BAPTIST HEALTH SYSTEM
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July 10, 2018

Physician Annual Notice of Laboratory Compliance

Dear Provider:

The Office of Inspector General (OIG) of the Department of Health and Human Services recommends in its Model Laboratory Compliance Plan that laboratories send an annual notice to physicians and other providers advising them of the elements of the laboratory's compliance program. This letter serves as our annual notice and provides helpful information regarding the ordering and processing of clinical laboratory tests. We are pleased to inform you that we will accept any form of requisition as long as it contains the information described in this letter. We are also pleased to inform you that our laboratories will accept orders of diagnostic laboratory panels approved by our Medical Staff rather than requiring you to individually order these tests. Note, however that organ and disease related panels will only be billed to and paid by Medicare when all components are medically necessary.

Physicians may be familiar with our LMRP Manager software, which we use to screen outpatient laboratory tests for medical necessity. The program screens tests ordered against diagnoses provided by the provider according to the National Coverage Decisions (NCDs) issued by the Centers for Medicare and Medicaid Services (CMS) and Local Coverage Determinations (LCD) issued by Novitas, the BHS Medicare Administrative Contractor (MAC). If a particular test that is ordered for a Medicare patient does not meet the NCD or LCD medical necessity guidelines, the patient will be provided with an Advanced Beneficiary Notice (ABN), which informs the patient of his/her potential financial responsibility for the tests if Medicare denies the claim. If an ABN is provided to the patient, the tests will first be submitted to Medicare for an initial determination. If Medicare denies the test, the patient will then be billed for the test. Your patients will also be provided the opportunity to refuse the test if it is not likely to be covered by Medicare. You can access the NCDs and LCDs from the CMS website, http://www.cms.gov/center/clinical.asp under the heading "Coverage".

To simplify the processing of tests in our LMRP Manager software, we encourage you to use the electronic entry of orders or the completion of the BHS Laboratory Requisition. However, our laboratories will accept any laboratory requisition or prescription pad that contains the following information, which is required by the CLIA regulations and/or necessary to screen the tests in LMRP Manager.

1. The patient's name or other unique identifier.
2. The name and telephone number or other suitable identifiers of the physician (or other person authorized under state law) ordering the test and, if applicable, the individual responsible for utilizing the test results or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminent life threatening laboratory results or panic value.

3. The name and/or CPT code of the test(s) to be performed including the CPT code for each component of any panels ordered. **Note that we prefer to have both the name and the CPT code.**
4. All of the patient's current ICD-10-CM codes or narrative diagnosis.
5. The date of specimen collection (for pap smears, the date of last menstrual period, age or date of birth and indication of whether the patient had a previous abnormal result, treatment or biopsy).
6. Additional information relevant and necessary to a specific test to assure accurate and timely testing and reporting of results as determined by the hospital. This information should include, if appropriate, the source of the specimen and time of collection.
7. The signature of the ordering physician or other person authorized to directly order clinical laboratory tests or a representative from the physician's practice.

Should we receive a requisition that does not contain the information listed above, we will return the requisition to your office via FAX for completion of the required information. Without appropriate documentation and /or all current diagnostic information the patient may refuse the test, delaying valuable information or may be required to pay for services that otherwise would be covered as a coverage benefit. We appreciate your cooperation in completing the required information.

We have also attached the list of the non-standard diagnostic panels and reflex tests approved by our Medical Staff and offered by our laboratories. The approved non- standard panels may be ordered as a whole rather than ordering each individual test. This list includes the name of the panel as it will appear on our requisition and the individual tests and corresponding CPT codes that make up the panel. To the extent that you order one of these non-standard panels, the OIG has asked us to advise you of the following:

1. The Medicare program provides separate reimbursement to the laboratory for each individual component contained in the non-standard panel;
2. Ordering non-standard panels may result in the ordering of tests which are not covered, reasonable or necessary and these tests will not be billed except for the purpose of receiving a denial; and
3. Any individual who knowingly causes a false claim to be submitted may be subject to sanctions or remedies available under civil, criminal and administrative law.

Reflex tests will be performed as noted unless you specifically opt out of the reflex test by noting this on the original order or requisition.

