



Technical Tip 16

ZEUS ELISA™ Test Systems

Subject: Guidelines For The Use of ELISA External Controls

Background: Although controls are included in all ZEUS ELISA Test System kits along with Quality Control criteria that must be met as defined in the package insert, additional controls may be tested according to guidelines or requirements of local, state and / or federal regulations or accrediting organizations. While it is the responsibility of each laboratory to define the individual use of external controls, below are some guidelines provided to assist in establishing expectations:

1. External controls may include known patient samples or purchased control material.
2. External controls **MUST** be stored and handled in the same manner as samples in order to ensure valid and accurate results. See the section Specimen Collection in the ZEUS ELISA Test System kit package insert.
3. Some ZEUS ELISA Test Systems are intended to be used for the **qualitative** detection of specific antibodies. In these cases, it is recommended that external controls should be interpreted qualitatively as Negative, Positive or Equivocal for assaying purposes.
4. Purchased external controls may include calculated **Index Value** or **OD Ratio** ranges provided by the control manufacturer. These ranges are typically recommended guidelines only and it is up to each laboratory to establish their own ranges.
 - ❖ External control ranges should be established using a minimum of twenty (20) data points.
 - ❖ External control ranges should be established using a minimum of three (3) kit lots over several different runs.
 - ❖ External control ranges need to be re-established when a new control lot is received.
 - ❖ External control ranges should be reviewed, monitored and re-assessed over time.



5. It is not recommended that external controls to monitor optical density (OD) or absorbance values only. OD or absorbance values normally fluctuate from run to run based on testing conditions such as laboratory temperature, incubation times, wash efficiency, etc.

Summary: Although the use of external controls may serve as a tool to monitor technique, instrumentation, reagent handling, etc. they should not be used exclusively but rather in conjunction with kit manufacturers recommendations and good laboratory practices. Refer to CLSI (formerly NCCLS) document C24: Statistical Quality Control for Quantitative Measurement for additional guidance on appropriate QC practices.