BAYLOR GENETICS

ClariFind
ClariFind Comprehensive DNA Panel

www.baylorgenetics.com | help@baylorgenetics.com
P: 1.800.411.4363 | F: 1.800.434.9850
2450 Holcombe Blvd, Houston TX 77021

Patient Name:	JOHN 12602	Test Code:	20010	Physician Name:	MGL Internal Provider
Date of Birth:		Date Collected:		Facility:	
Sex:	M	Date Received:	12/06/2017	Location:	Houston, TX, 77030
Medical Record #:		Date Ordered:	12/06/2017	Phone:	713-798-6075
Accession #:		Date Reported:	12/20/2017	Fax:	713-798-4187
Lab Number:	810326	Addt'l Report Date:			
Family Number:	682880	Sample Type:	BLOOD		
Zip Code:	74101	Collection Site:			
Indication:	Acute myeloid leukemia	Estimated Tumor Cellularity: N/A			

RESULTS SUMMARY

Significant Genomic Alterations	Associated Targeted Therapies	Potential Clinical Trials
DNMT3A p.Gly543Ala AMP Tier II (Potential Clinical Significance)	Azacitidine FDA APPROVED NCCN 2A Decitabine FDA APPROVED NCCN 2A	☑ Trial Enrollment Available
U2AF1 p.Ser34Phe AMP Tier II (Potential Clinical Significance)	No Therapies for This Alteration	☑ Trial Enrollment Available
CEBPA Wild Type	No Therapies for This Alteration	☑ Trial Enrollment Available NEARBY
FLT3 Wild Type	No Therapies for This Alteration	☑ Trial Enrollment Available
NPM1 Wild Type	No Therapies for This Alteration	☑ Trial Enrollment Available NEARBY
TP53 Wild Type	No Therapies for This Alteration	☑ Trial Enrollment Available

INTERPRETATION

We were requested to perform next-generation sequencing analysis as part of the Baylor Genetics ClariFind Comprehensive DNA Panel on the blood sample of this individual using the techniques described in the test methodology section. Our next-generation sequencing analysis identified two clinically significant alterations as listed above, both of which may help satisfy eligibility criteria for clinical trials and one of which may be considered as a therapeutic target. Several noteworthy genes listed above showed the absence of detectable genomic alterations (i.e. wild type) which may also help satisfy eligibility criteria for clinical trials. Next-generation sequencing-based copy number analysis did not detect any clinically significant copy number alterations in 39 reportable genes.

The DNMT3A G543A mutation has been previously reported in acute myeloid leukemia [PMID: 22749068; 23632886]. DNMT3A mutations occur in ~17% of acute myeloid leukemia cases [http://cancer.sanger.ac.uk/cosmic/gene/analysisln=DNMT3A] and have been reported to be associated with poor prognosis [PMID: 21067377; 22490330], although data is conflicting with certain groups of patients showing improved outcomes or no significant difference in survival [PMID: 22417203; 23632886]. Patient response to hypomethylating agents has been overall variable in recent studies [PMID: 24699305; 25693834].

The U2AF1 S34F mutation has been recurrently reported in acute myeloid leukemia and myelodysplastic syndrome in the COSMIC database [http://cancer.sanger.ac.uk/cosmic/mutation/overview?id=166866]. U2AF1 mutations are associated with acute myeloid leukemia with myelodysplasia-related changes [PMID: 25412851; 25487075]. Mutations in splicing factors including U2AF1 have been associated with poor prognosis for acute myeloid leukemia patients in several studies [PMID: 26812887; 25550361; 25412851].

Please note, cytogenetics and AML FISH studies performed on a corresponding bone marrow sample from the patient revealed a normal karyotype (see separate reports, lab number 243815).

Additional genomic alterations of uncertain clinical significance were identified in this case, including alterations which are novel/rare or may be germline in origin. A full list of these alterations is provided with this report.

Alterations classified as benign or likely benign based on current knowledge are not reported but are available upon request.

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SIGNIFICANT GENOMIC ALTERATIONS

Alterations	Interpretation
DNMT3A p.Gly543Ala	**AMP Tier:** II (Potential Clinical Significance) **Type of Evidence:** Therapeutic; Prognostic **Evidence-Based Variant Categorization:** Level C: FDA-approved therapies for different tumor types or investigational therapies; multiple small published studies with some consensus The DNA (cytosine-5-)-methyltransferase 3 alpha (DNMT3A) gene encodes a protein involved in epigenetic gene regulation [www.ncbi.nlm.nih.gov/gene/178; PMID: 17938196]. DNMT3A is most frequently mutated in hematologic malignancies such as acute myeloid leukemia and myelodysplastic syndromes, but it has also been observed in other cancers, including lung cancer [PMID: 23031157]. DNMT3A mutations occur in ~17% of acute myeloid leukemia cases [http://cancer.sanger.ac.uk/cosmic/gene/analysisln=DNMT3A]. DNMT3A mutations most often occur at the R882 residue of the protein, and they are believed to cause loss of function [PMID: 22898539]. Some have proposed categorizing DNMT3A mutations into a class of mutations occurring in epigenetic modifiers [PMID: 23359299; 22898539]. Similar to IDH1 and IDH2 mutations, DNMT3A mutations affect DNA methylation and as such, play a role in cancer development through deregulation of gene expression. DNMT3A mutations have been reported to be associated with poor prognosis in acute myeloid leukemia [PMID: 21067377;22490330], although data is conflicting with certain groups of patients showing improved outcomes or no significant difference in survival [PMID: 22417203; 23632886]. The DNMT3A G543A mutation has been previously reported in acute myeloid leukemia [PMID: 22749068; 23632886]. Targeted Treatment: Patient response to hypomethylating agents has been overall variable in recent studies [PMID: 24699305; 25693834].

