Texas Diagnostics Laboratories, LLC
2022 Test Catalog

Laboratory Reference Edition

Sorted By Test Name

Current as of January 1 2021

Definition of Specimen "Minimum Volume"

Defines the amount of specimen required to perform an assay once, including instrument and container dead space. Submitting the minimum specimen volume makes it impossible to repeat the test or perform confirmatory or perform reflex testing. In some situations, a minimum specimen volume may result in a QNS (quantity not sufficient) result, requiring a second specimen to be collected.

Policies
Texas Diagnostics Laboratories, LLC (TDL)

POLICY STATEMENTS

Animal Specimens

We do not accept animal specimens for laboratory testing.

Billing

Client—Each month you will receive an itemized invoice/statement which will indicate the date of service, patient name, CPT code, test name, and test charge. Payment terms are net 30 days. When making payment, please include our invoice number on your check to ensure proper credit to your account.

Patient—TDL does not routinely bill patient's insurance; however, if you have made advanced arrangements to have TDL bill your patient's insurance, please include the following required billing information: responsible party, patient's name, current address, zip code, phone number, Social Security number, and diagnosis code. Providing this information will avoid additional correspondence to your office at some later date. Please advise your patients that they will receive a bill for laboratory services from TDL for any personal responsibility after insurance payment. VISA® and MasterCard® are acceptable forms of payment.

Billing—CPT Coding

It is your responsibility to determine correct CPT codes to use for billing. While this catalog lists CPT codes to provide some guidance, CPT codes listed only reflect our interpretation of CPT coding requirements and are not necessarily correct. Particularly, in the case of a test involving several component tests, this catalog attempts to provide a comprehensive list of CPT codes for all the possible components of the test. Only a subset of component tests may be performed on your specimen. You should verify accuracy of codes listed.

Where multiple codes are listed, you should select codes for tests performed on your specimen. **TDL ASSUMES NO RESPONSIBILITY FOR BILLING ERRORS DUE TO RELIANCE ON CPT CODES LISTED IN THIS CATALOG.** For further reference, please consult the CPT Coding Manual published by the American Medical Association. If you have any questions regarding use of a code, please contact your local Medicare carrier.

Business Continuity and Contingency Planning

In the event of a local, regional, or national disaster, TDL performing sites have comprehensive contingency plans in place in each location to ensure that the impact on laboratory practice is minimized. With test standardization between our performing sites and medical practice locations throughout the country, we have worked to ensure that patient care will not be compromised.

Cancellation of Tests

Cancellations received prior to test setup will be honored at no charge. Requests received following

test setup cannot be honored. A report will be issued automatically and charged appropriately.

Chain-of-Custody
Chain-of-custody, a record of disposition of a specimen to document who collected it, who handled it, and who performed the analysis, is necessary when results are to be used in a court of law. TDL has developed packaging and shipping materials that satisfy legal requirements for chain-of-custody.

Compliance Policies
TDL is committed to compliance with applicable laws and regulations such as the Clinical Laboratory Improvement Amendments (CLIA). Regulatory agencies that oversee our compliance include, but are not limited to, the Centers for Medicare and Medicaid Services (CMS), the Food and Drug Administration (FDA), and the Department of Transportation (DOT). TDL develops, implements, and maintains policies, processes, and procedures throughout our organization which are designed to meet relevant requirements. We expect clients utilizing our services will ensure their compliance with patient confidentiality, diagnosis coding, anti-kickback statutes, professional courtesy, CPT-4 coding, CLIA proficiency testing, and other similar regulatory requirements. Also see "Accreditation and Licensure," "HIPAA Compliance," and "Reportable Disease."

Confidentiality of Results
TDL is committed to maintaining confidentiality of patient information. To ensure Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the COLA compliance for appropriate release of patient results, TDL has adopted the following policies:

Phone Inquiry Policy—One of the following unique identifiers will be required:

- TDL accession ID number for specimen; **or**
- Client account number from TDL along with patient name; **or**
- Client accession ID number interfaced to TDL; **or**
- Identification by individual that he/she is, in fact, "referring physician" identified on requisition form by TDL client

Under federal regulations, we are only authorized to release results to ordering physicians or health care providers responsible for the individual patient's care. Third parties requesting results including requests directly from the patient are directed to the ordering facility. We appreciate your assistance in helping TDL preserve patient confidentiality. Provision of appropriate identifiers will greatly assist prompt and accurate response to inquiries and reporting.

