EndomKit

Early detection of endometriosis

Demeditec is cooperating with the Belgian company apDia and now offers the EndomKIT in its own portfolio.

Disease Profile

Endometriosis is a chronic gynecological disorder with high prevalence and significant diagnostic delay. Despite clinically characteristic constellations of symptoms, establishing a diagnosis is often challenging, as mild and early stages cannot be adequately detected using imaging techniques. Surgical confirmation via laparoscopy continues to be considered the gold standard; however, it is invasive and contributes to diagnostic latency.

There are three clinical manifestations of endometriosis:

- Superficial endometriosis
- Ovarian endometriomas
- Deep infiltrating endometriosis (DIE)

Endometriosis is classified into four stages, ranging from mild superficial lesions to severe adhesions and cysts.

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The EndomKIT is a CE-marked in vitro diagnostic test that evaluates two serological markers (BDNF and CA125) in combination with six clinical variables. The results are integrated into a diagnostic overall score using validated software. The test is primarily designed as a rule-in procedure and achieves a very high specificity.

Indication:

Women with suspected endometriosis – particularly in cases of:

- unexplained chronic lower abdominal pain
- dysmenorrheic symptoms without a clear imaging finding
- suspected early-stage disease (Stage I–II), which is difficult to detect sonographically
- initial assessment in general or specialized gynecological practices

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Test Procedure and Execution

1. **Serological analysis** of BDNF and CA125 via ELISA.
2. **Collection of clinical parameters**, including pain intensity, age at first manifestation of dyspareunia-associated pain, previous surgeries, analgesic use, and history of ovarian cysts.
3. **Digital evaluation** using the EndomKIT software, providing a **positive** or **negative** result along with a structured diagnostic report

A positive result indicates a high likelihood of the presence of endometriosis and can support the decision to refer the patient to specialized centers.

Benefits for Clinical Practice

- support in the evaluation of unclear pain symptoms
- improved triage and prioritization of referrals
- resource-efficient: can also be performed in general medical practices or non-specialized gynecological clinics
- earlier identification of affected patients, enabling faster initiation of individualized treatment pathways

Clinical Performance Data

Validation data demonstrate:

- **Specificity:** 100 %
- **Weighted Sensitivity**: 46.2 %
- **AUC:** 0.758

  The test is therefore particularly well suited for confirming the disease in cases of clinical suspicion, including situations involving potentially confounding gynecological findings (e.g., ovarian cysts, fibroids).

For further information,
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