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Alterations	Interpretation
U2AF1 p.Ser34Phe	**AMP Tier:** II (Potential Clinical Significance) **Type of Evidence:** Prognostic **Evidence-Based Variant Categorization:** Level C: FDA-approved therapies for different tumor types or investigational therapies; multiple small published studies with some consensus U2 small nuclear RNA auxiliary factor 1 (U2AF1) is a gene that encodes for a member of the spliceosome. The protein coded by this gene is part of the U2 auxiliary factor, which plays an important role in RNA splicing [https://www.ncbi.nlm.nih.gov/gene/7307]. Spliceosome mutations are observed in myelodysplastic syndromes, chronic lymphocytic leukemia, acute myeloid leukemia, and chronic myelomonocytic leukemia, and these mutations can cause abnormal expression patterns of some genes involved in cancer pathogenesis [PMID: 23327988]. U2AF1 mutations are associated with acute myeloid leukemia with myelodysplasia-related changes [PMID: 25412851; 25487075]. Mutations in splicing factors including U2AF1 have been associated with poor prognosis for acute myeloid leukemia patients in several studies [PMID: 26812887; 25550361; 25412851]. The U2AF1 S34F mutation has been recurrently reported in acute myeloid leukemia and myelodysplastic syndrome in the COSMIC database [http://cancer.sanger.ac.uk/cosmic/mutation/overviewid=166866].

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ASSOCIATED TARGETED THERAPIES

Drug	Summary
Azacitidine *Vidaza, Azacitidine* For DNMT3A p.Gly543Ala	**Evidence-Based Therapeutic Categorization in This Patient:** FDA Approved; NCCN Level 2A **Description:** A pyrimidine nucleoside analogue that inhibits DNA methyltransferase, impairing DNA methylation. It is also an antimetabolite of cytidine, incorporated primarily into RNA. Azacytidine has been used as an antineoplastic agent. **Indication:** For treatment of patients with the following French-American-British myelodysplastic syndrome subtypes: refractory anemia or refractory anemia with ringed sideroblasts (if accompanied by neutropenia or thrombocytopenia or requiring transfusions), refractory anemia with excess blasts, refractory anemia with excess blasts in transformation (now classified as acute myelogenous leukemia with multilineage dysplasia), and chronic myelomonocytic leukemia. **Mechanism of Action:** Azacitidine (5-azacytidine) is a chemical analogue of the cytosine nucleoside used in DNA and RNA. Azacitidine is thought to induce antineoplastic activity via two mechanisms; inhibition of DNA methyltransferase at low doses, causing hypomethylation of DNA, and direct cytotoxicity in abnormal hematopoietic cells in the bone marrow through its incorporation into DNA and RNA at high doses, resulting in cell death. As azacitidine is a ribonucleoside, it incoporates into RNA to a larger extent than into DNA. The incorporation into RNA leads to the dissembly of polyribosomes, defective methylation and acceptor function of transfer RNA, and inhibition of the production of protein. Its incorporation into DNA leads to a covalent binding with DNA methyltransferases, which prevents DNA synthesis and subsequent cytotoxicity. **Targets:** DNA (cytosine-5)-methyltransferase 1, RNA, DNA

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Drug	Summary
Decitabine *Dacogen, Decitabine* For DNMT3A p.Gly543Ala	**Evidence-Based Therapeutic Categorization in This Patient:** FDA Approved; NCCN Level 2A **Description:** Decitabine is indicated for treatment of patients with myelodysplastic syndrome (MDS). It is a chemical analogue of cytidine, a nucleoside present in DNA and RNA. Cells in the presence of Decitabine incorporate it into DNA during replication and RNA during transcription. The incorporation of Decitabine into DNA or RNA inhibits methyltransferase thereby causing demethylation in that sequence. This adversely affects the way that cell regulatory proteins are able to bind to the DNA/RNA substrate. **Indication:** For treatment of patients with myelodysplastic syndromes (MDS) including previously treated and untreated, de novo and secondary MDS of all French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, refractory anemia with excess blasts in transformation, and chronic myelomonocytic leukemia) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups (scores >=0.5). **Mechanism of Action:** Decitabine is believed to exert its antineoplastic effects following its conversion to decitabine triphosphate, where the drug directly incorporates into DNA and inhibits DNA methyltransferase, the enzyme that is responsible for methylating newly synthesized DNA in mammalian cells. This results in hypomethylation of DNA and cellular differentiation or apoptosis. Decitabine inhibits DNA methylation in vitro, which is achieved at concentrations that do not cause major suppression of DNA synthesis. Decitabine-induced hypomethylation in neoplastic cells may restore normal function to genes that are critical for the control of cellular differentiation and proliferation. In rapidly dividing cells, the cytotoxicity of decitabine may also be attributed to the formation of covalent adducts between DNA methyltransferase and decitabine that has been incorporated into DNA. Non-proliferating cells are relatively insensitive to decitabine. Decitabine is cell cycle specific and acts peripherally in the S phase of the cell cycle. It does not inhibit the progression of cells from the G1 to S phase. **Targets:** DNA, DNA (cytosine-5)-methyltransferase 1

