

MAY 21

SUMMARY OF SAFETY AND EFFECTIVENESS

This section contains performance comparisons for 21 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 #
Albumin	B01-4121-01	Serum	Technicon DAX®	T01-1337-B3
Alkaline Phosphatase – AMP	B01-4134-01	Serum	Technicon DAX®	T01-1814
Amylase	B01-4136-01	Serum	Beckman Synchron CX®	442775
		Urine	Beckman Synchron CX7®	442775
Aspartate Aminotransferase	B01-4139-01	Serum	Technicon DAX®	T01-1750
Calcium	B01-4145-01	Serum	Technicon DAX®	T01-1476
		Urine	DuPont Dimension	DF23A
		Urine	Beckman Synchron CX3®	450214, 472095
Chloride	B01-4171-01	Serum	Technicon DAX®	T152-17
		Serum	Beckman Synchron CX7®	450214, 472095
		Urine	Beckman Synchron CX3/7®	450214, 472095
Creatine Kinase	B01-4137-01	Serum	Technicon DAX®	T01-1882
		Serum	Beckman Synchron CX7®	443794
Creatinine, Jaffe	B01-4126-01	Serum	Technicon DAX®	T01-1927
		Urine	Hitachi®	1040847
Creatinine, Enzymatic	B01-4127-01	Serum	Technicon DAX®	T01-1927
Bilirubin, Direct	B01-4123-01	Serum	Technicon DAX®	T01-1565
		Serum	Hitachi®	1109774
Glucose - Hexokinase	B01-4129-01	Serum	Technicon DAX®	T11-1832
		Urine	Hitachi®	1447521
Glucose - Oxidase	B01-4130-01	Serum	Technicon DAX®	T01-1492-56
		Urine	Beckman Synchron CX3/7®	443355
HDL Cholesterol	B01-4125-01	Serum	Boehringer Mannheim on RA-XT	543004
Inorganic Phosphorus	B01-4144-01	Serum	Technicon DAX®	T01-1303
		Serum	Beckman Synchron CX7®	465145
		Urine	Cobas Fara®	44031
Iron	B01-4147-01	Serum	Technicon DAX®	150-26E, 150-26F
		Serum	Sigma RA1000	565-1, 565-3
Magnesium	B01-4148-01	Serum	Technicon DAX®	T01-2878
		Serum/Urine	Hitachi®	1273582
Potassium	B01-4171-01	Serum	Technicon DAX®	T01-3161
		Urine	Beckman Synchron CX3®	443325, 443315
Sodium	B01-4171-01	Serum	Technicon DAX®	T01-3161
		Urine	Beckman Synchron CX3®	450124, 472095
Bilirubin, Total	B01-4122-01	Serum	Technicon DAX®	T01-1963
Uric Acid	B01-4131-01	Serum	Technicon DAX®	T01-2577
		Urine	Beckman Synchron CX7®	442785
		Urine	Cobas Fara®	828475
Urea Nitrogen	B01-4132-01	Serum	Technicon DAX®	T01-1823
		Urine	Beckman Synchron CX3/7®	443350

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1. ALB

SUMMARY OF SAFETY AND EFFECTIVENESS

Albumin Method for the Bayer ADVIA 1650 (g/dL)

Intended Use

This *in vitro* diagnostic assay is intended to measure albumin concentration in human serum and plasma on the ADVIA® 1650 Chemistry System. Such measurements are used in the diagnosis and treatment of chronic inflammatory diseases, collagen diseases, and liver and kidney disorders.

Imprecision

Advia 1650

Specimen type	Level	Total CV (%)
Serum	2.1	2.4
Serum	3.4	1.8

Technicon DAX

Level	Total CV (%)
2.2	3.3
3.4	2.5
4.8	2.0

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

Specimen type: Site	Comparison System (X)	N	Regression Equation	Syx	R	Sample Range
Serum: MSK	DAX	156	$Y=0.86X+0.55$	0.19	0.969	1.6-5.3
Plasma(y), Serum(x)	ADVIA 1650	58	$Y=0.96X+0.29$	0.05	0.978	4.5-5.7

Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	Analyte conc.	Effect	
			conc.	%
Bilirubin	25	4.2	0.0	0.0
Hemoglobin	500	3.7	0.3	8.1
Lipids (Trig)	500	4.1	0.3	7.3

Analytical Range

1 to 6 g/dL

Expected Values

3.4 - 4.8 g/dL

2. ALP-AMP

SUMMARY OF SAFETY AND EFFECTIVENESS

Alkaline Phosphatase AMP Method for the Bayer ADVIA 1650 (U/L)

Intended Use

This in vitro diagnostic assay is intended to measure alkaline phosphatase activity in human serum and plasma on an ADVIA® 1650 Chemistry System. Such measurements are used mainly in the diagnosis and treatment of hepatobiliary and bone disease.

