MNG LABORATORIES
Neurogenetic Answers™

Policy Statements

1. MNG Laboratories

1.1. Types of Clinical Services Offered

MNG Laboratories is a send-in clinical laboratory that performs genetic and biochemical testing on a variety of biological matrices.

1.2. Location and Hours of Operation

MNG Laboratories is located at 5424 Glenridge Dr. NE Atlanta, GA 30342. MNG Laboratories operates Monday through Saturday 8 am to 5 pm.

1.3. Examinations/Testing Offered

MNG Laboratories provides genetic, metabolic, and neurochemical testing and consultation for a variety of inherited disorders affecting children and adults.

Laboratory testing includes, but is not limited to amino acid analysis, cerebrospinal fluid neurochemistry studies, and complex biochemical and genetic analysis for a large variety of disorders.

Additional information may be found on our website: https://mnglabs.com/about/.

1.4. Licensing and Accreditation

MNG Laboratories is a College of American Pathologists (CAP) certified laboratory (#1441004). We additionally hold the following licenses and accreditations:

- CLIA accredited #11D0703390
- State of Georgia license
- State of Pennsylvania out of state license
- State of Maryland out of state license
- State of New York out of state license
- State of Florida out of state license
- State of California out of state license
- State of Rhode Island out of state license

2. Specimen Information

2.1. Sample Reception

Samples may be received at MNG Laboratories Monday through Saturday, 8 am to 5 pm. Samples are not accepted on Sundays and holidays.

2.2. Animal Specimens

MNG Laboratories does not accept animal specimens for diagnostic testing.

2.3.Non-Biologic Specimens

Due to the inherent exposure risk of non-biologic specimens, their containers, and the implied relationship to criminal, forensic, and medico-legal cases, MNG Laboratories does not accept nor refer non-biologic specimen types. Example specimens include: unknown solids and liquids in the forms of pills, powder, intravenous fluids, or syringe contents.

2.4.Sample Collection Kits

MNG Laboratories provides specialty kits for a variety of sample types that include appropriate container, instructions for collection, and test requisition. For all genetic testing, MNG Labs provides free shipping for samples collected in the kits. Kits may be ordered at any time from our website: https://mnglabs.com/kits/.

Important: MNG Laboratories is not licensed as a direct to consumer testing facility. We will not ship to residential address. Please have your referring physician or clinic coordinate the ordering of kits. If you are a licensed physician or clinic with a residential address, please contact us at quickresponse@mnglabs.com to coordinate your kit order.

2.5.Preparation of Patient/Patient Collected Samples

MNG Laboratories does not perform direct collection of any specimens. MNG Laboratories is not a direct-to-consumer laboratory. All primary samples must be collected and sent through a board certified physician and/or licensed healthcare facility.

2.6.Specimen Requirements

MNG Laboratories accepts many different tissue types. The specific required tissue type depends on the testing requested by the primary physician or facility. Details can be found on the company's website https://mnglabs.com/tests/ by test code or test name.

In general, for genetic testing, MNG Laboratories accepts extracted DNA, whole blood collected into an EDTA vacutainer, fibroblasts, urine epithelial cells, muscle, and buccal cells.

For metabolic and neurochemical testing, MNG Laboratories accepts cerebrospinal fluid, whole blood collected into an ACD vacutainer, plasma, serum, urine, and muscle.

MNG Laboratories accepts prenatal samples as chorionic villi, amniocytes that are confluent, and cord blood. We currently do not culture any prenatal samples. All prenatal samples, including cord blood collected at the time of birth, require a Maternal Cell Contamination report prior to analysis of these samples. MNG Laboratories does not perform Maternal Cell Contamination analysis.

The amount or volume of primary samples is dependent on the requested testing. Information regarding the volume of sample required for a specific test can be found on the company's website at https://mnglabs.com/tests/.

2.7.Sample Collection and Handling

Sample collection and handling instructions are provided on the company's website https://mnglabs.com/tests/ by test code/name or https://mnglabs.com/forms/ under specimen collection and processing forms.

