

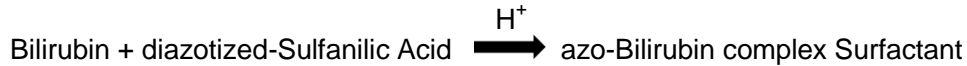
# Direct Bilirubin

## Intended Use

For **IN VITRO** diagnostic use in the quantitative determination of **Direct Bilirubin** in serum or plasma using manual or automated applications.

## Method Principle

The serum sample is mixed with diazotized-Sulfanilic Acid to form the azo-Bilirubin complex. The increase in absorbance is monitored at 550 nm. The reaction scheme below illustrates the reaction that occurs in this method.



## Method Performance Characteristics

**Sensitivity:** 0.0040 – 0.051 absorbance units per mg/dL

**Linear Range:** 0 – 15 mg/dL

**Precision:** Within-run and day-to-day precision is summarized below.

Direct Bilirubin	Within-Run Precision		Day-to-Day Precision		
	MEAN	SD	CV	SD	CV
mg/dL	mg/dL	%	mg/dL	%	
0.47	0.04	*	0.05	*	
6.43	0.8	1.20	0.10	1.60	
12.53	0.05	0.43	0.13	1.00	

\* CV% values are not meaningful when average approaches zero.

## Correlation

Using a reference method based on the procedure of Van den Berg and Muller, linear regression analysis produced the following results:

Correlation Data	
Parameter	Data Observed
N	30
Range	0.10 – 10.8
Regression	$Y = 1.00x + 0.002$
Correlation	$r = 0.999$
$S_{y,x}$	0.14