Imprecision

Advia 1650

Specimen type	Level	Total CV (%)
Serum	69	3.9
Serum	130	3.1

Technicon DAX

Level	Total CV (%)
79	2.5
186	2.2
571	1.9

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

Specimen type: Site	Comparison System (X)	N	Regression Equation	Syx	R	Sample Range
Serum: TRYTN	DAX	43	$Y=1.03X-2.1$	3.12	0.999	22-346
Plasma(y), Serum(x)	ADVIA 1650	54	$Y=1.06X+1.42$	5.37	0.972	33-149

Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	Analyte conc.	Effect	
			conc.	%
Bilirubin	25	69.3	1.7	2.5
Hemoglobin	500	100.3	-5.6	-5.6
Lipids (Trig)	500	71.0	1.3	1.8

Analytical Range

0-1100 U/L

Expected Values

25 to 100 U/L

3. AMY

SUMMARY OF SAFETY AND EFFECTIVENESS

Amylase Method for the Bayer ADVIA 1650 (U/L)

Intended Use

This *in vitro* diagnostic assay is intended to measure amylase activity in human serum, plasma and urine on an ADVIA® 1650 Chemistry System. Such measurements are used primarily in the diagnosis and monitoring of acute pancreatitis (inflammation of the pancreas).

Imprecision

Advia 1650

Specimen type	Level	Total CV (%)
Serum	60	1.2
Serum	242	1.3
Serum	322	1.2
Urine	792	7.2

Beckman CX7=Serum, Urine

Level	Total CV (%)
85.7	5.3
240	5.3
320	5.3
800	5.3

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

Specimen type: Site	Comparison System (X)	N	Regression Equation	Syx	R	Sample Range
Serum: MSK	CX4	102	$Y=0.72X+1.91$	3.5	0.998	6-549
Plasma(y), Serum(x)	ADVIA 1650	53	$Y=1.08X+1.46$	3.9	0.985	18-110
Urine: MSK	CX7	82	$Y=0.75X+0.74$	13.4	0.993	2-667

Bias expected in serum and urine correlation when run against Beckman instrument due to the different substrates used in each instrument.

Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	Analyte conc.	Effect	
			conc.	%
Bilirubin	25	68.3	-1.6	-2.3
Hemoglobin	500	174.3	-2.3	-1.3
Lipids (Trig)	500	66.3	1.4	2.1

Analytical Range

Serum/Plasma: 0 to 1500 U/L (from reagent stability study)

Urine 0 to 1500 U/L (from reagent stability study)

Expected Values

Serum: 20-104 U/L

Urine: 1-17 U/h (timed)

4. AST

SUMMARY OF SAFETY AND EFFECTIVENESS

Aspartate Aminotransferase Method for the Bayer ADVIA 1650 (U/L)

Intended Use

This *in vitro* diagnostic assay is intended to measure aspartate aminotransferase activity in human serum and plasma on an ADVIA® 1650 Chemistry System. Such measurements are used mainly to determine the progress and prognosis of patients with myocardial infarction and the diagnosis and monitoring of liver disease.

Imprecision

Advia 1650

Specimen type	Level	Total CV (%)
Serum	32	3.9
Serum	146	1.7

Technicon DAX

Level	Total CV (%)
55	5.4
203	2.5
471	3.3

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

Specimen type: Site	Comparison System (X)	N	Regression Equation	Syx	R	Sample Range
Serum: BERLIN	DAX	111	$Y=0.99X-6.3$	3.63	0.999	9.8-607.2
Plasma(y), Serum(x)	ADVIA 1650	54	$Y=1.00X-2.9$	3.01	0.954	16-85

Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	Analyte conc.	Effect	
			conc.	%
Bilirubin	25	31.0	-3.7	-11.9
Hemoglobin	500	74.7	18.6	24.9
Lipids (Trig)	500	29.7	-4.4	-14.8

Hemolyzed samples should not be used due to effect by RBC.