2.8.Sample Transport

Whole blood, buccal swabs, fibroblasts, skin punches, urine for DNA analysis, and extracted DNA samples should be shipped overnight to MNG Laboratories at room temperature to be received Monday through Saturday.

CSF, plasma, serum, urine for biochemical analysis, frozen muscle, and urine pellets should be frozen upon collection and shipped overnight on 3-5 pounds of dry ice to be received Monday through Saturday.

2.9.Specimen Identification

In compliance with and adherence to the CAP and the Joint Commission's 2008 patient safety goals, MNG Laboratories Policy states that all specimens received for testing must be correctly and adequately labeled to assure positive identification. Specimens must have 2 person-specific identifiers on the patient label. Person-specific identifiers may include: accession number, patient's first and last name, unique identifying number (eg, medical record number), or date of birth.

Specimens are considered mislabeled when there is a mismatch between the person-specific identifiers on the specimen and information accompanying the specimen (eg, computer system, requisition form, additional paperwork).

When insufficient or inconsistent identification is submitted, MNG Laboratories will require that a new specimen be obtained, if feasible.

2.10. Prenatal Specimens

1) All prenatal samples must have a maternal cell contamination (MCC) report prior to a report being issued. Reports will not be issued until a MCC is received.
2) MNG Laboratories does not provide MCC testing in house.
3) Amniocytes or chorionic villus received in a T-25 flask must be greater than 85 % confluent. MNG Laboratories does not grow these cells in house.
4) In the event of a request for expedited testing by a client, prenatal samples may be analyzed prior to receiving a MCC report; however no results shall be transmitted to the facility if greater than 20 % MCC has been determined to be present by the Chief Medical Officer until a MCC is received.

2.11. Extracted Specimens

For United States clients, MNG Laboratories only accepts extracted DNA from CLIA/CAP licensed laboratories (or a laboratory meeting equivalent requirements as determined by the CAP and/or CMS) for clinical testing. For out of country clients that are not subject to US regulations (CLIA and CAP), MNG Laboratories will accept extracted DNA from an appropriately qualified laboratory.

3. Cancellation of Tests

3.1.Client Requested Cancellations

Client requested cancellation of testing, after sample processing and analysis has begun at MNG Laboratories, is based on the published turnaround time of the test (described below). Outside of the guidance provided, charges may apply.

1) For all testing with a 4 week turnaround time:

   Testing may be cancelled by the client within 2 days of the date the test is released to the laboratory to begin work at no additional charge.

2) For all testing with a 2 week turnaround time:

   Testing may be cancelled by the client within 1 day of the date the test is released to the laboratory to begin work at no additional charge.

3) For all testing with a 1 week turnaround time:

   Testing may be not be cancelled by the client after samples have been released to the laboratory to begin work.

3.2.Cancellations by MNG Laboratories

MNG Laboratories reserves the right to cancel any testing given appropriate reasoning. Cancellation of testing by MNG Laboratories may be due to (but not limited to):

- Lack of sufficient sample (quantity not sufficient-QNS) for the requested testing. Cancellation will occur as soon as the quantity is verified as unacceptable.
- Sample quality, as determined by the laboratory, is below the required quality by the process.
- Non-payment/non-communication with the laboratory regarding billing or clarification of information.
- Missing New York State “non-permitted laboratory test” permit
- Duplicate testing ordered

4. Rejection of Samples

All tests are unique in their testing requirements. To avoid specimen rejection or delayed turnaround times, please check the collection and shipping requirements that are described for each test.

