



| Health Technology Review           |   |
|------------------------------------|---|
| Technology Ref.:                   | HTA-23044   |
| Technology Name:                   | Cancer Driver Mutation Detection Through Droplet Digital PCR (ddPCR) based diagnostic kit - Droplex KRAS Mutation Test v2 |
| Approvals by International Bodies: | Korean Ministry of Food and Drug Safety (KFDA).   |
| Company name:                      | CE (European Union Declaration of Conformity).  |
| Agent in UAE:                      | Gencurix Inc.   |
| Email:                             | Al Nawras Medi-Lab Supplies.  |

|   |   |
|---|---|
| <b>Short Description of the Technology:</b> | <p>The Droplex KRAS Mutation Test v2 is an in vitro diagnostic test for qualitative detection of defined mutations in codon 12, 13, 59, 61, 117, and 146 of the KRAS gene in DNA isolated from formalin-fixed paraffin-embedded (FFPET) tumor tissue and from circulating cell-free DNA (cfDNA) isolated from human plasma of colorectal cancer (CRC) patients. The test results are indicated as a companion diagnostic to aid in selecting CRC patients for treatment with Cetuximab (Erbix®).</p> <p>Also, the Droplex KRAS Mutation Test v2 is an in vitro diagnostic test for qualitative detection of defined mutations in codon G12C of the KRAS gene in DNA isolated from formalin-fixed paraffin-embedded (FFPET) tumor tissue 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 for treatment with Sotorasib (Lumakras®).</p> <p>Droplet digital polymerase chain reaction (ddPCR) is widely used for many clinical applications due to its unparalleled 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.</p> |
|---|---|

|  |   |
|--|---|
| <b>Health Technology Assessment Team Recommendation:</b>   | <b>Approve</b>  |
| <b>Summary of Review:</b>  |   |
| <p>Compared to traditional biopsy for gene mutation detection, blood samples require more sensitive testing because of their low DNA extraction. Digital PCR technology, ddPCR is advanced platform specialized in liquid biopsy samples because it can detect mutations accurately even with a small amount of DNA.</p> |   |
| <b>Advantages</b>  | <b>Disadvantages</b>  |
| Extremely high sensitivity and high accuracy platform for ctDNA detection in cancer patient.   | There are low risks to health care workers, such as the skin, eye contact of skin and eye. The users should be careful not to contact the material when using it. |



|   |   |
|---|---|
| High accuracy is a very accurate method of detecting mutations. The results are less likely to be affected by contamination or other factors. | It is a more expensive method than traditional PCR methods.   |
| Improved targeted therapy for cancer patients by monitoring cancer mutation development.  | It is a more complex technique to perform than traditional PCR methods. This requires specialized training and equipment.     |
| Higher detection rate in mutations with low abundance leading to less test failure rate.  | It can be a time-consuming process. This can be a limitation for laboratories that need to process a large number of samples. |
| Versatile: can be used to detect mutations in a variety of genes. This makes it a valuable tool for cancer research and diagnostics.          |   |
| Korean Ministry of Food and Drug Safety (KFDA) and CE (European Union Declaration of Conformity) are approvals.                               |   |

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

1. The approval on using Droplex KRAS Mutation Test v2:
2. To be performed by medical lab technology
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.

**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

# KRAS Mutation Test v2





## Population, setting and intended user for Technology “Droplex KRAS Mutatio”

### Population/ Intended User;

- patients currently getting treatment.
- patient with new cancer incidents, who need to be screened prior to prescribed for treatment.

### To be performed by:

- Medical lab technologist.

### Clinical Setting:

- Hospitals, special laboratory.

### Condition of use:

- The test helps identify CRC and NSCLC patients who are eligible for targeted treatment.
- Monitoring targeted therapy for cancer mutation development.

### Exclusion criteria:

- RAS mutation; MEK inhibitors; Pancreatic ductal adenocarcinoma; Prognosis; Quantitative PCR; Solid pancreatic masses.