



diagendo♀

EndoRNA

Endometriosis diagnostic medical device

An innovative diagnostic method



What is endometriosis?

Key facts

- Endometriosis is a disease where tissue similar to the lining of the uterus grows outside the uterus, causing pain and/or infertility
- It is a chronic disease associated with severe, life-impacting pain during periods, sexual intercourse, bowel movements and/or urination, chronic pelvic pain, abdominal bloating, nausea, fatigue, and sometimes depression, anxiety, and infertility.
- Endometriosis affects roughly 10% (190 million) of reproductive age women and girls globally

Endometriosis problem



Facts:

- On average, it takes 8 years to get a diagnosis from the onset of symptoms
- The prevalence of endometriosis in women with infertility is as high as 30–50%
- Endometriosis is the second most common gynaecological condition in many EU countries
- The cause of endometriosis is unknown, and there is no definite cure

Current problems in the **diagnosis** of endometriosis



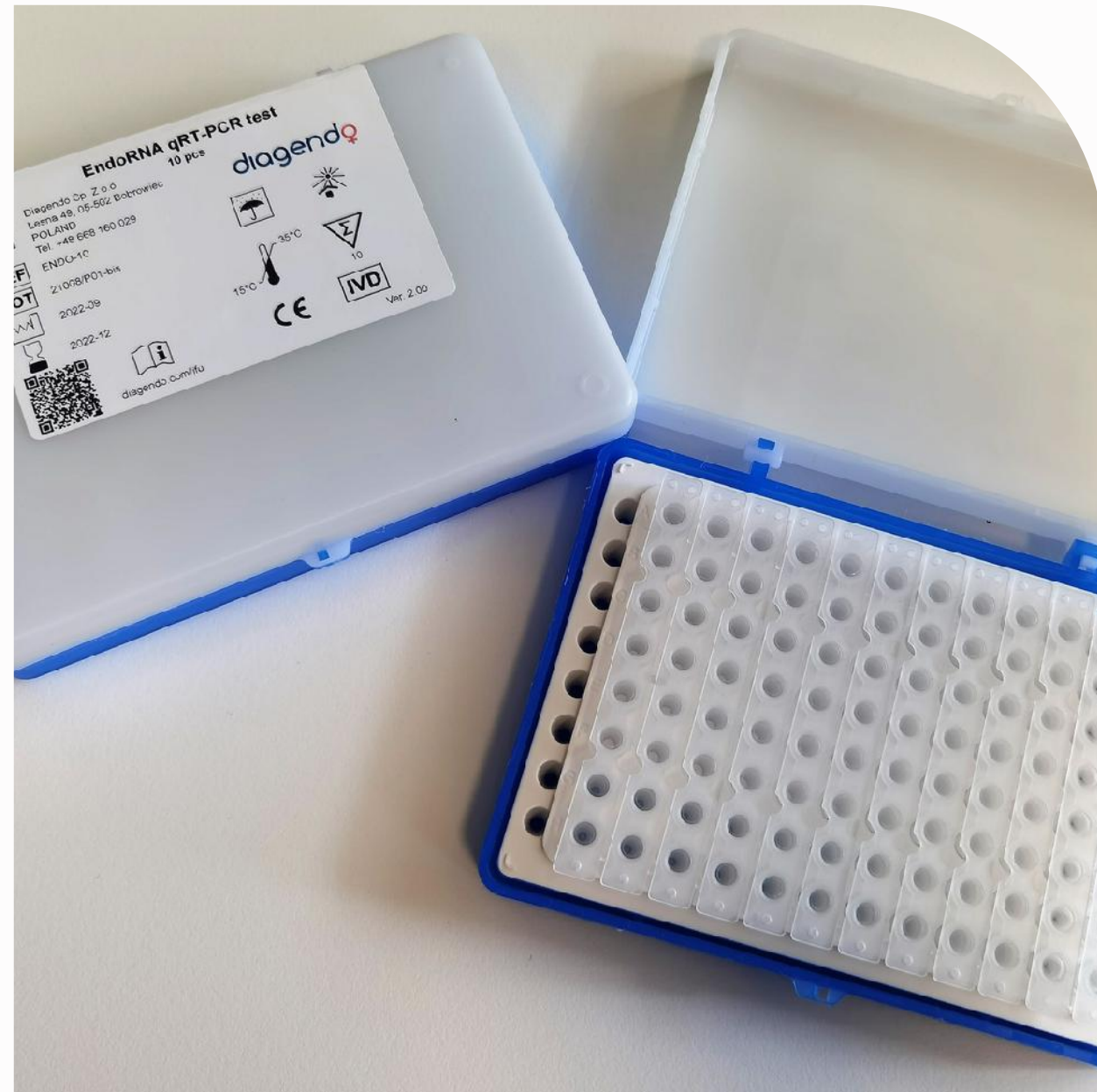
- clinical examination of symptomatic women does not reliably predict the presence of endometriosis in the abdomen and pelvis
- endometriosis cannot be reliably confirmed by imaging techniques, e.g., MRI, CT, USG (size and location of the lesion, diversity in equipment, radiologists experience)
- the only recognised diagnostic method is highly invasive laparoscopic surgery followed by histopathological analysis
- laparoscopic identification of endometriotic lesions is confirmed by histology, although negative histology does not entirely rule out the disease
- no specific biomarker of the disease has been identified so far ...

