

## General Information

### Laboratory Accreditation – Nichols Institute San Juan Capistrano, CA

#### U.S. Department of Health and Human Services

- CLIA (HCFA) Interstate Laboratory License #05D0643352
- Medicare Provider # X059092
- Tax ID 95-2701802

#### California State Department of Health

- Clinical Laboratory License No. CLF 2562
- Medi-Cal Provider # LAB43352F
- Blood Lead Testing Approval
- HIV Testing Approval
- Radioactive Material License #2247-30
- Cholinesterase Testing Approval

Children's Oncology Group (COG), Cytogenetics

#### College of American Pathologists (CAP)

- #22852-01

#### Drug Enforcement Administration Registration

- #RQ0231491

#### Florida State Department of Health

- #800001912

#### Maryland State Department of Health

- #290

#### New York State Department of Health

- PFI 2478
- Code 805730A0

#### North Carolina State Department of Health

- #LH00348

#### Ohio State Department of Health

- Clinical Lead Approval #C10009

#### Pennsylvania State Department of Health

- #022174

#### Rhode Island State Department of Health

- #194

#### TUV - ISO 9001: 2000

- CERTIFICATE Registration # 951 03 1573

#### West Virginia State Department of Health

- Certification for HIV Testing #HIV-RL-13

#### Participates in the following proficiency testing programs:

- Centers for Disease Control Lipid Standardization Program
- College of American Pathologists
- Foundation for Blood Research
- New York State Department of Health
- Onco Check
- PA Dept. of Health
- Quebec
- St. George Hosp. Med. School
- The Binding Site, UK
- Wisconsin Department of Health

### Chantilly, VA

#### CAP Original Accreditation - 1969

U.S. Department of Health and Human Services (CLIA ID Number) #49D0221801 (Centers for Medicare and Medicaid Services)

American Society for Histocompatibility and Immunogenetics (ASHI) #11-3-VA-05-1

California License #COS 8000071

Cancer and Leukemia Group B (CALGB) Approved Cytogenetics Laboratory

Centers for Disease Control and Prevention (CDC) Lipid Standard Program

CDC Import and Transport (West Nile Virus) #2007-11-013

CDC Import and Transport (Micro Organisms) #2007-06-107

Children's Oncology Group, Cytogenetics

College of American Pathologists (CAP) #13611-01

College of American Pathologists Forensic Toxicology #13611-05

Drug Enforcement Administration Registration #PN0084359

District of Columbia #C-D 005

Florida Clinical Laboratory License #800003416

Food and Drug Administration #3005010397

Maryland Permit #209

New York Permit #3745 847728A1

North Carolina

Pap Smear Certification - LP00170

HIV Testing Certificate - LH00170

Pennsylvania Permit #001136

Ohio clinical Lead #C 10002

OSHA Blood Lead Analysis

Radioactive Material License #45-13936-01

Rhode Island #00353

USDA Import and Transport (West Nile Virus) #48573

Virginia (Alcohol) - Permit # 533

West Virginia Certification for HIV Testing #HIV-RL-2

## General Information

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Nichols Institute, the world renowned “gold standard” in rare and unique testing, plays a critical role within Quest Diagnostics. Founded in 1971, Nichols Institute has pioneered many new tests and technologies and has often been first in providing access to advances in laboratory testing. In addition to its role as a highly specialized diagnostics laboratory, Nichols Institute serves as a center for Scientific Innovation, Research and Development. Quest Diagnostics Nichols Institute operates two esoteric laboratories in the United States, one in San Juan Capistrano, California, the other in Chantilly, Virginia. Nichols Institute is designed specifically to meet the needs of its hospital clients. Medical professionals, scientists, and pathologists ensure all aspects of high quality esoteric reference testing services are delivered to its thousands of customers. The benefit to you is more choice. You can use your local Quest Diagnostics laboratory or send your specimens directly to Quest Diagnostics Nichols Institute. Just call your account representative for more details.

## BILLING

### CLIENT BILLING

Quest Diagnostics Nichols Institute will bill your account either twice a month on the 15th and 30th or once a month on the 30th. The following information may be provided if submitted with the order:

- Patient Name
- Date of Service
- Accession Number
- Testing performed
- CPT codes
- Test Price
- Patient/Lab ID
- Referring Physician Name/Number
- Purchase Order Number

Payment is due upon receipt. Late payments may result in additional charges. Payment can be made via American Express, VISA or MasterCard. Please refer to your invoice for additional information. Transfers/rebillings must be submitted within 45 days or the invoice will be considered correct. Adjustments will appear on subsequent invoices. Requests received after 45 days may not be processed. We can also offer electronic formats for client invoicing and utilizations. Please contact your Client Account specialist.

