NEO GENOMICS

NEO | Comprehensive® – Heme Cancers

Harness the potential to impact the therapeutic course for patients with hematologic malignancies

Trust the experts with over 20 years of experience.

Elevate your clinical heme cancer assessments with comprehensive genomic profiling (CGP)

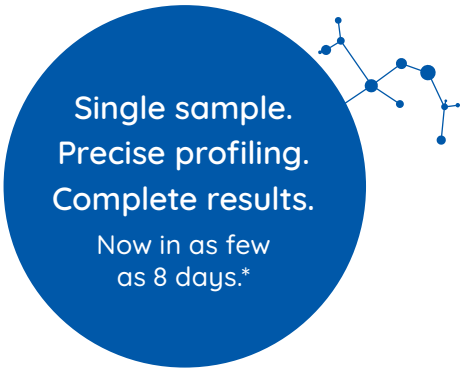
CGP in hematologic cancers provides precision diagnostics and classification information, while supporting patient inclusion in clinical trials.

Why Neo Comprehensive – Heme Cancers?

Neo Comprehensive – Heme Cancers targets a broad set of genomic alterations, which provides information that may be useful for diagnostic, prognostic, and therapy selection decision-making. The panel is designed in alignment with the latest guidelines and WHO 5th Edition classification, useful for both clinical and research purposes.

Target important genomic signatures for myeloid and lymphoid diseases with a single heme assay.

Over 300 genes (SNV, InDel, and CNV) are assessed by DNA sequencing combined with over 180 genes assessed by RNA sequencing for both known and novel fusions. To improve clinical utility, *FLT3* testing by PCR may be added on to achieve faster results for therapy selection decisions for patients newly diagnosed with AML.



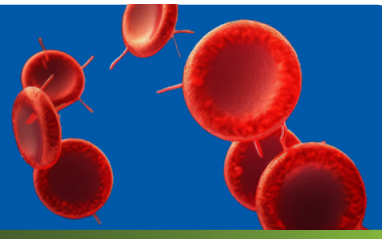
Superior assay performance

Variant type	Average sequencing depth	Sensitivity	Specificity	Reportable range (20% abnormal cells)
SNVs	≥500X	98.31%	99.96%	≥3% Hotspots, ≥5% all others
InDels		98.85%	99.99%	≥3% Hotspots, ≥5% all others
CNVs (Gain/Loss)		95.98%	98.36%	Gains (≥ trisomy) Loss (hetero-/homozygous)
Fusions (RNA-seq)	≥5M reads	97.01%	98.20%	≥5 reads and AI score

Neo Comprehensive – Heme Cancers

Analysis of 433 genes for comprehensive genomic data

- DNA Sequencing (302 genes): Detection of SNVs, InDels, and CNVs
- RNA Sequencing (184 genes): Detection of fusions



