A scenic landscape featuring the Grand Teton mountains in the background, their peaks reflected in a calm lake in the foreground. The foreground is dotted with autumn-colored trees and bushes. The sky is a clear, pale blue.

# Directory of Services



# Table of Contents

|   |       |
|---|-------|
| Introduction.....                         | 4     |
| Consultative Services.....                | 5     |
| Yellowstone Pathologists, P.C. .....      | 6, 7  |
| Professional and Technical Services ..... | 8     |
| Client Services.....                      | 9     |
| Specimen Collection Guidelines.....       | 10-13 |
| Completing Our Requisition.....           | 14    |
| ICD Coding and Medical Necessity .....    | 14-15 |
| Physician/Provider Information.....       | 16    |
| Medicare Advance Beneficiary Notice ..... | 17    |
| <br>TESTS                                 |       |
| 1.    Surgical Pathology Testing.....     | 18-19 |
| 2.    Cytology Testing.....               | 20    |
| 3.    Flow Cytometry Testing.....         | 21-26 |
| 4.    Molecular Pathology Testing .....   | 27-29 |
| Supplies .....                            | 30-31 |

# Introduction

About Yellowstone Pathology Institute, Inc. and Yellowstone Pathologists, P.C.

Yellowstone Pathologists, P.C., formerly Pathology Consultants, P.C. was formed in 1977 by a group of pathologists who had a commitment to quality, expertise, and patient care as provided by anatomic pathology services.

In February, 1999 the pathologists formed Yellowstone Pathology Institute, Inc., to better serve the needs of physicians, physician providers, hospitals and medical centers located throughout parts of Montana, Idaho and Wyoming. YPI is an independent reference laboratory offering services in

- ◆ Consultative Services
  - Medical Directorship in Anatomic and Clinical Pathology
  - Clinical and Technical Consultation
  - Continuing Medical Education
- ◆ Professional and Technical Services
  - Anatomic Pathology and Histopathology
  - Cytopathology and Women's Health
  - Hematopathology and Flow Cytometry
  - Molecular Genetic Pathology
- ◆ Client Services
  - Specimen Inquiry
  - Supplies
  - Billing

The pathologists and staff of YPI continue the commitment to excellence in client service, rigorous adherence to Federal and State regulations governing our practice, a devotion to personal and professional integrity, and a solemn dedication to the goal of providing the best quality laboratory services to our clients and their patients.

At YPI, our mission is to enhance patient care by providing the highest quality anatomic pathology and ancillary diagnostic services, consultation, education and esoteric testing development solutions. We value the strong relationships we have built throughout the years with our colleagues and believe that pathology services are best provided locally and will do our utmost to preserve and enhance those relationships.

Yellowstone Pathology Institute, Inc., maintains CLIA (Clinical Laboratory Improvement Act) certified and CAP (College of American Pathologists) accredited laboratories. Our pathologists are certified by the American Board of Pathology in their respective specialties and subspecialties. Our Cytotechnologists are registered with the American Society of Clinical Pathology CT(ASCP) and are licensed by the State of Montana as Clinical Laboratory Specialists. Our Medical Laboratory Scientists are registered with the American Society of Clinical Pathology MLS(ASCP) and specialized in Flow Cytometry SCYM(ASCP) and are licensed by the State of Montana as Clinical Laboratory Scientists. Our Histologic Technicians are registered with the American Society of Clinical Pathology HT(ASCP).

## College of American Pathologists accreditation

Billings, MT #6990201

CLIA certification

Billings, MT: #27D0946844 ~ Cody, WY: #53D1091161

## **Consultative Services**

### **Medical Directorship in Anatomic and Clinical Pathology**

Yellowstone Pathology Institute, Inc., and Yellowstone Pathologists, P.C., may enter into contractual agreements with hospitals, physicians, and laboratory entities wherein a board certified pathologist and/or a qualified medical technologist, acting in accordance with federal and state regulations, fulfills the duties and responsibilities of medical director for the laboratory. Site visits to the laboratory on at least a quarterly basis allow a cooperative and effective working relationship with the client's administrative, medical, and laboratory staff to achieve total quality management of laboratory services, including review of QC (Quality Control), QA (Quality Assurance), competency of laboratory technical staff, validation of testing methods, participation in CLIA or CAP inspections, and continuing education lectures to assist technical staff in meeting their re-licensure requirements.

### **Clinical and Technical Consultation**

Yellowstone Pathology Institute, Inc., and Yellowstone Pathologists, P.C., may enter into contractual agreements with hospitals, physicians, and laboratory entities wherein a board certified pathologist and/or a qualified medical technologist, acting in accordance with federal and state regulations, fulfills the duties and responsibilities of clinical consultant or technical supervisor. Site visits to the laboratory on at least a quarterly basis allow a cooperative and effective working relationship with the client's administrative, medical, and laboratory staff to achieve total quality management of laboratory services, including review of QC, QA, competency of laboratory technical staff, validation of testing methods, participation in CLIA or CAP inspections, and continuing education lectures to assist technical staff in meeting their re-licensure requirements.

### **Continuing Medical Education**

Our pathologists are actively involved in Continuing Medical Education in our region, providing lectures and demonstrations which promote the development of knowledge and skills in the fields of anatomic, clinical, and cytopathology. We are committed to the Montana Clinical Laboratory Licensure Law, and assist laboratorians in attaining continuing education credits required for annual re-licensure. In addition, we participate as guest lecturers in the Rocky Mountain College Physician Assistant program, and other formal and informal educational programs.