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POTENTIAL CLINICAL TRIALS

Trial Name	Phase	Matching Alteration(s)	Intervention(s)	NCT ID	Nearest Location	Miles Away
An Efficacy and Safety Study Of Pracinostat In Combination With Azacitidine In Adults With Acute Myeloid Leukemia	Phase 3	CEBPA Wild Type, NPM1 Wild Type	Pracinostat, Placebos, Azacitidine	NCT03151408	Oklahoma cancer specialist and research institute, Tulsa, Oklahoma, United States	5
Double Cord Versus Haploidentical (BMT CTN 1101)	Phase 3	CEBPA Wild Type, NPM1 Wild Type	Haploidentical Bone Marrow Transplant, Double Umbilical Cord Blood Transplant	NCT01597778	University of Oklahoma Medical Center, Oklahoma City, Oklahoma, United States	99
Safety, Tolerability, and Efficacy of TAK-659 in Adults With Relapsed or Refractory Acute Myelogenous Leukemia (AML)	Phase 1/Phase 2	FLT3 Wild Type	TAK-659	NCT02323113	Baylor University Medical Center, Dallas, Texas, United States	230
Improving Risk Assessment of AML With a Precision Genomic Strategy to Assess Mutation Clearance	Phase 2	NPM1 Wild Type	Cytarabine, Midostaurin	NCT02756962	Washington University School of Medicine, Saint Louis, Missouri, United States	356
Clinical Trial Using an Engineered Peripheral Blood Graft for Haploidentical Transplantation	Phase 1	DNMT3A p.Gly543Ala	Rituximab, Melphalan, Fludarabine, Cyclophosphamide, G-CSF	NCT02960646	University of Texas MD Anderson Cancer Center, Houston, Texas, United States	439
Fludarabine/Clofarabine/Busulfan Combined With SAHA in Acute Leukemia	Phase 1	CEBPA Wild Type, NPM1 Wild Type	Fludarabine, Clofarabine, Busulfan, SAHA, Thymoglobulin	NCT02083250	University of Texas MD Anderson Cancer Center, Houston, Texas, United States	439
NK Cells to Prevent Disease Relapse for Patients High Risk Myeloid Malignancies	Phase 1/Phase 2	DNMT3A p.Gly543Ala	Melphalan, Fludarabine, Mesna, Cyclophosphamide, Tacrolimus, Mycophenolate mofetil, G-CSF	NCT01904136	University of Texas MD Anderson Cancer Center, Houston, Texas, United States	439
Natural Killer (NK) Cells With HLA Compatible Hematopoietic Transplantation for High Risk Myeloid Malignancies	Phase 1/Phase 2	DNMT3A p.Gly543Ala	Busulfan, Fludarabine, Interleukin-2, G-CSF, Tacrolimus, Methotrexate	NCT01823198	University of Texas MD Anderson Cancer Center, Houston, Texas, United States	439

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Trial Name	Phase	Matching Alteration(s)	Intervention(s)	NCT ID	Nearest Location	Miles Away
Phase 1 Trial to Evaluate the Safety, Pharmacokinetics and Pharmacodynamics of Splicing Modulator H3B-8800 for Subjects With Myelodysplastic Syndromes, Acute Myeloid Leukemia, and Chronic Myelomonocytic Leukemia	Phase 1	U2AF1 p.Ser34Phe	H3B-8800	NCT02841540	The University of Texas MD Anderson Cancer Center, Houston, Texas, United States	439
A Study Of PF-06747143, As Single Agent Or In Combination With Standard Chemotherapy In Adult Patients With Acute Myeloid Leukemia	Phase 1	CEBPA Wild Type, NPM1 Wild Type	PF-06747143, Cytarabine, Daunorubicin, Azacitidine, Decitabine	NCT02954653	The University of Chicago Medical Center, Chicago, Illinois, United States	595
Safety Study of ALRN-6924 in Patients With Acute Myeloid Leukemia or Advanced Myelodysplastic Syndrome	Phase 1	TP53 Wild Type	ALRN-6924, ALRN-6924 in combination with cytarabine	NCT02909972	Institute for Translational Oncology Research (ITOR), Greenville, South Carolina, United States	763
Specialized Blood Cell Transplants for Cancers of the Blood and Bone Marrow	Phase 2	CEBPA Wild Type, NPM1 Wild Type		NCT00003838	National Institutes of Health Clinical Center, 9000 Rockville Pike, Bethesda, Maryland, United States	1047
Biomarkers in Predicting Treatment Response to Sirolimus and Chemotherapy in Patients With High-Risk Acute Myeloid Leukemia	Phase 2	CEBPA Wild Type, NPM1 Wild Type	Sirolimus, Mitoxantrone, Etoposide, Cytarabine	NCT02583893	Thomas Jefferson University, Philadelphia, Pennsylvania, United States	1157

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REPORTED ALTERATIONS BY NEXT-GENERATION SEQUENCING

BASE SUBSTITUTIONS, INSERTIONS, DELETIONS

AMP Tier	Gene	Protein Syntax	Coding Syntax	Genomic Change (GRCh37/hg19)	UMI Variant Reads/Total	Variant Allele Fraction (%)	COSMIC / dbSNP	Notes
II	DNMT3A	NP_072046.2:p.Gly543Ala	NM_022552.4:c.1628G>C	NC_000002.11:g.25467448C>G	852 / 1857	45.9	COSM256033 rs767226511	
II	U2AF1	NP_006749.1:p.Ser34Phe	NM_006758.2:c.101C>T	NC_000021.8:g.44524456G>A	465 / 993	46.8	COSM166866 rs371769427	
III	ABL1	NP_005148.2:p.Pro810Leu	NM_005157.4:c.2429C>T	NC_000009.11:g.133760106C>T	669 / 1341	49.9	COSM4888106 rs2229071	
III	ATM	NP_000042.3:p.Ser49Cys	NM_000051.3:c.146C>G	NC_000011.9:g.108098576C>G	978 / 2034	48.1	rs1800054	
III	CCND3	NP_001751.1:p.Ser259Ala	NM_001760.3:c.774_775delCTinsTG	NC_000006.11:g.41903782_41903783delAGinsCA	783 / 1483	52.8	rs386700585	
III	DOT1L	NP_115871.1:p.Asp1161Asn	NM_032482.2:c.3481G>A	NC_000019.9:g.2223370G>A	429 / 823	52.1	rs561499135	
III	EP300	NP_001420.2:p.Gln2268del	NM_001429.3:c.6798_6800delGCA	NC_000022.10:g.41574513_41574515delGCA	377 / 832	45.3	COSM5751555 rs886057570	
III	HOXB13	NP_006352.2:p.Gly84Glu	NM_006361.5:c.251G>A	NC_000017.10:g.46805705C>T	589 / 1161	50.7	COSM3889825 rs138213197	
III	JAK2	NP_004963.1:p.Asn1108Ser	NM_004972.3:c.3323A>G	NC_000009.11:g.5126715A>G	599 / 1225	48.9	COSM33708 rs142269166	
III	KMT2A	NP_001184033.1:p.Gly909Asp	NM_001197104.1:c.2726G>A	NC_000011.9:g.118344600G>A	1052 / 1658	63.4	rs139227835	
III	KMT2D	NP_003473.3:p.Pro2516Arg	NM_003482.3:c.7547C>G	NC_000012.11:g.49434006G>C	280 / 538	52		
III	NOTCH2	NP_077719.2:p.Arg91Leu	NM_024408.3:c.272G>T	NC_000001.10:g.120548095C>A	705 / 1586	44.5	COSM5415146 rs143195893	
III	POLD1	NP_001243778.1:p.Ala145Thr	NM_001256849.1:c.433G>A	NC_000019.9:g.50905151G>A	294 / 599	49.1	rs137953986	
III	XPO1	NP_003391.1:p.Thr159Ile	NM_003400.3:c.476C>T	NC_000002.11:g.61726962G>A	354 / 760	46.6		

