

RE: Laboratory Compliance - Annual Provider Notification Letter

The Office of Inspector General (OIG) of the Department of Health and Human Services recommends in its Model Laboratory Compliance Plan that laboratories, as participants in federally funded health care programs, provide an annual notice to physicians advising them of the elements of the laboratory's compliance program (available at <http://oig.hhs.gov/authorities/docs/cpqlab.pdf>). This letter serves as the annual notice to provide helpful information regarding compliant ordering and processing of clinical laboratory tests for our shared patient.

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

- ❑ The information you submit on the order/requisition accurately reflects the medical reasons for requesting the specified tests. The requisition and order information required by federal regulations and CLIA requirement includes: 1) Date of order, 2) Patient Name & 3) Date of birth, 4) Signs & Symptoms/ICD10 diagnosis (indications as to why the test is being ordered) 5) Ordering clinician's name, with signature or signed medical documentation. When an invalid order is received, the laboratory will contact the provider office to obtain the necessary information. Requested services will be postponed until the necessary information is provided. We appreciate your cooperation in submitting valid orders.
- ❑ Physicians and other health care providers should only order those tests they believe are medically necessary for the diagnosis, treatment and therapy of their patient. The ordering clinician is responsible for ensuring that lab procedures requested are medically necessary by federal guidelines in order to bill Medicare.
 - ❑ Organ or disease panels as defined by the American Medical Association (AMA) are used when all components are medically necessary. A diagnosis (ICD-10) must be provided for each test order.
 - ❑ When you order tests for purposes of screening for asymptomatic patients that you believe are appropriate even though the payer may not allow reimbursement, you acknowledge the fact that Medicare generally does not cover screening tests and that you or your staff have explained this to the patient and the order/requisition notes that the test is for screening purposes.
 - ❑ If a particular test that is ordered for a Medicare patient does not meet the NCD or LCD medical necessity guidelines, or is frequency restricted, the patient will be provided with an Advance Beneficiary Notice ("ABN"), which informs the patient of his/her potential financial responsibility for the tests if Medicare denies the service. If an ABN is provided to and signed by the patient, unless the patient waives billing Medicare, 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.
 - ❑ Bronson Laboratory offers a set of non-standard diagnostic panels approved by our Medical Staff. Medicare regulations require that we notify you annually to these tests and their appropriate use. These are a specific group of commonly ordered tests not defined by the American Medical Association (AMA) or Centers for Medicare and Medicaid services. These panels cascade when initial test results are positive or outside normal parameters and reflex to a second related test or further testing as medically appropriate. Mandated testing criteria set by government or accrediting agencies, evidence-guided practices in laboratory medicine, and avoidance of performing unnecessary testing help dictate which tests are subject to reflexive testing. Bronson Laboratory will perform reflex testing upon result of an initial laboratory test as outlined in the Test Catalog online at <http://bronsonlab.testcatalog.org/>. These panels may be ordered as a whole rather than ordering each test individually when each test is medically necessary. To the extent that you order one of these non-standard panels, the OIG has asked us to advise you of the following:

- ❑ The Medicare program provides separate reimbursement to the laboratory for each individual component contained in the non-standard panel;
 - ❑ Ordering non-standard panels may result in the ordering of tests which are not covered, reasonable or necessary and that tests will not be billed to Medicare except for the purpose of receiving a denial.

- ❑ Current Procedural Terminology (CPT) Codes and information on available services are also provided in the Bronson Laboratory Test Catalog as a convenience to our clients.

- ❑ The OIG takes the position that an individual who knowingly causes a false claim to be submitted may be subject to sanctions or remedies available under civil, criminal and administrative law. The laboratory will not knowingly bill Medicare for tests that are not covered, reasonable, or necessary.

- ❑ 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. This information is being provided to advise you of the federal program reimbursement the hospital will receive on the tests you order. The Medicare Laboratory Fee schedule is available at <http://www.cms.hhs.gov/ClinicalLabFeeSched>. Medicaid reimbursement will be equal to or less than Medicare reimbursement.

