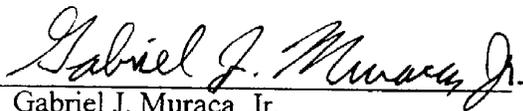


FEB 15 2000

SUMMARY OF SAFETY AND EFFECTIVENESS

This section contains performance comparisons for 8 clinical methods. For each method, ADVIA 1650 was compared to a similar device (or devices) that was granted clearance of substantial equivalence. The table below lists the predicate devices and part numbers.

Method	ADVIA 1650 Reagent Part #	Specimen Type	Predicate Device Name	Predicate Device Reagent Part #
Apolipoprotein A-1	B01-4154-01	Serum	Behring Nephelometer	OUED
Apolipoprotein B	B01-4155-01	Serum	Behring Nephelometer	OSAN
CO ₂	B01-4146-01	Serum	Technicon DAX	T09B-100-06
CRP	B01-4158-01	Serum	Behring Nephelometer	OQIY21
IgA	B01-4149-01	Serum	Behring Nephelometer	OSAR
IgG	B01-4150-01	Serum	Behring Nephelometer	OSAS
IgM	B01-4151-01	Serum	Behring Nephelometer	OSAT
Transferrin	B01-4152-01	Serum	Behring Nephelometer	OSAX



Gabriel J. Muraca, Jr.
 Manager, Regulatory Affairs
 Bayer Corporation
 511 Benedict Ave.
 Tarrytown, NY 10591-5097

1/3/2000
 Date

1. APO A-1

SUMMARY OF SAFETY AND EFFECTIVENESS

Apolipoprotein A-1 Method for the Bayer ADVIA 1650 (mg/dL)

Intended Use

This *in vitro* diagnostic assay is intended to measure apolipoprotein A-1 concentration in human serum and plasma on the ADVIA® 1650 Chemistry System. Such measurements are used to aid in the assessment of risk for arteriosclerosis and coronary artery disease.

Imprecision

ADVIA 1650

Specimen Type	Level	Total CV%
Serum	77.6	4.5
Serum	216.4	4.1

Behring Nephelometer=Serum

Level	Between Day CV%
145.3	5.7

Correlation (Y=ADVIA 1650, X=comparison system)

Specimen type: Site	Comparison System (X)	N	Regression Equation	Syx	R	Sample Range
Serum: ARI	BEHRING	78	$Y=0.70X-1.48$	5.49	0.986	48-273
Plasma(y), Serum(x)	ADVIA 1650	72	$Y=0.99X-0.38$	2.10	0.996	89.7-206.8

Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	Analyte Conc.	Effect	
			Conc.	%
Bilirubin	30	42.8	0.78	1.9%
Hemoglobin	525	40.3	1.77	4.2%
Lipids(Trig)	650	42.1	0.04	0.1%
Bilirubin	30	126.3	1.30	1.0%
Hemoglobin	525	124.6	0.47	0.4%
Lipids(Trig)	650	122.1	2.07	1.7%

Analytical Range

The analytical range for this method extends from 15 mg/dL to the APO A-1 concentration level in Apolipoprotein Calibrator Level 4.

Expected Values

79 mg/dL to 187 mg/dL

2. APO B

SUMMARY OF SAFETY AND EFFECTIVENESS

Apolipoprotein B Method for the Bayer ADVIA 1650 (mg/dL)

Intended Use

This *in vitro* diagnostic assay is intended to measure apolipoprotein B concentration in human serum and plasma on the ADVIA® 1650 Chemistry System. Such measurements are used to aid in the assessment of risk for arteriosclerosis and coronary artery disease.

