

# SPECIMEN INTEGRITY:



## BLOOD TRANSPORT STUDY

### SPECIMEN INTEGRITY...IMPACT ON QUALITY OF CARE

Home Healthcare Laboratory of America (HHLA) has developed an innovative method for collecting/transporting blood specimens for lab testing. The specimen is whole blood/plasma (versus the traditional serum specimen) and the transportation is accomplished with HHLA's patented Lab-in-a-Box™ kit that ensures temperature/agitation control. Validation of this new process was accomplished several years ago but a new study of comparative specimen integrity has yielded significant data regarding the quality of lab results for home care patients.

The study (as outlined below) had modest objectives primarily aimed at reconfirming that the Lab-in-a-Box™ system produced results that were similar if not identical to other clinical labs servicing the home care sector. In actuality the study results indicate that in many instances ***HHLA's specimen integrity is significantly superior.***

### OVERVIEW/OBJECTIVES

The study was designed in concert with a national home infusion provider and was intended to demonstrate the relative integrity of lab specimens obtained through home care's "standard" methods versus utilizing HHLA's system. The stated objectives were:

1. Demonstrate that HHLA's plasma specimens are as accurate as the serum specimens commonly used by other clinical laboratories.
2. Demonstrate that using the Lab-in-the-Box™ system and overnight FedEx delivery services will not adversely affect the integrity of the blood sample.

### STUDY METHODOLOGY & SAMPLING

Volunteer study subjects (recruited in home care branches across the country) were required to undergo a phlebotomy event in order to obtain blood samples for a panel of tests. One hundred three (103) subjects participated in the study.

