



Technical Tip 07

ZEUS AtheNA Multi-Lyte[®] Test Systems

Subject: Frequently Asked Questions on Control Values between AtheNA Multi-Lyte[®] Test System Lot Numbers

The AtheNA Multi-Lyte[®] Test System control values should not be expected to remain consistent from lot to lot. With every different test system lot number, different control values and ranges should be expected and are common.

1. In AtheNA Multi-Lyte[®] Test Systems with more than one Positive Control, such as the AtheNA Multi-Lyte[®] ANA II Plus Test System, will each control be positive for the same analytes with every kit lot number?

Not necessarily. Each lot of controls may be made of different raw materials, as a result the analytes for which that control is positive for may vary from lot to lot. Positive Controls are formulated using sera from donors having various systemic autoimmune diseases. Since the donors vary, their antibody profiles vary and the relative concentrations of the antibody vary, you can imagine that it is impossible for control lots to be formulated that behave exactly the same; lot to lot. For example, if one lot of PC1 was positive for 4 analytes, the next lot of PC1 may be positive for 3 different analytes.

2. Will controls be similar in value for each analyte between different lots?

Not necessarily. Different AtheNA Multi-Lyte[®] Test System lot numbers may contain different lots of controls. The values for these controls may vary from lot to lot due to different factors, such as the use of different raw material, differences in the production process and different lot specific calculations. Therefore, the values may not be and typically are not the same between control lots.

3. Should control values be similar between kits of the same lot number?

Yes, the control values should be similar but not necessarily identical between kits of the same lot. An acceptable range is set within the lot specific calibration CD for each control. Provided each control is within the set range, the test is considered valid and to be performing to QC specifications.