Critical Values
The "Critical Values Policy" of TDL, Houston, Texas, is described below. These values apply to TDL patients as well as external clients of TDL. Clients should provide "Critical Value" contact information to TDL. Inquiry to facilitate call-backs.

Definition of Critical Value—A critical value is defined as a value that represents a pathophysiological state at such variance with normal (expected values) as to be life-threatening unless something is done promptly and for which some corrective action could be taken.

Abnormal values are Not Considered Critical Values— Most laboratory tests have established reference ranges, which represent results that are typically seen in a group of healthy individuals. While results outside these reference ranges may be considered abnormal, "abnormal" results and "critical values" are not synonymous. Analytes on the TDL Critical Values List represent a subgroup of tests that meet the above definition.

Action Taken when a Result is Obtained that Exceeds the Limit Defined by the TDL Critical Values List—In addition to the normal results reporting (eg, fax, interface), TDL staff telephone the ordering physician or the client-provided contact number within 60 minutes following laboratory release of the critical test result(s). In the event that contact is not made within the 60-minute period, we continue to telephone until the designated party is reached and the result is conveyed in compliance and adherence to COLA.

Semi-Urgent Results— Semi-Urgent Results are defined by TDL as those infectious disease-related results that are needed promptly to avoid potentially serious health consequences for the patient (or in the case of contagious diseases, potentially serious health consequences to other persons exposed to the patient) if not acknowledged and/or treated by the physician. While not included on the Critical Values List, this information is deemed important to patient care in compliance and adherence to the COLA.

To complement TDL normal reporting mechanisms (eg, fax, interface), TDL staff will telephone results identified as significant findings to the ordering facility within 2 hours following laboratory release of the result(s). In the event that contact is not made within the 2-hour period, we will continue to telephone until the responsible party is reached and the result is conveyed. In addition, in most instances, you will see the comment **SIGNIFICANT RESULT** appear on the final report.

Disclosures of Results
Under federal regulations, we are only authorized to release results to ordering physicians or other health care providers responsible for the individual patient's care. Third parties requesting results, including requests directly from the patient, are directed to the ordering facility.

Fee Changes
Fees are subject to change without notification and complete pricing per accession number is available once accession number is final.

Framework for Quality
"Framework for Quality" is the foundation for the development and implementation of the quality program for TDL. Our framework builds upon the concepts of quality control and quality assurance providing an opportunity to deliver consistent, high-quality and cost-effective service to our clients. In addition, our quality program enhances our ability to meet and exceed the requirements of regulatory/ accreditation
agencies and provide quality service to our customers.

A core principle at TDL is the continuous improvement of all processes and services that support

the care of patients. Our continuous improvement process focuses on meeting the needs of you, our
client, to help you serve your patients.

"Framework for Quality" is composed of 12 "Quality System Essentials." The policies, processes, and procedures associated with the "Quality System Essentials" can be applied to all operations in the path of workflow (eg, pre-analytical, analytical, and post-analytical). Performance is measured through constant
monitoring of activities in the path of workflow and comparing performance through benchmarking internal and external quality indicators and proficiency testing.

Data generated by quality indicators drives process improvement initiatives to seek resolutions to system-wide problems. TDL utilizes "Failure Modes and Effects Analysis (FMEA)," "Plan Do Study Act (PDSA)," "LEAN," "Root Cause Analysis," and "Six Sigma" quality improvement tools to determine appropriate remedial, corrective, and preventive actions.

Quality Indicators— TDL produces hundreds of Key Performance Indicators for our business and operational areas, and we review them regularly to ensure that we continue to maintain our high standards. A sampling of these metrics includes:

- Pre-analytic performance indicators
    - Lost specimens*
    - On-time delivery
    - Special handling calls
    - Specimen acceptability*
    - Specimen identification*
    - Incoming defects*
- Analytic performance indicators
    - Proficiency testing
    - Quality control
    - Turnaround (analytic) times
    - Quantity-not-sufficient (QNS) specimens*
- Post-analytic performance indicators
    - Revised reports*
    - Critical value reports*
- Operational performance indicators
    - Incoming call resolution*
    - Incoming call abandon rate
    - Call completion rate
    - Call in-queue monitoring
    - Customer complaints
    - Customer satisfaction surveys

The system provides a planned, systematic program for defining, implementing, monitoring, and evaluating our services.

