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QUALITY UPDATE is a complimentary quarterly newsletter providing laboratory information for physicians and their staff.

OUR MISSION: Improve the health of our community through excellence in medical laboratory services.

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CompuNet® CLINICAL LABORATORIES

Quality Update

CompuNet Offers Advanced Lipid Testing

According to the CDC's most recent statistics, heart disease remains the #1 leading cause of death for both men and women in the U.S.[1] In a major study, it was found that 50% of people who suffered a cardiovascular event had normal cholesterol levels.[2]

CompuNet provides options beyond the standard cholesterol test to help you assess your patients' cardiovascular event risks. We now offer the Liposcience Reflex Lipid to NMR Advantage™ advanced lipid testing which may help you identify patients who have relatively normal LDL-C (< 130 mg/dL) but an increased LDL particle number (LDL-P). Patients with risk factors like diabetes, metabolic syndrome, family history of heart disease, previous heart attack, or if overweight/obese may benefit from advanced lipid testing.

LDL-P provides additional information and, combined with clinical history and a patient's risk factors, could help guide your patient's individual LDL management.

TO ORDER THE NMR ADVANTAGE™

- Order (Test) Code: 75477
- CPT Codes: 80061; Reflex 83704*

SPECIMEN COLLECTION

1 mL serum - Serum Separator Tube (SST) (minimum 0.5 mL) and 1 mL serum NMR LipoTube (Black-top with yellow ring gel barrier "bumble bee" tube) for reflex (minimum 1 mL). Use only the NMR LipoTube - test cannot be performed on any other gel barrier tubes.

INSTRUCTIONS

SST - Avoid hemolysis. Invert a minimum of 5 times then allow to clot in an upright position for 30 minutes. Centrifuge the SST for at least 10 minutes. Keep tightly stoppered. Transport: refrigerated preferred.

NMR LipoTube - Allow specimen to clot upright at room temperature for 30 minutes. Centrifuge sample for 15 minutes at 3000 rpm then refrigerate. **If specimen cannot be centrifuged immediately after clotting, it must be refrigerated at 2-8 C and centrifuged within 24 hours of collection.** Transport: Refrigerated only.

For more information contact your CompuNet sales representative or call (937) 297-8336.

**The CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payor being billed.*

[1]www.cdc.gov/nchs/fastats/lcod.htm

[2]Cromwell WC et al. Am J Cardiol 2006;98: 1599-1602.

New CDC Hepatitis C Recommendations and Testing Options

Ike Northern, Infectious Disease Testing and Immunology

On August 17, 2012, the Centers for Disease Control (CDC) published recommendations for screening all individuals born between 1945 and 1965 for Hepatitis C Virus (HCV) infection. There are several reasons for these recommendations[1]:

- **Hepatitis C virus (HCV) is an increasing cause of morbidity and mortality in the United States.**
- **Many of the 2.7–3.9 million persons living with HCV infection are unaware they are infected and do not receive care and treatment.**
- **The CDC estimates that although persons born during 1945–1965 comprise an estimated 27% of the population, they account for a proximately three-fourths of all HCV infections in the United States, 73% of HCV-associated mortality, and are at greatest risk for hepatocellular carcinoma and other HCV-related liver diseases.**
- **With the advent of new therapies that can halt disease progression and provide a virologic cure in most persons, targeted testing and linkage to care for infected persons in this birth cohort is expected to reduce HCV-related morbidity and mortality.**

The CDC is augmenting previous recommendations for HCV testing to recommend one-time testing for persons born during the above years with no known risk of HCV. Persons identified as having HCV infection should receive a brief screening for alcohol use and intervention as clinically indicated, followed by referral to appropriate care for HCV infection and related conditions. These recommendations do not replace previous guidelines for HCV testing that are based on known risk factors and clinical indications. Rather, they define an additional target population for testing. It is recommended that patients contact their insurance company to verify coverage for the Hepatitis C Antibody Screen.

ORDER CODE 8472 IS RECOMMENDED FOR HCV SCREENING.

HEPATITIS C (HCV) TESTING OPTIONS			
Assay	Order Code	Specimen Requirements	Purpose of Test
Hepatitis C Antibody	8472	1 mL serum	Initial screening test for Hepatitis C*
Hepatitis C RNA, Qualitative	34024	4 mL EDTA plasma	Detects the presence of viral RNA (Detected or Not Detected)
Hepatitis C RNA, Quantitative	35645	4 mL EDTA plasma	Quantifies the amount of viral RNA – detects down to 10 RNA copies/mL of plasma
Hepatitis C Genotyping	37811	2 mL of EDTA plasma	Determines strain of Hepatitis C to aid in treatment selection

*On low positive Hepatitis C Antibody results, Recombinant Immunoblot Assay (RIBA) is ordered as confirmation at an additional cost, however the RIBA kit is on backorder until further notice. Hepatitis C RNA, (#35645 or #34024) is recommended in place of the RIBA assay.

