



QCI® Interpret for Oncology

## Because oncologists and their patients rely on you



**Now more than ever, oncologists rely on molecular pathologists to inform and expedite the therapeutic decision-making process. Trusted by clinicians around the world, QCI Interpret for Oncology ensures you have the right information in the shortest amount of time.**

In the NGS era, molecular pathologists have become the clinician responsible for interpreting molecular data and optimizing patient outcomes through the delivery of accurate diagnoses and treatment guidance.

QCI Interpret for Oncology is a clinical decision support software powered by augmented molecular intelligence that helps clinical labs not only make faster decisions—but the right decisions.

- >3 million NGS patient test cases analyzed and interpreted worldwide
- >6.4 million variants characterized in 18,000 genes
- >5,000 new expert-curated variants are added each month

“The adoption of QCI Interpret has advanced our ability to efficiently classify somatic variants in solid tumors, confidently match therapies to biomarkers, and identify clinical trials located near a patient’s home—regardless of where they live in Europe. This highly customized informatics solution supports competitive turnaround time of matched precision medicine options to ordering clinicians for their cancer patients.”



**Manja Meggendorfer, Head of Molecular Genetics, Munich Leukemia Laboratory**



## QIAGEN Knowledge Base

Connected to the exclusive QIAGEN Knowledge Base, the industry's most comprehensive, manually curated resource that is updated weekly, QCI Interpret for Oncology dynamically computes pathogenicity and actionability based on the AMP/ASCO/CAP or ACMG/AMP guidelines for every variant in over 31,000 cancer types with full transparency. To simplify and accelerate interpretation, users have access to over 320,000 preformulated, oncologist-reviewed variant impact summaries to build custom, patient-specific reports with the latest diagnostic and prognostic information, as well as biomarker-directed therapies and clinical trials.

## What is augmented molecular intelligence?

The content core of QCI Interpret for Oncology, the QIAGEN Knowledge Base is the world's largest source of globally trusted molecular knowledge. Built manually over 20 years by hundreds of MD- and PhD-level expert curators and augmented by artificial intelligence to rapidly identify, extract, and enhance evidence, the QIAGEN Knowledge Base is unrivalled in breadth, depth, and accuracy.

## The QCI Interpret difference

### Workflow Agnostic

The software solution can be easily integrated with any pipeline to enable you to go from FASTQ or VCF to report within minutes.

### Fastest Growing Knowledge Base

Over 5,000 completely new variants are added each month to the QIAGEN Knowledge Base and it is updated weekly.

### Compute Any Variant for Any Disease

Proprietary algorithms dynamically and transparently compute AMP/ASCO/CAP classifications for every variant in any disease.

### Oncologist-reviewed Variant Summaries

Access to over 410,000 molecular function summaries and pre-written, oncologist-reviewed variant interpretive comments for faster report building.

### Interpretation of Co-occurring Mutations

The software identifies and lists co-occurring variants in each clinical sample, providing evidence on the clinical effect with reference to relevant guidelines.

### On-demand Interpretation Services

An ideal solution for labs working with rare or novel variants, QIAGEN's on-demand service does the research, curation, and interpretation for you. Any somatic NGS panel can be submitted.

# Automate your variant interpretation workflow

With QCI Interpret, every clinical recommendation you make is backed by the latest evidence. The platform- and panel-agnostic software simplifies and automates your workflow for faster results that your oncologists, and their patients can trust.

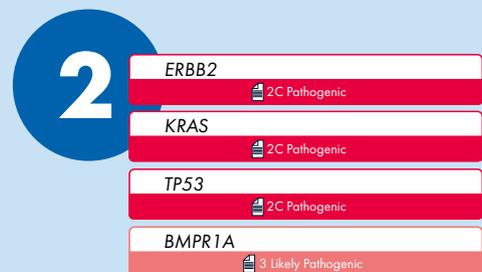


## Upload your variant files and enter patient information

- Select workflow
- Upload variant files for a patient sample
- Enter patient's diagnosis and relevant case details

## Retrieve list of auto-classified variants

- View list of ACMG/AMP and AMP/ASCO/CAP pathogenicity and actionability classifications for each variant
- Filter and rank by variants by significance
- View supporting evidence; manually adjust final assessment if desired



## Match actionable variants with therapies and clinical trials

- Identify potential therapeutic options
- Match genomic profile and diagnosis with treatments and region-specific clinical trials
- Review curated evidence to make final decision on reportability

## Add oncologist-friendly summaries

- Use over 410,000 oncologist-reviewed, report-ready variant interpretation comments
- Submit rare or novel variants to QIAGEN's professional variant interpretation service (optional)
- Receive results same day (cases vary)