### PHYSICIAN/CLIENT BILLING

An invoice is sent at the beginning of each month detailing the previous month’s services, unless Quest Diagnostics has agreed to an alternate billing cycle for your account. We have provided the American Medical Association’s (AMA) Current Procedural Terminology (CPT) codes for tests listed in this manual. It is the responsibility of the client to research and verify the accuracy of the CPT codes that they use for billing purposes. CPT guidelines are published by the AMA and are also available from many insurance carriers. This catalog lists CPT codes to provide some guidance, and is subject to change at any time. The CPT codes provided are based upon 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.

#### Additional Fees

In some instances, tests performed at Nichols Institute may require additional charges. These charges are for processing fees, infectious organism susceptibility reflexes and m-component identification.

### PATIENT BILLING

If requested, or as required by law, Nichols Institute will bill patients directly within the United States. In this case, the Patient Fee Schedule will apply. These fees vary from those charged to physicians/clients. Panels and/or profiles that do not conform to specific CPT codes will be billed as the individual test components performed.

The patient’s full name and address must appear on the test request form. Many patients subsequently request insurance billing for those plans with which Nichols Institute participates. In those cases, diagnosis information will be required in order to file a claim and we will not accept a diagnosis from a patient so we will call your office. If a patient is enrolled with a health plan with which we participate, provide the applicable diagnosis information from an International Classification of Diseases (ICD-9) code manual and request Nichols Institute bill the insurance carrier. We participate with a variety of traditional insurance plans and managed care organizations (HMOs and PPOs). Please contact your sales representative for an up-to-date list of those plans. When appropriate, we will bill the patient upon receipt of a claim rejection. Insurance plans are billed at the same prices billed to patients.

### THIRD PARTY AND CONTRACT BILLING

Nichols Institute may bill third party carriers directly if complete billing information is provided on the test request form or order screen. Your patient will be billed for amounts not covered or paid by their insurance. Check the third party billing box on the test request form. You must provide: the patient’s name, street address, city, state, zip code, area code/telephone number, date of birth, sex, referring physician name, UPIN, provider ID or NPI, ICD9 code by specificity, the responsible party’s name and relationship to patient, ID or policy number and group number. Attach a copy of the patient’s insurance card to the request. If the required information is not provided, the client may be billed for payment. For a listing of insurance carriers contracted by Nichols Institute, please contact your account representative.

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### MEDICARE AND MEDICAID/MEDICAL

Nichols Institute may bill Medicare, MediCal and various Medicaid programs directly for clients other than hospitals. Check the appropriate billing box on the Medicare or Medicaid/MediCal test request form or electronic order screen. Provide the following information: patient name, address, city, state, zip code, phone number, date of birth, sex, Medicare or Medicaid/MediCal policy number, insurance card copy, ICD9 code by specificity, referring physician name and UPIN number for Medicare patients or referring physician Medicaid provider number for Medicaid/MediCal patients. The physician signature is required in some states in order to bill Medicaid.

### MEDICARE

Under the Medicare statute, a laboratory must bill Medicare directly for clinical laboratory services. Physicians may not bill the Medicare program for laboratory tests they do not perform.

Clinical diagnostic laboratory tests are reimbursed on the basis of a fee schedule. The following procedures are exempted from fee schedule reimbursement:

- Clinical Pathology Consultations
- Blood Bank Services
- Blood Smears with Written Interpretations
- Certain Other Cytopathology Services
- Bone Marrow Smears and Biopsies
- Surgical Pathology Services

Medicare reimburses for these procedures at 80% of the approved amount and requires that the patient be billed for the remaining 20% copayment and any applicable deductible amounts.

When ordering tests for patients under Medicare, physicians or authorized individuals should only order tests that are medically necessary for the diagnosis and treatment of a patient, rather than for screening purposes. The Office of the Inspector General takes the position that a physician who orders medically unnecessary testing may be subject to civil penalties.

