KIT 36673524 3 01 52

Results are due no later than midnight, Central Time:

July 05, 2023

CAP # 1952901 - 22 SEQ # 01

Products:NGSHM
University of Kansas Health System
Sarah Dillon
TEL# 1-913-588-1710 FAX#

Next-Generation Sequencing (NGS) - Hematologic Malignancies Survey Result Form

Important

You must submit results online. Emailed, faxed, or mailed results are no longer accepted.

Variant Master List

â¢ The codes listed in the Variant Code column are to be used in the Results section to indicate the variants that your laboratory detects.
â¢ Select the "(Gene) not tested" bubble if your laboratory does not test for ANY variants in a given gene. **Laboratories selecting this response should not select the individual "Variants Not Tested" result option for that gene.**
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Gene	Variant	Genomic Description (hg19)	Variant Code	Variants Not Tested
ASXL1 (NM_015338.5)	ASXL1 c.1773C>A p.Y591*	chr20:31022288C>A	3893	010 ☐ (3894)
	ASXL1 c.1954G>A p.G652S	chr20:31022469G>A	1601	☐ (1703)
	ASXL1 c.2035G>T p.G679*	chr20:31022550G>T	1602	☐ (1704)
005 ☐ (2139) ASXL1 not tested	ASXL1 c.2077C>T p.R693*	chr20:31022592C>T	1603	☐ (1705)
	ASXL1 c.2324delT p.L775*	chr20:31022839delT	1604	☐ (1706)
	ASXL1 c.2893C>T p.R965*	chr20:31023408C>T	1605	☐ (1707)
ABL1 (NM_005157.6)	ABL1 c.763G>A p.E255K	chr9:133738363G>A	5734	☐ (5735)
	ABL1 c.944C>T p.T315I	chr9:133748283C>T	5736	☐ (5737)
	ABL1 c.943A>G p.T315A	chr9:133748282A>G	5738	☐ (5739)
065 ☐ (5546) ABL1 not tested	ABL1 c.951C>G p.F317L	chr9:133748290C>G	5740	☐ (5741)
	ABL1 c.949T>G p.F317V	chr9:133748288T>G	5742	☐ (5743)
	ABL1 c.1075T>A p.F359I	chr9:133748414T>A	5744	☐ (5745)
BRAF (NM_004333.5)	BRAF c.1781A>G p.D594G	chr7:140453154T>C	1817	☐ (1905)
	BRAF c.1798G>A p.V600M	chr7:140453137C>T	1820	☐ (1908)
	BRAF c.1798_1799delGTinsAA p.V600K	chr7:140453136_140453137delACinsTT	3381	☐ (3409)
125 ☐ (2140) BRAF not tested	BRAF c.1798_1799delGTinsAG p.V600R	chr7:140453136_140453137delACinsCT	2915	☐ (3018)
	BRAF c.1799T>A p.V600E	chr7:140453136A>T	1611	☐ (1713)
	BRAF c.1803A>T p.K601N	chr7:140453132T>A	2916	☐ (3019)

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Variant Master List, cont'd

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Gene	Variant	Genomic Description (hg19)	Variant Code	Variants Not Tested
BTK (NM_000061.3)	BTK c.946A>G p.T316A	chrX:100613633T>C	5746	010 (5747)
	BTK c.1421C>T p.T474I	chrX:100611185G>A	5748	(5749)
	BTK c.1421C>G p.T474S	chrX:100611185G>C	5750	(5751)
005 (5547) BTK not tested	BTK c.1441T>C p.C481R	chrX:100611165A>G	5752	(5753)
	BTK c.1442G>C p.C481S	chrX:100611164C>G	5754	(5755)
	BTK c.1442G>A p.C481Y	chrX:100611164C>T	5756	(5757)
CDKN2A (NM_000077.4)	CDKN2A c.9_32del p.A4_P11del	chr9:21974795_21974818del	5758	(5759)
	CDKN2A c.128G>T p.S43I	chr9:21974699C>A	5760	(5761)
	CDKN2A c.172C>T p.R58*	chr9:21971186G>A	2919	(3022)
065 (2901) CDKN2A not tested	CDKN2A c.213delinsGGTCG p.N71fs	chr9:21971145delinsCGACC	5762	(5763)
	CDKN2A c.238C>T p.R80*	chr9:21971120G>A	4482	(4483)
	CDKN2A c.330G>A p.W110*	chr9:21971028C>T	5764	(5765)
CEBPA (NM_004364.4)	CEBPA c.68delC p.P23fs	chr19:33793258delG	1618	(1720)
	CEBPA c.68dupC p.H24fs	chr19:33793258dupG	1619	(1721)
	CEBPA c.247delC p.Q83fs	chr19:33793075delG	1620	(1722)
125 (2142) CEBPA not tested	CEBPA c.917_934delGCAACGTGGAGACGCAGC p.R306_Q311del	chr19:33792392_33792409delGCTGCGTCTCCACGTTGC	5034	(5035)
	CEBPA c.937_939dupAAG p.K313dup	chr19:33792384_33792386dupCTT	1622	(1724)
	CEBPA c.949_950insGTC p.E316_L317insR	chr19:33792372_33792373insACG	1623	(1725)
CXCR4 (NM_001008540.2)	CXCR4 c.1012C>T p.R338*	chr2:136872498G>A	5048	(5049)
	CXCR4 c.1012C>G p.R338G	chr2:136872498G>C	5050	(5051)
	CXCR4 c.1024dupT p.S342fs	chr2:136872487dupA	5052	(5053)
185 (5033) CXCR4 not tested	CXCR4 c.1025C>A p.S342*	chr2:136872485G>T	5054	(5055)
	CXCR4 c.1026_1029delATCT p.S343fs	chr2:136872481_136872484delAGAT	5056	(5057)
	CXCR4 c.1043_1052delCTGAGTCTTCinsGT p.S348fs	chr2:136872458_136872467delGAAGACTCAGinsAC	5058	(5059)