FOR MORE INFORMATION

Contact Ike Northern, Infectious Disease Testing and Immunology at (937) 297-8334 or william.i.northern@questdiagnostics.com

A flow chart for diagnosing HCV infections and an Interpretation Guide are available at these CDC websites: www.cdc.gov/hepatitis/HCV/PDFs/hcv_flow.pdf • www.cdc.gov/hepatitis/HCV/PDFs/hcv_graph.pdf

[1] www.cdc.gov/mmwr/preview/mmwrhtml/rr6104a1.htm?s_cid=rr6104a1_w

Endocervical Curettage Specimen Collection Guidelines

Katrina St.Clair, CT (ASCP) and Amanda Clark, CT (ASCP)

An Endocervical Curettage (ECC) specimen is considered a histology specimen by the laboratory. Here are some collection guidelines for an ECC specimen to help ensure optimal results and avoid testing delays:

ECC specimen collected in Formalin is preferred. Tissue preservation is optimal when placed in formalin, and results in a higher quality sample for the pathologist reviewing the biopsy. Additionally, if there are multiple cervical biopsy specimens, it is best for them all to be processed, reviewed, and reported simultaneously to yield the most comprehensive review for your patient.

ECC specimens collected in ThinPrep vials are acceptable but not preferred. The specimen will be processed by the Histology department as a biopsy but this is not the preferred method. This collection method is ***not*** optimal because ECC specimens collected in Thin Prep vials - and marked as pap smears on the requisition - may be processed and reviewed as a pap smear. The pathologist will review the specimen only if there are abnormal cells present on the sample.

ECC specimens should be ordered as a histology test.
Use test (order) code 74316, then identify specimen source as an ECC.

Paper Requisition/Handwritten order – In the Pathology/Histology request section write the specimen source, ECC on the Spec. 1 line.

If HPV testing is desired - order this on a pap smear collected in a ThinPrep vial and use test code 9662. Please order the HPV separately from the ECC. **HPV testing cannot be performed on formalin fixed specimens.**

For questions regarding endocervical curettage specimens, please contact our cytology or histology staff:

Amanda Clark, Cytology Manager - (937) 297-8224
Katrina St.Clair, Cytology Team Leader - (937) 208-5050
Dan Sushereba, Histology Manager - (937) 208-4543
Kyhm Wood, Histology Team Leader - (937) 208-4563

Improvements to HIV Testing Algorithm

Ike Northern, Director of Infectious Disease Testing and Immunology

In December, 2012, CompuNet will be making improvements to the HIV testing strategy. These changes will increase sensitivity and reduce turn-around time for results on HIV-positive samples.

The current testing algorithm for determining exposure to HIV is to perform a highly sensitive screening test looking for the presence of HIV antibodies. Samples producing a positive result on the screening assay are then confirmed with a western blot test.

Although the western blot algorithm has been successful at identifying individuals with HIV exposure, it may not identify an individual who is newly exposed to HIV. Once a person is exposed to HIV, antibodies are detectable in a few weeks. This lag in antibody production creates a window of time when the person is infected, and able to pass the virus to another, but appears negative on the HIV screen. In addition, recent studies have shown the western blot is inferior as a confirmation test due to its lack of sensitivity when compared to newer assays. The current screening tests are highly sensitive and may detect HIV-positive individuals that will not be confirmed by the less sensitive western blot assay. [1]

Since the initial screening test will detect both antibody and antigen and the confirmation test will detect just antibody, it will be possible on rare occasions to have a sample that is positive on the screening test but negative on the confirmation test. In these instances, it is recommended that an HIV viral load be performed. Since the screening test is performed on serum and the viral load test is performed on plasma, another sample must to be drawn for this testing.

TO ORDER HIV ANTIBODY SCREEN	
QLS Test Code:	**6449**
Premier EPIC Test Code:	**LAB250**
Preferred Specimen:	2 mL serum (minimum 0.5 mL)
Instructions:	To insure patient confidentiality and identification, the name on the specimen must match the name on the requisition. If a code is desired for patient confidentiality (i.e. social security number) the code should be placed in the box for the patient name.
SST or Red top:	Avoid hemolysis. Invert a minimum of 5 times then allow to clot in an upright position for 30 minutes. Centrifuge the tube for at least 10 minutes. Keep tightly stoppered.
Transport Container:	SST (speckled top), Red top, Plastic Vial (transfer) tube
Transport Temperature:	Refrigerated (preferred)

Contact Ike Northern, Director of Infectious Disease Testing and Immunology, with any questions: (937) 297-8334 or William.i.northern@questdiagnostics.com.