The OIG's Model Compliance Plan also suggests that we inform you that our laboratories are relying on the following when we perform tests that you order:

1. The information you submit on the requisition accurately reflects the medical reasons for requesting the specified tests;
2. The medical necessity and order for each of the individual tests you order has been appropriately documented in the patient's medical record in your office;
3. Tests will only be ordered when each individual test is medically necessary for the diagnosis and treatment of the patient or the criteria in paragraph 5 below are satisfied;
4. You are treating the patient in connection with the diagnoses, complaints or reasons listed on the electronic order/ requisition;
5. When you order tests for purposes of screening for asymptomatic patients that you believe are appropriate you may want to consult the CMS Preventive Medicine website http://www.cms.gov/Medicare/Prevention/PrevntionGenInfo , the payor may not allow reimbursement unless the appropriate screening codes are used, Medicare usually does not cover screening tests other than those listed. This should has been explained to the patient, and on the requisition note that the test is for screening purposes; and
6. Upon request of the BHS hospital or its payors, you agree to provide documentation from your office that reflects that the test was ordered and medically necessary for the patient.

Lastly, the Model Compliance Plan also suggests that we provide you with a copy of the Medicare Laboratory fee schedule and advise you that the Medicaid reimbursement amount may be equal to or less than the amount of Medicare reimbursement that the hospital will receive on the tests you order. The Medicare fee schedule may be found on the CMS webpage at http://www.cms.gov/center/clinical.asp under the heading "Billing/Payment".

Our System Laboratory Medical Director is Dr. Jennifer R. Rushton and her phone number is 210-297-7842. We greatly appreciate your support for our Laboratory Compliance Program. If you have any questions or comments regarding the BHS Laboratory Compliance Program, please do not hesitate to contact the Regional Director of Laboratory Operations, Alma Castaneda at 210-297-9655 or the Regional Laboratory Coordinator for Compliance and Education, Carolyn J. Long at 210-297-9650.

Sincerely,

Jennifer R. Rushton, MD
System Laboratory Director

Attachment to Physician Annual Notice of Laboratory Compliance
Baptist Health System
June 4, 2018

Respiratory Bordetella by PCR results are reported as:

	Bordetella pertussis PCR
87798 X 3	Bordetella parapertussis
	Bordetella holmesli

LIST OF NON-STANDARD DIAGNOSTIC CLINICAL LABORATORY PANELS
APPROVED BY THE BAPTIST HEALTH SYSTEM MEDICAL EXECUTIVE COMMITTEE

Panel CPT Codes	**Test Listings**
MIXING STUDY PT	
85610	PROTHROMBIN TIME (INR)
85611	PROTIME PLASMA FRACTIONS (2)
MIXING STUDY PTT	
85730	PARTIAL THROMBOPLASTIN (PTT)
85732	PTT PLASMA FRACTIONS (2)
LUPUS ANTICOAGULANT SCREEN	
85610	PT
85730	PTT
85670	THROMBIN TIME
85613	DRVVT RATIO
85597	STA CLOT LA
	Pathology Interpretation
WET MOUNT PREPARATION HEMATOLOGY	
87205	GRAM STAIN
87210	WET MOUNT W SIMPLE STAIN
RESPIRATORY VIRAL PATHOGENS PCR	
	ADENOVIRUS
	RESPIRATORY SYNCYTIAL VIRUS A
87633	RESPIRATORY SYNCYTIAL VIRUS B
	INFLUENZA A
	INFLUENZA A H1
	INFLUENZA A H3
	INFLUENZA B

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PARAINFLUENZA TYPE 1	RHINOVIRUS
PARAINFLUENZA TYPE 2	HUMAN METAPNEUMOVIRUS
PARAINFLUENZA TYPE 3	
PARAINFLUENZA TYPE 4	

MENINGITIS/ENCEPHALITIS PCR

87483	ESCHERICHIA COLI K1
	HAEMOPHILUS INFLUENZA
	LISTERIA MONOCYTOGENES
	NEISSERIA MENINGITIDES
	STREPTOCOCCUS AGALACTIAE
	CRYPTOCOCCUS GATTI/NEOFORMANS
	HERPES SIMPLEX 1
	HERPES SIMPLEX 2
	HUMAN HERPES VIRUS 6
	ENTEROVIRUS
	HUMAN PARECHOVIRUS
	VARICELLA ZOSTER VIRUS

GASTROINTESTINAL PATHOGENS PCR

87506	CAMPYLOBACTER GROUP
	SALMONELLA SPECIES
	SHIGELLA SPECIES
	VIBRIO GROUP
	YERSINIS ENTEROCOLITICA
	NOROVIRUS GI/GII
	ROTAVIRUS A
	SHIGA TOXIN 1 AND SHIGA TOXIN 2 GENE VIRULENCE MARKERS

