



# Combur<sup>5</sup> Test HC

REF 11896954176



▽ 10

## English

### Intended use

Five-parameter test strips for graduated determinations of glucose, leukocytes, nitrite, protein and blood in urine.

Suitable for self-testing.

### Summary

**Combur<sup>5</sup> Test HC** provides a fast and easy means of early detection and clinical monitoring of diabetes mellitus and diseases of the kidneys and urinary tract.

**Combur<sup>5</sup> Test HC** supports your physician's efforts to detect these diseases in their early stages. It does this by indicating the presence of substances excreted in the urine, thereby providing evidence of disease even when no symptoms are present.

- **Test your urine for 2 to 3 days in succession.**
- **Self-testing cannot, however, be used in place of testing performed by a physician.**
- **Continue testing every 3 months using two to three test strips, even if your test results are normal or your physician does not detect any abnormalities. This will provide additional security.**
- **Please contact your physician if you detect + or ++ results on one or more test parameters. Please test your urine again if the test results are unclear. In case all parameters are 0 after the first measuring, please test your urin for 1 or 2 more days and show the results to you physician.**
- **There is a possibility that test results might be false-positives or false-negatives. In case of doubt please test your urine again.**
- **Always consult your physician before making any decision that could affect your treatment.**

### Precautions and warnings

The stopper of the test strip vial contains a non-toxic silicate-based desiccant which must not be removed. If ingested by accident, drink large quantities of water.

For in vitro diagnostic use.

Disposal of all waste material should be in accordance with local guidelines.

Safety data sheet available for professional user on request.

### Storage and stability

Store the package at 2-30 °C. When stored in the original container the test strips are stable up to the expiration date specified on the box and color label.

Tightly re-cap the container immediately after removing a test strip.

Do not use test strips if they are past the expiration date printed on the container and color label. Discard expired test strip.

### Specimen collection and preparation

Use only clean, well-rinsed vessels to collect urine.

Do not add preservatives to the urine.

Use fresh urine that has not been centrifuged.<sup>1</sup> The urine specimen should not stand for more than 2 hours before testing. For specimen collection and preparation only use suitable tubes or collection containers, as false-positive readings, particularly for glucose and protein, can result from residues of detergent or strongly oxidizing disinfectants in the specimen collection vessel.<sup>1</sup>

Using midstream urine is recommended to avoid contamination by commensal urethral flora in both sexes.<sup>1</sup> Do not expose urine specimens to sunlight as this induces oxidation of bilirubin and urobilinogen and hence leads to artificially low results for these two parameters.<sup>1</sup> Vaginal secretion or menstrual blood may contaminate urine from females.<sup>1</sup>

Diagnosis or therapy should never be based on one test result alone but should be established in the context of all other medical findings. In doubtful cases, it is therefore advisable to repeat the test after discontinuation of the medication.

### Materials provided

10 test strips

### Materials required (but not provided)

- A clean cup for collecting urine

### Directions for use

For optimum performance of the test follow the directions given below:

- When measuring urinary glucose, note that, in some cases, increased glucose values can only be detected after a meal. As such, performing the test 2 hours after a meal, preferably after breakfast, is recommended. If possible, this meal should include 3-4 slices of bread or 1-2 rolls.

Allowing the urine to remain in the bladder for long periods of time (4-8 hours, ideally overnight) is recommended as a means of ensuring a high level of accuracy.

- **⚠** In women, this test can yield false results for blood if carried out 3 days before or 3 days after menses; as such, women are advised against performing this test during this period.

### Before you test:

1. Always test your first morning urine. Wash your genitals carefully and rinse thoroughly with water (do not dry). To collect urine use only clean, well-rinsed vessels.

2. Allow some urine to flow into the toilet. Collect the rest of the stream in the specimen cup.

### Performing the test:

1. Remove test strip. Immediately after you take a test strip out of the vial, seal the vial with the original desiccant stopper. Failure to do this could result in false results, as moisture in the vial could potentially cause color changes in the test parameters.

2. Briefly dip the test strip into the urine (approximately 1 sec.), making certain to wet all of the test parameters (fig. 1).

3. When removing the test strip, wipe its edge along the rim of the specimen cup in order to remove any excess urine (fig. 2).

4. All test parameters should be read at 1 minute (up to 120 seconds for the leukocyte test area for not clearly assignable results). Compare the colors of the test parameters on the strip with the colors on the label (fig. 3).

Separate sets of color blocks are given for erythrocytes and hemoglobin. Compare the 5th (blood) test parameter area with both rows of colors.

