

JANUARY 2022

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Update Summary				
Update Existing Test	12/22/2021	180HC - "18-OH Corticosterone"		
Update Existing Test	1/4/2022	<u>CA125 - "CA 125"</u>		
Update Existing Test	1/25/2022	<u>CA199 - "CA 19-9"</u>		
Update Existing Test	12/22/2021	CFMP - "Cystic Fibrosis Mutation Panel"		
Update Existing Test	1/31/2022	CY2D6 - "Cytochrome P450 2d6 Genotype"		
Update Existing Test	12/22/2021	EUGLB - "Euglobulin Lysis Time"		
Update Existing Test	12/22/2021	F8INH - "Factor VIII Inhibitor"		
Update Existing Test	12/22/2021	GHBP - "Growth Hormone Binding Protein"		
Update Existing Test	12/22/2021	HEPCF - "Heparin Cofactor II"		
Update Existing Test	1/17/2022	IGFB3 - "IGF Binding Prtotein 3 (IGFBP 3)"		
Update Existing Test	12/22/2021	MMP9 - "Matrix Metalloproteinase-9 (MMP-9)"		
Update Existing Test	12/22/2021	PLSAG - "Plasminogen Antigen"		
Update Existing Test	12/22/2021	RPTL - "Reptilase Time"		
Update Existing Test	1/11/2022	STAHP - "Stachybotrys Panel I"		
Update Existing Test	1/17/2022	TICKI - "Tick ID-Reflex to Lyme DNA"		
Inactivate Test With Replacement	1/25/2022	CFMP - "Cystic Fibrosis Mutation Panel" replaced by CYCFS -		
		"Cystic Fibrosis Screen"		

Update Existing Test			
Effective Date	12/22/2021		
Name	18-OH Corticosterone		
Code	180HC		
Interface Order Code	3500245		
Legacy Code	180HC		
Notes	Updates to performing laboratory.		
Required Testing Changes			
Performing Laboratory	LabCorp		

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Update Existing Test				
Effective Date	1/4/2022			
Name	CA 125			
Code	CA125			
Interface Order Code	1010050			
Legacy Code	CA125			
Notes	Updates to transport temperature.			
Required Testing Cl	hanges			
Specimen Required	Specimen Preparation: Centrifuge, separate serum from cells and send 1.0 mL serum in a screw capped plastic vial. Transport Temperature: Frozen			

Update Existing Test				
Effective Date	1/25/2022			
Name	CA 19-9			
Code	CA199			
Interface Order Code	1010040			
Legacy Code	CA199			
Notes	Updates to transport temperature and reference range.			
Required Testing Cl	Required Testing Changes			
Specimen Required	Specimen Preparation: Centrifuge, separate serum from cells and send 1.0 mL serum in a screw capped plastic vial. Transport Temperature: Frozen			
Reference Range	< 2.0 U/mL			

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Update Existing Test				
Effective Date	12/22/2021			
Name		sis Mutation Pan	el	
Code		CFMP		
Interface Order Code	3	090525		
Legacy Code		CFMP		
Notes	Updates to performing la	ab and specimen	requirements.	
Required Testing C	hanges			
CPT Code(s)	81220 ZB3UW			
Stability	Whole Blood: Room temperature: 8 days Refrigerated: 8 days Frozen: Unacceptable			
Methodology	Multiplex Polymerase Chain Reaction Massively Parallel Sequencing			
Reference Range	See report			
Performed Days	Sunday - Saturday			
Turnaround Time	9 - 12			
Performing Laboratory	Quest SJC			
Result Code	Name	LOINC Code	AOE/Prompt ²	
3090590	Cystic Fibrosis Mutation Analysis	Not available	No	

Update Existing Test				
Effective Date	1/31/2022			
Name	Cytochrome P450 2d6 Genotype			
Code	CY2D6			
Interface Order Code	3423000			
Legacy Code	CYP2D6Q			
Notes	Updates to alternate specimen.			
Required Testing Changes				
Alternate Specimen	Bone Marrow collected in: EDTA (lavender or royal blue top), ACD solution B (yellow top) or sodium heparin (green top) tube			

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Update Existing Test			
Effective Date	12/22/2021		
Name	Euglobulin Lysis Time		
Code	EUGLB		
Interface Order Code	3502650		
Legacy Code	EUGLOB		
Notes	Updates to performing laboratory.		
Required Testing Changes			
Performing Laboratory	LabCorp		

Update Existing Test			
Effective Date	12/22/2021		
Name	Factor VIII Inhibitor		
Code	F8INH		
Interface Order Code	3502730		
Legacy Code	FAC8INH		
Notes	Updates to performing laboratory.		
Required Testing Changes			
Performing Laboratory	LabCorp		

