KIT 36673512 1 01 13


Results are due no later than midnight, Central Time:

July 10, 2023

CAP # 1952901 - 22 SEQ # 01

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

# Next-Generation Sequencing (NGS) - Solid Tumor Survey Result Form

**Important**

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

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## Variant Master List

- The codes listed in the Variant Code column are to be used in the Results section to indicate the variants that your laboratory detects.
- 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 "Variant Not Tested" result option for that gene.**
- If your laboratory tests for a listed gene, you must go through this entire master list and enter **ONLY** the variants that are **NOT** covered by your laboratory's assay in the Variant Not Tested column. **Do not skip this important step.**

| Gene | Variant | Genomic Description (hg19) | Variant Code | Variant Not Tested |
|---|---|---|---|---|
| ALK (NM_004304.4) | ALK c.3516-1G>T | chr2:29443702C>A | 1810 | 020 (1898) |
| | ALK c.3521T>G p.F1174C | chr2:29443696A>C | 1811 | (1899) |
| | ALK c.3589G>A p.E1197K | chr2:29443628C>T | 1812 | (1900) |
| 010 (2157) ALK not tested | ALK c.3605G>A p.G1202E | chr2:29443612C>T | 1813 | (1901) |
| | ALK c.3797C>T p.A1266V | chr2:29432691G>A | 1814 | (1902) |
| | ALK c.3824G>A p.R1275Q | chr2:29432664C>T | 1815 | (1903) |
| BRAF (NM_004333.4) | BRAF c.1798G>A p.V600M | chr7:140453137C>T | 1820 | (1908) |
| | BRAF c.1798_1799delGTinsAA p.V600K | chr7:140453136_140453137delACinsTT | 4199 | (4200) |
| | BRAF c.1798_1799delGTinsAG p.V600R | chr7:140453136_140453137delACinsCT | 4201 | (4202) |
| 080 (2140) BRAF not tested | BRAF c.1799T>A p.V600E | chr7:140453136A>T | 1611 | (1713) |
| | BRAF c.1799_1800delTGinsAA p.V600E | chr7:140453135_140453136delCAinsTT | 2914 | (3017) |
| | BRAF c.1803A>T p.K601N | chr7:140453132T>A | 2916 | (3019) |
| EGFR (NM_005228.3) | EGFR c.1391C>T p.S464L | chr7:55227924C>T | 4211 | (4212) |
| | EGFR c.1393G>A p.G465R | chr7:55227926G>A | 5162 | (5163) |
| | EGFR c.2236_2250del15 p.E746_A750delELREA | chr7:55242466_55242480delGAATTAAGAGAAGCA | 4213 | (4214) |
| 150 (2158) EGFR not tested | EGFR c.2303G>T p.S768I | chr7:55249005G>T | 3470 | (3518) |
| | EGFR c.2369C>T p.T790M | chr7:55249071C>T | 1822 | (1910) |
| | EGFR c.2582T>A p.L861Q | chr7:55259524T>A | 5164 | (5165) |

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## Variant Master List, cont'd

