Warde Medical Laboratory

TEST DIRECTORY UPDATE

SEPTEMBER 2022 UPDATE A

Update Notes

Update Summary		
Update Existing Test	9/27/2022	BLQA - "MyVista® Blastomyces QN Antigen EIA"
Update Existing Test	9/20/2022	CORTS - "Cortisol, Saliva, LC/MS/MS"
Update Existing Test	9/20/2022	INHA - "Inhibin A"
Update Existing Test	9/12/2022	MIXAM - "Microsporidia Exam"
Update Existing Test	9/20/2022	MVHIS - "Histoplasma Quantitative Antigen EIA"
Update Existing Test	9/12/2022	PARID - "Parasite Identification"
Inactivate Test With Replacement	9/12/2022	BVVSS - "Bacterial Vaginosis/Vaginitis, SureSwab®" replaced by VATMA - "SureSwab® Advanced Vaginitis, TMA"
Inactivate Test With Replacement	9/12/2022	CRYDE - "Cryptosporidium Antigen Detect" replaced by CRYSP - "Cryptosporidium Antigen, EIA"
Inactivate Test With Replacement	9/12/2022	CYCIE - "Cyclospora and Isospora Examination" replaced by CYIEL - "Cyclospora and Isospora Examination"
Inactivate Test With Replacement	9/12/2022	GACAP - "Giardia and Crytosporidium Antigen Panel" replaced by GACAG - "Giardia and Cryptosporidium Ag Panel"
Inactivate Test With Replacement	9/12/2022	GLAG - "Giardia lamblia Antigen" replaced by GAESL - "Giardia Antigen, EIA, Stool"
Inactivate Test With Replacement	9/20/2022	HERNF - "HER-2/NEU (FISH)" replaced by HERFI - "FISH, HER-2/neu, Paraffin Block"
Inactivate Test With Replacement	9/12/2022	OAPCP - "Ova and Parasites, Concentrate and Permanent Smear" replaced by OPCPS - "Ova and Parasites, Conc. and Perm Smear"
Inactivate Test With Replacement	9/27/2022	PAI1G - "Plas Act Inhib (PAI-1) Genotype" replaced by PAIIP - "Plasminogen Activator Inhibitor-1 (PAI-1) 4G/5G"

Warde Medical Laboratory

TEST DIRECTORY UPDATE

SEPTEMBER 2022 UPDATE A

Update Existing Test	
Effective Date	9/27/2022
Name	MyVista® Blastomyces QN Antigen EIA
Code	BLQA
Interface Order Code	3700035
Legacy Code	BLQA
Notes	Updates to turnaround time.
Required Testing Changes	
Turnaround Time	**6 - 8 days**

Update Existing Test	
Effective Date	9/20/2022
Name	Cortisol, Saliva, LC/MS/MS
Code	CORTS
Interface Order Code	3511840
Legacy Code	CORTSAL
Notes	Updates to stability.
Required Testing Changes	
Stability	**Room temperature: 3 days** Refrigerated: 21 days **Frozen: 6 months**

Update Existing Test	
Effective Date	9/20/2022
Name	Inhibin A
Code	INHA
Interface Order Code	3708470
Legacy Code	INHIBINSP
Notes	Updates to stability.
Required Testing Changes	
Stability	**Room temperature: 14 days** **Refrigerated: 14 days** Frozen: 28 days

Warde Medical Laboratory

TEST DIRECTORY UPDATE

SEPTEMBER 2022 UPDATE A

Update Existing Test	
Effective Date	9/12/2022
Name	Microsporidia Exam
Code	MIXAM
Interface Order Code	3700096
Legacy Code	MIXAM
Notes	Update to performing laboratory.
Required Testing Changes	
Performing Laboratory	**Quest SJC**

Update Existing Test	
Effective Date	9/20/2022
Name	Histoplasma Quantitative Antigen EIA
Code	MVHIS
Interface Order Code	3432600
Legacy Code	MVHIS
Notes	Updates to turnaround time.
Required Testing Changes	
Turnaround Time	**6 - 8 days**