Please review that the following has been checked and completed prior to submitting a specimen to MNG Laboratories:

- Specimen Type
- Specimen Volume
- Proper Identification of specimen
- Completed test requisition with identifying patient information, testing requested, informed consent, and clinical history
- Transport temperature of specimen

Specimen rejection by MNG Laboratories may be due to (but not limited to):

- Unacceptable sample type received for requested testing.
- A sample is received in a compromised state that will affect the outcome of the results (i.e. thawed; severely clotted; improper storage conditions, etc.).
- Unlabeled or improperly labeled specimen received
- Specimens received with inconsistencies with paperwork
- Grossly bloody CSF specimens

Delays in Testing

Although MNG Laboratories strives to get results to each client within our published turnaround time, there are circumstances that may delay the testing and therefore the results of your patient. Some of the circumstances that lead to delays in testing include (but are not limited to):

- Incomplete test requisition:
  - Missing billing information
  - Missing testing information
  - Missing patient information (i.e. Date of Birth)
  - Missing specimen information (i.e. Date of Collection)
  - Missing physician information
- Missing New York State permit for non-permitted laboratory tests
- Missing Informed Consent
- Missing Clinical Information (Exome/Genome testing)
- Unforeseen instrument or testing delays

5. Testing Information and Requirements

5.1. Billing

Physicians and Healthcare Facilities: MNG Laboratories is a direct bill (institutional bill) facility. We do not accept insurance payment options at this time. Each month you will receive an itemized invoice which will indicate date of service, patient name, CPT code, test name, and test charge. Weekly and bi-weekly billing is also available. Payment terms are net 30 days. When making a payment, please include our invoice number on your check to ensure proper credit to your account. Checks can be mailed to PO Box 17668 Clearwater, FL 33762. Additionally, we accept payments via ACH, wire transfer or via credit card on our client portal. If you are interested in any of these options, please email billinginformation@mnglabs.com to obtain further information.

Patient: MNG Laboratories accepts self-payment from patients. Payment must be received prior to the start of testing. MNG Laboratories will not bill patients after completion of testing. Payment may be made via check mailed to PO Box 17668 Clearwater, FL 33672, or via credit card using our website at https://mnglabs.com/patients/self-pay/. Patients also have the option of paying by phone at 678-225-0222.

5.2.Billing-CPT coding

While we strive to have the most up to date and accurate CPT codes in our catalog in an effort to provide some guidance, CPT codes listed only reflect our interpretation of CPT coding requirements and are not necessarily correct. Particularly, in the case of a test involving several component tests, this catalog attempts to provide a comprehensive list of CPT codes for all of the possible components of the test. Only a subset of component tests may be performed on your specimen. You should verify accuracy of codes listed. Where multiple codes are listed, you should select codes for tests actually performed on your specimen.

5.3.Test Requisitions

Test requisitions must be completely filled out with patient name, both first and last, patient date of birth (month/day/year), gender, specimen collection date (month/day/year), and specimen type. Submitting personnel may also provide a hospital or patient identification number and an ICD-10 code or diagnosis. Inclusion of clinical history will provide our team of interpreters with better information for a clinical review of data and is encouraged. For Whole Genome/Exome testing, the clinical history is required.

All test requisitions must also contain information on the referring physician/facility to include a name and the preferred method of receiving reports/correspondence: email, fax, or both. We also require the ordering physician's NPI #. Email is the preferred route for all correspondence. All information included in the referring physician section of the test requisition will be primary source for sending reports and correspondence and will be stored for future use.

The billing information must be filled out completely for testing to proceed, including a facility name, phone number, and one or both of the following: email or fax.

5.4.Add-on Testing

For additional testing that is requested to be performed on samples already at our facility, an Add-On test requisition form is required to be either emailed (quickresponse@mnglabs.com) or faxed (678-225-0212) to our facility. These forms are found on our website at https://mnglabs.com/forms/ under Test Request Forms.

Add-on test requisitions must be completely filled out with patient name, both first and last, patient date of birth (month/day/year), gender, specimen collection date (month/day/year), specimen type, and billing information. Submitting personnel may also provide a hospital or patient identification number and an ICD-10 code or diagnosis.

All add-on test requisitions must also contain information on the referring physician/facility to include a name and the preferred method of receiving reports/correspondence: email, fax, or both. Email is the preferred route for all correspondence. All information included in the referring physician section of the test requisition will be primary source for sending reports and correspondence and will be stored for future use.