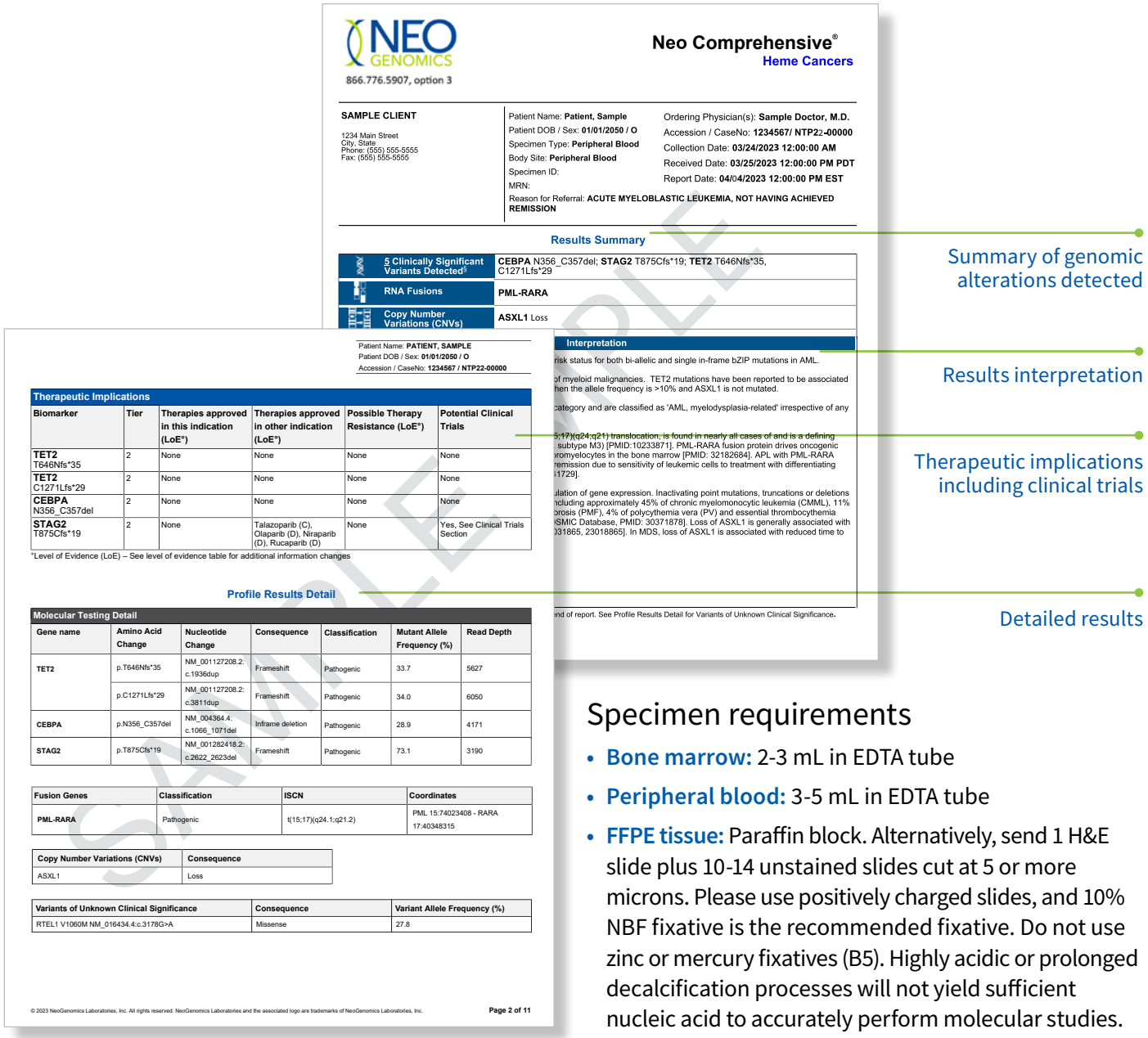
A complete list of genes is available on NeoGenomics.com.

For more information on **Neo Comprehensive – Heme Cancers,** please contact your NeoGenomics Sales Representative, call our Client Services team at 866.776.5907, option 3.

SNVs = single-nucleotide variants, InDels = insertions/deletions, CNVs = copy number variants

*Turnaround time for this test is 8-11 days.

All pertinent genomic information in one clear and simple report



NEO GENOMICS
866.776.5907, option 3

Neo Comprehensive®
Heme Cancers

SAMPLE CLIENT
1234 Main Street
City, State
Phone: (555) 555-5555
Fax: (555) 555-5555

Patient Name: **Patient, Sample**
Patient DOB / Sex: **01/01/2050 / O**
Specimen Type: **Peripheral Blood**
Body Site: **Peripheral Blood**
Specimen ID:
MRN:
Reason for Referral: **ACUTE MYELOBLASTIC LEUKEMIA, NOT HAVING ACHIEVED REMISSION**

Ordering Physician(s): **Sample Doctor, M.D.**
Accession / CaseNo: **1234567/ NTP22-00000**
Collection Date: **03/24/2023 12:00:00 AM**
Received Date: **03/25/2023 12:00:00 PM PDT**
Report Date: **04/04/2023 12:00:00 PM EST**

Results Summary

5 Clinically Significant Variants Detected§	**CEBPA** N356_C357del; **STAG2** T875Cfs*19; **TET2** T646Nfs*35, C1271Lfs*29
RNA Fusions	**PML-RARA**
Copy Number Variations (CNVs)	**ASXL1** Loss

Patient Name: **PATIENT, SAMPLE**
Patient DOB / Sex: **01/01/2050 / O**
Accession / CaseNo: **1234567 / NTP22-00000**