Update Existing Test	
Effective Date	9/12/2022
Name	Parasite Identification
Code	PARID
Interface Order Code	3427500
Legacy Code	PARIQ
Notes	Updates to specimen requirements, stability and rejection criteria.
Required Testing Changes	
Specimen Required	*Collect:* **Suspect nematode, cestode, trematode or other parasite** *Specimen Preparation:* Submit tapeworm in saline and other parasites in 70% alcohol **as soon as possible** in a screw capped plastic container that is **leak proof**. Specify specimen source.
Rejection Criteria	Stool sample, frozen sample, **pinworm paddle, arthropods**
Stability	**Room temperature: Dependant on organism integrity** **Refrigerated: Dependant on organism integrity** Frozen: Unacceptable

Inactivate Test With Replacement	
Effective Date	9/12/2022
Inactivated Test	
Name	Bacterial Vaginosis/Vaginitis, SureSwab®
Code	BVVSS
Legacy Code[1]	BVVSS
Interface Order Code	3400317
Notes	
Replacement Test	
Name	SureSwab® Advanced Vaginitis, TMA
Code	VATMA
CPT Code(s)	81513, 87481 x 2, 87661
Notes	
Specimen Requirements	
Specimen Required	*Collect:* Vaginal swab *Specimen Preparation:* Collect one vaginal swab. Follow instructions in the Aptima® Multitest Collection Kit (Orange Label). *Minimum Volume:* 1 swab *Transport Temperature:* Room temperature
Rejection Criteria	Transport tubes: *with no swab *with 2 swabs *with non-Aptima® swabs *submitted with swab inverted Samples submitted: *with excess mucus *in Aptima® tubes with pierced lids *in broken containers *in leaking containers *with Swab in viral transport media
Stability	Room temperature: 30 days Refrigerated: 30 days Frozen: 60 days

Performing Information	
Methodology	Transcription Mediated Amplification (TMA)
Reference Range	SureSwab® Adv Bacterial Vaginosis (BV), TMA — Negative Candida species — Not detected Candida glabrata — Not detected *Trichomonas vaginalis* (TV), TMA — Not detected
Performed Days	Sunday - Saturday
Turnaround Time	2 - 4 days
Performing Laboratory	Quest SJC
Interface Information	
Legacy Code[1]	VATMA
Interface Order Code	3400683

Result Code	Name	LOINC Code	AOE/Prompt[2]
3400684	SureSwab® Advanced Bacterial Vaginosis (BV), TMA	94420-7	No
3400685	Candida Species	47000-5	No
3400686	Candida glabrata	94421-5	No
3400687	Trichomonas vaginalis	46154-1	No

Warde Medical Laboratory

LABORATORY REPORT

QC ACCOUNT (WARDE)
300 W. TEXTILE
ANN ARBOR MI 48108

EXAMPLE, REPORT
WX0000003481 F 12/08/1988 33 Y

Referral Testing

Collected: 09/08/2022 13:25 Received: 09/08/2022 13:25

Test Name	Result	Flag	Ref-Ranges	Units	Site
SureSwab Advanced Vaginitis, TMA					
SureSwab® Advanced Bacterial Vaginosis (BV), TMA	**POSITIVE**	**AB**			QCRL

REFERENCE RANGE: NEGATIVE

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

Candida Species	**DETECTED**	**AB**			QCRL
Candida glabrata	**DETECTED**	**AB**			QCRL

C. glabrata, which is responsible for the majority of non-albicans CV in the U.S., may have decreased susceptibility to standard antimycotic therapeutic intervention compared to C. albicans.

REFERENCE RANGE: NOT DETECTED

Candida species C. albicans, C. tropicalis, C. parapsilosis, and/or C. dubliniensis can be detected but not differentiated, in the Candida spp. result.

