



# Carci Reagent<sup>®</sup>

**Test kit for the detection of an indicative amount of  
monohydroxyphenolic metabolites (tyrosine) in urine  
(Lay Semi-Quantitative Test for Self-Assessment)  
(Chemical chromogenic method)**

**Author: Mag. Martin Muzikant, Ph.D.  
Company: CNEU MEDICAL s.r.o.**



**Carci Reagent**



# The current situation in the prevention of oncological diseases

## SCREENING PROGRAMS OF HEALTH INSURANCE COMPANIES - Czech Republic

- ▶ Since 2014, addressed invitations for screening
- ▶ Over 8 million invitations in 4 years
- ▶ Aimed at breast, cervical and colon cancer screening
- ▶ Nevertheless, low interest of citizens and high non-participation



# The current situation in the prevention of oncological diseases



## Cancer prevention: The impact of the covid epidemic

- ▶ Half of people neglect colon and cervical cancer screenings  
approx. 50% of people do not go regularly, of which 20-25% at all!!!
- ▶ During covid, around 14% of people postponed key prevention, some did not go thanks to covid, up to 30% in the short term and approx. 15% in the long term did not participate in prevention
- ▶ CITIZENS CAN'T BE RETURNED TO REGULAR PREVENTION!

# Blood tests for the prevention of oncological diseases



## Tumor markers from blood and their price in the laboratory

- ▶ Currently, tumor markers are monitored either in blood or in tissue samples taken (biopsies)
- ▶ The total price of all available blood tumor markers is more than 400 USD, and this is only basic testing with variable sensitivity (60-80%).
- ▶ For example, the PSA test has 68-80% sensitivity, improved urine sediment test for PCA3 marker (Progenisa urine test) costs approx. 200 USD

# Basic examination in the framework of the prevention of oncological diseases I.



## Procedure in the prevention of oncological disease

- ▶ **Self-examination** - any findings on your body or doubts must be consulted with the treating general practitioner
- ▶ Patience when a malignant disease is suspected - unfortunately, at present, it is not possible to carry out all the examinations at once, it takes time.
- ▶ **Basic oncological examination** - blood and urine examination, imaging methods (SONO, Mammogram, X-ray, possibly CT), direct methods (gastroscopy, colonoscopy, bronchoscopy)

# Basic examination in the framework of the prevention of oncological diseases II.

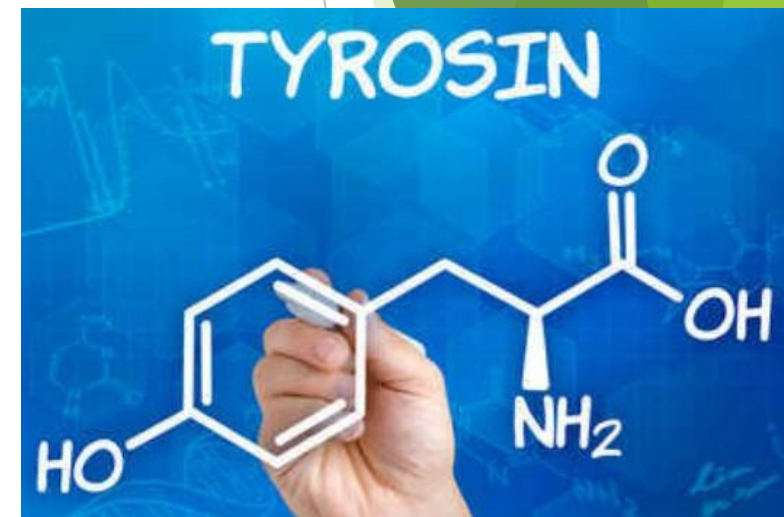


## Basic examination prices for self-payers

- ▶ A basic examination for a possible oncological disease costs on average about 400 USD (self-pay)
- ▶ But if we are dealing with complex oncological examinations, then the prices are already over 1.200 USD (self-pay)
- ▶ And subsequent treatment of late-caught cancer costs hundreds of thousands USD

# What is Tyrosine?

- ▶ Non-essential amino acid (formed from essential phenylalanine)
- ▶ It plays a key role in resistance to stress!
- ▶ Tyrosine is excreted in the urine and its limit amount in a healthy adult population is max 200mg/per liter of urine  
(child under 1 year - 1500mg/L, juveniles under 18 years of age - 500mg/L)



