

BECKMAN

K964009

Summary of Safety & Effectiveness IMMAGE™ Immunochemistry System Therapeutic Drug Monitoring Reagents [Gentamicin (GEN) and Tobramycin (TOB)]

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1.0 **Submitted By:**

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2.0 **Date Submitted:**

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3.0 **Device Name(s):**

3.1 **Proprietary Names**

IMMAGE™ Immunochemistry System Gentamicin (GEN) Reagent
IMMAGE™ Immunochemistry System Tobramycin (TOB) Reagent
Beckman Drug Calibrator 3 Plus

3.2 **Classification Names**

Gentamicin Test System (21 CFR §862.3450)
Tobramycin Test System (21 CFR §862.3900)
Calibrator (21 CFR §862.1150)

4.0 **Predicate Device(s):**

| IMMAGE System Reagent | Predicate | Manufacturer | Docket Number |
|--------------------------|---------------------------|----------------------------|---------------|
| Gentamicin (GEN) Reagent | TDx®** Gentamicin Reagent | Abbott* Laboratories, Inc. | K904226 |
| Tobramycin (TOB) Reagent | TDx Tobramycin Reagent | Abbott Laboratories, Inc. | K904226 |

*Abbott Laboratories, Abbott Park, IL 60064

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5.0 Description:

The IMMAGE Immunochemistry System (TDM) GEN and TOB Reagents in conjunction with Beckman Drug Calibrator 3 Plus, are intended for use in the quantitative determination of gentamicin and tobramycin concentrations respectively in human serum and plasma samples on Beckman's IMMAGE Immunochemistry System.

6.0 Intended Use:

The IMMAGE Immunochemistry System Gentamicin (GEN) reagent, when used in conjunction with the Beckman IMMAGE™ Immunochemistry Systems and Beckman Drug Calibrator 3 Plus, is intended for the quantitative determination of gentamicin in human serum or plasma by rate nephelometric inhibition immunoassay.

The IMMAGE Immunochemistry System Tobramycin (TOB) reagent, when used in conjunction with the Beckman IMMAGE™ Immunochemistry Systems and Beckman Drug Calibrator 3 Plus, is intended for the quantitative determination of tobramycin in human serum or plasma by rate nephelometric inhibition immunoassay.

Beckman Drug Calibrator 3 Plus, used in conjunction with IMMAGE reagents, is intended for use on Beckman's IMMAGE™ Immunochemistry Systems for the calibration of Gentamicin and Tobramycin test systems.

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 | | |
| IMMAGE System (GEN & TOB) Reagents | Intended use. | Same as Abbott TDx Reagents |
| | Liquid stable reagents. | |
| DIFFERENCES | | |
| IMMAGE System (GEN & TOB) Reagents | IMMAGE utilizes nephelometric inhibition immunoassay | Abbott TDx reagents utilize fluorescence polarization immunoassay |
| IMMAGE System (GEN & TOB) Reagents | Antibody source for IMMAGE GEN & TOB reagents is mouse. | Antisera source for TDx Gentamicin and Tobramycin is sheep. |

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 TDx Reagents to the IMAGE System Reagents.

**Method Comparison* Study Results
 IMAGE System GEN, TOB, PHY, and THE Reagents**

| Analyte | Slope | Intercept | r | n | Predicate Method |
|------------|-------|-----------|-------|-----|-----------------------|
| Gentamicin | 0.994 | -0.05 | 0.998 | 135 | Abbott TDx Gentamicin |
| Tobramycin | 1.009 | -0.12 | 0.996 | 94 | Abbott TDx Tobramycin |

* Deming Regression statistics used

Stability Study Results

| Reagent | Product Claim |
|-----------------|--|
| IMAGE GEN & TOB | 24 month shelf-life 14 day open container stability 14 day calibration stability |

Estimated Within-Run Imprecision

| Sample | Mean (µg/mL) | S.D. (µg/mL) | %C.V. | N |
|-------------------------|--------------|--------------|-------|----|
| Gentamicin (GEN) | | | | |
| Level 1 | 1.52 | 0.095 | 6.2 | 80 |
| Level 2 | 5.96 | 0.107 | 1.8 | 80 |
| Level 3 | 11.0 | 0.26 | 2.4 | 80 |

| Sample | Mean (µg/mL) | S.D. (µg/mL) | %C.V. | N |
|---------------------------------|--------------|--------------|-------|----|
| Tobramycin (TOB) Reagent | | | | |
| Level 1 | 1.5 | 0.073 | 4.9 | 80 |
| Level 2 | 5.93 | 0.098 | 1.7 | 80 |
| Level 3 | 10.9 | 0.23 | 2.1 | 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.