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

Trichomonas vaginalis	**DETECTED**	**AB**			QCRL

REFERENCE RANGE: NOT DETECTED

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

Warde Medical Laboratory

LABORATORY REPORT

QC ACCOUNT (WARDE)
300 W. TEXTILE
ANN ARBOR MI 48108

EXAMPLE, REPORT
WX0000003481 F 12/08/1988 33 Y

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

E108000000
WX0000003481
Printed D&T: 09/08/22 14:15

Ordered By: CLIENT CLIENT
WX00000000002063

William G. Finn, M.D. - Medical Director
Form: MM RL1

Warde Medical Laboratory

TEST DIRECTORY UPDATE

SEPTEMBER 2022 UPDATE A

Inactivate Test With Replacement	
Effective Date	9/12/2022
Inactivated Test	
Name	Cryptosporidium Antigen Detect
Code	CRYDE
Legacy Code[1]	CRYDESP
Interface Order Code	3719100
Notes	
Replacement Test	
Name	Cryptosporidium Antigen, EIA
Code	CRYSP
CPT Code(s)	87328
Notes	
Specimen Requirements	
Specimen Required	*Collect:* Stool in Total-Fix® *Specimen Preparation:* Send 10.0 g or 10.0 mL stool in a Total-Fix® transport vial. *Minimum Volume:* 5.0 g or 5.0 mL *Transport Temperature:* Room temperature
Alternate Specimen	Stool: Cary-Blair media or 10% formalin
Rejection Criteria	Stool in PVA, concentrated specimens. Unpreserved stool.
Stability	Room temperature: 18 months Refrigerated: Unacceptable Frozen: Unacceptable
Performing Information	
Methodology	Immunoassay
Reference Range	Not detected
Performed Days	Tuesday, Thursday, Saturday
Turnaround Time	3 - 5 days
Performing Laboratory	Quest SJC
Interface Information	
Legacy Code[1]	CRYSP

Interface Order Code	3400607		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt²**
3400607	Cryptosporidium Antigen, EIA	6371-9	No

Warde Medical Laboratory

LABORATORY REPORT

QC ACCOUNT (WARDE)
300 W. TEXTILE
ANN ARBOR MI 48108

EXAMPLE, REPORT
WX0000003481 F 12/08/1988 33 Y

Referral Testing

Collected: 09/08/2022 14:17 Received: 09/08/2022 14:17

Test Name	Result	Flag	Ref-Ranges	Units	Site
Cryptosporidium Antigen, EIA	NOT DETECTED				QCRL

REFERENCE RANGE: NOT DETECTED

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

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

E108000005
WX0000003481
Printed D&T: 09/08/22 14:18

Ordered By: CLIENT CLIENT
WX00000000002063

William G. Finn, M.D. - Medical Director
Form: MM RL1

Inactivate Test With Replacement	
Effective Date	9/12/2022
Inactivated Test	
Name	Cyclospora and Isospora Examination
Code	CYCIE
Legacy Code[1]	CYCIE
Interface Order Code	3700457
Notes	
Replacement Test	
Name	Cyclospora and Isospora Examination
Code	CYIEL
CPT Code(s)	87207, 87015
Notes	
Specimen Requirements	
Specimen Required	*Patient Preparation:* Stool must not contain barium from diagnostic procedures. *Collect:* Stool in Total-Fix® *Specimen Preparation:* Place 10.0 g in a Total-Fix® vial within 30 minutes of collection. Fill to the line on the transport vial. *Minimum Volume:* 5.0 g or 5.0 mL *Transport Temperature:* Room Temperature
Alternate Specimen	Stool: 10% formalin
Rejection Criteria	Received frozen. Unpreserved stool. Stool specimens preserved in transport media not listed as acceptable
Stability	Room temperature: 6 months Refrigerated: Not recommended Frozen: Unacceptable
Performing Information	
Methodology	Microscopic Exam of Modified Acid-Fast Stain
Reference Range	See report
Performed Days	Sunday - Saturday
Turnaround Time	6 - 8 days

Performing Laboratory	Quest SJC		
Interface Information			
Legacy Code[1]	CYIEL		
Interface Order Code	3400672		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3400675	Cyclospora Exam	10656-7	No
3400676	Isospora Exam	10656-7	No

Warde Medical Laboratory

LABORATORY REPORT

QC ACCOUNT (WARDE)
300 W. TEXTILE
ANN ARBOR MI 48108

EXAMPLE, REPORT
WX0000003481 F 12/08/1988 33 Y

Referral Testing

Collected: 09/08/2022 14:18 Received: 09/08/2022 14:18

Test Name	Result	Flag	Ref-Ranges	Units	Site
Cyclospora and Isospora Examination					
Cyclospora Exam	NOT DETECTED				QCRL
Isospora Exam	NOT DETECTED				QCRL

REFERENCE RANGE: NOT DETECTED

Test performed using a Modified Acid-Fast Smear.