## Yellowstone Pathologists, PC



Angela F. Durden  
MD, FCAP  
GI & Hepatic Pathology



Michael S. Brown  
MD, FCAP  
Hematopathology



Christopher J. Nero,  
MD, FCAP  
Molecular Pathology



Kerrie R. Emerick  
MD, FCAP  
Dermatopathology

## Yellowstone Pathologists, PC



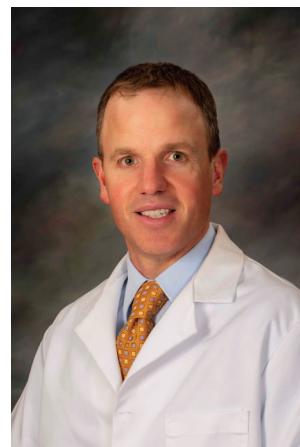
Austin Green  
MD, FCAP  
Dermatopathologist



Nick Luem  
MD, FCAP  
Hematopathology



Kelli Schneider  
MD, FCAP  
Hematopathology



Christopher Rozelle  
MD, FCAP  
Dermatopathology

## Professional and Technical Services

Yellowstone Pathology Institute Inc. boasts the expertise of eight full time board certified pathologists with collectively more than 100 years experience in anatomic and clinical pathology, as well as subspecialties in cytopathology, dermatopathology, hematopathology, and molecular genetic pathology. Our technical staff is made up of board registered and state licensed cytotechnologists, medical technologists, and histologic technicians. The pathologists and technical staff actively participate in total quality management to ensure that all areas of the laboratory produce the highest quality patient results. Our pathologists are available to provide consultations to providers regarding the ordering of appropriate tests and the medical significance of laboratory data.

### Anatomic Pathology

The histopathology department processes samples of body tissues which have been taken for diagnosing disease processes. The first step is a gross (visual) examination, where the pathologist documents the description of the specimen and then places all or selected parts of it into a small plastic cassette. The cassette and tissue are processed for several hours through a series of chemical steps to preserve the tissue permanently in as life-like a state as possible. Then the tissue is embedded into paraffin, forming a "block," and cut into ultra thin sections, placed on glass slides that are stained and then examined microscopically by the pathologist, and a diagnosis rendered. A large percentage of the specimens received at YPI are skin specimens, which are diagnosed by our Dermatopathologists.

### Cytopathology

The cytopathology department performs microscopic analysis of cytological specimens, i.e., samples of cells scraped or suctioned or otherwise collected. The specimens evaluated include gynecologic specimens, non-gynecologic cytology specimens, and fine-needle aspiration specimens. Our emphasis is on detecting and interpreting cellular abnormalities indicating malignant and pre-malignant lesions. Specific infectious agents and other non-malignant findings are also noted when appropriate. Recommendations for follow-up procedures on patients with abnormal results may be given, and consultation with physicians will be offered.

At Yellowstone Pathology Institute we are proud to offer the ThinPrepPap® Test with Dual Imaging. The ThinPrep®Pap Test has demonstrated increased detection of abnormalities (LSIL or more severe diagnosis) by 65% in screening populations, and by 6% in high-risk populations. We also perform HPV RNA testing on ThinPrep® specimens, as well as Chlamydia and Neisseria screening by Nucleic Acid Amplification.

### Hematopathology

The flow cytometry department of Yellowstone Pathology Institute, Inc., performs a variety of assays which are useful in diagnosis and management of disease processes by analyzing multiple parameters of individual cells using fluorescently labeled antibodies. The most commonly performed tests are: Fetal Hemoglobin; Leukemia & Lymphoma Phenotyping; Platelet Antibodies; Reticulated Platelet Counts; and Stem Cell Enumeration.

### Molecular Genetic Pathology

A newly emerging specialty, Molecular Pathology crosses the boundaries between clinical pathology and anatomic pathology with the performance of specialized testing using DNA extraction, nucleic acid amplification, and other methods to assist in diagnosing infectious diseases as well as genetic abnormalities.

## **Client Services**

In a continuing effort to provide the best possible service to our referring physicians, we are available by phone, fax, and email for consultative services, to answer questions, fill supply requests, and to fax or mail patient reports. Our pathologists are available for consultations at 406-238-6360 or 888-400-6640 during regular business hours, and may be reached for emergency consultation after hours at (406) 238-6371.

### **Specimen Inquiry**

For questions regarding specimen requirements, specimen transport, and patient reports, we can be reached at 406-238-6360 or 888-400-6640 during regular business hours, Monday through Friday (exclusive of holidays) 8:30 am to 5 pm. Please refer to the Test Listing on the following pages for specimen requirements.

### **Patient Reports**

Patient reports are routinely sent via auto-fax, interface, or mail. If a report is needed urgently, please let us know; we will be happy to fax a copy of the report to your office as soon as it becomes available. Additionally, patient reports are available online through a secure web portal designated for your facility. For more information on internet access to patient reports, please contact client services at 406-238- 6360 or 888-400-6640 during regular business hours, Monday through Friday (exclusive of holidays) 8:30 am to 5 pm.

### **Supplies**

Yellowstone Pathology Institute, Inc., is happy to provide our clients with the supplies necessary for the collection and transport of patient specimens. To request supplies or requisitions, contact us at 406- 238-6360 or 888-400-6640 during regular business hours, Monday through Friday (exclusive of holidays) 8:30 am to 5 pm. Alternatively, you may fax a completed supply order form, or include a completed supply order form with your specimens. A list of available supplies and a supply order form follows the Supply section.

### **Billing**

Our billing agency is comprised of experienced personnel who are committed to compliant billing practices. They are available to answer questions regarding patient billing, client billing, and third party billing at 800-849-8085 during regular business hours, Monday through Friday (exclusive of holidays) 6 am to 7 pm. You may also visit the website at <https://apsmedbill.com/>.

To ensure proper and compliant billing services, we respectfully request that you supply the necessary billing information and demographics for your patients' specimens. Please refer to COMPLETING OUR REQUISITION section for further information.

## Specimen Collection Guidelines

All specimens must be labeled with patient's name and at least one other unique identifier, such as date of birth or MR#. Label the bottle, not the lid. All specimens must be accompanied by a fully completed requisition. Please refer to the "COMPLETING OUR REQUISITION" section.

### Cytology

Patient history is also an important part of a complete requisition form. Variances in patient age and menstrual history may affect what is considered "normal" gynecological cytology.

Failure to provide the required information may result in a "Satisfactory but limited by lack of clinical information" statement of specimen adequacy.

Recommended additional information that may be helpful in interpretation of the specimen includes:

- ◊ History of significant Pap smear and biopsy diagnoses
- ◊ History of hormone therapy
- ◊ History of gynecological surgical procedures
- ◊ History of chemotherapy and radiotherapy

Failure to provide the recommended history may result in a delay of specimen processing

### ThinPrep®Pap Test™ Specimens

- ◊ Obtain PreservCyt® Solution (ThinPrep Vial), broom devices or spatulas and brushes, and requisitions from Yellowstone Pathology Institute, Inc., by calling (406)238-6360 and asking for client services.
- ◊ Complete a Yellowstone Pathology requisition, and label vial with patient name.

