Warde Medical Laboratory

TEST DIRECTORY UPDATE

JUNE 2020

Update Notes

Please replace Prenatal Information Sheet with the revised 04/15/20 version included in the update.

Update Summary

Update Existing Test	6/1/2020	AMLNK - "Acute Myeloid Leukemia Prognostic Panel (Normal Karyoype)"
Update Existing Test	6/29/2020	C5C - "Complement Component C5"
Update Existing Test	5/26/2020	COV2G - "SARS Coronavirus 2 IgG Antibody"
Update Existing Test	6/1/2020	FLT3M - "LeukoStrat CDx FLT3 Mutation Assay"
Update Existing Test	6/1/2020	FLUOR - "Fluoride, Serum/Plasma"
Update Existing Test	6/15/2020	HHQ - "Hemochromatosis, Hereditary"
Update Existing Test	6/22/2020	TESFM - "Testosterone (TMS), Female/Ped"
Update Existing Test	6/22/2020	TFTLC - "Testosterone, Free (Dialysis) and Total .LC/MS/MS"
Update Existing Test	6/15/2020	YCMIC - "Y Chromosome Microdeletion, DNA Analysis"
Inactivate Test With Replacement	6/23/2020	CKITM - "C-KIT Mutation Analysis, Cell-Based" replaced by CKMAC - "C-KIT Mutation Analysis, Cell-Based"

Update Existing Test

Effective Date	6/1/2020
Name	Acute Myeloid Leukemia Prognostic Panel (Normal Karyoype)
Code	AMLNK
Interface Order Code	3700155
Legacy Code	AMLNK
Notes	Specimen and Alternate Specimen changes.

Required Testing Changes

Specimen Required	Draw blood in a lavender EDTA tube and a green sodium heparin tube. Send 5.0 mL whole blood (3.0 mL minimum) collected in EDTA and 5.0 mL whole blood (3.0 mL minimum) in green sodium heparin. Send room temperature. **Test requires both specimens.**
Alternate Specimen	**Bone marrow:** 3.0 mL bone marrow (1.0 mL minimum) collected in lavender EDTA **AND** 3.0 mL bone marrow (1.0 mL minimum) collected in green sodium heparin. **Cell Pellet:** Requires cell pellet **AND** whole blood or bone marrow collected in lavender EDTA **AND** green sodium heparin.

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Update Existing Test

Effective Date	6/29/2020
Name	Complement Component C5
Code	C5C
Interface Order Code	3420120
Legacy Code	C5CQ
Notes	Days performed change.

Required Testing Changes

Performed Days	**Tuesday, Thursday, Saturday**

Update Existing Test

Effective Date	5/26/2020
Name	SARS Coronavirus 2 IgG Antibody
Code	COV2G
Interface Order Code	3000068
Legacy Code	COV2G
Notes	Updated LOINC.

Required Testing Changes

Result Code	Name	LOINC Code	AOE/Prompt[2]
3000068	SARS Coronavirus 2 IgG Antibody	**94563-4**	No

Update Existing Test

Effective Date	6/1/2020
Name	LeukoStrat CDx FLT3 Mutation Assay
Code	FLT3M
Interface Order Code	3741029
Legacy Code	FLT3M
Notes	Specimen and Alternate specimen changes. Updated Rejection Criteria.

Required Testing Changes

Specimen Required	Draw blood in **green sodium heparin tube**. Send 2.0 mL whole blood (1.0 mL minimum) refrigerated.
Alternate Specimen	Bone Marrow: 0.5 mL (0.25 minimum), **green sodium heparin**
Rejection Criteria	Specimen collected with anticoagulant other than sodium heparin.