NOTE: Due to intermittent shedding, one negative sample does not necessarily rule out the presence of a parasitic infection.

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

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

E108000006
WX0000003481
Printed D&T: 09/08/22 14:19

Ordered By: CLIENT CLIENT
WX00000000002063

William G. Finn, M.D. - Medical Director
Form: MM RL1

Inactivate Test With Replacement	
Effective Date	9/12/2022
Inactivated Test	
Name	Giardia and Crytosporidium Antigen Panel
Code	GACAP
Legacy Code[1]	GACAP
Interface Order Code	3700511
Notes	
Replacement Test	
Name	Giardia and Cryptosporidium Ag Panel
Code	GACAG
CPT Code(s)	87328, 87329
Notes	
Specimen Requirements	
Specimen Required	*Patient Preparation:* The patient must not use barium products, antacids, antidiarrheal medications, or laxatives containing oil prior to collection of a specimen for parasitological exam. *Collect:* Stool in Total-Fix® *Specimen Preparation:* Send 10.0 g or 10.0 mL preserved stool in a Total-Fix® transport vial. Stool should be placed in preservative within 30 minutes of collection. Fill to the line on transport vial. Mix contents thoroughly until homogenous. *Minimum Volume:* 5.0 g or 5.0 mL *Transport Temperature:* Room temperature
Alternate Specimen	Stool in 10% formalin (Add formalin to cover stool sample)
Rejection Criteria	Unpreserved stool; Stool specimens that have been previously concentrated; Stool specimens preserved Cary-Blair, PVA, or SAF.
Stability	Room temperature: 60 days Refrigerated: Unacceptable Frozen: Unacceptable
Performing Information	
Methodology	Immunoassay
Reference Range	See report

Performed Days	Tuesday, Thursday, Saturday		
Turnaround Time	3 - 5 days		
Performing Laboratory	Quest SJC		
Interface Information			
Legacy Code[1]	GACAG		
Interface Order Code	3400658		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3400660	Specimen Source	31208-2	**Yes**
3400661	Cryptosporidium Ag, EIA	Not available	No
3400663	Giardia Ag, EIA, Stool	6412-1	No

Warde Medical Laboratory

LABORATORY REPORT

QC ACCOUNT (WARDE)
300 W. TEXTILE
ANN ARBOR MI 48108

EXAMPLE, REPORT
WX0000003481 F 12/08/1988 33 Y

Referral Testing

Collected: 09/08/2022 14:20 Received: 09/08/2022 14:20

Test Name	Result	Flag	Ref-Ranges	Units	Site
Giardia and Cryptosporidium Ag Panel					
Specimen Source	STOOL				QCRL
Cryptosporidium Ag, EIA	**DETECTED**	**AB**			QCRL

