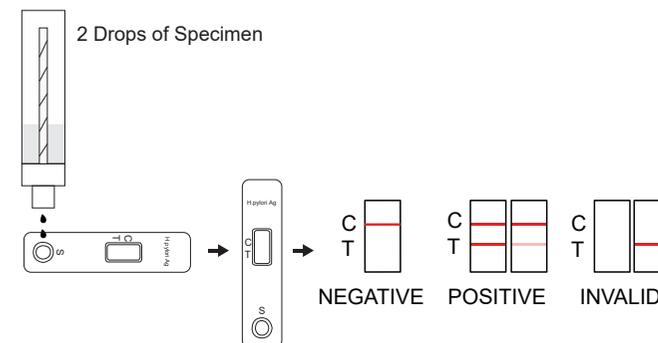
Hold the dropper vertically, aspirate fecal specimens, and then transfer 2 drops (approximately 80 µL) into the specimen collection tube containing the dilution buffer. Screw on and tighten the cap onto the specimen collection tube, then shake the specimen collection tube vigorously to mix the specimen and the dilution buffer. Leave the tube alone for 2 minutes.



## TEST PROCEDURE

1. Remove the test device from its foil pouch by tearing along the notch and use it as soon as possible.
2. Specimen collection. See also specimen collection.
3. Holding the sample collection device upright, carefully break off the tip of collection device.
4. Squeeze 2 drops (~80 µL) of the sample solution in the sample well of the cassette, as in the illustration.
5. Read the test results in 10 minutes. It is important that the background is clear before the result is read. Do not read results after 10 minutes. To avoid confusion, discard the test device after interpreting the result.

## INTERPRETATION OF RESULTS



# H. pylori Ag Rapid Test Cassette (Feces)

Positive: Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).

Negative: One colored line appears in the control line region(C). No line appears in the test line region (T).

Invalid: Control line fails to appear.

## QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

## LIMITATIONS

1. The Assay Procedure and the Assay Result Interpretation must be followed closely when testing the presence of H. Pylori antigen in feces from individual subjects. Failure to follow the procedure may give inaccurate results.

2. H. pylori Ag Rapid Test Cassette (Feces) is limited to the qualitative detection of H. Pylori antigen in feces. The intensity of the test band does not have linear correlation with the antigen titer in the specimen.

3. A negative result for an individual subject indicates absence of detectable H. Pylori antigen. However, a negative test result does not preclude the possibility of exposure to or infection with H. Pylori.

4. A negative result can occur if the quantity of the H. Pylori antigen present in the specimen is below the detection limits of the assay, or the antigen that are detected are not present during the stage of disease in which a sample is collected.

5. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

## PERFORMANCE CHARACTERISTICS

A study was performed with 165 patient feces samples including both symptomatic gastrointestinal disorders and samples from non-symptomatic patients and 100 normal feces samples. Comparison for all subjects with H. pylori Ag Rapid Test Cassette (Feces) and reference ELISA kit is showed in the following table:

Method		EIA		Total Results
H.P Test Cassette	Results	Positive	Negative	
	Positive	163	0	163
	Negative	2	100	102
Total Results		165	100	265

Relative sensitivity: 98.8%

Relative specificity: 100%

Accuracy:98.9%

## REFERENCE

1. Marshall,B.J.et.al. Pyloric Campylobacter infection and gastroduodenal disease. Med. J. Australia.149:439-44, 1985.

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