



## Technical Tip 03

# ZEUS AtheNA Multi-Lyte<sup>®</sup> Test System

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### **Subject:** Invalid (INV) Results

The “Status” column on both the Interpretive and Numeric Results tab and printout indicates whether the individual sample run passed or failed internal quality control (QC). An “OK” status indicates that the sample passed all internal QC checks. In the case of a failed internal QC check, one of the following Invalid (INV) codes will appear:

- **A:** slope out of range
- **B:** intercept out of range
- **C:** r squared out of range
- **D:** value ratio out of range
- **NSC:** NS control out of range
- **TO:** Sample Time-Out

#### **Why does this occur?**

**INV A, B, C, D:** Through the use of *Intra-Well Calibration Technology*<sup>®</sup>, all calculations are performed automatically when using an AtheNA Multi-Lyte<sup>®</sup> Test System. *Intra-Well Calibration Technology*<sup>®</sup> performs a regression analysis of the internal standards and then adjusts the calculated unit values based upon an additional standard and the characteristics of the serum sample. Specimen validity is based upon the characteristics of the calibration beads and their interactions with the patient sera. There are various parameters monitored automatically through *Intra-Well Calibration Technology*<sup>®</sup>. If any of the criteria are found to be out of specification, the patient’s results are considered invalid and should be repeated.

Most commonly, INV results could be caused by abnormally low or high IgG levels in the serum sample or a strong Rheumatoid Factor (RF) positive patient sample.



**INV NSC:** All AtheNA Multi-Lyte<sup>®</sup> Test System bead suspensions include a non-specific control (NSC) bead designed to measure non-specific interactions. If there is too much activity on the NSC bead, *Intra-Well Calibration Technology*<sup>®</sup> will invalidate that particular specimen. This implies that the patient's antibody is non-specifically interacting with the beads. High NSC activity could be due to a number of reasons. This could be caused by abnormal antibody levels in the serum sample, a strong RF positive patient sample, or perhaps issues surrounding storage of the serum.

**INV TO:** When a single plate well is read on the AtheNA Multi-Lyte<sup>®</sup> Reader, each analyte in the test system must reach a bead count of 50 or more before the set time limit of 90 seconds in order for the well to succeed. An invalid time out (INV:TO) will occur when one or multiple analytes do not reach this specified bead count in the appropriate amount of time. It means the minimum amount of 50 beads per analyte were not read by the instrument. Some possible causes for a sample to time out are: insufficient volume of bead mix added to well; insufficient mixing or sonicating of bead mix; improper probe height on instrument; clog in probe or fluid lines; incorrect vacuum settings during the plate washing step (See Technical Tips 9 and 10 for proper vacuum settings); faulty filter plate.

### **How can I see the result?**

Although the result for an invalid sample run does not appear in either the Interpretive or Numeric Results tab, the result can be viewed and printed by using the "Select and Print Individual Result" located within the "Statistics and Output" tab of the AtheNA Multi-Lyte software.

### **How should I proceed?**

If you receive an **INV A, B, C, D** or **NSC**, the sample should be rerun. If the same status is generated, another sample should be obtained from the patient. If you receive an **INV TO**, the sample should be repeated ensuring that: the proper amount of bead mix per well has been added; the bead mix has been thoroughly mixed and sonicated prior to adding to well; AtheNA Multi-Lyte<sup>®</sup> instrument maintenance has been performed including – probe sonication and probe height adjustment. If the sample times out upon repeat, please contact your regional distributor for further technical support.