



Test with Confidence™

Understanding the ELISA certificate of analysis

IDEXX tests are manufactured in lots per strict quality standards. Lot approval by regulatory authorities, such as the USDA, is based upon the results of internal quality control testing for each. The certificate of analysis (C of A) for a test documents the performance of the test at the time of release testing. The performance data include the optical density (OD) values of the test controls and the calculated results and/or qualitative interpretation of a selected group of samples used during manufacturing. All these values must be within a specified range for the test lot to be approved for sale.

The OD values of the test controls do not need to remain within the C of A ranges during the lifetime of the test. Optical density values may change over time, without compromising test quality.

Diagnostic tests are composed of biological components that are not always stable when removed from their natural environment. Despite stabilizers used to control shelf life, most biological components lose some activity with time. When this occurs, OD values can decrease. The decrease in OD values of the test controls parallels the decrease of OD values in the tested samples, so the calculated results remain the same. Lower OD values than those on the C of A are acceptable so long as the validity specifications in the test insert are met for the assay.

The validity criteria in the insert differ from the values noted on the C of A. Validity criteria in the insert usually specify a limit on a control OD value or a ratio of control OD values. If a test plate performs within the validity specifications of the insert, then the test is working properly and the test results can be used.

The shelf life of an IDEXX diagnostic test can vary from 9 months to 2 years depending upon the product. The test is designed to give valid results throughout its shelf life.

With any ELISA, reproducibility and reliability depend on proper technique, equipment, environmental factors and attention to detail. The C of A serves as a guideline for anticipated test performance.

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