REFERENCE RANGE: NOT DETECTED

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

Giardia Ag, EIA, Stool	**DETECTED**	**AB**			QCRL

REFERENCE RANGE: NOT DETECTED

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

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

E108000007
WX0000003481
Printed D&T: 09/08/22 14:22

Ordered By: CLIENT CLIENT
WX00000000002063

William G. Finn, M.D. - Medical Director
Form: MM RL1

Inactivate Test With Replacement	
Effective Date	9/12/2022
Inactivated Test	
Name	Giardia lamblia Antigen
Code	GLAG
Legacy Code[1]	GLAGSP
Interface Order Code	3715150
Notes	
Replacement Test	
Name	Giardia Antigen, EIA, Stool
Code	GAESL
CPT Code(s)	87329
Notes	
Specimen Requirements	
Specimen Required	*Collect:* Stool in Total-Fix® vial *Specimen Preparation:* Send 10.0 g or 10 mL stool in a Total-Fix® vial. Stool should be placed in preservative within 30 minutes of collection. Fill to line on transport vial and mix contents thoroughly. *Minimum Volume:* 5.0 g or 5.0 mL *Transport Temperature:* Total-Fix: Room temperature Cary-Blair: Refrigerated (Cold Packs) Unpreserved: Frozen
Alternate Specimen	10% formalin transport vial Stool in Cary Blair media Unpreserved stool
Rejection Criteria	Concentrated fecal specimens. Stool in transport media that is not listed above. Swab
Stability	**Total-Fix** Room temperature: 14 days Refrigerated: 7 days Frozen: Unacceptable **10% formalin** Room temperature: 18 months Refrigerated: 7 days Frozen: Unacceptable

	Cary-Blair Room temperature: Unacceptable Refrigerated: 7 days Frozen: 7 days **Unpreserved:** Room temperature: Unacceptable Refrigerated: 48 hours Frozen: 14 days
Performing Information	
Methodology	Immunoassay
Reference Range	See report
Performed Days	Sunday - Saturday
Turnaround Time	3 - 4 days
Performing Laboratory	Quest SJC
Interface Information	
Legacy Code[1]	GAESL
Interface Order Code	3400667

Result Code	Name	LOINC Code	AOE/Prompt[2]
3400668	Source:	31208-2	**Yes**
3400670	Giardia Result:	6412-1	No

Warde Medical Laboratory

LABORATORY REPORT

QC ACCOUNT (WARDE)
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ANN ARBOR MI 48108

EXAMPLE, REPORT
WX0000003481 F 12/08/1988 33 Y

Referral Testing

Collected: 09/08/2022 14:23 Received: 09/08/2022 14:23

Test Name	Result	Flag	Ref-Ranges	Units	Site
Giardia Antigen, EIA, Stool					
Source:	STOOL				QCRL
Giardia Result:	NOT DETECTED				QCRL

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

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

E108000008
WX0000003481
Printed D&T: 09/08/22 14:23

Ordered By: CLIENT CLIENT
WX00000000002063

William G. Finn, M.D. - Medical Director
Form: MM RL1

Inactivate Test With Replacement	
Effective Date	9/20/2022
Inactivated Test	
Name	HER-2/NEU (FISH)
Code	HERNF
Legacy Code[1]	HER2NRFISH
Interface Order Code	3503257
Notes	
Replacement Test	
Name	FISH, HER-2/neu, Paraffin Block
Code	HERFI
CPT Code(s)	88377
Notes	
Specimen Requirements	
Specimen Required	*Collect:* Formalin fixed, paraffin embedded tissue *Specimen Preparation:* Send formalin fixed paraffin embedded tissue. Specimen must be fixed in 10% neutral buffered formalin. Fixation between 6 and 72 hours and cold ischemic time of less than 1 hour is recommended. Pathology report must be included with specimen. *Transport Temperature:* Room temperature
Alternate Specimen	5 micron (4 micron minimum) sections collected on each of 6 charged slides
Rejection Criteria	Non-invasive breast tumors
Stability	Room temperature: Dependent on sample sent Refrigerated: Dependent on sample sent Frozen: Unacceptable* ***Do not freeze. Do not reject.**
Performing Information	
Methodology	Fluorescence in situ Hybridization (FISH)
Reference Range	See report
Performed Days	Sunday - Saturday
Turnaround Time	6 - 7 days
Performing Laboratory	Quest SJC
Interface Information	
Legacy Code[1]	HERFI

Interface Order Code	3400678		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt²**
3400679	Specimen Type/Source	31208-2	**Yes**
3400680	HER-2/neu, FISH	31150-6	No
3400681	Clinical info	55752-0	**Yes**

Warde Medical Laboratory

LABORATORY REPORT

QC ACCOUNT (WARDE)
300 W. TEXTILE
ANN ARBOR MI 48108

EXAMPLE, REPORT
WX0000003481 F 12/08/1988 33 Y

Referral Testing

Collected: 09/08/2022 14:24 Received: 09/08/2022 14:24

Test Name	Result	Flag	Ref-Ranges	Units	Site
FISH, HER-2/neu, Paraffin Block					
Specimen Type/Source	Breast Tissue				QCRL
HER-2/neu, FISH	SEE NOTE				QCRL

