This collection of reports, protocols and files serves as a validation package for the CDC Program ELISA. Each document with its associated data files is located in its individual subdirectory on the distribution CD. The documents include the following:

The Introduction which contains this document.

A Process Verification and Qualification Development Report which details the theoretical foundations for the method programmed into the software. This document provides mathematical formulas used to implement the methods and also details how various quantities are calculated in the program. While not a formal validation document, it does provide example calculations which are compared with published results to illustrate the calculation formulas have been implemented correctly. The formal report refers to sample data files which are located in the subdirectory \Process Qualification Report. Both Adobe Acrobat and Microsoft Word versions of the report are included. The Microsoft Word version is provided in the event a user wishes to adapt the document or use portions of it for customized applications in their research environments.

An Installation Qualification Protocol which provides precise instructions for the installation of the ELISA program. This protocol is provided in both Adobe Acrobat and Microsoft Word versions and is located in the subdirectory \Installation Qualification Protocol. The Microsoft Word version may be used to create a specific installation protocol for use in any given research environment.

An Operational Qualification Protocol which provides a detailed series of steps to confirm the software is installed correctly and that the program is delivering results within acceptable specifications. This protocol is provided in both Adobe Acrobat and Microsoft Word versions and is located in the subdirectory \Operational Qualification Protocol. The Microsoft Word version may be used to create a specific operational protocol for use in any given research environment. The associated files that accompany this protocol are located in the subdirectory \Test Data.

A Validation Protocol and Report which describes the formal validation procedures for the software and reports the results of the validation process. These are the documents that describe the formal validation of the ELISA program and are located in the subdirectory \Validation Protocol. Both Adobe Acrobat and Microsoft Word versions of the protocol and report are included. The Microsoft Word version is provided in the event a user wishes to adapt the documents or use portions of them for customized applications in their research environments. The associated data files that accompany the protocol and report are located in subdirectories beneath \Validation Protocol.

The User's Guide for the software is located in the \Documentation subdirectory.

A SAS Verification and Qualification Report is included in the subdirectory \SAS Qualification Report. The validation of the ELISA program was performed by comparing results obtained in ELISA with those calculated by procedures implemented in the SAS software system. The SAS 912 Qualification Tools Users Guide details the procedures required to verify that SAS is operating correctly in our computer environment. The CDC SAS 912 Operational Qualification Report presents the results of the verification process.

The Reference subdirectory contains the original reference that lays the foundation for the use of the robust fitting techniques in the four-parameter logistic-log function: B. D. Plikaytis, G. M. Carlone, P. Edmonds, and L. W. Mayer, Robust estimation of standard curves for protein molecular weight and linear-duplex DNA base-pair number after gel electrophoresis, (1986) Analytical Biochemistry, **152**:346-364. Erratum: **154**:702 (1986).

The Software subdirectory contains a .ZIP files containing the ELISA software.

The remainder of this document details the subdirectory structure with all the files distributed with this validation package.

Main Directory \Protocols_Distr

- Introduction.doc
- \Documentation
  - ELISA Manual.pdf
- \Installation Qualification Protocol
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