

Update Summary		
New Test Activation	9/23/2025	1433P - "14-3-3 eta Protein"
New Test Activation	9/23/2025	TCHPV - "ThinPrep PAP Test with Co-Test HPV"
Update Existing Test	9/9/2025	ALUMS - "Aluminum, Serum"
Update Existing Test	9/15/2025	CFBLD - "Culture, Fungus, Blood"
Update Existing Test	9/9/2025	CLOME - "Clobazam and Metabolite, Serum/Plasma"
Update Existing Test	9/15/2025	CUFUN - "Culture, Fungus, Skin, Hair or Nails"
Update Existing Test	9/15/2025	HEOBA - "Helicobacter pylori Culture with Reflex to Susceptibility"
Update Existing Test	9/15/2025	NOSHN - "Culture, Fungus, Not Hair, Skin, Nails"
Update Existing Test	9/2/2025	OMEGC - "OmegaCheck"

New Test Activation

Effective Date	9/23/2025
Name	14-3-3 eta Protein
Code	1433P
CPT Code(s)	83520
Notes	This test was previously inactivated but is now being offered again. New York DOH Approval Status: Yes

Specimen Requirements

Specimen Required	Collect: Serum Separator Tube (SST) Specimen Preparation: Centrifuge, separate serum from cells and send in a screw capped plastic vial. Minimum Volume: 0.5 mL Transport Temperature: Room temperature
Alternate Specimen	Red top
Stability	Room temperature: 7 days Refrigerated: 7 days Frozen: 1 year

Performing Information

Methodology	Enzyme-linked Immunosorbent Assay (ELISA)
Reference Range	See report
Performed Days	Monday, Wednesday, Friday
Turnaround Time	5 - 9 days
Performing Laboratory	Quest

Interface Information

Legacy Code	1433P		
Interface Order Code	3427700		
Result Code	Name	LOINC Code	AOE/Prompt
3427700	14-3-3 eta Protein	75880-5	No



LABORATORY REPORT

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

EXAMPLE, REPORT

WX0000000237 F 12/05/1988 36 Y

Referral Testing

Collected: 08/22/2025 08:24

Received: 08/22/2025 08:24

<u>Test Name</u>	<u>Result</u>	<u>Flag</u>	<u>Ref-Ranges</u>	<u>Units</u>	<u>Site</u>
14-3-3 eta Protein	<0.2		<0.2	ng/mL	QCRL

The 14-3-3eta protein is a marker of synovial inflammation that is released into synovial fluid and peripheral blood in rheumatoid arthritis (RA) and erosive psoriatic arthritis. One in five RF and CCP seronegative early stage RA patients is found to be positive for 14-3-3eta protein. Patients with active joint RA disease have higher values of 14-3-3eta protein than those with inactive RA or psoriasis without arthritis. 14-3-3eta protein has a 93% specificity in patients with RA. Values ≥ 0.2 ng/mL are elevated and indicative of RA disease or erosive psoriatic arthritis. Values >0.50 ng/mL are associated with more aggressive RA disease and poorer outcomes. Unlike RF and CCP, 14-3-3eta protein is a therapeutically modifiable marker to monitor response to therapy. A decrease in 14-3-3eta protein in response to DMARDs (disease-modifying antirheumatic drugs) and anti-TNF (tumor necrosis factor) drugs indicates better clinical outcomes; an increase is associated with worse outcomes despite apparent clinical remission.

For further information please visit:

<http://www.questdiagnostics.com/testcenter/testguide.action?dc=TS-RmArthPnl>

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

Reported Date: 08/22/2025 08:26 1433P

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

E022000002
WX0000000237

Printed D&T: 08/22/25 08:27

Ordered By: CLIENT CLIENT
WX00000000000336

Kajal V. Sitwala, MD, PhD - Medical Director

Form: MM RL1

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New Test Activation

Effective Date	9/23/2025
Name	ThinPrep PAP Test with Co-Test HPV
Code	TCHPV
CPT Code(s)	88175; If reviewed by pathologist add 88141; HPV 87624
Notes	New York DOH Approval Status: No