*Measured using Six Sigma defects per million (dpm) method.

HIPAA Compliance
TDL is fully committed to compliance with all privacy, security, and electronic transaction code requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). All services provided by TDL that involve joint efforts will be done in a manner which enables our clients to be HIPAA and the COLA compliant.

Infectious Material
The Centers for Disease Control (CDC) in its regulations of July 21, 1980, has listed organisms and diseases for which special packaging and labeling must be applied. Required special containers and packaging instructions can be obtained from us.

Shipping regulations require that infectious substances affecting humans be shipped in a special manner. See "Infectious Material." A copy of the regulations can be requested from the International Air Transport Association (IATA).

Informed Consent Certification
Submission of an order for any tests contained in this catalog constitutes certification to TDL by ordering physician that: (1) ordering physician has obtained "Informed Consent" of subject patient as required by any applicable state or federal laws with respect to each test ordered; and (2) ordering physician has obtained from subject patient authorization permitting TDL to report results of each test ordered directly to ordering physician.

On occasion, we forward a specimen to an outside reference laboratory. The laws of the state where the reference laboratory is located may require written informed consent for certain tests. TDL will request that ordering physician pursue and provide such consent. Test results may be delayed or denied if consent is not provided.

Non-Biologic Specimens
Due to the inherent exposure risk of non-biologic specimens, their containers, and the implied relationship to criminal, forensic, and medico-legal cases, TDL does not accept nor refer non-biologic specimen types. Example specimens include: unknown solids and liquids in the forms of pills, powder, intravenous fluids, or syringe contents.

Patient Safety Goals
One of COLA goals for the Laboratory Services Program is to improve the accuracy of patient identification by using at least 2 patient identifiers when providing care, treatment, or services.

TDL uses multiple patient identifiers to verify the correct patient is matched with the correct specimen and the correct order for the testing services. As a specimen is received at TDL, the client number, patient name, and patient age date of birth are verified by comparing the labels on the specimen tube or container with the electronic order and any paperwork (paper requisition) which may accompany the specimen to be tested. When discrepancies are identified, TDL Inquiry will call the client to verify discrepant information to assure TDL is performing the correct testing for the correct patient. When insufficient or inconsistent identification is submitted, TDL will

recommend that a new specimen be obtained, if feasible.

Parallel Testing
Parallel testing may be appropriate in some cases to re-establish patient baseline results when converting to a new methodology at TDL.

Proficiency Testing
We are a CLIA-licensed facility that voluntarily participates with College of American Pathologists (CAP) for our external proficiency testing and internal proficiency testing programs. It is TDL expectation that clients utilizing our services will adhere to CLIA requirements for proficiency testing (42 CFR 493.801), including a prohibition on discussion about samples or results and sharing of proficiency testing materials with TDL during the active survey period.

TDL proficiency testing includes participation in CMS-approved programs. TDL also performs alternative assessment using independent state, national, and international programs when proficiency testing is not available. TDL also conducts comparability studies to ensure the accuracy and reliability of patient testing, when necessary. We comply with the regulations set forth in Clinical Laboratory Improvement Amendments (CLIA-88), the Occupational Safety and Health Administration (OSHA), or the Centers for Medicare & Medicaid Services (CMS).

It is TDL expectation that clients utilizing our services will adhere to CLIA requirements for proficiency testing including a prohibition on discussion about samples or results and sharing of proficiency testing materials with TDL during the active survey period. Referring of specimens is acceptable for comparison purposes when an approved proficiency-testing program is not available for a given analyte.

Record Retention
TDL retains all test requisitions and patient test results at a minimum for the retention period required to comply with and adhere to the COLA. A copy of the original report can be reconstructed including reference ranges, interpretive comments, flags, and footnotes with the source system as the TDL laboratory information system.

Referral of Tests to Another Laboratory
IF TDL forwards tests to other laboratories as a service to its clients. This service should in no way represent an endorsement of such test or referral laboratory or warrant any specific performance for such test. TDL will invoice for all testing referred to another laboratory at the price charged to TDL. In addition, TDL may charge an administrative fee per test for such referral services.

