Pancreatic Amylase reagent is a liquid, ready to use, bi-reagent colorimetric turbidimetric assay. The Pancreatic amylase increasingly enters the blood when pancreas is inflamed or damaged. Pancreatic amylase is secreted by the pancreas and is an enzyme that aids in the digestion of starches. Starches are the only type of carbohydrates that amylase digests. Food then travels down the esophagus to the stomach and eventually makes its way into the intestinal tract. PAMY assays are suitable for diagnosing and monitoring acute pancreatitis, as well as for identifying acute attacks during chronic pancreatitis. The enzymatic colorimetric assay for PAMY determination develops in two steps: 1) Incubation: human salivary α-amylase, forming: G2PNP, 2 G3PNP and G4PNP, which are hydrolyzed by α-glucosidase into p-nitrophenol (PNP) and glucose. PAMY activities are proportional to the absorbance increase due to PNP formation. Beckman Coulter, a fully automated clinical chemistry system, which performs colorimetric, enzymatic, as well as turbidimetric assays. The study compared serum samples results on Beckman Coulter AU5800 versus AU480, and to Abbott Architect c8000. Linearity was determined on at least 11 test dilutions at concentrations spanning the desired linearity range of the assay. The percent recovery for each sample was calculated. The difference between the observed result and the expected value was within the acceptance criteria for each sample.

**RESULTS**

**On Board Reagent Stability**

On Board reagent stability was assessed by comparing recovery % of a panel of human sera pool and commercial control sera vs initial measurement. Acceptance criteria was % recovery 95% - 110%.

**Instrument Comparison**

This testing was performed on the Beckman Coulter AU5800 in comparison to AU480 and to Abbott Architect c8000. The data obtained on AU480 were compared versus Architect c8000. Linear regression analysis was used to determine the degree of agreement between the assays on the different systems.

**CONCLUSIONS**

Sentinel CH. Pancreatic Amylase assay performance on Beckman Coulter AU5800 analyzer met the Acceptance criteria based on NCCLS/CLSI variation database specifications. The data obtained and reported as imprecision, comparison and stability confirm the quality of the system (SCH reagent + AU analyzer) in comparison with the reference system.