CarciReagent Package Leaflet

Name of the in vitro diagnostic device for self-testing: **CarciReagent**

Product number (catalogue no.): CR/001

Product description

Test kit for the detection of an indicative amount of monohydroxyphenol metabolites (tyrosine) in urine (Lay semi-quantitative self-test)(Chemical chromogenic method)

This test is indicative, and the result should be consulted with a physician.

An IVD in vitro diagnostic medical device for self-testing for single-use

 Read the package leaflet before using this test

Package contents:

1 pc vial with 0.6 ml ± 0.05 ml reagent (clear liquid)

1 pc protective cap for opening the vial

1 pc dropper

1 pc colour scale of test result (for comparison)

1 pc package leaflet

1 pc control coupon with QC marking

To perform the test, you will also need:

1 pc clean urine collection container (not included in the package)

Intended use:

CarciReagent – in vitro diagnostic device for self-testing, designed for the detection of monohydroxyphenol metabolites (tyrosine) and its indicative amount in the patient's urine (Lay semi-quantitative test for self-testing).

For more information, including links to references, please visit www.carcireagent.com

This is a **chemical chromogenic method**. The idea is that the presence of the substance of interest in the test sample is detected by a chemical reaction that produces visible colour changes. The result can then be compared to a colour scale.

The in vitro diagnostic tool is designed for semi-quantitative detection of an indicative amount of monohydroxyphenol metabolites (tyrosine), which means that an indicative amount of monohydroxyphenol metabolites (tyrosine) in the patient's urine can be easily detected on the basis of a colour reaction according to the attached scale (8 possible colours) (semi-quantitative –

describing the phenomenon in a semi-quantitative manner, on an agreed scale, without precise numbers and physical or chemical units).

The characteristic colour of the test result is produced by the reaction between the reagent in the vial and the tyrosine content in urine. Based on colour after the reaction, an indicative amount of tyrosine in urine can be determined. The agent can be used as an early warning of a serious illness. The result of the test is only indicative, and it is always necessary to consult a doctor about the medical condition and the result of the test.

Principle:

The basic principle of the test is based on the improved Millon's reagent method, when elevated levels of monohydroxyphenol metabolites (tyrosine) (monohydric phenolic amino acids and their metabolites) are monitored in urine. Based on the colour change of the mixture in the vial after the addition of 3 ml of morning urine (midstream urine), the reaction colour cascade can be used to determine whether the urine samples contain elevated levels of these metabolites. The reagents in the vial and the tyrosine levels in urine show a characteristic chromogenic reaction that can be used for clinical diagnosis of intracellular metabolic abnormalities (detecting possible changes or disturbances in metabolism within the human cell). The detected indicative tyrosine levels in urine (according to the attached table from 0 - 2,000 mg per litre of urine) react with a chemical reagent and, depending on the amount, becomes coloured. According to the attached colour scale, the test result can be read from No. 1 to No. 8.

Result from No. 1 to No. 3, is the amount of tyrosine in normal concentration, thus the result is considered negative, and no increased amount of tyrosine has been shown.

Result from No. 4 to No. 5 is already a positive finding of increased amount of tyrosine in urine.

If the concentration of tyrosine is higher than 500 mg per litre of urine, i.e. result No. 6, No. 7 or No. 8, it is a positive result, high levels of tyrosine in urine may indicate a serious disease.

In case of positive results, a more thorough examination by a general practitioner is recommended to rule out the risk of a possible serious disease.

Composition:

Composition: Zinc acetate, nitric acid, lithium carbonate, sodium nitrite, sodium acetate trihydrate, hydrogen peroxide (30%), distilled water.

Stability:

The product has been tested and its shelf-life is set at 3 years from manufacture under the indicated storage conditions.

Storage and operating temperature:

Storage of unused product is suitable in dry, closed environment and at a temperature between 5 °C and 40 °C.

At operating temperatures between 5 °C and 40 °C, the test reaction time is between 3 and 5 minutes.

Functional capability:

Specificity of the in vitro diagnostic is 99,4% (see table below).

