

GUNDERSEN

ST. JOSEPH'S HOSPITAL AND CLINICS

January 1, 2026

LABORATORY ANNUAL NOTICE TO PROVIDERS

To: Gundersen St. Joseph's Hospital and Clinics Clinicians

From: Sean Agger, PhD, Medical Director of Gundersen St. Joseph's Hospital and Clinics; Keith Frye, Administrative Director, Gundersen Health System Laboratory; Candice Blaha, Gundersen St. Joseph's Hospital and Clinics Manager of Laboratory Services.

cc: Kari Adank, Vice President, Compliance; Taryn Zubich, Director of Compliance (GLMC); Peter Weidenheim, Director of Compliance (Critical Access Hospitals)

To comply with Medicare requirements, Gundersen St. Joseph's Hospital and Clinics Laboratory must send an annual notice to providers who use our testing services. As required, this annual notice includes the following:

Medical Necessity Requirements

Laboratory tests are reimbursed under federally funded programs if they are deemed "medically necessary" for the diagnosis and treatment of the patient. The Centers for Medicare and Medicaid Services (CMS) has developed national and local coverage decisions that identify those tests that CMS determined will be covered under the Medicare program. Coverage for these services is based on the diagnosis / sign / symptom you assign to the office visit. CMS' National Coverage Decisions (NCDs) and Local Medical Review Policies (LMRP) can be accessed at <http://www.cms.gov/medicare-coverage-database/search.aspx>

Physicians may order any laboratory tests, including screening tests that they believe are appropriate for the treatment of their patients. Tests that are considered screening tests are generally not covered. Therefore, it is a requirement that a diagnosis or symptom is linked to each test ordered.

Advance Beneficiary Notice (ABN or Waiver)

Advance Beneficiary Notices are used when you believe that Medicare may not cover an ordered service. The ABN (CMS-R-131) Form Approved OMB No. 0938-0566 is the only written notice recognized by Medicare to satisfy the requirement for alerting Part B fee-for-service beneficiaries when they may be financially liable for an item or service that Medicare will likely deny. The Notice of Denial of Medical Coverage is used when you believe that Medicare Part C (Medicare Advantage) may not cover an ordered service. Each Medicare Part C plan is required to have their own NDMC and cannot use the Medicare approved ABN. Gundersen Health System is using the Senior Preferred Notice of Denial Medical Coverage.

Before the specimen is collected, the patient should be notified, in writing, of the possibility that payment will be denied. A valid ABN or NDMC must include written estimates for the cost of services. An

ABN or NDMC is never required in emergent or urgent care cases. The form provides a space to write the test(s) that are ordered and a check-off list of the reasons the claim may be denied.

This information must be completed before the patient is asked to sign the ABN. Patients cannot be asked to sign a blank or incomplete form. Patients do not need to sign the Senior Preferred Notice of Denial Medical Coverage. The patient's name and the patient or guarantor's signature and date of service must be on the form. The ABN or NDMC should only be used when you believe that "medical necessity" requirements may not be met. The patient must be given a copy of the ABN or NDMC form, and a copy should be kept at your facility. In order to meet these requirements, the ABN or NDMC form prints to be filled out by the patient, the original form is scanned back in as a document after the patient signs the ABN or has been provided a SP-NDMC, and the patient receives a copy.

Panels/Profiles

Gundersen St. Joseph's Hospital and Clinics Laboratory offers a small number of disease-oriented test groups, often referred to as profiles or panels that are found in the Current Procedural Terminology (CPT) coding manual. It should be noted that tests that make up the panels can be ordered separately. If all tests that make up a designated panel are ordered separately the panel will be billed.

This letter informs physicians that using a customized profile may result in the ordering of tests for which Medicare may deny payment.