[1]Criteria for Laboratory Testing and Diagnosis of Human Immunodeficiency Virus Infection; Approved Guideline M53-A, published by the Clinical Laboratory Standards Institute in 2011.

Inclement Weather Process for Specimen Pick-up

Transportation Department

When bad weather hits, snow and ice covered roads may cause problems with your specimen pick-up schedule. CompuNet wants to maintain the integrity of your specimens by getting them into the lab for testing in as timely a manner as possible.

Here is information to help you during the upcoming months:

OFFICE CLOSURES DURING INCLEMENT WEATHER

- If your office needs to close early due to inclement weather please call ***CompuNet's Dispatch at (937) 297-8262***.
- If bad weather continues the next day please call CompuNet to inform us if you will remain closed or if you will reopen.
- If the office is closed and then reopens later in the day because of clearing weather, please inform us.
- On any consecutive days of closure please call us, if you will remain closed. In the interest of providing the best specimen integrity possible we cannot rely on a non-dated recording.

LEVEL 3 SNOW/ICE EMERGENCY

- If you are in a ***Level 3 Snow/Ice Emergency*** area or if CompuNet is in a Level 3 Area, CompuNet, by law, cannot pick up your specimens. In Ohio it is illegal for anyone, other than emergency vehicles or an individual with a personal emergency situation, to be on the road.If you have an emergency testing/patient care issue please have the patient go to an emergency room or call 911.
- If you have already drawn a patient's blood work before a Level 3 has been called, check CompuNet's on-line Directory of Services (DOS) for storage information at www.compunetlab.com or call our Client Services Department (937) 297-8260.

WHEN CALLING COMPUNET

Please have the following information available when calling CompuNet for an office close/open status change:

- Account name and Account number.
- Closing time and how long you will be closed, if known.
- Where the specimens will be after closing time.
- An after hours contact number, so that we can confirm open/closed status.
- An email address, if available, so that we can contact you if we cannot reach you any other way.

You may also contact the Transportation Department for general weather related questions or issues at compunettransportation@questdiagnostics.com.

Additional Updates

IMPORTANT CHANGE TO CEREBRAL SPINAL FLUID FLOW TESTING

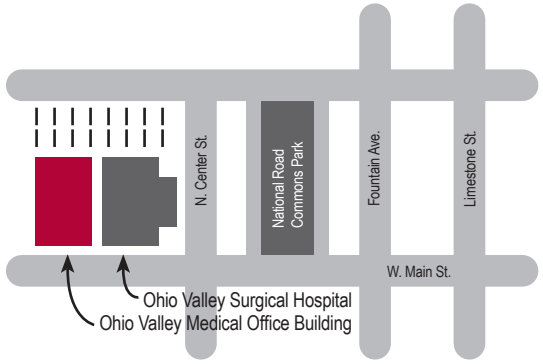
Effective immediately, Flow testing on CSF must be placed into 1 mL of RPMI/media and refrigerated for transport. No ice is needed. The following test codes are affected:

- **QLS test codes:** 71151 (CLL lymphoma on CSF) and 71152 (Acute Leukemia on CSF)
- **Premier EPIC test codes:** LAB4484 CLL lymphoma panel fluid and LAB4483 Acute leukemia profile fluid
- **Specimen Requirement:** CSF 3-5 mL with 1 mL of RPMI or media added

For questions, please contact Susan Millsaps - Flow Cytometry at (937) 208-4297 or susan.d.millsaps@questdiagnostics.com.

SPRINGFIELD PATIENT SERVICE CENTER

CompuNet's newest Patient Service Center is open and accepting patients. No appointments are needed. For more information contact: (937) 325-5327.



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Sat 7:30am – 12:00pm

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How Clotting Impacts CBC Results

Ann Throckmorton, MLS (ASCP)SH Hematology

The value of the complete blood count (CBC), as a test to help determine an individual's general health status and screen for a wide range of conditions and diseases, is well-known. The CBC can help diagnose anything from mild anemia or infection to a life-threatening acute leukemia.

When collecting a specimen for Hematology it is important to make sure that the sample does not start to clot during the collection process. White blood cells, Red blood cells and Platelets need to remain free flowing from the time of the collection to the time of analysis in our laboratory.

When a clot occurs during the collection it can potentially have a negative impact on the patient. Our laboratory has criteria for physically checking specimens for clots. However, if the clot is the result of the collection process (butterfly tubing, "poured over" tube, syringe), we may not detect the clot and in some circumstances could report life-threatening WBC, Hgb or Platelet results. These results would be the outcome of a collection issue and not reflect the patient's true condition.

