

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

A. 510(k) Number: K030003

B. Analyte: Direct Bilirubin

C. Type of Test: Quantitative Diazo Colorimetric Test

D. Applicant: Elan Diagnostics

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

F. Regulatory Information:

1. Regulation section: 21 CFR § 862.1110 and 21 CFR § 862.3645
2. Classification: Class II
3. Product Code: CIG, JIS
4. Panel: Chemistry (75)

G. Intended Use:

1. Intended use(s):
ATAC® Direct Bilirubin Reagent is for the quantitative determination of conjugated bilirubin in serum and plasma using the ATAC® 8000 Random Access Chemistry System.
2. Indication(s) for use:
ATAC® Direct Bilirubin Reagent Kit, which contains both reagent and calibrator, is intended for use with the ATAC® 8000 Random Access Chemistry System as a system for the quantitative determination of conjugated bilirubin in serum and plasma. Conjugated 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® Direct Bilirubin Reagent Kit is a two reagent assay to be used in the ATAC® 8000 Random Access Chemistry System. It is composed of a Direct Bilirubin reagent which contains sulfanilic acid and hydrochloric acid and a Nitrite activator containing sodium nitrite. The kit includes a Direct Bilirubin Calibrator.

I. Substantial Equivalence Information:

1. Predicate device name(s):
Direct Bilirubin, Acid Diazo Method (Trace Scientific)
2. Predicate K number(s):
K870365
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Detection of Direct Bilirubin	Detection of Direct Bilirubin
Methodology	Acid Diazo Method	Acid Diazo Method
Differences		
Item	Device	Predicate
Matrix	Human serum and plasma	Human serum
Chemistry Analyzers	ATAC® 8000 Random Access Chemistry System	COBAS MIRA analyzers

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). Conjugated bilirubin in the sample reacts with this diazo form to form a red-purple complex. Measurement of absorbance at 546 nm is proportional to the direct 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 20 times over a 27 day period. Approximately half the runs were calibrated concurrently.

Sample	n	Mean	Within-run		Total	
			SD	%CV	SD	%CV
Serum 1	60	0.9	0.10	10.3	0.09	9.2
Serum 2	60	3.8	0.11	3.0	0.13	3.4
Serum 3	60	6.7	0.12	1.9	0.18	2.7

b. Linearity/assay reportable range:

Linearity was assessed between the level of detection and 20 mg/dL in three instruments using nine 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 calculated at 0.5 mg/dL to be a %CV of about 20.

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 3.5 mg/dL of direct 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 120 mg/dL which produced a negative bias of approximately 0.2 mg/dL.

f. Assay cut-off:

The literature derived reference range for normal values for serum and plasma is 0.0 to 0.2 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 conjugated bilirubin were analyzed with the device and its predicate. Deming regression analysis gave the following fit

$$\text{ATAC 8000} = 1.143 * (\text{Predicate}) - 0.10 \text{ mg/dL}$$

with $S_{y.x} = 0.32 \text{ mg/dL}$

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 devices detection limit.

M. Conclusion:

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