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| Gene | Variant | Genomic Description (hg19) | Variant Code | Variant Not Tested |
|---|---|---|---|---|
| ERBB2 (NM_004448.2) | ERBB2 c.929C>A p.S310Y | chr17:37868208C>A | 3383 | 020 (3411) |
| | ERBB2 c.929C>T p.S310F | chr17:37868208C>T | 3384 | (3412) |
| | ERBB2 c.2313_2324dupATACGTGATGGC p.Y772_A775dup | chr17:37880984_37880995dupATACGTGATGGC | 2935 | (3038) |
| | ERBB2 c.2326_2327insTGT p.G776delinsVC | chr17:37880997_37880998insTGT | 4215 | (4216) |
| 010 (2159) ERBB2 not tested | ERBB2 c.2333G>A p.G778D | chr17:37881004G>A | 3385 | (3413) |
| | ERBB2 c.2521C>G p.L841V | chr17:37881329C>G | 3387 | (3415) |
| FGFR1 (NM_023110.2) | FGFR1 c.448C>T p.P150S | chr8:38285864G>A | 3941 | (3942) |
| | FGFR1 c.776C>T p.A259V | chr8:38282187G>A | 3943 | (3944) |
| | FGFR1 c.1638C>A p.N546K | chr8:38274849G>T | 3945 | (3946) |
| | FGFR1 c.1681G>A p.V561M | chr8:38273561C>T | 4506 | (4507) |
| 080 (3940) FGFR1 not tested | FGFR1 c.1966A>G p.K656E | chr8:38272308T>C | 3947 | (3948) |
| | FGFR1 c.2201G>T p.R734L | chr8:38271527C>A | 3949 | (3950) |
| FGFR3 (NM_000142.4) | FGFR3 c.742C>T p.R248C | chr4:1803564C>T | 3954 | (3955) |
| | FGFR3 c.746C>G p.S249C | chr4:1803568C>G | 3956 | (3957) |
| | FGFR3 c.1108G>T p.G370C | chr4:1806089G>T | 4509 | (4510) |
| | FGFR3 c.1111A>T p.S371C | chr4:1806092A>T | 4511 | (4512) |
| 150 (3953) FGFR3 not tested | FGFR3 c.1118A>G p.Y373C | chr4:1806099A>G | 3958 | (3959) |
| | FGFR3 c.1948A>G p.K650E | chr4:1807889A>G | 5841 | (5842) |
| IDH1 (NM_005896.3) | IDH1 c.392G>A p.G131D | chr2:209113115C>T | 3388 | (3416) |
| | IDH1 c.394C>G p.R132G | chr2:209113113G>C | 1638 | (1740) |
| | IDH1 c.394C>T p.R132C | chr2:209113113G>A | 1639 | (1741) |
| | IDH1 c.394_395delCGinsTC p.R132S | chr2:209113112_209113113delCGinsGA | 3389 | (3966) |
| 220 (2145) IDH1 not tested | IDH1 c.395G>T p.R132L | chr2:209113112C>A | 1641 | (1743) |
| | IDH1 c.395G>A p.R132H | chr2:209113112C>T | 1853 | (1941) |

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## Variant Master List, cont'd

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- 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 "Variant Not Tested" result option for that gene.**
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| Gene | Variant | Genomic Description (hg19) | Variant Code | Variant Not Tested |
|---|---|---|---|---|
| IDH2 (NM_002168.2) | IDH2 c.514A>T p.R172W | chr15:90631839T>A | 3390 | 020 (3418) |
| | IDH2 c.514A>G p.R172G | chr15:90631839T>C | 1644 | (1746) |
| | IDH2 c.515G>A p.R172K | chr15:90631838C>T | 1645 | (1747) |
| 010 (2146) IDH2 not tested | IDH2 c.515G>C p.R172T | chr15:90631838C>G | 3391 | (3419) |
| | IDH2 c.515G>T p.R172M | chr15:90631838C>A | 3392 | (3420) |
| | IDH2 c.516G>C p.R172S | chr15:90631837C>G | 1646 | (1748) |
| KIT (NM_000222.2) | KIT c.1504_1509dupGCCTAT p.A502_Y503dup | chr4:55592180_55592185dupGCCTAT | 3106 | (3107) |
| | KIT c.1961T>C p.V654A | chr4:55594258T>C | 1858 | (1946) |
| | KIT c.2446G>C p.D816H | chr4:55599320G>C | 3394 | (3422) |
| 080 (2148) KIT not tested | KIT c.2446G>T p.D816Y | chr4:55599320G>T | 1857 | (1945) |
| | KIT c.2447A>T p.D816V | chr4:55599321A>T | 1656 | (1758) |
| | KIT c.2466T>A p.N822K | chr4:55599340T>A | 1657 | (1759) |
| KRAS (NM_004985.3) | KRAS c.34G>T p.G12C | chr12:25398285C>A | 4229 | (4230) |
| | KRAS c.35G>A p.G12D | chr12:25398284C>T | 1864 | (1952) |
| | KRAS c.37G>C p.G13R | chr12:25398282C>G | 3395 | (3423) |
| 150 (2163) KRAS not tested | KRAS c.38_39delGCinsAA p.G13E | chr12:25398280_25398281delGCinsTT | 3442 | (3446) |
| | KRAS c.181C>A p.Q61K | chr12:25380277G>T | 3697 | (3719) |
| | KRAS c.436G>C p.A146P | chr12:25378562C>G | 1867 | (1955) |
| MET (NM_001127500.2) | MET c.2942-9_2942-7delTGTinsGG p.? | chr7:116411894_116411896delTGTinsGG | 5182 | (5183) |
| | MET c.3072_3082+2del p.F1025fs | chr7:116412033_116412045delTTTTCCA GAAGGT | 5184 | (5185) |
| | MET c.3082+1G>T p.? | chr7:116412044G>T | 4233 | (4234) |
| 220 (2164) MET not tested | MET c.3082G>T p.D1028Y | chr7:116412043G>T | 5843 | (5844) |
| | MET c.3082G>C p.D1028H | chr7:116412043G>C | 4239 | (4240) |
| | MET c.3757T>G p.Y1253D | chr7:116423428T>G | 1869 | (1957) |