### Broom-Like Device Protocol:

- ◊ Obtain an adequate sampling from the ectocervix by inserting the central bristles of the broom into the endocervical canal deep enough to allow the shorter bristles to fully contact the ectocervix. Push gently, and rotate the broom in a clockwise direction five times.
- ◊ Rinse the broom in the PreservCyt® Solution vial by pushing the broom into the bottom of the vial 10 times, forcing the bristles apart. As a final step, swirl the broom vigorously to further release material. Discard the broom.

### Endocervical Brush/Spatula Protocol:

- ◊ Obtain an adequate sampling from the ectocervix using a plastic spatula.
- ◊ Rinse the spatula into the PreservCyt® Solution (ThinPrep vial) by swirling the spatula vigorously in the vial 10 times. Discard the spatula.
- ◊ Obtain an adequate sampling from the endocervix using an endocervical brush device. Insert the brush into the cervix until only the bottommost fibers are exposed. Slowly rotate  $\frac{1}{4}$  or  $\frac{1}{2}$  turn in one direction. DO NOT OVER-ROTATE.
- ◊ Rinse the brush in the PreservCyt® Solution by rotating the device in the solution 10 times while pushing against the PreservCyt® vial wall. Swirl the brush vigorously to further release material. Discard the brush.

## Specimen Collection Guidelines, continued

### Final steps for both broom-like device and brush/spatula:

- ◊ Tighten the cap on vial so that the torque line on the cap passes the torque line on the vial.
- ◊ Place the vial and matching requisition into a zip lock bag marked with a biohazard label and containing padding and absorbent material sufficient to absorb all the liquid in case of a leak.
- ◊ Place all specimens in courier pickup area or place into a properly marked and labeled Yellowstone Pathology pre-paid padded envelope or cardboard box and send via the US mail. Refer to packaging and shipping instructions for more information.

### Non-GYN Specimens

#### Bronchial Wash

- ◊ Submit specimen either fresh or in a vial of Cytolyt fixative\*. If fresh, the specimen must be delivered immediately to the laboratory. If washing is obtained evenings or on weekends, the specimen must be preserved in Cytolyt fixative.\*

#### Bronchial Brush

- ◊ Smears of the brushing material are to be made by the clinician and/or assistant at the time of bronchial washing and are sent to the laboratory fixed in Cytolyt fixative\*.
- ◊ Swish the brush several times in the fixative. This motion removes the cells from the brush and suspends them in the fluid.

#### Sputum

- ◊ Up to three successive early morning sputum samples are obtained by deep cough and are collected directly in 30 mL of Cytolyt fixative\* and submitted to the lab.
- ◊ The sample must be a deep sputum specimen; saliva from the mouth is not an adequate specimen and will be rejected.

#### Urine Barbotage/Urine Cytology

- ◊ A random urine sample is acceptable.
- ◊ The specimen should be added to Cytolyt fixative\* as soon as possible after collection since cellular material in urine tends to degenerate rapidly. Add equal volumes: 1 part specimen to 1 part Cytolyt.

#### Effusions: Pericardial, Pleural, Thoracentesis, Chest Fluid, Abdominal Peritoneal

- ◊ After aspiration of fluid, the specimen should be sent fresh to the laboratory.

#### Cerebrospinal Fluid

- ◊ Specimens should be delivered to the laboratory immediately.
- ◊ If this is impossible, the specimen should be placed in Cytolyt fixative\* and sent to the laboratory.

#### Breast Fluid

- ◊ The clinician may send aspirate fluid or prepared slides to the laboratory.
- ◊ Smears should be fixed immediately with PAP fixative.
- ◊ Breast fluid should be added to Cytolyt fixative\* and sent to the laboratory.

# Specimen Collection Guidelines, continued

## Fine Needle Aspirate

FNA Tray;

YPI requisition; ThinPrep fixative vial      OR

Non-frosted slides; Coplin jar with 95% ETOH; Bottle with formalin

- ◊ Label pairs of non-frosted slides with the patient's name, and label on slide of the pair "AD" for air-dried.
- ◊ Obtain the aspirate and place one drop of material in the center of the labeled slide.
- ◊ Place the other slide in the pair face-down directly over the slide with the drop.
- ◊ Let the drop spread between the two slides, and just before the drop stops spreading completely, slide the two slides apart sideways.
- ◊ Immediately plunge the non-AD labeled slide in 95% alcohol, and let the "AD" labeled slide air dry.
- ◊ Prepare at least one pair of slides (one alcohol-fixed and one air-dried) for each pass with the needle.
- ◊ After the slides are prepared, each needle may be rinsed into a container of Cytolyt for a cell block. You may rinse each needle into the same bottle for a pooled specimen.
- ◊ As soon as practical, send the slides and Cytolyt container to the laboratory.

\*Cytolyt fixative is available from Yellowstone Pathology Institute, Inc., by calling (406) 238-6360.

## Histopathology

- ◊ Specimen should be submitted in formalin if it will not be delivered to YPI within ten minutes.
- ◊ For large specimens, the specimen container should be large enough to hold the tissue sample and contain enough fixative solution to entirely surround the specimen. For small specimens, the optimal ratio of fixative to tissue volume is 10-20:1.
- ◊ For immediate diagnosis/frozen section examination, specimen must be delivered to YPI as quickly as possible.
- ◊ ***Important Fixation Guidelines for HER2 and ER/PR testing***
- ◊ 1. Specimens should be immersed in fixative within one hour of biopsy or resection.
- ◊ 2. If delivery of a resection specimen to the pathology department is delayed (e.g. specimens from remote sites), the tumor should be bisected prior to immersion in fixative. In such cases, it is important that the surgeon ensure that the identity of the resection margins is retained in the bisected specimen; alternatively, the margins may be separately submitted.
- ◊ 3. The time of removal of the tissue and the time of immersion of the tissue in fixative should be recorded and submitted to the laboratory.