- ❑ Further National Coverage Determinations (NCD) and Local Coverage Determinations (LCD) information:
 - ❑ For all Bronson Laboratories, NCD policies available at: <https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx>
 - ❑ For Bronson Methodist, Lakeview, and South Haven Laboratories, WPS MAC, Jurisdiction 8 local policies available at: <https://www.wpsgha.com/wps/portal/mac/site/policies/guides-and-resources/lcds-and-coverage-articles/>
 - ❑ For Bronson Battle Creek Laboratory, NGS MAC, Jurisdiction 6 local policies available at: https://www.ngsmedicare.com/ngs/portal/ngsmedicare/newngs/home-lob/pages/medical-policy-center/medical%20policy%20center_jk%20and%20j6/

We greatly appreciate your support for our Laboratory Compliance Program. If you have any questions or comments regarding the hospital's Laboratory Compliance Program, please do not hesitate to contact one of us at the numbers listed below.

Sincerely,

Lois VanEnk, MBA MT(ASCP)SC
 Bronson Laboratory System Director
 269 341-7670

Christine Sangalli
 VP Chief Compliance Officer
 Bronson Healthcare Group
 269 341-6065

AMA Approved Panels	Tests Included in Panel
Acute Hepatitis Panel	Hepatitis B surface antigen, Hepatitis B core antibody IgM, Hepatitis A antibody IgM, Hepatitis C Antibody
Basic Metabolic Panel/Calcium	Sodium, Potassium, Chloride, Carbon Dioxide, Creatinine, Urea Nitrogen (BUN), Glucose, Calcium
Basic Metabolic Panel/Ionized Ca	Sodium, Potassium, Chloride, Carbon Dioxide, Creatinine, Urea Nitrogen (BUN), Glucose, Ionized Ca
Comprehensive Metabolic Panel	Sodium, Potassium, Chloride, Carbon Dioxide, Creatinine, Urea Nitrogen (BUN), Glucose, Calcium (Total), Total Protein, Albumin, AST, ALT, Alkaline Phosphatase, Total Bilirubin
Electrolyte Panel	Sodium, Potassium, Chloride, Carbon Dioxide
Hepatic Function Panel	Albumin, Alkaline Phosphatase, ALT, AST, Total Bilirubin, Direct Bilirubin, Total Protein
Lipid Panel	Cholesterol, HDL Cholesterol, Triglycerides, Calculated LDL Cholesterol, Non HDL Cholesterol
Renal Panel	Sodium, Potassium, Chloride, Carbon Dioxide, Creatinine, Urea Nitrogen (BUN), Glucose, Calcium (Total), Albumin, Phosphorus
Additional Panels Offered at Bronson Laboratory	
Allergen Panels	<p><i>See full descriptions in the Bronson Laboratory Users Guide.</i></p> <p>Childhood Panel: Alternaria, Cat, Cladosporium, Dust Mite(DF), Dust Mite(DP), Dog, Roach, Cod, Egg, Milk, Peanut, Soy, Shrimp, Walnut, Wheat and Total IGE.</p> <p>Food Panel: Milk, Egg White, Peanut, Soybean, Wheat, Codfish, Corn, Walnut, Clam, Scallop, Shrimp, Sesame seed, Total IgE</p> <p>Respiratory Panel : Alternaria, Cat, Dust mite(DF & DP), Dog, Roach, Aspergillus, Bermuda Grass, Red Cedar, Cladosporium, Cottonwood, Timothy Grass, Mulberry, Nettle, Penicillium, Russian Thistle, Birch, Elm, Maple, Marsh Elder, Ragweed, Oak, Total IGE.</p> <p>Venom Panel: Venom from honey bee, paper wasp, white faced hornet, yellow hornet, yellow jacket</p>
