



Characteristics of the Cornell Kinetics Johne's ELISA (KELA)

The Cornell Johne's KELA ELISA is intended primarily as herd or group screening test to be used in conjunction with fecal culture of individuals with elevated values. Within the limits of the ELISA, it is also used in preliminary assessment of the risk of infection in individuals.

- ⊙ The Cornell Johne's KELA uses a multiple cut-off interpretation system to increase information gained from the test and more accurately reflect the biology of *M. paratuberculosis* infection.
- ⊙ Four cut-offs define four categories which represent increasing probability or risk that an individual is infected.

KELA ELISA units of: 0-39 = Lowest risk of infection (background activity)
 40-54 = Moderate risk of infection
 55-164 = Moderately high risk of infection
 >164 = High risk of infection

- ⊙ Within the herd or group, the distribution of KELA values falling within the four categories is summarized. These distributions aid in assessing the probability or degree of infection in the group.
- ⊙ A KELA value equivalent to a single cut-off with 98% specificity is 80-90 units. The corresponding sensitivity in this range is 30-50%, based on animals determined infected by fecal culture. The sensitivity of a KELA value of 40 (cut-off for low risk) is 60-70%, with specificity 65%.
- ⊙ The KELA result is a normalized slope value, a continuous number generally from 0 to 200, but as high as 250. Result values are reasonably comparable from test to test in the same sample or animal, within farm, and to a reasonable extent between farms. Due to many unknown factors, ELISA performance does vary farm to farm.

Kinetics ELISA (KELA) is a more robust method of measuring the antibody concentration in a sample. It is not subject to many of the variables that affect static ELISAs (test kits, etc)

- ⊙ Kinetics (KELA) ELISA removes a large proportion of error associated with kits such as IDEXX ELISA. The major source of error, based on evaluation of several hundred plates, is that the IDEXX result varies about 22% from day to day i.e., Coefficient of variation comparing the same samples day to day across plates. In kinetics ELISA, the variation is in the range of 5%.
- ⊙ KELA measures the rate of change in color (OD) over time, instead of at an endpoint.
- ⊙ Rate or slope of color change, like intensity of final OD, is related to amount of antibody in a sample.
- ⊙ KELA uses a set of 5 standard control samples of varying antibody concentration to generate a standard curve from which the antibody concentration of test samples is calculated. This adjustment or normalization yields a similar result for the test sample run on successive days. Because of variables in the method, such as temperature, duration of incubation of the reaction, etc, the color response on the same sample may vary from day to day.