# Urinary tyrosine as a marker of malignant tumor

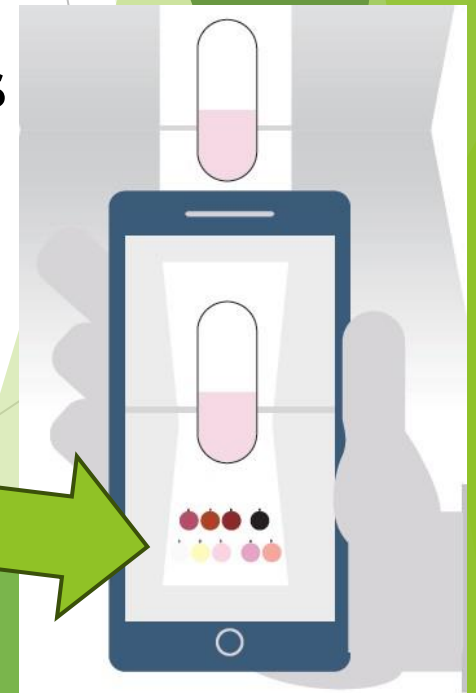
- ▶ High levels of tyrosine in the urine indicate a serious problem in the body (adult max. 200mg/L)
- ▶ Tyrosine plays an important role in cancer (current scientific studies)
- ▶ Urine is a medium that is ideal for non-invasive and rapid diagnosis of possible cancer



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# CarciReagent for self-testing

- ▶ CarciReagent - in vitro diagnostic medical device for self-testing, intended for the detection of metabolites of monohydroxyphenol (tyrosine) and its indicative amount in the patient's urine
- ▶ The test uses a chemical chromogenic method. The idea is that the presence of a substance of interest in a test sample is detected by a chemical reaction that produces visible color changes. The result can then be compared to a color scale.



# CarciReagent for self-testing

Detailed representation (video) of the workflow:



# CarciReagent for self-testing

Rating (according to the color scale included in the package):

**Result #1, 2, 3: NEGATIVE - The amount of tyrosine in the urine is not increased**

**Result #4, 5: POSITIVE – The amount of tyrosine in the urine is increased. It is recommended to consult the result with a doctor and take an interest in your health.**

**Result No. 6, 7, 8: POSITIVE – The amount of tyrosine in the urine is significantly increased. It is recommended to see a doctor immediately and consult the test result.**

Table with approximate amount of tyrosine in urine in mg/L

| Result #:                                         | č.1<br>Negativ                                                                      | č.2<br>Negativ                                                                      | č.3<br>Negativ                                                                      | č.4<br>Positiv                                                                       | č.5<br>Positiv                                                                        | č.6<br>Positiv                                                                        | č.7<br>Positiv                                                                        | č.8<br>Positiv                                                                        |
|---------------------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|
| Approximate amount of<br>tyrosine in urine (mg/L) | 0                                                                                   | 167                                                                                 | 200                                                                                 | 250                                                                                  | 324                                                                                   | 500                                                                                   | 1000                                                                                  | 2000                                                                                  |
|                                                   | 1.                                                                                  | 2.                                                                                  | 3.                                                                                  | 4.                                                                                   | 5.                                                                                    | 6.                                                                                    | 7.                                                                                    | 8.                                                                                    |
|                                                   |  |  |  |  |  |  |  |  |



# CarciReagent for self-testing

## ► Real negative test results



## ► Real positive test results



# CarciReagent for self-testing

Sensitivity (Malignant tumor 96.7%) and specificity (99.4%) of the CarciReagent tester

| Disease                                    | Senzitivity          |
|--------------------------------------------|----------------------|
| <b><u>Malignant tumors</u></b>             | <b><u>96,70%</u></b> |
| Pigment disorders                          | 22,10%               |
| Diabetes                                   | 21,50%               |
| Gastritis                                  | 15,10%               |
| Gastric ulcers                             | 14,10%               |
| Tuberculosis                               | 8,90%                |
| Viral hepatitis                            | 8,80%                |
| Benign prostatic hyperplasia               | 7,10%                |
| Inflammation of the gallbladder            | 7,00%                |
| Pneumonia                                  | 6,90%                |
| Esophagitis                                | 5,40%                |
| Inflammation of the small intestine        | 4,50%                |
| <b>Specificity in a healthy population</b> | <b>99,40%</b>        |