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## Variant Master List, cont'd

- The codes listed in the Variant Code column are to be used in the Results section to indicate the variants that your laboratory detects.
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| Gene | Variant | Genomic Description (hg19) | Variant Code | Variant Not Tested |
|---|---|---|---|---|
| MYOD1 (NM_002478.5) | MYOD1 c.365T>G p.L122R | chr11:17741694T>G | 5845 | 020 (5846) |
| | MYOD1 c.364C>A p.L122M | chr11:17741693C>A | 5847 | (5848) |
| | MYOD1 c.361C>T p.R121C | chr11:17741690C>T | 5849 | (5850) |
| | MYOD1 c.452G>A p.R151H | chr11:17741781G>A | 5851 | (5852) |
| 010 (5840) MYOD1 not tested | MYOD1 c.508G>A p.A170T | chr11:17741837G>A | 5853 | (5854) |
| | MYOD1 c.434C>T p.P145L | chr11:17741763C>T | 5855 | (5856) |
| NRAS (NM_002524.4) | NRAS c.34G>A p.G12S | chr1:115258748C>T | 3699 | (3721) |
| | NRAS c.34_36delGGTinsTGG p.G12W | chr1:115258746_115258748delACCinsCCA | 4241 | (4242) |
| | NRAS c.38G>A p.G13D | chr1:115258744C>T | 3701 | (3723) |
| | NRAS c.38G>C p.G13A | chr1:115258744C>G | 3702 | (3724) |
| 080 (2165) NRAS not tested | NRAS c.181C>A p.Q61K | chr1:115256530G>T | 1876 | (1964) |
| | NRAS c.182A>T p.Q61L | chr1:115256529T>A | 3399 | (3427) |
| PDGFRA (NM_006206.4) | PDGFRA c.100G>A p.E34K | chr4:55127312G>A | 3401 | (3429) |
| | PDGFRA c.1658C>T p.P553L | chr4:55141012C>T | 3402 | (3430) |
| | PDGFRA c.1698_1712delCCCAGATGGACATGA p.S566_E571delinsR | chr4:55141052_55141066delCCCAGATGGACATGA | 3403 | (3431) |
| 150 (1640) PDGFRA not tested | PDGFRA c.2255C>T p.S752F | chr4:55146581C>T | 3404 | (3432) |
| | PDGFRA c.2525A>T p.D842V | chr4:55152093A>T | 3703 | (3725) |
| | PDGFRA c.2536G>A p.D846N | chr4:55152104G>A | 3406 | (3434) |
| PIK3CA (NM_006218.3) | PIK3CA c.323G>A p.R108H | chr3:178916936G>A | 3407 | (3435) |
| | PIK3CA c.1624G>A p.E542K | chr3:178936082G>A | 2973 | (3072) |
| | PIK3CA c.1624G>C p.E542Q | chr3:178936082G>C | 2977 | (3076) |
| | PIK3CA c.1625A>T p.E542V | chr3:178936083A>T | 2976 | (3075) |
| 220 (2166) PIK3CA not tested | PIK3CA c.1636C>G p.Q546E | chr3:178936094C>G | 3408 | (3436) |
| | PIK3CA c.3140A>G p.H1047R | chr3:178952085A>G | 1880 | (1968) |

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## Variant Master List, cont'd

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| Gene | Variant | Genomic Description (hg19) | Variant Code | Variant Not Tested |
|---|---|---|---|---|
| POLE (NM_006231.4)<br><br>010 (5159) POLE not tested | POLE c.857C>G p.P286R | chr12:133253184G>C | 5186 | 020 (5187) |
| | POLE c.1100T>C p.F367S | chr12:133252327A>G | 5188 | (5189) |
| | POLE c.1231G>C p.V411L | chr12:133250289C>G | 5190 | (5191) |
| | POLE c.1231G>A p.V411M | chr12:133250289C>T | 5192 | (5193) |
| | POLE c.1270C>G p.L424V | chr12:133250250G>C | 5194 | (5195) |
| | POLE c.1376C>T p.S459F | chr12:133249847G>A | 5196 | (5197) |
| TP53 (NM_000546.5)<br><br>080 (2155) TP53 not tested | TP53 c.403T>G p.C135G | chr17:7578527A>C | 3705 | (3727) |
| | TP53 c.404G>T p.C135F | chr17:7578526C>A | 3454 | (3458) |
| | TP53 c.482C>A p.A161D | chr17:7578448G>T | 3707 | (3729) |
| | TP53 c.482C>T p.A161V | chr17:7578448G>A | 3708 | (3730) |
| | TP53 c.742C>T p.R248W | chr17:7577539G>A | 3709 | (3731) |
| | TP53 c.861_874delGAATCTCCGCAAGA p.N288fs | chr17:7577068_7577081delGCGGAGATTCTCTT | 5857 | (5858) |