## Hematopathology

- ◊ Peripheral Smear Review: two stained or unstained smears with copy of recent CBC report
- ◊ Flow Cytometry: refer to individual test specimen requirements

## Specimen Collection Guidelines, continued

### Molecular Pathology

- ◊ Specimens for DNA extraction should be un-entered prior to being sent to YPI.
- ◊ Refer to individual test specimen requirements

## Completing Our Requisition

When submitting a specimen to Yellowstone Pathology Institute, Inc., CMS, CLIA and CAP regulations require that certain conditions be met before testing can be completed. To ensure proper and compliant billing services, testing will be performed on specimens for which authorization is received,

in the form of a requisition, which must be completed with the following information:

- Patient's full name
- Unique identifying number (SS#), accession #
- Date of birth
- Name of ordering physician or provider
- Date and time of specimen collection
- Site of specimen
- Type of specimen
- Brief clinical history and clinical diagnosis
- Responsible Party/Insurance Guarantor
- Medicare number if applicable
- Medicaid number if applicable
- Insurance Policy/Group numbers
- Complete address of insurance carrier
- Appropriate billing identifiers (ICD code)
- A current patient chart face sheet may be submitted with billing information

When submitting a specimen for biopsy, non-gyn cytology, peripheral smear review, flow cytometry, molecular testing, or surgical pathology consultation, please complete the clinical information and specimen description sections of the requisition with whatever pertinent information is available.

## ICD Coding and Medical Necessity

In order to bill for laboratory services performed at YPI, we require appropriate ICD codes to be included on the requisition when submitting a specimen. Medicare and many insurance companies have specific guidelines defining the clinical situations and frequency under which an order for laboratory testing is considered medically necessary and reimbursable, or not reimbursable because the test is considered to be for research or investigational use only. In these instances, we must rely on you to obtain a signed **Advance Beneficiary Notice (ABN)** from the patient, **before testing can commence**.

**Table 1 on the following page describes how often Part B covers screening Pap tests, pelvic exams, and HPV screening.**

**Table 1. Medicare-Covered Screening Pap Tests, Pelvic Exams, & HPV Screening**

| Covered for  | How often   | Additional information   |
|--|---|--|
| Any asymptomatic female patient  | Every 24 months (at least 23 months after the most recent screening Pap test or pelvic exam)                                    | N/A  |
| A female patient who meets any of these criteria: <ul style="list-style-type: none"> <li>Evidence (based on their medical history or other findings) that they're at high risk for developing cervical or vaginal cancer and their physician (or authorized practitioner) recommends they have the test more frequently than every 2 years</li> <li>Female of childbearing age* who had a screening Pap test or pelvic exam during any of the previous 3 years indicating the presence of cervical or vaginal cancer or other abnormality</li> </ul> | Annually (at least 11 months after the most recent screening Pap test or pelvic exam)   | High risk factors for cervical and vaginal cancer are: <ul style="list-style-type: none"> <li>Early onset of sexual activity (under 16 years old)</li> <li>Multiple sexual partners (5 or more in a lifetime)</li> <li>History of STI (including HIV infection)</li> <li>Fewer than 3 negative Pap tests or no Pap tests within the previous 7 years</li> <li>Diethylstilbestrol (DES) — exposed daughters of women who took DES during pregnancy</li> </ul> |
| Any asymptomatic female patient ages 30–65 years when done with a screening Pap test   | <b>HPV Screening:</b> Once every 5 years (at least 4 years and 11 months (59 months total) after the most recent HPV screening) | Refer to the <a href="#">Cervical Cancer Screening with HPV Tests service</a> in the Medicare Preventive Services educational tool   |

Please refer to the Physician/Provider information on page 16 (which is also on the back of our requisition), and mark the appropriate box regarding screening pap, high risk screening pap, or diagnostic pap on the front of the requisition in the GYN CYTOLOGY section.

**PLEASE NOTE: TESTS WITH NATIONAL OR LOCAL COVERAGE DECISIONS (NCD/LCD) WILL NOT BE PERFORMED WITHOUT ICD CODES AND/OR A SIGNED ADVANCE BENEFICIARY NOTICE, AS APPROPRIATE.**

## Physician/Provider Information

The information below is offered to assist the Provider in differentiating between a Pap performed on a "High Risk" Patient and one performed for diagnostic purposes.

### DEFINITION OF "HIGH RISK" PATIENT:

- ◊ The patient is of childbearing age and has had an examination that indicated the presence of cervical or vaginal cancer or some other abnormality during any of the preceding three years; or
- ◊ Regardless of the patient's age, she is considered to be at high risk of developing cervical or vaginal cancer due to at least one of the following factors:
  - Early onset (under 16 years of age) of sexual activity;
  - Multiple sexual partners (five or more to date);
  - History of a sexually transmitted disease (including HIV infection);
  - Fewer than three negative Pap smears within the previous seven years; or
  - Mother took DES (diethylstilbestrol) during pregnancy with patient.

### DEFINITION OF A "DIAGNOSTIC PAP":

A "diagnostic PAP smear" is one that is ordered by the referring physician using that distinction based on his/her finding that one or more of the following circumstances applies to the Medicare patient (beneficiary) at hand.

- ◊ The patient has been previously diagnosed with cancer of the vagina, cervix, or uterus that has been or is presently being treated;
- ◊ The patient has had a previous abnormal PAP smear;
- ◊ The patient presents with any current abnormal findings of the vagina, cervix, uterus, ovaries, or adnexa;
- ◊ The patient presents any significant complaint referable to the female reproductive system; or
- ◊ The patient shows any sign or symptom that might, in the referring physician's judgment, reasonable to be related to a gynecologic disorder.

## Medicare Advance Beneficiary Notice

If you believe the test you are ordering for your Medicare patient may not be covered by Medicare, please refer to the sample CMS-approved Advance Beneficiary Notice on the next page (actual ABN forms available from YPI), and explain to the patient that the physician may occasionally order tests that he or she believes to be necessary for care. When requested, the laboratory performs these tests and then bills Medicare for these services. Medicare will pay only for the services 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 otherwise be covered, is not "reasonable and necessary" under Medicare standards, Medicare will deny payment for that service or test. In those cases, where Medicare denies coverage, the billing will be forwarded to the patient, who will be responsible for payment.

The advance notice must give the patient (beneficiary) an idea of why the physician/provider is predicting the likelihood of Medicare denial so that the patient (beneficiary) can make an informed decision whether or not to receive the service and pay for it out-of-pocket.