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# CarciReagent for self-testing



- ▶ **THIS LAY TEST IS USED AS AN EARLY WARNING TO PREVENT POSSIBLE SERIOUS ONCOLOGICAL DISEASE!**
- ▶ **The results of the examination must be consulted with a doctor. The test is intended for single use. The test is intended for healthy persons over 18 years of age.**



# EU CERTIFICATION No. 22 0196 CN/NB



## CarciReagent IVD self-test in vitro diagnostic tool

meets the basic requirements defined in Annex I., Section A, Section B, in Annex III. § 6., directive of the European Parliament and the Council 98/79 / EC, which apply to it taking into account the intended purpose of use as defined in Government Regulation No. 56/2015 Coll.

The following requirements are met

- EN ISO 13485:2016
- EN 13532:2002
- EN 13612:2002
- EN ISO 14971:2012
- EN ISO 15223-1:2016
- EN ISO 18113-1:2011
- EN ISO 18113-4:2011
- EN ISO 23640:2015



# EU CERTIFICATION No. 22 0196 CN/NB



Carci Reagent



CNEU MEDICAL, s.r.o.  
Jirábkova 1459/8, 149 00 Prague 4, Czech Republic

## EC Declaration of Conformity

No. of IVDR: CR/901

Pursuant to Art No. 23(1)(97) CoL, On technical requirements for products, as amended, Government Decree No. 56/2015 Coll., Laying down technical requirements for medical devices for self-testing, as amended and in accordance with the requirements of the Directive 98/79 / EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

Manufacturer: CNEU MEDICAL  
Registered office: Prague 4, Jirábkova  
ID: 082 90 458  
Hereby declares that the diagnostic device

CarciReagent

meets the basic requirements defined in / Directive 98/79 / EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

Description of the notified device:  
CarciReagent - in vitro diagnostic device measuring hydroxyphenol metabolites (tyrosin) (Lys semi-quantitative test for self-testing)

These requirements are met during the period of validity of the following standards:  
EN ISO 13485:2016  
EN 13512:2002  
EN 13612:2003  
EN ISO 14971:2012  
EN ISO 13223-1:2016  
EN ISO 18113-1:2011  
EN ISO 18113-2:2011  
EN ISO 22640:2015

The notified body participated in the CE marking process.  
Notified body reference: 1023  
Notified body number: 1023  
ID: 179 0 381

ID: 082 90 458  
Bank CZK: FIO Bank; IBAN: CZ24 2010 0000 0023 0174 9129; BIC: FIOBCZPPXXX  
Bank USD: FIO Bank; IBAN: CZ49 2010 0000 0023 0174 9132; BIC: FIOBCZPPXXX  
Bank EUR: FIO Bank; IBAN: CZ39 2010 0000 0023 0174 9133; BIC: FIOBCZPPXXX  
[www.carciareagent.com](http://www.carciareagent.com)



CNEU MEDICAL, s.r.o.  
Jirábkova 1459/8, 149 00 Prague 4, Czech Republic

## EC Certificate No.: 22 0196 CN/NB

Valid from: 2022-05-20  
Valid until: 2025-05-26  
First issued: 2022-05-20



EC Certificate issued for the diagnostic device in vitro CarciReagent.

In Prague on: May 27, 2022



Responsible person: Mag. Martin Muzikant, Ph.D.

On behalf of company: CNEU MEDICAL, s.r.o., Jirábkova 1459/8, Prague 4, Czech Republic

ID: 082 90 458  
Bank CZK: FIO Bank; IBAN: CZ24 2010 0000 0023 0174 9129; BIC: FIOBCZPPXXX  
Bank USD: FIO Bank; IBAN: CZ49 2010 0000 0023 0174 9132; BIC: FIOBCZPPXXX  
Bank EUR: FIO Bank; IBAN: CZ39 2010 0000 0023 0174 9133; BIC: FIOBCZPPXXX  
[www.carciareagent.com](http://www.carciareagent.com) [info@carciareagent.com](mailto:info@carciareagent.com)



Notified Body 1023  
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,  
Jirábkova 258, Louky, 753 02 Zlín, Czech Republic

## EC Design-Examination Certificate No. 22 0196 CN/NB

Issued for manufacturer

CNEU Medical, s.r.o.