Analytical Range

0-1000 U/L (from reagent stability study)

Expected Values

M: 15 - 40 U/L.

F: 13 - 35 U/L.

5. Ca

SUMMARY OF SAFETY AND EFFECTIVENESS

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

Intended Use

This *in vitro* diagnostic assay is intended to measure calcium concentration in human serum, plasma and urine on an ADVIA® 1650 Chemistry System. Such measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease, and tetany.

Imprecision

Advia 1650			Technicon DAX = Serum		Dupont Dimension=Urine	
Specimen type	Level	Total CV (%)	Level	Total CV (%)	Level	Between Day CV (%)
Serum	5.9	2.7	7.7	2.3	8.8	0.6
Serum	10.8	2.9	10.3	1.6	14.5	2.6
Serum	12.0	3.5	12.5	1.5		
Urine	6.2	2.4				
Urine	21.2	2.5				

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

Specimen type	Comparison System (X)	N	Regression Equation	Syx	R	Sample Range
Serum – ARI	DAX	100	$Y=0.99X + 0.13$	0.223	0.971	7.0 – 13.2
Plasma(y), Serum(x)	ADVIA 1650	59	$Y=0.94X + 0.82$	0.094	0.963	9.0 – 10.8
Urine – ARI	Dimension	32	$Y=1.2X - 2.25$	0.165	0.999	3.7 – 14.5
Urine – MSK	CX3	63	$Y=1.07X + 0.03$	0.558	0.988	2.1 – 14.7

Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	Analyte conc.	Effect	
			conc.	%
Bilirubin	25	8.0	0.0	0.0
Hemoglobin	500	8.8	0.2	2.3
Lipids (Trig)	500	8.0	0.3	3.8

Analytical Range

Serum/Plasma: 1 to 15 mg/dL
 Urine: 1 to 15 mg/dL

Expected Values

Serum/Plasma: 8.6 to 10.0 mg/dL
 Urine: 100 to 300 mg/d

6. Cl

SUMMARY OF SAFETY AND EFFECTIVENESS

Chloride Method for the Bayer ADVIA 1650 (mmol/L)

Intended Use

This *in vitro* diagnostic assay is intended to measure chloride concentration in human serum, plasma and urine on an ADVIA® 1650 Chemistry System. Such measurements are used for their inferential value and are helpful in diagnosing disorders of acid-base and water balance. It is especially important to measure chloride during the correction of hypokalemic alkalosis and also during severe, prolonged vomiting, which can lower the serum chloride level.

Imprecision

Advia 1650			Beckman CX7=Serum,Urine		Technicon DAX=Serum	
Specimen type	Level	Total CV (%)	Level	Total CV (%)	Level	Total CV (%)
Serum	88.4	1.6	80	1.3	97	1.5
Serum	111.8	2.0	118.8	1.1	112	1.8
Urine	86.8	1.7	89.4	3.4		
Urine	290.4	3.8	250	1.5		

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

Specimen type	Comparison System (X)	N	Regression Equation	Syx	R	Sample Range
Serum - ARI	CX7	115	Y=1.00X + 1.3	1.6	0.985	76 - 128
Serum - MSK	DAX	154	Y=0.98X + 3.3	2.2	0.914	86 - 122
Plasma(y), Serum(x)	ADVIA 1650	69	Y=0.86X+15.9	1.20	0.944	102-118
Urine - ARI	CX7	76	Y=1.05X - 0.9	4.9	0.996	29 - 280

Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	Analyte conc.	Effect	
			conc.	%
Bilirubin	25	85.0	0.4	0.5
Hemoglobin	500	82.7	0.0	0.0
Lipids (Trig)	500	83.3	2.4	2.9

Analytical Range

Serum/Plasma: 15 to 200 mmol/L
 Urine: 15 to 400 mmol/L

Expected Values

Serum: 98 - 107 mEq/L
 Urine: 110 - 250 mmol/d

7. CK

SUMMARY OF SAFETY AND EFFECTIVENESS

Creatine Phosphokinase Method for the Bayer ADVIA 1650 (U/L)

Intended Use

This *in vitro* diagnostic assay is intended to measure creatine kinase activity in human serum and plasma on an ADVIA® 1650 Chemistry System. Such measurements are used mainly in the diagnosis and treatment of myocardial infarction and muscle diseases such as Duchenne progressive muscular dystrophy.