Yellowstone Pathology Institute, Inc. ~ Yellowstone Pathologists, P.C.  
 2900 12<sup>th</sup> Ave. N. #295W Billings, MT 59101  
 Ph. 406.238.6360 ~ 888.400.6640 ~ Fax 406.238.6361

**A. Notifier:**

**B. Patient's Name:**

**C. Identification Number:**

**Advance Beneficiary Notice of Noncoverage (ABN)**

**NOTE:** If Medicare doesn't pay for the D. Laboratory Test(s) below, you may have to pay.

Medicare does not pay for everything, even some care that you or your health care provider have good reason to think you need. We expect Medicare may not pay for the laboratory tests below.

| <b>D. Laboratory Test(s)(Circle one)</b> | <b>E. Reason Medicare May Not Pay:</b>   | <b>F. Estimated Cost:</b> |
|--|--|---------------------------|
| Pap Test                                 | Medicare does not pay for this test as often as this (denied as too frequent). | \$71.00-81.00             |

**WHAT YOU NEED TO DO NOW:**

- Read this notice, so you can make an informed decision about your care.
- Ask us any questions that you may have after you finish reading.
- Choose an option below about whether to receive the D. \_\_\_\_\_ listed above.

**Note:** If you choose Option 1 or 2, we may help you to use any other insurance that you might have, but Medicare cannot require us to do this.

**G. OPTIONS:** **Check only one box. We cannot choose a box for you.**

**OPTION 1.** I want the D. \_\_\_\_\_ listed above. You may ask to be paid now, but I also want Medicare billed for an official decision on payment, which is sent to me on a Medicare Summary Notice (MSN). I understand that if Medicare doesn't pay, I am responsible for payment, but I **can appeal to Medicare** by following the directions on the MSN. If Medicare does pay, you will refund any payments I made to you, less co-pays or deductibles.

**OPTION 2.** I want the D. \_\_\_\_\_ listed above, but do not bill Medicare. You may ask to be paid now as I am responsible for payment. I **cannot appeal if Medicare is not billed**.

**OPTION 3.** I don't want the D. \_\_\_\_\_ listed above. I understand with this choice I am not responsible for payment, and I **cannot appeal to see if Medicare would pay**.

**H. Additional Information:**

**This notice gives our opinion, not an official Medicare decision.** If you have other questions on this notice or Medicare billing, call 1-800-MEDICARE (1-800-633-4227/TTY: 1-877-486-2048).

Signing below means that you have received and understand this notice. You also receive a copy.

**I. Signature:**

**J. Date:**

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0566. The time required to complete this information collection is estimated to average 7 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.

Form CMS-R-131 (03/11)

Form Approved OMB No. 0938-0566



## Surgical Pathology Testing

### FNA (Fine Needle Aspirate)

|                       |   |
|-----------------------|---|
| Methodology:          | Thin Prep Papanicolaou stain; Direct Slide Wright-Giemsa stain; microscopic exam  |
| Specimen Requirement: | Aspirate in Cytolyt. Air-dried smears in slide folder. Label specimen with patient's name and a second unique identifier. Unlabeled specimens will be rejected. |
| Storage & Transport:  | Ambient temperature   |
| Performed:            | Monday-Friday   |
| Report Time:          | 1-2 days after receipt in the laboratory  |
| CPT Codes             | 88173 and/or 88172  |

### Bronchioalveolar Lavage for Lipids

|                       |  |
|-----------------------|--|
| Methodology:          | Oil Red O Stain  |
| Specimen Requirement: | Fresh BAL specimen. Label with patient's name and a second unique identifier. Do not add preservative. Bring to the laboratory ASAP. Unlabeled specimens will be rejected. |
| Storage & Transport:  | Ambient temperature  |
| Performed:            | Monday - Friday  |
| Report Time:          | 1-2 days after receipt in the laboratory   |
| CPT Codes             | 88313  |

### Muscle or Nerve Biopsy

|                       |  |
|-----------------------|--|
| Methodology:          | H&E stain; microscopic examination   |
| Specimen Requirement: | Specimen is processed at YPI for send out to a reference laboratory. Tissue in Formalin and/or 2.5% gluteraldehyde. Call the laboratory prior to collection for special instructions. Use a leak-proof container. Label specimen with patient's name and a second unique identifier. Unlabeled specimens will be rejected. |
| Storage & Transport:  | Ambient temperature  |
| Performed:            | Monday—Friday  |
| Report Time:          | 1-2 days after receipt in the laboratory   |
| CPT Codes             | varies   |

**Non Gyn Cytology (Urine, Sputum, CSF, Pleural, Peritoneal, Breast Fluids)**

|                       |  |        |
|-----------------------|--|--------|
| Methodology:          | Cytoc liquid formula; Papanicolaou stain;microscopic examination; Direct Smear Interpretation  | Inter- |
| Specimen Requirement: | Collect urine or other body fluid aseptically; add 10-25 mL to Cytolyt solution, to achieve a 1:1 ratio of Cytolyt to specimen. If Cytolyt cannot be added to specimen immediately, store at 2-8°C until Cytolyt is added. Label specimen with patient's name and a second unique identifier. Unlabeled specimens will be rejected. Alternatively, specimen may be submitted on a glass slide which has been submersed in isopropanol. |        |
| Storage & Transport:  | Ambient temperature in Cytolyt®Collection Vial or isopropanol.   |        |
| Performed:            | Monday-Friday  |        |
| Report Time:          | 3-5 working days after receipt in the laboratory   |        |
| CPT Codes             | 88104 or 88112, as applicable  |        |

**Peripheral Smear Review**

|                       |   |
|-----------------------|---|
| Methodology:          | Wright's stain; microscopic examination   |
| Specimen Requirement: | 2 unstained peripheral smears labeled with patient name and a second identifier, plus a copy of recent CBC results. Unlabeled specimens will be rejected. |
| Storage & Transport:  | Ambient temperature   |
| Performed:            | Mon-Friday  |
| Report Time:          | 1-2 days after receipt in the laboratory  |
| CPT Codes             | 85060   |

**Tissue Specimen for Surgical Pathology**

|                       |   |
|-----------------------|---|
| Methodology:          | H&E stain; microscopic examination  |
| Specimen Requirement: | Tissue in formalin. Use a leak-proof container. Label specimen with patient's name and a second unique identifier. Unlabeled specimens will be rejected. For breast specimens, please indicate the time specimen was placed in formalin. For muscle, renal, or nerve biopsies, please contact the histology laboratory for collection and transport instructions. |
| Storage & Transport:  | Ambient temperature   |
| Performed:            | Monday-Friday   |
| Report Time:          | 1-2 days after receipt in the laboratory  |
| CPT Codes             | varies  |