Anaerobe Culture	Aerobic Culture ordered in conjunction with Anaerobe Culture
Blood Culture Identification Panel	Positive blood cultures reflex to PCR panel to detect Enterococcus, Listeria monocytogenes, Staphylococcus species, Staph aureus, Streptococcus species, Strep agalactiae, Strep pneumonia, Strep pyogenes, Acinetobacter baumannii, Enterobacteriaceae family, Enterobacter cloacae complex, Escherichia coli, Klebsiella pneumonia, Proteus species, Serratia marcescens, Haemophilus influenza, Neisseria meningitides, Pseudomonas aeruginosa, Candida albicans, Candida glabrata, Candida krusei, Candida parapsilosis, Candida tropicalis and the three resistance genes, KPC (carbapenemase), mecA(methicillin), and vanA /B (vancomycin).
Bilirubin Panel	Total Bilirubin, Direct Bilirubin, Calculated Indirect Bilirubin
Cardiolipin Antibodies	AntiCardiolipin IgG & IgM
CBC	CBC without and with differential are panels offered. Orders for combinations of individual CBC component tests which include a differential will be converted to CBC with differential to ensure adequate specimen quality assessment per policy.
Celiac Disease Cascade	Anti-gliadin (deamidated) IgA antibody & Anti-tissue transglutaminase IgA antibody*. Reflex tests can include: tissue transglutaminase IgG and gliadin (deamidated) IgG.
Coagulation Genetic Testing	Factor II (G20210A) and Factor V Leiden (G1691A) mutations
Connective Tissue Disease Cascade	Anti-nuclear antibody (ANA) and Anti-cyclic citrullinated peptide (CCP)* Reflex tests can include: Anti-DNA Double Strand and ENA reflex panel- Ro(SSA), LA(SSB), Chromatin, Riboprotein, SCL70, Centromere, JO-1, RNP70, and Smith RNP, RNP and Smith.
CSF Evaluation	Cell count and differential, protein, glucose and microbiology culture including Meningitis/Encephalitis Panel by PCR.
DIC Screen	D-Dimer, fibrinogen, partial thromboplastin time, platelet count, prothrombin time, and peripheral blood review for the presence of schistocytes
Epstein Barr Antibody Panel	EBV Early Antigen EA, Heterophile Ab, Nuclear Antigen NA IgG, Viral Capsid VCA IgG & IgM
Gastrointestinal PCR Panel	Campylobacter (C.jejuni/C.coli/C.upsaliensis), Clostridium difficile (C. difficile) toxin A/B, Plesiomonas shigelloides, Salmonella, Vibrio (V. parahaemolyticus/V. vulnificus/V. cholera), including specific identification of Vibrio cholera, Yersinia enterocolitica, Enteropathogenic Escherichia coli (EPEC), Enteroaggregative Escherichia coli (EAEC), Enterotoxigenic Escherichia coli (ETAC) lt/st, Shiga-like toxin-producing Escherichia coli (STEC) stx1/stx2 (including specific identification of the E.coli O157 serogroup within STEC), Cryptosporidium, Cyclospora cayentensis, Entamoeba histolytica, Giardia lamblia, Adenovirus F 40/41, Astrovirus, Norovirus GI/GII, Rotavirus A, Sapovirus (Genogroups I,II,IV, and V)

