510K SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is: K060709

COMPANY/CONTACT PERSON

Seradyn, Inc
7998 Georgetown Road, Suite 1000
Indianapolis, IN 46268

JUN 15 2006

Establishment registration No: 1836010

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DATE PREPARED

March 14, 2006

Product Code: LCD

DEVICE NAME

Trade Name:	Multigent® Gentamicin
Common Name:	Enzyme Immunoassay, Gentamicin
Device Classification:	21 CFR 862.3450; Gentamicin Test System; Class II

INTENDED USE

The Multigent® Gentamicin assay is intended for the quantitative determination of Gentamicin in human serum or plasma on the Architect C8000 System.

LEGALLY MARKETED DEVICE TO WHICH EQUIVALENCY IS CLAIMED

Abbott TDx®/TDxFLx® Gentamicin (K904226)

DESCRIPTION OF DEVICE

The Multigent® Gentamicin assay system is a homogeneous assay utilizing particle agglutination technology and is based on the competitive binding principle. The assay consists of reagents R1: anti-gentamicin monoclonal antibody and R2: gentamicin-coated microparticles. A six-level set of Multigent® Gentamicin Calibrators (A through F) is used to calibrate the assay.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

	Device Multigent® Gentamicin	**Predicate** Abbott TDx®/TDxFLx® Gentamicin
Intended Use	The Multigent® Gentamicin assay is intended for the quantitative determination of Gentamicin in human serum or plasma on the Architect C8000 System.	The TDx®/TDxFLx® Gentamicin assay is a reagent system for the quantitative measurement of Gentamicin, an antibiotic drug in human serum or plasma.
Indications for Use	The results obtained are used in the diagnosis and treatment of Gentamicin overdose and in monitoring levels of Gentamicin to ensure appropriate therapy.	The measurements obtained are used in the diagnosis and treatment of Gentamicin overdose to ensure appropriate therapy.
Methodology	Homogeneous particle-enhanced turbidimetric immunoassay (particle agglutination)	Fluorescence Polarization Immunoassay (FPIA) technology.
Reagent Components	Two (2) reagent system: • Anti-Gentamicin Antibody Reagent (R1) in buffers containing stabilizers with sodium azide • Gentamicin-coated Microparticle Reagent (R2) in buffer containing stabilizers with sodium azide	Three (3) reagent system: • Pretreatment Solution (P) Surfactant in buffer containing protein stabilizer and sodium azide. • S Gentamicin Antiserum (Sheep) in buffer with protein stabilizer and Sodium azide. • T Gentamicin Fluorescein Tracer in buffer with protein stabilizer, surfactant and Sodium azide
Calibration	Multigent® Gentamicin Calibrators – six levels	Gentamicin Calibrators – six levels

SUMMARY OF CLINICAL TESTING

Precision

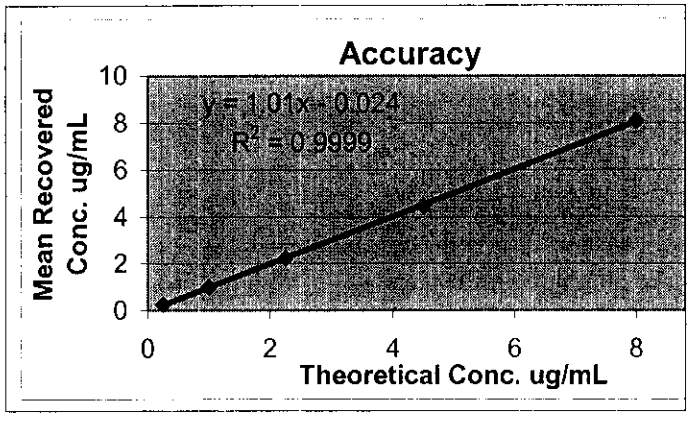
A precision study was performed using the Clinical and Laboratory Standards Institute (CLSI) Guideline NCCLS *EP5: Evaluation of Precision Performance of Clinical Chemistry Devices.*

			Within Run		**Between Day**		**Between Run**		**Total**	
	N	**Mean µg/mL**	**SD**	**CV (%)**	**SD**	**CV (%)**	**SD**	**CV (%)**	**SD**	**CV (%)**
Low Control	80	2.68	0.08	2.93	0.12	4.37	0.06	2.17	0.15	5.69
Mid Control	80	6.47	0.07	1.09	0.12	1.91	0.07	1.07	0.16	2.44
High Control	80	9.41	0.14	1.53	0.13	1.34	0.07	0.70	0.20	2.15

Accuracy

Accuracy was determined using a procedure described in CLSI Guideline NCCLS EP6-A. The samples were analyzed in triplicate using the Multigent® Gentamicin assay. A mean of the replicates for each sample was determined and percent recovery calculated.

