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510(k) Summary of Safety and Effectiveness

Serum bilirubin measurement is widely used as a screening test for liver functions. The methods most widely used for determination of serum bilirubin are the diazo coupling method ¹⁾²⁾³⁾ and the bilirubin oxidase enzymatic method⁴⁾. However, these methods have disadvantages such as interference by coexistent serum substances unsatisfactory stability of reagents after preparation. Wako Total Bilirubin V is based on a chemical oxidation method, utilizing vanadate as an oxidizing agent, shows good correlation with conventional methods, practically no interference by coexistent serum substances, and is convenient ready-to-use liquid type reagent⁵⁾.

When a sample is mixed with the reagent containing the detergent and the vanadate, at around pH 3, direct bilirubin in the sample is oxidized to biliverdin. This causes the absorbance of yellow, specific to bilirubin, to decrease. Therefore, the direct bilirubin concentration in the sample can be obtained by measuring the absorbance before and after the vanadate oxidation.

The safety and effectiveness of the Wako Direct Bilirubin V assay is demonstrated by its substantial equivalency to our previous Direct Bilirubin assay (510(k)#K912024/A). Both test systems are used to measure total bilirubin in serum. In comparison studies against the predicate assay, a correlation coefficient of 0.997 and a regression equation $y=1.003x + 0.09$ was obtained with serum samples. Precision studies indicate acceptable values can be obtained on a day to day basis. The minimum detectable level of this method is 0.03 mg/dL. The Wako Direct Bilirubin V assay is linear to 20 mg/dL.

References

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