Source:
European Society of Human Reproduction and Embryology
https://www.eshre.eu/-/media/sitecore-files/Guidelines/Endometriosis/ESHRE-GUIDELINE-ENDOMETRIOSIS-2022_2.pdf?la=en&hash=E1628E24D374F3EE6C9651EDB33235F8EB8ACBDA

Deep Endometriosis Analysis group
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2880548/pdf/nihms201765.pdf>

EndoRNA

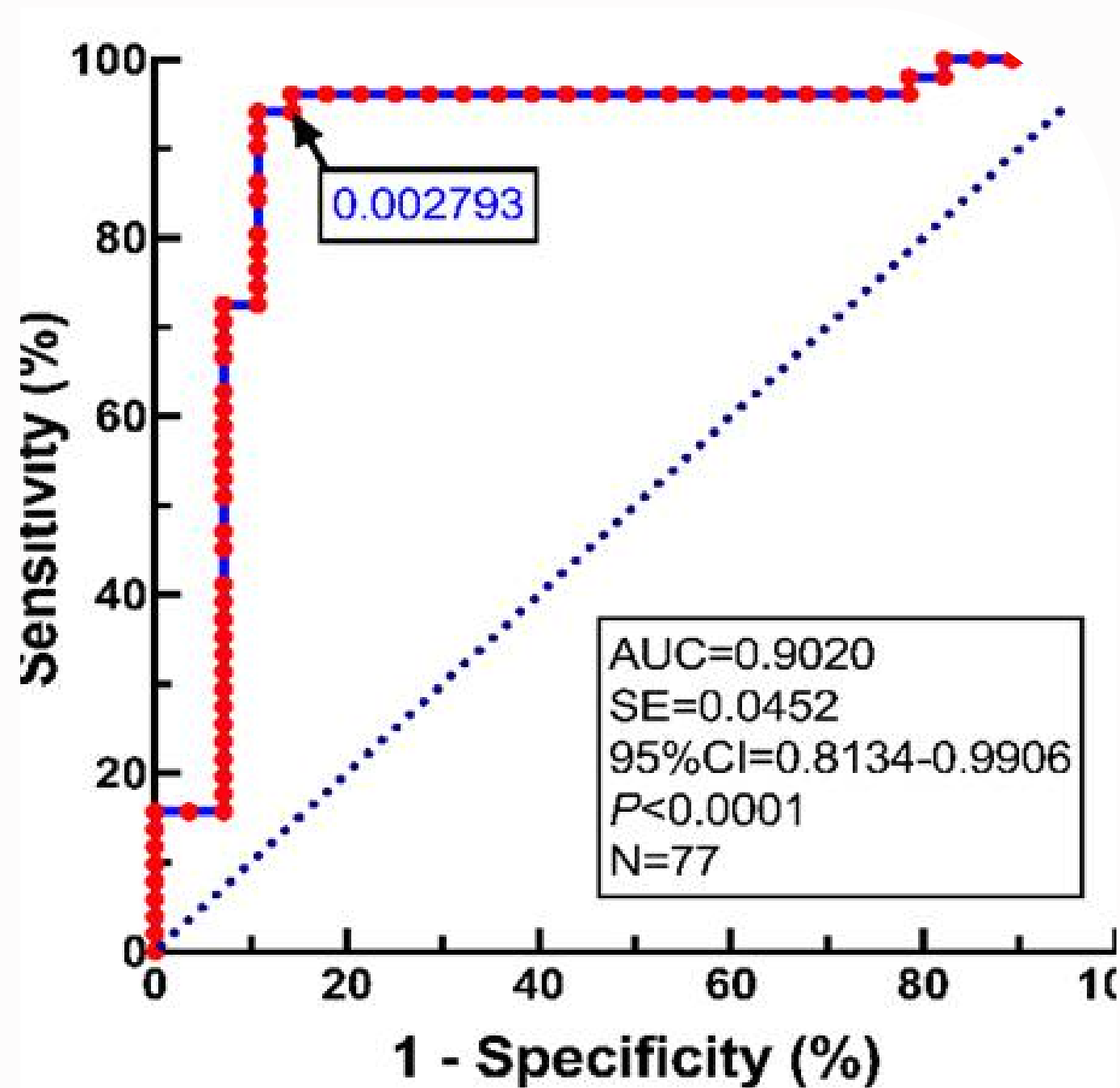
First, qRT-PCR test (medical device) for quantifying the expression level of FUT4 gene: A marker of endometriosis