Update Existing Test			
Effective Date	12/22/2021		
Name	Growth Hormone Binding Protein		
Code	GHBP		
Interface Order Code	3503120		
Legacy Code	GHBP		
Notes	Updates to performing laboratory and CPT Codes.		
Required Testing Changes			
CPT Code(s)	83520		
Performing Laboratory	LabCorp		

Update Existing Test			
Effective Date	12/22/2021		
Name	Heparin Cofactor II		
Code	HEPCF		
Interface Order Code	3503290		
Legacy Code	HEPCOF		
Notes	Updates to performing laboratory.		
Required Testing Cl	Required Testing Changes		
Performing Laboratory	LabCorp		

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Update Existing Test				
Effective Date	1/	17/2022		
Name	IGF Binding F	Prtotein 3 (IGFBP	3)	
Code		IGFB3		
Interface Order Code	3711330			
Legacy Code	IGFBP3SP			
Notes	Update to performing lab and CPT Codes.			
Required Testing Changes				
CPT Code(s)	83520			
Performing Laboratory	Quest SJC			
Result Code	Name	LOINC Code	AOE/Prompt ²	
3711330	IGF Binding Protein 3 (IGFBP 3)	2483-6	No	

Update Existing Test		
Effective Date	12/22/2021	
Name	Matrix Metalloproteinase-9 (MMP-9)	
Code	MMP9	
Interface Order Code	3500005	
Legacy Code	MMP9	
Notes	Update to performing lab.	
Required Testing Changes		
Performing Laboratory	LabCorp	

Update Existing Test			
Effective Date	12/22/2021		
Name	Plasminogen Antigen		
Code	PLSAG		
Interface Order Code	3509025		
Legacy Code	PLASAGESTX		
Notes	Update to performing lab.		
Required Testing Changes			
Performing Laboratory	LabCorp		

Update Existing Test		
Effective Date	12/22/2021	
Name	Reptilase Time	
Code	RPTL	
Interface Order Code	3516200	
Legacy Code	RPTL	
Notes	Updates to performing lab.	
Required Testing Changes		
Performing Laboratory	LabCorp	

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Update Existing Test		
Effective Date	1/11/2022	
Name	Stachybotrys Panel II	
Code	STAHP	
Interface Order Code	3300261	
Legacy Code	STAHP	
Notes	Update to Test Name.	
Required Testing Changes		
Name	Stachybotrys Panel I	

Update Existing	g Test		
Effective Date	1/17/2022		
Name	Tick ID-Reflex to Lyme DNA		
Code	TICKI		
Interface Order Code	3515060		
Legacy Code	TICKINFLX		
Notes	Updates to specimen requirements, rejection criteria, methodology, performed days and TAT.		
Required Testing Changes			
Specimen Required	Specimen Preparation: Send tick, insect, larva, etc. in 70% alcohol in a sterile, screw capped plastic container.		
Rejection Criteria	Dried samples		
Methodology	Microscopic and Macroscopic Examination		
Performed Days	Monday - Saturday		
Turnaround Time	6 - 9 days		

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Inactivate Test	With Replacement			
Effective Date	1/25/2022			
	Inactivated Test			
Name	Cystic Fibrosis Mutation Panel			
Code	CFMP			
Legacy Code ¹	CFMP			
Interface Order Code	3090525			
Notes				
	Replacement Test			
Name	Cystic Fibrosis Screen			
Code	CYCFS			
CDT C - 4-/-)	81220			
CPT Code(s)	ZB3UW			
Notes				
Specimen Requirer	nents			
Specimen Kequirer	Collect: Lavender EDTA			
Specimen Required	Specimen Preparation: Send 4.0 mL whole blood collected in lavender EDTA tube. Minimum Volume: 3.0 mL Transport Temperature: Room temperature			
Alternate Specimen	Whole blood: ACD (yellow top) or Sodium heparin (green top) tube			
Rejection Criteria	Frozen samples			
Stability	Whole Blood: Room temperature: 8 days Refrigerated: 8 days Frozen: Unacceptable			
Performing Informa	ation			
Methodology	Multiplex Polymerase Chain Reaction • Massively Parallel Sequencing			
Reference Range	See report			
Performed Days	Sunday - Saturday			
Turnaround Time	9 - 12 days			
Performing Laboratory	Quest SJC			

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Interface Information			
Legacy Code ¹	CYCFS		
Interface Order Code	3400629		
Result Code	Name	LOINC Code	AOE/Prompt ²
3400635	Ethnicity	32624-9	Yes
3400630	CF Result	21654-9	No
3400631	Interpretation	38404-0	No
3400632	Mutations/Polymorphisms	21656-4	No
3400633	Method	49549-9	No
3400634	Reviewer	69047-9	No

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LABORATORY REPORT

Example Client, XYZ123 1234 Warde Road Ann Arbor MI 48108

EXAMPLE, REPORT

WX0000003039 M 12/05/1988 33 Y

Referral Testing

Collected: 12/22/2021 14:55 Received: 12/22/2021 14:55

<u>Test Name</u> <u>Result</u> <u>Flag Ref-Ranges</u> <u>Units</u> <u>Site</u>

Cystic Fibrosis Screen

EthnicityHispanic or LatinoQCRLCF ResultNEGATIVENEGATIVEQCRLInterpretationSEE NOTEQCRL

This result does not rule out the presence of a mutation or a diagnosis of cystic fibrosis disease (CF). The risk for mutations that cause CF other than the ones tested depends greatly on family history, clinical presentation, and ethnicity.

