

GCC-B1™ Test Order Form

These tests cannot be performed without the signature of the ordering physician or other approved health care provider.



Targeted Diagnostics & Therapeutics, Inc.
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CLIA ID 39D1006449

Targeted Diagnostics & Therapeutics, Inc. (TDT), has developed the GCC-B1 Blood test for use in patient care under the Federal CLIA '88 regulations for clinical laboratories.

Test Ordered

Test Type	Sample Collection Date
GCC-B1 Blood Test	Date _____
Cost \$495/test	Time _____ <input type="checkbox"/> AM <input type="checkbox"/> PM

Special Lab Instructions

PATIENT IDENTIFICATION NUMBER _____

OFFICE USE ONLY

PATIENT NAME (FIRST, MI, LAST) - Please Print _____ Social Security# (U.S. Only) _____

Phone _____ Date of Birth _____ Male Female

NAME OF RESPONSIBLE PARTY – if different than patient (LAST, FIRST, MIDDLE) _____

STREET ADDRESS (including apartment number) No PO Boxes _____

CITY: _____ STATE: _____ ZIP: _____

Clinical History (to be entered by Physician)

CEA Values/Dates: _____, _____, _____
 Tumor Differentiation: Poor Moderate Well
 Known Metastases: Node Liver Other _____
 Stage: Dukes A B C D
 TNM 1 2 3 4
 # Nodes ____ Pos ____ Neg
 LD ____ AP ____ ALP ____ ALT ____ AST ____

General Observations:

Referring Physician(s)

Physician _____
 UPIN _____
 Street Address _____
 City _____
 State _____ ZIP _____
 Country _____
 Phone _____
 FAX _____
 Email _____

Payment Information

Credit Card Type VISA Master Card
 Credit Card Number _____
 Expiration Date _____
 Cardholder Name _____
 Cardholder Signature _____

Please fax or mail a copy of this form to TDT at the address listed at the top of this form.

Upon receipt of payment:

Collection materials (kit) will be sent directly to the patient.

CPT Codes: 83890, 83891, 83892, 83894, 83896, 83897, 83898, 83901, 83902, 83912
ICD 9 Codes: 153.0-153.9; 154.0-154.8; 197.5, 235.2, 239.0
V Codes: V10.05

Physician's Signature

Patient / Responsibility Signature

Blood Collection

Please designate the laboratory to which the patient will be sent for the blood draw.

Hospital / Lab Name _____
 Street Address _____
 City _____
 State _____ ZIP _____
 Phone _____
 Fax _____

(NOTE: Blood Specimen Collection Kits will be sent directly to the Patient address as listed at the top right section of this form, unless otherwise directed here below.)

Check here to have kits sent to:

Your Office Laboratory Patient
 (Point of Draw)

I have read the ABN on the back and I agree to assume full and direct responsibility for payment to TDT for identified services. Subsequent reimbursement from any national or private insurance programs will be my sole responsibility.

I acknowledge that retained samples may be used anonymously for research purposes.

TDT is not a participating Medicare or Medicaid provider and does not bill either of these programs for the costs associated with these tests. TDT will provide the patient with the standard information required by insurance companies for reimbursement. The patient may elect to submit these materials and may receive full, partial or no reimbursement from his or her health care insurer. The patient's credit card will be charged upon receipt by TDT. If collection materials (kits) are shipped and a specimen is not subsequently returned to TDT, within 60 days, **TDT will retain a \$100.00 handling fee** and all other monies received will be returned.

Instructions to Providers:

1. The signature of the ordering provider is required to process the test under CLIA '88 regulations.
2. Please fax the top (white) copy of this form to TDT (1-610-431-0805). Upon receiving this form and designated payment, TDT will send collection kits to the patient or hospital lab specified.
3. Please keep the top copy of this form for your records and dispatch others as labeled.
4. Please use a separate form if ordering more than one test type at a time for an individual patient.
5. It is TDT's policy that retained samples and aggregated test results will be rendered anonymous and may be used for on-going research purposes.

White Copy – Physician's Office

Yellow Copy – Patient

Pink Copy – TDT

NOTICE TO PHYSICIANS

Targeted Diagnostics and Therapeutics, Inc. is working to ensure compliance with all guidelines governing the submission of Medicare claims for laboratory services. This is to inform you that you need to be aware of the policies regarding medical necessity, Medicare Billing, CPT/HCPCS codes, Medicare National Limitation Amounts and laboratory testing.

