

Alissa Interpret

The Next Evolution of Cartagenia Bench

Alissa Interpret Delivers

- Inherited and somatic sample workflows
- Molecular and structural variant classification and curation
- Clinical-grade standard operating procedure (SOP) implementation
- Database access and lab report drafting with ease
- Team of experts as partners

Make your Variant Assessment Flow

Alissa Interpret allows clinical genetics and molecular pathology labs to efficiently triage, curate and report genomic variants. Whether from NGS or arrays, this genomics data management solution automates the lab's clinical workflow from variant filtration and annotation, over curation and classification, to draft lab report. Rely on a team of experts to deploy new assays quickly and ramp up volumes as your lab grows.

Designed for Clinical Diagnostics

Alissa is built with the diagnostic lab in mind. The software provides access to a wealth of clinical annotation sources and databases, supports ACMG guideline variant curation, and features a wide range of in-depth analytic tools for inheritance modes, phenotype context, and reviewing variant effect.

A Single Platform for all Clinical Applications across NGS and CGH

Imagine identifying a deletion or LOH region that spans a recessive variant. Alissa Interpret combines CNVs, SNPs, indels and fusion genes in an integrated workflow. Alissa integrates your application workflows from molecular pathology to inherited disease, your variants from molecular to structural, and your data from secondary to tertiary analysis—all flowing on a single platform.

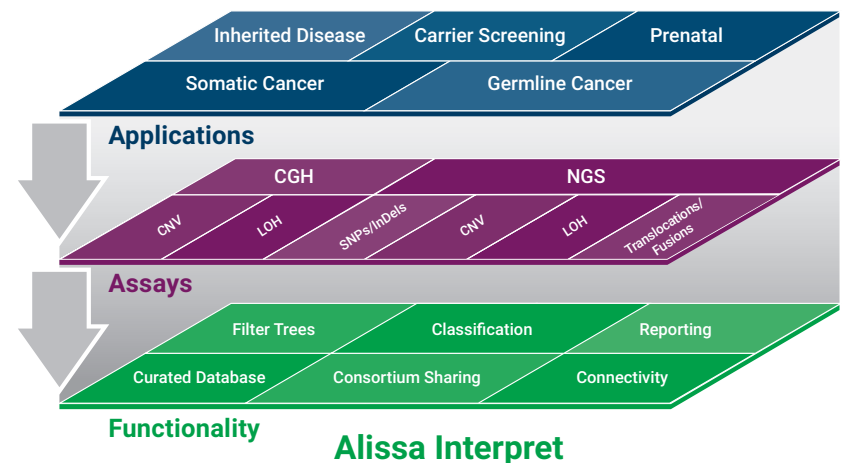


Figure 1. A 3D rendering illustrating how the tools and functionality provided by Alissa Interpret deliver clinically relevant variant assessment across different application areas and genomic events.

Deploy New Tests and Scale to Volume

Labs that implement their standard operating procedures on Alissa Interpret free up time for their molecular geneticists and pathologists to focus on review and signing out cases. This fast and precise variant assessment and reporting solution allows labs to run efficiently and scale to high throughput across the menu of tests they offer.

Advancing Filtration System Decision Trees

Automate your lab's variant assessment workflow in configurable, versioned pipelines. Slice and dice to quickly drill down to your variants of interest for further manual review. Store and version your pipelines to support increasing volumes and scale your sample throughput with ease.