Sensitivity of the in vitro diagnostic to selected diseases (see table):

Disease	Number of tested	Result		Sensitivity	Specificity
		Positive	Negative		
Malignant tumours	4,375	4,230	145	96.70%	
Pigment disorders	68	15	53	22.10%	
Diabetes	93	20	73	21.50%	
Gastritis	166	25	141	15.10%	
Gastric ulcers	78	11	67	14.10%	
Tuberculosis	56	5	51	8.90%	
Viral hepatitis	102	9	93	8.80%	
Benign prostatic hyperplasia	28	2	26	7.10%	
Gallbladder inflammation	115	8	107	7.00%	
Pneumonia	87	6	81	6.90%	
Esophagitis	74	4	70	5.40%	
Enteritis	66	3	63	4.50%	
Parkinson’s disease	40	0	40	0.00%	
Depression	36	0	36	0.00%	
Albinism	22	0	22	0.00%	
Phenylketonuria (PKU)	10	0	10	0.00%	
Healthy population	2,662	16	2,646		99.40%

Occupational Safety, Safe disposal:

Caution

Carry out the test immediately after opening the vial with liquid (reagent)!

The liquid (reagent) in the vial is harmful if swallowed and irritating to eyes and skin. Use with extreme caution. If splashed on skin or clothes, wash quickly with soapy water. If eye contact occurs, rinse immediately with running water and seek medical attention.

After the test has been evaluated and the vial used, the contents should be diluted with at least two litres of clean water and then they may be disposed of in a normal manner (the liquid may be poured down the drain after dilution and the glass vial, including other tester components, may be disposed of in municipal waste). The test should be carried out at home.

Working procedure:

1, Always use fresh first morning urine (midstream urine) collected in a clean container without traces of detergents or disinfectants for testing.

2, Using a protective plastic cap, cover the vial and carefully break off the vial tip. Handle the vial carefully, it contains acid. Test immediately after opening the vial.

3, Draw a urine sample into the dropper.

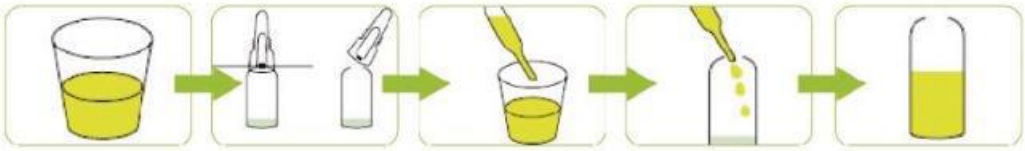
4, Add 3 ml of urine to the vial (repeat until you have filled the urine to the mark on the vial).

5, After 3-5 minutes of exposure, evaluate the colour of the liquid (or possible sediment) by visual comparison with the included colour scale.

6, After evaluation, determine whether the detection for tyrosine levels in urine are negative or positive (the table provides indicative amounts of tyrosine in urine). If positive, please follow the advice in this package leaflet.

(Caution, after a prolonged reaction (more than 10 minutes) of urine with the reagent, the mixture degrades, and the colour no longer complies with the possible test result)

Graphical overview of the work procedure:



1, Always use fresh urine for testing (midstream urine).	2, Using the protective plastic cap, carefully break off the vial tip.	3, Draw a urine sample into the dropper.	4, Add 3 ml of urine to the vial (until it reaches the 3.6 ml mark on the vial)	5, After 3-5 minutes of exposure, evaluate the colour of the liquid.

Evaluation (according to the colour scale included in the package):

Result No. 1, 2, 3: **NEGATIVE** – The tyrosine levels in urine are not elevated.

Result No. 4, 5: **POSITIVE** – The tyrosine levels in urine are elevated. It is recommended to consult the result with a physician and be concerned about the health condition.

Result No. 6, 7, 8: **POSITIVE** – The tyrosine levels in urine are significantly elevated. It is recommended to visit a physician and discuss the test result immediately.

Result No. 9 - Test failed. Please send a message to CNEU MEDICAL, s.r.o.