Estimated Tumor Mutational Burden (variants listed above / MB of genome targeted (0.84)) = 16.67

COPY NUMBER ALTERATIONS

No reportable copy number alterations identified.

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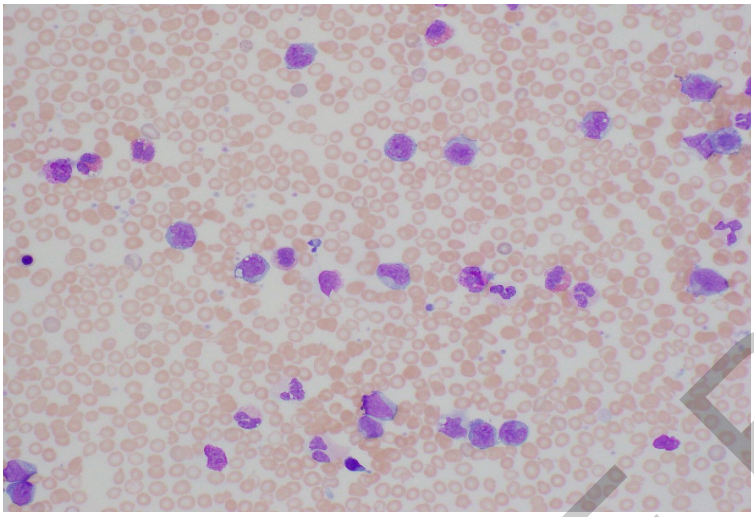
SPECIMEN DETAILS



Wright-Giemsa stained peripheral blood smear at 400x magnification.

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TEST DESCRIPTION

The ClariFind Comprehensive DNA Panel is a next-generation sequencing assay covering all coding regions (+/- 5-10bp flanking intronic sequences and including the TERT promoter region) of 277 key cancer genes for both solid tumors and hematologic malignancies and is designed for the detection of somatic base substitutions, insertions, deletions, and copy number alterations in a patient's tumor sample. Copy number alterations are reported for 39 key cancer genes (designated by * below).