The Centers for Medicare and Medicaid Services (CMS) has implemented uniform National Coverage and Administrative Policies for clinical laboratory services that ensure the medical necessity of certain services rendered to Medicare beneficiaries. In addition to the National Coverage Policies subject to National Coverage Determination (NCD), CMS allows Medicare Contractors to develop their own Local Coverage Determination policies (LCD). These LCDs vary among Medicare carrier jurisdictions. Many of the procedures subject to NCD or LCD are for clinical laboratory testing. These tests are often referred to as Limited Coverage Tests.

Medicare Contractors require medical necessity documentation in order to determine coverage for tests that are subject to NCD or LCD. A carrier will deny coverage for a limited coverage test when it is submitted without specific diagnosis information that supports the medical necessity for the testing. Documentation of medical necessity for laboratory tests is reported to the carrier with a code from the International Classification of Diseases (ICD-9). ICD-9 manuals are available from various publishers.

Whenever you order a test that is subject to NCD or LCD, an ICD-9 code is required on the test request form. The ICD-9 code should indicate the medical necessity that you believe is appropriate for the test. Please provide the ICD-9 code that most accurately describes the patient's condition. Do not choose a code merely to secure claim payment. ICD-9 codes must be provided in valid format, including 4th and 5th digit specificity when required. The ICD-9 code that you provide must appear in the patient's medical records in order to support the necessity of the testing in the event of a post-payment review.

Whenever possible, tests that are subject to NCD or LCD established by Nichols Institute's Medicare carrier are printed in red on the test request forms. The Medicare carrier may adopt additional LCD for other tests at any time. Copies of our Medicare carrier's LCD are available. We will advise you of new LCD or updates whenever they are issued.

### Advance Beneficiary Notice

In the event that a test is determined by Nichols Institute's Medicare carrier to be medically unnecessary, the laboratory may only bill the patient if an Advance Beneficiary Notice (ABN) has been completed and signed by the patient before the time that the specimen is collected.

Medicare's medical necessity requirements for coverage may not always be consistent with the reasons why you believe a test is appropriate for a patient. Nevertheless, when you have reason to believe that a test may be considered medically unnecessary by Medicare, the patient should be asked to sign a completed ABN. A new ABN must be completed and signed each time such conditions exist. An ABN signature may not be requested solely on the basis that a test being ordered is subject to NCD or LCD.

The ABN ensures that the patient understands that he/she will be responsible to pay for any services marked on the form that Medicare does not cover for one of the following reasons:

- The test is subject to NCD or LCD and the diagnosis for which the test is ordered is not considered to be indicative of medical necessity by Medicare.
- The test is ordered more frequently than Medicare considers medically necessary.
- The test is for research or investigational use only and is not approved by the Food and Drug Administration.

All of the information on the ABN must be completed. The test(s) that you believe will be considered by Medicare to be medically unnecessary must be clearly marked. If you must write in a test name on the ABN, please write the test name as it appears on the test request form. Do not use synonyms or abbreviations.

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Please be sure that the patient reads, understands, and signs the ABN prior to the specimen being collected. The form must be dated and the date should correspond to the date on which the specimen is collected. If the patient is unable to sign, the form should be marked with an "X" and the patient's guardian, guarantor, or other responsible party should sign the form.

ABN forms are available for those clients who order Medicare tests electronically. A bar code label for the accession related to the ABN should be placed in the upper right hand corner of the ABN. The completed ABNs should be placed in a separate envelope and sent directly to the billing department via your daily courier service.

Please see the request form's completion instructions for more information.

### MEDICAID

Nichols Institute participates with several state Medical Assistance programs. As with Medicare, most Medicaid programs do not allow physicians to file claims for services they do not perform. If the patient is enrolled with an additional insurer, such as Medicare or a private carrier, Medicaid can only be billed after those parties have been billed. Please be sure to provide all necessary billing information on the request form, including the ordering physician's original signature and Medicaid provider identification number. In cases where the patient is enrolled in a Medicaid HMO program, please verify that we are a participating provider with that program before submitting specimens for testing.

Medicaid carriers require diagnosis information in order to process a claim. This information is reported to carriers with a code from the International Classification of Diseases (ICD-9). ICD-9 manuals are available from various publishers. Diagnosis information should be provided in ICD-9 format when Medicaid billing is requested.

