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Date: November 15, 2016  
To: Physicians and Providers ordering tests from UCHHealth Northern Colorado Laboratories  
Subject: Laboratory Compliance Notice  
From: Robyn Sorrell, Laboratory Director  
Karen Getzy, Laboratory Compliance Coordinator

Please take note of the information that follows. This annual notice is in compliance with the guidance of the Office of Inspector General (OIG) of the Department of Health and the regulations and requirements Human Services and the Center for Medicare and Medicaid Services (CMS). The Office of the Inspector General's "OIG Compliance Program Guidance for Clinical Laboratories" recommends that hospital laboratories provide annual notification to their clients and physicians regarding pertinent Medicare rules, regulations, and policies and billing requirements.

A. Resources:

1. Medicare has National Coverage Determinations (NCDs) that state the medical conditions for which laboratory tests are covered, reasonable and necessary on a national level.  
[https://www.cms.gov/CoverageGenInfo/04\\_LabNCDs.asp](https://www.cms.gov/CoverageGenInfo/04_LabNCDs.asp)
2. The Medicare contractor, Novitas Solutions, Inc., has Local Coverage Determinations (LCDs) that apply to the local area.  
<http://www.novitas-solutions.com/>

Note: The above coverage determinations include frequency limitations and the covered ICD-9-CM/ ICD-10-CM code(s) for each of the listed laboratory services.

3. The Medicare Laboratory outpatient fee schedule is listed online at:  
<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSch/index.html>  
Medicaid reimbursement is equal to or less than Medicare reimbursement.
- B. More information regarding laboratory services may be obtained in the online Laboratory Manual located at <http://uchealth-pvhmcr.testcatalog.org/>
- C. Laboratory/Pathology Clinical Consultant(s) are available to assist you with any questions. Please call 970-495-8740.

Christopher Bee, M.D.  
H. Wenzell Hamner, M.D.  
Michael Walts, M.D.



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## Physician Notice: Test Ordering and Billing Practices

The Annual Compliance Notice helps to ensure that regulatory policies are enforced, and at the same time, it supports the mission of University of Colorado Health. As part of the laboratory's ongoing commitment to compliance, this annual review is being provided to help identify your role in clinical laboratory compliance. Several topics pertinent to the process of ordering laboratory tests used to diagnose and treat your patients will be outlined below. On-line ordering or UHealth Laboratory test requisition forms should be used to order clinical laboratory tests whenever possible.

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## A. Medicare Medical Necessity

Medicare regulations encourage laboratories to take all reasonable steps to ensure that claims are submitted only for services that are medically necessary. The Office of Inspector General (OIG) takes the position that an individual, including any provider, who knowingly causes a false claim to be submitted, may be subject to sanctions or remedies available under civil, criminal and administrative law. This communication supports the ordering of tests that “are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member” (Social Security Act, Section 1862 (a) (1) (A)). Medicare requires thorough documentation to substantiate claims; therefore pertinent information is detailed below.

Only tests that are medically necessary for the diagnosis or treatment of the patient will be reimbursed. This includes any and all tests that are components of ordered panels. Medicare may deny payment where there is insufficient documentation in the medical record to support the medical necessity of ordering the test(s). Of note, the OIG takes the position that a physician who orders medically unnecessary tests for which Medicare or Medicaid reimbursement is claimed, may be subject to civil penalties under the False Claims Act. A general note: Medicaid reimbursement will be equal to, or less than Medicare reimbursement.

The Centers for Medicare and Medicaid Services (CMS) has 24 National Coverage Determinations (NCDs) regarding clinical diagnostic laboratory tests. These decisions, on a national level, state the medical conditions for which laboratory tests are covered, reasonable, and necessary. Additionally, Medicare Administrative Contractors have the authority to develop and implement Local Coverage Determinations (LCDs) as long as they do not conflict with the national determinations. (Refer to web sites on page 1.)

## B. Laboratory Requisitions

Laboratory requisitions are designed to emphasize physician choice. Laboratories cannot alter the physician’s order in any way either increasing or decreasing the number of services performed without the express consent of the ordering physician or other authorized individual. If a laboratory receives a specimen without a valid test order or with a test order which is ambiguous, the laboratory must verify the tests which the physician wants and perform them before submitting a claim for reimbursement to Medicare. Medicare may deny payment where there is insufficient documentation in the medical record to support the medical necessity of ordering the test(s).



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## C. ICD-10-CM Codes

ICD-10-CM codes must be included on all Medicare Part B claims to establish medical necessity when a diagnostic test is ordered. Therefore, all requisitions must include ICD-10-CM codes as the reasons for the testing. Codes for signs and symptoms must be used when a definitive diagnosis has not been established. When appropriate ICD-10-CM codes are not provided on the requisition, the physician will be contacted to provide the information.