Fig. 1

Fig. 2

Fig. 3

Fig. 4

Fig. 1

Fig. 2

Fig. 3

Fig. 4

Fig. 1

Fig. 2

Fig. 3

Fig. 4

Fig. 1

Fig. 2

Fig. 3

Fig. 4

Fig. 1

Fig. 2

Fig. 3

Fig. 4

Fig. 1

Fig. 2

Fig. 3

Fig. 4

Fig. 1

Fig. 2

## Additional information for Healthcare Professionals

### Reagents

Each test contains per 1 cm<sup>2</sup> reactive paper area the following:

**Leukocytes:** Indoxylcarbonic acid ester 15.5 µg; methoxymorpholinobenzene diazonium salt 5.5 µg

**Nitrite:** 3-hydroxy-1,2,3,4-tetrahydro-7,8-benzoquinoline 33.5 µg; sulfanilamide 29.1 µg

**Protein:** 3',3'',5',5''-tetrachlorophenol-3,4,5,6-tetrabromosulphthaléine 13.9 µg

**Glucose:** 3',3',5',5''-tétraméthylbenzidine 103.5 µg; GOD 6 U, POD 3 U

**Blood:** 3',3',5',5''-tétraméthylbenzidine 52.8 µg; 2,5-diméthyl-2,5-dihydroperoxyhexane 297.2 µg

### Test principle

Test parameters on each strip contain indicator reagents. As soon as the test parameters have been wetted with urine, a chemical reaction takes place that causes the color of the test parameters to change in proportion to the concentration of the substance in question. The color change can then be assessed by comparing it with the color scale given on the vial label. **Glucose (GLU):** Glucose in the urine is almost always an indication of diabetes mellitus. Testing with **Combur<sup>5</sup> Test HC** is especially important for relatives of diabetics and for those at risk of diabetes (e.g., overweight individuals). **Combur<sup>5</sup> Test HC** detects substances that are excreted in the urine with a certain degree of variability. Because individual urine samples from diabetics could occasionally be glucose free, for instance, failure of the glucose parameter to change color does not rule out diabetes. Under certain circumstances (such as pregnancy) glucose may be present in the urine, even if blood glucose levels are normal.

**Leukocytes (LEU):** In case of an inflammation or infection of the kidneys or the urinary tract, more white blood cells are excreted than usual. Antibiotics containing imipenem, meropenem and clavulanic acid as active agents can result in false (positive) test results.

**Nitrite (NIT):** The most common cause of urinary tract infections is *E. coli*, which, along with most other pathogenic organisms of the urinary tract, converts the nitrate consumed in food into nitrite. The presence of nitrite is indicated by a pinkish red color on the test parameter, thereby providing indirect evidence of nitrite-forming bacteria in the urine. Even a faint pink color indicates a significant increase in the bacteria count.

**Protein (PRO):** Excreting protein in the urine can be an indication of kidney and urinary tract disease. Evidence of protein in the urine is not enough by itself to make an unambiguous diagnosis; the presence of protein could also have harmless causes (such as physical strain).

**Blood (ERY/Hb):** Kidney and urinary tract disease are the primary causes of blood in the urine. Hemoglobin, the component of blood that gives red blood cells (erythrocytes) their red color, may be released under certain conditions (e.g., physical strain, burns, ingestion of toxins, infectious processes). The vial label provides separate color scales for erythrocytes and hemoglobin. Individual or clustered green dots on the yellow test parameter are a sign of intact erythrocytes. Hemoglobin and/or damaged erythrocytes or myoglobin (a human protein similar to hemoglobin) are indicated by a uniform green color in the test parameter.

### Limitations - interference

The following drugs and substances were tested with Combur-Test technology test strips in the latest interference study from November 2013.

Therapeutic drugs	Endogenous substances	
Acetaminophen	Hydrochlorothiazide	Ammonium
N-Acetylcysteine	Hydroxychloroquine	Calcium chloride
Amoxicillin	Ibuprofen	Creatinine
Amlodipine besylate	Levodopa	α-D(+)-Glucose
Ascorbic acid	Levithroxine	Hemoglobin
Cefoxitin	Lisinopril	β-3-Hydroxybutyrate
Cetirizine	Methyldopa	Immunoglobulin G
Cotrimoxazol	Ofloxacin	Nitrite
Cyclosporine	Phenazopyridine	Urea
Furosemide	Salicylic acid	Uric acid
Gentamycin sulfate	Tetracycline	Urobilinogen
		pH 4.5-9

In case of doubt, please check if a repetition is reasonable after discontinuation of the medication.

