Health Technology Review	
Technology Ref.:	HTA23018
Technology Name:	Elecsys PlGF & Elecsys sFlt-1
Approvals by International Bodies:	CE mark and MoHaP
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Short Description of the Technology:	**Elecsys PlGF & Elecsys sFlt-1** is an Immunoassay for the in vitro quantitative determination of placental growth factor (PlGF) in human serum. And immunoassay for the in vitro quantitative determination of soluble fms-like tyrosine kinase-1 (sFlt-1) in human serum. The sFlt-1/PlGF ratio is intended for use as an aid in the diagnosis of preeclampsia in conjunction with other diagnostic and clinical information. In addition the sFlt-1/PlGF ratio is intended for use as an aid in short-term prediction of preeclampsia (rule-out and rule-in) in pregnant women with suspicion of preeclampsia in conjunction with other diagnostic and clinical information. The sFlt-1/PlGF ratio seems a reliable tool for discriminating between different types of pregnancy-related hypertensive disorders. sFlt-1/PlGF has potential relevance as a prognostic parameter in PE and may be useful in prediction of preeclampsia and related maternal and fetal adverse outcomes, risk stratification and management. The sFlt-1/PlGF ratio can also improve the prediction of early-onset preeclampsia for women with risk factors (including: history of intrauterine growth restriction (IUGR); preeclampsia; eclampsia; hemolysis, elevated liver enzymes and low platelet count (HELLP) syndrome; pre-gestational diabetes; abnormal uterine artery Doppler ultrasound). A high sFlt 1/PlGF ratio is associated with a shorter remaining pregnancy duration and a higher risk of preterm delivery. The use of the sFlt-1/PlGF ratio was demonstrated to influence clinical decision making towards appropriate hospitalization in a considerable proportion of women with suspected preeclampsia.

Health Technology Assessment Team Recommendation:	**Approve**
Summary of Review:	

Elecsys PlGF and Elecsys sFlt-1 are biomarkers used in obstetrics and gynecology. Elecsys PlGF measures the levels of a protein called Placental Growth Factor in maternal blood to assess placental function and the risk of conditions like preeclampsia. Elecsys sFlt-1 measures the levels of a protein that regulates blood vessel growth and helps diagnose preeclampsia when combined with PlGF testing. These tests provide quantitative measurements and aid in clinical decision-making. Consulting a healthcare provider is advised for a comprehensive understanding. Healthcare providers may use the sFlt-1/PlGF ratio in conjunction with other clinical parameters and assessments to help determine the severity of preeclampsia, guide treatment decisions, and potentially predict adverse outcomes. However, it's important to note that the interpretation and cutoff values of the sFlt-1/PlGF ratio may vary based on specific guidelines and clinical practices.

Advantages	Disadvantages
CE mark and MoHaP approval	Interpretation complexities, interpreting the results of PlGF and sFlt-1 tests requires clinical expertise. The results need to be evaluated in conjunction with other clinical parameters, patient history, and medical context to ensure accurate interpretation. A single test result may not provide a definitive diagnosis and should be considered within a broader clinical picture.
Risk assessmentt as these tests provide quantitative measurements of PlGF and sFlt-1 levels, aiding in the assessment of the risk of developing preeclampsia. They providers make informed decisions regarding patient management and potential interventions.	False positives and negatives: Like any diagnostic test, Elecsys PlGF and Elecsys sFlt-1 tests have a margin of error. False-positive or false-negative results can occur, leading to potential misdiagnosis or overlooking of a condition.
Monitoring PlGF and sFlt-1 levels over time can help in the early detection of preeclampsia. Detecting preeclampsia early allows for timely medical intervention and monitoring, potentially reducing the risk of complications for both the mother and the fetus.	False positives and negatives: Like any diagnostic test, Elecsys PlGF and Elecsys sFlt-1 tests have a margin of error. False-positive or false-negative results can occur, leading to potential misdiagnosis or overlooking of a condition.
By identifying individuals at high risk for preeclampsia, these tests enable healthcare providers to implement proactive management strategies	Test limitations: While Elecsys PlGF and Elecsys sFlt-1 tests provide valuable information, they have limitations. These tests are specific to the measurement of PlGF and sFlt-1 levels and do not provide a comprehensive evaluation of all factors contributing to preeclampsia. Other clinical assessments and investigations are also necessary for a comprehensive evaluation of maternal and fetal well-being.
Personalized care, Elecsys PlGF and Elecsys sFlt-1 tests provide individualized risk assessments, allowing healthcare providers to tailor care plans based on a patient's specific situation.	

We recommend an **approve of using this technology** with the following conditions:

1. The technology may only be used after being prescribed by a healthcare professional.
2. To be performed by medical laboratory professional in laboratory setting.
3. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees and patients.
4. Provision of regular updates and reports outcome about the product to DOH upon request.

Moreover, DOH has the right to stop the product at any stage if deemed necessary, initial conditions and any subsequent conditions must be satisfied before obtaining final approval. Failure to do so will reflect in provoking the approval.

Technology Image

Population, setting and intended user for Technology "Elecsys PlGF & Elecsys sFlt-1"

- **Population/ Intended User**;
  - Obstetrics and gynaecology
- **To be performed by**:
  - Trained Laboratory staff
- **Clinical Setting:**
  - Hospitals
  - Laboratory setting
- **Condition of use:**
  - As per manufacturer guidelines
- **Exclusion criteria:**
  - Exclusion criteria may include specific medical conditions or comorbidities that could interfere with the test results or pose a risk to the individual. For example, if the test involves drawing blood, individuals with bleeding disorders or those on anticoagulant medications may be excluded.
  - Individuals who are taking certain medications or have undergone specific interventions that could affect the test results or its interpretation.