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## Results

### NGSST-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.

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 030 Variant Code 1: | 3470 | 040 Total coverage depth at Variant 1 position: | 1559 | 050 Variant 1 allele fraction: | 11.2 | % |
| 060 Variant Code 2: (if applicable) | 1638 | 070 Total coverage depth at Variant 2 position: | 958 | 080 Variant 2 allele fraction: | 11.5 | % |
| 090 Variant Code 3: (if applicable) | 1867 | 100 Total coverage depth at Variant 3 position: | 784 | 110 Variant 3 allele fraction: | 13.3 | % |
| 120 Variant Code 4: (if applicable) | 2973 | 130 Total coverage depth at Variant 4 position: | 1505 | 140 Variant 4 allele fraction: | 8.3 | % |
| 150 Variant Code 5: (if applicable) | | 160 Total coverage depth at Variant 5 position: | __ __ __ __ __ | 170 Variant 5 allele fraction: | __ __ __ . __ | % |
| 180 Variant Code 6: (if applicable) | | 190 Total coverage depth at Variant 6 position: | __ __ __ __ __ | 200 Variant 6 allele fraction: | __ __ __ . __ | % |

### NGSST-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.

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 230 Variant Code 1: | 4201 | 240 Total coverage depth at Variant 1 position: | 2176 | 250 Variant 1 allele fraction: | 12.4 | % |
| 260 Variant Code 2: (if applicable) | 1864 | 270 Total coverage depth at Variant 2 position: | 873 | 280 Variant 2 allele fraction: | 10.4 | % |
| 290 Variant Code 3: (if applicable) | | 300 Total coverage depth at Variant 3 position: | __ __ __ __ __ | 310 Variant 3 allele fraction: | __ __ __ . __ | % |
| 320 Variant Code 4: (if applicable) | | 330 Total coverage depth at Variant 4 position: | __ __ __ __ __ | 340 Variant 4 allele fraction: | __ __ __ . __ | % |
| 350 Variant Code 5: (if applicable) | | 360 Total coverage depth at Variant 5 position: | __ __ __ __ __ | 370 Variant 5 allele fraction: | __ __ __ . __ | % |
| 380 Variant Code 6: (if applicable) | | 390 Total coverage depth at Variant 6 position: | __ __ __ __ __ | 400 Variant 6 allele fraction: | __ __ __ . __ | % |

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## Results, cont'd

**NGSST-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 4211 | Total coverage depth at Variant 1 position: | 040 552 | Variant 1 allele fraction: | 050 10.1 | % |
| Variant Code 2: (if applicable) | 060 3106 | Total coverage depth at Variant 2 position: | 070 1122 | Variant 2 allele fraction: | 080 20.1 | % |
| Variant Code 3: (if applicable) | 090 3454 | Total coverage depth at Variant 3 position: | 100 1581 | Variant 3 allele fraction: | 110 11.9 | % |
| 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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## 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 ☑ 274 Single nucleotide variants ☑ 275 Small insertions and deletions (eg, < 50 bp) ☐ 557 Copy number variations (CNVs)

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

| Variant Type | Single nucleotide variants | Small insertions and deletions |
|---|---|---|
| **Lower limit of detection** | 050 1.0 % | 060 1.0 % |

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 for the single assay being described in this program? (Select all that apply.)