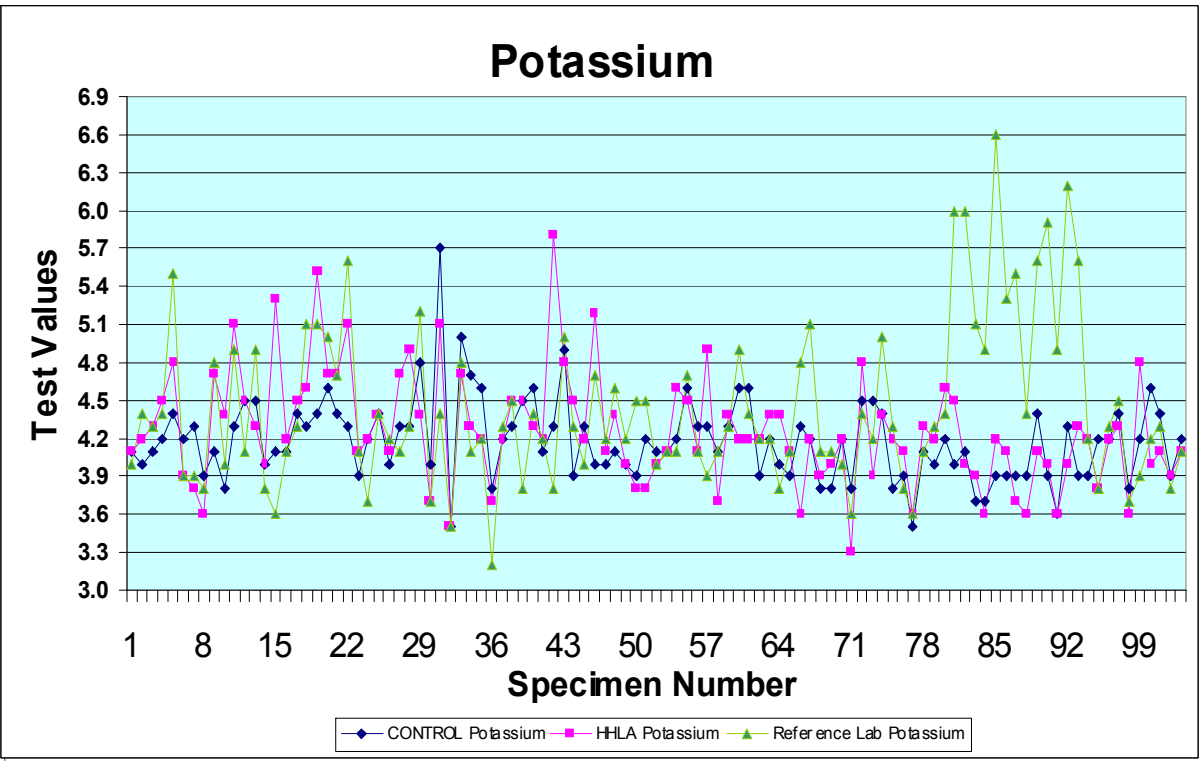
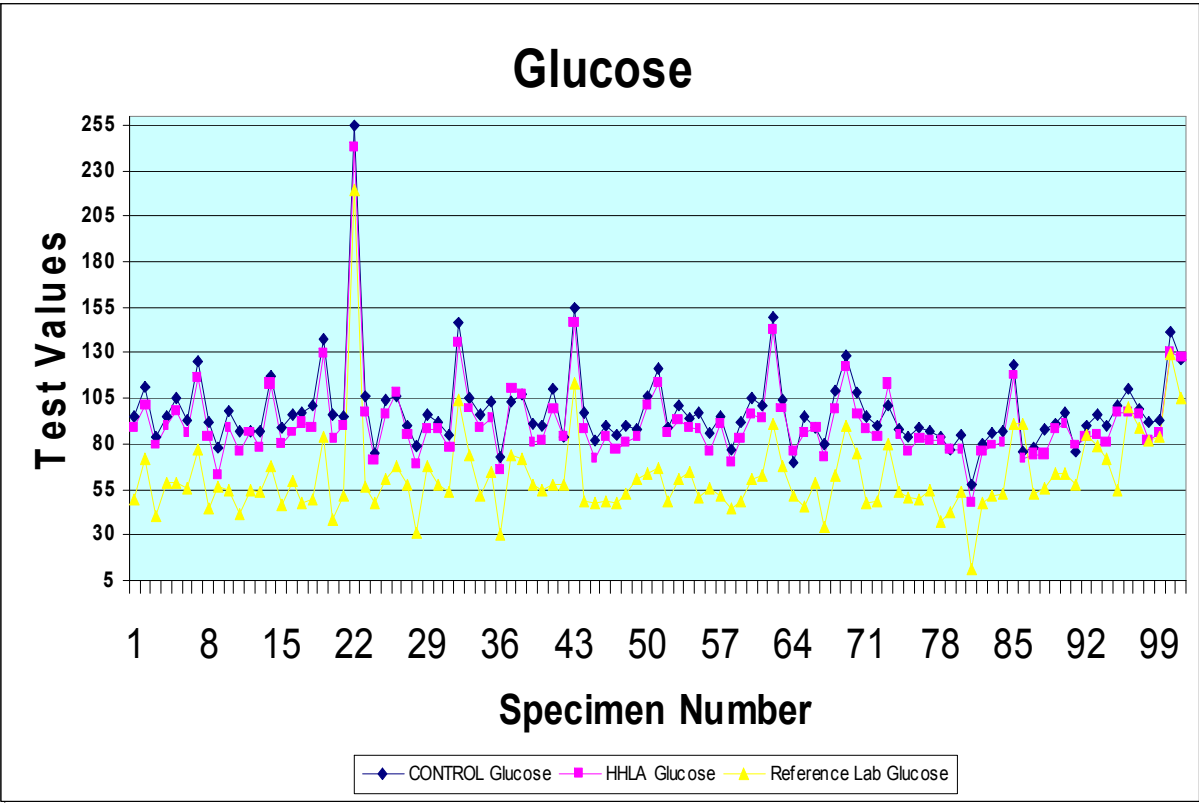
In order to validate the objectives of the study, each study subject had three sets of blood specimens drawn by a licensed clinician or laboratory phlebotomist. The blood specimens were handled in the following manner:

- Set #1 was immediately centrifuged and the serum was frozen, packed on dry ice and transported to HHLA's lab to be used as the control.
- Set #2 was handled/processed according to the standard operating procedures of the home care company and the laboratory requirements of a national clinical laboratory servicing the home care branch. These specimens were tested by the national clinical lab (NCL).
- Set #3 was handled/processed according to standard operating procedure and laboratory requirements of Home Healthcare Laboratory of America. These specimens were tested by HHLA.

### CONCLUSION

The data from all three sample sets was collated and compared. The majority of the analytes were statistically identical. But in several cases the potassium and/or glucose levels of the three specimen sets yielded significant variances. Since potassium and glucose are considered to be among the more unstable analytes, this outcome was not unanticipated. HHLA anticipated that both the HHLA and the NCL potassium/glucose results would differ from the control but would yield similar variances to the control. In actuality the HHLA test results showed only a slight variance to the control sample whereas in several cases NCL test results showed a significant variance.

The graph of glucose data points (for all three sets) most clearly illustrates the specimen integrity differences. Since clinical decisions concerning treatment and re-hospitalization are often made based on laboratory results, it is clear that ***poor specimen integrity can have a serious impact on the quality and cost of patient care.***



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