

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE**

A. 510(k) Number: K030014

B. Analyte: Total Bilirubin

C. Type of Test: Quantitative Diazo Colorimetric test

D. Applicant: Clinical Data

E. Proprietary and Established Names: ATAC® Total Bilirubin Reagent Kit

F. Regulatory Information:

1. Regulation section: 21 CFR § 862.1110
2. Classification: Class II
3. Product Code: CIG
4. Panel: Chemistry (75)

G. Intended Use:

1. Intended use(s):
ATAC® Total Bilirubin Reagent is for the quantitative determination of total bilirubin in serum and plasma using the ATAC® 8000 Random Access Chemistry System.
2. Indication(s) for use:
ATAC® Total Bilirubin Reagent Kit is intended for use with the ATAC® Calibrator and the ATAC® 8000 Random Access Chemistry System as a system for the quantitative determination of total bilirubin in serum and plasma. Total bilirubin results are used for the diagnosis and treatment of liver, hemolytic hematological, and metabolic disorders, including hepatitis and gall bladder block
3. Special condition for use statement(s):
For prescription use
4. Special instrument Requirements:
ATAC® 8000 Random Access Chemistry System

H. Device Description:

The ATAC® Total Bilirubin Reagent Kit is a two reagent assay to be used in the ATAC® 8000 Random Access Chemistry System. It is composed of a Total Bilirubin reagent which contains sulfanilic acid and hydrochloric acid in 50% dimethylsulfoxide and a Nitrite activator containing sodium nitrite. The kit includes the ATAC® Calibrator (K030621).

I. Substantial Equivalence Information:

1. Predicate device name(s):
Beckman Synchron Total Bilirubin Reagent
2. Predicate K number(s):
K902801
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Detection of Total Bilirubin	Detection of Total Bilirubin
Matrix	Human serum and plasma	Human serum and plasma
Differences		
Item	Device	Predicate
Methodology	Acid Diazo Method	Time end-point Diazo Method
Chemistry Analyzers	ATAC® 8000 Random Access Chemistry System	Beckman Synchron

J. Standard/Guidance Document Referenced (if applicable):

Not Applicable

K. Test Principle:

When the reagent is reconstituted, the sulfanilic acid reacts with sodium nitrite to form a diazotized sulfanilic acid (diazo). In the presence of dimethylsulfoxide (DMSO) conjugated and free bilirubin in the sample react with this diazo form to form a red-purple complex. Measurement of absorbance at 546 nm is proportional to the total bilirubin concentration in the sample.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. Precision/Reproducibility:
Total and within run imprecision were calculated from three serum controls each assayed in triplicate 12 times over a 7 day period. Eight of the 12 runs were calibrated concurrently.

Sample	n	Mean	Within-run		Total	
			SD	%CV	SD	%CV
Serum 1	36	0.6	0.04	6.5	0.10	16.3
Serum 2	36	3.4	0.06	1.6	0.11	3.4
Serum 3	36	6.3	0.12	1.9	0.17	2.7

b. Linearity/assay reportable range:

Linearity was assessed between the level of detection and 25 mg/dL in three instruments using seven bilirubin linearity standards with concentrations distributed evenly over the entire range.

c. Traceability (controls, calibrators, or method):

The calibrator is traceable to NIST reference materials.

d. Detection limit:

Total imprecision was assessed at 0.6 mg/dL to have a %CV of 16.3.

e. Analytical specificity:

Effects of interference from additives such as sodium heparin, ammonium heparin, and lithium heparin and from hemoglobin and triglycerides were assessed. Additives were added to a serum pool spiked to 4 mg/dL of total bilirubin at concentration of 40 U/mL. Comparison of results from the bilirubin spiked pool with and without additive showed statistically insignificant biases. Hemoglobin at levels of 40, 80, 120, 160, and 200 mg/dL and triglycerides at 400, 800, 1200, 1600 and 2000 mg/dL were assessed for bias as above. The largest biased observed was for hemoglobin at 160 mg/dL which produced a positive bias of approximately 0.2 mg/dL.

f. Assay cut-off:

The literature derived reference range for normal values for serum and plasma is 0.3 to 1.2 mg/dL.

2. Comparison studies:

a. Method comparison with predicate device:

Sixty serum and 60 heparinized plasma specimens from individual adult patients were selected to contain both normal and abnormal levels of total bilirubin were analyzed with the device and its predicate. Deming regression analysis gave the following fit

$$\text{ATAC 8000} = 1.013 * (\text{Predicate}) - 0.05 \text{ mg/dL}$$

with $S_{y.x} = 0.31 \text{ mg/dL}$

- b. Matrix comparison:*
See above

3. Clinical studies:

- a. Clinical sensitivity:*
Not applicable
- b. Clinical specificity:*
Not applicable
- c. Other clinical supportive data (when a and b are not applicable):*
See comparison study above.

4. Clinical cut-off:

No clinical cut-off was determined.

5. Expected values/Reference range:

Literature was reference for the normal expected values, which are below the device's detection limit.

M. Conclusion:

Based upon the information provided, I recommend that the ATAC® Total Bilirubin Reagent Kit be found substantially equivalent to predicate devices according to 21 CFR § 862.1110 and 21 CFR § 862.3645.