

Title: POLICY FOR RELEASING TEST RESULTS TO PATIENTS	
POLICY #:	Effective Date:

PURPOSE

On February 6, 2014, the following changes to the CLIA regulations were published in the Federal Register. 42 CFR §493.1291(l) was modified as: *"Upon request by a patient (or the patient's personal representative), the laboratory may provide patients, their personal representatives and those persons specified under 45 CFR 164.524(c)(3)(ii), as applicable, with access to completed test reports that, using the laboratory's authentication process, can be identified as belonging to that patient."*

The HIPAA Privacy Rule was amended at 45 CFR §164.524 to remove the exceptions that relate to CLIA and affect an individual's right of access. This change preempts any contrary provision of State Law.

This policy and procedure details the verification and documentation requirements that are required when a patient or his authorized representative requests a laboratory test report that was performed by the [Lab Name].

POLICY

It will be the policy of the [Lab Name] to comply with the CLIA regulations and to release the completed patient test report within 30 days of request, providing the requestor has completed the request form and provided acceptable documentation of identity. The laboratory will mail the results back to the address on the form, unless other arrangements are made.

The [Lab Name] is responsible for releasing any laboratory results that are in our records. The QA Coordinator will be the primary contact for handling the results requests. The QA Manager will provide back-up support. Documentation will be maintained for at least 6 years.

PROCEDURE

1. When a patient or patient's guardian/representative contacts the laboratory for results, the person receiving the call should direct the caller to the *Patient Request for Release of Laboratory Results* form on the [Lab Name] website and ask the requestor to complete the form and fax or mail it back to the laboratory along with a copy of the required identification. If the caller does not have access to the website, you may mail or fax a copy of the form. Instructions for completing the request are listed on the back of the form.
2. Once the form and identification documentation has been received in the laboratory, forward it to the QA Coordinator, along with a copy of the original laboratory test submission form.
 - a. Acceptable forms of documentation include; driver's license, identification card issued by federal, state, or local government, passport, school ID card with photograph, and original or certified birth certificate.

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- b. If the requestor is the parent or guardian of a patient under 18 years of age and requesting laboratory test results, ask for a copy of the minor's birth certificate or other proof of guardianship or adoption in addition to the identification documentation for the parent/guardian.
 - c. Review the date of birth on all requests for STD results (HIV, chlamydia/GC, and/or syphilis). If the tests were performed on a minor (under 18 years of age) contact the provider who ordered the test to determine who consented to have the test performed. If the parent/guardian consented, then you can release the test results to the parent/guardian. However, if the parent/guardian is requesting test results and the minor consented to the testing, you cannot release the test results to the parent/guardian, but you can release the results to the minor on whom the test was performed.
 - d. If the requestor is the personal representative of the patient, ask for a copy of the Healthcare or Durable Powers of Attorney documentation.
 - e. If the patient is deceased, results may be released to a family member provided a copy of the death certificate is provided.
3. The QA Coordinator or designee will match up the information received on the original submission form with the information on the request form. If the information matches, he will mail or fax a copy of the requested test report back to the submitter and document this action on the form, along with any notes.
4. If the laboratory does not have a test report on this patient during the time period in which it was requested, the QA Coordinator or designee will send a written response that this test result was not in our records and the requestor should contact the original submitter.
5. If the QA Coordinator or designee is not able to verify the identity of the requestor in order to link it to the records request, he will send a written response to the submitter.
6. If the QA Coordinator or designee has concerns about releasing the laboratory test results to a personal representative, he should contact the original provider for assistance. In the event the provider determines that providing the test results to the personal representative is reasonably likely to cause substantial harm to the patient, the laboratory may deny releasing the results. This denial must be in writing and all information supporting this denial must be documented and kept with the original request.
7. Unless special arrangements are made, laboratory test results will be mailed using standard first-class mail or faxed to a requested fax number.
8. The QA Coordinator or designee has up to 30 days to verify identity and release results. One 30-day exemption may be granted if additional time is needed to complete identity verification. If the requested results are recent (within 3 months), the Coordinator will wait at least 21 days

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after the report has been sent to the provider before releasing the results to the patient or patient's representative. This delay allows the medical provider an opportunity to review the results and make any medical decisions. If the test result is older than 3 months, the reports may be released as soon as identification has been verified.

9. The laboratory is not responsible for interpreting the laboratory test results and if asked, should request they contact their submitter.
10. Documentation will consist of the completed request form, copy of identification, copy of submission form and copy of test report form that was sent. This information will be stapled together and filed in the QA Offices / archives for at least 6 years.