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Variant Master List, cont'd

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Gene	Variant	Genomic Description (hg19)	Variant Code	Variants Not Tested
DNMT3A (NM_022552.4)	DNMT3A c.2141C>G p.S714C	chr2:25463541G>C	1625	010 (1727)
	DNMT3A c.2207G>A p.R736H	chr2:25463286C>T	1624	(1726)
	DNMT3A c.2644C>A p.R882S	chr2:25457243G>T	1626	(1728)
005 (2143) DNMT3A not tested	DNMT3A c.2644C>T p.R882C	chr2:25457243G>A	1627	(1729)
	DNMT3A c.2645G>A p.R882H	chr2:25457242C>T	1628	(1730)
	DNMT3A c.2645G>C p.R882P	chr2:25457242C>G	1629	(1731)
IDH1 (NM_005896.3)	IDH1 c.392_396delGTCGinsTCCTG p.G131_R132delinsVL	chr2:209113111_209113115delACGACinsCAGGA	4584	(4585)
	IDH1 c.394C>A p.R132S	chr2:209113113G>T	1637	(1739)
	IDH1 c.394C>G p.R132G	chr2:209113113G>C	1638	(1740)
065 (2145) IDH1 not tested	IDH1 c.394C>T p.R132C	chr2:209113113G>A	1639	(1741)
	IDH1 c.395G>A p.R132H	chr2:209113112C>T	1853	(1941)
	IDH1 c.395G>T p.R132L	chr2:209113112C>A	1641	(1743)
IDH2 (NM_002168.2)	IDH2 c.418C>G p.R140G	chr15:90631935G>C	5766	(5767)
	IDH2 c.419G>A p.R140Q	chr15:90631934C>T	1643	(1745)
	IDH2 c.419G>T p.R140L	chr15:90631934C>A	3437	(3438)
125 (2146) IDH2 not tested	IDH2 c.514A>G p.R172G	chr15:90631839T>C	1644	(1746)
	IDH2 c.514A>T p.R172W	chr15:90631839T>A	3390	(3418)
	IDH2 c.515G>T p.R172M	chr15:90631838C>A	3392	(3420)
JAK2 (NM_004972.3)	JAK2 c.1611_1616delTCACAA p.F537_K539delinsL	chr9:5070022_5070027delTCACAA	1648	(1750)
	JAK2 c.1622_1627delGAAATG p.R541_E543delinsK	chr9:5070033_5070038delGAAATG	1649	(1751)
	JAK2 c.1624_1629delAATGAA p.N542_E543del	chr9:5070035_5070040delAATGAA	1650	(1752)
185 (2147) JAK2 not tested	JAK2 c.1627_1632delGAAGAT p.E543_D544del	chr9:5070038_5070043delGAAGAT	1651	(1753)
	JAK2 c.1849G>T p.V617F	chr9:5073770G>T	1652	(1754)
	JAK2 c.1852T>C p.C618R	chr9:5073773T>C	1653	(1755)