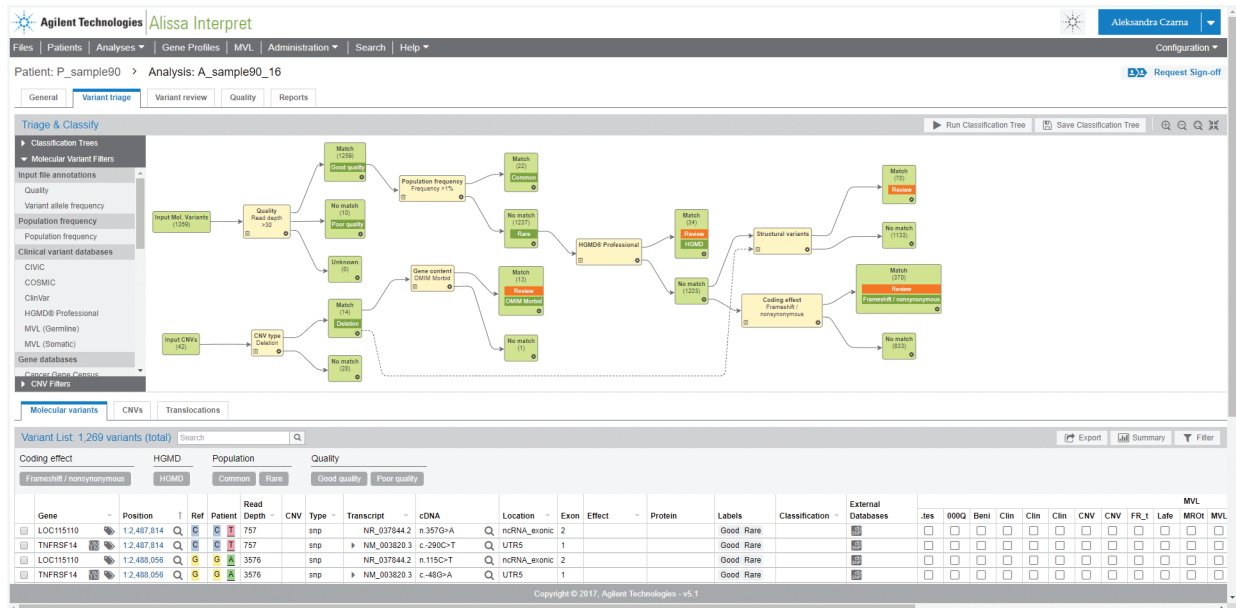


Figure 2. Classification tree with CNV integration.

Building and Accessing Curated Variant Databases

Collaboratively curate your internal knowledgebase while also tapping into an expansive array of public databases, including variant adaptations and effect annotations, frequency databases, clinically relevant peer-reviewed findings, and many others.

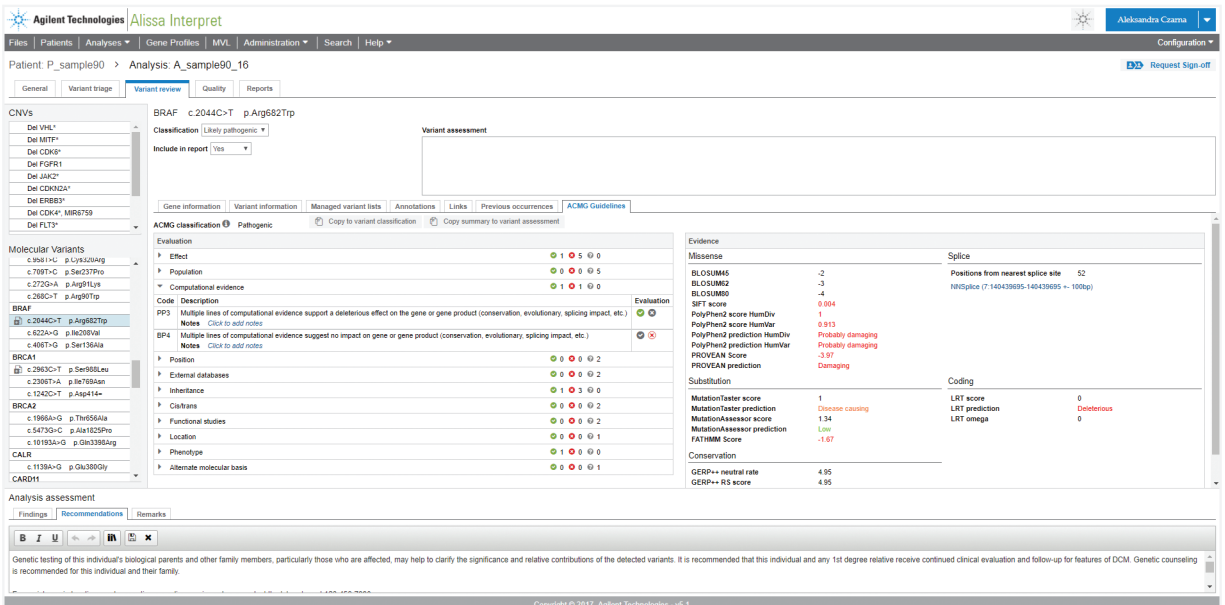


Figure 3. Variant curation using ACMG guideline automation. In this case, the "affected gene information" heading automatically includes a section on the BRAF gene, because that variant is reported.

Comprehensive Report Templates

With Alissa Interpret, reports can be fully configured towards lab needs, both in content as well as layout. For comprehensive report templates, you can include information on your sample, findings, public information, databases, and literature annotations.