## D. Screening Tests

Medicare generally does not cover routine physical exams and associated lab tests. Certain screening tests are subject to frequency limitations such as PSA, PAP smears, and tests for occult blood.

## E. Reflex Testing Policy

Reflex testing may be performed in the absence of a specific written order when results of initial testing indicate that a second, related test is medically appropriate. For questions regarding specific tests, please refer to the table of reflex tests performed in the UHealth Northern Colorado Laboratories (Appendix A). Providers who prefer that reflex testing not be performed may contact the laboratory. Reflex testing policies are presented by the laboratory medical director to the medical executive committee for approval.

In Microbiology, additional specimen processing, identification, susceptibility (MIC) and reflex testing will be performed on positive cultures, when medically appropriate per procedure. They will be billed as “add-on” tests.

## F. Panel Testing and Pricing Policy

All routine chemistry tests should be ordered separately except for those contained in federally defined laboratory panels. Test panel pricing is based on the cost of each component included in a test panel. In no case are individual tests or profiles priced below cost. No tests are provided to customers or potential customers free of charge or at below cost either as a professional courtesy or in order to secure additional business. Panels are paid and billed only when all components are medically necessary.

UHealth Northern Colorado Laboratories has a number of test profiles offered for ordering convenience. Providers have the option to select or opt out of any test in any grouping. A listing of test groups, CPT codes and Medicare reimbursement is attached. (Appendix B)



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Charges for calculations derived from other test results are not submitted for billing. The reporting of such calculations as a part of the test results does not affect any claims for reimbursement to federal or privately funded health care programs.

Organ and disease panel tests are only covered when all of the components of the panel are medically necessary. Other than for monthly dialysis composite lab tests, direct billing is required for Medicare-reimbursed laboratory tests.

The laboratory assumes financial responsibility for tests sent to outside reference laboratories unless third party billing arrangements have been made.

## G. CPT Codes

While this communication lists CPT codes in an effort to provide some guidance, the CPT codes listed only reflect our interpretation of CPT coding requirements and may not be accurate in all cases. The laboratory assumes no responsibility for billing errors due to reliance on the CPT codes suggested in this document. You should verify the accuracy of the codes listed, and where multiple codes are listed, you should select the codes for the tests actually performed on your specimen. For further reference, please consult the CPT Coding Manual published by the American Medical Association, and if you have any questions regarding the use of a code, please contact your local Medicare carrier.

## H. Standing Order Policy

A standing order directs the laboratory to perform a particular test or tests at specified intervals or as requested for a defined time period without having to submit a new requisition form each time. Standing orders must be renewed in writing every year. If additional tests are needed during the year, the patient must bring an additional written request at the time of the visit.

## I. ABNs

An Advance Beneficiary Notice (ABN) gives the patient advance notice that Medicare may not pay for the test or service ordered. When ordering tests or services that do not meet LCD or NCD, physicians should explain to the beneficiary why the test is being ordered and that Medicare may not pay for the test and therefore an ABN must be signed. An ABN must be offered to the patient before the test or service is performed.



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Medicare frequently denies claims for laboratory tests for the following reasons:

- Medicare does not usually pay for this service for the diagnosis provided.
- Medicare will not pay for research or investigational use tests.
- Medicare does not pay for this service based on frequency limitations.
- Medicare does not pay for most routine screening tests.
- Medicare does not pay for annual physical exams.

## J. Point of Care (POC) Testing

All federal guidelines that apply to general laboratory testing also apply to POC testing. POC testing sites will be monitored in the same manner as other laboratory sites to ensure compliance.

## K. Prohibited Referrals

It is the policy of UCHHealth Northern Colorado and the laboratory to comply with all aspects of the self-referral prohibitions and exceptions established by Stark I and II. More detailed information may be found at:

<http://www.cms.hhs.gov/PhysicianSelfReferral/>

## L. Inducements

UCHHealth Northern Colorado and the laboratories do not offer any inducements to physicians or entities in order to secure Medicare billings. All supplies and equipment provided to customers are directly related to specimen collection, processing, and reporting of test results. Any form of suspected inducement should be reported to the Ethics, Compliance, and Privacy Officer, for investigation. You may also call the toll free, 24 hour a day, seven day a week confidential Integrity Hotline 1-855-824-6287.

## M. Monitoring

All laboratory testing sites are regularly monitored to safeguard against unintentional violation of federal compliance guidelines. Monitoring activities are also aimed at raising awareness of federal guidelines and assisting in developing mechanisms for successfully meeting them.