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Variant Master List, cont'd

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Gene	Variant	Genomic Description (hg19)	Variant Code	Variants Not Tested
KIT (NM_000222.2)	KIT c.251C>T p.T84M	chr4:55561861C>T	1654	010 (1756)
	KIT c.1669T>C p.W557R	chr4:55593603T>C	1655	(1757)
	KIT c.1961T>C p.V654A	chr4:55594258T>C	1858	(1946)
005 (2148) KIT not tested	KIT c.2447A>T p.D816V	chr4:55599321A>T	1656	(1758)
	KIT c.2466T>A p.N822K	chr4:55599340T>A	1657	(1759)
	KIT c.2663G>A p.R888Q	chr4:55602953G>A	1659	(1761)
KRAS (NM_004985.3)	KRAS c.34G>A p.G12S	chr12:25398285C>T	2962	(1950)
	KRAS c.35G>A p.G12D	chr12:25398284C>T	1864	(1952)
	KRAS c.34_36delinsTGG p.G12W	chr12:25398283_25398285delinsCCA	5768	(5769)
065 (2163) KRAS not tested	KRAS c.183A>C p.Q61H	chr12:25380275T>G	2965	(3065)
	KRAS c.351A>T p.K117N	chr12:25378647T>A	5770	(5771)
	KRAS c.38_39delGCinsAA p.G13E	chr12:25398280_25398281delGCinsTT	3442	(3446)
MYD88 (NM_002468.4)	MYD88 c.436G>A p.A146T	chr3:38181423G>A	1666	(1768)
	MYD88 c.517C>T p.R173C	chr3:38181893C>T	1667	(1769)
	MYD88 c.656C>G p.S219C	chr3:38182032C>G	1668	(1770)
125 (2150) MYD88 not tested	MYD88 c.695T>C p.M232T	chr3:38182259T>C	1669	(1771)
	MYD88 c.728G>A p.S243N	chr3:38182292G>A	1670	(1772)
	MYD88 c.794T>C p.L265P	chr3:38182641T>C	1671	(1773)
NRAS (NM_002524.4)	NRAS c.34_36delGGTinsTGG p.G12W	chr1:115258746_115258748delACCinsCCA	4241	(4242)
	NRAS c.35G>A p.G12D	chr1:115258747C>T	2969	(3066)
	NRAS c.38_39delGTinsAA p.G13E	chr1:115258743_115258744delACinsTT	5060	(5061)
185 (2165) NRAS not tested	NRAS c.182A>T p.Q61L	chr1:115256529T>A	3399	(4260)
	NRAS c.351G>T p.K117N	chr1:115252289C>A	5772	(5773)
	NRAS c.436G>A p.A146T	chr1:115252204C>T	3896	(3897)

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Gene	Variant	Genomic Description (hg19)	Variant Code	Variants Not Tested
NOTCH1 (NM_017617.3)	NOTCH1 c.4793G>C p.R1598P	chr9:139399350C>G	1672	010 (1774)
	NOTCH1 c.4799T>C p.L1600P	chr9:139399344A>G	1673	(1775)
	NOTCH1 c.5015G>A p.R1672H	chr9:139399128C>T	1674	(1776)
005 (2151) NOTCH1 not tested	NOTCH1 c.5033T>C p.L1678P	chr9:139397768A>G	1675	(1777)
	NOTCH1 c.7375C>T p.Q2459*	chr9:139390816G>A	1676	(1778)
	NOTCH1 c.7401delinsTTCACA p.L2468fs	chr9:139390790delinsTGTGAA	5774	(5775)
RUNX1 (NM_001754.4)	RUNX1 c.319C>T p.R107C	chr21:36259172G>A	4262	(4263)
	RUNX1 c.422C>T p.S141L	chr21:36252940G>A	4264	(4265)
	RUNX1 c.485G>A p.R162K	chr21:36252877C>T	4266	(4267)
065 (4261) RUNX1 not tested	RUNX1 c.497G>A p.R166Q	chr21:36252865C>T	4268	(4269)
	RUNX1 c.593A>G p.D198G	chr21:36231791T>C	4270	(4271)
	RUNX1 c.597dupG p.P200fs	chr21:36231789dupC	5198	(5199)
SF3B1 (NM_012433.2)	SF3B1 c.1866G>T p.E622D	chr2:198267491C>A	1684	(1786)
	SF3B1 c.1874G>A p.R625H	chr2:198267483C>T	1685	(1787)
	SF3B1 c.1986C>G p.H662Q	chr2:198267371G>C	1686	(1788)
125 (2153) SF3B1 not tested	SF3B1 c.1997A>G p.K666R	chr2:198267360T>C	1687	(1789)
	SF3B1 c.2098A>G p.K700E	chr2:198266834T>C	1688	(1790)
	SF3B1 c.2225G>A p.G742D	chr2:198266611C>T	1689	(1791)
STAG2 (NM_001042751.1)	STAG2 c.577G>A p.D193N	chrX:123179128G>A	4755	(4756)
	STAG2 c.646C>T p.R216*	chrX:123179197C>T	4757	(4758)
	STAG2 c.775C>T p.R259*	chrX:123181311C>T	4759	(4760)
185 (4729) STAG2 not tested	STAG2 c.1544_1547delATAG p.D515fs	chrX:123195630_123195633delATAG	4761	(4762)
	STAG2 c.1545_1546delTA p.D515fs	chrX:123195631_123195632delTA	4763	(4764)
	STAG2 c.1919_1920delGT p.C640*	chrX:123197795_123197796delGT	5064	(5065)