CONTRIBUTING FACTORS TO CLOTTED SAMPLES

Slow flow of blood – Any time there is a slow down in the flow rate of the blood – there can be a clot. This may not be visible to the person collecting the sample.

Winged Infusion Sets (Butterfly Needles) –The tubing on the Butterfly collection device is not coated with an anticoagulant – so there is nothing to prevent the blood from clotting other than flow rate into the tube. A lavender or blue top tube has an anticoagulant so gently inverting the tube several times will help the anticoagulant mix with the blood.

Syringe Collections

If a syringe is used for the collection, and the transfer of the blood does not take place before the patient's clotting process starts – it will yield results not reflecting the patient's condition.

Pouring Over

Pouring over occurs when a sample is collected in a different tube (such as an SST or red top tube) and poured into a lavender or blue tube. Clotting can occur immediately in the SST or red top tube.

HOW TO PREVENT CLOTTING ISSUES

If you know it was a difficult draw – document this on the test requisition.
If you can see a clot floating in the specimen – recollect the specimen or have another individual try to collect.
Gently invert all tubes with anticoagulant per package instructions.
Do not use Butterfly Needles for routine blood draws.
Do not pour over from other tubes.
If it is a capillary collection – make sure the blood flow is good during the entire collection process.

By avoiding circumstances that can lead to CBC specimen clotting and by informing the laboratory of a CBC difficult draw, we can provide you with accurate results and possibly avoid a situation that incorrectly flags a patient as requiring emergency care.

For questions, please contact Ann Throckmorton, MLS(ASCP)SH Hematology Specialist (937) 290-7327 or (937) 208-5012.

STEM CELL ENUMERATION (CD34)

Flow Cytometry is now performing an improved method for Stem Cell Enumeration (CD34). The improved method more closely follows the 1998 modified ISHAGE guidelines: single tube platform testing with fluorescent counting beads, addition of a viability dye, and increased counting of nucleated cells to 75,000.

This test is performed to enumerate the number of progenitor cells in the submitted sample. Components reported are: CD34 %, CD34 absolute, and CD34 viability. This test is commonly ordered for patients undergoing bone marrow transplant. Test turnaround time is one day. Analysis is performed Monday - Friday 7:00 AM - 6:00 PM.

- **QLS test code:** 76245
- **Specimen Collection/Collection type**: 1 mL of apheresis product submitted in a sterile container, 1 mL bone marrow aspirate submitted in EDTA, 1 mL peripheral blood submitted in EDTA, 1 mL cord blood submitted in EDTA. Transport without delay at room temperature. If unable to transport within 6 hours of specimen collection then refrigerate sample for transport.

RX DRUG MONITORING UPDATE

According to the CDC, 1 in 20 Americans report misusing prescription drugs[1]

Based on a medMATCH™ Trending Report of our own patient population, 55% of patients tested "Inconsistent". An"Inconsistent" result means that drugs prescribed by the physician did not match the drugs found in the patient's urine specimen.

If your practice prescribes controlled pain medication, how do you monitor compliance? Can you be certain that your patients are taking the prescribed medications as directed? Ask your CompuNet Sales Representative about our Rx Drug Monitoring urine drug testing program with a menu specifically designed to include all major prescription drugs used in chronic pain treatment and substances of abuse.

[1]Centers for Disease Control and Prevention (CDC). Vital Signs: Overdoses of Prescription Opioid Pain Relievers - United States, 1999-2008.

NEW TESTS AVAILABLE

CERVICAL CANCER, TERC, FISH 8707591027	
Effective Date:	Immediately
Clinical Significance:	This FISH assay detects increases in the copy number of the telomerase component gene TERC in cervical cytology specimens, which is a finding common in high-grade squamous intraepithelial neoplasia (HSIL) and invasive carcinoma. A positive result in this assay is presence of extra copies of the TERC gene by either locus-specific 3q26 amplification or polysomy of chromosome 3. This is associated with HSIL and a subset of ASC-H which may require more intensive follow-up.
Uses of this assay include:	• Assist in separating HSIL from ASC-H detected on Pap smear; • Assist in separating HSIL from LSIL detected on Pap smear • Further evaluation of atypical Pap findings when high risk HPV is negative.
Test Code:	91027
CPT Code(s):	88271 (x2), 88275 (x2), 88291
Performing Site:	Quest Diagnostics
Department:	Tumor Markers
Specimen Requirements:	15 mL Residual specimen in ThinPrep® vial (3 mL minimum), 10 mL Residual specimen in SurePath® vial (1 mL minimum) is Acceptable. Cytopathology report must accompany test order.
Transport Temperature:	Room Temperature
Specimen Stability:	Room Temperature and Refrigerated: 30 days
Frozen:	Unacceptable
Testing laboratory will assess specimen for cellularity, Do Not Reject	
Rejection Criteria:	Serum; Non-centrifuged PPT; Frozen PPT; Heparininzed plasma; Gross hemolysis and Lipemia
Methodology:	Fluorescence In Situ Hybridization
Additional Information:	If results are not possible due to insufficient cells for analysis, this test will be canceled and replaced with Cervical Cancer, TERC, FISH Insufficient Specimen, at no charge.
CPU Interface Mapping:	Result Code: Result Name: 86008457 CERVICAL CANCER, TERC, FISH 85997860 SPECIMEN TYPE/SOURCE/VOL 86007537 CLINICAL INDICATION: 86008581 HX LSIL/HSIL PRIOR PAP/BX 86008582 HISTORY OF HPV 86007469 CLIENT ACCESSION #