**Hormone Evaluation (Note: Will not be reported exclusive of a ThinPrep® Pap)**

|                      |  |
|----------------------|--|
| Methodology:         | Microscopic examination  |
| Specimen             | A vaginal specimen is required for hormone evaluation.   |
| Requirement:         | If the patient has no cervix, the hormone evaluation will be performed on a vaginal specimen in ThinPrep® vial or on a slide. If the patient has a cervix, and you are requesting ThinPrep® Pap, place the cervical specimen in the ThinPrep® vial and place the vaginal specimen on a slide. Label specimen with patient's name and a second unique identifier. Unlabeled specimens will be rejected. |
| Storage & Transport: | N/A  |
| Performed:           | Monday-Friday  |
| Report Time:         | 3-5 working days after receipt in the laboratory   |
| CPT Codes            | 88155  |

**ThinPrep® Pap Test**

|                      |   |
|----------------------|---|
| Methodology:         | Cytc liquid formula; Papanicolaou stain; microscopic examination utilizing ThinPrep® Imaging System with Dual Review. If abnormal cells are observed, the smear will be reviewed/interpreted by a Pathologist at an additional charge.  |
| Specimen             | Cervical & Endocervical specimen collected with brush and spatula or broom rinsed in the ThinPrep® Collection Vial. Label specimen with patient's name and a second unique identifier. Unlabeled specimens will be rejected. Specimens greater than 21 days old will be rejected. |
| Requirement:         |   |
| Storage & Transport: | Ambient temperature in ThinPrep® Collection Vial.   |
| Performed:           | Monday-Friday   |
| Report Time:         | 1-2 working days after receipt in the laboratory  |
| CPT Codes            | 88175 or 88142  |



## Flow Cytometry Testing

### Fetal Hemoglobin (Hgb F) Analysis

|                           |   |
|---------------------------|---|
| Methodology:              | Flow Cytometry (Quantitative)   |
| Test Name:                | Fetal Hemoglobin (Hgb F) Analysis   |
| Test Description:         | Markers include Mouse monoclonal antibody to Human Fetal Hemoglobin (Hgb F).  |
| Clinical Significance:    | Fetal Hemoglobin testing is used to detect and quantify the extent of fetal to maternal hemorrhages. Monoclonal antibodies directed against Hgb F are conjugated to a fluorochrome, and used in a multiparametric flow cytometry assay to quantitate fetal red blood cells in maternal blood. |
| Specimen Requirements:    | Peripheral Blood: 5 mL EDTA preferred. Refrigerate samples ASAP to preserve specimen integrity, as testing must be performed within 72 hours of collection. Ambient samples submitted within 12 hours are acceptable. Please provide a recent CBC report & face sheet for insurance purposes. |
|                           | Label specimen with patient's name and a second unique identifier. Unlabeled specimens will be rejected.  |
| Storage & Transportation: | Refrigerated specimens are good for 72 hours. Transport immediately. Use a cold pack for transportation, (thawed in the winter and frozen in the summer) making sure cold pack is not in direct contact with specimen. This will ensure specimen integrity for our seasonal changes.          |
| Turn Around Time:         | 24 hours  |
| CPT Codes:                | 86356   |

This page is left intentionally blank.

**Leukemia / Lymphoma Immunophenotyping**

|   |  |
|---|--|
| Methodology:                            | Flow Cytometry (Qualitative)   |
| Test Name::                             | Leukemia / Lymphoma Phenotyping  |
| Test Description:                       | Additional markers are dependent on screening results or diagnosis.  |
| Screening Markers:                      | CD2, CD3, CD4, CD5, CD7, CD8, CD10, CD19, CD20, CD22, CD23, CD33, CD34, CD38, CD45, CD117, Kappa & Lambda.   |
| For Paucicellular/Low Cellular Samples: | CD3, CD4, CD5, CD10, CD19, CD20, CD34, CD45, Kappa & Lambda.   |
| For Acute Myeloid Leukemia/MDS:         | CD2, CD3, cytoplasmic CD3, CD4, CD5, CD7, CD8, CD10, CD11b, CD14, CD14my4, CD15, CD16, CD19, CD20, CD22, CD23, CD25, CD33, CD34, CD36, CD38, CD41, CD45, CD56, CD64, CD71, cytoplasmic CD79a, CD117, CD123, CD163, CD235a, Kappa & Lambda, cytoplasmic Lysozyme, cytoplasmic Myeloperoxidase, cytoplasmic TdT. |
| For Cytopenia:                          | CD2, CD3, CD4, CD5, CD7, CD8, CD10, CD11b, CD14, CD15, CD16, CD19, CD20, CD22, CD23, CD27, CD28, CD33, CD34, CD38, CD41, CD45, CD56, CD64, CD71, CD117, CD138, CD200, CD235a, cytoplasmic Kappa & Lambda   |
| For Plasma Cells:                       | CD2, CD3, CD4, CD5, CD7, CD8, CD10, CD19, CD20, CD22, CD23, CD27, CD28, CD33, CD34, CD38 CD45, CD56, CD117, CD138, CD200, cytoplasmic Kappa & Lambda   |
| B Cell Lymphoma:                        | D2, CD3, CD4, CD5, CD7, CD8, CD10, CD11c, CD19, CD20, CD22, CD23, CD25, CD33, CD34, CD38, CD45, CD49d, CD52, CD58, CD79b, CD99, CD103, CD117, CD123, Bcl-2(if indicated), FMC7, Kappa & Lambda, Mu.  |
| T Cell/NK Lymphoma:                     | CD2, CD3, CD4, CD5, CD7, CD8, CD10, CD16, CD19, CD20, CD22, CD23, CD25, CD26, CD33, CD34, CD38, CD45, CD52, CD56, CD57, CD117, Alpha/Beta, Gamma/Delta, Kappa & Lambda, TCRCB1.  |
| <b>Clinical Significance:</b>           | Useful to aid in the diagnosis of leukemia and lymphoma, and for post treatment follow up.   |
| Specimen Requirements:                  | Bone Marrow Aspirate: 1-3 mL EDTA preferred. 1-3 mL sodium heparin is acceptable. Please provide a recent CBC & face sheet with insurance information.   |
|   | Peripheral Blood: 1-3 mL EDTA preferred. 1-3 mL sodium heparin is acceptable. Please provide a recent CBC & face sheet with insurance information.   |
|   | Fresh, unfixed tissue: 0.2 cm <sup>3</sup> minimum in RPMI or Saline. Please provide a face sheet with insurance information.  |
|   | Fluids: Equal parts RPMI and specimen or may be submitted without any anticoagulant or preservative. Please provide a recent cell count & face sheet with insurance information.   |
|   | Label specimen with patient's name and a second unique identifier. Unlabeled specimens will be rejected.   |
| Storage & Transportation:               | Transport immediately. Use a cold pack for transportation, (thawed in the winter and frozen in the summer) making sure cold pack is not in direct contact with specimen. This will ensure specimen integrity for our seasonal changes.   |
| Turn Around Time:                       | 24 hours   |