Imprecision

ADVIA 1650

Specimen Type	Level	Total CV%
Serum	29	5.7
Serum	110.5	3.3

Behring Nephelometer=Serum

Level	Between Day CV%
108	2.4

Correlation (Y=ADVIA 1650, X=comparison system)

Specimen type: Site	Comparison System (X)	N	Regression Equation	Syx	R	Sample Range
Serum: Tarrytown	BEHRING	59	$Y=1.03X+0.53$	3.66	0.993	42.1-172.8
Plasma(y), Serum(x)	ADVIA 1650	71	$Y=1.00X-1.67$	1.74	0.997	49.6-157.8

Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	Analyte Conc.	Effect	
			Conc.	%
Bilirubin	30	42.8	0.08	0.2
Hemoglobin	525	41.7	0.97	2.3
Bilirubin	30	163.6	1.61	1.0
Hemoglobin	525	159.5	4.06	2.5

Analytical Range

The analytical range for this method extends from 15 mg/dL to the APO B concentration level in Apolipoprotein Calibrator Level 4.

Expected Values

Males: 46 mg/dL to 174 mg/dL

Females: 46 mg/dL to 142 mg/dL

3. CO₂

SUMMARY OF SAFETY AND EFFECTIVENESS

Carbon Dioxide Method for the Bayer ADVIA 1650 (mg/dL)

Intended Use

This *in vitro* diagnostic assay is intended to measure carbon dioxide concentration in human serum and plasma on the ADVIA[®] 1650 Chemistry System. Such measurements assist in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.

Imprecision

ADVIA 1650

Specimen Type	Level	Total CV%
Serum	12.2	6.7
Serum	25.6	4.6

Technicon DAX=Serum

Level	Total CV%
13.5	6.3
23.8	5.3
27.4	4.5

Correlation (Y=ADVIA 1650, X=comparison system)

Specimen type: Site	Comparison System (X)	N	Regression Equation	Syx	R	Sample Range
Serum: Tarrytown	DAX	146	Y=0.90X-0.86	1.26	0.963	11.0-36.0
Plasma(y), Serum(x)	ADVIA 1650	79	Y=0.94X+0.08	1.98	0.839	14.2-27.0

Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	Analyte Conc.	Effect	
			Conc.	%
Bilirubin	30	17.1	0.8	5.4%
Hemoglobin	525	13.9	0.9	6.4%
Lipids(Trig)	650	14.1	0.4	2.8%
Bilirubin	30	34.0	2.8	8.5%
Hemoglobin	525	33.5	0.6	2.0%
Lipids(Trig)	650	32.9	0.0	0.0%

Analytical Range

10 – 40 mEq/L

Expected Values

Serum: 23 - 29 mEq/L

Plasma: 22 - 28 mEq/L

4. CRP

SUMMARY OF SAFETY AND EFFECTIVENESS

C-Reactive Protein Method for the Bayer ADVIA 1650 (mg/L)

Intended Use

This *in vitro* diagnostic assay is intended to measure C-reactive protein concentration in human serum on the ADVIA[®] 1650 Chemistry System. Such measurements are used in the evaluation of the amount of injury to body tissues. This test is useful in following the progress of rheumatic fever, rheumatoid arthritis, myocardial infarction and malignancies.

Imprecision

ADVIA 1650

Specimen Type	Level	Total CV%
Serum	5	13.6
Serum	42	4.6

Behring Nephelometer=Serum

Levels	Between Day CV%
10,15,25,45,60	2.6 to 5.7

Correlation (Y=ADVIA 1650, X=comparison system)

Specimen type: Site	Comparison System (X)	N	Regression Equation	Syx (mg/L)	R	Sample Range (mg/L)
Serum: Tarrytown	BEHRING	56	Y=0.96X-3.33	2.34	0.984	5.4-67.7

Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	Analyte Conc.	Effect	
			Conc.	%
Bilirubin	30	9.6	3.06	24.2%
Hemoglobin	525	11.3	1.37	10.8%
Lipids(Trig)	60*	12.5	0.20	1.4%
Bilirubin	30	39.1	0.58	1.5%
Hemoglobin	525	37.0	2.67	6.7%
Lipids(Trig)	650	25.6	14.0	35.4%

* Levels tested above 60 mg/dL caused a high interference and no results were generated.

Analytical Range

The analytical range for this method extends from 5 mg/L to the level in CRP Calibrator Level 5.