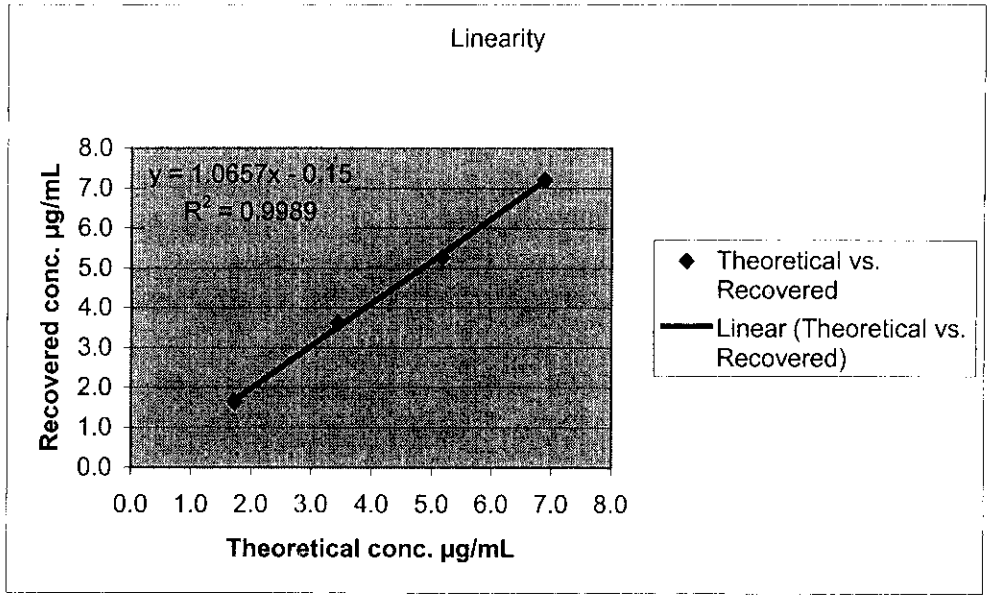
THEORETICAL CONC. (µg/mL)	Rep 1	Rep 2	Rep 3	Mean	SD	CV	% Recovery Acceptance Criteria: 100±10% or 0.1 µg/mL
0.25	0.23	0.28	0.26	0.26	0.025	9.82	102.67%
1.00	1.02	0.99	0.98	1.00	0.021	2.09	99.67%
2.25	2.24	2.22	2.21	2.22	0.015	0.69	98.81%
4.50	4.44	4.55	4.42	4.47	0.070	1.57	99.33%
8.00	8.12	7.99	8.15	8.09	0.085	1.05	101.08%
Mean Percent Recovery							100.31%



Linearity

A Gentamicin linearity standard was serially diluted and run in triplicate using the Multigent® Gentamicin assay. A mean of the replicates for each sample was determined and percent recovery was calculated.

THEORETICAL CONC. (MG/ML)	Rep 1	Rep 2	Rep 3	Mean Recovered Conc.	SD	%CV	% Recovery Acceptance Criteria: 100±10%
6.88	7.14	7.31	7.14	7.20	0.098	1.36	104.60
5.16	5.20	5.23	5.39	5.27	0.102	1.94	102.20
3.44	3.50	3.65	3.70	3.62	0.104	2.88	105.14
1.72	1.59	1.67	1.66	1.64	0.044	2.66	95.35
Mean Percent Recovery							101.82



Sensitivity

The Analytical Sensitivity or Least Detectable Dose (LDD) of the assay is defined as the concentration at which the lowest concentration is distinguishable from zero with 95% confidence.

A calibration curve was run. Calibrator A (0 µg/mL) was run for a total of 20 replicates. The LDD was calculated using the following formula:

$$\text{LDD} = \frac{2 \times (\text{SD rate of Zero Cal})}{(\text{rate of Zero Cal} - \text{rate of } 1^{st} \text{ non-zero cal})} \times (\text{Conc of } 1^{st} \text{ non-zero cal})$$

Where:

- Zero Cal = Cal A (0 µg/mL)
- SD Zero Cal = standard deviation of the multiple determinations
- 1st Non-Zero Cal = Cal B (0.5 µg/mL)

The average LDD is 0.09 µg/mL, supporting a claim of 0.1µg/mL.

