

InSight Crea-Vet System Compared with Beckman AU480 System in Blood Samples

1. Performance Parameters

Parameter	Whole Blood Accuracy Requirements
Creatinine	Test range $\geq 89 \mu\text{mol/L}$, absolute deviation is not more than $\pm 18 \mu\text{mol/L}$. Test range $> 89 \mu\text{mol/L}$, relative deviation is not more than $\pm 15\%$.

2. Protocol

- Comparative System: Beckman AU480 Chemistry Analyser
- Testing System: InSight Crea-Vet System
- Methodology: Dry electrochemical method
- Sample Type: Fresh venous and capillary whole blood from the intended subjects
- Sample Size: 1,445 samples

3. Results

3.1 Scatter Plot

The scatter plot (Figure 1) was generated to illustrate the relationship between the Investigational System (capillary whole blood) and the Reference Measurement Procedure (venous whole blood).

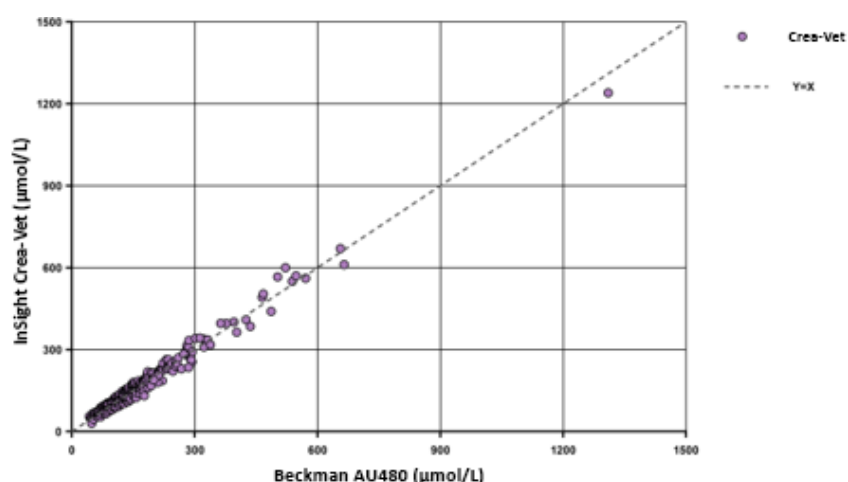


Figure 1 Scatter Plot of the Data (μmol/L)

3.2 Difference Plot

The difference plot (Figure 2) was generated by using the reference system's measurement values on the x-axis and the differences between the investigational system and the reference system on the y-axis.

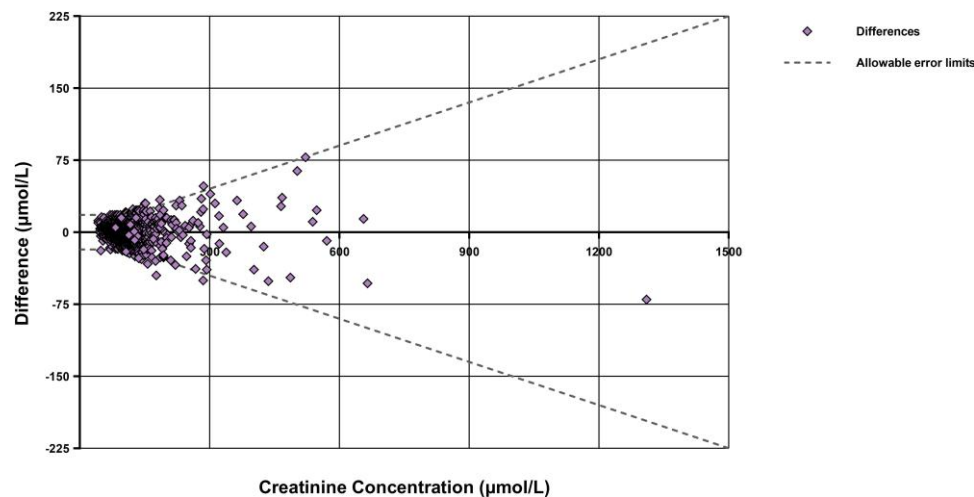


Figure 2 Difference Plot (µmol/L)

4. Conclusion

Among the 1,445 paired results, 1,375 met the predefined performance criteria: an absolute deviation within $\pm 18 \mu\text{mol/L}$ for results $\leq 89 \mu\text{mol/L}$ and a relative deviation within $\pm 15\%$ for results $> 89 \mu\text{mol/L}$. The overall compliance rate was approximately 95.2%.

The investigational testing system (InSight Crea-Vet) demonstrated acceptable agreement with the comparison method (Beckman AU480) and met the clinical performance requirements for creatinine measurement.