The EndoRNA qRT-PCR test is an in vitro diagnostic real-time reverse transcription-PCR assay intended for quantification of the relative level of expression of the FUT4 gene, a marker of endometriosis in relation to the expression of GAPDH reference gene. Analysis was performed on a biopsy taken from a patient's endometrium in the secretory phase of the menstrual cycle, in whom endometriosis was suspected.

EndoRNA

**First, qRT-PCR test (medical device)
for quantifying the expression level of
FUT4 gene: A marker of endometriosis**

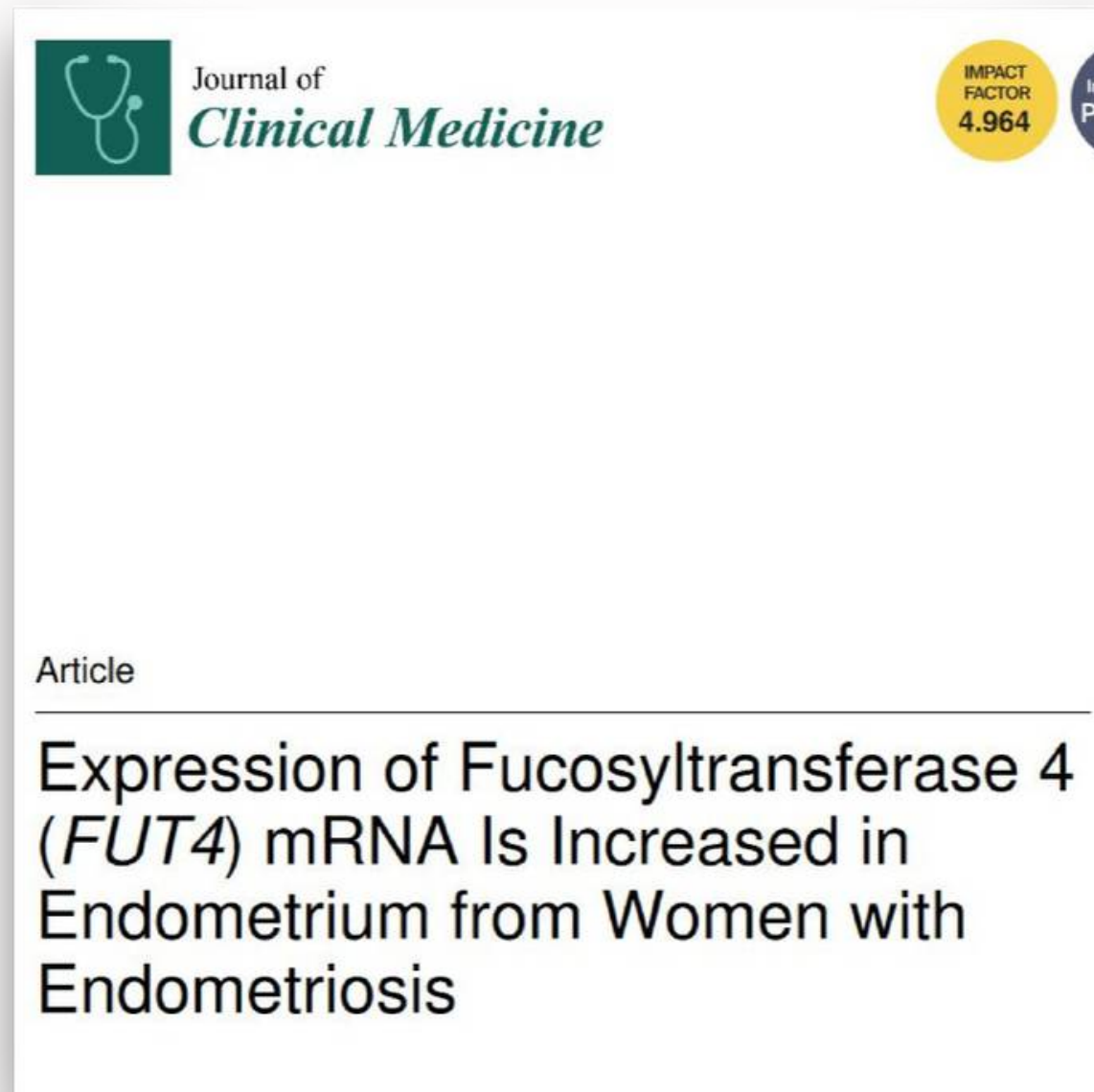


Diagnostic value of the proposed method:

- Sensitivity - 94,12% (84,08% - 98.40%)
- Specificity - 89,29% (72,80% - 96,29%)
- Positive predictive value (PPV) - 93,9%
- Probability index - 8,784
- Accuracy - 92,2%
- Youden index - 0,8341

EndoRNA

First, qRT-PCR test (medical device) for quantifying the expression level of FUT4 gene: A marker of endometriosis



Our studies resulted in the identification of a FUT4 gene which expression at mRNA level is significantly increased in the eutopic endometrium of women with endometriosis as compared to women without clinical symptoms of the disease.

Evaluation of expression of this gene in eutopic endometrium is a specific and reliable method for diagnosing endometriosis.

Discovery was patented. **Diagendo** is the sole owner to all rights to the patent.

<https://pubmed.ncbi.nlm.nih.gov/36233470/>

Overview of the diagnostic process



SAMPLE COLLECTION

Collection of endometrial biopsy by sampler/curette. Many different types are commercially available.



Transportation to diagnostic lab

Collected sample transport in preservative solution to diagnostic laboratory



Laboratory testing

EXTRACTION of mRNA and DETECTION of FUT4 expression



Office for Registration
of Medicinal Products, Medical Devices and Biocidal Products

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NIP 521-32-14-182 REGON 015249601

Warsaw, 2022-12-08