Jirábkova 1459/8, 149 00 Prague 4, Czech Republic

in accordance with requirements of

Directive 98/79/EC

on in vitro diagnostic medical devices, Annex III (6)

for the following product category(ies):

CarciReagent

The Notified Body No. 1023 has performed an examination of the design dossier relating to devices / device categories in accordance with IVDD Annex III (6). The design of the devices conforms to the requirements of this Directive.

Valid from: 2022-05-20  
Valid until: 2025-05-26  
First issued: 2022-05-20  
Revision: -



Mgr. Jiří Hoš  
Representative of the Notified Body No. 1023

Date: 2022-05-20

Page 1/1



Notified Body 1023  
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,  
Jirábkova 258, Louky, 753 02 Zlín, Czech Republic

## Design-Examination Certificate

No. 22 0196 CN/NB

Issued for manufacturer:

CNEU Medical, s.r.o.  
450/8, 149 00 Prague 4, Czech Republic

| Reference Number | Action        |
|------------------|---------------|
| 813001009        | Certification |



Mgr. Jiří Hoš  
Representative of the Notified Body No. 1023

Date: 2022-05-20  
Revision: -

Page 2/2



# REGISTRATION WITH THE STATE OFFICE FOR DRUG CONTROL, CZECH REPUBLIC, EU



Carci Reagent



|                                                              |                                                      |                                                                      |                                           |
|--------------------------------------------------------------|------------------------------------------------------|----------------------------------------------------------------------|-------------------------------------------|
| STÁTNÍ ÚSTAV<br>PRO KONTROLU LÉČIV                           | Šrobárova 48<br>100 41 Praha 10                      | Telefon: +420 272 183 111<br>Fax: +420 271 732 377                   | E-mail: posta@sukl.cz<br>Web: www.sukl.cz |
| ADRESÁT<br>CNEU MEDICAL s.r.o.<br>Mag. Martin Muzikant Ph.D. | ADRESA<br>Jeřábkova 1459/8<br>Praha-Chodov<br>149 00 |                                                                      |                                           |
| Číslo jednací<br>sukl283943/2022                             | Spisová značka<br>sukls253355/2022                   | Vyřizuje / e-mail<br>Ing. Jarmila Bártová<br>jarmila.bartova@sukl.cz | Datum<br>29. 12. 2022                     |

## ROZHODNUTÍ

Státní ústav pro kontrolu léčiv, se sídlem v Praze 10, Šrobárova 48 (dále jen „Ústav“), jako správní orgán příslušný na základě § 5 odst. 1 ve spojení s § 74 odst. 8 zákona č. 375/2022 Sb., o zdravotnických prostředcích a diagnostických zdravotnických prostředcích in vitro, ve znění pozdějších předpisů (dále jen „zákon o prostředcích“) v souladu s čl. 113 odst. 3 písm. f) ve spojení s čl. 26 nařízení Evropského parlamentu a Rady (EU) 2017/746 ze dne 5. dubna 2017 o diagnostických zdravotnických prostředcích in vitro a o zrušení směrnice 98/79/ES a rozhodnutí Komise 2010/227/EU, nebo čl. 123 odst. 3 písm. d) ve spojení s čl. 29 nařízení Evropského parlamentu a Rady (EU) 2017/745 ze dne 5. dubna 2017 o zdravotnických prostředcích, změně směrnice 2001/83/ES, nařízení (ES) č. 178/2002 a nařízení (ES) č. 1223/2009 a o zrušení směrnice Rady 90/385/EHS a 93/42/EHS, rozhodl ve správním řízení, sp. zn. sukls253355/2022, v souladu s § 67 zákona č. 500/2004 Sb., správní řád, ve znění pozdějších předpisů (dále jen „správní řád“),

takto:

Ústav tímto vyhovuje žádosti osoby registrační číslo 081023, CNEU MEDICAL s.r.o., se sídlem Jeřábkova 1459, 14900 Praha, IČ: 08290458, o notifikaci prostředku ve smyslu § 2 odst. 3 zákona o prostředcích.

| Evidenční číslo | Název prostředku           | Registrační číslo výrobce | Výrobce             |
|-----------------|----------------------------|---------------------------|---------------------|
| 01119521        | CarciReagent               | 081023                    | CNEU MEDICAL s.r.o. |
|                 | Identifikační kód varianty | Doplňkový název           | Katalogové číslo    |
|                 | 0001                       | CarciReagent              | CR/001              |

Platnost notifikace výše uvedeného prostředku / uvedených prostředků činí pět let ode dne nabytí právní moci tohoto rozhodnutí.

