**Billing**

To accurately bill for laboratory services, it is necessary to have the following information for our records.

- Patient’s full name, middle initial, if available
- Patient’s address (including zip code), date of birth, sex, Social Security number, responsible party, and home phone number
- Patient’s Medicare number (if applicable). The membership number and diagnosis code are required. This should include a suffix. If the suffix is other than A, the spouse’s name is required. The patient’s Social Security number may not necessarily be the membership number. If the patient has secondary insurance, please provide the insurance name and policy number.
- Name (first and last) of the insured individual if different from the patient.
- Indicate the patient’s relationship to the insured.
- Patient’s diagnosis or symptoms are required for insurance billing.
- Patient’s primary physician, ordering physician, date of specimen collection, and time drawn.

**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.

**Guide for Medicare Patients**

A guide to understanding diagnostic therapeutic services.

- **How Will I Be Billed**
  — Our laboratory receives a written request from your physician/clinician for laboratory testing. The laboratory will bill Medicare directly for these tests. The laboratory gives Medicare your Medicare number, the tests performed, and your diagnosis that is provided by your physician.

- **Medical Necessity Requirement**

  — Medicare covers only those tests and services which are necessary and reasonable for your treatment. Medicare requires all care providers to report information relative to the patient’s symptoms(s) and/or diagnosis when seeking payment so that they can determine whether the tests ordered are medically necessary.

- **Advance Beneficiary Notice of Noncoverage (ABN)**
  — An ABN is to give you advance notice that the test or tests you are having performed may not be covered by Medicare. The ABN outlines the test(s) which are in question. If Medicare denies payment, this informs you that you will be financially responsible for your bill. When the ABN form is required, you will be asked to sign this before laboratory testing can be performed.

- **Options**
  — When presented with the ABN, you have several options:
    - Agree to be responsible for payment of test(s) that Medicare may deny and receive these tests
    - Refuse to be responsible for payment of these tests that Medicare may not cover and not receive these services

- **If I Decline to Sign the ABN**
  — If you decide to not sign the ABN and demand the test(s), the laboratory testing will be performed; and you will be held responsible for payment if Medicare denies coverage.

- **If Medicare Denies Payment, Does that Mean I Do Not Need This Test**
  — No. Your physician/clinician bases many decisions about laboratory testing on a variety of factors which may include your medical history, acceptable medical practices, and various medications you are taking. Your physician may request a particular test that may give him/her information to provide quality care for you, and it is possible that Medicare may not consider this test to be medically necessary with your symptom or diagnosis.

- **Other Questions**
  — It is important that you discuss your questions with your health-care provider at the time of service. If you have further questions, contact your physician or visit the Medicare website at: www.medicare.gov.

**Informed Consent Certification**

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

Patient Identification Accuracy
Hallmark Health must adhere to proper identification of patient specimens for good patient care, for both quality and safety reasons. The need for proper identification is specified by the College of American Pathologists (CAP) Laboratory General Checklist Commentary GEN 40700: “Specimens lacking proper identification or an accompanying requisition should not be accepted by the laboratory.”

To be compliant, it is important that each specimen be properly labeled with the same demographics that appear on the paperwork. If a discrepancy has been identified upon specimen arrival at Hallmark Health, we will contact you to make you aware of the discrepancy and cancel the test order.

Phlebotomy Service Policy
Hallmark Health provides inpatient phlebotomy service 24 hours a day, 7 days a week. Outpatient Phlebotomy Services are available Monday through Friday, 7 a.m. to 8 p.m., and Saturday and Sunday 7 a.m. to 3 p.m. STAT requests are available any time.

• Outpatients:
  — All laboratory test orders must be signed by a physician or other appropriate clinician. Please include the reason for the test.
  — All orders for laboratory work must be written. If verbal orders are necessary, they must be followed up with a written order.
  — Upon arrival at the hospital, the patient reports to Admitting to register. The laboratory receptionist will key the patient and test information into the computer.
  — If specimens are dropped off at the laboratory for testing, the specimens must be in a biohazard bag. (Bags may be obtained from the laboratory.)

See “Hallmark Health Drawing Sites” in “General Information” for a complete list of locations and hours of operations.

Quality Improvement
Quality assurance (QI) at Hallmark Health is establishing and controlling all processes that affect laboratory results. It includes properly preparing the patient, collecting valid specimens, correctly implementing analytical processes, validating test results, correctly recording and reporting test results, and reporting those results into the patient’s record. Consequently, adequate records describing quality assurance practices and quality of analyses are documented, maintained, and available for review.