For more detailed information on interfering substances, please contact our support via the Roche homepage [www.roche.com/contact.htm](http://www.roche.com/contact.htm).

### Common limitations

The test should not be performed within 3 days of treatment with antibiotics and/or chemotherapy. Relatively large quantities of vitamin C (ascorbic acid) can result in false (negative) test results.

Other factors, such as intense jogging, can increase erythrocyte (blood) and protein values without indicating illness.

**Leukocytes:** Formaldehyde (stabilizer) and medication with imipenem, meropenem and clavulanic acid may cause false-positive reactions.<sup>2</sup> If the urine specimen has a pronounced intrinsic color (for example due to the presence of bilirubin or nitrofurantoin), the reaction color may be intensified due to an additive effect.<sup>1</sup> Urinary protein excretions in excess of 500 mg/dL and urinary glucose excretions in excess of 3 g/dL<sup>2</sup> may diminish the intensity of the reaction color, as may cephalixin and drugs belonging to the group of cephalosporins, if administered in high daily doses, or boric acid if used as a preservative.<sup>1</sup> Antibiotics containing large daily doses of cephalixin and gentamycin as active agents can also result in false (albeit negative) test results.

**Nitrite:** Prolonged urinary retention in the bladder (4-8 hours) is essential in order to obtain an accurate result.<sup>1</sup> Administration of antibiotics or chemical drugs should be discontinued 3 days before the test.<sup>4</sup> More than 80 % of all bacteria responsible for urinary tract infections are Gram-negative rods (*E. coli*, Klebsiella, Enterobacter and Proteus species).<sup>2</sup> Most gram-negative bacteria have the ability to reduce urinary nitrate to nitrite and can therefore be detected indirectly with the test strips.<sup>1</sup> Normal nutrition as a rule ensures a sufficiently high content of nitrate in the urine for the detection of bacteria.<sup>5</sup> Some common uropathogens, e.g. Enterococcus spp. and Staphylococcus spp. (5-15 % of bacteria responsible for urinary tract infections),<sup>5</sup> do not reduce urinary nitrate to nitrite and will therefore not be detected whatever their urinary concentration.<sup>1</sup> False-negative results may occur as a result of strong diuresis with frequent voiding of urine, insufficient nitrate intake or too short retention of urine in the bladder.<sup>1</sup>

Large amounts of ascorbic acid decrease the sensitivity of the test and can result in false (negative) results.<sup>1</sup> Drugs that turn red in an acid environment (e.g. phenazopyridine) may produce false-positive readings or reddish colorations on the test parameter for nitrite.<sup>7</sup>

Attention: Nitrogen oxides present in the atmosphere may have an influence on the stability of the nitrite test parameter.<sup>7</sup> The test should not be performed within 3 days of treatment with antibiotics and/or chemotherapy.

**Protein:** False-positive readings may be found after infusion of polyvinylpyrrolidone (blood substitute), or when the urine collection vessel contains chlorhexidine or traces of disinfectants possessing quaternary ammonium groups.<sup>1</sup>

**Glucose:** The effect of ascorbic acid has been largely eliminated so that glucose concentrations of 100 mg/dL and ascorbic acid concentrations up to 400 mg/L are not likely to give false-negative results.<sup>8</sup>

**Blood/ERY:** Ascorbic acid has virtually no effect on the test.<sup>9</sup> In women the test for blood may be falsified from 3 days before to 3 days after a period. It is therefore advisable not to perform the test during this time. After physical activity, e.g. strenuous jogging, raised values for erythrocytes and protein may occur without being signs of disease.<sup>10</sup>

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

### Expected and result values

Based on literature. Current medical guidelines are leading.

Parameter	Expected values	Additional information
LEU	< 10 LEU/µL <sup>1</sup>	10-100 LEU/µL borderline <sup>1</sup>
NIT	< 1 µmol (< 0.005 mg/dL) <sup>11</sup>	A positive result is indicative of urinary tract infection (UTI), but a negative result does not rule out UTI. <sup>1</sup>
PRO	≤ 30 mg/dL <sup>12</sup>	> 30 mg/dL proteinuria <sup>12</sup>

Parameter	Expected values	Additional information
GLU	< 25 mg/dL < 1.4 mmol/L <sup>13</sup>	For daytime urine
ERY	< 18 ERY/µL (< 3 ERY/HPF) <sup>14</sup>	Hematuria ≥ 18 ERY/µL (≥ 3 ERY/HPF) <sup>15,16</sup>
	Conversion factor 5.8 to translate chamber counting high-power field (HPF) into µL <sup>1</sup>	