Order ID: 21-12345

Specimen Type: Tissue

Clinical Indication: Invasive lobular carcinoma

RESULT:
HER2 GENETIC HETEROGENEITY IS PRESENT (SEE COMMENTS BELOW)

Amplified area:
HER2/D17Z1 ratio: 3.8
Average HER2 copy number: 6.8 signals/cell
Average D17Z1 copy number: 1.8 signals/cell

Non-amplified area:

HER2/D17Z1 ratio: 1.3
Average HER2 copy number: 3.2 signals/cell
Average D17Z1 copy number: 2.5 signals/cell

INTERPRETATION:
This FISH assay revealed HER2 (ERBB2) amplification of aggregated cells in a distinct population representing approximately 10% of the tumor cells. The remaining tumor cells were negative for HER2 amplification. Histopathologic correlation is indicated.

The CAP/ASCO guidelines recommend HER2 testing on every primary invasive breast cancer and on metastatic sites, if tissue is available.
Please expect the results of any other concurrent study in a separate report.

Image analysis method: Manual
Cells Counted: 40

SAMPLE INFORMATION:

Block ID: S21-5678 A1

Specimen site: Right Breast

QC ACCOUNT (WARDE)
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ANN ARBOR MI 48108

EXAMPLE, REPORT
WX0000003481 F 12/08/1988 33 Y

Referral Testing

Collected: 09/08/2022 14:24 Received: 09/08/2022 14:24

Test Name	Result	Flag	Ref-Ranges	Units	Site

Specimen type: Core Biopsy

Cold ischemic time: Less than 1 hour

Type of fixation: Formalin

Duration of fixation: 6-72 hours

Type of tissue processing: Not provided

IHC result for HER2 overexpression: Not available

NOMENCLATURE:
Amplified area: nuc ish(D17Z1x1-3,HER2x3-17)(20)
Non-amplified area: nuc ish(D17Z1x1-4,HER2x2-4)(20)

ASSAY INFORMATION:
According to the CAP/ASCO guidelines (J Clin Oncol. 2018 Jul 10;36(20):2105-2122. PMID: 29846122):

- A ratio of >/=2.0 and an average HER2 copy number >/=4.0 in >10% of tumor cells indicates amplification.
- A ratio of <2.0 and an average HER2 copy number <4.0 indicates absence of amplification.
- Any other FISH result should be reviewed together with the IHC result using sections from the same tissue sample used for FISH.

Slides from this sample were evaluated by an in-house pathologist and deemed adequate for HER2 FISH analysis by evaluating the invasive tumor per ASCO/CAP guidelines. Controls provided the anticipated results. This case was reviewed by at least 2 observers. Note that improper handling and fixation could affect the results if the cold ischemic time is > 1 hour, or if the fixation time is < 6 hours or > 72 hours. Results from this test are intended for use as an adjunct to existing clinical and pathologic information currently used as prognostic factors in patients with invasive breast carcinoma. The performance of this test has not been fully investigated for other tumors. Clinical correlation is recommended. This test is also indicated as an aid in the assessment of patients for whom HER2 targeted therapy (e.g. Herceptin; Trastuzumab) is being considered.

This fluorescence in situ hybridization (FISH) test was performed using the probes specific for the HER2 (ERBB2; 17q12) and the D17Z1 (CEN-17; centromeric region of chromosome 17) loci (DAKO HER2 IQFISH pharmDx Kit).

The analytical performance characteristics of this assay have been determined by Quest Diagnostics Nichols Institute, San Juan

Warde Medical Laboratory

LABORATORY REPORT

QC ACCOUNT (WARDE)
300 W. TEXTILE
ANN ARBOR MI 48108

EXAMPLE, REPORT
WX0000003481 F 12/08/1988 33 Y

Referral Testing

Collected: 09/08/2022 14:24 Received: 09/08/2022 14:24

Test Name	Result	Flag	Ref-Ranges	Units	Site

Capistrano, CA. The modifications have not been cleared or approved by the U.S. Food and Drug Administration. This assay has been validated pursuant to the CLIA regulations and is used for clinical purposes.

