| Health Technology Review | |
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| **Technology Ref.:** | HTA-23026 |
| **Technology Name:** | DropleX EGFR Mutation Test v2(Epidermal growth factor receptor). |
| **Approvals by International Bodies:** | Korean Ministry of Food and Drug Safety (KFDA).<br>CE (European Union Declaration of Conformity). |
| **Company name:** | Al Nawras Medi-Lab Supplies |
| **Agent in UAE:** | Sharjah, United Arab Emirates |
| **Email:** | Dawood@alnawras.ae |

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| **Short Description of the Technology:** | The Droplex EGFR Mutation Test v2 is an in vitro diagnostic test for the qualitative detection of defined mutations in exons 18, 19, 20 and 21 of the epidermal growth factor receptor (EGFR) gene in DNA isolated from formalin-fixed paraffin-embedded tumor tissue (FFPET) and circulating cell-free DNA (cfDNA) isolated from human plasma of non-small cell lung cancer (NSCLC) patients. The test results are indicated as a companion diagnostic to aid in selecting NSCLC patients<br><br>Droplet digital polymerase chain reaction (ddPCR) is widely used for many clinical applications due to its unparallel sensitivity and precision. ddPCR technology and its diagnostic kit can quantify mutations in major cancer genes at the single molecular level, making it possible to detect samples with low mutation rate.<br><br>ddPCR uses a water-in-oil emulsion to generate up to 20,000 nanolitre-sized droplets that each contain no or some copies of a template and undergo separate end-point amplification. Studies found that ddPCR based diagnostic kit is less labour intensive and highly sensitive compared to the PCR of Fluorescence in situ (Fish) method and has higher turnaround time with less cost compared to standard DNA-sequencing. |

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

The Droplex EGFR Mutation Test v2 is an in vitro diagnostic test for the qualitative detection of defined mutations in exons 18, 19, 20 and 21 of the epidermal growth factor receptor (EGFR) gene in DNA isolated**.** The test utilizes droplet digital PCR (ddPCR) technology which has higher specificity and sensitivity compared with real-time PCR and immunohistochemistry (IHC) method. The mutations can be identified from a very small amount of DNA**.**

| Advantages | Disadvantages |
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| The mutations can be identified from a very | Higher cost of ddPCR prohibits its usage as it |

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| small amount of DNA. Therefore, the time and cost of sample preparation can be reduced, and patients can be relieved of the burden of examination | currently stands |
| KFDA (Korean Food and Drug Administration) approved and CE marked. | It is more complex to operate than the current real-time PCR system |
| Wider range of variants detectable compared to real-time PCR | Alternative solutions are easier to operate e.g. Idylla Biocartis EGFR |
| Better sensitivity and limit of detection | |

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

1. This product should be used by healthcare professionals.
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.

**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 "Droplet EGFR Mutation Test v2"

- **Population/ Intended User**;
  - Prevalent major cancer patients currently getting treatment, as well as patient with new cancer incidents, who need to be screened prior to prescribed for treatment.

- **To be performed by**:
  - be used by healthcare professionals.
- **By Clinical Setting:**
  - Hospitals and specialized clinics (oncology)
- **Condition of use:**
  - EGFR mutation testing is ordered after the patient has been diagnosed with non-small cell lung cancer, especially adenocarcinoma.
- **Exclusion criteria:**
  - These tests are not helpful for identifying patients with lung cancer who may benefit from EGFR-targeted tyrosine kinase inhibitor therapy.