Imprecision

Advia 1650			Technicon DAX		Beckman CX7	
Specimen type	Level	Total CV (%)	Level (U/L)	Total CV (%)	Level	Total CV (%)
Serum	139	2.7	177	4.8	144	5.3
Serum	449	3.0	590	2.5	460	5.3

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

Specimen type: Site	Comparison System (X)	N	Regression Equation	Syx	R	Sample Range
Serum: MSK	DAX	151	Y=0.97X+1.19	3.3	0.999	6-700
Serum: ARI	CX7	145	Y=1.01X+0.8	6.50	1.000	13-1187
Plasma(y), Serum(x)	ADVIA 1650	56	Y=1.05X-9.02	7.88	0.997	41-507

Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	Analyte conc.	Effect	
			conc.	%
Bilirubin	25	70.0	2.7	3.9
Hemoglobin	500	98.0	24.3	24.8
Lipids (Trig)	500	65.0	6.0	9.2

Analytical Range

0-1300 U/L

Expected Values

M: 38 - 174 U/L.

F: 26 - 140 U/L.

8. CREAT

SUMMARY OF SAFETY AND EFFECTIVENESS

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

Intended Use

This *in vitro* diagnostic assay is intended to measure creatinine concentration in human serum, plasma and urine on the ADVIA® 1650 system. Such measurements are used in the diagnosis and treatment of renal diseases, and in monitoring renal dialysis.

Imprecision

Advia 1650			Technicon DAX=Serum	
Specimen type	Level	Total CV %	Level	Total CV (%)
Serum	1.8	3.8	1.8	4.3
Serum	8.4	3.7	5.0	4.5
Urine	84.6	2.9	10.5	3.7
Urine	209.3	4.0		

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

Specimen type: Site	Comparison System (X)	N	Regression Equation	Syx	R	Sample Range
Serum: BERLIN	DAX	112	$Y=0.92X+0.06$	0.15	0.995	0.33-8.3
Plasma(y), Serum(x)	ADVIA 1650	58	$Y=1.02X+0.04$	0.02	0.992	0.9-1.4
Urine: BERLIN	HITACHI	86	$Y=1.13X+0.40$	2.61	0.995	21-160

Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	Analyte conc.	Effect	
			conc.	%
Bilirubin	25	1.0	-0.8	-80.0
Hemoglobin	500	7.3	0.1	1.4
Lipids (Trig)	500	1.0	0.0	4.5

Analytical Range

Serum/Plasma: 0 - 25 mg/dL
 Urine: 17 - 160 mg/dL

Expected Values

Serum: M: 0.9 - 1.3 mg/dL
 F: 0.6 - 1.1 mg/dL.
 Urine: M: 14 - 26
 F: 11 - 20

9. CREAT-E

SUMMARY OF SAFETY AND EFFECTIVENESS

Creatinine-Enzymatic Method for the Bayer ADVIA 1650 (mg/dL)

Intended Use

This *in vitro* diagnostic assay is intended to measure creatinine concentration in human serum and plasma on an ADVIA® 1650 Chemistry System. Such measurements are used in the diagnosis and treatment of renal diseases, and in monitoring renal dialysis.

Imprecision

Advia 1650

Specimen type	Level	Total CV (%)
Serum	0.9	6.4
Serum	6.1	2.3
Serum	9.5	2.0

Technicon DAX

Level	Total CV (%)
1.8	4.3
5.0	4.5
10.5	3.7

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

Specimen type: Site	Comparison System (X)	N	Regression Equation	Syx	R	Sample Range
Serum: MSK	DAX	155	$Y=0.99X-0.06$	0.16	0.955	0.3-3.9
Plasma(y), Serum(x)	ADVIA 1650	57	$Y=0.96X+0.16$	0.07	0.925	0.7-1.4

Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	Analyte conc.	Effect	
			conc.	%
Bilirubin	25	0.7	-0.2	-28.6
Hemoglobin	500	7.8	-0.1	-1.3
Lipids (Trig)	500	0.7	-1.2	-171.4

Analytical Range

0-30 mg/dL

Expected Values

M: 0.9 - 1.3 mg/dL,

F: 0.6 - 1.1 mg/dL.