ABL1 NM_005157.4	ACVR1B NM_020328.3	AKT1 NM_001014432.1	AKT2* NM_001626.4	AKT3 NM_005465.4	ALK* NM_004304.4	AMER1 NM_152424.3	APC NM_000038.5	AR* NM_000044.3	ARAF NM_001654.4	ARID1A NM_006015.4	ARID1B NM_020732.3	ARID2 NM_152641.2	ASXL1 NM_015338.5
ATM* NM_000051.3	ATR NM_001184.3	ATRX NM_000489.3	AURKA NM_198433.1	AURKB NM_004217.3	AURKC NM_003160.2	AXIN1 NM_003502.3	AXIN2 NM_004655.3	B2M NM_004048.2	BAP1 NM_004656.3	BCL2 NM_000633.2	BCL2L1 NM_138578.1	BCL6 NM_001706.4	BCOR NM_017745.5
BCORL1 NM_021946.4	BCR NM_004327.3	BIRC3 NM_001165.4	BLM NM_000057.2	BRAF* NM_004333.4	BRCA1 NM_007294.3	BRCA2 NM_000059.3	BRIP1 NM_032043.2	BTK NM_000061.2	CALR NM_004343.3	CARD11 NM_032415.4	CBL NM_005188.3	CBLB NM_170662.3	CBLC NM_012116.3
CCND1* NM_053056.2	CCND3 NM_001760.3	CCNE1* NM_001238.2	CD274 NM_014143.3	CD79A NM_001783.3	CD79B NM_000626.2	CDC73 NM_024529.4	CDH1 NM_004360.3	CDK12 NM_016507.2	CDK4* NM_000075.3	CDK6* NM_001259.6	CDKN2A* NM_000077.4	CDKN2B NM_004936.3	CDKN2C NM_001262.2
CEBPA NM_004364.3	CHEK1 NM_001114122.2	CHEK2 NM_007194.3	CIC NM_015125.3	CREBBP NM_004380.2	CRLF2 NM_022148.3	CSF1R NM_005211.3	CSF3R NM_156039.3	CTCF NM_006565.3	CTNNA1 NM_001903.2	CTNNB1 NM_001904.3	CUX1 NM_181552.3	CXCR4 NM_001008540.1	CYLD NM_015247.2
DAXX NM_001350.4	DDR1 NM_001954.4	DDR2 NM_001014796.1	DICER1 NM_177438.2	DNM2 NM_001005360.2	DNMT3A NM_022552.4	DOT1L NM_032482.2	EED NM_003797.3	EGFR* NM_005228.3	EGLN1 NM_022051.2	EP300 NM_001429.3	EPAS1 NM_001430.4	EPHA3 NM_005233.5	EPHA5 NM_004439.5
ERBB2* NM_004448.2	ERBB3* NM_001982.3	ERBB4 NM_005235.2	ERG NM_004449.4	ESR1* NM_001122742.1	ETNK1 NM_018638.4	ETV6 NM_001987.4	EXO1 NM_130398.3	EZH2 NM_004456.4	FAM175A NM_139076.2	FAM46C NM_017709.3	FANCA NM_000135.2	FANCC NM_000136.2	FANCD2 NM_033084.3
FANCE NM_021922.2	FANCF NM_022725.3	FANCG NM_004629.1	FAS NM_000043.4	FBXW7 NM_033632.3	FGF4 NM_002007.2	FGF6 NM_020996.1	FGFR1* NM_023110.2	FGFR2* NM_000141.4	FGFR3* NM_000142.4	FGFR4* NM_213647.1	FH NM_000143.3	FLCN NM_144997.5	FLT3* NM_004119.2
FLT4 NM_002020.4	FOXL2 NM_023067.3	FUBP1 NM_003902.3	GALNT12 NM_024642.4	GATA1 NM_002049.3	GATA2 NM_032638.4	GATA3 NM_001002295.1	GEN1 NM_182625.3	GNA11 NM_002067.2	GNAQ NM_002072.3	GNAS NM_000516.4	GREM1 NM_013372.6	GRIN2A NM_000833.3	H3F3A NM_002107.4
HGF NM_000601.4	HIST1H3B NM_003537.3	HNF1A NM_000545.5	HOXB13 NM_006361.5	HRAS NM_005343.2	HSP90AA1 NM_001017963.2	ID3 NM_002167.4	IDH1 NM_005896.2	IDH2 NM_002168.2	IGF1R* NM_000875.3	IKZF1 NM_006060.5	IKZF3 NM_012481.4	IL7R NM_002185.3	INHBA NM_002192.2
IRF4 NM_002460.3	JAK1 NM_002227.2	JAK2* NM_004972.3	JAK3 NM_000215.3	KAT6A NM_001099412.1	KDM5C NM_004187.3	KDM6A NM_021140.2	KDR NM_002253.2	KEAP1 NM_012289.3	KIT* NM_000222.2	KMT2A NM_001197104.1	KMT2B NM_014727.1	KMT2C NM_170606.2	KMT2D NM_003482.3
KRAS* NM_004985.3	LRP1B NM_018557.2	MAP2K1 NM_002755.3	MAP2K2 NM_030662.3	MAP2K4 NM_003010.3	MAP3K1 NM_005921.1	MAP3K14 NM_003954.3	MAPK1 NM_002745.4	MCL1 NM_021960.4	MDM2* NM_002392.5	MDM4* NM_002393.4	MED12 NM_005120.2	MEF2B NM_001145785.1	MEN1 NM_130799.2
MET* NM_001127500.1	MITF NM_000248.3	MLH1 NM_000249.3	MPL NM_005373.2	MRE11A NM_005590.3	MSH2 NM_000251.2	MSH6 NM_000179.2	MTOR NM_004958.3	MUTYH NM_012222.2	MYC* NM_002467.4	MYCL* NM_001033082.2	MYCN* NM_005378.4	MYD88 NM_002468.4	NF1* NM_001042492.2
NF2 NM_000268.3	NFE2L2 NM_006164.4	NFKBIA NM_020529.2	NKX2-1 NM_003317.3	NOTCH1 NM_017617.3	NOTCH2 NM_024408.3	NOTCH3 NM_000435.2	NPM1 NM_002520.6	NRAS* NM_002524.4	NSD1 NM_022455.4	NTRK1 NM_002529.3	NTRK2 NM_006180.3	NTRK3 NM_002530.3	PAK3 NM_002578.3
PALB2 NM_024675.3	PAX5 NM_016734.2	PBRM1 NM_181042.4	PDGFRA* NM_006206.4	PDGFRB* NM_002609.3	PHF6 NM_032458.2	PIK3CA* NM_006218.2	PIK3R1 NM_181523.2	PIK3R2 NM_005027.3	PIM1 NM_002648.3	PLCG1 NM_002660.2	PMS1 NM_000534.4	PMS2 NM_000535.5	POLD1 NM_001256849.1
POLE NM_006231.2	PPM1D NM_003620.3	PPP2R1A NM_014225.5	PRDM1 NM_001198.3	PRKAR1A NM_212472.2	PRKDC NM_006904.6	PRSS1 NM_002769.4	PTCH1 NM_000264.3	PTEN* NM_000314.4	PTPN11 NM_002834.3	RAC1 NM_006908.4	RAD21 NM_006265.2	RAD50 NM_005732.3	RAD51 NM_002875.4
RAF1 NM_002880.3	RB1* NM_000321.2	RET* NM_020975.4	RHEB NM_005614.3	RHOA NM_001664.2	RIT1 NM_006912.5	RNF43 NM_017763.4	ROS1 NM_002944.2	RUNX1 NM_001754.4	SDHB NM_003000.2	SETBP1 NM_015559.2	SETD2 NM_014159.6	SF3B1 NM_012433.2	SMAD2 NM_005901.5
SMAD4 NM_005359.5	SMARCA4 NM_001128844.1	SMARCB1 NM_003073.3	SMC1A NM_006306.3	SMC3 NM_005445.3	SMO NM_005631.4	SOCS1 NM_003745.1	SOX2 NM_003106.3	SOX9 NM_000346.3	SPOP NM_001007226.1	SRC NM_005417.4	SRSF2 NM_003016.4	STAG2 NM_001042751.1	STAT3 NM_139276.2
STK11* NM_000455.4	SUFU NM_016169.3	SUZ12 NM_015355.2	TAL1 NM_003189.2	TCF3 NM_003200.3	TERT NM_198253.2	TET2 NM_001127208.2	TGFBR2 NM_003242.5	TNFAIP3 NM_006290.3	TNFRSF14 NM_003820.2	TP53* NM_000546.5	TRAF3 NM_145725.2	TSC1 NM_000368.4	TSC2 NM_000548.3
TSHR NM_000369.2	U2AF1 NM_006758.2	U2AF2 NM_007279.2	VHL NM_000551.3	WHSC1 NM_001042424.2	WT1 NM_024426.4	XPO1 NM_003400.3	XRCC2 NM_005431.1	XRCC3 NM_001100119.1	ZNF217 NM_006526.2	ZRSR2 NM_005089.3			