Expected Values

Less than 10 mg/L

5. IgA

SUMMARY OF SAFETY AND EFFECTIVENESS

Immunoglobulin A Method for the Bayer ADVIA 1650 (mg/dL)

Intended Use

This *in vitro* diagnostic assay is intended to measure immunoglobulin A concentration in human serum and plasma on the ADVIA® 1650 Chemistry System. Such measurements are used to aid in the diagnosis of abnormal protein metabolism and the body's inability to resist infectious agents.

Imprecision

ADVIA 1650

Specimen Type	Level	Total CV%
Serum	150.5	2
Serum	405.7	2

Behring Nephelometer=Serum

Level	Between Day CV%
296	3.5

Correlation (Y=ADVIA 1650, X=comparison system)

Specimen type: Site	Comparison System (x)	N	Regression Equation	Sy.x (mg/dL)	R	Sample Range (mg/dL)
Serum: Tarrytown	BEHRING	74	$y=1.02X-1.34$	14.28	0.997	103-1110
EDTA Plasma(y), Serum(x)	ADVIA 1650	68	$y=0.92X+1.48$	13.99	0.986	85.7-517.9
Heparin Plasma(y), Serum(x)	ADVIA 1650	69	$y=0.97X+2.08$	19.42	0.975	82.9-517.9

Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	Analyte Conc.	Effect	
			Conc.	%
Bilirubin	30	131.6	17.7	15.6%
Hemoglobin	525	142.9	29.1	25.5%
Lipids(Trig)	650	367.1	253.2	222.4%
Bilirubin	30	362.5	14.5	4.2%
Hemoglobin	525	379.9	31.9	9.2%
Lipids(Trig)	650	629.8	281.8	81.0%

Analytical Range

The analytical range for this method extends from 15 mg/dL to the IgA concentration level in Specific Protein Reference Serum Calibrator Level 5.

Expected Values

40 to 350 mg/dL

6. IgG

SUMMARY OF SAFETY AND EFFECTIVENESS

Immunoglobulin G Method for the Bayer ADVIA 1650 (mg/dL)

Intended Use

This *in vitro* diagnostic assay is intended to measure immunoglobulin G concentration in human serum and plasma on the ADVIA® 1650 Chemistry System. Such measurements are used to aid in the diagnosis of abnormal protein metabolism and the body's inability to resist infectious agents.

Imprecision

ADVIA 1650

Specimen Type	Level	Total CV%
Serum	926.7	2.4
Serum	2946	1.7

Behring Nephelometer=Serum

Level	Between Day CV%
1317	2.7

Correlation (Y=ADVIA 1650, X=comparison system)

Specimen type: Site	Comparison System (x)	N	Regression Equation	Sy.x (mg/dL)	R	Sample Range (mg/dL)
Serum: Tarrytown	BEHRING	60	$y=1.04X-32.0$	78.46	0.999	574-5392
EDTA Plasma(y), Serum(x)	ADVIA 1650	72	$y=0.97X-30.0$	51.13	0.974	527-1537
Heparin Plasma(y), Serum(x)	ADVIA 1650	73	$y=0.97X+11.4$	63.28	0.962	527-1537

Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	Analyte Conc.	Effect	
			Conc.	%
Bilirubin	30	719.5	27.7	4.0%
Hemoglobin	525	723.0	31.2	4.5%
Lipids(Trig)	650	1034.3	342.5	49.5%
Bilirubin	30	2153.9	64.2	3.1%
Hemoglobin	525	2149.6	59.9	2.9%
Lipids(Trig)	650	2553.3	463.6	22.2%

Analytical Range

The analytical range for this method extends from 85 mg/dL to the IgG concentration level in Specific Protein Reference Serum Calibrator Level 5.

Expected Values

650 to 1600 mg/dL

7. IgM

SUMMARY OF SAFETY AND EFFECTIVENESS

Immunoglobulin M Method for the Bayer ADVIA 1650 (mg/dL)

Intended Use

This *in vitro* diagnostic assay is intended to measure immunoglobulin M concentration in human serum and plasma on the ADVIA® 1650 Chemistry System. Such measurements are used to aid in the diagnosis of abnormal protein metabolism and the body's inability to resist infectious agents.