Chance of Having a CF Mutation

Detection Before After Negative Ethnic Group Test Result Rate Ashkenazi Jewish 94% 1 in 24 1 in 400 Non-Hispanic 888 1 in 25 1 in 208 Caucasian 1 in 46 Hispanic-American 72% African-American 1 in 65 1 in 186 65% 1 in 94 Asian-American 49% 1 in 184 insufficient data available Other Health care providers, please contact your local Quest Diagnostics' genetic counselor or call Quest Genomics Client Services at 866-GENEINFO (866-436-3463) for assistance with interpretation of

Mutations/Polymorphisms SEE NOTE QCRL

MUTATIONS ANALYZED:

these results.

G85E (c.254G>A)	S549N (c.1646G>A)
394delTT (c.262delTT)	G551D (c.1652G>A)
R117H (c.350G>A)	R553X (c.1657C>T)
621+1 G>T (c.489+1G>T)	R560T (c.1679G>C)
711+1 G>T (c.579+1G>T)	1898+1 G>A (c.1766+1G>A)
1078delT (c.948delT)	2183AA>G (c.2051delAAinsG)
R334W (c.1000C>T)	2184delA (c.2052delA)
R347H (c.1040G>A)	2789+5 G>A (c.2657+5G>A)
R347P (c.1040G>C)	3120+1 G>A (c.2988+1G>A)
A455E (c.1364C>A)	R1162X (c.3484C>T)
I507del (c.1519delATC)	3659delC (c.3528delC)
F508del (c.1521delCTT)	3849+10kb C>T (c.3717+12191C>T)
V520F (c.1558G>T)	3876delA (c.3744delA)
1717-1 G>A (c.1585-1G>A) 3905insT (c.3773insT)

LAB: L - LOW, H - HIGH, AB - ABNORMAL, C - CRITICAL, $\,$. - NOT TESTED

D222000002 WX0000003039 Printed D&T: 12/22/21 16:32 Ordered By: CLIENT CLIENT WX0000000000001595

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LABORATORY REPORT

Example Client, XYZ123 1234 Warde Road Ann Arbor MI 48108 **EXAMPLE, REPORT**

WX0000003039 M 12/05/1988 33 Y

Referral Testing

Collected: 12/22/2021 14:55 Received: 12/22/2021 14:55

Test Name Result Flag Ref-Ranges Units Site

G542X (c.1624G>T) W1282X (c.3846G>A) S549R (c.1645A>C or c.1647T>G) N1303K (c.3909C>G)

This assay detects thirty-two mutations, including the twenty-three core mutations recommended by the American College of Medical Genetics (ACMG) and the American Congress of Obstetricians and Gynecologists (ACOG) for population-based CF carrier screening. In addition to the ACMG/ACOG panel, this assay detects nine additional mutations. While these mutations are rare in the US population, the scientific and medical literature indicates that these mutations are not benign polymorphisms. The status of the intron 9 (formerly intron 8) polyT tract is reported only when the R117H mutation is detected.

Method SEE NOTE QCRL

The mutations are detected by multiplex-polymerase chain reaction (PCR) amplification of specific CF gene regions, followed by nucleotide sequence analysis on a massively parallel sequencing platform. Although rare, false positive or false negative results may occur. All results should be interpreted in the context of clinical findings, relevant history, and other laboratory data.

Reviewer SEE NOTE QCRL

TEST RESULTS ENTERED BY SUJATA MOHANTY

For additional information, please refer to http://education.questdiagnostics.com/faq/cfscreen (This link is being provided for informational/educational purposes only.)

This test was developed and its analytical performance characteristics have been determined by Quest Diagnostics Nichols Institute San Juan Capistrano. It has not been cleared or approved by FDA. This assay has been validated pursuant to the CLIA regulations and is used for clinical purposes.

Test Performed at:
Quest Diagnostics Nichols Institute
33608 Ortega Highway
San Juan Capistrano, CA 92675-2042 I Maramica MD, PhD, MBA

Performing Site

QCRL: QUEST DIAGNOSTICS REFERENCE LAB CAPISTRANO 33608 Ortega Highway San Juan Capistrano CA 92675

LAB: L - LOW, H - HIGH, AB - ABNORMAL, C - CRITICAL, . - NOT TESTED

D222000002 WX0000003039 Printed D&T: 12/22/21 16:32 Ordered By: CLIENT CLIENT WX0000000000001595

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