### CUSTOMER SERVICE

At Quest Diagnostics Nichols Institute the framework for a customer-focused quality management system includes philosophy, management policies, procedures and tools. Quality customer service is imperative in laboratory medicine. Managers from all disciplines meet daily to discuss all issues that impact our clients. Issues are assigned to the responsible managers and prompt resolution is expected. The Customer Services Department tracks resolution and monitors trends. There is nothing unique about the concept of holding a daily meeting attended by all management. What is special is that it is so dynamic that improvements are made cooperatively and in real time. Quest Diagnostics Nichols Institute is committed to applying these changes and reengineering the way we do business in response to our clients' needs.

### COURIER SERVICES

Quest Diagnostics has more than 25 years experience in providing logistics services over broad geographical boundaries. To ensure specimen integrity and fast turnaround time, local courier service to all major metropolitan areas and many rural areas is provided through our regional offices. More than 3500 logistic professionals, trained in customer service and specimen handling, provide specimen pickup, supplies, and test reports. Specimens are air shipped nightly for immediate processing.

### QUALITY ASSURANCE

The Quality Assurance department actively monitors quality performance indicators for the entire process of laboratory services, from specimen submission to laboratory performance, reporting, and billing. Performance is measured through customer surveys, employee surveys, audits and process measures. These indicators are used to identify quality improvement opportunities that are then implemented using the Six Sigma process. All indicators and activities are closely monitored by Quest Diagnostics Nichols Institute Management Team. The commitment to quality is demonstrated by the implementation of a quality systems and a vigorous approach to process improvement using Six Sigma.

### SUPPLIES

To order supplies and test request forms call your local laboratory. Supplies include serum and urine transfer tubes, tissue bags, and special collection kits as defined in the Alphabetical Test Listing section. A list of special supplies for infectious disease is provided in the Specimen Collection section.

### TEST REPORTING SYSTEMS

We offer unmatched system and data integration expertise including experience with all leading healthcare information systems and experience in building interfaces quickly and maintaining them worry free. We are proven in our ability to execute smooth implementations with a support team that installs, trains and provides support 24/7. And, we are always a step ahead of developing new features and functionality through MedPlus®, the healthcare technology subsidiary of Quest Diagnostics. Call your sales representative for the latest options for your hospital.

We start with a complete needs assessment and then develop a plan for the optimal solution for your hospital from a broad array of options including:

- Enterprise Portal
- ChartMaxx® Electronic Patient Record Solution
- Care360™ Lab Orders and Results
- LIS Interface

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### TEST REQUEST FORMS

Test request forms may be ordered from the local courier or by calling your local lab. Quest Diagnostics Nichols Institute provides various computer generated test menu options. Many clients select a menu based on their own ordering history. This menu will include the client's most frequently ordered tests. For a list of special test request forms contact your sales or service representative.

### TESTING POLICIES

#### ANIMAL SPECIMENS

Animal specimens are generally not acceptable for laboratory testing and will not be tested. Human Specimen Acceptability Requests for uncommon specimen type testing will be rejected, and the order cancelled, unless validation information is available.

#### CANCELLATIONS

Tests may be cancelled without charge while specimens are in transit. A nominal fee will be charged for cancellations after specimens have been accessioned but not yet assayed. For cancellation requests call Client Services.

#### REFERENCE RANGES

Quest Diagnostics Nichols Institute establishes its own reference ranges for analytes whenever possible. Many of our pediatric ranges have been developed in conjunction with major healthcare institutions. For some procedures, it is necessary to use ranges suggested by the reagent manufacturer or reported in the literature.

#### SPECIMEN RETENTION

After testing is completed, samples are kept refrigerated for 14 days and then discarded. Samples that must be retained for longer than 14 days are kept frozen. The retention times for all samples will vary and are based on such criteria as:

- state and federal regulations
- test manufacturer's recommendations
- deterioration of the analyte
- CAP requirements and NCCLS guidelines
- acute/convalescent testing requirements
- pending litigation

Appropriateness of testing is ultimately a technical decision and is made by the technical staff using test-specific criteria. Quest Diagnostics Nichols Institute's Sample Storage Policy assures availability of adequate and reliable specimens. Please call customer service at your lab for more details.

#### SPECIMEN REQUIREMENTS

Although test specific specimen requirements are provided in the alphabetical test listing, please refer to this section first. This section offers more extensive instructions for selected assays in Coagulation, Genetics, Infectious Disease, Oncology, and Toxicology. When necessary, there will be a reference from the Alphabetical Test Listing section to this section.