Currently we offer the following AMA defined panels:

CMP CPT 80053

Carbon Dioxide
Chloride
Potassium
Sodium
BUN
Creatinine
Calcium
Glucose
AST
ALT
ALKP
Total Bilirubin
Total Protein
Albumin

BMP CPT 80048

Carbon Dioxide
Chloride
Potassium
Sodium
BUN
Creatinine
Calcium
Glucose

Lipid Panel Lipoprotein Analysis CPT 80061

Cholesterol, Total
HDL Cholesterol
Triglycerides

Electrolyte Panel CPT 80051

Carbon Dioxide
Chloride
Potassium
Sodium

Bacterial Enteric Panel CPT 87505

Salmonella spp.
Shigella spp./EIEC,
Campylobacter spp. (jejuni and coli)
Shiga toxin-producing organisms (STEC, Shigella dysenteriae).

Respiratory Infection, Multiplex (BioFire Film Array) CPT 0202U

Adenovirus	Coronavirus 229E	Coronavirus HKU1
Coronavirus NL63	Coronavirus OC43	Middle East Respiratory Syndrome Coronavirus
Severe Acute Respiratory Syndrome Coronavirus	Human Metapneumovirus	Human Rhinovirus/ Enterovirus
Influenza A H1-2009	Influenza A H3	Influenza B
Parainfluenza Virus 1	Parainfluenza Virus 2	Parainfluenza Virus 3
Parainfluenza Virus 4	Respiratory Syncytial Virus	

Bacteria

Bordetella parapertussis (IS 1001)	Bordetella pertussis (ptxP)
Chlamydia pneumoniae	Mycoplasma pneumoniae

4Plex CPT 0241U

Covid-19 Influenza A, B RSV

INRSV CPT 87631

RSV
Influenza A, B

Blood Culture Identification Panel CPT 87150 (per organism)

Gram Positive Bacteria				
<i>Enterococcus faecalis</i> <i>Enterococcus faecium</i> <i>Listeria monocytogenes</i>		<i>Staphylococcus</i> spp. <i>S. aureus</i> <i>S. epidermidis</i> <i>S. lugdunensis</i>		<i>Streptococcus</i> spp. <i>S. agalactiae</i> (Group B) <i>S. pneumoniae</i> <i>S. pyogenes</i> (Group A)
Gram Negative Bacteria				
<i>Acinetobacter calcoaceticus-baumannii</i> complex <i>Bacteroides fragilis</i> group <i>Haemophilus influenzae</i> <i>Neisseria meningitidis</i> <i>Pseudomonas aeruginosa</i> <i>Stenotrophomonas maltophilia</i>		Enterobacterales - <i>E. cloacae</i> complex - <i>E. coli</i> - <i>K. aerogenes</i> - <i>K. oxytoca</i> - <i>K. pneumoniae</i> group - <i>Proteus</i> spp. - <i>Salmonella</i> spp. - <i>S. marcescens</i>		
Yeast				
<i>Candida albicans</i> <i>Candida auris</i> <i>Candida glabrata</i>		<i>Candida krusei</i> <i>Candida parapsilosis</i> <i>Candida tropicalis</i>		<i>Cryptococcus neoformans/gattii</i>
Antimicrobial Resistance Genes				
CTX-M	KPC	mecA/C, MREJ	NDM	van A/B
IMP	Mcr-1	OXA-48-like	VIM	

Joint Infection Panel CPT 87627

The following organisms are identified using the BIOFIRE JI Panel:

GRAM POSITIVE BACTERIA				
<i>Anaerococcus prevotii/vaginalis</i> <i>Clostridium perfringens</i> <i>Cutibacterium</i> <i>avidum/granulosum</i> <i>Enterococcus faecalis</i> <i>Enterococcus faecium</i>		<i>Fingoldia magna</i> <i>Parvimonas micra</i> <i>Peptoniphilus</i> <i>Peptostreptococcus anaerobius</i> <i>Staphylococcus aureus</i> <i>Staphylococcus lugdunensis</i>		<i>Streptococcus</i> spp. <i>Streptococcus agalactiae</i> <i>Streptococcus pneumoniae</i> <i>Streptococcus pyogenes</i>
GRAM NEGATIVE BACTERIA				
<i>Bacteroides fragilis</i> <i>Citrobacter</i> <i>Enterobacter cloacae complex</i> <i>Escherichia coli</i> <i>Haemophilus influenzae</i>		<i>Kingella kingae</i> <i>Klebsiella aerogenes</i> <i>Klebsiella pneumoniae</i> group <i>Morganella morganii</i> <i>Neisseria gonorrhoeae</i>		<i>Proteus</i> spp. <i>Pseudomonas aeruginosa</i> <i>Salmonella</i> spp. <i>Serratia marcescens</i>
YEAST				
<i>Candida</i> <i>Candida albicans</i>				
ANTIMICROBIAL RESISTANCE GENES				
CTX-M	KPC	NDM	vanA/B	
IMP	mecA/C and MREJ (MRSA)	OXA-48 like	VIM	