Imprecision

ADVIA 1650

Specimen Type	Level	Total CV%
Serum	54.8	7.4
Serum	172.8	3.7

Behring Nephelometer=Serum

Level	Between Day CV%
117	1.9

Correlation (Y=ADVIA 1650, X=comparison system)

Specimen type: Site	Comparison System (x)	N	Regression Equation	Sy.x (mg/dL)	R	Sample Range (mg/dL)
Serum: Tarrytown	BEHRING	74	$y=0.76X+17.9$	7.91	0.98	26.8-300.8
EDTA Plasma(y), Serum(x)	ADVIA 1650	69	$y=0.99X-4.27$	8.75	0.989	35.6-293.1
Heparin Plasma(y), Serum(x)	ADVIA 1650	70	$y=0.99X-0.23$	11.13	0.982	35.6-293.1

Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	Analyte Conc.	Effect	
			Conc.	%
Bilirubin	30	75.6	21.9	40.8%
Hemoglobin	525	103.0	49.3	91.8%
Lipids(Trig)	650	367.6	313.8	584.2%
Bilirubin	30	181.0	24.6	15.8%
Hemoglobin	525	210.0	53.7	34.4%
Lipids(Trig)	650	487.1	330.8	211.6%

Analytical Range

The analytical range for this method extends from 12 mg/dL to the IgM concentration level in Specific Protein Reference Serum Calibrator Level 5.

Expected Values

50 to 300 mg/dL

8. Transferrin

SUMMARY OF SAFETY AND EFFECTIVENESS

Transferrin Method for the Bayer ADVIA 1650 (mg/dL)

Intended Use

This *in vitro* diagnostic assay is intended to measure transferrin concentration in human serum and plasma on the ADVIA® 1650 Chemistry System. Such measurements are used to aid in the diagnosis of malnutrition, chronic infection, acute hepatitis, polycythemia, pernicious anemia, and red blood cell disorders, such as iron deficiency anemia.

Imprecision

ADVIA 1650

Specimen Type	Level	Total CV%
Serum	193.9	4.7
Serum	473.1	3.7

Behring Nephelometer=Serum

Level	Between Day CV%
303	2.3

Correlation (Y=ADVIA 1650, X=comparison system)

Specimen type: Site	Comparison System(X)	N	Regression Equation	Sy.x	R	Sample Range
Serum: Tarrytown	BEHRING	78	Y=1.20X-39.2	10.6	0.976	161-344
EDTA Plasma(y), Serum(x)	ADVIA 1650	71	Y=0.94X-5.51	5	0.993	196-402
Heparin Plasma(y), Serum(x)	ADVIA 1650	72	Y=0.98X-8.45	7.31	0.987	196-402

Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	Analyte Conc.	Effect	
			Conc.	%
Bilirubin	30	122.5	0.11	0.1%
Hemoglobin	525	124.6	1.93	1.6%
Lipids(Trig)	650	132.9	10.24	8.4%
Bilirubin	30	370.4	3.43	0.9%
Hemoglobin	525	376.0	2.16	0.6%
Lipids(Trig)	650	372.7	1.15	0.3%

Analytical Range

The analytical range for this method extends from the lowest calibration value of Specific Protein Reference Serum Level 1 to the Transferrin concentration level in Specific Protein Reference Serum Level 5.

Transferrin (continued)

Expected Values

Males: 215 mg/dL to 365 mg/dL

Females: 250 mg/dL to 380 mg/dL



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 18 2002

Mr. Gabriel J. Muraca, Jr.
Manager Regulatory Affairs
c/o **Kenneth T. Edds, Ph.D.**
Manager Regulatory Affairs
Bayer Diagnostics
511 Benedict Avenue
Tarrytown, NY 10591

Re: k992662
Trade/Device Name: Bayer ADVIA® 1650 Additional Assays
Regulation Number: 21 CFR 862.1475
Regulation Name: Lipoprotein Test System
Regulatory Class: II
Product Code: MSJ, CFN, DCN, JNM, KHS
Dated: January 3, 2002
Received: January 5, 2002

Dear Dr. Edds:

This letter corrects our substantially equivalent letter of dated February 15, 2000, regarding the missing product codes cleared for use in the determination.