Medicare will only pay for tests that meet the Medicare definition of medical necessity. The Office of the Inspector General (OIG) wants to ensure that Physicians order only medically necessary tests and that Physicians know that the OIG may impose civil penalties on those who order otherwise. The OIG does recognize that a Physician must be able to order any test, including screening tests and investigative or research tests, they believe appropriate for the treatment of their patients. Medicare may deny payment for a test that the Physician believes appropriate but which does not meet the Medicare definition of medical necessity. In this case, a properly executed Advance Beneficiary Notice (ABN) should accompany the orders. An ABN is incorporated into the Targeted Diagnostics and Therapeutics requisition/order form. If you have questions regarding appropriate testing and ordering, please contact Targeted Diagnostics and Therapeutics Laboratory Compliance Officer at (610) 431-0800.

Targeted Diagnostics and Therapeutics, Inc. does not offer laboratory profiles that contain multi-channel chemistry tests or other automated multiple test results. Targeted Diagnostics and Therapeutics, Inc. offers highly specialized testing, which may or may not have CPT codes available. The Medicare Limitation Amount for each CPT/HCPCS code can be found in the Medicare National Limitation Amount reference supplied to physician's offices by Medicare.

IMPORTANT INFORMATION FOR MEDICARE PATIENTS CONCERNING NON-COVERED SERVICES

1. What is "Medical Necessity"?

Medicare covers only those services it has defined a reasonable and necessary for your treatment. Medicare requires all providers to report information regarding the patient's diagnosis when seeking payment so that they can determine whether the services ordered were medically necessary.

2. What is an ABN?

An ABN is an Advance Beneficiary Notice. The purpose of the ABN is to give you advance notice that Medicare may not pay for your services. You will be asked to sign the ABN before the services are performed.

3. If Medicare will not pay for a service, does that mean I do not need the service?

No. Your doctor bases decisions on a wide range of factors including your personal medical history, any medications you might be taking and generally accepted medical practices. Even if your doctor believes that a medical test or service is "good medicine," and useful information to have in order to provide the best care for you, it is possible that a TDT test may not meet the Medicare standardized definition of "medical necessity".

4. What options do I have?

You have two options when an ABN is presented to you for signature (see front of this form). You may, (1) agree to be responsible for payment of services that Medicare does not cover and receive the services, or (2) refuse to be responsible for payment of services that Medicare does not cover and, therefore, not receive the tests or services. And you always have the option to submit a claim to Medicare and/or your health care provider directly, using the appropriate CPT and/or ICD-9 coding.

5. What if I have questions?

If you have questions, you should discuss them with your physician and/or health care provider at the time of service.

ADVANCED BENEFICIARY NOTICE (ABN)

This notice applies if one or more TDT tests are requested by a physician for a patient with Medicare and/or private insurance coverage, AND

- The patient diagnosis DOES NOT match any of the ICD-9 codes established as eligible for coverage by the insurance carrier, or the test(s) is/are being performed more frequently than Medicare or the insurance carrier allows. AND/OR
- Medicare or the insurance carrier determines that the test(s) is/are not "reasonable and necessary" under their program standards. Medicare will only pay for services that it determines to be "reasonable and necessary" under section 1862(a)(1) of the Medicare law. If Medicare determines that a particular service, although it would be covered, is not "reasonable and necessary" under Medicare program standards, Medicare will deny payment for that service. Other insurance carriers could have similar standards.

EXPLANATION OF INSURANCE CODES

CPT Codes

83890	Molecular diagnostics; molecular isolation or extraction
83891	Molecular diagnostics; isolation or extraction of highly purified nucleic acid
83892	Nuclear molecular diagnostics; enzymatic digestion
83894	Nuclear molecular diagnostics; separation (e.g., dot blot, electrophoresis)
83896	Nuclear molecular diagnostics; nucleic acid probe, each
83897	Molecular diagnostics; nucleic acid transfer (e.g., Southern, Northern)
83898	Molecular diagnostics; amplification of patient nucleic acid (e.g., PCR, LCR), single primer pair, each primer pair – Revised 2001
83901	Molecular diagnostics; amplification of patient nucleic acid, multiplex, each multiplex reaction
83902	Molecular diagnostics; reverse transcription
83912	Nuclear molecular diagnostics; interpretation and report

ICD 9 Codes

There are a wide variety of diagnosis codes that can be used with the molecular diagnostic testing. The diagnosis is truly dependent on the reason for the visit, e.g., colorectal cancer, history of colorectal cancer, metastasis of colorectal cancer.

The range of codes can include:

153.0 to 153.9
154.0 to 154.8

And also if applicable

197.5 Secondary malignant neoplasm of large intestine and rectum
235.2 Neoplasm of uncertain behavior of stomach, intestines and rectum
239.0 Neoplasm of unspecified nature, digestive system

V-Codes

V10.05 Personal history of malignant neoplasm colon