Other test groups, such as Hepatitis Panel, are offered but do not include the exact makeup of tests that CMS specifies. In these cases, individual members of the test group are billed separately, and each

component of a panel must have a diagnosis linked to it. Unless all components of the panel are “medically necessary”, according to Medicare’s (NCD)-LMRP-, the claim will be denied.

The Office of Inspector General takes the position that a provider should only order those tests which the provider believes are medically necessary for each patient; therefore, all components of a customized profile must be medically necessary and will be reimbursed separately in accordance with the clinical laboratory fee schedule. A provider, who knowingly causes a false claim to be submitted by ordering a customized profile that all components are not medically necessary, may be subject to civil penalties.

Medicare Reimbursement

Critical Access Hospitals are reimbursed for laboratory services by a cost percentage. At Gundersen St. Joseph’s Hospital and Clinics all payers are charged the same, and it is our understanding that the Medicaid reimbursement amount is equal to or less than the amount of Medicare reimbursement.

CPT or HCPCS Codes

Gundersen Health System will maintain detailed, up-to-date billing codes, policies, and procedures to ensure accuracy of billing for all laboratory services. Compliance, Revenue Cycle, LIS, and Laboratory is charged with responsibility to accurately maintain all information necessary for coding and billing of laboratory services. Details can be found in RevCycl-1005 (Laboratory Coding and Chargemaster Maintenance)

Reflex Testing Protocols

In a limited number of predefined circumstances and based on initial test results, additional subsequent laboratory tests will be performed. These are referred to as reflex testing protocols. When performed, the reflex tests are billed to the patient. If the patient’s condition does not warrant the additional testing, providers have the option to order the initial test without the automatic reflex testing. The following is a list of additional tests that laboratory staff automatically performs after a positive initial test result:

Blood Bank:

A positive antibody screen will reflex to an antibody identification testing, including a DAT and relevant antigen typing, including an ABO/Rh and/or red cell genotyping. Antibody identification may not be completed by the hospital blood bank, further testing will be sent to the Versiti, WI Immunohematology Reference Lab.

When a clinically significant antibody is identified and red cell products are ordered, reflex testing will include antigen typing of donor cells and IAT crossmatch for each red cell product.

When the DAT (Coombs) test is positive, reflex testing is based on patient history and may include an antibody eluate or auto adsorption.

For patients requiring partial or full antigen matching of transfused red cell units, reflex testing will include red cell genotyping of the patient, and serologic antigen typing of donor cells. For sickle cell and

thalassemia patients, serologic testing of the patient's red cells for Rh (D, C, c, E, e) and K antigens may be performed if a transfusion is requested before red cell genotyping is completed.

For Rh-negative Rho (D) Immune Globulin candidates a fetal hemoglobin stain follows a positive fetal bleed screen. For potential candidates who do not qualify for a fetal bleed screen, a fetal hemoglobin stain will be performed.

For patients with discrepant or potential variant expression of Rh(D) typing, molecular Rh(D) typing may be reflexed. This may include Weak RhD genotyping and/or Partial RhD Analysis completed by Versiti, WI.

When blood products are ordered to be available and/or transfused to a patient with only one blood type on file (tested by) the blood bank, a confirmatory ABO/Rh (separate draw) will be reflexed. For pre-surgical patients who have a type and screen ordered and only one documented blood type on file, a confirmatory ABO/Rh will be reflexed for collection on the day of surgery. The reflex test will be a lab directed order manually entered by blood bank staff with the Medical Director as the ordering provider. These orders will not require an additional manual countersign.

