

BECKMAN

Summary of Safety & Effectiveness IMMAGE™ Immunochemistry System Digoxin (DIG) Reagent

1.0 **Submitted By:**

K963062

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2.0 **Data Submitted:**

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3.0 **Device Name(s):**

3.1 **Proprietary Names**

IMMAGE™ Immunochemistry System Digoxin Reagent
Beckman Drug Calibrator 2

3.2 **Classification Names**

Digoxin immunological test system (21 CFR 866.5775)
Clinical toxicology calibrator (21 CFR 862.3200)

4.0 **Predicate Device(s):**

Behring Diagnostics N Latex RF, K942328
Abbott TDx Digoxin II Reagent, K882233

5.0 **Description:**

The IMMAGE System Digoxin (DIG) Reagent is designed for optimal performance on the IMMAGE Immunochemistry System. It is intended for use in the quantitative determination of digoxin concentrations in human serum and plasma samples.

6.0 **Intended Use:**

The IMMAGE Immunochemistry System Digoxin (DIG) Reagent, in conjunction with Beckman Drug Calibrator 2, is intended for use in the quantitative determination of digoxin in human serum and plasma samples by turbidimetric immunoassay. This assay is designed for use with the IMMAGE Immunochemistry System.

7.0 Comparison to Predicate(s):

The following table shows similarities and differences between the predicates identified in Section 4.0 of this summary.

Reagent	Aspect/Characteristic	Comments
Similarities		
DIG Reagent	Intended use for the measurement of digoxin at 37°C	Same as TDx Digoxin II Reagent
	Reagent measures digoxin in both human plasma and serum samples	Same as TDx Digoxin II Reagent
	Analytic Range of 0.2 to 5 ng/mL	Same as TDx Digoxin II Reagent
Differences		
DIG Reagent	Assay Type	IMMAGE System DIG Reagent uses turbidimetric inhibition immunoassay technology while the predicate uses fluorescence polarization immunoassay technology
	Sample Pretreatment	IMMAGE System DIG Reagent does not require sample pretreatment while the predicate requires sample pretreatment

8.0 Summary of Performance Data:

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to chemistry test systems already in commercial distribution. Equivalence is demonstrated through method comparison, stability, and imprecision experiments that relate results obtained from the Abbott Digoxin II Reagent to the IMMAGE DIG Reagent.

Method Comparison Study Results*
IMMAGE DIG Reagent vs. Abbott Digoxin II Reagent

IMMAGE DIG	Abbott Digoxin II	Correlation Coefficient (r)	Predicate
1.011 ± 0.037	0.047 ± 0.0016	0.978	Abbott TDx Digoxin II

* Deming regression analysis

Stability Study Results

Reagent	Product Claim
IMMAGE DIG	18 months shelf-life 14-day on board
Drug Calibrator 2	24 months shelf-life 14-day calibration

Estimated Within-Run Imprecision

Material	MEAN (U/mL)	SD (U/mL)	%CV	Number of Results
Level 1	0.87	0.042	4.8	15
Level 1	1.32	0.068	5.1	80
Level 2	2.63	0.079	3.0	80
Level 3	4.10	0.095	2.3	80

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.