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Appendix A – Reflex Test Listing

Initial test:	Warrants reflex if:	Reflex test to be performed:
Antibody Screen	Positive	Antibody identification
Type and Screen	Clinically significant antibody presence or previous history	Complete crossmatch for 2 units and screens for antigen-negative units
Pre-Admit Type and Screen for Surgery	Positive antibody or patient does not meet pre-admit criteria for 30 day sample	Type and screen repeated within 3 days of surgery
Direct Antiglobulin Test	Positive	Mono-specific DAT studies
Antibody Panel	Positive	Patient antigen typing, antigen typing to identify antigen negative units, complete crossmatch, and Direct Antiglobulin Test, if indicated
Prenatal Testing	Positive	Antibody identification. Titer if clinically significant antibody identified.
Fetal Screen	Positive	FetalDEX (Kleihauer-Betke)
Rh Immune Globulin Rh Type	Negative	Rh Immune Globulin workup
ABO/Rh Type	Discrepant	ABO/Rh as indicated with different methods to determine patient blood type. (Techniques may include warming, cold screen, antigen typing or ID)
Massive Transfusion Situation		Automatic orders are instituted based on the Massive Transfusion Policy.
Sickle Cell Disease		Red cell antigen matching of all donor units
Blood Type	First blood type on the patient at this facility	Confirmatory blood type from a second venipuncture
Cord blood	There is no previous maternal blood type recorded at this facility	Blood type performed on maternal sample from admission
Cord Blood Workup	Based on maternal and infant blood types	Direct Antiglobulin Test



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Appendix A – Reflex Test Listing

Initial test:	Warrants reflex if:	Reflex test to be performed:
HIV screen	Positive	Immune-chromatographic confirmation
Total Antibodies to Hepatitis A	Positive	Hepatitis A IgM
Hepatitis B surface antigen	Equivocal	Confirmation by neutralization
Syphilis IgG antibody (Treponema pallidum)	Positive or equivocal	T. pallidum particle agglutination test and RPR titer (tests performed by reference lab)
Culture	Positive	Identifications and susceptibilities as appropriate
Culture	Suspected Multi Drug Resistant Organism	Confirmation and susceptibilities as appropriate
Culture	Aerobic Actinomyces	Identifications and susceptibilities as appropriate
Gram stain	Source is NOT: Catheter tip Nose/Nasal/Nares Stool Throat Urine	Aerobic culture
Acid Fast Culture	Positive	Identifications and susceptibilities as appropriate
Perinatal Strep screen	Patient allergic to penicillin or cephalosporins	Susceptibility to Clindamycin
Rapid strep screen	Negative	Throat strep screen culture
MRSA	Pre-Op and Inpatient	Test performed by PCR
Stool Culture	Inpatients	Test performed by PCR, susceptibilities if indicated.
Blood parasite smear	Positive	Speciation and quantitation





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Appendix A – Reflex Test Listing

Initial test:	Warrants reflex if:	Reflex test to be performed:
Urinalysis	Cath specimen on child $\leq 18$ years old	Urine culture (unless ordered as UA Dipstick Only)
CBC with automated differential	Flagged abnormal	Manual smear review or manual differential depending on criteria established by the hematology lab with the hematopathologist
TEG Panels	Reflexes are dependent upon several factors.	Please contact MCR Laboratory for specific information.
Whole blood prothrombin time/INR	INR $\geq 4.5$ or $< 2.0$	PT/INR from venipuncture
ANA reflex	Positive ANA screen	dsDNA, chromatic, SS-A, SS-B, Sm (Smith), RNP, SM/RNP, Scl-70, Jo-1, Centromere B
Celiac IgA	Tissue transglutaminase (tTG) IgA and deaminated gliadin peptide (DGP) negative with IgA deficiency	Celiac IgG - Tissue transglutaminase IgG (tTG) and deaminated gliadin peptide IgG (DGP)
Gross lab procedures		Performed based on previously-determined algorithms from the pathologists
Lipid panel	400 < Trig < 1292	Direct measured LDL



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**Appendix B – Panel Profile Information**

The following list includes panels that are performed in University of Colorado Health Northern Region Laboratories. It is provided to offer guidance with respect to billing laboratory testing panels performed on site. Please contact the laboratory if you have questions about allergy panels, panels that are sent to reference labs for testing, or about any aspect of testing or billing.

In addition to those listed below, the laboratories will perform some panels under specific conditions. These include Trauma Panels performed for the Emergency Department, Occupational Health Panels, Cardiac Coagulation Panels for the OR, and others. Please contact the laboratory if you have questions about panels not listed below.