LUNG CANCER (NSCLC), ALK 2P23 REARRANGEMENT, FISH	
Effective Date:	Immediately
Clinical Significance:	Non-small cell lung cancer is the leading cause of cancer death worldwide. Tyrosine kinase inhibitors have been demonstrated to reduce lung cancer cell proliferation. The therapeutic efficacy of inhibiting ALK in tumors that were selected by ALK positivity using FISH has been demonstrated in an early-phase clinical trial of a small molecular inhibitor of the ALK tyrosine kinase. The Vysis ALK Break Apart FISH probe kit is a qualitative test to detect rearrangements involving the ALK gene in formalin-fixed paraffin embedded non-small cell lung cancer tissue specimens to aid in identifying those patients eligible for treatment with XALKOR (crizotinib).
Test Code:	91028
CPT Code(s):	88271 (x2), 88274, 88291
Performing Site:	Quest Diagnostics
Department:	Tumor Markers
Specimen Requirements:	Formalin fixed paraffin embedded tissue in IHC specimen transport kit.
Instructions:	Lung tissue biopsy, formalin fixed paraffin-embedded block or charged/+slides from formalin fixed paraffin embedded tissue. Specimen MUST be fixed in 10% neutral buffered formalin. Fixation between 6 and 48 hours is recommended. Pathology report must accompany paraffin block or slides. Information required in this report include: Physician identification, specimen identifiers (case and block number), specimen site and type, tissue processing used (routine or microwave), type of fixative, time and duration of fixation, pathologic diagnosis. Do not freeze.
Transport Temperature:	Room temperature
Specimen Stability: Frozen: Unacceptable	Room Temperature: Indefinite, Refrigerated: Indefinite,
Methodology:	Fluorescence In-Situ Hybridization (FISH)
CPU Interface Mapping:	Result Code Result Name: 86008458 Lung Cancer (NSCLC), ALK 2P23 Rearrangement,FISH Specimen 85997860 Type/Source/Vol: 86007537 Clinical Indication: 86007538 Referring Physician: 85997863 Referring Physician Phone: 85997864 Client/Phone #: 86007469 Client Accession #: 86007539 Patient ID:

NEW TESTS AVAILABLE

BCR-ABL1 GENE REARRANGEMENT, QUANTITATIVE PCR

Includes:	BCR-ABL1/ABL1 * P190 BCR-ABL1 * P210 BCR-ABL1
Effective Date:	Immediately
Clinical Significance:	This reverse-transcription PCR-based assay detects the BCR-ABL1 transcript produced by the t(9;22) chromosomal translocation associated with chronic myelogenous leukemia (CML) and a subset of lymphoblastic leukemias. For the P190 transcript associated with the minor t(9;22) breakpoint in lymphoblastic leukemia, BCR-ABL1 transcript levels are expressed as a percent ratio of BCR-ABL1 to the normalizing ABL1 transcript. For the P210 transcript associated with CML, quantitation is further adjusted to the international scale (IS) to allow comparison with other IS-compliant BCR-ABL1 assays. Optimal therapy in CML is associated with transcript levels below the major molecular response (MMR) milestone indicated by a BCR-ABL1/ABL1 % (IS) below 0.1.
Test Code:	91065
CPT Code(s):	83891, 83902, 83898, 83896, 83912 OR 81206*

*The 2012 AMA CPT codebook contains Tier 1 and Tier 2 Molecular Pathology Procedures as well as Molecular Pathology Procedures to be coded by procedure rather than analyte. Please direct any questions regarding coding to the payor being billed.

Performing Site:	Quest Diagnostics
Department:	Tumor Markers
Specimen Requirements:	6 mL whole blood collected in EDTA (lavender-top) tube

Collect 6 mL of whole blood or 3 mL bone marrow in an EDTA (lavender-top) tube. Whole blood or bone marrow is shipped at room temperature or refrigerated. Do not freeze whole blood or bone marrow. After collection of the sample, draw date and time, as well as sample type, must be written on the tube and included as requested information. Ship sample immediately due to short stability of 72 hours. If the stability of the sample cannot be determined, delay in result or cancellation of test may occur.