Interpretation

risk status for both bi-allelic and single in-frame bZIP mutations in AML.

of myeloid malignancies. TET2 mutations have been reported to be associated hen the allele frequency is >10% and ASXL1 is not mutated.

category and are classified as 'AML, myelodysplasia-related' irrespective of any

5;17)(q24;q21) translocation, is found in nearly all cases of and is a defining subtype M3) [PMID:10233871]. PML-RARA fusion protein drives oncogenic promyelocytes in the bone marrow [PMID: 32182684]. APL with PML-RARA remission due to sensitivity of leukemic cells to treatment with differentiating 1729].

ulation of gene expression. Inactivating point mutations, truncations or deletions ncluding approximately 45% of chronic myelomonocytic leukemia (CMML), 11% brosis (PMF), 4% of polycythemia vera (PV) and essential thrombocythemia SMIC Database, PMID: 30371878]. Loss of ASXL1 is generally associated with 031865, 23018865]. In MDS, loss of ASXL1 is associated with reduced time to

nd of report. See Profile Results Detail for Variants of Unknown Clinical Significance.

Therapeutic Implications

Biomarker	Tier	Therapies approved in this indication (LoE*)	Therapies approved in other indication (LoE*)	Possible Therapy Resistance (LoE*)	Potential Clinical Trials
TET2 T646Nfs*35	2	None	None	None	None
TET2 C1271Lfs*29	2	None	None	None	None
CEBPA N356_C357del	2	None	None	None	None
STAG2 T875Cfs*19	2	None	Talazoparib (C), Olaparib (D), Niraparib (D), Rucaparib (D)	None	Yes, See Clinical Trials Section

*Level of Evidence (LoE) – See level of evidence table for additional information changes

Profile Results Detail

Molecular Testing Detail

Gene name	Amino Acid Change	Nucleotide Change	Consequence	Classification	Mutant Allele Frequency (%)	Read Depth
TET2	p.T646Nfs*35	NM_001127208.2: c.1936dup	Frameshift	Pathogenic	33.7	5627
	p.C1271Lfs*29	NM_001127208.2: c.3811dup	Frameshift	Pathogenic	34.0	6050
CEBPA	p.N356_C357del	NM_004364.4: c.1066_1071del	Inframe deletion	Pathogenic	28.9	4171
STAG2	p.T875Cfs*19	NM_001282418.2: c.2622_2623del	Frameshift	Pathogenic	73.1	3190

Fusion Genes	Classification	ISCN	Coordinates
PML-RARA	Pathogenic	t(15;17)(q24.1;q21.2)	PML 15:74023408 - RARA 17:40348315

Copy Number Variations (CNVs)	Consequence
ASXL1	Loss

Variants of Unknown Clinical Significance	Consequence	Variant Allele Frequency (%)
RTEL1 V1060M NM_016434.4:c.3178G>A	Missense	27.8

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Summary of genomic alterations detected

Results interpretation

Therapeutic implications including clinical trials

Detailed results

Specimen requirements

- **Bone marrow:** 2-3 mL in EDTA tube
- **Peripheral blood:** 3-5 mL in EDTA tube
- **FFPE tissue:** Paraffin block. Alternatively, send 1 H&E slide plus 10-14 unstained slides cut at 5 or more microns. Please use positively charged slides, and 10% NBF fixative is the recommended fixative. Do not use zinc or mercury fixatives (B5). Highly acidic or prolonged decalcification processes will not yield sufficient nucleic acid to accurately perform molecular studies.

Specimen stability

Fresh samples must be received at NeoGenomics Laboratories within 7 days of collection. Ship same day as drawn whenever possible. Please select Extract and Hold — TNA if specimen hold service is desired. **Extract and hold is available for fresh samples only.**

Turnaround time (TAT)

Turnaround time is 8-11 days. Results are integrated into a final comprehensive report. If *FLT3* by PCR is added on, it reports separately as soon as completed (approximately 5 days).

We pride ourselves on our unparalleled client services team. If you have questions regarding test information, specimen requirements, turnaround times, test add-ons, and patient results, please contact us:

Client.Services@NeoGenomics.com or call 866.776.5907, option 3.

Neo Comprehensive – Heme Cancers is approved by the New York State Department of Health.

NEO GENOMICS

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