Specimen Requirements

Specimen Required	<p><i>Collect:</i> Cervical specimen</p> <p><i>Specimen Preparation:</i> Send cervical specimen in a ThinPrep Pap Test Collection Vial. Transport cervical specimen in the original collection kit.</p> <p><i>Minimum Volume:</i> 1 ThinPrep vial</p> <p><i>Transport Temperature:</i> Room temperature</p>
Rejection Criteria	Specimens not collected in a ThinPrep Pap Test collection vial, or specimens submitted in an expired collection vial. Cervical swabs in Digene® HC cervical sampler. Digene vials. Swabs. Samples received frozen
Stability	<p>Room temperature: 21 days</p> <p>Refrigerated: 21 days</p> <p>Frozen: Unacceptable</p>

Performing Information

Methodology	Qualitative Microscopy / Qualitative Computer Assisted Analysis
Reference Range	See report
Performed Days	Monday - Friday
Turnaround Time	5 - 9 days
Performing Laboratory	ARUP Reference Laboratory

Interface Information

Legacy Code	TCHPV		
Interface Order Code	3600538		
Result Code	Name	LOINC Code	AOE/Prompt
3600539	ThinPrep PAP Test		No
3600541	HPV High-Risk with Reflex to Genotype		No



LABORATORY REPORT

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

EXAMPLE, REPORT W
WX0000003826 F 12/05/1988 36 Y

Referral Testing

Collected: 08/15/2025 10:22

Received: 08/15/2025 10:22

Test Name	Result	Flag	Ref-Ranges	Units	Site
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This test detects E6/E7 viral messenger RNA of 14 high-risk HPV types (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68) associated with cervical cancer and its precursor lesions. This test does not discriminate between the 14 high-risk HPV types. Sensitivity may be affected by specimen collection methods, stage of infection, and the presence of interfering substances. Results should be interpreted in conjunction with other available laboratory and clinical data. A negative high-risk HPV result does not exclude the presence of other high-risk HPV types.

HPV testing should not be used for screening or management of atypical squamous cells of undetermined significance (ASCUS) in women under age 21.

Performed by ARUP Laboratories
500 Chipeta Way, Salt Lake City, UT 84108
Jonathan R. Genzen, MD, PhD, Laboratory Director

HPV High-Risk with Reflex to Genotype

SEE BELOW

WMAR

Test	Result	Flag
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ThinPrep PAP Test Final Report

ThinPrep Pap Specimen	Cervical
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Clinical History
None

Specimen Adequacy	Satisfactory for evaluation.
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Interpretation
Atypical squamous cells of undetermined significance.

_ Cytotechnologist: _
Reviewed by: _
_ Verified by: _
electronic signature

University of Utah Health Care, Department Of Pathology
Huntsman Cancer Institute
2000 Circle of Hope, RM 3100
Salt Lake City UT 84112

CPT Codes
This test has been processed utilizing the FDA approved

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

H615000000
WX0000003826
Printed D&T: 08/15/25 10:23

Ordered By: CLIENT CLIENT
WX00000000002823

Kajal V. Sitwala, MD, PhD - Medical Director
Form: MM RL1
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LABORATORY REPORT

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

EXAMPLE, REPORT W

WX0000003826 F 12/05/1988 36 Y

Referral Testing

Collected: 08/15/2025 10:22

Received: 08/15/2025 10:22

<u>Test Name</u>	<u>Result</u>	<u>Flag</u>	<u>Ref-Ranges</u>	<u>Units</u>	<u>Site</u>
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Hologic Genius screening system.

Comments

The Pap test is a screening test for cervical cancer and its precursors with an inherent false-negative rate.

Fellow

Human Papillomavirus (HPV) High Risk Screen by Transcription-Mediated Amplification (TMA), with Reflex to Genotypes 16 and 18/45, ThinPrep

Test	Result	Flag
HPV Source	Cervical	
HPV, High Risk by TMA	Detected	AB

HPV, High Risk by TMA is detected.
HPV Genotype has been added. Additional charges apply.