Clotted specimens are unacceptable. Do not reject.

Transport Temperature:	Room Temperature
Specimen Stability: Unacceptable	Room temperature and Refrigerated: 72 hours, Frozen:
Methodology:	Quantitative Real-Time Polymerase Chain Reaction
Additional Information:	If P190 transcript expression was previously documented, only P190 BCR-ABL1 will be added (CPT codes: 83898; 83896 OR 81207*). If P210 transcript expression was previously documented, only P210 BCR-ABL1 will be added (CPT codes: 83898; 83896 OR 81206*). If no prior positive is documented P190 BCR-ABL1 and P210 BCR-ABL1 will be added (CPT codes: 83898(x2); 83896 (x2) OR 81206, 81207*).

CPU Interface Mapping:

Result Code:	Result Name:
86008600	Prior Result
86007404	Source:
86008603	BCR ABL1/ABL1 %
86008604	BCR ABL1/ABL1 % (IS)
86008605	Interpretation

ROMA™ (RISK OF OVARIAN MALIGNANCY ALGORITHM)

Effective Date:	Immediately
Clinical Significance:	The Risk of Ovarian Malignancy Algorithm (ROMA™) test is intended to aid in assessing the risk of ovarian cancer in women with a pelvic mass based on the patient's HE4 and CA125 levels, and their menopausal status. Women with ROMA™ levels above the cutoff have an increased risk of ovarian cancer. ROMA™ must be interpreted in conjunction with an independent clinical and radiological assessment.
Test Code:	91155
CPT Code(s):	86304, 86305
Performing Site:	Quest Diagnostics
Department:	Tumor Markers
Specimen Requirements:	1 ML Serum
Instructions:	Remove serum from the clot or red cells, respectively, as soon as possible after clotting and separation.
Transport Temperature:	Refrigerated
Specimen Stability:	Room Temperature: 24 hours Refrigerated: 7 days Frozen: 28 days
Rejection Criteria:	Icteric specimens, Lipemia, Moderate and gross hemolysis, Received room temperature.
Methodology:	Calculation, Immunoassay

CPU Interface Mapping:

Result Code	Result Name:
86008767	ROMA Premenopausal
86008768	ROMA Postmenopausal
86008814	CA125
86008778	HE4

LUNG CANCER MUTATION PANEL (EGFR, KRAS, ALK)

Includes:	Epidermal Growth Factor Receptor (EGFR) Mutation Analysis, KRAS Mutation Analysis, Lung Cancer (NSCLC), ALK 2p23 Rearrangement, FISH
Effective Date:	Immediately
Clinical Significance:	This panel is comprised of mutational analysis of the EGFR and KRAS genes and assessment for ALK locus rearrangement using an FDA-cleared FISH assay. These are the most common tumor-associated genetic changes that have been shown to have prognostic and therapeutic consequences in non-small cell lung cancer (NSCLC) and help guide therapy. Patients with EGFR mutations are generally responsive to EGFR-directed kinase inhibitors, whereas those with evidence of ALK gene rearrangements are candidates for treatment with the ALK inhibitor crizotinib. The presence of KRAS mutation in lung adenocarcinoma predicts for non-response to kinase inhibitors and for tumors with inferior outcome.
Test Code:	91216
CPT Code(s):	83891, 83892, 83898 (x4), 83909 (x4), 83904 (x4), 83912, 83898 (x2), 83892 (x2), 83909 (x2), 83904 (x4), 83912, 88271 (x2), 88274, 88291
Performing Site:	Quest Diagnostics
Department:	Tumor Markers
Specimen Requirements:	Formalin fixed paraffin embedded tissue block See instructions for individual assays
Transport Temperature:	Room temperature
Specimen Stability: Frozen: Unacceptable	Room Temperature: Indefinite, Refrigerated: Indefinite,
Methodology:	See individual assays

%16460ARQEZ – EGFR Mutation Analysis
Reporting Title: LUNG CANCER MUTATION PANEL

Result Code:	Result Name:
86001745	Source
86006525	EGFR Mutation
86006498	Specimen Block Number

%16510CRQEZ – KRAS Mutation Analysis

Result Code:	Result Name:
86006502	KRAS Mutation

%91028RQEZ – Lung Cancer (NSCLC), ALK 2p23 Rearrangement, FISH

Result Code:	Result Name:
86008458	Lung Cancer (NSCLC), ALK 2p23
85997860	Rearrangement, FISH
86007537	Specimen Type/Source/Vol
86007538	Clinical Indication:
85997863	Referring Physician:
85997864	Referring Physician Phone:
86007469	Client/Phone #:
86007539	Client Accession #: Patient ID:

TEST CHANGES (CHANGES ARE INDICATED IN BOLD PRINT)

IMPORTANT CHANGE TO CEREBRAL SPINAL FLUID FLOW TESTING:

Effective immediately, Flow testing on CSF must be placed into 1 mL of RPMI/media and refrigerated for transport. NO ice is needed. The following test codes are affected:
QLS test codes: 71151 (CLL lymphoma on CSF) and 71152 (Acute Leukemia on CSF)
EPIC codes: CLL lymphoma panel fluid and Acute leukemia profile fluid
Specimen Requirements: CSF 3-5 mL with 1 mL of RPMI or media added

EBV QUANTITATIVE PCR

Aliases:	**Transplant EBV QPCR Transplant EBV DNA quant Epstein Barr virus DNA, QN RT PCR Epstein Barr virus quant EBV quant**
Effective Date:	**IMMEDIATELY**
Test Name:	**EBV Quantitative PCR** Formerly called Transplant EBV QPCR
Test Code:	74790
Performing Site:	**CompuNet Clinical Laboratories**
Department:	**Molecular Diagnostics**
Preferred Specimen Requirements:	**2 ml EDTA plasma (lavender top)**
Instructions:	**Avoid hemolysis. Invert a minimum of 8 times. Then allow to clot in an upright position for 30 minutes. Centrifuge the tube for at least 10 minutes. Transfer plasma to a completely labeled plastic transport tube within 6 hours of collection. Freeze plasma pour off.**
Container type:	**Sterile plastic pour off tube; EDTA lavender top tube**
Other Acceptable Specimen Requirements:	**1 ml whole blood collected in a sterile tube containing EDTA - refrigerated 1 ml whole blood collected in sterile tube with ACD - refrigerated**
Transport Temperature:	**Plasma - frozen or refrigerated**
	Whole blood - refrigerated
CPU Interface mapping:	**OLD** **2004092 - EBV QPCR** **NEW** **2004426 - SOURCE:** **2004427 - EBV DNA** **2004428 - EBV DNA LOG**

C2 COMPLEMENT COMPONENT

Effective Date:	IMMEDIATELY
Test Code:	433
Specimen Requirements:	mL serum
Collection Instruction:	**Separate serum within one hour of time drawn and refrigerate. Can be drawn on gel barrier but needs to be separated within one hour of draw time.**
Specimen Stability:	**Room Temperature: 28 days Refrigerated: 28 days Frozen: 28 days**
Specimen Condition:	**Gross hemolysis (acceptable), Light hemolysis (acceptable), Moderate hemolysis (acceptable) Gross lipemic (unacceptable)**
Transport Temperature:	Refrigerated
Performing Site:	Quest Diagnostics Nichols Institute
Department:	Chemistry
CPU Interface Mapping:	Result Code: 85991140 Result Name: C2, SERUM

DRUG ABUSE SCREEN 7, SERUM

Effective Date:	IMMEDIATELY
Test Code:	19767
Specimen Requirements:	10 ML SERUM COLLECTED IN A RED-TOP TUBE (NO GEL)
Rejection Criteria:	**SERUM SEPARATOR TUBE WILL BE REJECTED**
Transport Temperature:	Refrigerated
Performing Site:	Quest Diagnostics
Department:	Toxicology Studies
CPU Interface Mapping:	Result Code: / Result Name:

Result Code:	Result Name:
86004591	MARIJUANA
86004599	DELTA 9 THC
86004600	DELTA 9 THC CARBOXY ACID
85998074	AMPHETAMINES
85998072	AMPHETAMINE
85998073	METHAMPHETAMINE
85996774	MDA
85996775	MDMA
86004592	BARBITURATES
86004606	BUTALBITAL
86004607	BUTABARBITAL
86004608	AMOBARBITAL
86004609	PENTOBARBITAL
86004610	SECOBARBITAL
86004611	PHENOBARBITAL
86004593	BENZODIAZEPINES
86004601	OXAZEPAM
86004602	NORDIAZEPAM
86004603	DESALKYFLURAZEPAM
86004604	LORAZEPAM
86004605	ALPROZOLAM
86004594	COCAINE
85996678	COCAINE
85996680	BENZOYLECGONINE
85996681	COCAETHYLENE
85996682	ECGONINE METHYL ESTER
86004625	OPIATES
86002001	MORPHINE
86002002	CODEINE
86002003	HYDROCODONE
86002004	HYDROMORPHONE
86002005	OXYCODONE
86004598	PCP (PHENCYCLINIDINE)
86004621	PHENCYCLINDINE
86002263	COMMENT

CITRIC ACID, 24 HOUR URINE (WITH CREATININE)

