Health Technology Review	
Technology Ref.:	HTA22030
Technology Name:	Guardant360®
Approvals by International Bodies:	Approved by the New York State Department of Health (NYSDoH)
Company name:	Guardant Health, AMEA
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Short Description of the Technology:	Guardant360® is a qualitative next generation sequencing-based test that uses targeted high throughput hybridization-based capture technology for detection of single nucleotide variants (SNVs), insertions and deletions (indels) in 74 genes, copy number amplifications (CNAs) in eighteen (18) genes, and fusions in six (6) genes. Guardant360 utilizes circulating cell-free DNA (cfDNA) from plasma of peripheral whole blood collected in Cell-Free DNA Blood Collection Tubes (BCTs). Guardant360 provides genomic results including high microsatellite instability (MSI-High) in 7 days from sample receipt at the laboratory using a routine blood draw, eliminating the need to solely rely on tissue testing. Guardant360 enables informed treatment decisions for advanced solid-tumour cancer patients and identifies treatment options or clinical trials for patients before first-line therapy or at progression.

Health Technology Assessment Team Recommendation:	**Approve**

Summary of Review:

Guardant360® is a liquid biopsy intended to be used for tumour mutational profiling only. It is a test done on a sample of blood to look for cancer cells from a tumour that are circulating in the blood or for pieces of DNA from tumour cells that are in the blood. This laboratory test is performed with a blood sample from cancer patients in an advanced stage (stage III or IV) in order to find an appropriate therapy option for a therapy with targeted drugs. Also, Guardant360® can be used for monitoring and aftercare of a cancer therapy. A liquid biopsy might be used to determine the best cancer therapy, to track how a patient is responding to treatment, or to discover whether a cancer has returned. With Guardant360® the efficacy of so-called targeted drugs can be tested. Chemotherapeutics cannot be tested.

Advantages	Disadvantages
Results for **liquid biopsy is Faster** than tissue biopsy sequencing; informed real time decisions; also help as Real time monitoring tool for drug response.	**Liquid biopsy is not always sufficient for an initial histologic diagnosis** which need to be obtained by tissue biopsy. Assays for ctDNA do not provide any insight into many tumour properties important for grading and staging

	and only indirectly suggest overall tumour burden.
Liquid Biopsy Testing in Cancer Patients may potentially be used as an **alternative to tumour biopsy** in inaccessible or risky location or for patients who cannot have surgery.	**Liquid biopsy tests need to be ordered in the context of the patient**, the type of cancer and their disease burden.
The test can be **performed frequently** when required as painful, expensive and risky biopsies are avoided.	**Validation & Efficacy**; larger prospective studies for a larger population are needed to further validate the test efficacy and to assess ctDNA assays as a multi-cancer screening tool.
Non-invasive; which means no intervention (surgery or biopsy) is necessary, only some blood has to be drawn.	**Possibility of false negative**; Laboratories performing these assays need to be mindful of appropriate test utilization, the risks of false positives and false negatives, and the potential for "over interpretation" in the clinical context.
Useful tool in treatment plan; Guardant360® test Empower patients and doctors with options for treatments; Via liquid biopsy it can be determined before start of a therapy, which targeted drugs could lead to a positive response in individual patients. Thereby ineffective therapies are avoided and valuable time is saved during therapy.	**Accuracy**; **Liquid** biopsy find mutations from all sorts of other sources such as white blood cell mutations.
Comprehensive; With liquid biopsy all types of present mutations of the cancer cells are detected at the same time and thus the therapy can be adapted much better; represents a greater mixture of subclones in a tumour and any metastases than any single biopsied site	**Guardant360 is not indicated for the diagnosis or minimal residual disease detection in cancer patients**
The laboratory of Guardant Health is **CLIA-certified and CAP-accredited.**	

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

1. Guardant360 is not indicated for the diagnosis or minimal residual disease detection in cancer patients.
2. To conduct the test on the applicable patients as per criteria only.
3. The compliance with UAE law of Information Security Compliance and Data Privacy.
4. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
5. Provision of regular updates and reports about the product to DOH upon request.
6. 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 "Guardant360®"

- **Population/ Intended User**;
  - Cancer patients. Guardant360 is indicated for use only in patients with an established diagnosis of an advanced solid tumor and test requests without such confirmation from the physician are canceled by the clinical laboratory.
  - Guardant360® can be applied for the monitoring and aftercare of a cancer therapy as well
  - Indicated for:
    - Advanced solid tumors
    - Before first-line therapy or at progression
- **To be ordered by**:
  - Oncologist.
- **Clinical Setting:**
  - Authorized Laboratories (The test analyzed abroad in US in the laboratory of Guardant Health)
- **Condition of use:**
  - The specimen collection & shipping shall follow the international standards & manufacturer guidelines.
- **Exclusion criteria:**
  - Not indicated for:
    - Hematologic malignancies
    - Early stage cancers
    - When disease is stable or responding to therapy