

# QClamp® IDH1 R132H Mutation Detection

*Identify IDH1 R132H mutation with limited tissue/blood samples*

## Clinical significance of IDH1 Mutation detection

### **IDH1 R132H Mutation**

IDH1 is frequently mutated in glioma and acute myeloid leukemia (AML), among other cancer types. IDH1 R132H mutation (the major mutation) occurs in approximately 70% of gliomas, including astrocytomas and oligodendroglial tumors. The presence of the IDH1 mutations in patients with glioma is associated with better prognosis. Thus, the IDH1 mutations are one of the most important diagnostic and prognostic factors for adult diffuse gliomas. The IDH1 gene mutations were also found in around 6 - 10% of people with AML.

### **IDH1 inhibitors**

FDA has approved two IDH1 inhibitors to treat patients with IDH1 mutations. Ivosidenib is available for the treatment of patients with relapsed or refractory AML harboring IDH1 mutations as well as for the treatment of newly diagnosed AML who are  $\geq 75$  years of age or are ineligible for intensive chemotherapy with a susceptible IDH1 mutation. The Ivosidenib was also approved for advanced or metastatic cholangiocarcinoma. Olutasidenib is another IDH1 inhibitor for relapsed or refractory AML with a susceptible IDH1 mutation.

### **Companion Diagnostics**

Different IDH1 mutation detection assays are approved for companion diagnostic use with the above two drugs for different types of cancer. Our IDH1 R132H detection is a research-use-only (RUO) product that can be validated in clinical labs as an LDT test for diagnostic purposes.

## QClamp® IDH1 Mutation Detection Kit

### **XNA technology**

Based on our proprietary XNA technology, we have developed QClamp® IDH1 mutation detection kit to detect IDH1 R132H mutation. The advantage of applying the XNA technology to standard allele-specific qPCR assay is that it helps to identify the mutation even when samples are limited.



**Key highlights**



**Sample types**

tissue or blood samples



**Sample amount**

10ng DNA input



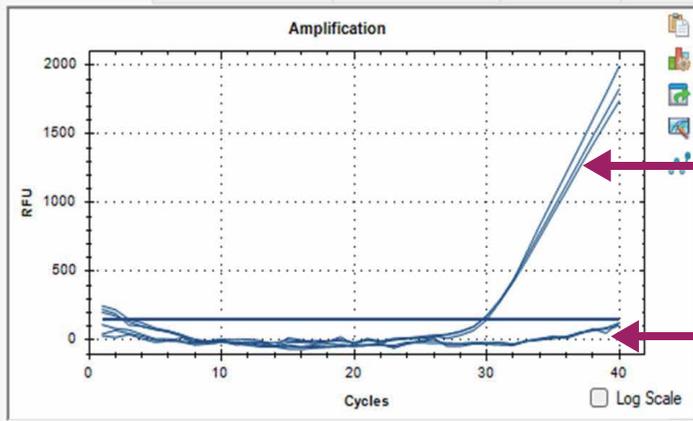
**Validated machines**

Thermo Fisher Scientific (ABI) QuantStudio® 5 and Bio-Rad CFX384™



**High sensitivity**

The assay can detect as low as 0.33% variant allele frequency (VAF) of IDH1 R132H mutation



**Positive**

**Negative**

*IDH1 R132H mutation detection using XNA-based qPCR showing positive and negative controls*



The QClamp® IDH1 Mutation Detection Kit offers a solution for detecting mutations in plasma samples, particularly when the amount of cell-free DNA (cfDNA) is low. This is especially beneficial for patients with low-grade glioma who are not suitable for biopsy.

**Product Name: QClamp® IDH1 Mutation Detection Kit**

**Catalog Number:**

- Pack size of 10-sample: DC-10-0002R
- Pack size of 30-sample: DC-10-0003R