## Odůvodnění

Podle § 68 odst. 4 správního řádu není odůvodnění rozhodnutí třeba, jestliže správní orgán prvního stupně všem účastníkům v plném rozsahu vyhověl.



|                                                              |                                                      |                                                                  |                                           |
|--------------------------------------------------------------|------------------------------------------------------|------------------------------------------------------------------|-------------------------------------------|
| STÁTNÍ ÚSTAV<br>PRO KONTROLU LÉČIV                           | Šrobárova 48<br>100 41 Praha 10                      | Telefon: +420 272 183 111<br>Fax: +420 271 732 377               | E-mail: posta@sukl.cz<br>Web: www.sukl.cz |
| ADRESÁT<br>CNEU MEDICAL s.r.o.<br>Mag. Martin Muzikant Ph.D. | ADRESA<br>Jeřábkova 1459/8<br>Praha-Chodov<br>149 00 |                                                                  |                                           |
| Číslo jednací<br>sukl249934/2022                             | Spisová značka<br>sukls248911/2022                   | Vyřizuje / e-mail<br>Ing. Lenka Votravá<br>lenka.votrava@sukl.cz | Datum<br>15. 11. 2022                     |

## POTVRZENÍ SPLNĚNÍ OHLAŠOVACÍ POVINNOSTI

Státní ústav pro kontrolu léčiv, se sídlem v Praze 10, Šrobárova 48, jako správní orgán příslušný na základě § 9 písm. b) zákona č. 268/2014 Sb., o diagnostických zdravotnických prostředcích in vitro, ve znění pozdějších předpisů s ohledem na čl. 113 odst. 3 písm. f) nařízení Evropského parlamentu a Rady (EU) 2017/746 ze dne 5. dubna 2017 o diagnostických zdravotnických prostředcích in vitro a o zrušení směrnice 98/79/ES a rozhodnutí Komise 2010/227/EU, nebo na základě § 9 písm. b) zákona č. 268/2014 Sb., o zdravotnických prostředcích a o změně zákona č. 634/2004 Sb., o správních poplatcích, ve znění účinném do 25. 5. 2021, s ohledem na ustanovení § 74 odst. 4 zákona č. 89/2021 Sb., o zdravotnických prostředcích a o změně zákona č. 378/2007 Sb., o léčivech a o změnách některých souvisejících zákonů (zákon o léčivech), ve znění pozdějších předpisů, potvrzuje tímto splnění ohlašovací povinnosti níže uvedené osoby.

|                   |                                                                          |
|-------------------|--------------------------------------------------------------------------|
| Registrační číslo | 081023                                                                   |
| IČ                | 08290458                                                                 |
| Název             | CNEU MEDICAL s.r.o.                                                      |
| Sídlo             | Jeřábkova 1459/8, 14900 Praha, Česká republika                           |
| Kontaktní osoba   | Mag. Martin Muzikant Ph.D., martin.muzikantcz@gmail.com, +420722 170 087 |

## Seznam činností

- výrobce diagnostických zdravotnických prostředků in vitro



# EARLY WARNING OF SERIOUS DISEASE

- ▶ Currently, we have offered a tester to Czech health insurance companies for preventive programs within their projects.
- ▶ We are negotiating with representatives of the Czech Medical Chamber and other institutions that deal with health protection and prevention of oncological diseases



# EARLY WARNING OF SERIOUS DISEASE



- ▶ An examination is recommended at least once a year, more often in case of doubts about the state of health or other circumstances
- ▶ The recommended retail price is set at 79 USD
- ▶ You can find it on google - CarciReagent

# Thank you for your attention!

## Are you interested in providing a tester to your customers?

Do not hesitate to contact us!

Mag. Martin Muzikant, Ph.D.

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