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TET2 (NM_001127208.2)	TET2 c.679delG p.E227fs	chr4:106155778delG	3898	010 (3899)
	TET2 c.1648C>T p.R550*	chr4:106156747C>T	1691	(1793)
	TET2 c.2746C>T p.Q916*	chr4:106157845C>T	1692	(1794)
005 (2154) TET2 not tested	TET2 c.4138C>T p.H1380Y	chr4:106190860C>T	1693	(1795)
	TET2 c.5219T>A p.L1740*	chr4:106196886T>A	1694	(1796)
	TET2 c.5618T>C p.I1873T	chr4:106197285T>C	1695	(1797)
TNFRSF14 (NM_003820.2)	TNFRSF14 c.35G>A p.W12*	chr1:2488138G>A	5776	(5777)
	TNFRSF14 c.76T>G p.Y26D	chr1:2489171T>G	5778	(5779)
	TNFRSF14 c.125G>A p.C42Y	chr1:2489220G>A	5780	(5781)
065 (5548) TNFRSF14 not tested	TNFRSF14 c.136G>A p.E46K	chr1:2489231G>A	5782	(5783)
	TNFRSF14 c.335C>T p.S112F	chr1:2491292C>T	5784	(5785)
	TNFRSF14 c.345_346delGA p.N116fs	chr1:2491302_2491303delGA	5786	(5787)
U2AF1 (NM_006758.2)	U2AF1 c.101C>T p.S34F	chr21:44524456G>A	4288	(4289)
	U2AF1 c.101C>A p.S34Y	chr21:44524456G>T	4290	(4291)
	U2AF1 c.104G>T p.R35L	chr21:44524453C>A	4292	(4293)
125 (4730) U2AF1 not tested	U2AF1 c.467G>A p.R156H	chr21:44514780C>T	4294	(4295)
	U2AF1 c.470A>C p.Q157P	chr21:44514777T>G	4296	(4297)
	U2AF1 c.470A>G p.Q157R	chr21:44514777T>C	4298	(4299)

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Results

NGSHM-01

010 ☐ 103 None of the listed variants in the Variant Master List are detected

020 ○ 11
Exception Code ○ 33

If variants are detected, enter the variant code from the Variant Master List, found on the result form, for each variant.

Variant Code 1:	030 3893	Total coverage depth at Variant 1 position:	040 503	Variant 1 allele fraction:	050 13.3	%
Variant Code 2: (if applicable)	060 1628	Total coverage depth at Variant 2 position:	070 1421	Variant 2 allele fraction:	080 9.4	%
Variant Code 3: (if applicable)	090 1652	Total coverage depth at Variant 3 position:	100 438	Variant 3 allele fraction:	110 10.3	%
Variant Code 4: (if applicable)	120 4288	Total coverage depth at Variant 4 position:	130 535	Variant 4 allele fraction:	140 25.6	%
Variant Code 5: (if applicable)	150	Total coverage depth at Variant 5 position:	160 ___ ___ ___ ___ ___	Variant 5 allele fraction:	170 ___ ___ ___ . ___	%
Variant Code 6: (if applicable)	180	Total coverage depth at Variant 6 position:	190 ___ ___ ___ ___ ___	Variant 6 allele fraction:	200 ___ ___ ___ . ___	%

NGSHM-02

210 ☐ 103 None of the listed variants in the Variant Master List are detected

220 ○ 11
Exception Code ○ 33

If variants are detected, enter the code from the Variant Master List, found on the result form, for each variant.

Variant Code 1:	230 2916	Total coverage depth at Variant 1 position:	240 1313	Variant 1 allele fraction:	250 13.4	%
Variant Code 2: (if applicable)	260 1858	Total coverage depth at Variant 2 position:	270 1472	Variant 2 allele fraction:	280 10.7	%
Variant Code 3: (if applicable)	290 2965	Total coverage depth at Variant 3 position:	300 955	Variant 3 allele fraction:	310 13.6	%
Variant Code 4: (if applicable)	320 5772	Total coverage depth at Variant 4 position:	330 1358	Variant 4 allele fraction:	340 10.5	%
Variant Code 5: (if applicable)	350	Total coverage depth at Variant 5 position:	360 ___ ___ ___ ___ ___	Variant 5 allele fraction:	370 ___ ___ ___ . ___	%
Variant Code 6: (if applicable)	380	Total coverage depth at Variant 6 position:	390 ___ ___ ___ ___ ___	Variant 6 allele fraction:	400 ___ ___ ___ . ___	%

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Results, cont'd

NGSHM-03

010 ☐ 103 None of the listed variants in the Variant Master List are detected

020 ○ 11
Exception Code ○ 33

If variants are detected, enter the variant code from the Variant Master List, found on the result form, for each variant.