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Update Existing Test	
Effective Date	6/1/2020
Name	Fluoride, Serum/Plasma
Code	FLUOR
Interface Order Code	3515280
Legacy Code	FLUOR
Notes	Stability changes.
Required Testing Changes	
Stability	Room Temperature: 30 days; Refrigerated: 30 days; **Frozen: 28 months**

Update Existing Test	
Effective Date	6/15/2020
Name	Hemochromatosis, Hereditary
Code	HHQ
Interface Order Code	3426000
Legacy Code	HHQ
Notes	Alternate specimen changes and performed days.
Required Testing Changes	
Alternate Specimen	Whole Blood: **green sodium heparin or yellow ACD tube**
Performed Days	**Monday - Saturday**
Turnaround Time	**9 – 11 days**

Update Existing Test	
Effective Date	6/22/2020
Name	Testosterone (TMS), Female/Ped
Code	TESFM
Interface Order Code	3719140
Legacy Code	TMSTESFEM
Notes	Changes to the volume and minimum volume. Clarification of the alternate specimen.
Required Testing Changes	
Specimen Required	Draw blood in a red-top tube. Centrifuge, separate and send **1.0 mL serum (0.5 mL minimum)** refrigerated in a screw-capped plastic vial.
Alternate Specimen	**Plasma: Sodium or lithium heparin**

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Update Existing Test	
Effective Date	6/22/2020
Name	Testosterone, Free (Dialysis) and Total .LC/MS/MS
Code	TFTLC
Interface Order Code	3723600
Legacy Code	TFTLC
Notes	Specimen volume changes and Alternate specimen updated.
Required Testing Changes	
Specimen Required	Draw blood in a red-top tube (no gel). Centrifuge, remove serum from cells and send **1.8 mL serum** (**0.9 mL minimum**) refrigerated in a screw-capped plastic vial.
Alternate Specimen	**Plasma: Sodium or Lithium heparin**
Performing Laboratory	Quest Valencia

Update Existing Test	
Effective Date	6/15/2020
Name	Y Chromosome Microdeletion, DNA Analysis
Code	YCMIC
Interface Order Code	3428900
Legacy Code	YCMIC
Notes	Alternate specimens updated.
Required Testing Changes	
Alternate Specimen	Whole Blood: **Yellow ACD or green sodium heparin**

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TEST DIRECTORY UPDATE

JUNE 2020

Inactivate Test With Replacement

Effective Date	6/23/2020

Inactivated Test

Name	C-KIT Mutation Analysis, Cell-Based
Code	CKITM
Legacy Code[1]	CKITM
Interface Order Code	3433600
Notes	

Replacement Test

Name	C-KIT Mutation Analysis, Cell-Based
Code	CKMAC
CPT Code(s)	81272 ZBOPJ
Notes	

Specimen Requirements

Specimen Required	Draw blood in a lavender EDTA, Send 3.0 mL whole blood (1.0 mL minimum) room temperature in a screw-capped plastic vial.
Alternate Specimen	Bone marrow: EDTA; Tissue: Formalin fixed, paraffin embedded
Rejection Criteria	
Stability	Whole Blood/Bone Marrow: Room temperature: 7 days; Refrigerated: 14 days; Frozen: Unacceptable Tissue: Room temperature: Indefinite: Refrigerated: Indefinite; Frozen: Unacceptable

Performing Information

Methodology	Polymerase Chain Reaction (PCR)
Reference Range	Not detected
Performed Days	Monday, Thursday
Turnaround Time	5 - 7 days
Performing Laboratory	Quest SJC

Interface Information

Legacy Code[1]	CKMAC
Interface Order Code	3400266

Result Code	Name	LOINC Code	AOE/Prompt[2]
3400267	c-KIT Specimen Source	31208-2	**Yes**
3400268	Paraffin Block #	57723-9	**Yes**
3400269	C-KIT Mutation, Cell-based	55201-8	No

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000003039 M 12/05/1988 31 Y

Referral Testing

Collected: 05/22/2020 13:11 Received: 05/22/2020 13:11

Test Name	Result	Flag	Ref-Ranges	Units	Site
c-KIT Mutation Analysis, Cell Based					
c-KIT Specimen Source	Whole Blood				QCRL
Paraffin Block #	20-123456				QCRL
C-KIT Mutation, Cell-based	**DETECTED**	**AB**			QCRL

Reference Range:
NOT DETECTED

Activating c-kit mutations have been identified in various human cancers. The mutations are not detected in normal individuals. C-kit exon 8 and 17 mutations have been described in patients with CBF-AMLs and usually confer a poor prognosis with increased relapse rate. C-kit exon 9, 11, 13, 17 mutations have been reported in 90% GIST patients. The presence of a mutation usually predicts poor survival. C-kit exon 17 mutation has been reported in patients with systemic mastocytosis.