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 original 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). 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.

Page 2

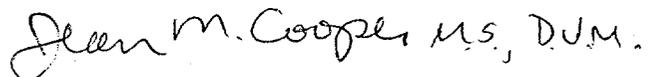
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-___. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Jean M. Cooper, M.S., D.V.M.

Branch Chief

Chemistry and Toxicology I Branch

Division of Clinical Laboratory Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

510(k) Number (if known):

Device Name: **Bayer ADVIA® 1650 Additional Assays**

Indications For Use:

The *Bayer ADVIA 1650 Apolipoprotein A-1 (APO-A)* assay is an *in vitro* diagnostic method intended to measure *Apolipoprotein A-1 concentration* in human serum and plasma on an Advia 1650 Chemistry System. Measurements are used to aid in the assessment of risk for arteriosclerosis and coronary artery disease.

The *Bayer ADVIA 1650 Apolipoprotein B (APO-B)* assay is an *in vitro* diagnostic method intended to measure *Apolipoprotein B concentration* in human serum and plasma on an Advia 1650 Chemistry System. Measurements are used to aid in the assessment of risk for arteriosclerosis and coronary artery disease.

The *Bayer ADVIA 1650 Carbon Dioxide (CO2)* assay is an *in vitro* diagnostic method intended to measure *Carbon Dioxide concentration* in human serum and plasma on an Advia 1650 Chemistry System. Measurements obtained using this method assist in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.

The *Bayer ADVIA 1650 C-Reactive Protein (CRP)* assay is an *in vitro* diagnostic method intended to measure *C-Reactive Protein concentration* in human serum and plasma on an Advia 1650 Chemistry System. Measurements are used to aid in the evaluation of the amount of injury to body tissues. This test is useful in following the progress of rheumatic fever, rheumatoid arthritis, myocardial infarction, and malignancies.

~~Division Sign-Off~~
Division of Clinical Laboratory Devices
K992662
K992662

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

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

510(k) Number (if known):

Device Name: **Bayer ADVIA® 1650 Additional Assays**

Indications For Use:

The *Bayer ADVIA 1650 Immunoglobulin A (IGA)* assay is an *in vitro* diagnostic method intended to measure *Immunoglobulin A (IGA) concentration* in human serum and plasma on an Advia 1650 Chemistry System. Measurements are used to aid in the diagnosis of abnormal protein metabolism and the body's inability to resist infectious agents.

The *Bayer ADVIA 1650 Immunoglobulin G (IGG)* assay is an *in vitro* diagnostic method intended to measure *Immunoglobulin G (IGG) concentration* in human serum and plasma on an Advia 1650 Chemistry System. Measurements are used to aid in the diagnosis of abnormal protein metabolism and the body's inability to resist infectious agents.

The *Bayer ADVIA 1650 Immunoglobulin M (IGM)* assay is an *in vitro* diagnostic method intended to measure *Immunoglobulin M (IGM) concentration* in human serum and plasma on an Advia 1650 Chemistry System. Measurements are used to aid in the diagnosis of abnormal protein metabolism and the body's inability to resist infectious agents.

Sean Cooper
Division Sign-Off
Division of Clinic
510(k) Number K992662

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

510(k) Number (if known):

Device Name: **Bayer ADVIA® 1650 Additional Assays**

Indications For Use:

The *Bayer ADVIA 1650 Transferrin (TFR)* assay is an *in vitro* diagnostic device intended to measure Transferrin concentration in human serum and plasma on an Advia 1650 Chemistry System. Such measurements are used to aid in the diagnosis of malnutrition, chronic infection, acute hepatitis, polycythemia, pernicious anemia, and red blood cell disorders, such as iron deficiency anemia.

Sean Cooper
(Division Sign-Off)
Division of Clinical Laboratory
510(k) Number 18992662

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)