Variant Code 1:	030 1637	Total coverage depth at Variant 1 position:	040 440	Variant 1 allele fraction:	050 10.9	%
Variant Code 2: (if applicable)	060 5198	Total coverage depth at Variant 2 position:	070 683	Variant 2 allele fraction:	080 16.0	%
Variant Code 3: (if applicable)	090 5768	Total coverage depth at Variant 3 position:	100 590	Variant 3 allele fraction:	110 18.1	%
Variant Code 4: (if applicable)	120	Total coverage depth at Variant 4 position:	130 ___ ___ ___ ___ ___	Variant 4 allele fraction:	140 ___ ___ ___ . ___	%
Variant Code 5: (if applicable)	150	Total coverage depth at Variant 5 position:	160 ___ ___ ___ ___ ___	Variant 5 allele fraction:	170 ___ ___ ___ . ___	%
Variant Code 6: (if applicable)	180	Total coverage depth at Variant 6 position:	190 ___ ___ ___ ___ ___	Variant 6 allele fraction:	200 ___ ___ ___ . ___	%

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TEL# 1-913-588-1710 FAX#

Assay Characteristics

1. Using the NGS Platform Master List on the kit instructions, indicate which platform is used in your laboratory for somatic variant detection for this assay: 010 [2923]

2. Which categories of somatic variants are detected by the assay described in Question #1? (Select all that apply.)

020
- [x] 274 Single nucleotide variants
- [x] 275 Small insertions and deletions (eg, < 50 bp)
- [ ] 557 Copy number variations (CNVs)

3. What is the lower limit of detection for your assay in terms of somatic allele percentage? If the limit of detection varies depending on the gene and region, please indicate the highest allele percentage.

Variant Type	Single nucleotide variants	Small insertions and deletions
Lower limit of detection	050 5.0 %	060 5.0 %

4. Is a sensitivity control at or near the lower limit of detection of the assay included in each run?

070
- (●) 179 Yes
- ( ) 180 No

5. Which sequencing strategies are used by your laboratory for somatic variant detection in hematologic malignancies for the single assay being described in this program? (Select all that apply.)

080
- [ ] 223 Exome sequencing
- [ ] 224 Genome sequencing
- [ ] 225 RNA sequencing
- [x] 367 Targeted sequencing of cancer genes or mutation hotspots, such as custom or commercial targeted amplicon or hybrid capture panels
- [ ] 010 Other(s), specify: 130 _____

6. How would you characterize the selection method used by your laboratory's library preparation?

140
- ( ) 559 Hybrid capture
- (●) 560 Amplicon-based
- ( ) 010 Other, specify: 150 _____

7. Which of the following best describes the source of the content of your laboratory's NGS panel?

160
- (●) 558 Our laboratory uses a commercial kit covering content predesignated by the vendor (Answer Question #8, skip Question #9.)
- ( ) 118 Our laboratory designed its own library content (Skip to Question #9.)

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Assay Characteristics, cont'd

8. If your laboratory uses a commercial kit with predesignated content, which method does your laboratory use?

010
- ○ 325 Agilent ClearSeq AML
- ○ 640 Archer FusionPlex Heme v2 for Illumina (RNA Input)
- ○ 641 Archer FusionPlex Heme v2 for Ion Torrent (RNA Input)
- ○ 642 Archer FusionPlex Myeloid for Illumina (RNA Input)
- ○ 643 Archer FusionPlex Myeloid for Ion Torrent (RNA Input)
- ○ 645 Archer VariantPlex Core Myeloid (DNA Input)
- ○ 646 Archer VariantPlex Myeloid (DNA Input)
- ○ 392 Fluidigm Access Array
- ○ 252 Illumina TruSight Myeloid Sequencing Panel
- ○ 330 RainDance ThunderBolts Myeloid Panel
- ○ 393 Roche NimbleGen Comprehensive Cancer Design
- ○ 651 Thermo Fisher AmpliSeq Myeloid
- ○ 394 Thermo Fisher Ion AmpliSeq Cancer Hotspot Panel
- ○ 254 Thermo Fisher Ion AmpliSeq Comprehensive Cancer Panel
- ○ 532 Thermo Fisher Oncomine Myeloid Assay
- ○ 249 Not applicable; our laboratory performs exome or genome sequencing for somatic variant detection
- ● 010 Other, specify:

020 Qiagen QIAseq Human Myeloid Panel

9. If your laboratory designed its own library content, what library preparation method does your laboratory use?

030
- ○ 255 Agilent Custom SureSelect
- ○ 256 Agilent HaloPlex Custom Kit
- ○ 257 Illumina TruSeq Custom Amplicon
- ○ 258 Ion AmpliSeq Custom DNA Panel
- ○ 259 Nextera Rapid Capture Custom Enrichment Kit
- ○ 260 RainDance Custom Gene Panel
- ○ 395 Roche NimbleGen SeqCap EZ Designs
- ○ 010 Other, specify:

040 _____

10. What is the read configuration used by your laboratory for the assay used for somatic variant detection in hematologic malignancies?