TEST METHODOLOGY

The ClariFind Comprehensive DNA Panel is performed on genomic DNA extracted from the patient's specimen. For formalin-fixed paraffin-embedded (FFPE) tissue samples, a histopathologic review is performed to determine tissue adequacy, identify the appropriate area with tumor for DNA extraction, and estimate the tumor cellularity in that area. Manual microdissection is then performed to isolate the designated area with tumor for DNA extraction. For all other sample types, tumor enrichment is not performed. Sequencing libraries are constructed incorporating unique molecular identifiers (UMIs) for each original DNA molecule. Target enrichment is performed using multiplex PCR with region-specific and universal primers. Next-generation sequencing is performed on the Illumina HiSeq platform. Base substitutions, insertions, deletions, and copy number alterations are identified using a Baylor Genetics proprietary pipeline that includes the QIAGEN Biomedical Genomics Workbench (API version 10.1.1), Pindel (0.2.5b8), and other custom tools, then annotated against the GRCh37 (hg19) reference human genome. Genomic alterations identified according to internal recommendations are curated and categorized by clinical significance according to the Standards and Guidelines for the Interpretation and Reporting of Sequence Variants in Cancer [PMID: 27993330], supported by the Association for Molecular Pathology (AMP). Benign or likely benign variants (AMP Tier IV) are not reported. Whenever pertinent, the absence of an alteration (i.e. wild type) may also be reported. Variant nomenclature is based on the convention recommended by the Human Genome Variation Society (http://varnomen.hgvs.org/). Confirmation of genomic alterations is

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Patient Name:	JOHN 12602	Test Code:	20010	Physician Name:	MGL Internal Provider
Date of Birth:		Date Collected:		Facility:	
Sex:	M	Date Received:	12/06/2017	Location:	Houston, TX, 77030
Medical Record #:		Date Ordered:	12/06/2017	Phone:	713-798-6075
Accession #:		Date Reported:	12/20/2017	Fax:	713-798-4187
Lab Number:	810326	Addt'l Report Date:			
Family Number:	682880	Sample Type:	BLOOD		
Zip Code:	74101	Collection Site:			
Indication:	Acute myeloid leukemia	Estimated Tumor Cellularity: N/A			

performed according to internal recommendations by Sanger sequencing, orthogonal next-generation sequencing, or other methods. The information provided in the report (including the interpretation, genomic alteration details, targeted therapies, therapies associated with decreased response or resistance, and potential clinical trials) is generated from proprietary tools and analyses of relevant peer-reviewed publications, public and proprietary databases, society guidelines, and other publicly available information identified by Baylor Genetics.

TECHNICAL PERFORMANCE

ACCURACY	**Tumor Cellularity**	**Variant Allele Fraction**	**Performance**
Sensitivity: Base Substitutions	>=20%	2%	97.4% (PPV = 94.6%)
	>=20%	>=5%	>99.9% (PPV = 97.5%)
Sensitivity: Insertions/Deletions (1-52 bp)	>=20%	5-15%	96%
	>=20%	>15%	>99%
Sensitivity: Copy Number Alterations (amplifications with copy number >=6 or homozygous deletions)	>=30%	-	>99%
Specificity: All Variant Types	-	-	>99%
Average Unique Molecular Identifier Coverage Across All Targets	>1500X		
REPRODUCIBILITY			
Intra-Batch Precision	100%		
Inter-Batch Precision	99.8%		

The following are regions in the panel with generally less than 100X median unique molecular identifier (UMI) coverage at 95% of base positions, which may result in decreased sensitivity:

AKT3 Exon 5, ARID1B Exon 14, ATR Exon 37, AURKB Exon 2, AURKC Exon 6, AXIN1 Exon 11, BCR Exon 18, BRCA2 Exon 18, CBL Exon 5, CD79A Exon 2, CSF3R Exon 12, EED Exon 6, EGFR Exon 6, EP300 Exon 13, EPAS1 Exon 16, FANCG Exon 1, FBXW7 Exon 1, FGFR1 Exon 16, IRF4 Exon 2, JAK1 Exon 9, JAK1 Exon 23, KMT2B Exon 1, KMT2C Exon 41, MCL1 Exon 3, MED12 Exon 42, MEN1 Exon 1, MSH2 Exon 14, NF2 Exon 4, NOTCH1 Exon 18, NOTCH2 Exon 33, NTRK1 Exon 3, PIK3CA Exon 14, PMS2 Exon 1, PMS2 Exon 2, PMS2 Exon 4, POLD1 Exon 17, PPP2R1A Exon 4, RAD50 Exon 16, SF3B1 Exon 21, TP53 Exon 10, U2AF2 Exon 8.