Reflex Testing
TDL identifies tests that reflex when medically appropriate. In many cases, TDL offers components of reflex tests individually as well as together. Clients should familiarize themselves with the test offerings and make a decision whether to order a reflex test or an individual component. Clients, who order a reflex test, can request to receive an “Additional Testing Notification Report” which indicates the additional testing that has been performed. This report will be faxed to the client.

Reportable Disease
TDL, in compliance with and adherence to COLA Criteria strives to comply with laboratory reporting requirements for each state health department regarding reportable disease conditions. We report by mail, fax, and/or electronically, depending upon the specific state health department regulations. Clients shall be responsible for compliance with any state specific statutes concerning reportable conditions, including, but not limited to, birth defects registries or chromosomal abnormality registries. This may also include providing patient address/demographic information. TDL reporting does not replace the client or physician responsibility to report as per specific state statues.

Request for Physician Name and Number
TDL endeavors to provide high quality, timely results so patients are able to receive appropriate care as quickly as possible. While providing esoteric reference testing, there are times when we need to contact the ordering physician directly. The following are 2 examples:

> When necessary to the performance of a test, the ordering physician's name and phone number are requested as part of "Specimen Required." This information is needed to allow our physicians to make timely consultations or seek clarification of requested services. If this information is not provided at the time of specimen receipt, we will call you to obtain the information. By providing this information up front, delays in patient care are avoided.
>
> In some situations, additional information from ordering physician is necessary to clarify or interpret a test result. At that time, TDL will request physician's name and phone number so that one of our staff can consult with the physician.

We appreciate your rapid assistance in supplying us with the ordering physician's name and phone number when we are required to call. Working together, we can provide your patients with the highest quality testing services in the shortest possible time.

Special Handling
TDL serves as a reference laboratory for clients. Our test information, including days and time assays are performed as well as analytic turnaround time. Unique circumstances may arise with a patient resulting in a physician request that the specimen or results receive special handling. There are several options available.

There is a nominal charge associated with any special handling.

- ***Hold*:** If you would like to send us a specimen and hold that specimen for testing pending initial test results performed at your facility, please call TDL. We will initiate a hold and stabilize the specimen until we hear from you.
- ***Expedite*:** If you would like us to expedite the specimen to the performing laboratory, you can call TDL and request that your specimen be expedited. Once the shipment is received in our receiving area, we will deliver the specimen to the performing laboratory for the next scheduled analytic run. We will not set up a special run to accommodate an expedite

request.

- ***STAT*:** In rare circumstances, STAT testing from the reference laboratory may be required for patients who need immediate treatment. These cases typically necessitate a special analytic run to turn results around as quickly as possible. To arrange STAT testing, please have your pathologist, physician, or laboratory director call TDL. He/she will be connected with one of our medical directors to consult about the patient's case. Once mutually agreed upon that there is a need for a STAT, arrangements will be made to assign resources to run the testing on a STAT basis when the specimen is received.

Specimen Identification Policy

In compliance with and adherence to the COLA, TDL policy states that all specimens received for testing must be correctly and adequately labeled to assure positive identification. Specimens must have **2** person-specific identifiers on the patient label. Person-specific identifiers may include accession number, patient's first and last name, unique identifying number (e.g., medical record number), or date of birth. Specimens are considered mislabeled when there is a mismatch between the person-specific identifiers on the specimen and information accompanying the specimen (e.g., computer system, requisition form, additional paperwork).

When insufficient or inconsistent identification is submitted, TDL will recommend that a new specimen be obtained, if feasible.

Specimen Rejection

All tests are unique in their testing requirements. To avoid specimen rejection or delayed turnaround times, please check the "Specimen Required" field within each test. You will be notified of rejected or problem specimens upon receipt.

Please review the following conditions prior to submitting a specimen to TDL:

- Collection tool (swab) present in collection tube
- Collector's Name and Collection Time
- Specimen type (nasopharyngeal or oral)
- Specimen volume
- Patient information requested
- Proper identification of patient/specimen
- Specimen container (metal-free and appropriate preservative, etc.)
- Temperature (ambient, frozen, refrigerated)

Specimen Volume

The "Specimen Required" section of each test includes 2 volumes - preferred volume and minimum volume.