5.5.Informed Consent

MNG Laboratories is now asking that a signed Informed Consent form accompany all genetic testing samples – this includes, but is not limited to, test codes beginning with MOL and NGS. This form can be found on the company's website, https://mnglabs.com/forms/

under Consent Forms. Failure to include this form may delay the testing of a patient specimen. WES/WGS test codes have a separate Informed Consent specific to Whole Genome/Exome Sequencing. Physicians may sign an informed consent in lieu of the patient when informed consent is provided to the patient verbally (i.e. over the phone).

For samples arriving from the state of New York, an informed consent (available on the company's website at https://mnglabs.com/forms/ under Consent Forms) is required. Patient consent is required in the state of New York.

5.6. New York State Testing

New York facilities/physician will also need to provide a New York State Department of Health permit for any tests not currently approved. Failure to provide a permit will delay or cancel the testing of the patient. Instructions for obtaining a permit and a list of approved tests can be found on the company's website https://mnglabs.com/forms/.

5.7. Order Clarifications

Any orders that are received for testing over the phone or by email will require the verbal order/order clarification form to be filled out and signed by the client: https://mnglabs.com/forms/.

Any uncertainty regarding patient testing, include unclear test orders, unclear name or DOB, or lack of any pertinent patient information must be verified by the client prior to proceeding with requested testing. Most of this information will be required to be proved in writing and the use of the verbal/unclear order form is encouraged: https://mnglabs.com/forms/.

5.8. Custom Testing/Special Handling

In an effort to assist in a diagnosis, MNG Laboratories will create custom next-generation sequencing testing panels, for validated genes found on our website, in cases where only a few genes are required or when genes are omitted from a larger panel that the physician believes will be useful in the diagnosis of a disease/disorder. All custom NGS panels must be cleared by MNG Laboratories prior to ordering. Please call 678-225-0222 or email quickresponse@mnglabs.com for more information.

Unique circumstances may arise that require special handling of a particular specimen. MNG Laboratories will make an effort to accommodate these requirements, within reason. Please call 678-225-0222 or email quickresponse@mnglabs.com for more information.

5.9. Factors Impacting Performance of Testing

This information may be found on the company's website https://mnglabs.com/tests/, as each individual test offered has its own performance requirements. Additional information regarding the factors that may impact the performance of the testing order may be obtained by call our customer support team at 678-225-0222 or emailing us a quickresponse@mnglabs.com.

5.10. Reference Intervals/values

MNG Laboratories has reference intervals that were determined during the rigorous validation procedures used to validate the tests we provide. These reference intervals are used for the determination of positive, negative, or equivocal testing results with all quantitative and semi-

quantitative testing. Clients may obtain our reference intervals for a specific test by calling our customer support team at 678-225-0222 or emailing us a quickresponse@mnglabs.com.

5.11. Critical Values

For quantitative testing, values outside of the established ranges are reported to the designated director of the department to determine if the values are "Critical". If the values are determined to be critical, the data will be reported by phone or fax to the referring clinician/laboratory.

5.12. Confirmation Testing

It is MNG Laboratories policy that all positive next generation sequencing results are confirmed by an alternate technology or method, such as targeted PCR followed by Sanger Sequencing or alternative next generation sequencing method, prior to the reporting of the result to the client.

6. Quality Management and Compliance

Compliance with applicable statutes and regulations is fundamental to how MNG Laboratories does business. We abide by the regulations set forth by the Clinical Laboratory Improvement Amendments (CLIA), Occupational Safety and Health Administration (OSHA), the Department of Transportation (DOT), Health Insurance Portability and Accountability Act (HIPAA) and the Office of the Inspector General (OIG), in addition to other state and federal regulations.

We expect that clients utilizing our services will ensure their compliance with patient confidentiality, diagnosis coding, anti-kick back statutes, and professional courtesy.

