APR - 1 2005

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: K050419

COMPANY/CONTACT PERSON

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DATE PREPARED

February 17, 2005

DEVICE NAME

Trade Name:	QMS® Vancomycin
Common Name:	Vancomycin Test System
Device Classification:	21 CFR 862.3950; Class II

INTENDED USE

The QMS® Vancomycin assay is intended for the quantitative determination of vancomycin in human serum or plasma on the Hitachi 717 analyzer.

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

LEGALLY MARKETED DEVICE TO WHICH EQUIVALENCY IS CLAIMED

TDX® Vancomycin (K813218)

DESCRIPTION OF DEVICE

The QMS® Vancomycin assay is a homogeneous particle-enhanced turbidimetric immunoassay. The assay is based on competition between drug in the sample and drug coated onto a microparticle for antibody binding sites of the vancomycin antibody reagent. The vancomycin-coated microparticle reagent is rapidly agglutinated in the presence of the anti-vancomycin antibody reagent and in the absence of any competing drug in the sample. The rate of absorbance change is measured photometrically, and is directly proportional to the rate of agglutination of the particles. When a sample containing vancomycin is added, the agglutination reaction is partially inhibited, slowing down the rate of absorbance change. A concentration-dependent classic agglutination inhibition curve can be obtained, with maximum rate of agglutination at the lowest vancomycin concentration and the lowest agglutination rate at the highest vancomycin concentration.

The assay consists of reagents R1: vancomycin monoclonal antibody and R2: vancomycin-coated microparticles. A six-level set of QMS® Vancomycin Calibrators (A through F) is used to calibrate the assay.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

	Device Seradyn QMS® Vancomycin	**Predicate** Abbott TDx®/TDxFLx® Vancomycin
Intended Use	The QMS® Vancomycin assay is intended for the quantitative determination of vancomycin in human serum or plasma on the Hitachi 717 analyzer.	The TDx/TDxFLx Vancomycin assay is a reagent system for the quantitative measurement of vancomycin, an antibiotic drug, in serum or plasma.
Indications for Use	The results obtained are used in the diagnosis and treatment of vancomycin overdose and in monitoring levels of vancomycin to ensure appropriate therapy.	The measurements obtained are used in the diagnosis and treatment of vancomycin overdose and in monitoring levels of vancomycin to ensure appropriate therapy.
Methodology	Homogeneous particle-enhanced turbidimetric immunoassay (particle agglutination)	Fluorescence Polarization Immunoassay (FPIA)
Reagent Components	Two (2) reagent system: • Anti-Vancomycin Antibody Reagent (R1) in buffers containing protein stabilizers • Vancomycin-coated Microparticle Reagent (R2) in buffer containing surfactant as stabilizers with sodium azide	Three (3) Reagent System: • Vancomycin Antiserum in buffer with protein stabilizers • Vancomycin Fluorescein Tracer in buffer containing surfactants and protein stabilizers with sodium azide • Pretreatment Solution. Surfactants in buffer containing protein stabilizers with sodium azide
Calibration	Seradyn QMS Vancomycin Calibrators - six levels	TDx/TDxFLx Vancomycin Calibrators - six levels
Assay Range	0 - 100 µg/mL	0 - 100 µg/mL

SUMMARY OF CLINICAL TESTING

Precision

A precision study was performed using the National Committee for Clinical Laboratory Standards (NCCLS) guideline *EP5-A: Evaluation of Precision Performance of Clinical Chemistry Devices.* Representative results are shown below.

			Within Run		**Between Run**		**BETWEEN DAY**		**Total**	
	N	**Mean**	**SD**	**CV (%)**	**SD**	**CV (%)**	**SD**	**CV (%)**	**SD**	**CV (%)**
Low Control	80	7.57	0.27	3.59	0.43	5.70	0.43	5.72	0.70	8.84
Mid Control	80	20.79	0.51	2.44	0.69	3.30	0.97	4.66	1.29	6.21
High Control	80	33.65	0.80	2.37	1.19	3.54	0.95	2.83	1.72	5.12