080 ☐ 223 Exome sequencing
☐ 224 Genome sequencing
☐ 225 RNA sequencing
☑ 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
- ○ 250 Agilent HaloPlex Cancer Research Panel
- ○ 639 Archer Comprehensive Solid Tumor Panel for Illumina
- ○ 644 Archer FusionPlex Solid Tumor (RNA Input)
- ○ 647 Archer VariantPlex Solid Tumor (DNA Input)
- ○ 392 Fluidigm Access Array
- ○ 755 Illumina AmpliSeq Focus Panel
- ○ 756 Illumina AmpliSeq Hotspot Panel v2
- ○ 501 Illumina TruSight Tumor 15 Panel
- ○ 502 Illumina TruSight Tumor 26 Panel
- ○ 503 Illumina TruSight Tumor 170 Panel
- ○ 648 Illumina TruSight Tumor 500 Panel
- ○ 394 Thermo Fisher Ion AmpliSeq Cancer Hotspot Panel
- ○ 253 Thermo Fisher Ion AmpliSeq Cancer Hotspot Panel v2
- ○ 518 Thermo Fisher Ion AmpliSeq Lung and Cancer Panel
- ○ 519 Thermo Fisher Ion AmpliSeq Lung and Cancer Panel v2
- ○ 757 Thermo Fisher Oncomine Childhood Research Assay
- ○ 649 Thermo Fisher Oncomine Comprehensive Assay Plus
- ○ 175 Thermo Fisher Oncomine Comprehensive Assay v3
- ○ 520 Thermo Fisher Oncomine Focus Cancer Panel
- ○ 650 Thermo Fisher Oncomine Precision Assay
- ○ 249 Not applicable; our laboratory performs exome or genome sequencing for somatic variant detection
- ○ 010 Other, specify:

020 _____

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

030
- ○ 255 Agilent Custom SureSelect
- ○ 758 Archer Custom VariantPlex
- ○ 759 IDT xGen Custom Panel
- ○ 258 Ion AmpliSeq Custom DNA Panel
- ● 760 Qiagen QIAseq Targeted DNA Custom Panel
- ○ 761 Roche KAPA HyperChoice Custom Panel
- ○ 395 Roche NimbleGen SeqCap EZ Designs
- ○ 745 Twist Bioscience Custom Panel
- ○ 010 Other, specify:

040 _____

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

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

060 _____

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

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 Our laboratory does not establish 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 1,000 - 1,500 reads
- ○ 299 1,501 - 2,500 reads
- ○ 300 > 2,500 reads
- ○ 301 Our laboratory does 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
- ○ 762 Archer Analysis
- ● 303 CLC Genomics Workbench
- ○ 304 DNASTAR Lasergene Genomics Suite
- ○ 305 Illumina MiSeq Reporter
- ○ 763 Illumina TruSight Software Suite
- ○ 307 NextGENe
- ○ 764 SOPHiA DDM
- ○ 308 Strand Avadis NGS
- ○ 306 Thermo Fisher Ion Reporter Software
- ○ 765 Thermo Fisher Torrent Suite

Other, specify software used for:

a. Alignment: (Select all that apply)

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

080

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

090
- ☐ 533 PICARD
- ☐ 534 SAMtools
- ☐ 010 Other, specify:

120

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

130
- ☐ 403 Alamut Visual
- ☐ 528 Ensembl Variant Effect Predictor
- ☐ 522 Freebayes
- ☐ 405 GATK
- ☐ 766 Illumina DRAGEN
- ☐ 767 Illumina Pisces
- ☐ 406 Internally developed pipeline
- ☐ 768 LoFreq
- ☐ 525 Mutect
- ☐ 407 Pierian
- ☐ 526 Pindel
- ☐ 534 SAMtools
- ☐ 770 Scalpel
- ☐ 409 SnpSift
- ☐ 524 Vardict
- ☐ 523 Varscan
- ☐ 010 Other, specify:

300

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## Assay Characteristics, cont'd

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

010

- ☐ 527 Annovar
- ☐ 762 Archer Analysis
- ☐ 528 Ensembl Variant Effect Predictor
- ☐ 772 GenomOncology
- ☐ 399 Illumina BaseSpace
- ☐ 763 Illumina TruSight Software Suite
- ☐ 332 Illumina VariantStudio
- ☐ 531 Internally developed
- ☐ 307 NextGENe
- ☐ 702 PierianDX
- ☑ 529 Qiagen Clinical Insight
- ☐ 530 SNPEFF
- ☐ 764 SOPHiA DDM
- ☐ 306 Thermo Fisher Ion Reporter Software
- ☐ 765 Thermo Fisher Torrent Suite
- ☐ 010 Other, specify:

170 _____

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

180

- ○ 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 ☐ 773 Air dried cytology slides
☐ 232 FFPE cell blocks
☑ 231 FFPE tissues
☐ 234 Fine-needle aspirates
☐ 235 Frozen tissues
☑ 322 Fresh bone marrow
☑ 323 Fresh peripheral blood
☐ 233 Fresh tissue
☐ 010 Other, specify: 190 _____