Fatih Z. Boyar, MD, FACMG (800) NICHOLS-4307
Alireza Bazooband, MD, FCAP, FASCP

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

Clinical info Not provided QCRL

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

Inactivate Test With Replacement	
Effective Date	9/12/2022
Inactivated Test	
Name	Ova and Parasites, Concentrate and Permanent Smear
Code	OAPCP
Legacy Code[1]	OAPCP
Interface Order Code	3700502
Notes	
Replacement Test	
Name	Ova and Parasites, Conc. and Perm Smear
Code	OPCPS
CPT Code(s)	87209, 87177
Notes	
Specimen Requirements	
Specimen Required	*Patient Preparation:* Interfering substances: Bismuth, Barium (wait 7 - 10 days), Antimicrobial agents (wait 2 weeks), Gallbladder dye (wait 3 weeks after procedure) *Collect:* Stool *Specimen Preparation:* Place 10.0 g or 10.0 mL stool in a Total-Fix® vial within 30 minutes of collection. *Minimum Volume:* Stool: 5.0 g or 5.0 mL Urine: 10.0 mL Sputum or BAL: 2.0 mL *Transport Temperature:* Stool, sputum, and BAL (preserved): Room temperature Urine, sputum, and BAL (unpreserved): Refrigerated
Alternate Specimen	Para-Pak SVT transport vial. Stool preserved in 10% formalin and polyvinyl alcohol transport. Urine: Send 25.0 mL urine in sterile screw capped container. **Note:** Urine maybe submitted unpreserved for exam for Schistosoma. Collect at mid-day. Peak egg secretion occurs between noon and 3 pm. **DO NOT SUBMIT FIRST MORNING SPECIMEN.** In patients with hematuria, eggs may be found in last voided portion of urine specimens. Sputum: Send 10.0 mL sputum in a sterile screw capped container or with 10% formalin. Specimen should be a deep expectorated sputum preferably collected in early morning. 24-hour sputum collection is also acceptable.

Rejection Criteria	Unpreserved stool. Specimens containing barium. Stool preserved in medium other than parasitology fixative. Specimens received frozen. Stool submitted in expired transport vial. Preserved urine. Unpreserved sputum and urine received room temperature or frozen. Liver abscess or aspirate. ECOFIX® transport vials.
Stability	**Stool (preserved)** Room temperature: 6 months Refrigerated: 6 months Frozen: Unacceptable **Urine, Sputum, BAL (unpreserved)** Room temperature: Unacceptable Refrigerated: 48 hours Frozen: Unacceptable **Sputum, BAL (preserved)** Room temperature: 6 months Refrigerated: Unacceptable Frozen: Unacceptable

Performing Information			
Methodology	Microscopic Examination of Concentrate, Permanent Stained Smear		
Reference Range	No ova and parasites seen		
Performed Days	Sunday - Saturday		
Turnaround Time	6 - 8 days		
Performing Laboratory	Quest SJC		
Interface Information			
Legacy Code[1]	OPCPS		
Interface Order Code	3400652		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3400653	Specimen Source	31208-2	**Yes**
3400658	Trichrome Result	43227-8	No
3400657	Concentrate Result	10701-1	No

Warde Medical Laboratory

LABORATORY REPORT

QC ACCOUNT (WARDE)
300 W. TEXTILE
ANN ARBOR MI 48108

EXAMPLE, REPORT
WX0000003481 F 12/08/1988 33 Y

Referral Testing

Collected: 09/08/2022 14:32 Received: 09/08/2022 14:32

Test Name	Result	Flag	Ref-Ranges	Units	Site
Ova and Parasites, Conc. and Perm Smear					
Specimen Source	STOOL				QCRL
Trichrome Result	NO OVA AND PARASITES SEEN				QCRL
Concentrate Result	NO OVA AND PARASITES SEEN				QCRL

REFERENCE RANGE: NO OVA AND PARASITES SEEN

Routine Ova and Parasite exam may not detect some parasites that occasionally cause diarrheal illness. Cryptosporidium Antigen and/or Cyclospora and Isospora Exam may be ordered to detect these parasites. One negative sample does not necessarily rule out the presence of a parasitic infection.

