Date: October 29, 2021

Re: Laboratory Annual Notice

To: MWMC Referring Physicians and Licensed Independent Practitioners

From: John Goulart, MWMC Hospital Compliance Officer

-----------------------------------------------------------------------------------------------------------------------------------------------------------

As an integral part of MetroWest Medical Center’s Laboratory Compliance Program, I am providing you with our annual notice. The contents of this notice are based on recommendations from the United States Health and Human Services (HHS) Office of Inspector General (OIG) who explains our shared obligations under federally-funded programs, such as: Medicare and MassHealth (Medicaid) in the Model Laboratory Compliance Plan at: <https://oig.hhs.gov/authorities/docs/cpglab.pdf>.

The MWMC Laboratory relies on the following information when performing testing ordered by referring physicians and licensed independent practitioners:

1. The patient’s full legal name, gender, date of birth, or other unique identifier.
2. The name and telephone number or other suitable identifiers of the submitting 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 critical values.
3. The guarantor’s identification and insurance information.
4. The name and CPT code (both are preferred) of the test(s) to be performed.
5. All of the patient’s current ICD-10 CM diagnosis codes or a narrative diagnosis / signs and symptoms supported by your medical record documentation.
6. The ordering date.
7. The collection date and time of the specimen, if appropriate.
8. For microbiology:
	1. The source.
9. For pap smears:
	1. The source: (cervical or vaginal).
	2. The date of patient’s last menstrual cycle.
	3. Other historical information, such as: whether the patient is pregnant, post-menopausal, had a previous abnormal result, treatment or biopsy.
10. The dated, handwritten signature of the physician or licensed independent practitioner authorized to directly order clinical laboratory tests under state law (requisitions marked by a signature stamp will be rejected for insufficient documentation)

In addition to our preferred requisition, the MWMC Laboratory accepts any form of order request as long as it meets all the above requirements. When physicians and licensed independent practitioners submit a testing request to MWMC Laboratory, they agree to cooperate with any audits which may be conducted by the hospital or outside entities which may include review of medical record documentation to support the accuracy of the Laboratory request as far back as ten years from the date of service.

When you submit a requisition / request for testing, we are relying on the fact that:

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.
3. Tests, including those that are components of American Medical Association-approved organ / disease-oriented panels, will only be ordered when each individual test is medically necessary for the diagnosis and treatment of the patient or to meet the preventing /screening criteria provided. These panels will only be billed to and paid by Medicare when all components meet medical necessity.
4. You are treating the patient in connection with the diagnoses, complaints or reasons listed on the requisition.
5. When you order tests for purposes of screening for asymptomatic patients that you believe are appropriate, even though the payer may not allow reimbursement, the fact that Medicare generally does not cover screening tests has been explained to the patient, and the requisition notes that the test is for screening purposes.
6. Upon request of the hospital, payer, or auditor, you agree to provide documentation from your office that reflects that the test was ordered and medically necessary for the patient.

When the MWMC Laboratory receives a requisition that does not contain the information listed above, it will be returned for completion. Without appropriate documentation and/or all current diagnostic information, the patient may refuse the test or be required to pay for services that would otherwise be a covered benefit.

MWMC Laboratory utilizes Local Medical Review Policy software, which is used 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 (LCDs) issued by Wisconsin Physician Services, the hospital’s 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 Advance 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 test 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 Laboratory NCDs and LCDs at:

* CMS Laboratory NCDs: <https://www.cms.gov/medicare-coverage-database/search-results.aspx?keyword=Laboratory&keywordType=starts&areaId=all&docType=NCD&contractOption=all>
* WPS LCDs: <https://www.cms.gov/medicare-coverage-database/search-results.aspx?keyword=WPS&keywordType=starts&areaId=all&docType=F,P&contractOption=all>

The MWMC Laboratory does not offer custom chemistry testing panels because these produce increased charges to payers / patients and often result in testing that is not medically necessary.

Reflex and Confirmatory testing and Composite orders, listed on pages six and seven of this notice, will be performed as noted below. You can opt out of reflex testing by noting “no reflex” on the requisition / request.

The CMS Medicare Clinical Laboratory Fee Schedule is located at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Laboratory-Fee-Schedule-Files.html>. The MassHealth (Medicaid) reimbursement amount may be equal to or less than the amount of Medicare reimbursement. This is the reimbursement that the hospital will receive for the test(s) we perform at the direction of your order.