INTERPRETIVE INFORMATION: HPV, High Risk by TMA

This test detects E6/E7 viral messenger RNA of 14 high-risk HPV types (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68) associated with cervical cancer and its precursor lesions. This test does not discriminate between the 14 high-risk HPV types. Sensitivity may be affected by specimen collection methods, stage of infection, and the presence of interfering substances. Results should be interpreted in conjunction with other available laboratory and clinical data. A negative high-risk HPV result does not exclude the presence of other high-risk HPV types.

HPV testing should not be used for screening or management of atypical squamous cells of undetermined significance (ASCUS) in women under age 21.

Human Papillomavirus (HPV) Genotypes 16 and 18/45, by Transcription-Mediated Amplification (TMA), ThinPrep

Test	Result	Flag
HPVG Source	Cervical	
HPV Genotype 16 by TMA	Detected	
HPV Genotype 18/45 by TMA	Detected	

INTERPRETIVE INFORMATION: HPV Genotype

This test detects E6/E7 viral messenger RNA of the high-risk

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

H61500000
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Printed D&T: 08/15/25 10:23

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WX00000000002823

Kajal V. Sitwala, MD, PhD - Medical Director
Form: MM RL1
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LABORATORY REPORT

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

EXAMPLE, REPORT W
WX0000003826 F 12/05/1988 36 Y

Referral Testing

Collected: 08/15/2025 10:22 Received: 08/15/2025 10:22

<u>Test Name</u>	<u>Result</u>	<u>Flag</u>	<u>Ref-Ranges</u>	<u>Units</u>	<u>Site</u>
	HPV types 16, 18, and 45 only. It is intended for use in women 21 years and older with ASC-US cervical cytology results and in women 30 years and older as a follow-up to a positive high-risk HPV screen. Sensitivity may be affected by specimen collection methods, stage of infection, and the presence of interfering substances. Results should be interpreted in conjunction with other available laboratory and clinical data. This test is not intended for use as a stand-alone test.				
	HPV testing should not be used for screening or management of atypical squamous cells of undetermined significance (ASCUS) in women under age 21.				
	Performed by ARUP Laboratories 500 Chipeta Way, Salt Lake City, UT 84108 Jonathan R. Genzen, MD, PhD, Laboratory Director				

Reported Date: 08/15/2025 10:23 TCHPV

Performing Site:

WMAR: ARUP LABORATORIES 500 Chipeta Way Salt Lake City UT 841081221

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

H615000000
WX0000003826

Printed D&T: 08/15/25 10:23

Ordered By: CLIENT CLIENT
WX000000000002823

Kajal V. Sitwala, MD, PhD - Medical Director

Form: MM RL1

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Update Existing Test

Effective Date	9/9/2025
Name	Aluminum, Serum
Code	ALUMS
Interface Order Code	3701240
Legacy Code	ALUMSP
Notes	Update to specimen requirements, stability, and performed days.

Required Testing Changes

Specimen Required	<p><i>Collect:</i> Dark blue trace element no additive</p> <p><i>Specimen Preparation:</i> Draw blood in a dark blue no additive tube and allow serum to clot in an upright position. Centrifuge and separate by pouring (do not pipette) the serum into a Quest trace element serum transport tube (red label). Send 2.0 mL serum.</p> <p><i>Minimum Volume:</i> 0.7 mL</p> <p><i>Transport Temperature:</i> Refrigerated</p>
Stability	<p>Room temperature: 14 days</p> <p>Refrigerated: 21 days</p> <p>Frozen: 30 days</p>
Performed Days	Monday - Saturday

Update Existing Test

Effective Date	9/15/2025
Name	Culture, Fungus, Blood
Code	CFBLD
Interface Order Code	3400724
Legacy Code	CFBLD
Notes	Update to alternate specimen, stability, and turnaround time.

Required Testing Changes

Alternate Specimen	No alternate specimen
Stability	<p>Room temperature: 72 hours</p> <p>Refrigerated: Unacceptable</p> <p>Frozen: Unacceptable</p>
Turnaround Time	30 - 44 days

Update Existing Test

Effective Date	9/9/2025
Name	Clobazam and Metabolite, Serum/Plasma
Code	CLOME
Interface Order Code	3300192
Legacy Code	CLOME
Notes	Update to alternate specimen.

