CLIA Policy: Data Confidentiality Policy Date: 3/6/2013 Supercedes: New Ohio Department of Health, Bureau of Public Health Laboratory

Data Confidentiality Policy

Purpose: This policy has been developed to meet the Clinical Laboratory Improvement Amendments (CLIA) Standard 493.1231 (Standard Requirements for Confidentiality of Patient Information).

Principle: The Ohio Department of Health Laboratory is a secure facility; however, there are times when a non-employee has access to the facility. As a result, it is important that all patient information at the laboratory is held or stored in a confidential manner. Maintaining data confidentiality can be accomplished in a variety of ways, including protecting the integrity of computers and limiting access to patient data to authorized individuals.

1. Ohio Department of Health Agency Initiatives

- 1.1. The Ohio Department of Health (ODH) Directive 601 "General Policy on Data Confidentiality" provides ODH staff with guidelines regarding the protection of confidential information. All employees (upon hire) are required to acknowledge that they have received, read and understood the Policy.
- 1.2. The ODH Directive 7B "Use and Security of Agency IT Resources" provides ODH staff with guidelines regarding the use and the security of the agency IT resources such as Internet Use, E-mail use and the use of the agency's information and date resources.
- 1.3. The ODH Directive 23 "Information Technology and Sensitive Equipment Management" provides ODH staff with guidelines for receipt, distribution, inventory, and salvage of information technology and sensitive equipment.
- 1.4. The ODH Directive 24A "Data Stewardship" provides ODH Staff with guidelines on data access, data release, and data management.
- 1.5. The Office of Management Information Systems (OMIS) Letter 3 "Subject: Confirmation of User Access Listing (COAL)" provides ODH Staff guidelines on access rights for IT systems.
- 1.6. OMIS Letter 4A "Subject: Information Technology Code of Responsibility (ITCOR) Renewal" provides ODH Staff with guidelines on the annual renewal of the ITCOR.

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- 1.7. OMIS Letter 6 "Subject: Unauthorized Personal Information Disclosure and Notification" provides ODH Staff with guidelines on appropriate action to take following unauthorized disclosure of protected health information or confidential personal information.
- 1.8. Ohio Revised Code (ORC) Chapter 3701.17 "Protected Health Information" and ORC Chapter 1347.15 "Access Rules for Confidential Personal Information" provides ODH Staff with guidelines on means to protect, handle, and release personal health information.

2. Ohio Department of Health Laboratory Initiatives

- 2.1. All ODH staff will comply with the above Directives, Letters, and ORC to ensure confidentiality of patient information throughout all phases of the testing process under the laboratory's control.
 - 2.1.1. Assure all requisition forms, test reports, or other documents containing patient information are handled in a confidential manner and only by staff that require access to the information in order to perform their duties.
 - 2.1.2. Assure computer displays are locked or closed when unattended.
 - 2.1.3. Comply with OMIS policies regarding frequency of password changes.
 - 2.1.4. Assure all paperwork or packaging containing patient information is stored in a secure location that maintains patient confidentiality when no longer in active use.
 - 2.1.5. Assure all paperwork of packaging containing patient information are destroyed (use of a sealed document destruction receptacle) once this information is no longer required to be held by the laboratory.
- 2.2. The following are additional measures that the staff will take to ensure patient data confidentiality:
 - 2.2.1. All visitors to the laboratory will complete the "ODH Visitor Confidentiality and Non-Disclosure Agreement" before the visitor is allowed to enter areas that may contain sensitive patient information. These forms will be retained by the Laboratory Director or designee.
 - 2.2.2. Before laboratory reports are to be sent by fax to the client, the client fax number must be listed in the secure fax database.
- 2.3. Any breach in data confidentiality will immediately be reported to the Laboratory Director or the Quality Assurance (QA) office. A "Request for Remedial Action Form" will be completed and retained by the Laboratory Director or designee.

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3. References

- 3.1. CLIA Standard 493.1231; Standard requirements for Confidentiality of Patient Information
- 3.2. ODH Directive 601, Directive 7B, Directive 23 and Directive 24A
- 3.3. OMIS Letter 3, Letter 4A and Letter 6
- 3.4. ORC Chapter 3701.17 and Chapter 1347.15

Signature Approvals

QA Officer Date

Laboratory Director Date

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