**Standing orders** for patients with repeat testing are allowed when they are submitted on a completed requisition and have the following additional elements for each test: 1.) A duration (up to one year is permissible), 2.) A frequency (“PRN” or “as needed” is prohibited), and 3). A medically necessary diagnosis.

**Verbal orders** are not accepted by the laboratory during normal office business hours. During these times, providers must fax completed requisitions to the Laboratory. Verbal orders, called in outside of normal business hours, will require the provider to review and sign the Verbal Order Fax Back Form or the Add-on Form that has been completed by the personnel receiving the verbal order.

**Add-on testing** for hospitalized patients should be placed in order entry along with the test code “ADDON”. Add-on testing for ambulatory patients requires a completed requisition.

I greatly appreciate your support of MWMC’s Laboratory Compliance Program. If you have any questions or comments regarding MWMC’s Laboratory Compliance Program, please do not hesitate to contact our Laboratory Administrative Director, Deborah Rustin (Deborah.Rustin@mwmc.com | (508) 383-1221), the Laboratory’s Medical Director, Saint AuFranc, MD. (Saint.Aufranc@mwmc.com | (508) 383-1090), or myself.

|  |  |  |
| --- | --- | --- |
| Thank you for your commitment to your patients. Best Regards,John

|  |  |
| --- | --- |
|  |  |

John A. Goulart, Jr.,MSM-HCA, BSMT(ASCP), CHC, 340B ACE October 29, 2021Group Compliance Officer Lead | Massachusetts MarketHospital Compliance Officer | MetroWest Medical Center |
| Monday, Wednesday, and Friday:Framingham Union Hospital85 Lincoln Street #1109, Framingham, MA 01701T: (508) 383-1515 | Tuesday and Thursday:Leonard Morse Hospital67 Union Street, #379, Natick, MA 01760T: (508) 650-7639 |

**LIST OF NON-STANDARD DIAGNOSTIC CLINICAL LABORATORY PANELS**

**APPROVED BY THE METROWEST MEDICAL CENTER MEDICAL EXECUTIVE COMMITTEE**

MTHFR

Thyroglobulin, Quant

IGG Synthesis + Synthesis Rate

Lupus Anticoagulant

Factor II (Prothrombin DNA Analysis)

Ova & Parasites

Hemoglobinopathy Profile

Protein Electrophoresis, 24 Hour & Random

Microalbumin/Creatinine Ratio, random urine

Chlamydia/GC Nucleic Acid Amplification

AFB Culture, Smear, & Sensitivity

Viral Culture (HSV & Varicella)

Antineutrophil Cytoplasmic Antibody (ANCA)

Herpes Simplex (HSV) 1&2, PCR

Factor V Leiden Mutation Analysis

Primidone

RBC Folate

Heavy Metals Profile I, Urine

Gliadin Antibody Profile

Testosterone, Free with Total

Lyme Disease Antibodies, Reflex to Western Blot

Hereditary Hemachromatosis, DNA Analysis

Immunofixation

Antiphosphatidylserine, IGG, IGM, IGA

Sjogren’s Antibodies

Drug Coma/Overdose Profile, Blood

Anticardiolipin Antibody IGG, IGM, IGA

Parvovirus B19, Human IGG/IGM

Aspergillus Antibodies, Quant DID

Antidiuretic Hormone Profile

Protein Electrophoresis, Serum

Cyclospora Smear, Stool

Influenza A&B, Direct Immunoassay

Ehrlichiosis (Granulocyte & Monocytic) Profile

Hypersensitivity Pneumonitis Profile

Chlamydia Trachomatic Culture

Platelet Antibody Profile

West Nile Virus Antibody, IGG, IGM

CMV Culture

Cadmium, Urine

Protein S Antigen

Thyroid Antibodies

Urine Drug Screen

Influenza A&B Antigen

Protein S Deficiency Panel

Saccharomyces Cerevisiae Profile

West Nile Virus Ab, CSF

Echovirus Antibodies

Coxsackie Virus Group B Antibodies by CF

**METROWEST MEDICAL CENTER**

**DEPARTMENT OF LABORATORY MEDICINE**

**SUBJECT: 1.2.5 Reflexive, Confirmatory, and Composite Testing**

 **SUBMITTED BY: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Saint AuFranc, M.D., Laboratory Medical Director

**APPROVED BY: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Medical Executive Committee

**DATE APPROVED: 9/20/21 C&C, 10/5/21 MEC**

**PURPOSE:** To ensure Laboratory Reflex Testing is approved annually by the Medical Staff, meets medical necessity and is in accordance with Medicare, Medicaid and other payer requirements. Reflex testing is performed as a result of INITIAL test results and is used to further identify significant diagnostic information required for appropriate patient care.