Required Testing Changes

Alternate Specimen	Lavender (K2 or K3EDTA); Pink (K2EDTA)
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Update Existing Test

Effective Date	9/15/2025
Name	Culture, Fungus, Skin, Hair or Nails
Code	CUFUN
Interface Order Code	3700499
Legacy Code	CUFUN
Notes	Update to alternate specimen and rejection criteria.

Required Testing Changes

Alternate Specimen	Swab in bacterial transport media or sterile container.
Rejection Criteria	Specimens other than hair, skin or nails; specimens transported in alcohol or formalin.

Update Existing Test	
Effective Date	9/15/2025
Name	Helicobacter pylori Culture with Reflex to Susceptibility
Code	HEOBA
Interface Order Code	3400451
Legacy Code	HEOBA
Notes	Update to specimen requirements, alternate specimen, rejection criteria, and stability.
Required Testing Changes	
Specimen Required	<p>Collect: Gastric/antral or duodenal biopsy</p> <p>Specimen Preparation: Send 3 mm gastric/antral or duodenal biopsy in Brucella broth or Trypticase Soy Broth (TSB) with 10 - 20% glycerol. Do not send in a swab container. Send frozen -70°C (dry ice).</p> <p>Minimum Volume: No minimum</p> <p>Transport Temperature: Brucella Broth or equivalent with glycerol: -70°C</p> <p>Broth with or without glycerol, or sterile non-bacteriostatic saline: Refrigerated</p>
Alternate Specimen	<p>Broth with or without glycerol 2 - 8°C (not recommended)</p> <p>Sterile non-bacteriostatic saline 2 - 8°C (not recommended)</p>
Rejection Criteria	<p>Transport swab with or without gel; stool</p> <p>Specimens frozen at -20°C.</p>
Stability	<p>Specimens with glycerol:</p> <p>Room temperature: Unacceptable</p> <p>Refrigerated: 48 hours</p> <p>Frozen (-70°C): 5 days</p> <p>All other specimens:</p> <p>Room temperature: Unacceptable</p> <p>Refrigerated: 48 hours</p> <p>Frozen: Unacceptable</p>

Update Existing Test

Effective Date	9/15/2025
Name	Culture, Fungus, Not Hair, Skin, Nails
Code	NOSHN
Interface Order Code	3700472
Legacy Code	NOSHN
Notes	Update to specimen requirements, rejection criteria, and methodology.

Required Testing Changes

Specimen Required	<i>Collect:</i> Various acceptable sample types <i>Specimen Preparation:</i> Send 3.0 mL Cerebrospinal fluid (CSF) (or body fluid or eye fluid) in a screw capped plastic vial. <i>Minimum Volume:</i> 1.0 mL <i>Transport Temperature:</i> Raw specimens: refrigerated; Swab specimens in transport medium: room temperature
Rejection Criteria	Whole blood, skin, hair, nails, stool, frozen specimens, serum, specimens in alcohol or formalin. Timed urine or sputum collection.
Methodology	Culture; Isolation and Identification

Update Existing Test

Effective Date	9/2/2025
Name	OmegaCheck
Code	OMEGC
Interface Order Code	3400931
Legacy Code	OMEGC
Notes	Update to New York approval, specimen requirements, and stability.

Required Testing Changes

New York Approval	New York DOH Approval Status: No
Specimen Required	<i>Patient Preparation:</i> Overnight fasting is preferred but not required. <i>Collect:</i> Lavender EDTA <i>Specimen Preparation:</i> Send 1.0 mL whole blood. Gently invert tube 8 - 10 times immediately after draw. DO NOT SHAKE. <i>Minimum Volume:</i> 0.5 mL <i>Transport Temperature:</i> Refrigerated
Stability	Room temperature: 28 days Refrigerated: 28 days Frozen (-20°C): Unacceptable Frozen (-70°C): 28 days