050
- ● 262 Paired-end reads
- ○ 261 Single-end reads
- ○ 010 Other, specify: 060 _____

11. What is the read length in base pairs for the assay used for somatic variant detection in hematologic malignancies?

070
- ○ 263 25 bp
- ○ 264 36 bp
- ○ 265 50 bp
- ○ 266 75 bp
- ○ 267 100 bp
- ○ 268 125 bp
- ● 269 150 bp
- ○ 270 200 bp
- ○ 271 250 bp
- ○ 272 300 bp
- ○ 273 400 bp
- ○ 010 Other, specify:

080 ____ bp

12. What is the average number of reads that covers the targeted bases in your laboratory's assay?

090
- ○ 279 0 - 50X
- ○ 280 51 - 150X
- ○ 281 151 - 250X
- ○ 282 251 - 350X
- ○ 283 351 - 500X
- ○ 284 501 - 750X
- ● 285 751 - 1,000X
- ○ 286 1,001 - 1,500X
- ○ 287 1,501 - 2,500X
- ○ 288 > 2,500X
- ○ 289 We have not established this metric

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Assay Characteristics, cont'd

13. What is the minimum number of reads that your laboratory requires for each targeted base in the assay?

010
- ○ 290 0 - 25 reads
- ○ 291 26 - 50 reads
- ○ 292 51 - 150 reads
- ● 293 151 - 250 reads
- ○ 294 251 - 350 reads
- ○ 295 351 - 500 reads
- ○ 296 501 - 750 reads
- ○ 297 751 - 1,000 reads
- ○ 298 1,001 - 1,500 reads
- ○ 299 1,501 - 2,500 reads
- ○ 300 > 2,500 reads
- ○ 301 We do not have a minimum read requirement

14. Which analysis software is used for alignment, data pre-processing, and somatic variant calling for this assay?

020
- ○ 302 Agilent SureCall
- ● 303 CLC Genomics Workbench
- ○ 304 DNASTAR Lasergene Genomics Suite
- ○ 305 Illumina MiSeq Reporter
- ○ 307 NextGENe
- ○ 308 Strand Avadis NGS
- ○ 306 Thermo Fisher Ion Reporter Software

Other, specify software used for:

a. Alignment: (Select all that apply.)

030
- ☐ 397 BWA-MEM
- ☐ 398 BWA, other
- ☐ 399 Illumina BaseSpace
- ☐ 400 Novocraft NovoAlign
- ☐ 401 Torrent Suite
- ☐ 010 Other, specify:

090 _____

b. Data pre-processing (if applicable): (Select all that apply.)

100
- ☐ 533 PICARD
- ☐ 534 SAMtools
- ☐ 010 Other, specify:

130 _____

c. Somatic variant calling: (Select all that apply.)

140
- ☐ 402 Agilent Cartagenia
- ☐ 403 Alamut Visual
- ☐ 528 Ensembl Variant Effect Predictor
- ☐ 405 GATK
- ☐ 406 Internally developed pipeline
- ☐ 525 Mutect
- ☐ 407 Pierian
- ☐ 526 Pindel
- ☐ 408 Qiagen ANNOVAR
- ☐ 409 SnpSift
- ☐ 523 Varscan
- ☐ 010 Other, specify:

260 _____

15. Which software is used for annotation, filtering, and/or prioritization for this assay? (Select all that apply.)

270
- ☐ 302 Agilent SureCall
- ☐ 331 Agilent GeneSpring NGS
- ☐ 527 Annovar
- ☐ 304 DNASTAR Lasergene Genomics Suite
- ☐ 332 Illumina VariantStudio
- ☐ 333 Ingenuity Variant Analysis
- ☐ 531 Internally developed
- ☐ 307 NextGENe
- ☐ 407 Pierian
- ☐ 308 Strand Avadis NGS
- ☐ 306 Thermo Fisher Ion Reporter Software
- ☑ 010 Other, specify:

390 Qiagen QCI-I

16. Regarding manual variant review, or visual inspection of variants, which of the following best fits your laboratory practice?

400
- ● 633 Every variant is manually reviewed before report generation/sign-out
- ○ 634 Select variants are manually reviewed before report generation/sign-out
- ○ 635 Our laboratory does not perform manual review of variants before report generation/sign-out

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Specimen Requirements

17. Does your laboratory perform tumor-normal paired testing?

010
- ○ 179 Yes
- ● 180 No

18. If you answered yes to Question #17, does your bioinformatics pipeline **require** a paired normal specimen to analyze tumor variant calls?

020
- ○ 652 Yes, always
- ○ 653 Sometimes (eg, when a paired normal specimen is available)
- ○ 180 No

19. If you answered Yes to Question #17, what control tissue(s) does your laboratory use? (Select all that apply.)

030
- ☐ 319 Buccal swabs
- ☐ 151 Fixed "normal" tissue
- ☐ 150 Fresh "normal" tissue (eg, skin biopsy)
- ☐ 320 Peripheral blood
- ☐ 010 Other, specify: 080 _____

20. If you answered Yes to Question #17, does your laboratory report constitutional variants?

090
- ○ 179 Yes
- ○ 180 No

21. Which specimen types does your laboratory test for somatic variant detection for the single assay being described? (Select all that apply.)