Parameter	Result values
LEU	neg., ~ 75, ~ 500 LEU/µL 0, +, ++
NIT	neg., pos. 0, +, ++
PRO	neg., 30, 100 mg/dL neg., 0.3, 1 g/L 0, +, ++
GLU	norm., 50, 100 mg/dL norm., 2.8, 5.6 mmol/L 0, +, ++
ERY	neg., ~ 5-10, ~ 50 ERY/µL 0, +, ++

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

### Specific performance data

Representative performance data are given below. Results obtained in individual laboratories may differ. The values for neg. and pos. indicate the proportion of concordant negative or positive results.

The values specified for the **limit of detection** are defined as the concentration of the analyte which leads to a positive result in ≥ 90 % of the examined urines.

The **method comparison** data for visual reading are based on the comparison with the instrument **cobas u 411** with Combur<sup>10</sup> Test M using at least 232 clinical samples per parameter. All test parameters were covered.

Parameter	Limit of detection	Method comparison <sup>9)</sup>
LEU	36 LEU/µL	neg.: 100 %, pos.: 62 %
NIT	0.05 mg/dL	neg.: 95 %, pos.: 91 %
PRO	14 mg/dL (albumin)	neg.: 85 %, pos.: 99 %
GLU	30 mg/dL	neg.: 96 %, pos.: 100 %
ERY/Hb	Intact erythrocytes; 6 ERY/µL Hemoglobin; 6 ERY/µL	neg.: 99 %, pos.: 94 %

a) The values for neg. and pos. indicate the proportion of concordant negative or positive results.

### Precision

Precision experiments comprised an assessment of repeatability (within-run precision) and intermediate precision using control material.

**Repeatability** was checked for 3 test strip lots in 3 separate runs with 21 measurements per run and lot.

For details see table below.

Precision		
Repeatability with human spiked samples		
Parameter	Target concentration <sup>9)</sup>	Exact agreement
LEU	0	100.00 %
	+	100.00 %
	++	100.00 %
GLU	0	100.00 %
	+	80.95 %
	++	100.00 %
NIT	0	100.00 %
	+	100.00 %
	++	100.00 %
PRO	0	100.00 %
	+	100.00 %
	++	100.00 %
ERY intact	+	100.00 %
	++	100.00 %
	0	100.00 %
ERY lysed	+	100.00 %
	++	100.00 %
	0	100.00 %

b) Sample concentration corresponds to the colour block

A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

## Français

### Domaine d'utilisation

Bandelettes réactives à cinq paramètres pour la détermination par échelons du glucose, des leucocytes, des nitrites, des protéines et du sang dans l'urine.

Convient pour l'autocontrôle.

### Caractéristiques

Les bandelettes **Combur<sup>5</sup> Test HC** constituent un moyen rapide et simple de détection précoce et de surveillance clinique du diabète sucré, des troubles rénaux et des affections des voies urinaires. Les bandelettes

**Combur<sup>5</sup> Test HC** indiquent la présence de certaines substances excrétées dans l'urine et permettant ainsi de confirmer ces maladies, même en l'absence de symptômes, ce qui aide votre médecin à poser précocement un diagnostic.

- **Tester l'urine pendant 2 à 3 jours d'affilée.**
- **L'autocontrôle ne peut toutefois pas remplacer un examen par un médecin.**

**Répéter ensuite le test tous les 3 mois à l'aide de deux ou trois bandelettes réactives, même en cas de résultats normaux ou en l'absence d'anomalie détectée par votre médecin. Ces tests vous apportent une assurance supplémentaire.**

**Contactez votre médecin si au moins l'un des paramètres analysés donne un résultat + ou ++. Si les résultats ne sont pas clairs, répéter le test. Si tous les paramètres donnent un résultat de 0 lors de la dernière mesure, tester l'urine pendant 1 ou 2 jours supplémentaires et montrer les résultats obtenus à votre médecin.**

- **Il est possible que les résultats soient des faux positifs ou des faux négatifs. En cas de doute, répéter le test.**
- **Consulter systématiquement votre médecin avant de prendre une décision susceptible d'affecter votre traitement.**

### Précautions d'emploi et mises en garde

Le bouchon du tube de bandelettes contient un dessiccant non toxique, à base de silicate, qui ne doit pas être retiré. En cas d'ingestion, boire abondamment.