**Platelet Antibodies (Direct Method- IgG/IgM)**

|                           |  |
|---------------------------|--|
| Methodology:              | Flow Cytometry (Qualitative)   |
| Test Name:                | Platelet Antibodies  |
| Test Description:         | Markers include Goat F(ab')2 Anti-Human IgG, Goat F(ab')2 Anti-Human IgM, Goat F(ab')2 IgG Control, CD42b.   |
| Clinical Significance:    | Useful for the detection of IgG and/or IgM antibodies that is used to separate thrombocytopenia of immune origin from non-immune origin. Dual staining and flow cytometric analysis insures that only platelets are analyzed.          |
| Specimen Requirements:    | Peripheral Blood: 5 mL EDTA preferred. Please provide a recent CBC report and a face sheet including insurance information.  |
|                           | Label specimen with patient's name and a second unique identifier. Unlabeled specimens will be rejected.   |
| Storage & Transportation: | Transport immediately. Use a cold pack for transportation, (thawed in the winter and frozen in the summer) making sure cold pack is not in direct contact with specimen. This will ensure specimen integrity for our seasonal changes. |
| Turn Around Time:         | 24 hours   |
| CPT Codes:                | 86023  |

**PNH Detection, High Sensitivity (Paroxysmal Nocturnal Hemoglobinuria)**

|                           |  |
|---------------------------|--|
| Methodology:              | Flow Cytometry (Quantitative)  |
| Test Name:                | PNH Detection, High Sensitivity (Paroxysmal Nocturnal Hemoglobinuria)  |
| Test Description:         | Markers are CD14, CD15, CD24, CD33, CD34, CD45, CD59, CD64, CD117, CD235a, and FLAER(Fluorescent mutant Aerolysin). In validation studies, this assay was shown to detect Erythorocyte, Monocyte, and Granulocyte PNH clones with a frequency down to 0.01%.   |
| Clinical Significance:    | Useful for the diagnosis of Paroxysmal Nocturnal Hemoglobinuria and monitoring the response to therapy. Small PNH clones may also be identified in patients with Aplastic Anemia and MDS who may respond to immune modulation therapy. This test also identifies patients at increased risk of developing overt PNH. This assay is consistent with the International Clinical Cytometry Society (ICCS) Guidelines. |
| Specimen Requirements:    | Peripheral Blood: 5 mL EDTA preferred. Specimen must be received within 48 hours post collection. Please provide a recent CBC report & face sheet for insurance information.   |
|                           | Label specimen with patient's name and a second unique identifier. Unlabeled specimens will be rejected.   |
| Storage & Transportation: | Transport immediately. Use a cold pack for transportation, (thawed in the winter and frozen in the summer) making sure cold pack is not in direct contact with specimen. This will ensure specimen integrity for our seasonal changes.   |
| Turn Around Time:         | 24 hours   |
| CPT Codes:                | 88184 x 1, 88185 x 7, 88187 x 1  |

**Reticulated Platelet Enumeration**

Methodology: Flow Cytometry (Qualitative)

Test Name: Reticulated Platelet Enumeration

Test Description: Markers include Thiazole Orange and CD41.

Clinical Significance: Young platelets are characterized by a high RNA content, which is increased and useful in the diagnosis of ITP. Measuring reticulated platelets has been shown to discriminate well between thrombocytopenic patients with normal or increased megakaryopoiesis (such as ITP) and those patients with decreased megakaryopoiesis (such as malignancy). The RNA content is then evaluated using a fluorescent dye (thiazole orange) which has a high binding affinity for RNA. The percentage of isolated platelets containing RNA is then established.

Specimen Requirements: Peripheral Blood: 5 mL preferred. Specimen must be received within 48 hours post collection. Any specimen older than 48 hours old will be rejected. Please provide a recent CBC & face sheet with insurance information.

Label specimen with patient's name and a second unique identifier. Unlabeled specimens will be rejected.

Storage & Transportation: Transport immediately. Use a cold pack for transportation, (thawed in the winter and frozen in the summer) making sure cold pack is not in direct contact with specimen. This will ensure specimen integrity for our seasonal changes.

Turn Around Time: 24 hours

CPT Codes: 85055

**Thrombocytopenia Profile**

|                           |   |
|---------------------------|---|
| Methodology:              | Flow Cytometry (Qualitative & Quantitative)   |
| Test Name:                | Thrombocytopenia Profile (Reticulated Platelet Enumeration & Platelet Antibodies)   |
| Test Description:         | Markers include Thiazole Orange, Goat F(ab')2 Anti-Human IgG, Goat F(ab')2 Anti-Human IgM, Goat F(ab')2 IgG Control, CD41, CD42b.   |
| Clinical Significance:    | Young platelets are characterized by a high RNA content, which is increased and useful in the diagnosis of ITP. Measuring reticulated platelets has been shown to discriminate well between thrombocytopenic patients with normal or increased megakaryopoiesis (such as ITP) and those patients with decreased megakaryopoiesis (such as malignancy). The RNA content is then evaluated using a fluorescent dye (thiazole orange) which has a high binding affinity for RNA. The percentage of isolated platelets containing RNA is then established. Useful for the detection of IgG and/or IgM antibodies that is used to separate thrombocytopenia of immune origin from non-immune origin. Dual staining and flow cytometric analysis ensures that only platelets are analyzed. Combined together, both flow cytometric analyses can determine the origin of the thrombocytopenia. |
| Specimen Requirements:    | Peripheral Blood: 5 mL preferred. Specimen must be received within 48 hours post collection. Any specimen older than 48 hours will be rejected. Please provide a recent CBC & face sheet with insurance information.  |
|                           | Label specimen with patient's name and a second unique identifier. Unlabeled specimens will be rejected.  |
| Storage & Transportation: | Transport immediately. Use a cold pack for transportation, (thawed in the winter and frozen in the summer) making sure cold pack is not in direct contact with specimen. This will ensure specimen integrity for our seasonal changes.  |
| Turn Around Time:         | 24 hours  |
| CPT Codes:                | 85055, 86023  |



