**Purpose:** This describes the policy of GENETWORx regarding the criteria for determination of accreditation of laboratories used as reference laboratories and for how outside results may be reported through the Laboratory Information System (LIS).

**Policy:**

**REFERENCE LABORATORIES**

1. Any request to use a reference laboratory must be made through the Laboratory Director.

# Each reference lab will be required to submit appropriate documentation of their current licensure in all states from which GENETWORx receives patient’s samples.

1. This information will be kept on file in the laboratory and will be reviewed as needed to maintain current licensure documentation for all laboratories in use.
2. To be considered as a reference laboratory for GENETWORx the lab must demonstrate that it can meet the needs of our medical staff both in testing required and turn-around-time.
3. Samples from the State of New York may only be referred to a New York State Permitted Reference lab. Once all credentials are received, the Laboratory Director will present the reference laboratory at the next Executive Committee meeting for approval.
4. When the Executive Committee has approved the laboratory it may be used as a reference laboratory for GENETWORx.
5. The reference lab must supply hardcopy reports for GENETWORx files.
6. All results from the reference laboratory will be entered into the LIMS system as closely as possible to the reference laboratory’s format to become a part of the patient’s permanent medical record and should contain documentation of the name and address of the reference lab that performed the test.
7. GENETWORx shall not revise or alter, in any way, the result(s) or information directly related to the interpretation of the result(s) of any test provided by the testing laboratory.
8. Reports are to be retained for 2 years or as required by regulation. An exact duplicate of the testing laboratory’s report must be available to GENETWORx through the referral laboratory upon request of an authorized person who ordered the examination.
9. A current list of reference laboratories in use is maintained in the laboratory.
10. Testing will not be referred to a reference laboratory if that test is already performed at GENETWORx unless GENETWORx needs to do so for technical reasons.
11. For specimens sent to referral laboratories, GENETWORx will follow all requisition, collection, and handling specifications of the referral Laboratory
12. Referrals for Next Generation Sequencing
    1. The laboratory director, in consultation with the institutional medical staff or physician clients (where appropriate), is responsible for the selection and evaluation of referral laboratories.
    2. Referral may include the total NGS analytical testing process or portions of the process (e.g. only the wet bench or bioinformatics portions).
    3. For laboratories subject to US regulations referring the total NGS analytical testing process, or portions of the process (e.g. only the wet bench or bioinformatics portions), referrals must be made to a CLIA-certified or a laboratory meeting equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS).
    4. Specimens referred for NGS testing may undergo total NGS analytical testing, or portions of the testing (e.g. only the wet bench portion or the bioinformatics portions) or sub-portions therein. For example, a laboratory may convert a specimen into high quality DNA and then send the DNA sample to a referral laboratory for sequencing. A referral laboratory may convert the DNA into an NGS library and perform sequencing to generate file formatted sequencing reads (e.g. FASTQ files) and send it to another referral laboratory to perform bioinformatics to align reads to a reference sequence and identify and annotate variants. There must be records of each of these transfer steps between the primary/referring and recipient referral laboratories to describe unambiguously when and how specimens and data (including file formats) are transferred and/or exchanged. Labeling of the sample, material, or file must comply with COM.06200.

**Policy: REPORTING OUTSIDE ELEMENTS**

Currently GENETWORx does not report outside results through our LIS. If outside results are received, they can be uploaded into the case as a linked document but will not be integrated into the primary reporting system.

**Policy: PROTECTION of PATIENT CONFIDENITALITY**

All reports and information containing Private Health information (PHI) will be transferred confidentially via the secure Laboratory Information System (LIS).

**Regulatory requirements**

10 NYCRR § 58-1.9

42 CFR § 493.1242

CAP Checklist MOL.53840 MOL.35845

**Revision History**

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| --- | --- | --- | --- |
| Revision Number | Reason for Revision | Author | Effective Date |
| 0 | Original SOP | Bill Miller | Upon Signature |
| 1 | Reformat Quality System, Add CEO signature Line | Sarah Jacobs-Helber | 07/21/2017 |
| 2 | Addition of requirements for referral of Next Generation Sequencing samples | Sarah Jacobs-Helber | 02/12/2018 |
| 3 | Addition of handling requirements for Referred Specimens and reporting outside results | Sarah Jacobs-Helber | 04/16/2019 |

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| **Review & Approval History** | | |
| **Printed Name** | **Signature** | **Date** |
| Sarah Jacobs-Helber, PhD HCLD(ABB), Laboratory Director |  |  |
| William Miller, HTL, MBA Chief Executive Officer |  |  |

**Reviewed by:**

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| **Printed Name** | **Signature** | **Date** |
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