SWEAT CHLORIDE ANALYSIS

89230	SWEAT COLLECTION BY IONTOPHORESIS
82438	CHLORIDE, OTHER SOURCE

ABO/RH TYPE

86900	ABO TYPE ONLY
86901	RH TYPE

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LIST OF REFLEX TESTING APPROVED BY THE BAPTIST HEALTH SYSTEM MEDICAL EXECUTIVE COMMITTEE

Ordered Test:	**Criteria**	**Required Reflex Testing Ordered:**
ANA Screen	● Any positive or equivocal result	ANA panel includes: • Anti dsDNA quantitative • Anti Sm (Smith) IgG • Anti SM/RNP IgG • Anti SSA IgG • Anti SSB IgG • Anti Sci-70 • Anti JO-1 IgG • Anti RNP • Anti Centromere B • Anti Chromatin • Anti Ribosomal P
CBC/Platelet Count	Platelet count less than 50,000	Immature Platelet Fraction (IPF)
CBC/Hemogram	Hgb <9g/dl and MCV <78	ReticCyto (Ret-HE, RetAB,IRF,RetIRE)
CBC/CBC auto Diff	Any abnormal parameter on CBC or automated Differential	Smear Review
Pathologist Review of Peripheral Blood Smear	All request for Pathologist review of peripheral smear	CBC with automated differential
Pathology review of a peripheral smear triggered by either abnormal parameters established by the Hematology Lab or physician request	Suspicion of acute leukemia by pathologist	Flow cytometric analysis of peripheral blood
LUPUS ANTICOAGULANT Screen (DRVVT)	Positive result	DRVVT (Sure) DRVVTMIX 1:1
RPR	Reactive	Syphilis IgG
Syphilis Screen (Syphilis IgG)	Any positive or equivocal result	Reflex to RPR, if positive an RPR titer is performed
Syphilis IgG RPR	Reactive/Equivocal result RPR Non-reactive	Treponema Pallidum Particle Agglutination (TP-PA)

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Ordered Test:	Criteria	Required Reflex Testing Ordered:
Urinalysis w Microscopic examination if indicated	Any of the following results are: • Positive for leukocyte esterase • Positive for nitrite • Positive for occult blood • Positive for protein	Microscopic exam Reflex to culture if any one of the following are met: WBC's: 6 – 10 Leukocyte esterase: Trace + Nitrite: Trace + Bacteria: Moderate/Many
Urinalysis Complete (UA auto w microscopic)	• Leukocyte esterase: Trace + • Nitrite: Trace + • WBC's: 6-10 • Bacteria: Moderate to Many	Urine culture
Hbs Ag	Any positive or equivocal result	Hbs Ag confirmatory
AFB smear on sputum	Positive result	Mycobacteria tuberculosis by PCR
Mycobacteria tuberculosis PCR on sputum	Any result	AFB culture
Cryptococcal antigen	Positive result	Fungal culture
C. difficile screen (specimens only accepted if loose, watery or mucoid and conform to the shape of the container)	Positive GDH and Negative Toxic Antigen Screen or Negative GDH and Positive Toxic Antigen Screen	C. difficile toxin PCR
Microbiology Cultures	Identification of pathogen	Gram Stain Anaerobic & aerobic cultures performed as appropriate for specimen source Antibiotic susceptibility where applicable. Susceptibilities not automatically performed on all pathogens.
Microbiology Blood Cultures	Positive growth of gram positive or gram negative bacteria	Gram positive and/or Gram negative nucleic acid test
Microbiology Stool Culture	Stool Culture Positive for Shiga Toxin	E.Coli O157:H7 culture