22. How does your laboratory assess tumor content?

200 ○ 390 Computationally derived from the sequencing data
● 388 Histologic review by a pathologist
○ 389 Histologic review by a trained individual, who is not a pathologist
○ 387 Laboratory does not assess tumor content

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

210 ○ 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

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

220 ☐ 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: 320 _____
☐ 010 Other, specify: 340 _____

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## Reporting, cont'd

25. 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

26. 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

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

030
- [x] 372 Biological function, known
- [ ] 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

28. 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

29. Who generates the final interpretive report?

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

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

180
- [x] 1255 hg19 (GRCh37)
- [ ] 1256 hg38 (GRCh38)
- [ ] 3967 Telomere-to-telomere (T2T)
- [ ] 0010 Other, specify: 220 _____

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## Additional NGS Testing Questions

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

010
- ○ 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

32. How many NGS-based assays for the detection of somatic variants does your laboratory currently perform?

020
- ○ 334 1
- ○ 335 2
- ○ 336 3
- ● 337 4
- ○ 338 5
- ○ 339 > 5, specify number:

030 ____

33. Which categories of somatic variants are detected by any of your laboratory's assays for solid tumors? (Select all that apply.)

040
- ☐ 754 Amplifications
- ☐ 277 Copy number variants (> 1 kb)
- ☐ 276 Intermediate sized insertions and deletions (eg, 50 bp - 1 kb)
- ☑ 274 Single nucleotide variants
- ☑ 275 Small insertions and deletions (eg, < 50 bp)
- ☐ 278 Other structural variants (eg, translocations)
- ☐ 010 Other, specify:

110 _____

34. Which categories of somatic variants are detected by your laboratory's NGS panel for solid tumors? (Select all that apply.)

120
- ☐ 754 Amplifications
- ☐ 277 Copy number variants (> 1 kb)
- ☐ 276 Intermediate sized insertions and deletions (eg, 50 bp - 1 kb)
- ☑ 274 Single nucleotide variants
- ☑ 275 Small insertions and deletions (eg, < 50 bp)
- ☐ 278 Other structural variants (eg, translocations)
- ☐ 010 Other, specify:

190 _____

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

| | | |
|---|---|---|
| 200 2923 | 220 | 240 |
| 210 3482 | 230 | 250 |

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

260
- ○ 179 Yes
- ● 180 No
- ○ 147 Not applicable

36a. If yes, what is the upper limit?

270
- ○ 664 ≤ 5
- ○ 460 6 - 10
- ○ 665 11 - 15
- ○ 666 16 - 25
- ○ 667 ≥ 26

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## General Supplemental Questions

1. Does your laboratory intend to offer tests for somatic testing for homologous recombination deficiency?

010 ○ 184 Yes, currently
○ 186 Yes, in the next 12 months
○ 183 Yes, in the next 24 months
● 180 No

1a. If yes, which genes and/or techniques will be employed? (Select all that apply.)

020 ☐ 201 Somatic sequencing of *BRCA1*
☐ 202 Somatic sequencing of *BRCA2*
☐ 203 Somatic sequencing of some or all of the following: *MRE11, RAD50, NBS2, CtIP, RAD51, ATM, H2Ax, PALB2, RPA, RAD52*
☐ 204 Loss of heterozygosity analysis
☐ 205 Telomeric allelic imbalance
☐ 206 Large-scale state transitions
☐ 010 Other, specify:

090 _____

2. Does your laboratory analyze and report tumor mutational signatures?

100 ○ 184 Yes, currently
○ 186 Yes, in the next 12 months
○ 183 Yes, in the next 24 months
● 180 No

2a. If yes, which tumor mutational signatures does your laboratory report? (Select all that apply.)

110 ☐ 189 Smoking
☐ 190 Age
☐ 191 UV
☐ 192 MMR
☐ 181 POLE
☐ 193 APOBEC
☐ 194 Temozolomide
☐ 010 Other, specify:

190 _____

3. Does your laboratory perform in-house or send-out global methylation profiling in primary central nervous system tumors?

200 ○ 749 Yes, in-house
○ 750 Yes, send-out
● 180 No

3a. If yes, with what frequency is testing performed?

210 ○ 751 Routinely (most specimens)
○ 752 Occasionally (select cases)

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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 NGSST-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.

170

**Signatures will not display when viewed online.**