Additionally, easy-to-read overviews of variants are provided with their various characteristics, such as read depth, nomenclature, transcripts, gene definitions, and classification can be included in table listings. Automatically generated text can be injected in a context-sensitive way.

The screenshot shows a web interface for a report template. At the top, it displays 'Patient: P_GHI3_NSCLC_spike > Analysis: A_GHI3_NSCLC_spike_2 > Report: draft'. Below this is a 'Report Details' section with a search bar containing 'egf' and a 'Number of report texts found: 1' indicator. A search result shows 'VAR KRAS c.436G>C' with a description: 'The A146P mutation results in an amino acid substitution at position 146 in KRAS, from an alanine (A) to a proline (P). Multiple studies have now shown that patients with tumors harboring mutations in KRAS are unlikely to benefit from...'. A 'Copy to active editor' button is visible below the search result.

The main report area is titled 'Lung Cancer Panel Report - MyLab Genetics'. It includes patient information: 'To: OncoCen Inc Cancer Center, CONCORD ST, SPRINGFIELD, MA 01702', 'Patient: Bemards, I., Hosp. N: A34N/N442N, DOB: 22 Sep 1954, SEX: M, Location: INPATIENT, Requester: D. Rivoni', and 'Sample: 10009, Ext Ref: NN-129637N, Collected: 01/11/2012, Received: 13/2/2012, Tumour Type: Lung (NSCLC), Tissue Block: 43-C23.2 (F14)'. The clinical details state 'Lung cancer, NSCLC Stage 4, Adenocarcinoma'. A disclaimer follows: 'This sample report illustrates capabilities of the Bench Lab NGS report template system. Any information in this report is for illustration purposes only. No clinical assessments are made. This document only serves illustration purposes. Note that reports are customized based on lab requirements, and that pre-configured templates are available as well, e.g. based on ACMG guidelines. This document is confidential and not to be distributed.'

The 'Results' section contains a table with the following data:

Gene	Reference	Nucleotide Change	Protein Change	Read Depth ¹	Classification
PIK3CA	NM_006218.2	c.1624G>A	p.E542K	532/1794	Definitely Pathogenic
KRAS	NM_004985.3	c.436G>C	p.A146P	686/1090	Likely Pathogenic
TP53	NM_000546.5	c.853G>A	p.E285K	273/710	Definitely Pathogenic

Below the table, it notes 'variant reads / total reads'. The 'Interpretation' section provides detailed explanations for each mutation: 'The E542K mutation results in an amino acid substitution at position 542 in PIK3CA, from a glutamic acid (E) to lysine (K). This mutation occurs within the highly conserved helical domain. Mutant PIK3CA proteins have increased catalytic activity resulting in enhanced downstream signalling and oncogenic transformation in vitro'. 'The PIK3CA E542K mutation is a common mutation in cancer. PIK3CA mutations predict a favourable response to PI3K/AKT/mTOR inhibitors such as rapamycin'. 'The A146P mutation results in an amino acid substitution at position 146 in KRAS, from an alanine (A) to a proline (P). This mutation causes constitutive activation of the KRAS protein and has been previously reported in lung cancer. Approximately 25% of lung adenocarcinomas have KRAS mutations but they are uncommon in lung squamous cell carcinoma and small cell carcinoma. 'The E285K mutation results in an amino acid substitution from glutamic acid (E) to lysine (K) at position 285 in the conserved DNA binding motif of TP53. This is a known TP53 inactivating mutation. TP53 mutations are common in all lung cancer types'. The 'Recommendations' section states 'Refer patient for follow-up with Dr. B. Arnolds.'

Figure 4. An example of an automatically drafted report based on a report template.

A Clinical-grade Environment

HIPAA compliant and manufactured in an ISO13485 certified facility, Alissa Interpret supports the lab's accreditation and compliance with features like database versioning and audit trails. Organize your lab's workflow by having experts review and sign off on cases collaboratively.

One Source

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Intended Use Statement

Alissa Interpret software is intended for variant storage, visualization, and annotation using public, commercial and customer internal data sources. It allows end users to set up pipelines to perform or automate the triage and classification of genetic variants. It provides features for recording variant assessments and the drafting of variant analysis reports. The integration capabilities allow for the automated exchange of variant and report information with external software systems.

Alissa Interpret software is intended to be used by trained lab professionals, clinical geneticists and molecular pathologists as a decision-support software platform for the analysis and interpretation of genetic variants identified in human samples in the context of clinical information recorded for a sample.

www.agilent.com/lifesciences/alissa

**Alissa Interpret is a USA Class I Exempt Medical Device,
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