Preferred volume has been established to optimize testing and allows the laboratory to quickly process specimen containers, present containers to instruments, perform test, and repeat test, if necessary. Many of our testing processes are fully automated; and as a result, this volume allows hands-free testing and our quickest turnaround time (TAT). Since patient values are frequently

abnormal, repeat testing, dilutions, or other specimen manipulations often are required to obtain a reliable, reportable result. Our preferred specimen requirements allow expeditious testing and reporting.

When patient conditions do not mandate reduced collection volumes, we ask that our clients submit preferred volume to facilitate rapid, cost-effective, reliable test results. Submitting less than preferred volume may negatively impact quality of care by slowing TAT, increasing the hands-on personnel time (and therefore cost) required to perform test.

TDL makes every possible effort to successfully test your patient's specimen. If you have concerns about submitting a specimen for testing, please call TDL at 713-571-2894. Our staff will discuss the test and specimen you have available. While in some cases specimens are inadequate for desired test, in other cases, testing can be performed using alternative techniques.

Supplies
Shipping boxes, specimen vials, special specimen collection containers, and request forms are supplied without charge. Supplies can be requested by calling TDL at 713-571-2894.

Test Classifications
Analytical tests offered by TDL are classified according to the FDA labeling of the test kit or reagents and their usage. Where appropriate, analytical test listings contain a statement regarding these classifications, test development, and performance characteristics.

Test Development Process
TDL serves patients and health care providers from TDL and our reference laboratory clients. We are dedicated to providing clinically useful, cost-effective testing strategies for patient care. Development, validation, and implementation of new and improved laboratory methods are major components of that commitment.

Each assay utilized at TDL, whether developed on site or by others, undergoes an extensive validation and performance documentation period before the test becomes available for clinical use. Validations follow a standard protocol that includes:

- Precision
- Accuracy
- Sensitivity
- Specificity and interferences
- Reportable range
- Specimen stability
- Specimen type comparisons, if applicable
- Urine preservative studies: stability at ambient, refrigerated, and frozen temperatures
- Comparative evaluation with current and potential methods, if applicable
- Reference intervals: reference intervals provided by TDL are derived from studies performed in our laboratories or adopted from the manufacturer package insert after internal verification. When reference intervals are obtained from other sources, the source is indicated in the "Reference Values" field.

- Workload recording
- Limitations of the assay
- Clinical utility and interpretation written by TDL medical experts, electronically available.

Test Result Call-Backs
Results will be phoned to a client when requested from the client (either on TDL request form or from a phone call to TDL from the client).

Time-Sensitive Specimens
Please contact TDL at 713-571-2894 prior to sending a specimen for testing of a time-sensitive nature. Relay the following information: facility name, account number, patient name and/or TDL accession number, shipping information (i.e., courier service, UPS, FedEx®, etc.), date to be sent, and test to be performed. Place specimen in a separate TDL temperature appropriate bag. Please write "Expedite" in large print on outside of bag.

Turnaround Time (TAT)
TDL extensive test menu reflects the needs of our own health care practice. We are committed to providing the most expedient TAT possible to improve diagnosis and treatment. We consider laboratory services as part of the patient care continuum wherein the needs of the patient are paramount. In that context, we strive to fulfill our service obligations. Our history of service and our quality metrics will document our ability to deliver on all areas of service including TAT.

TDL defines TAT as the analytical test time (the time from which a specimen is received at the testing location to time of result) required. TAT is monitored continuously by each performing laboratory site within TDL. For the most up-to-date information on TAT for individual tests, please contact TDL at 713-571-2894.

Unlisted Tests
TDL does not list all available test offerings in the paper catalog. New procedures are developed throughout the year; therefore, some tests are not listed in this catalog. Although we do not usually accept referred tests of a more routine type, special arrangements may be made to provide your laboratory with temporary support during times of special need such as sustained instrumentation failure.

Test Catalog

COVID-19	**Specimen Requirements:** Viral Transport Media (VTM) Specimen Volume: 3 mL Specimen type: swab in viral transport media (VTM) **Specimen Minimum Volume: 1 mL** **Transport Temperature:** Specimen Type Temperature Time Special Container Ambient (preferred) 3 days 2 -8 °C 3 days Frozen 15 days

COVID CPT Cash Price List:

CPT	Charge
U0003	$230.00
U0005	$75.00
G2023	$120.00