Test/Panel Name	CPT Codes Included	Medicare Reimbursement
AFB Culture	AFB culture AFB smear	87116 \$14.71 87206 \$7.33
Basic Metabolic Panel	Calcium, carbon dioxide, chloride, creatinine, glucose, potassium, sodium, urea nitrogen (BUN)	80048 \$11.52
Body Fluid Panel	Cell count with diff Glucose, BF other than blood Protein, other source LDH	89051 \$7.50 82945 \$5.35 84157 \$5.00 83615 \$8.22
Celiac IgA	Deamidated Gliadin Peptide IgA tTG (Anti-Tissue Transglutamase) IgA	83516 \$15.71 83516 \$15.71
Celiac IgG	Deamidated Gliadin Peptide IgG TtG (Anti-Tissue Transglutamase) IgG	83516 \$15.71 83516 \$15.71
Comprehensive Metabolic Panel	Albumin, ALT, AST, bilirubin, calcium (total), carbon dioxide, chloride, creatinine, glucose, alkaline phosphatase, potassium, total protein, sodium, urea nitrogen (BUN)	80053 \$14.39
Cortisol Stimulation	Baseline cortisol 30 minutes 60 minutes	82533 \$22.21 82533 \$22.21 82533 \$22.21
Cortisol Suppression	AM cortisol 4PM 11PM (optional)	82533 \$22.21 82533 \$22.21 82533 \$22.21
CSF Panel	Cell count with diff Glucose, BF other than blood Protein, other source	89051 \$7.50 82945 \$5.35 84157 \$5.00



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Test/Panel Name	CPT Codes Included	Medicare Reimbursement
Drug Abuse Screen, Urine	Amphetamine, barbiturates, benzodiazepine, cocaine, marijuana, methamphetamine, opiate, phencyclidine, tricyclic antidepressants G0477	\$14.86
DRVVT Panel	DRVVT With reflex to mixing study 85613	\$13.05
	85732	\$8.81
	Thrombin time 85670	\$7.86
EBV Panel	EBV IgG VCA (viral capsid Ag) 86665	\$19.45
	EBV IgG EA-D (early Ag det.) 86663	\$17.87
	EBV IgG EBNA (EB nuclear Ag) 86664	\$19.45
	EBV IgM VCA (viral capsid Ag) 86665	\$19.45
	EBV IgM Heterophile 86308	\$7.05
Electrolyte Panel	Carbon dioxide, chloride, potassium, sodium 80051	\$9.55
General Health Panel	Comprehensive metabolic panel, CBC w/ diff, TSH 80050	\$0.00 Not covered by Medicare Patient will be responsible
GI PCR Panel	GI PCR (standard) 87507	\$567.75
	Supplemental culture 87046	\$12.86
Giardia/Cryptosporidium Antigen Panel	Giardia lamblia antigen 87329	\$16.33
	Cryptosporidium antigen 87328	\$16.33
Glucose Tolerance	3 specimens, including glucose 82951	\$8.74
	each additional specimen 82952	\$5.34
Hepatic Function Panel	Albumin, total bilirubin, direct bilirubin, alkaline phosphatase, total protein, AST, ALT 80076	\$11.13
Hepatitis Panel, acute	Hepatitis A ab IgM, hepatitis B core ab IgM, hepatitis B surface ag, hepatitis C antibody 80074	\$64.89
HSV Panel	HSV 1 IgG 86695	\$17.97
	HSV 2 IgG 86696	\$26.37
HSV PCR (Amplivue)	HSV 1 HSV 2 87529x2	\$95.60