Table with indicative tyrosine levels in urine in mg/L

Result number:	1 Negative	2 Negative	3 Negative	4 Positive	5 Positive	6 Positive	7 Positive	8 Positive
Indicative tyrosine levels in urine (mg/L)	0	167	200	250	324	500	1000	2000

Special warning: A green or dark green test result is also positive; milky colouration may indicate acute or chronic disease. It is recommended to consult the result with a physician. Please contact CNEU MEDICAL, s.r.o. if other discolourations occur.

The sensitivity of the test may be influenced by variations in the urine composition, diet, the patient's diagnosis or medication; for this reason, the test is only indicative and in case of doubt, further specialized tests for tyrosine levels in urine should always be performed in consultation with a physician.

THIS LAY TEST IS ONLY INDICATIVE!

The results of the test must be consulted with a physician. The test is intended for single-use. The test is intended for lay persons over 18 years old.

Caution

Carry out the test immediately after opening the vial with liquid (reagent)!

The result of the test may be affected by false positives such as hormonal drugs, leukaemia drugs, ethanol extracts in traditional medicine, neurological drugs, amino acid drugs and nutrients, protein drugs and salicylic acid-based drugs.

The test result may be affected by false negatives such as tyrosine inhibitors, sedatives, analgesics and hypertension drugs, as well as drugs for cancer or tyrosinemia treatment.

If you are using any of the above medications, please consult your physician whether to use the test.

The result of the test can be affected by both false positives and false negatives due to the food and nutrient composition. It is therefore recommended to avoid food such as high protein, high fat, dairy products, coffee, tea and alcohol for at least 48 hours before the test execution. These foods include cheese, chocolate and citrus fruits, canned sardines, tomatoes, milk, lactic acid drinks, cheese, animal liver, beef, yoghurt, condensed milk, sausage, ham, fermented foods, beans, lentils, pineapple, bananas, figs, grapes, vinegar, seafood and fish.

And finally, the patient's physical condition (fatigue, stress) or other diseases such as diabetes, bilirubinemia (liver disease), stomach ulcers (Helicobacter pylori) or other diseases that cause unusual urine colouration may affect the result.

Examples of diseases or medical conditions that affect the amount of tyrosine in urine (for links to scientific studies, visit www.carcireagent.com):

Low levels of tyrosine in urine:

Parkinson's disease, depression (upon tyrosine deficiency), albinism (genetic disorder), phenylketonuria (PKU), tyrosinemia (inherited metabolic disorder)

Possibly increased amounts of tyrosine in urine:

Pigment disorders (freckles, brown spots), diabetes, stomach ulcers and gastritis

Increased amount of tyrosine in urine:

Malignant tumours: mainly including malignant tumours of the digestive tract (stomach cancer, intestinal cancer), liver cancer, nasopharyngeal cancer, malignant lymphomas, breast cancer, gynaecological malignancies, lung cancer, etc.

The specificity and sensitivity of the in vitro diagnostic tool for the selected diseases is given in the table above (Functional Capability).

More information on the scientific studies concerning the above warnings, including links to references, can be found at www.carcireagent.com

In the absence of a control coupon or obvious damage to the contents, please contact

CNEU MEDICAL s.r.o. directly.

Notes

If you have any questions or in the case of any defect of the CarciReagent in vitro diagnostic device, please contact CNEU MEDICAL s.r.o. at info@carcireagent.com or at the following postal address: Jeřábkova 1459/8, 149 00 Prague 4, Czech Republic.

Company website: www.carcireagent.com

The company's website also comprises a questionnaire for post-sale evaluation

of satisfaction with CarciReagent (link to https://www.carcireagent.com/survio/).

Further information about the product can be found on our website.

This is only a translation of the original text of the leaflet. Original text is in Czech language.

CE 1023

Package leaflet version

(August 2022 – ID No. 0001)

(Date of update/revision – Identification number)

Explanation of the markings on the packaging:


Read the package leaflet carefully


Name and address of manufacturer

An IVD in vitro diagnostic medical device for self-testing


Waning: Harmful if swallowed


Do not reuse/ For single-use only


Handle carefully


FRAGILE


Store at a dry place and at a temperature between 5° and 40°C

Batch number


Date of manufacture


Expiry date