Precision Medicine

Addressing Challenges to Biomarker Testing During the COVID-19 Pandemic

Prioritizing Comprehensive Cancer Care While Helping Minimize the Risks of Exposure to COVID-19

Guidelines recommend limiting in-person contact to protect patients and healthcare workers[1,2]

- Reschedule all nonessential visits and use telemedicine when possible[1,2]
- **Consider liquid biopsies for molecular testing in certain circumstances[1]**

Patient management should be approached on a case-by-case basis, balancing the risk of COVID-19 infection with the risk of cancer progression[3]

Molecular Testing Remains a Standard of Care for Patients With Select Cancers[4-7]

Liquid biopsy and germline testing using blood samples are less invasive options to assess for actionable biomarkers[7,8]

- The identification of clinically relevant driver gene mutations or deficiencies in HRR pathways may help guide patient management in select cancers; however, sufficient tumor tissue may not always be available for molecular testing[6,7,9,10]

CONSIDER LESS INVASIVE TESTING OPTIONS AS APPROPRIATE TO LIMIT EXPOSURE

	TISSUE-BASED TESTING	GERMLINE TESTING	LIQUID-BIOPSY (ctDNA) TESTING
Sample Type	Tumor sample (eg, tissue biopsy, surgical material)[6,10]	Blood or saliva[10]	Blood (ctDNA extracted from plasma)[11]
Clinical Relevance	• Determines total mutation status (germline + somatic) but does not distinguish between the two[12]	• For certain tumor types, may have prognostic and predictive value and familial implications[10,13]	• An option when tumor tissue is insufficient for molecular profiling or an invasive procedure is contraindicated[14-16] • Positive results are actionable in certain tumors[8,16] • Shorter turnaround time compared with tissue testing[17,18]
Limitations	• Inadequate or insufficient tumor sample can present a challenge[6,7,9]	• Does not identify patients with only tumor (somatic) mutations[7,13] • Can require genetic counseling[7]	• Mutation profiling is dependent on tumor shedding of DNA[8] • Negative results require confirmation with tissue[16]

Consult with clinical practice guidelines for specific testing recommendations as these vary by tumor type and disease stage.

Use of mobile phlebotomy may further reduce barriers to testing during COVID-19.[19,a]

A phlebotomist collects a blood sample in the patient's home and sends it to the lab for analysis[19]

Abbreviations: ***ALK***, anaplastic lymphoma kinase; ***ATM***, ataxia-telangiectasia mutated; ***BRAF***, v-Raf murine sarcoma viral oncogene homolog B; ***BRCA1***, breast cancer susceptibility gene 1; ***BRCA2***, breast cancer susceptibility gene 2; ***CDK12***, cyclin-dependent kinase 12; **CDx**, companion diagnostic; ***CHEK2***, checkpoint kinase 2; **COVID-19**, coronavirus disease 2019; **ctDNA**, circulating tumor DNA; ***EGFR***, epidermal growth factor receptor; ***ERBB2***, erb-B2 receptor tyrosine kinase 2; **HRR**, homologous recombination repair; ***KRAS***, v-Ki-ras2 Kirsten rat sarcoma viral oncogene homolog; ***MAP2K1***, mitogen-activated protein kinase kinase 1; ***MET***, MET proto-oncogene, receptor tyrosine kinase; ***NRAS***, neuroblastoma RAS; ***PALB2***, partner and localizer of *BRCA2*; ***PIK3CA***, phosphatidylinositol-4, 5-bisphosphate 3-kinase catalytic subunit alpha; ***RET***, rearranged during transfection; ***ROS1***, ROS proto-oncogene 1, receptor tyrosine kinase; ***TP53***, tumor protein p53.

AstraZeneca

Multiple Laboratories Offer Mobile Phlebotomy or At-Home Germline Testing Kits in Times of Physical Distancing

LIQUID BIOPSY TESTING OPTIONS OFFERING MOBILE PHLEBOTOMY AND ENHANCED SAFETY MEASURES

Examples of molecular tests available to identify clinically actionable mutations in select tumor types[b]

LABORATORY	TEST NAME	GENES	CAPABILITY	FOR ADDITIONAL INFORMATION
Biocept[20,21]	Target Selector™ NGS Lung Panel	*ALK*, *BRAF*, *EGFR*, *ERBB2*, *KRAS*, *MAP2K1*, *MET*, *NRAS*, *PIK3CA*, *RET*, *ROS1*, *TP53*	☑ Mobile phlebotomy	888.332.7729 biocept.com
Biodesix®[22,23]	Biodesix Lung Reflex® genestrat®	*EGFR*, *ALK*, *ROS1*, *RET*, *BRAF*, *KRAS*		866.432.5930 biodesix.com
Foundation Medicine[19,24]	FoundationOne® Liquid	70 genes (includes *EGFR*, *ALK*, *ROS1*, *BRAF*, *MET*, *RET*, and HRR genes: *BRCA1/2*, *ATM*, *PALB2*, *CHEK2*, *CDK12*)		888.988.3639 foundationmedicine.com
Guardant Health[25,26]	Guardant360®[c]	73 genes		855.698.8887 guardanthealth.com
Inivata[27,28]	InVisionFirst® Lung	37 genes (includes *ALK*, *BRAF*, *EGFR*, *RET*, *KRAS*)		844.646.8282 inivata.com
Tempus[29-31]	Tempus xF	105 genes		800.739.4137 tempus.com
Other laboratories offer enhanced safety measures to help protect patients needing a liquid biopsy test, including hours dedicated to patients with underlying medical conditions				
LabCorp[17, 32-34]	Resolution ctDx-Lung Assay™	21 genes	☑ Enhanced safety measures at test sites	labcorp.com
	cobas® EGFR Test v2[c]	*EGFR*		
Quest Diagnostics™[35-37]	cobas® EGFR Test v2[c]	*EGFR*		866.697.8378 questdiagnostics.com

GERMLINE TESTING OPTIONS OFFERING MOBILE PHLEBOTOMY AND DIRECT-TO-PATIENT SALIVA KITS

Examples of multigene tests available to identify clinically relevant HRR pathway mutations in select tumor types[b]

LABORATORY	TEST NAME	GENES	CAPABILITY	FOR ADDITIONAL INFORMATION
Ambry Genetics®[38-42]	CancerNext®	34 genes	☑ Mobile phlebotomy ☑ At-home germline test kit	949.900.5500 ambrygen.com
	BRCA1 and *BRCA2*	*BRCA1*, *BRCA2*		
Invitae[43-48]	*BRCA1* and *BRCA2* STAT Panel	*BRCA1*, *BRCA2*	☑ Mobile phlebotomy ☑ At-home germline test kit	800.436.3037 invitae.com
	Common Hereditary Cancers Panel	47 genes		
	Multi-Cancer Panel	84 genes		
Myriad[49-51]	BRACAnalysis® CDx[c]	*BRCA1*, *BRCA2*	☑ Mobile phlebotomy	800.469.7423 myriad.com
	myRisk® Hereditary Cancer Panel	35 genes	☑ Mobile phlebotomy ☑ At-home germline test kit	

[a]Mobile phlebotomy is offered in certain areas; availability may vary based on location.
[b]Available tests and fundamental parameters may influence test selection. Tables were developed based on publicly available information as of June 4, 2020 and are not intended to be a comprehensive list of testing options. See the individual laboratory websites for additional information on mobile phlebotomy services. If the lab you currently use is not included, please contact customer service regarding their mobile phlebotomy capabilities.
[c]FDA-approved diagnostic.

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