CPT Codes: 88184 (1 marker), 88187 (2-4 markers), 88188 (9-15 markers), 88189 (16+ markers)

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

## Molecular Pathology Testing

### Chlamydia/Neisseria (CT/NG) Screening

|                       |  |
|-----------------------|--|
| Methodology:          | Nucleic Acid Amplification   |
| Specimen Requirement: | Cervical & Endocervical specimen collected with brush and spatula or broom rinsed in the ThinPrep® Collection Vial. Label specimen with patient's name and a second unique identifier. Unlabeled specimens will be rejected. Specimens greater than 21 days old will be rejected.<br>NOTE: Test must be ordered at the time specimen is submitted. Cannot be added after ThinPrep® Pap vial has been processed for GYN Cytology. |
| Storage & Transport:  | Ambient temperature in ThinPrep® Collection Vial   |
| Performed:            | Tuesday, Thursday  |
| Report Time:          | 1-8 days after testing   |
| CPT Codes             | 87491, 87591   |

### Her-2 by D-ISH

|                       |   |
|-----------------------|---|
| Methodology:          | Dual in-situ hybridization  |
| Specimen Requirement: | Formalin-fixed, paraffin embedded tissue blocks that contain tissue representative of tumor. Label specimen with patient's name and a second unique identifier. Unlabeled specimens will be rejected. |
| Storage & Transport:  | Ambient temperature (20-25°C).  |
| Performed:            | As needed   |
| Report Time:          | 1-8 days after receipt in the laboratory  |
| CPT Codes             | 88377 x 1   |

**Human Papillomavirus) RNA Probe (High Risk Probe)**

|                       |   |
|-----------------------|---|
| Methodology:          | Nucleic Acid Amplification  |
| Specimen Requirement: | Cervical & Endocervical specimen collected with brush and spatula or broom rinsed in the ThinPrep® Collection Vial. Label specimen with patient's name and a second unique identifier. Unlabeled specimens will be rejected. Specimens greater than 21 days old will be rejected. |
| Storage & Transport:  | Ambient temperature in ThinPrep® Collection Vial  |
| Performed:            | Tuesday, Thursday   |
| Report Time:          | 1-8 days after request or reflex from ThinPrep®   |
| CPT Codes             | 87624   |

**HPV 16,18/45 Genotyping (on Head, Neck Squamous Cell Carcinomas; ThinPrep® Paps)**

|                       |   |
|-----------------------|---|
| Methodology:          | DNA Extraction; PCR (tissue), Nucleic Acid Amplification (ThinPrep Vial)  |
| Specimen Requirement: | Three sections (45 um thick) paraffin-embedded tissue, plus two Hematoxylin & Eosin (H&E) slides. Label specimen with patient's name and a second unique identifier. Unlabeled specimens will be rejected. Cervical & Endocervical specimen collected with brush and spatula or broom rinsed in the ThinPrep®Collection Vial. Label specimen with patient's name and a second unique identifier. Unlabeled specimens will be rejected. Specimens greater than 21 days old will be rejected. |
| Storage & Transport:  | ThinPrep®: Ambient temperature in ThinPrep®Collection Vial;<br>Tissue: Ambient temperature  |
| Performed:            | As needed   |
| Report Time:          | 1-5 days after receipt in the laboratory  |
| CPT Codes             | Tissue: 87625   |

**Trichomonas vaginalis**

|                       |  |
|-----------------------|--|
| Methodology:          | Nucleic Acid Amplification   |
| Specimen Requirement: | Cervical & Endocervical specimen collected with brush and spatula or broom rinsed in the ThinPrep® Collection Vial. Label specimen with patient's name and a second unique identifier. Unlabeled specimens will be rejected. Specimens greater than 21 days old will be rejected. NOTE: Test must be ordered at the time specimen is submitted. Cannot be added after ThinPrep®Pap vial has been processed for GYN Cytology. |
| Storage & Transport:  | Ambient temperature in ThinPrep® Collection Vial   |
| Performed:            | Tuesday, Thursday  |
| Report Time:          | 2-4 days after receipt in laboratory   |
| CPT Code              | 87661  |

## Supplies

The following supplies are available from Yellowstone Pathology Institute, Inc., for our clients' use in collecting and transporting specimens to us. You are welcome to contact us by phone or fax for supplies, or simply complete a supply order form and include it with your specimens. Supply order forms are available by calling our office at 406.238.6360 or 888.400.6640.

### Biopsy Specimen Containers:



Biopsy specimen container w/ formalin  
Available in 20ml, 40ml and 60ml sizes



16 oz container/lid w/ no additive



32 oz. Container/lid with no additive



82 oz. Container/lid with no additive



182 oz. Container/lid with no additive

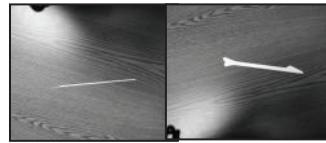
### ThinPrep Pap Collection Supplies:



ThinPrep Collection Vial



Broom Device



Brush/Spatula Devices

## Specimen Transport Items



Biohazard Specimen Bags



Padded Mailing Envelope



Post-paid Mailing Label



Mailing Canister

## Forms

Regular Requisition Pre-printed with Client Name

Frozen Section Requisition Pre-printed with Client Name

Advance Beneficiary Notice

Women's Health Requisition Pre-printed with Client Name

Client Supply Order Form



**Billings**

2900 12th Avenue North  
Suite 295 W  
Billings, MT 59101

**Fax: 406.238.6361**

**Toll Free: 888-400-6640**