Accuracy

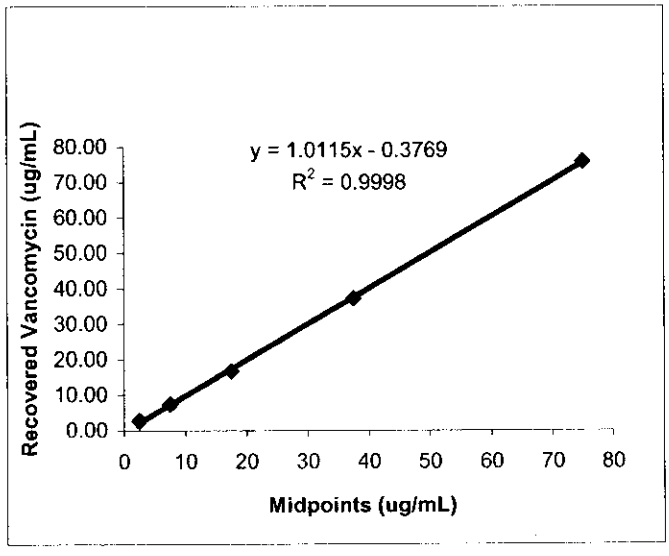
Accuracy by Recovery was determined by spiking USP traceable vancomycin into human serum negative for the drug to achieve concentrations across the assay range. The samples were analyzed in triplicate with the QMS Vancomycin assay. Representative results are shown below.

THEORETICAL CONC. (µG/ML)	Rep 1	Rep 2	Rep 3	Mean Recovered Conc.	SD	CV	% Recovery
100.00	93.50	95.68	95.87	95.02	1.32	1.39	95.02
75.00	73.82	76.14	69.76	73.24	3.23	4.41	97.65
50.00	52.45	50.66	53.64	52.25	1.50	2.87	104.50
37.50	42.15	38.36	38.60	39.70	2.12	5.35	105.88
25.00	27.30	28.71	26.95	27.65	0.93	3.37	110.61
17.50	16.53	18.45	17.36	17.45	0.96	5.52	99.70
10.00	9.20	9.39	9.22	9.27	0.10	1.13	92.70
7.50	6.79	6.93	6.78	6.83	0.08	1.23	91.11
5.00	5.11	4.89	4.90	4.97	0.12	2.50	99.33
						Mean Percent Recovery	**99.61**

Linearity

Linearity by Dilution was determined by a study based on the NCCLS guideline *EP6-A: Evaluation of the Linearity of Quantitative Measurement*. Representative results are shown below.

THEORETICAL CONC. (µg/mL)	Rep 1	Rep 2	Rep 3	Mean Recovered Conc.	SD	CV	% Recovery
75.00	76.68	74.77	75.85	75.77	0.96	1.26	101.02
37.50	37.45	36.86	37.30	37.20	0.31	0.82	99.21
17.50	17.03	16.54	16.68	16.75	0.25	1.51	95.71
7.50	7.37	7.36	7.25	7.33	0.07	0.91	97.69
2.50	3.15	2.64	2.72	2.68	0.06	2.11	107.20
						Mean Percent Recovery	**100.17**



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.

The LDD was calculated using the following formula:

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

Where:

- Zero Cal = Cal A (0µg/mL)
- SD Zero Cal = standard deviation of the duplicate determinations
- 1st Non-Zero Cal = Cal B (5µg/mL)

The LDD was determined to be 0.46 µg/mL, supporting a claim of 0.55 µg/mL.

Specificity

In vivo, vancomycin degrades to its metabolite CDP-I (crystalline degradation product-I).

Percent cross-reactivity was tested with the metobolite at 100 µg/mL in serum containing 25 µg/mL vancomycin and was determined according to NCCLS guidance *EP7-A: Interference Testing in Clinical Chemistry.*

Results show that CDP-I has <5% cross-reactivity.

Interferences

Interference studies were conducted using NCCLS Guideline *EP7-A: Interference Testing in Clinical Chemistry.*

1) Endogenous Substances

The following compounds, when tested at the concentrations indicated, resulted in less than 10% error in detecting vancomycin.

Interfering Substance	Interferent Concentration	N	Target (No Interferent) µg/mL	Mean Recovery µg/mL	% Recovery
Albumin	10 g/dL	3	26.61	24.92	93.64
Bilirubin	70 mg/dL	3	26.98	27.00	100.07
Cholesterol	500 mg/dL	3	26.61	25.97	97.58
IgG (Gamma Globulin)	6 g/dL	3	26.61	25.90	97.34
Hemoglobin	1150 mg/dL	3	23.12	21.18	91.64
Heparin	500 units/mL	3	26.61	26.46	99.44
Triglyceride	1000 mg/dL	3	10.16	9.41	92.62
Rheumatoid Factor	1100 IU/mL	3	7.19	6.70	93.23

2) 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.

HAMA Type-1 and Type-2 samples were spiked to achieve 25 µg/mL vancomycin. The mean recovery for each (Type-1 and Type-2) of the triplicate HAMA samples was compared to the mean recovery of each respective Control (normal human serum). Representative results are shown below.

