

# CANYON DIAGNOSTICS, INC.

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## 510(k) Submission Summary

This summary regarding the enclosed 501(k) submission is intended to support safety and effectiveness information in accordance with requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

CANTROL Serum Iron and Total Iron Binding Capacity test system provides a simple, but effective, method for quantitating the level of serum iron and total iron binding capacity in human blood serum. The methods and procedures used in this assay protocol follow well documented, published and accepted methods for determination of the analytes as defined in the 510(k) reference section.

In the CANTROL Serum Iron procedure Iron is released from its carrier, transferrin, by an acidic reagent containing hydroxylamine and thiourea which reduces the iron to its ferrous state. A chromogen reagent, ferene, reacts with the ferrous iron to produce a colored complex, the color of which is proportional to the quantity of Iron in the test sample. Color of the reaction is measured spectrophotometrically.

Total Iron Binding Capacity analysis uses the same color reaction to test serum samples which have been saturated with iron by use of an ion exchange resin in the presence of ferric ammonium citrate, prior to the iron determination. The bound iron remaining in the serum after treatment with the resin compound is the Total Iron Binding Capacity.

Precision, Linearity and Correlation data is submitted to demonstrate product performance and substantial equivalency with another legally marketed predicate device.

Submitted by:

Date:

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1-17-97

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