QI is our comprehensive set of policies, procedures, and practices that are necessary to ensure the quality of laboratory tests. Our QI program includes 7 basic areas:

• Written Policies, Guidelines, and Procedures
  — These give our laboratory established methods of operation and standardize the process within the laboratory. These are reviewed annually by the Medical Director and any revisions signed and dated by the Medical Director when adopted.
• Laboratorian Training and Safety
  — This is assured by having proper training prior to test performance, a complete personnel file with an employee performance checklist, regular employee performance evaluations, and a thorough safety program orientation with updates and reviews as necessary.
  — Hallmark Health currently utilizes the CAP Competency Assessment Program for training technical staff.
• Calibration of Instrumentation
  — This is done on a regular basis and in accordance with good laboratory practice (as specified by the manufacturer). This date is recorded in each department and available for the Medical Director to review.
• Maintenance
  — This is performed on a regular basis according to manufacturers’ recommendations. Each instrument has a log to record all changes to the instrument and all preventive maintenance. Other activities to be recorded include: daily temperature checks of refrigerators and freezers, waterbaths, centrifuge and microscope maintenance.
• Quality Control (QC) Testing
  — QC specimens are analyzed each day and/or shift that patient specimens are analyzed. Assay results of QC specimens are recorded and, when an out-of-control situation is identified, the action taken must follow established protocols and be documented.
See individual department procedures for documentation protocols. The supervisors review and initial QC data on a regular basis.

• Reporting Patient Results
  — This is done by having complete and clearly documented records of patient testing in the laboratory computer system. Patient reports are generated by the laboratory computer system and distributed to the physician for outpatients, to the floor locations for inpatients, and to medical records.
  — Information on the report form includes the following:
    • Patient’s full name (first and last)
    • Date and time of collection
    • Date of testing
    • Name of test
    • Abnormal flags
    • Results
    • Condition of unsatisfactory or inappropriate specimen
    • Ordering physician
    • Other pertinent or significant information if edited in
    • Reference intervals for test, if relevant
    • Performing laboratory
  — Critical values are defined and receive immediate attention. (See “Critical Value List” in “General Information”)

• Proficiency Testing (PT)
  — This is performed as required by Clinical Laboratory Improvement Amendments of 1988 (CLIA’88), which enables our laboratory to perform tests on unknown specimens from an outside agency. PT monitors our laboratory’s accuracy by comparing PT results of our laboratory to others performing the same test by similar instrumentation and methods. Unacceptable PT performance is investigated, and a report is submitted to the Medical Director for review. All survey summaries are reviewed by the Medical Director or designee on a timely basis.

Rejected Specimens by Laboratory
The physician’s office will be notified of any specimen rejection, and a request will be made to submit a new specimen. A written report will be sent with the reason for rejection. See “Unacceptable Specimens” in “General Information.”

Microbiology: These guidelines are established to assure specimen integrity and accuracy of results.

• Specimen submitted in a non-sterile container (except for stools)
• Specimen grossly contaminated with foreign material internally and externally
• Specimen submitted on a dry swab, except for a rapid strep
• Specimen submitted >24 hours after it was obtained if for Neisseria gonorrhoeae or other fastidious organisms
• Specimen not properly labeled with patient’s full name (first, last, and middle initial) and date of birth or medical record number are required
• Specimen quantity is inadequate
• Stool specimen collected >3 hours prior and not refrigerated
• Multiple specimens on same day will not be accepted for the same test
• Sputum specimen that appears to be saliva (after review of Gram stain, the tech will notify floor or physician’s office)
• Unpreserved urine (yellow-top tube preserves cultures) left at ambient temperature for >1 hour or refrigerated for >24 hours
• Wet prep not submitted in saline
• Specimen submitted in expired transport media

Parasitology: These guidelines are established to assure specimen integrity and accuracy of results.

• Wet prep specimen for Trichomonas which is not submitted in physiological saline
• Stool of patient who had barium within the previous 7 days
• Specimen which is dried out
• Stool specimen which is not of sufficient quantity to perform the concentration technique and trichrome stain if for ova and parasites
• Specimen not properly labeled with patient’s full name (first, last, and middle initial) and date of birth or medical record number, which are required

Note: When a specimen is rejected, the nursing unit or physician’s office will be notified immediately so that a new specimen can be obtained in a timely manner. Specimen is not discarded until a new specimen is collected. An exception may need to be made to process the specimen, but only with physician approval.
Pathology and Cytology: Pathology specimens will be rejected for any of the following reasons:

- Inadequate identification (name, date of birth, address, etc.)
- No specimen in container
- Improper labeling or no label on container
- Inadequate preservation
- Form missing information, specimen site, insurance, etc.

**Note:** Offices will be advised of specimen rejection and need to take responsibility to come to pathology and relabel specimen or fill out paperwork properly.

### Unacceptable Specimens

Some specimens cannot be analyzed because of improper collection or degradation in transit. Other specimens may have prolonged turnaround times because of lack of necessary ancillary specimens or patient information.

You will be notified of rejected or problem specimens upon receipt.

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### Request for Physician Name and Number

Hallmark Health 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, Hallmark Health will request physician’s name and phone number so that 1 of our staff can consult with the physician.

### Supplies

Mailing cartons, specimen vials, special specimen collection containers and kits, sterile vials, stool containers, and request forms are supplied without charge upon request. Please fill out a supply order form. See supply list in “Request Forms” in “Special Instructions.”

### Test Turnaround Time

The Laboratory Service Directory lists the days on which testing is set up as a guide to expected analytical turnaround times. Repeated tests take additional time.