	Rep 1 µg/mL	Rep 2 µg/mL	Rep 3 µg/mL	Mean Recovery µg/mL	SD	CV	% Recovery
HAMA Type-1	29.45	28.51	26.86	28.27	1.31	4.63	105.31
Control	27.75	27.05	25.74	26.85	1.02	3.80	
HAMA Type-2	29.36	30.20	29.43	29.66	0.47	1.58	103.91
Control	29.67	28.13	27.84	28.55	0.98	3.43	

3) Common Co-Administered Drugs

Cross-reactivity was tested with drugs that are routinely administered with vancomycin. Testing also determined whether these compounds affect the quantitation of vancomycin concentrations. Cross-reactants were analyzed at 500µg/mL in a vancomycin spiked serum pool at 25µg/mL. The samples were assayed and the vancomycin concentrations of the spiked samples were compared to a control serum. All of the following cross-reactants showed <0.3% cross-reactivity.

Cross-Reactants

Acetaminophen	Ethambutol	Oxytetracycline
Amikacin	5-Fluorocytosine	Penicillin G
Amphotericin B	Furosemide	Penicillin V
Ampicillin	Fusidic Acid	Phenacetin
Bendroflumethiazide	Gentamicin	Nitrofurantoin
Caffeine	Hydrochlorothiazide	Prednisolone
Carbenicillin	Ibuprofen	Prednisone
Cefamandole Nafate	Isoniazide	Rifampicin
Cefazolin	Kanamycin A	Salicyclic Acid
Cephalexin	Kanamycin B	Sisomycin
Cephalosporin C	Lincomycin	Spectinomycin
Cephalothin	Methotrexate	Sulfadiazine
Chloramphenicol	Methylprednisolone	Sulfamethoxazole
Chlorothiazide	Nalidixic Acid	Sulfisoxazole
Clindamycin	Naproxen	Tetracycline
Erythromycin	Neomycin Sulfate	Tobramycin
Ethacrynic Acid	Niacin	Trimethoprim

4) Structurally Related Drug

The cross-reactivity of the QMS® Vancomycin antibody to teicoplanin, a structurally similar compound, was examined. Teicoplanin was spiked into human serum containing 25µg/mL vancomycin and tested in the QMS Vancomycin assay. Representative results are shown below.

$$\% \text{ cross-reactivity} = \frac{\text{measured concentration of vancomycin}}{\text{teicoplanin concentration}} \times 100$$

Teicoplanin Concentration (µg/mL)	% Cross- Reactivity
100	0.68
50	0.29
25	0.20
10	0.03

Method Comparison

A study was conducted according to NCCLS Guideline *EP9-A: Method Comparison and Bias Estimation Using Patient Samples* to compare accuracy of recovery of vancomycin in serum assayed by the QMS® Vancomycin assay to the Abbott TDx® Vancomycin assay.

Serum samples, ranging from 0.04 to 100 µg/mL vancomycin, were first tested using Abbott's TDx Vancomycin assay. The same samples were then tested by the QMS Vancomycin assay on Hitachi 717 analyzers using two reagent lots on two separate calibration curves.

Mean values for the TDx reference method were plotted against those for the QMS on Hitachi 717. The results using Passing-Bablok Linear Regression are:

N =146
Slope = 1.031
y-intercept = 1.115
R^2= 0.970

Results show excellent correlation between the two assays.

On-Board Stability

1) Calibration Curve stability

Calibration curve stability for a period of 31 days is supported by the data.

2) Reagent On-Board Stability

A 62 day on-board reagent stability claim is supported by the data.

CONCLUSION

As summarized above, the QMS® Vancomycin assay is substantially equivalent to the Abbott TDx®/TDxFLx® Vancomycin assay. Substantial equivalence has been demonstrated through performance testing to verify that the device functions as intended and that design specifications have been satisfied.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR - 1 2005

Mr. Jack Rogers, MS, RAC
Manger of Regulatory Affairs
Seradyn, Inc.
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Re: k050419
Trade/Device Name: QMS® Vancomycin
Regulation Number: 21 CFR 862.3950
Regulation Name: Vancomycin test system
Regulatory Class: Class II
Product Code: LEH
Dated: February 17, 2005
Received: February 18, 2005

Dear Mr. Rogers

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,

Jean M. Cooper MS, DVM

Jean M. Cooper, MS, D.V.M.
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): K050419

Device Name: QMS® Vancomycin

Indications for Use:

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

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

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K050419