COVERAGE LIMITATIONS FOR THIS SAMPLE

The following are variants recorded in the COSMIC database (v81) which showed less than 100X unique molecular identifier (UMI) coverage in this patient's sample:

AKT3 c.928C>G (p.P310A), AKT3 c.929C>G (p.P310R), ASXL1 c.24G>A (p.K8K), AURKC c.630C>A (p.H210Q), BCR c.3075C>T (p.I1025I), BCR c.3106A>G (p.R1036G), CD79A c.190G>A (p.V64I), CD79A c.205G>A (p.V69I), EED c.587T>A (p.L196Q), EGFR c.630G>T (p.L210L), EPAS1 c.2565G>A (p.T855T), FANCG c.1766T>C (p.L589P), FGFR1 c.109C>T (p.P37S), NF2 c.364 (p.V122_K149del), NF2 c.424G>A (p.A142T), NF2 c.425C>T (p.A142V), NF2 c.430 (p.Y144fs*1), NF2 c.432C>A (p.Y144*), NF2 c.436G>A (p.V146I), NF2 c.447+1G>A (p.?), NF2 c.447+2T>C (p.?), NOTCH2 c.112G>A (p.E38K), NOTCH2 c.137A>G (p.N46S), NOTCH2 c.20A>G (p.N7S), NTRK1 c.221G>A (p.R74H), NTRK1 c.311G>A (p.R104H), NTRK1 c.320C>T (p.A107V), PMS2 c.2007-4G>A (p.?), PMS2 c.2013G>A (p.T671T), PMS2 c.2466T>C (p.L822L), PMS2 c.2570G>C (p.G857A), RAD50 c.2149C>T (p.Q717*), RAD50 c.2566C>T (p.Q856*), SF3B1 c.423A>G (p.K141K), SF3B1 c.494A>T (p.E165V), TP53 c.11C>T (p.P4L), TP53 c.13C>T (p.Q5*), TP53 c.28G>A (p.V10I), TP53 c.30C>T (p.V10V), TP53 c.31G>A (p.E11K), TP53 c.31G>C (p.E11Q), TP53 c.8A>G (p.E3G), U2AF2 c.757G>A (p.V253M), U2AF2 c.789C>T (p.I263I)

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Patient Name:	JOHN 12602	Test Code:	20010	Physician Name:	MGL Internal Provider
Date of Birth:		Date Collected:		Facility:	
Sex:	M	Date Received:	12/06/2017	Location:	Houston, TX, 77030
Medical Record #:		Date Ordered:	12/06/2017	Phone:	713-798-6075
Accession #:		Date Reported:	12/20/2017	Fax:	713-798-4187
Lab Number:	810326	Addt'l Report Date:			
Family Number:	682880	Sample Type:	BLOOD		
Zip Code:	74101	Collection Site:			
Indication:	Acute myeloid leukemia	Estimated Tumor Cellularity: N/A			

GLOSSARY

Amplification: Estimated copy number >=6 in diploid tumors or high-level copy number gain in aneuploid tumors (relative to the estimated tumor cellularity, if known, and quality of data), as determined by our algorithm.

AMP Tier: Genomic alterations are categorized by clinical significance according to the Standards and Guidelines for the Interpretation and Reporting of Sequence Variants in Cancer [PMID: **27993330**], supported by the Association for Molecular Pathology (AMP), as follows:

- **AMP Tier I:** Strong clinical significance
- **AMP Tier II:** Potential clinical significance
- **AMP Tier III:** Unknown clinical significance
- **AMP Tier IV:** Benign or likely benign variants (not reported)

Estimated Tumor Mutational Burden: Calculated as the total number of base substitutions, insertions, and deletions classified as AMP Tier I-III (excluding benign or likely benign variants), as listed in the Reported Alterations by Next-Generation Sequencing table, divided by the megabases of genome targeted in our panel (0.84). For further information, please see [PMID: **28420421**].

Equivocal Copy Gain: There is evidence, which may not be unambiguous, that the genomic alteration meets criteria for a copy number gain but does not meet the threshold for amplification (relative to the estimated tumor cellularity, if known, and quality of data), as determined by our algorithm.

Equivocal Copy Loss: There is evidence, which may not be unambiguous, that the genomic alteration meets criteria for a copy number loss but does not meet the threshold for a homozygous deletion (relative to the estimated tumor cellularity, if known, and quality of data), as determined by our algorithm.

Evidence-Based Variant Categorization: Genomic alterations are subcategorized by levels of evidence according to the Standards and Guidelines for the Interpretation and Reporting of Sequence Variants in Cancer [PMID: **27993330**], supported by the Association for Molecular Pathology (AMP), as follows:

- **Level A:** FDA-approved therapy; included in professional guidelines
- **Level B:** Well-powered studies with consensus from experts in the field
- **Level C:** FDA-approved therapies for different tumor types or investigational therapies; multiple small published studies with some consensus
- **Level D:** Preclinical trials or a few case reports without consensus

FDA Approved: Drug is approved by the United States Food and Drug Administration (FDA) for clinical use for the patient's cancer type.

Homozygous Deletion: Estimated copy number at or near 0 (relative to the estimated tumor cellularity, if known, and quality of data), as determined by our algorithm.

Investigational New Drug: Drug is not currently FDA approved for clinical use and is still under investigation.

NCCN Category: Drug is categorized by the National Comprehensive Cancer Network (NCCN) Categories of Evidence and Consensus [**https://www.nccn.org/professionals/physician_gls/categories_of_consensus.aspx**] for the patient's cancer type according to the following:

- **Level 1:** Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
- **Level 2A:** Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
- **Level 2B:** Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
- **Level 3:** Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

Off-Label Use: Drug is FDA approved for clinical use but not for the patient's cancer type.

PMID: PubMed identification number; unique identifier for an article in PubMed.