Except for D816V mutation, most other mutations are believed to be sensitive to Gleevec therapy.

The sensitivity of this sequencing assay is 20% of mutant cell in the background of normal cells.

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 92690-6130 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

Warde Medical Laboratory

Physician Name_____
Phone (_____) _____-_____
Fax (_____) _____-_____

Place SOFT Media Label Here

Prenatal Information Sheet

☐ ***QUAD*** (15w,0d to 22w,6d) ☐ ***MSAFP*** AFP single marker – NTD only (15w,0d to 22w,6d) ☐ ***SI1*** Serum Integrated Screen Part 1 (10w,0d to 13w,6d) ☐ ***SI2*** Serum integrated Screen Part 2 (15w,0d to 22w,6d)	**NT measurement *required* for the following tests:** ☐ ***FTS*** First Trimester Screen (CRL 42 to 79.9 mm) ☐ ***SS1*** Sequential Screen Part 1 (CRL 36 to 79.9 mm) ☐ ***SS2*** Sequential Screen Part 2 (15w,0d to 22w,6d) ☐ ***FI1NT*** Full Integrated Screen Part 1 (CRL 32 to 79.9 mm) ☐ ***FI2NT*** Full Integrated Screen Part 2 (15w,0d to 22w,6d)

Section I – Required Patient Information

Please fill out completely and send with sample to ensure timely results.

Name: _____ Date of Birth: _____/_____/_____

- Weight: _____lbs. (Weight is ***required*** for risk assessment)
- Race: ☐ White ☐ Black ☐ Hispanic ☐ Other
- Insulin Dependent Diabetic? ☐ Yes ☐ No (Select Yes if patient was on insulin ***prior*** to this pregnancy; otherwise, select No)
- Does the patient currently smoke cigarettes? ☐ Yes ☐ No
- Has the patient had a previous pregnancy/child with a Neural Tube Defect? ☐ Yes ☐ No • If yes, when? _____
- Has the patient had a previous pregnancy/child with Down syndrome? ☐ Yes ☐ No • If yes, at what age? _____
- Is this an IVF pregnancy? ☐ Yes ☐ No •If yes, were donor eggs used? ☐ Yes ☐ No
  - What is the donor's DOB or age at retrieval? _____
- Is this a repeat screen for the ***current*** pregnancy? ☐ Yes ☐ No

Section II – QUAD, MSAFP or Serum Integrated Screening

EDD _____/_____/_____ based on ☐ Ultrasound ☐ LMP ☐ Exam DATING IS UNCERTAIN ☐

Note: Ultrasound improves screening performance

Number of Fetuses: ☐ Singleton ☐ Twins ☐ Unknown (Risk estimates are not available for triplets)

Section III – First Trimester, Full Integrated or Sequential Screening

Date of Ultrasound _____/_____/_____

CRL (mm) _____

NT (mm) _____

N.B. ☐ Yes ☐ No ☐ Unable to report

Name or Certification # of Sonographer _____

Note: Sonographer ***must*** be certified through either FMF or NTQR.

If Twins:

CRL Twin B (mm) _____

NT Twin B (mm) _____

N.B. Twin B ☐ Yes ☐ No ☐ Unable to report

☐ Monochorionic ☐ Dichorionic

300 W. Textile Road
Ann Arbor, MI 48108
Phone (800)760-9969
Fax (734) 214-0399

Please have blood drawn between

_____/_____/_____ **&** _____/_____/_____

Revised 04/15/2020