Specificity

The Multigent® Gentamicin assay utilizes a mouse derived (ascites) Gentamicin monoclonal antibody directed against Gentamicin. There are no metabolites of Gentamicin.

Interferences

Interference were assessed using the Dose Response Method.

A. Endogenous Substances

Bilirubin

A Bilirubin Stock was prepared by adding bilirubin to normal human serum at 400 mg/dL. Dilutions were then made to produce bilirubin levels of 20, 40, and 60mg/dL. An Analyte Stock was prepared by adding Gentamicin to 10 mL of normal human serum. A 1:100 dilution of the Analyte Stock was prepared using each level of bilirubin. The control was prepared by diluting the Analyte Stock 1:100 with normal human serum. Each level was assayed. Only the 20 mg/dL data is shown.

Hemoglobin

A Hemoglobin stock solution was prepared from a human blood hemolysate. The hemolysate was added to normal human serum at 1.0 and 2.0g/dL hemoglobin. The Analyte Stock from above was diluted 1:100 with each level of hemoglobin. A control was prepared using normal human serum. Each level was assayed. Only the 2g/dL data is shown.

Triglyceride

A 1691 mg/dL patient pool was spiked with Gentamicin stock. The spiked sample was run in triplicate.

Total Protein

A 12 g/dL stock of Human Serum Albumin (HSA) in saline was prepared. The sample was spiked with Gentamicin stock. The spiked sample was run in triplicate.

Rheumatoid Factor

A 582 IU patient pool was spiked with Gentamicin stock and run in triplicate.

Results are shown in the table Below.

ENDOGENOUS INTERFERING SUBSTANCE

Interfering Substance	Interferent Concentration	N	Target (No Interferent) µg/mL	Mean Recovery µg/mL	% Recovery Acceptance Criteria: 100±10%
Bilirubin	20mg/dL	3	3.44	3.42	99.52
Hemoglobin	2g/dL	2	3.44	3.38	98.26
Triglyceride	1691 mg/dL	3	3.44	3.30	95.83
Total Protein	12 g/dL	3	3.44	3.21	93.41
Rheumatoid Factor	582 IU	3	2.46	3.26	132.34

B. HAMA

As with any assay employing mouse antibodies, the possibility exists for interference by human anti-mouse antibodies (HAMA) in the sample, which could cause falsely elevated results.

For this study, HAMA Type-1 and Type-2 samples were spiked with Gentamicin. The Mean Recovery for each (Type-1 and Type-2) of the duplicate HAMA samples was compared to the Mean Recovery of each respective Control (normal human serum).

Results are shown in the table below.

HAMA

	Rep 1 µg/mL	Rep 2 µg/mL	Mean Recovery µg/mL	SD	CV	% Recovery Acceptance Criteria: 100±10%
HAMA Type-1	3.31	3.29	3.30	0.014	0.43	99.10
Control	3.40	3.26	3.33	0.099	2.97	100.00
HAMA Type-2	3.08	3.07	3.08	0.007	0.23	93.34
Control	3.40	3.26	3.33	0.099	2.97	100.00

C. Common Co-Administered Drugs

Gentamicin was spiked into normal human serum. Co-Administered drug stock concentrates were prepared at 100X or 10X of the initial concentration tested. A test aliquot was then prepared for each cross-reactant by combining 99 (or 9) volumes of the Gentamicin-spiked whole serum with 1 volume of the 100X or 10X cross-reactant stock. Additional dilutions were prepared as needed.

A control aliquot was prepared for each solvent system by combining 99 (or 9) volumes of the stock analyte solution with 1 volume of normal human whole serum, where appropriate, with the amount of the corresponding solvent used for the cross-reactant concentrate (no cross-reactant).

The test samples and control samples were then assayed in duplicate. Percent cross- reactivity was calculated using the following formula:

$$\text{Percent Cross-Reactivity} = ((D_A - D_T) / C) \times 100$$

Where:
D_T = average observed concentration of the control solution
D_A = average of the observed concentration of the cross-reactant test solution
C = concentration at which the cross-reactant is tested

Tabulated data is shown in the table below.