For additional information, please refer to https://education.questdiagnostics.com/faq/FAQ203 (This link is being provided for informational/ educational purposes only.)

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

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

E108000010
WX0000003481
Printed D&T: 09/08/22 14:37

Ordered By: CLIENT CLIENT
WX00000000002063

William G. Finn, M.D. - Medical Director
Form: MM RL1

Warde Medical Laboratory

TEST DIRECTORY UPDATE

SEPTEMBER 2022 UPDATE A

Inactivate Test With Replacement	
Effective Date	9/27/2022
Inactivated Test	
Name	Plas Act Inhib (PAI-1) Genotype
Code	PAI1G
Legacy Code[1]	PAI1GQ
Interface Order Code	3426020
Notes	
Replacement Test	
Name	Plasminogen Activator Inhibitor-1 (PAI-1) 4G/5G
Code	PAIIP
CPT Code(s)	81400
Notes	
Specimen Requirements	
Specimen Required	*Collect:* Lavender EDTA *Specimen Preparation:* Send 5.0 mL whole blood in original collection tube. Physician attestation required for patient consent if ordering facility is located in KY, DE, FL, GA, IA, MA, MN, NV, NJ, OR, SD or VT or test is performed in MA. *Minimum Volume:* 3.0 mL *Transport Temperature:* Room temperature
Alternate Specimen	Whole blood: Sodium or lithium heparin, ACD A, ACD B
Rejection Criteria	Frozen samples
Stability	Room temperature: 8 days Refrigerated: 8 days Frozen: Unacceptable
Performing Information	
Methodology	Polymerase Chain Reaction and Detection
Reference Range	See report
Performed Days	Wednesday, Saturday
Turnaround Time	8 - 12 days
Performing Laboratory	Quest SJC

Interface Information			
Legacy Code[1]	PAIIP		
Interface Order Code	3400604		
Result Code	**Name**	**LOINC Code**	**AOE/Prompt[2]**
3400605	PAI-1 4G/5G Polymorphism	52752-2	No
3400606	Interpretation	50398-7	No

Warde Medical Laboratory

LABORATORY REPORT

QC ACCOUNT (WARDE)
300 W. TEXTILE
ANN ARBOR MI 48108

EXAMPLE, REPORT
WX0000003481 F 12/08/1988 33 Y

Referral Testing

Collected: 09/08/2022 14:39 Received: 09/08/2022 14:39

Test Name	Result	Flag	Ref-Ranges	Units	Site

Plasminogen Activator Inhibitor - 1 (PAI-1) 4G/5G

PAI-1 4G/5G Polymorphism — SEE NOTE — QCRL

RESULT: 5G/5G (NORMAL)

The 4G variant (AF386492.2:g.837del) in the promoter of the PAI-1 (SERPINE 1) gene is associated with an increase in the level of PAI-1 in plasma, relative to that associated with the normal 5G variant. Increased plasma PAI-1 activity may increase the risk for venous thrombosis and myocardial infarction, especially in the presence of other thrombophilic risk factors.

METHODOLOGY: The 4G/5G variants in the promoter of the PAI-1 gene are detected by Fluorescent PCR amplification and capillary electrophoresis of the products. Since genetic variation and other factors can affect the accuracy of direct mutation testing, these results should be interpreted in light of clinical and familial data.

For assistance with the interpretation of these results, please contact your local Quest Diagnostics genetic counselor or call 1-866-GENEINFO (436-3463).

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.

Interpretation — SEE NOTE — QCRL

INTERPRETATION: This individual is negative for the 4G variant in the PAI-1 (SERPINE1) gene. Increased risk of thrombophilia can be caused by a variety of genetic and non-genetic factors not screened for by this assay.

Laboratory testing supervised and results monitored by Felicitas L. Lacbawan, MD, FCAP, FACMG.

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