An antibody titer will reflex an antibody ID if the antibody is currently demonstrating reactivity, or an antibody screen if the antibody is currently not demonstrating reactivity or is not demonstrating reactivity at the correct phase or in the correct method to titer.

Urinalysis:

A positive Protein, Occult Blood, Leukocytes, or Nitrites is reflexed to a microscopic examination. When the color of the urine specimen is red, amber, or green or the specimen is turbid, a microscopic exam is also reflexed. If urine Dipstick Only is ordered, the microscopic exam is not performed for positive dipstick tests

A urine culture will be reflexed on a urinalysis test if the microscopic results meet any of the following conditions:

- For children <4 years old: a urine culture will always be reflexed if a microscopic is reflexed
- For children age 4-14: If the white blood cells are greater than 5/hpf **AND** if the squamous epithelial cells are not classified as "Many" (greater than 10/hpf)
- For those age 15 and over: If the white blood cells are greater than 10/hpf **AND** if the squamous epithelial cells are not classified as "Many" (greater than 10/hpf)

Hematology:

A manual differential is done when instrument flagging indicates the need.

A manual body fluid differential is reflexed on serous fluids when instrument flagging criteria is exceeded, or the Fluid WBC exceeds 200.

A manual CSF differential is reflexed when the electronic TNC exceeds the normal range for the patient's age group.

A Body Fluid or CSF Cell Count and Diff with large mononuclear cells present, reflexes to a pathologist review.

Immunology:

When ANA is positive and ANA titer will be performed.

Microbiology:

The following positive cultures reflex antibiotic susceptibility testing:

- Wound and fluid cultures growing small to large number of pathogens
- CSF cultures with any growth
- Positive blood cultures
- Urine cultures with pathogenic growth
- Respiratory cultures growing large number of pathogens

Wound, tissue, fluid or sputum cultures reflex to a gram stain.

A negative Strep screen reflexes to a Strep culture on patients less than 18 years old.

A positive Clostridium difficile antigen/negative C. diff toxin will reflex a C.diff PCR.

A positive Clostridium difficile by PCR will reflex a C. Diff enzyme immunoassay for detection of C. Diff toxins A and B.

A positive Cryptococcal Antigen will reflex a Cryptococcal Antigen Titer.

A positive HPV reflexes HPV 16 18/45 Genotype Assay

Specimens submitted for pathology review

Surgical specimens submitted for pathology review will be processed and evaluated with the use of routine macroscopic and microscopic techniques, and, when applicable and medically necessary, special/ancillary stains or other diagnostic laboratory studies performed on the specimen. The utilization of any special/ancillary stains or other studies are at the discretion of the pathologist responsible for the diagnostic assessment and will be used to establish an accurate and complete diagnosis. Microscopic examination is, with very rare exception, required for all tissue specimens submitted, unless specifically exempted according to Gundersen Health System policy Lab-2500. If a submitting provider wishes to limit or otherwise restrict the use of special/ancillary stains or other diagnostic studies on a particular specimen submitted to the laboratory for pathologic evaluation, this request should be made in writing and should accompany the specimen upon its submission to the pathology department.

Consultants

Gundersen Health System laboratory makes the following consultants available to providers to discuss appropriate testing, test ordering, and test interpretation.

(608) 782-7300 or (800) 362-9567

Daniel Schraith MD, Extension 52701
Rasleen Saluja MD, Extension 50381
Sean Agger PhD, Extension 50410
Richard Wittchow MD, Extension 52709
Gordon Zeng MD, Extension 52262
Sarah Hughes MD, Extension 52640
Christopher Cogbill MD, Extension 54612
Grzegorz Gurda MD, Extension 52107
Stefan Brettfeld DO, Extension 52820
Arick Sabin DO, Extension 52817
Stephen Bloechl MD, Extension 59645
Lacey Schrader MD, Extension 56477
Sarah Pendley MD, Extension 52640