Tabulated Data

Cross-reactant Drug	Conc. Tested µg/mL	Percent Cross-Reactivity
5-Fluorocytosine	30	0.5333
Acetaminophen	200	ND
Acetyl Cysteine	1000	ND
Acetylsalicylic Acid	300	ND
Amikacin	300	ND
Amphotericin B	100	ND
Ampicillin	50	ND
Ascorbic Acid	30	-0.2333
Carbenicillin	2500	ND
Cefamandole Naftate	250	ND
Cefoxitin	1000	ND
Cephalexin	320	ND
Cephalosporin C	1000	ND
Cephalothin	1000	ND
Chloramphenicol	250	ND
Clindamycin	2000	ND
Cyclosporin	6000	ND
Erythromycin	500	ND
Ethacrynic Acid	400	ND
Furosemide	100	ND
Fusidic Acid	1000	ND
Ibuprofen	7000	ND
Kanamycin A	400	0.1017
Kanamycin B	400	ND
Levodopa	1000	ND
Lincomycin	2000	ND
Methicillin	200	ND
Methotrexate	50	ND
Methylprednisolone	200	ND
Metronidazole	1000	ND
Neomycin	1000	ND
Netilmicin	125	0.2533
Oxytetracycline	2000	ND
Penicillin V	10	ND
Phenylbutazone	1000	ND
Prednisolone	12	-0.2920
Rifampin	50	ND
Sisomicin	10	50.35
Spectinomycin	100	ND
Streptomycin	400	ND
Sulfadiazine	1000	ND
Sulfamethoxazole	400	ND
Tetracycline	2000	ND
Theophylline	200	ND
Ticarcillin	100	-0.4400
Tobramycin	100	0.1633
Trimethoprim	20	0.3000
Vancomycin	400	ND

*ND = Not Detected

D. Anticoagulants

Studies were conducted to determine the performance characteristics of the assay for both serum and plasma samples containing Gentamicin.

Blood was drawn from at least ten healthy donors (no Gentamicin therapy) for each tube type listed below:

- plastic K2 EDTA tube
- glass K3 EDTA tube
- glass Plasma separator lithium heparin tube
- glass sodium heparin tube
- glass lithium heparin tube
- glass serum separator tube
- plastic tube with clot activator
- glass tube; no additive (served as the control)
- plastic tube; no additive

All tubes were processed per the manufacturers instructions. The serum or plasma was removed from the collection tubes and aliquoted into new tubes for testing. Serum or plasma from each tube type was spiked with Gentamicin. The samples were analyzed on the Architect C8000 analyzer in duplicate. Baseline results were obtained on day zero for each type of tube.

The results indicate that there is no significant difference between the recovery of Gentamicin in serum or plasma. The collection tubes evaluated show no adverse effects on the recovery of Gentamicin, within the experimental error for the spiking study.

A claim for assay application to both serum and plasma samples is thus supported.

Method Comparison

A study was conducted according to CLSI Guideline NCCLS *EP9-A2: Method Comparison and Bias Estimation Using Patient Samples* to compare accuracy of recovery of Gentamicin in serum assayed by the Multigent® Gentamicin assay to the Abbott TDx®/TDxFLx® Gentamicin assay.

Serum and plasma samples, ranging from 0.78 to 9.02µg/mL Gentamicin, were first tested using Abbott's TDx Gentamicin assay. The same samples were then tested by the Multigent® Gentamicin assay on the Architect C8000 analyzer.

Mean values for the Abbott TDx®/TDxFLx® Gentamicin assay reference method were plotted against those for the Multigent® Gentamicin assay on the Architect C8000 (Figure 3). The results, using Passing – Bablok parameters, are:

N = 55
Slope = 1.165
y-intercept = -0.719
R = 0.996
R^2 = 0.992

Results show excellent correlation between the two assays.

On-Board Stability

1) Calibration Curve stability

Calibration curve stability of a period of 28 days is supported by the data.

2) Reagent On-Board Stability

A 40 day on-board reagent stability claim is supported by the data.

CONCLUSION

The Multigent® Gentamicin assay has been shown to be substantially equivalent to the Abbott TDx®/TDxFLx® Gentamicin assay. The performance testing verifies that the device functions as intended and that design specifications have been satisfied.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 15 2006

Earl E. Knight III, MPA
Regulatory Affairs Associate
Seradyn, Inc.
7998 Georgetown Road
Suite 1000
Indianapolis, IN 46268-5260

Re: k060709
Trade/Device Name: Multigent® Gentamicin
Regulation Number: 21 CFR§862.3450
Regulation Name: Gentamicin test system
Regulatory Class: Class II
Product Code: LCD
Dated: May 23, 2006
Received: May 24, 2006

Dear Mr. Knight:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Multigent® Gentamicin

Indications for Use: k060709

The Multigent Gentamicin assay is intended for the quantitative determination of Gentamicin in human serum or plasma on the Architect C8000 System.

The results obtained are used in the diagnosis and treatment of gentamicin overdose and in monitoring levels of gentamicin to help ensure appropriate therapy.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Office of In Vitro Diagnostic Device

k060709