Pour diagnostic in vitro.

L'élimination de tous les déchets devrait être effectuée conformément aux dispositions légales. Fiche de données de sécurité disponible sur demande pour les professionnels.

### Conservation et stabilité

Conservé le conditionnement entre 2 et 30 °C. Les bandelettes sont stables dans le tube d'origine jusqu'à la date de péremption figurant sur la boîte et la gamme colorimétrique.

Toujours bien refermer le tube immédiatement après en avoir extrait une bandelette.

Ne pas utiliser les bandelettes au-delà de la date de péremption indiquée sur le tube et la gamme colorimétrique. Éliminer les bandelettes réactives ayant dépassé la date de péremption.

### Prélevement et préparation des échantillons

Pour le recueil de l'urine, n'utiliser que des récipients propres et bien rincés.

Ne pas utiliser de conservateurs de l'urine.

Utiliser de l'urine fraîchement émise, non centrifugée.<sup>1</sup> Ne pas effectuer l'analyse avec des échantillons d'urine recueillis depuis plus de 2 heures. Pour le prélèvement et la préparation des échantillons, utiliser uniquement des tubes ou récipients de recueil appropriés. Des restes de détergent ou de désinfectant très oxydants dans le récipient de recueil de l'urine peuvent conduire à des résultats faussement positifs, notamment pour le glucose et les protéines.<sup>1</sup>

Il est recommandé d'utiliser de l'urine émise en cours de miction pour éviter toute contamination par la flore commensale urétrale chez les personnes des deux sexes.<sup>1</sup> Protéger l'urine des rayons solaires : l'obtention de résultats artificiellement bas pour la bilirubine et l'urobilinogène suite à une oxydation peut ainsi être évitée.<sup>1</sup> Chez la femme, les sécrétions vaginales et la menstruation peuvent contaminer l'urine.<sup>1</sup>

Tout diagnostic ou mise en place d'un traitement devrait se fonder non pas sur un résultat isolé, mais sur l'ensemble des résultats d'examen médicaux. En cas de doute, il est recommandé de refaire le test après arrêt du traitement.

### Matériel fourni

10 bandelettes réactives

### Matériel annexe nécessaire

- Coupelle propre pour le recueil de l'urine

### Mode d'emploi

Pour des performances optimales, suivre les instructions suivantes :

- Lors de la mesure du glucose dans l'urine, les taux de glucose augmentés ne sont parfois détectables qu'à la fin du repas. Il est recommandé dans ce cas d'effectuer le test 2 heures après le repas, de préférence après le petit-déjeuner. Ce repas devrait comprendre, si possible, 3 ou 4 tranches de pain et 1 ou 2 petits pains ou viennoiseries.

Il est recommandé d'accumuler l'urine dans la vessie pendant de longues périodes (4 à 8 heures, idéalement toute une nuit) pour garantir une exactitude optimale.

- **⚠** Il est déconseillé aux femmes d'utiliser ce test durant la période des menstruations (de 3 jours avant à 3 jours après), car il peut alors donner des résultats sanguins erronés.

### Avant la mesure :

- 1. Toujours utiliser la première urine du matin. Laver soigneusement les parties génitales et les rincer abondamment à l'eau, sans les sécher. Pour le recueil de l'urine, n'utiliser que des récipients propres et bien rincés.

2. Laisser les premières gouttes d'urine couler dans les toilettes, puis recueillir le reste dans la coupelle.

### Réalisation du test :

1. Retirer une bandelette réactive. Refermer le flacon immédiatement après avoir sorti la bandelette à l'aide du bouchon hydrophile d'origine. Si cela n'est pas fait, la présence d'humidité dans le flacon pourrait provoquer un changement de couleur des zones réactives et donner des résultats erronés.

2. Immerger brièvement (environ 1 seconde) la bandelette réactive dans l'urine en veillant à ce que toutes les zones réactives soient recouvertes (fig. 1).

3. Égoutter la bandelette en passant la tranche de celle-ci contre le bord de la coupelle de manière à éliminer l'excès d'urine (fig. 2).

4. Au bout d'1 minute (ou maximum 120 secondes pour la zone réactive des leucocytes en cas de résultat non tranché), comparer la couleur de chaque zone réactive de la bandelette avec celle des gammes colorimétriques (fig. 3).

Deux ensembles distincts de blocs de couleur sont donnés pour les érythrocytes et l'hémoglobine. Comparer la couleur de la 5ème zone réactive (sang) avec les deux gammes colorimétriques.

Fig. 1

Fig. 2



