Health Technology Review	
Technology Ref.:	HTA22053
Technology Name:	DxPG80.Lab
Approvals by International Bodies:	CE marked, ANSM registered DMDIV202200052
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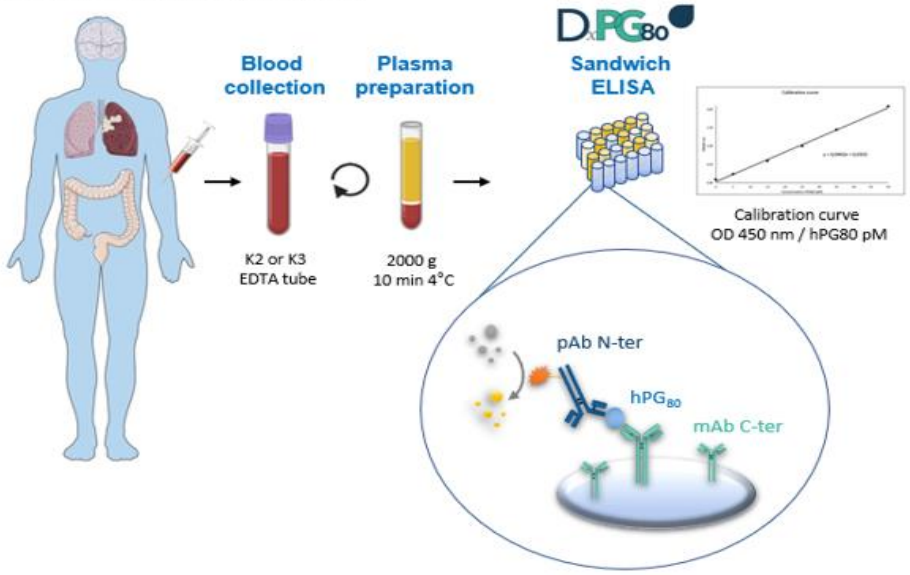
Short Description of the Technology:	DxPG80.Lab is an IVD test for the quantitative measurement of hPG80 (circulating progastrin) in human EDTA plasma. The test is based on the principle of a sandwich ELISA (Enzyme-Linked ImmunoSorbent Assay) to measure the concentration of hPG80 in plasma specimens that have been anticoagulated with EDTA; Figure 3.  **Figure 3.** Principle of the DxPG80.Lab test: sandwich ELISA performed on human plasma sample, signal is proportionate to the hPG80 blood concentration

Health Technology Assessment Team Recommendation:	**Conditional Approve**
Summary of Review:	
It's a blood-based tumour marker for early cancer detection. The test is based on the principle of a sandwich ELISA to measure the concentration of hPG80 in plasma samples that have been collected in EDTA tubes. hPG80 (progastrin) is released from tumour cells, promotes cancer stem cells (CSC) self-renewal and is detected in the blood of patients. The kit has CE marked. The blood samples analyzed abroad and takes 7 days from day of departure	
Advantages	**Disadvantages**

Useful diagnostic Tools that can detect different cancer types	The technology has not yet approved/endorsed by International bodies (FDA, NHS) as a standard testing protocol for cancer early detection.
Because oncogenic hPG80 is expressed in tumour cells from different origins and because circulating hPG80 in the blood is related to the burden/activity of the tumour, it is a promising cancer target for therapy and for disease monitoring.	The results obtained with this test should never be used as the sole basis for a clinical diagnosis and/or therapeutic consequences. The test results should be used by a physician in conjunction with information available from clinical evaluations and another diagnostic procedures.
Simple and safe blood test	The test analysed outside the country – to ensure patient data safety compliance
7 days analysis timeline	The test is intended for professional laboratory use only.
CE marked	New screening method that require further studies to prove its efficacy and accuracy in early diagnosis of cancers.
Detects More than 16 Different Types of Cancer	Sensitivity and specificity of the test needs to be determined in large prospective studies.

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

1. To utilize the test in a clinical trial setting to provide further evidences on the efficacy of the test.
2. Ensure data residency and compliance with DOH Data regulation.
3. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
4. Provision of regular updates and reports about the product to DOH upon request.
5. Any other documents or information requested regarding the product and cost to finalize the approval process.

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 "DxPG80.Lab"

- **Population/ Intended User**;

*hPG80 detects more than 16 types of cancer

- Brain tumors
- All Cancers of Head and Neck
- Skin cancer
- Lung cancer
- Liver cancer
- Pancreatic cancer
- Stomach cancer
- Colon cancer
- Rectal cancer
- Prostate cancer
- Uterine cancer
- Cervical cancer
- Neuroendocrine tumors
- Ovarian cancer
- Kidney cancer
- Breast cancer

- **To be order by**:
  - By ONCOLOGIST
- **Clinical Setting:**
  - Hospitals, Medical centers.
- **Condition of use:**
  - As per Manufacturer instruction.
- **Exclusion criteria:**
  - Patient: Not for children (under 18 years old) or for pregnant women.
  - Professional users of the test: Label warning: Caution, consult instructions for use, contains human blood or plasma derivatives, contains biological material of human origin, keep in dry conditions, do not use if package is damaged, Warning: Irritant.