



- Reporting and Interpretation of Blood Test Results -

Results Reporting:

- Results will be reported to the Central Lab within 12 weeks after the specimen is sent out to the testing laboratories. If the testing site needs more time to test and report the results, a letter must be submitted for documentation. RE: testing of the XXX Virus/XXX Gene and time allowance needed in excess of 12 weeks, or requested.

Testing Laboratories:

- Testing labs will be notified of the initiation of this Central Lab for the sole purpose of testing patients with blood disorders for new and emerging pathogens.
- A letter must accompany all requests for samples indicating the Primary Investigator responsibility name, title, lab facility, and all affiliations regarding this testing. The letter must also state the test for which it is intended for, and agree to provide the results on documented result sheets, and sign an agreement to report the results back to the Central Lab within a period of 12 weeks. If the testing lab needs more time to analyze the results, they must request this at this time.
- The Primary Investigator, Dr. B. Ritchie and the research committee of the AHCDC will review all requests. No request will be unjustly denied.
- Testing will be done only with blinded samples. The Central Lab will have the only link to notify the clinics-patients of the results.
- All data will be entered into the database within a period of 4-6 weeks by the Central Lab, upon receipt of results.
- All testing must comply with the regulations outlined in the protocol (see section 8.4). re: No commercial benefits can be assumed with testing of these samples.

This page will be sent to all testing laboratories, and a signature page must be signed before any samples can be released.

Validation of results:

- The research committee of the AHCDC (identified in the protocol) will have the primary responsibility for validating all testing done on any of the samples. If they feel it necessary to involve other experts who are not immediately identified in the protocol, they may do so for the sole purpose of validating the results.

This must be documented in a letter, stating the person(s), affiliation, title, reason for involvement(s), and kept on file.

- If there is reason to believe any errors have been made with the testing procedure, this matter will be dealt directly with the research committee of the AHCDC, and conduct a search as they deem necessary. This will be all under the authority of Dr. B. Ritchie and the research committee of the AHCDC.