## Generate and sign-off on final report

- Build easy-to-understand, customizable reports for oncologists
- Include key details to guide patient treatment, such as variant therapeutic, prognostic and diagnostic relevance and co-occurring variant interactions
- Back all reports with a comprehensive bibliography of evidence

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|                                                                                                                |                                                                                             |                                                                                                                                      |
|----------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|
| <b>Consulting physician</b>                                                                                    | <b>Patient</b>                                                                              | <b>Sample</b>                                                                                                                        |
| Provider: General Hospital<br>Physician: Dr. E. Smith<br>Pathologist: Dr. R. Jones<br>Report Date: May 7, 2020 | Name: Michelle Doe<br>Age: 67<br>Gender: Female<br>Diagnosis: Breast carcinoma<br>Stage: IV | Accession Number: TSO500 QCI Interpret<br>One demo Report<br>Collection site: Breast<br>Type: Biopsy<br>Collection date: May 7, 2020 |

**Panel Analysis: TruSight™ Oncology 500**

**Overall comment**  
Patient specific information for this case can be described here

**Analysis results: Positive**

| 2 Variants of strong clinical significance, Tier 1    | Approved treatments                                                                      | Other findings                                                                                      |
|-------------------------------------------------------|------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| ERBB2: amplification, Pathogenic                      | DS-8201a<br>Lapatinib<br>Neratinib<br>Pertuzumab<br>Trastuzumab<br>Trastuzumab emtansine | Resistance: cetuximab, erlotinib, osimertinib<br>Trials: 3 Phase 3<br>6 Phase 2<br>1 Early Phase 1  |
| PIK3CA, p.H1047R, Pathogenic                          | Alpelisib/fulvestrant                                                                    | Resistance: vemurafenib<br>Trials: 1 Expanded Access<br>2 Phase 2<br>1 Phase 1/Phase 2<br>6 Phase 1 |
| 2 Variants of potential clinical significance, Tier 2 | Approved treatments                                                                      | Other findings                                                                                      |
| CCND1: amplification, Pathogenic                      | -                                                                                        | Trials: 3 Phase 2                                                                                   |
| TP53 t: p.L348*, Pathogenic                           | -                                                                                        | Other Indications: bortezomib /rituximab, lenalidomide/rituximab, rituximab                         |
| 1 Variant of biological significance, Tier 3          | 12 Variants of uncertain significance, Tier 3                                            |                                                                                                     |
| MYCN: amplification, Pathogenic                       |                                                                                          |                                                                                                     |

† Allele Fraction (AF) >40%. AF suggests that it may be germline and pathogenic or likely pathogenic. Recommend obtaining confirmatory germline testing.

**Interactions**  
Clinically relevant co-occurring variants are reported in the "interactions" section starting on page 2.

**Guidelines**  
Potentially relevant guidelines are reported in the "guidelines" section starting on page 2.

**Approval**  
  
Electronically signed on: May 7, 2020 by Dr. Jones

**Report content**

|                              |         |
|------------------------------|---------|
| Result overview and approval | Page 1  |
| Guidelines and interactions  | Page 2  |
| Treatment options            | Page 2  |
| Available clinical trials    | Page 4  |
| Variant details              | Page 8  |
| Report information           | Page 17 |
| Selected references          | Page 19 |

Michelle Doe  
Accession: TSO500 QCI Interpret One demo Report

Somatic cancer  
Report Date: May 7, 2020

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With QCI Interpret, you can easily generate a final report with only the most relevant findings. While labs can customize the layout to fit branding and reporting needs, standard reports include:

- A summary of the high-level results, including biomarker findings, significant variants, and associated therapies.
- Identification of potential interactions.
- Individual variant interpretations, including AMP/ACMG classifications, biomarker summaries, disease summaries, details on molecular function and incidence, and diagnostic and prognostic significance with region-specific clinical trials and approved drugs (FDA, EMA) for each patient.
- A bibliography containing all evidence considered in the final report.

### Special feature:

For labs using the Illumina® TruSight Oncology 500 assay, QCI Interpret provides a preconfigured workflow that accepts FASTQ and VCF files.



Want to see what content QCI Interpret for Oncology can provide for your variants? Visit [www.digitalinsights.qiagen.com/qci-interpret/oncology](http://www.digitalinsights.qiagen.com/qci-interpret/oncology) to learn more.

QCI Interpret is an evidence-based decision support software intended as an aid in the interpretation of variants observed in genomic next-generation sequencing data. The software evaluates genomic variants in the context of published biomedical literature, professional association guidelines, publicly available databases, annotations, drug labels, and clinical-trials. Based on this evaluation, the software proposes a classification and bibliographic references to aid in the interpretation of observed variants. The software is NOT intended as a primary diagnostic tool by physicians or to be used as a substitute for professional healthcare advice. Each laboratory is responsible for ensuring compliance with applicable international, national, and local clinical laboratory regulations and other specific accreditations requirements.

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