100
- ☐ 232 FFPE cell blocks
- ☐ 231 FFPE tissues
- ☐ 234 Fine-needle aspirates
- ☑ 322 Fresh bone marrow
- ☑ 323 Fresh peripheral blood
- ☐ 233 Fresh tissue
- ☐ 235 Frozen tissues
- ☐ 010 Other, specify: 180 _____

22. Which quantity of purified genomic DNA does your laboratory require to perform this assay?

190
- ● 236 0 - 100 ng
- ○ 237 101 - 200 ng
- ○ 238 201 - 500 ng
- ○ 239 501 - 1,000 ng
- ○ 240 1,001 - 2,000 ng
- ○ 241 > 2,000 ng

Reporting

23. If your laboratory performs confirmatory testing on any somatic variants for this assay, what methods are used? (Select all that apply.)

200
- ☐ 200 Droplet digital PCR (ddPCR)
- ☐ 396 Fragment analysis
- ☐ 636 Multiplex ligation-dependent probe amplification (MLPA)
- ☐ 312 Pyrosequencing
- ☐ 311 Sanger sequencing
- ☐ 313 Sequenom
- ☐ 637 Single Nucleotide Polymorphism Array (SNPArray)
- ☑ 310 Not applicable; somatic variants are reported without confirmation
- ☐ 314 Other targeted mutation testing (eg, allele-specific PCR or real-time PCR)
- ☐ 315 Other NGS-based platform, specify: 300 _____
- ☐ 010 Other, specify: 320 _____

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Reporting, cont'd

24. In your laboratory's clinical reports, does your laboratory list the variant allele fraction?

010
- (●) 368 Yes, for all reported variants
- ( ) 369 Yes, when allele fraction and tumor content suggest subclonality
- ( ) 180 No

25. In your laboratory's clinical reports, does your laboratory report total coverage depth (variant and reference reads) at the variant position?

020
- (●) 179 Yes
- ( ) 180 No

26. What types of interpretation does your laboratory **routinely** provide? (Select all that apply.)

030
- [x] 372 Biological function, known
- [x] 373 Biological function, speculative
- [x] 371 Categorization of variants into classes of medical significance
- [ ] 374 Clinical implications, known
- [ ] 375 Clinical implications, speculative
- [ ] 379 Listing of clinically significant mutations that were not detected, disease-specific
- [ ] 378 Listing of clinically significant mutations that were not detected, general
- [ ] 381 Listing of undercovered/underperforming regions that were not detected, disease-specific
- [ ] 380 Listing of undercovered/underperforming regions that were not detected, general
- [ ] 377 Specific treatment recommendations, investigational therapies
- [x] 376 Specific treatment recommendations, standard of care
- [ ] 370 No interpretation provided beyond listing the mutations detected

27. Does your laboratory report variants using a tiered approach (ie, tier 1: variants known to be associated with the disease in question; tier 2: variants known to be associated disease, but in a different disease type, tier x: variant with unknown disease association)?

150
- (●) 179 Yes
- ( ) 180 No

28. Who generates the final interpretive report?

160
- ( ) 382 Bioinformatics program
- ( ) 383 Bioinformatician(s)
- ( ) 638 Certified technologist
- ( ) 133 Clinician
- ( ) 136 Laboratory geneticist
- ( ) 385 Hematopathologist(s)
- ( ) 139 Medical scientist
- ( ) 384 Molecular pathologist(s)
- ( ) 144 Other pathologist(s)
- (●) 386 Team with members from various disciplines
- ( ) 010 Other, specify: 170 _____

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Reporting, cont'd

29. Which reference genome(s) are being used currently in your laboratory? (Select all that apply.)

010
- [x] 1255 hg19 (GRCh37)
- [ ] 1256 hg38 (GRCh38)
- [ ] 3967 Telomere-to-telomere (T2T)
- [ ] 0010 Other, specify: 050 _____

30. If your laboratory is still using hg19 (GRCh37), what is your timeline to convert to hg38 (GRCh38)?

060
- ○ 3396 In the next 6 months or less
- ○ 3397 In the next 7 - 12 months
- ○ 3398 In the next 13 - 18 months
- ○ 3399 In the next 19 - 24 months
- ○ 3400 Beyond the next 25 months
- ● 3401 We do not have plans to convert to hg38

Additional NGS Testing Questions

31. How many NGS-based assays for the detection of somatic variants in hematologic malignancies does your laboratory currently perform?

070
- ○ 334 1
- ● 335 2
- ○ 336 3
- ○ 337 4
- ○ 338 5
- ○ 339 > 5, specify number: 080 [ ]

32. Which categories of somatic variants are detected by any of your laboratory's assays for hematologic malignancies? (Select all that apply.)