Bronson Panels	Tests in Panel
Group B Strep PCR	Positive specimens on Penicillin allergic patients reflex to a Susceptibility.
Hemoglobin Electrophoresis Scr	Electrophoresis repeated with acid pH when abnormal hemoglobins are detected
Herpes Simplex IgG Antibodies	Herpes Simplex Type 1 and Type 2 IgG Antibodies
Herpes Simplex & Varicella zoster PCR	Herpes Simplex Type 1, Type 2 & Varicella zoster PCR
Influenza Panel	Influenza A, Influenza B and RSV
Meconium Toxicology; Screen and Reflex Confirmation	Amphetamines, Methamphetamines, THC, Cocaine, Opiates Methadone, Oxycodone, Buprenorphine, Tramadol - See full description in the Bronson Laboratory Users Guide.
Meningitis/Encephalitis Panel	Screens for Escherichia coli K1, Haemophilus influenza, Listeria monocytogenes, Neisseria meningitides, Streptococcus agalactiae, Streptococcus pneumonia, Cytomegalovirus (CMV), Enterovirus, Herpes simplex 1 & 2 (HSV-1 & 2), Human herpesvirus 6 (HHV-6), Human parechovirus, Varicella zoster virus (VZV), and Cryptococcus neoformans/gattii.
Methicillin Resistant Staphylococcus aureus screen	Screen for Staphylococcus aureus and Methicillin Resistant Staphylococcus aureus by PCR.
Microbiology Cultures	The following culture orders will always include Gram Stain/Smear: Acid Fast Bacilli (AFB), Respiratory, Quantitative, & Bacterial (abscess fluid, sterile body fluid and all surgical specimens). Reflex Identification testing and Susceptibilities as appropriate.
Monoclonal Protein Evaluation	Serum protein electrophoresis, Serum kappa and lambda free light chains, Serum Immunofixation performed if indicated by pathologist review.
Obstetric Panel	ABO & Rh Blood Typing, Antibody Screen*, Syphilis IgG antibody, Rubella antibody, Complete Blood Count (CBC) w/diff, Hepatitis B surface antigen, HIV screen. Reflex Syphilis testing confirmation as appropriate.
Ova and Parasite Complete Screen	Ova and parasites (direct and concentrated exam), Ova & Parasite Screen Giardia, Ova Parasite Cryptosporidium, Trichrome Stain
PAP reflex to HPV	ThinPrep Pap smears of patients ≥21 years of age with a diagnosis of atypical squamous cells of undetermined significance (ASCUS) will be reflexively forwarded for Human Papillomavirus (HPV) DNA High Risk with 16/18 genotyping per Bronson Cytology reflex HPV policy.
Respiratory Infectious Agent Panel	See full descriptions in the Bronson Laboratory Users Guide. Screens for Flu A, Flu B, RSV, Parainfluenza, Adenovirus, Rhinovirus, Metapneumovirus, Enterovirus, Coronavirus, Pertussis, Mycoplasma pneumoniae, Chlamydia pneumoniae.
STD Panels	Chlamydia trachomatis by PCR, Gonococcus by PCR Chlamydia trachomatis by PCR, Gonococcus by PCR, Trichomonas Vaginalis by PCR
Sweat Chloride	Two arm reporting: Testing will be done on each arm and each order will consist of 2 times the analysis and 2 times the collection.
Syphilis Testing	Treponemal antibody (Syphilis IgG): Positive and equivocal results reflex to RPR. RPR: Non-reactive specimens are forwarded to MDCH for further testing.
Thrombophilia Cascade	Anti-thrombin III activity, protein C activity, protein S antigen, prothrombin time, factor VIII activity, partial thromboplastin time, DRVVT, mixing studies*
Thyroid Function Cascade	If TSH is <0.27 mIU/mL, then free T4 is performed. If free T4 is <2.0 ng/mL and TSH is <0.1 mIU/mL, then total T3 is performed. If TSH is >4.2 mIU/mL, then free T4 and anti-thyroid peroxidase are performed.
Type and Screen	ABO / Rh Blood Type and Antibody Screen*
Urine Culture If	Urinalysis with reflex to culture if indicated by selected criteria
Urine Drug of Abuse Screen	Amphetamine, barbiturate, benzodiazepine, cocaine, opiates, THC
Urine Drug Screen 8	Amphetamine, barbiturate, benzodiazepine, cocaine, opiates, THC, oxycodone & fentanyl
Urine Opioid Drug Screen	Opiate, buprenorphine, methadone, oxycodone, fentanyl

Reference lab testing is also covered by Medicare regulations with regard to medical necessity. Bronson utilizes [Mayo Clinic Laboratories](http://www.mayoclinic.com). The information above is contained in the Bronson Laboratory Users Guide available in print and on the Bronson Intranet at <http://bronsonlab.testcatalog.org>

*Additional tests may be performed based on initial test results. See testing algorithm in the Bronson Laboratory Users Guide.