**A required Reflex test** is a test which, if positive, requires an additional follow up test in order to have clinical value.

Physicians may opt out of the specified Reflex testing by making a notation on the laboratory requisition or calling the laboratory at the time of the order.

| **Initial Test** | **CPT** | **Result** | **Reflex Order** | **CPT** |
| --- | --- | --- | --- | --- |
| ANA Screen | 86038 | Positive | ANA Titer | 86039 |
| ASO Screen | 86063 | Positive | ASO Titer | 86060 |
| BB Antibody Screen | 86850 | Positive | Antibody Identification And Antigen Typing | 8687086905 |
| CBC with Diff | 85025 | Immature or abnormal cells present in significant quantities  | Manual Differential |  |
| C. Difficile EIA | 8744987324 | Indeterminate | C. Difficile DNA | 87493 |
| CK and CKMB | 8255082553 | CK < 135 U/L | CKMB Deleted | 82550only |
| Cold Agglutinin | 86156 | Abnormal | CAG Titer | 86157 |
| Cryptococcal Antigen | 87450 | Positive | Cryptococcal Titer | 86406 |
| DAT | 86880 | Positive | IgG + ComplementIgG positive: Elution | 86880x286860 |
| Fetal Screen | 85461 | Positive | Fetal Hgb | 85460 |
| Hepatitis A Antibody | 86708 | Reactive | HAVAB, IgM | 86709 |
| Herpes Culture | 87252 | Positive  | Herpes Typing | 87140 |
| Lipid w Reflex Direct LDL | 80061 | Triglyceride > 400 mg/dL | Direct LDL | 83721 |
| Microbiology Culture | \*\* | OrganismGrowth | Organism IDAntibiotic Sensitivity | 8718687077 |
| TSH w Reflex to FrT4 | 84443 | Abnormal | Free T4 | 84439 |
| UA w Sediment if needed | 81003 | Defined Abnormal Parameters | Urinalysis Sediment | 81001 |
| UA w Sediment and Culture if needed | 81003 | Positive leukocytesPositive Nitrite>5 WBCs/HPFAll patients < 2yrs | Urine SedimentUrine CultureAntibiotic Sensitivity | 810018718687077 |

**Reflexive, Confirmatory and Composite Testing**

**A Confirmatory test** is an additional test procedure, which is performed to validate the accuracy of the initial test result**.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Initial Test** | **CPT** | **Result** | **Confirmatory Test** | **CPT** |
| Bilirubin, Urine | 81003 | Positive | Bilirubin Confirmation | 81002 |
| Protein, Urine | 81003 | Abnormal Colored Urine | SSA |  |
| HIV | 86703 | Positive | HIV1 RNA | 87535 |
| Lyme Antibody | 86618 | Positive | Western Blot Confirm | 84182x2 |
| Rapid Strep | 87880 | Negative | Strep Culture | 87081 |
| Anti-treponemal IGG ELISA | 86592 | ReactiveEquivocal | RPR / RPR Titer | 8678086593 |

**A Composite order** is a testing protocol that is used to further identify significant diagnostic information required for appropriate patient care.

|  |  |  |  |
| --- | --- | --- | --- |
| **Initial Test** | **CPT** | **Composite Order** | **CPT** |
| Tissue Culture | 87070 | Anaerobic Culture | 87075 |
| Anaerobic Culture | 87075 | Aerobic Culture | 87070 |
| CSF, Fluid, Tissue, Deep Wound, and Respiratory Cultures | 87070 | Gram Stain | 87205 |
| Stool Culture | 87045 | Salmonella & ShigellaCampylobacter | 8704587046 |
| Stool CultureBloody Stool | 87045 | Shiga Toxin | 87427 |
| Legionella Antigen | 87899 | S. Pneumonia Antigen | 87899 |
| Ova & Parasite (OP) | 87177 | Giardia Antigen DFACryptosporidium DFA | 8726987272 |
| Giardia Antigen | 87269 | Giardia Antigen DFA Cryptosporidium DFA | 8726987272 |
| Cryptosporidium Antigen | 87272 | Giardia Antigen DFACryptosporidium DFA | 8726987272 |
| Pre-Natal Antibody ID | 86870 | Antibody Titer | 86886 |
| Urinalysis from ED on patients < 2 years old | 81001or 81003 | Urine Culture | 87186 |