CERTIFICATE OF FREE SALE No. 853/2022

In reference to application for a certificate of free sale submitted by the

Diagendo Sp. z o.o.
(applicant for certificate of free sale)

it is concluded that the in vitro diagnostic medical device listed below:

Name of the device	Type
EndoRNA qRT-PCR	-

manufactured by:

Diagendo Sp. z o.o.
Ul. Leśna 49, 05-502 Bobrowiec, Poland
(identification of the manufacturer)

on the basis of the statement of the manufacturer the aforementioned medical device is CE marked at the sole responsibility of the manufacturer. Medical device marked with the CE mark for conformity with the requirements of the Act on Medical Devices of 20th May 2010 (O.J. of 2021, item 1565) which implements Directive 98/79/WE may be placed on the market or put into service in the territory of Republic of Poland until the date specified in accordance with art. 110.3 of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostics medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU. The export of the above-mentioned product is not prohibited.

EndoRNA

EndoRNA is a **medical device**.

- The EndoRNA qRT-PCR meets the essential requirements of the Directive 98/79/EC Annex I
- IVD categorization – Directive 98/79/EC Other IVDs (non-annex II, non-self-test)
- Conformity assessment procedure – Directive 98/79/EC Annex III

Diagedno and our device :

Is on Poland's innovation map -

<https://www.gov.pl/web/zdrowie/mapa-innowacji>

Was listed in :

Top Distributors in Healthcare 2022 report on page 64 -

<https://aiwzdrowiu.pl/wp-content/uploads/2022/06/Raport-Top-Disruptors-in-Healthcare.pdf>

Forbes

<https://www.forbes.pl/biznes/diagedno-pogromcy-endometriozy/xhsj717>

Awards:

Start-Up Med (Health Challenges Congress 2023) - 1st award for innovative startup

<https://www.rynekzdrowia.pl/E-zdrowie/Kongres-Wyzwan-Zdrowotnych-2023-znamy-zwyciezcow-konkursu-Start-Up-Med,243212,7.html>



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