Trial Enrollment Available Nearby: Potential clinical trial may be available for patient enrollment within 100 miles of the provided zip code.

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DISCLAIMER

The Report: The ClariFind Comprehensive DNA Panel report incorporates analyses of relevant peer-reviewed publications, public and proprietary databases, society guidelines, and other publicly available information identified by Baylor Genetics. These may include associations between genomic alterations (or lack of genomic alterations), targeted therapies or therapies associated with decreased response or resistance, and potential clinical trials. Genomic alterations, targeted therapies or therapies associated with decreased response or resistance, and potential clinical trials are not ranked in order of potential or predicted efficacy for the patient. Baylor Genetics makes every effort to ensure that the information provided is up-to-date at the time the report is generated; however, information may be continuously updated in the public domain and should also be investigated by the physician and medical staff.

Incidental Findings: Unless otherwise specified, this test is performed on a patient's tumor sample without a paired germline sample. The ClariFind Comprehensive DNA Panel report may include genomic alterations which may be of germline origin, including those which may be clinical significant for the patient and/or the patient's family; however, this test is designed and validated for the detection and reporting of somatic genomic alterations and is not meant for the detection and reporting of germline genomic alterations or to diagnose any germline condition. When clinically warranted, genetic counseling and appropriate germline testing performed on a germline sample from the patient should be considered for further evaluation.

Variants with Low-Level Variant Allele Fractions: The ClariFind Comprehensive DNA Panel report may include variants of strong or potential clinical significance with low-level variant allele fractions between 2-5%. Certain COSMIC hotspot mutations, or variants previously identified in the same patient, may also be reported with variant allele fractions between 1-2%, at the discretion of the laboratory director. Variants with allele fractions less than 1% are not reported. The report may also include variants of unknown clinical significance when the detected variant allele fractions are >=5%. Variants of unknown clinical significance with variant allele fractions <5% will not be routinely reported.

Large Insertions or Deletions: The detection of large (>52 bp) insertions or deletions may be limited by this next-generation sequencing assay; however, if detected, clinically significant large insertions or deletions will still be reported. FLT3 internal tandem duplications will also be reported when detected. However, separate FLT3 mutation analysis (test code 9045) is recommended for all patients with newly diagnosed acute myeloid leukemia, especially for expedited consideration of FLT3-inhibitor therapy (see NCCN Guidelines for Acute Myeloid Leukemia at https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf).

Copy Number Alterations: The ClariFind Comprehensive DNA Panel report may include copy number alterations identified by next-generation sequencing. Variations in sample quality, sample input, and estimated tumor cellularity (if known), or the presence of pseudogenes or other homologous sequences may result in a signal-to-noise ratio that precludes analysis of some regions or the entire sample. In addition, copy number changes are reported at the gene level, unless otherwise specified. Thus, next-generation sequencing analysis may not detect all copy number changes. A normal next-generation sequencing copy number result does not exclude the possibility of copy number changes of a gene or a portion of a gene. For more detailed copy number evaluation, other testing may be considered such as chromosomal microarray studies (test codes 9505 or 9515) or FISH analysis.

Laboratory Errors: The chance that rare laboratory errors may occur cannot be completely excluded. Possible sources of laboratory errors include, but are not limited to, sample mix-ups, cross-contamination, and sequencing errors. Sequencing errors can result from poor quality and/or low-input samples, from contamination issues, from genetic variants or difficult sequences (such as repetitive or homologous regions) which interfere with assay performance and/or analysis, from subclonal alterations at levels below standard detection, and from other sources.

No Guarantee of Clinical Benefit: The ClariFind Comprehensive DNA Panel report makes no promises or guarantees that any targeted therapies will provide clinical benefit for the patient and that any therapies associated with decreased response or resistance will result in decreased or lack of clinical benefit for the patient. The therapies listed in the report may include FDA-approved drugs (for the patient's cancer type or for off-label use) or investigational new drugs.

No Guarantee of Clinical Trial Enrollment: The ClariFind Comprehensive DNA Panel report makes no promises or guarantees that any potential clinical trials listed will be open and available for enrollment or that the patient will qualify for enrollment in any clinical trials. The potential clinical trials listed in the report are not meant to be a complete list of all available trials, and Baylor Genetics does not promise or guarantee that other clinical trials are not also available for the patient. Not all locations for the clinical trials are listed; when a United States ZIP code is provided, Baylor Genetics will attempt to provide the nearest location for the clinical trial, if this information is available. For additional information regarding a specific clinical trial, please go to clinicaltrials.gov and type in the NCT ID into the search field.

No Guarantee of Reimbursement: Baylor Genetics makes no promises or guarantees of reimbursement for the cost of testing from any healthcare provider, insurer, or other third-party payor, whether private or governmental.

Treatment Decisions are the Responsibility of the Patient's Physician: The ClariFind Comprehensive DNA Panel report must be interpreted by the patient's physician within the appropriate clinical context and in conjunction with all other relevant information. Treatment decisions should not be solely

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Indication:	Acute myeloid leukemia	Estimated Tumor Cellularity:	N/A		

based on the results of this test or the information provided in this report. All responsibility and liability regarding treatment decisions arising from this test and report reside with the patient's physician and not Baylor Genetics.

Christine M. Eng, M.D.
Medical Director

Brian Y. Merritt, M.D.
Medical Director, Cancer Genetics Section

This test was developed and its performance characteristics determined by Baylor Genetics. It has not been cleared or approved by the United States Food and Drug Administration (FDA). The FDA does not require this test to go through premarket FDA review. This test is used for clinical purposes. It should not be regarded as purely investigational or for research only. This laboratory is certified under the Clinical Laboratory Improvement Amendments (CLIA) as qualified to perform high-complexity clinical laboratory testing (CAP# 2109314 / CLIA# 45D0660090; Lab Director: Christine M. Eng, MD).