Health Technology Review	
Technology Ref.:	HTA23066
Technology Name/Version/Model:	Quidel Triage PlGF Test (98800EU) and Quidel Triage PlGF Control 1 (98813EU) and Control 2 (98814EU)
Approvals by International Bodies:	**510(k) premarket approval by FDA**
Company name:	**Gulf Med Medicines LLC**
Agent in UAE:	Vijay Ankam
Email:	vijay_ankam@gulfmedfze.com

Short Description of the Technology:	The Quidel Triage PlGF Test is a fluorescence immunoassay to be used with the Quidel Triage Meter for the quantitative determination of Placental Growth Factor (PLGF) in EDTA anticoagulated plasma specimens. The test is used in conjunction with other clinical information as an aid in the diagnosis of preterm pre-eclampsia and as an aid in the prognosis of delivery, in women presenting with signs & symptoms of pre-eclampsia after 20 weeks and prior to 35 weeks of gestation. Pre-eclampsia is a potentially serious complication of pregnancy, thought to be related to problems with the development of the placenta. It requires referral to a specialist and hospital admission to monitor the mother and unborn baby and is only cured by the birth of the baby. Pre-eclampsia is characterized by high blood pressure (hypertension) and proteinuria, which is when the kidneys leak protein into the urine. Either, on its own indicates a risk of developing pre-eclampsia. Other symptoms include headache, visual disturbances, right upper quadrant abdominal (epigastric) pain, oedema (swelling of the hands, face or feet) and oliguria (low urine output). If pre-eclampsia is not diagnosed and closely monitored, it can lead to potentially life-threatening complications including eclampsia, HELLP syndrome (hemolysis, elevated liver enzymes and low platelets), disseminated intravascular coagulation, and stroke or organ dysfunction. Women who have hypertension or pre-eclampsia during pregnancy may have a higher risk of placental abruption. Gestational hypertension and pre-eclampsia may also affect the unborn baby by slowing growth or leading to premature birth. Placental growth factor (PLGF)-based testing can reassure pregnant women with hypertension who are anxious about complications and risks to the baby and themselves and increase their confidence in treatment plans. PLGF testing can improve risk assessment and enable early planning for a safe birth and may also help avoid stressful last-minute medical interventions. Early planning for at-risk pregnancies also means women at centres without facilities for preterm baby care can be safely transferred to a suitably equipped centre in good time. This improves the outcome for the baby and can avoid stressful situations, such as the mother and baby being cared for in different centres. Another benefit of the tests is better identification of

	women who will not develop preterm pre-eclampsia, reducing unnecessary hospitalization and associated costs.

Health Technology Assessment Team Recommendation:	**Approve**

Summary of Review:

The Test is a rapid blood test utilizing the technology of fluorescence immunoassay along with Quidel Triage meter. the test is used to measure maternal circulating PIGF in EDTA anticoagulated plasma specimens, it indicated for pregnant women (between 20 to 35 weeks) as an aid tool in the management of suspicious pre-eclampsia. The test has premarket authorization approval by FDA and been recommended by NICE. Upon reviewing the provided published studies and clinical trials the test proved its efficacy in ruling out in patient's evaluated for suspected preeclampsia, and shown effective as aid tool in the management of suspicious pre-eclampsia.

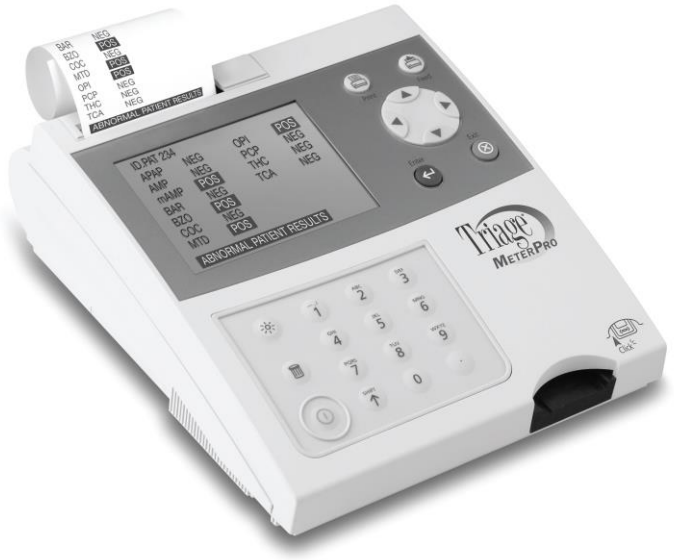
Advantages	Disadvantages
FDA Approved device with no evidence of device recalls or safety alerts on the test.	PLGF-based test results should be used alongside clinical information for decision making
Real-world" data has shown that interpretation of PlGF-based test results can aid clinicians in improving maternal outcomes and a growing body of evidence has implied a role for sFlt-1/PlGF in the prognostication of adverse pregnancy and perinatal events.	Further research is required to ascertain the benefits of elective early delivery on perinatal outcomes when utilizing PlGF-based testing as more than just an adjunct to other clinical information in decision-making
Evidence that knowledge of PlGF levels can reduce serious maternal morbidity	The tests are not a substitute for clinical assessment
There is emerging evidence of the potential advantages of angiogenic biomarkers to diagnose and predict other complications including fetal growth restriction and stillbirth.	Clinical experts also explained that a low PLGF test result does not always mean a woman has pre-eclampsia and can be associated with other conditions affecting the placenta
The Triage PLGF Test can be used at the point of care and in the laboratory.	Further research is recommended into how well the tests work when women are pregnant with more than 1 baby to find out if different cut-offs are needed
Help in better identification of women who will not develop preterm pre-eclampsia, reducing unnecessary hospitalization	The PlGF-based test does not indicate the severity of the condition. PlGF-based test results should not be used to make decisions about timing of birth in people with preterm pre-eclampsia
Placental growth factor (PLGF)-based testing can reassure pregnant women with hypertension who are anxious about complications and risks to the baby and themselves, and increase their confidence in treatment plans Clinical experts said that the tests can improve risk assessment and enable early planning for a safe birth.	The value of serial assays of placental growth factor preeclampsia needs further studying and remains to be confirmed.

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

1. Approval of Technology Quidel Triage PlGF Test (98800EU) and Quidel Triage PlGF Control 1 (98813EU) and Control 2 (98814EU) as an aid test alongside with other clinical information to help diagnose preterm pre-eclampsia in women who are between 20 weeks and 35 weeks pregnant with signs and symptoms of pre-eclampsia.
2. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
3. Provision of regular updates and reports about the product to DOH upon request.
4. Communicate the need for screening strategy for pre-eclampsia to ADPHC utilizing the new technologies such as this test "Quidel Triage PlGF Test".

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 "Quidel Triage PlGF Test"

- **Population/ Intended User**;
  - The test is used with other clinical information to help diagnose preterm pre-eclampsia in women who are between 20 weeks and 35 weeks pregnant with signs and symptoms of pre-eclampsia.
- **To be ordered by**:
  - By Obstetrics and gynecology
- **Clinical Setting:**
  - Healthcare Facilities
- **Condition of use:**
  - As per the manufacturer instructions
- **Exclusion criteria:**
  - Other conflicting medical issues