MNG Laboratories is committed to quality. Our laboratory has adopted a quality management system (QMS), in accordance with CAP and CLIA regulations. The goal of this system is to establish a leadership structure through the path of quality workflow that enables our laboratory to provide the highest quality laboratory services. All employees are committed to the culture of quality.

Data generated by quality indicators drives process improvement initiatives to seek resolutions to system wide problems. The following list is some of the many quality indicators we monitor:

- Lost Specimens
- Specimen acceptability
- Canceled/rejected testing
- Proficiency testing
- Turnaround times
- Amended/revised reports

6.1.Confidentiality of Results/Disclosure of Results

MNG Laboratories strictly adheres to Health Insurance Portability and Accountability Act (HIPAA) with regards to the release of personal information including, but not limited to, name, date of birth, records, results, and samples.

6.2.Referral of Tests to Another Laboratory

MNG Laboratories does not currently refer out testing to other laboratories. All testing provided is performed at MNG Laboratories.

6.3.Proficiency Testing

We are a College of American Pathologists (CAP)-accredited, CLIA-licensed facility that voluntarily participates in many diverse external and internal proficiency testing programs. It is MNG Laboratories expectation that clients utilizing our services will adhere to CLIA requirements for proficiency testing, including a prohibition on discussion about samples or results and sharing of proficiency testing materials with MNG Laboratories during the active survey period. MNG Laboratories proficiency testing includes participation in CMS-approved programs.

MNG Laboratories also performs alternative assessment using independent state, national, and international programs when proficiency testing is not available. MNG Laboratories also conducts comparability studies to ensure the accuracy and reliability of patient testing, when necessary. We comply with the regulations set forth in Clinical Laboratory Improvement Amendments (CLIA-88). Referring of specimens is acceptable for comparison purposes when an approved proficiency-testing program is not available for a given analyte.

6.4.Record Retention

MNG Laboratories retains all test requisitions and patient test results for the retention period required to comply with and adhere to the CAP and/or Georgia state regulations, whichever is longer.

6.5.Specimen Retention

Retention of the samples is done according to the laboratory's policy and respects CLIA, CAP, and other state regulations (i.e. New York), as appropriate.

6.6.Turnaround Time (TAT)

Turnaround time for tests performed at MNG Laboratories is dependent on the requested testing and ranges from 2-6 weeks. Specific turnaround times for each assay are published on our website at https://mnglabs.com/tests/ by specific test code or name.

Any testing that does not meet published turnaround time will be conveyed to the ordering physician and/or facilities by telephone, fax, and/or email should it become apparent that testing will be delayed.

The information provided to the physician/facility will include, but is not limited to, the date report was due and when report can be expected to be remitted to facility/physician. A follow up phone call, fax, or email will be provided should timeframe quoted in initial contact not be met.

7. Business Continuity and Contingency Planning

In the event of a local, regional, or national disaster, MNG Laboratories has comprehensive contingency plans in place to ensure that the impact on laboratory practice is minimized.

8. Availability of Clinical Advice/Interpretation

Technologists, scientists, and clinicians are available for advice through email at quickresponse@mnglabs.com or by phone at (678) 225-0222. MNG Laboratories employs a

genetic counselor, who can assist clients in the interpretation of the report based on the data provided. The genetic counselor will provide advice on what to do with the information (i.e. how to proceed with patient care). We will be able to suggest additional testing that may assist the physician in patient care.

9. Complaints

MNG Laboratories is concerned with the satisfaction of our clients and patients. We receive complaints (non-compliance related) by phone at (678) 225-0222 x 124 or email at quickresponse@mnglabs.com.

MNG Laboratories is committed to investigating all complaints thoroughly and providing a resolution to our clients within a timely manner.

If there are complaints that are in regards to Compliance (Office of the Inspector General), please use our hotline at (678) 225-0222 x107 or contact the Chief Compliance Officer or Compliance Manager:

- Chief Compliance Officer:
  - Keith Hyland, PhD
  - 678-225-0222 x 112
- Compliance Manager:
  - Margaret Teasdale, PhD
  - 678-225-0222 x 125