090
- [ ] 277 Copy number variants (> 1 kb)
- [ ] 316 Gene rearrangements for B cell receptors
- [ ] 317 Gene rearrangements for T cell receptors
- [ ] 276 Intermediate sized insertions and deletions (eg, 50 bp - 1 kb)
- [x] 274 Single nucleotide variants
- [x] 275 Small insertions and deletions (eg, < 50 bp)
- [ ] 278 Other structural variants (eg, translocations)
- [ ] 010 Other, specify: 170 _____

33. Which categories of somatic variants are detected by your laboratoryâ™s NGS panel for hematological malignancies? (Select all that apply.)

180
- [ ] 277 Copy number variants (> 1 kb)
- [ ] 316 Gene rearrangements for B cell receptors
- [ ] 317 Gene rearrangements for T cell receptors
- [ ] 276 Intermediate sized insertions and deletions (eg, 50 bp - 1 kb)
- [x] 274 Single nucleotide variants
- [x] 275 Small insertions and deletions (eg, < 50 bp)
- [ ] 278 Other structural variants (eg, translocations)
- [ ] 010 Other, specify: 260 _____

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Additional NGS Testing Questions, cont'd

34. Using the NGS Platform Master List on the kit instructions, indicate which platform(s) are used in your laboratory for detection of somatic variants in hematologic malignancies.

010 2923	030	050
020 3482	040	060

35. Does your laboratory have an upper limit of length of detection for indels/insertions/deletions?

070
- ○ 179 Yes
- ◉ 180 No
- ○ 147 Not applicable

36. If yes, what is the upper limit?

080
- ○ 664 ≤ 5
- ○ 460 6 - 10
- ○ 665 11 - 15
- ○ 666 16 - 25
- ○ 667 ≥ 26

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Next-Generation Sequencing (NGS) Program Format Supplemental Questions

The CAP is considering a new format for proficiency testing involving NGS. Instead of completing a result form, participants would upload output files from their bioinformatic pipeline to a custom website. The new system would be more efficient, reduce data entry errors, and align proficiency testing with the nature of NGS testing. However, it would require some data manipulation by participating laboratories. Answer the questions below to help us better understand whether your laboratory would be able and willing to participate.

1. Is your laboratory able to obtain the following file(s) from your pipeline, and would your laboratory be willing to submit them as part of a proficiency testing challenge?

	Able to Obtain			Willing to Submit		
	Yes	No	Unknown/Unsure	Yes	No	Unknown/Unsure
BED	010 ○ 1341	● 1342	○ 1319	020 ○ 1341	● 1342	○ 1319
FASTQ	030 ● 1341	○ 1342	○ 1319	040 ● 1341	○ 1342	○ 1319
Unaligned BAM	050 ○ 1341	● 1342	○ 1319	060 ○ 1341	● 1342	○ 1319
Unfiltered VCF	070 ● 1341	○ 1342	○ 1319	080 ● 1341	○ 1342	○ 1319

2. Would your laboratory be able and willing to submit your VCF file in lieu of a result form?

090 ● 1257 Yes, able and willing
○ 1258 No, unable
○ 1179 No, unwilling
○ 1319 Unknown/unsure

3. Would your laboratory be willing and able to perform an initial batch upload of your responses using a standardized Excel spreadsheet in lieu of a result form?

100 ● 1257 Yes, able and willing
○ 1258 No, unable
○ 1179 No, unwilling
○ 1319 Unknown/unsure

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Attestation/Use of Other Form

Attestation Statement

As stated in the February 28, 1992 United States Federal Register under Subpart H 493-801 (b) (1), "the individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient work load using the laboratory's routine methods." The laboratory director or designee and the testing personnel must sign on the result form.

You may use the attestation page provided in the kit instructions or, alternatively, print, sign, and retain a copy of this page for your records and inspection purposes.

If your laboratory requires additional space for signatures, copy this form as needed.

We, the undersigned, recognizing that some special handling may be required due to the nature of proficiency testing (PT) materials, have as closely as is practical, performed the analyses on these specimens in the same manner as regular patient specimens. We confirm that results were not shared or PT specimens referred or tested outside our CLIA identification number.

Director (or Designee) (signature required)

010 Stephen Hyter

040

Survey Mailing Information

070 NGSHM-A 2023

Testing Personnel (signature required)

080 Chunhua Li

Testing Personnel (signature required)

110

Testing Personnel (signature required)

140

Use of Other

If applicable, use this section to list methodology information not found on the master lists or result form. For online entry, you can enter only 255 characters. CAP Accreditation Program Participants: Do not use this section to make changes to your test/activity menu. Update your test/activity menu using Organization Profile on cap.org via e-LAB Solutions Suite.

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Signatures will not display when viewed online.