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Test/Panel Name	CPT Codes Included		Medicare Reimbursement
HyperCoag Panel A Patient on heparin, or no anticoag therapy	Antithrombin III activity	85300	\$16.15
	Protein C activity	85303	\$18.84
	Protein S activity	85306	\$20.88
	Homocysteine	83090	\$22.98
	*Factor II DNA	81240	\$67.03
	*Anticardiolipin antibodies	86147x2	\$41.64
	*Beta-2 glycoprotein abs	86146x3	\$62.46
	*Factor VIII activity	85240	\$24.39
	Thrombin time	85670	\$7.86
	DRVVT	85613	\$13.05
	with reflex to mixing study	85732	\$8.81
	*Activated protein C resistance	85307	\$20.88
*Test sent to reference lab	*with reflex to factor V Leiden DNA	81241	\$83.24
HyperCoag Panel B Patient on coumadin	Antithrombin III activity	85300	\$16.15
	Homocysteine	83090	\$22.98
	*Factor II DNA	81240	\$67.03
	*Anticardiolipin antibodies	86147x2	\$41.64
	*Beta-2 glycoprotein abs	86146x3	\$62.46
	*Factor VIII activity	85240	\$24.39
	*Activated protein C resistance	85307	\$20.88
	*with reflex to factor V Leiden DNA	81241	\$83.24
	*Protein C antigen	85302	\$16.37
	*Protein S antigen, total	85305	\$15.81
	*Factor IX antigen	85250	\$26.94
	*Protein C antigen : factor IX antigen ratio	Calculation	No charge
*Test sent to reference lab	*Protein S antigen : factor IX antigen ratio	Calculation	No charge
Immunoglobulin panel	IgG, IgM, IgA	82784 x3	\$7.77 ea.
Influenza A/B screen (Rapid Immunoassay)	Influenza A	87804	\$16.33
	Influenza B	87804-91	\$16.33
Influenza/RSV PCR	Flu, RSV	87631	\$174.76
	Flu	87502	\$115.92
	RSV	87798	\$48.80
Iron Panel	Ferritin	82728	\$18.57
	Iron	83540	\$8.82
	Transferrin	84466	\$17.39
Lipid Panel	Total cholesterol, direct measure HDL cholesterol, triglycerides	80061	\$18.24



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Test/Panel Name	CPT Codes Included		Medicare Reimbursement
Lupus Panel	APTT	85730	\$8.18
	With reflex to mixing study	85732	\$8.81
	With reflex to hex phase testing	85598	\$20.93
	Thrombin time	85670	\$7.86
	DRVVT	85613	\$13.05
MI Panel	CBC w/ diff	85025	\$9.63
	Basic metabolic panel	80048	\$11.52
	Troponin	84484	\$9.11
Obstetric Panel	CBC w/ diff, HBsAg, rubella antibody, qualitative syphilis test, RBC antibody screen, ABO & Rh type	80055	\$65.12
Ova & Parasites (O&P)	Complex special O&P stain	87209	\$23.31
	Concentration	87177	\$12.12
Pathologist Review of WBC Differential Smear	CBC and automated diff	85025	\$9.63
	<b>OR</b>		
	CBC and Manual diff	85027	\$6.79
	<b>AND</b>	85007	\$4.68
	Pathologist review of smear		No charge
Renal Function Panel	Albumin, calcium, carbon dioxide, chloride, creatinine, glucose, phosphorus, potassium, sodium, urea nitrogen	80069	\$11.83
Respiratory PCR Panel	Chlamydia pneumoniae	87486	\$47.80
	Mycobacteria pneumoniae	87581	\$47.80
	Respiratory virus 12 – 25 targets	87633	\$567.75
	Additional organism	87798	\$47.80
Rheumatoid Panel	CCP	86200	\$17.63
	RF	86431	\$7.73
	CRP	86140	\$7.05
Routine culture	Aerobic culture	87071	\$12.86
	Gram stain	87205	\$5.82
Stool Composite Culture	Aerobic culture Salmonella, Shigella, preliminary	87045	\$12.86
	Additional pathogens	87046x2	\$25.72
	Shigatoxin 1 & 2	87427x2	\$32.66
Synovial Fluid Panel	Cell count with diff	89051	\$7.50
	Viscosity	85810	\$15.90
	Crystals	89060	\$9.75



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Test/Panel Name	CPT Codes Included	Medicare Reimbursement	
TEG	Platelet, aggregation (in vitro) Fibrinogen activity Coagulation time, activated (Contact the laboratory for list of reported values.)	85576 85384 85347	\$29.27 \$11.57 \$5.80
Rapid TEG	Platelet, aggregation (in vitro) Fibrinogen activity Coagulation time, activated (Contact the laboratory for list of reported values.)	85576x2 85384x2 85347x2	\$58.54 \$23.14 \$11.60
TEG with Platelet Mapping	Platelet, aggregation (in vitro) Fibrinogen activity Coagulation time, activated (Contact the laboratory for list of reported values.)	85576x4 85384 85347	\$117.08 \$11.57 \$5.80
ToRCH Panel	Toxoplasma gondii Rubella CMV HSV1, HSV2	86317 86762 86644 86695, 86696	\$20.42 \$19.61 \$19.61 \$17.97, \$26.37
Vasculitis Screen	Myeloperoxidase Proteinase (PR3)	83516 83516	\$15.71 \$15.71
Wet Prep Panel	KOH prep Gram stain Wet mount	87220 87205 87210	\$5.82 \$5.82 \$5.82