Effective Date:	**IMMEDIATELY**
Test Code:	4616
Specimen Requirements:	Aliquot of 24 hour urine collection. Collect urine without preservative. Refrigerate during and after collection. Record total volume on specimen and test requisition.
Rejection Criteria:	Acidified urine, **RECEIVED ROOM TEMPERATURE**
Performing Site:	Quest Diagnostics
Department:	Chemistry
CPU Interface Mapping:	Result Code: / Result Name:

Result Code:	Result Name:
85996211	24 HR URINE VOLUME
85997954	CITRIC ACID, 24 HOUR$URINE
85997955	CITRIC ACID, 24 HOUR$URINE
85997956	CREATININE, 24 HOUR URINE

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TEST CHANGES (CHANGES ARE INDICATED IN BOLD PRINT)

BLADDER CANCER, FISH

Effective Date:	**IMMEDIATELY**
Test Code:	10107
Former Test Name:	FISH, Vysis® UroVysion®, Bladder Cancer
Specimen Requirements:	50 mL urine in sterile screw cap container **Bladder washing is an acceptable specimen type.** **A urine preservative transport kit, with handling instructions, is available.**
Collection Instruction:	Perform urine collection (50 mL) at the physician's office or Patient Service Center in a sterile 100 mL urine specimen container. Mix voided urine with CytoLyt OR ethanol 50% in a 1:1 solution. Alternatively, mix urine with preservative Carbowax (2% polyethylene glycol in 50% ethanol) 2:1 (v:v). **Or perform bladder-washing collection (50 mL) at the physician's office in a sterile 100 mL urine specimen container. Mix bladder washing with CytoLyt OR ethanol 50% in a 1:1 solution. Alternatively, mix bladder washing with preservative Carbowax (2% polyethylene glycol in 50% ethanol) 2:1 (v:v).** It is recommended that specimens be processed within 72 hours of collection. Samples received without preservative will be assayed; any study under these conditions yielding insufficient cells or an abnormal result should have a follow-up study with urine in a preservative. Cold packs are recommended during transportation. **If bladder washing is not shipped immediately after collection, refrigerate immediately (DO NOT FREEZE). Under no circumstances should bladder-washing specimens be stored or shipped at temperatures at or above 37 degrees C.** Specimen viability decreases during transit. Send specimen to testing lab for viability determination. DO NOT REJECT.
Transport Temperature:	Refrigerated
Performing Site:	Quest Diagnostics
Department:	Tumor Markers
CPU Interface Mapping:	Result Code: / Result Name: 85997858 BLADDER CANCER 85997859 RESULTS RECEIVED 85997860 SPECIMEN TYPE/SOURCE/VOL 85997861 CLINICAL INDICATION 85997862 PRIOR THERAPY 85997863 REFERRING PHYSICIAN PHONE 85997864 CLIENT/PHONE # 85997865 CLIENT ACCESSION NUMBER 85997866 PATIENT ID

BKV QUANTITATIVE PCR

Aliases:	**BK VIRUS DNA, QN** **TRANSPLANT BKV PCR QUANT** **TRANSPLANT BKV QPCR** **BKV QUANT** **BK QUANT**
Effective Date:	**IMMEDIATELY**
Test Name:	BKV QUANTITATIVE PCR Formerly called TRANSPLANT BKV qPCR
Test Code:	74788
Performing Site:	**CompuNet Clinical Laboratories**
Department:	**Molecular Diagnostics**
Preferred Specimen Requirements:	**2 ML EDTA PLASMA (LAVENDER TOP).**
INSTRUCTIONS:	**Avoid hemolysis. Invert a minimum of 8 time then allow to clot in an upright position for 30 minutes. Centrifuge the tube for at least 10 minutes. Transfer plasma to a completely labeled plastic transport tube within 6 hours of collection. Freeze plasma pour off.**
Container Type:	**Sterile Plastic Pour Off Tube; EDTA Lavender Top Tube**
Other Acceptable Specimen Requirements:	**1 ml whole blood collected in a sterile tube containing EDTA - refrigerated 1 ml whole blood collected in sterile tube with ACD - refrigerated**
Transport Temperature:	**Plasma - frozen or refrigerated** **whole blood - refrigerated**
CPU Interface mapping:	**OLD** **2004090 - BKV QPCR** **NEW** **2004423 - SOURCE:** **2004424 - BKV DNA** **2004425 - BKV DNA LOG**

DISCONTINUED TEST

FISH, BLADDER CANCER, BLADDER WASHING

Effective Date	Immediately
Test Code	19085
Performing Site	Quest Diagnostics
Additional Information	This test has been replaced with 1 0107 Bladder Cancer, FISH

You can view the current and past issues of the Quality Update at **www.compunetlab.com** under Healthcare Providers tab.
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