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Ordered Test:	Criteria	Required Reflex Testing Ordered:
Cryptosporidium parvum immunoassay	Any result	Entamoeba histolytica and Giardia lamblia immunoassays
Entamoeba histolytica immunoassay	Any result	Cryptosporidium parvum and Giardia lamblia immunoassays
Giardia lamblia immunoassay	Any result	Cryptosporidium parvum and Entamoeba histolytica immunoassays
Rapid Strep Group A	Any negative result	Streptococcal Screen Culture Group A
Antibody Screen	Positive antibody screen	Antibody Identification, Antigen Testing Two Unit Cross-match if surgical patient with s hemoglobin <10 or has special conditions (i.e. sickle cell)
Direct Antibody Test (DAT) on cord blood	Positive result	Total and Direct Bilirubin
Rh on Mother and Baby	Rh negative mother/ Rh positive baby	Fetal Hemoglobin Scr.(85641)
Fetal Hemoglobin Screen	Positive result	Feto-maternal Bleed by Flow Cytometry (86356)
Transfusion of any product without current order for ABO/RH and Antibody Sc	Order for blood product transfusion with no specific order for ABO/RH and Antibody screen	ABO/RH Antibody Screen
Direct Coombs-Poly	Positive Result	Direct Coombs-Anti IgG Direct Coombs-Anti C3
Rapid Flu A	Any result	Rapid Flu B
Rapid Flu B	Any result	Rapid Flu A
Stool Culture	Bloody specimen	E. coli O157 culture
Stool Culture	Any result	Campylobacter culture/immunoassay
Rapid Malaria Antigen	Positive	Malaria smear
Malaria Smear	Any result	Rapid malaria antigen
CSF Bactogen	Negative or positive result	CSF Culture
TSH	Abnormal result	Free T4
Urine 24 HR or Random Immunoelectrophoresis	Possible monoclonal pattern	Immunoelectrophoresis with immunofixation
Serum Protein Electrophoresis	Monoclonal spike	Immunoelectrophoresis with immunofixation, quantitative Immunoglobins and free Kappa/Lambda light chains
Hgb Electrophoresis	Presumed Hb-S Abnormal patterns	Acid Electrophoresis technique
Flow Cytometry Leukemia/Lymphoma	Path review	Pathologist reviews blood smear prior to sending specimen for testing.

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Ordered Test:	Criteria	Required Reflex Testing Ordered:
Surgical and cytological pathology	Breast cancer diagnosis made	HER2 testing by FISH and/or IHC and ER, PR, Ki67 testing by IHC
Surgical and cytological pathology	Metastatic colorectal carcinoma diagnosis made	KRAS, NRAS, BRAF mutation analysis
Surgical and cytological pathology	Metastatic or inoperable locally advanced gastric or gastroesophageal junction adenocarcinoma diagnosis made	HER2 by IHC and, if negative or equivocal, HER2 by FISH
Surgical and cytological pathology	Plasma cell neoplasm diagnosis made	Myeloma prognostic panel by FISH
Surgical and cytological pathology	Head and Neck squamous cell carcinoma diagnosis made	P16 by IHC
Surgical and cytological pathology	Gastric or gastroesophageal junction adenocarcinoma diagnosis made	Immunohistochemical screening for microsatellite instability
Surgical and cytological pathology	Diagnosis made of: All primary colorectal or small bowel carcinomas All primary colorectal or small bowel adenomas in patients below the age of 40	Screening for HNPCC/Lynch Syndrome/microsatellite instability by IHC.: If staining for both *MLH1* and *PMS2* is negative, *BRAF* mutation with reflex to *MLH1* Promoter Methylation will be performed.
Surgical and cytological pathology	All primary endometrial carcinoma diagnoses	Screening for HNPCC/Lynch Syndrome by IHC.: If staining for both *MLH1* and *PMS2* is negative, *MLH1* Promoter Methylation will be performed.
Surgical and cytological pathology	Metastatic melanoma diagnosis made	*BRAF* mutation analysis (Assay must be FDA approved for this specific purpose)
Surgical and cytological pathology	New myelodysplasia syndrome diagnosis made	MDS/FISH panel and/or cytogenetic studies
Surgical and cytological pathology	New acute myelogenous leukemia (AML) diagnosis made	AML FISH panel and/or cytogenetic studies and/or molecular analysis
Surgical and cytological pathology	New myeloproliferative neoplasm diagnosis made	Qualitative JAK2 PCR, quantitative BCR/ABL by PCR and cytogenetic studies
Surgical and cytological	Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL)	Prognostic CLL/SLL FISH Panel
Surgical and cytological	Acute Lymphoblastic Leukemia	FISH and/or cytogenetic studies
Surgical and cytological pathology	BCR/ABL FISH positive myeloproliferative neoplasm	Quantitative BCR/ABL test

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Ordered Test:	Criteria	Required Reflex Testing Ordered:
Surgical and cytological pathology	New adenocarcinoma of lung or non-small cell Carcinoma, NOS diagnosis made	ALK, EGFR, ROS1 testing
Surgical and cytological pathology	Non-small cell lung carcinoma biopsies	PD-L1 Immunochemistry