10. DBILI

SUMMARY OF SAFETY AND EFFECTIVENESS

Direct Bilirubin Method for the Bayer ADVIA 1650 (mg/dL)

Intended Use

This *in vitro* diagnostic assay is intended to measure direct bilirubin concentration in human serum and plasma on the ADVIA® 1650 Chemistry System. Such measurements are used in the diagnosis of common bile duct obstruction caused by a stone and of patients with Dubin-Johnson syndrome.

Imprecision

Advia 1650			Technicon DAX	
Specimen type	Level	Total CV (%)	Level	Total CV (%)
Serum	0.3	4.6	0.2	**
Serum	1.6	4.4	1.5	5.7
			4.0	2.3

**Value not significant when level approaches zero.

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

Specimen type	Comparison System (X)	N	Regression Equation	Syx	R	Sample Range
Serum – TRYTN	DAX	145	$Y=1.34X - 0.10$	0.18	0.994	0 - 6.12
Serum – BERLIN	HITACHI	92	$Y=1.07X + 0.06$	0.14	0.997	0.02 - 9.26
Plasma (y), Serum (x)	ADVIA 1650	49	$Y=0.98X-0.01$	0.02	0.988	0.1 – 0.6

Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	Analyte conc.	Effect	
			conc.	%
Hemoglobin	200	0.3	-0.6	.
Hemoglobin	500	0.3	-1.5	.
Lipids (Trig)	500	0.2	-0.5	.

Analytical Range

0 - 10 mg/dL (from reagent stability study)

Expected Values

<0.2 mg/dL

11. GLU-HEX

SUMMARY OF SAFETY AND EFFECTIVENESS

Glucose-Hexokinase Method for the Bayer ADVIA 1650 (mg/dL)

Intended Use

This *in vitro* diagnostic assay is intended to measure glucose in human serum, plasma and urine on an ADVIA® 1650 Chemistry System. Such measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia, and insulin overdose.

Imprecision

Advia 1650			Technicon DAX=Serum	
Specimen type	Level	Total CV	Level	Total CV (%)
Serum	77	2.4	71	4.2
Serum	279	3.3	262	2.1
Urine	42	3.5	367	1.7
Urine	285	3.6		

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

Specimen type	Comparison System (X)	N	Regression Equation	Syx	R	Sample Range
Serum – BERLIN	DAX	109	Y= 1.05X - 2.8	5.42	0.995	19 – 262
Urine – BERLIN	HITACHI	81	Y= 0.99X - 11.2	9.88	0.997	4 – 476
Plasma (y) Serum (x)	ADVIA 1650	60	Y= 1.03X - 6.6	9.00	0.986	36 – 384

Interfering Substances

Analyte	Interfering Substance	Interfering Sub. Conc. (mg/dL)	Analyte conc.	Effect	
				conc.	%
GLU-HEX	Bilirubin	10	95.5	-8.2	-8.6
GLU-HEX	Bilirubin	25	95.5	-24.4	-25.5
GLU-HEX	Hemoglobin	200	95.9	-22.2	-23.1
GLU-HEX	Hemoglobin	500	95.9	-59.9	-62.5
GLU-HEX	Lipids (Trig)	900	189.0	2.2	1.2

Analytical Range

Serum/Plasma: 0 - 700 mg/dL
 Urine: 0 – 700 mg/dL

Expected Values

Serum/Plasma 74 – 106 mg/dL
 Urine: <0.5 g/day

12. GLU-OX

SUMMARY OF SAFETY AND EFFECTIVENESS

Glucose-Oxidase Method for the Bayer ADVIA 1650 (mg/dL)

Intended Use

This *in vitro* diagnostic assay is intended to measure glucose in human serum, plasma and urine on an ADVIA® 1650 Chemistry System. Such measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia and insulin overdose.

Imprecision

Advia 1650			Technicon DAX=Serum	
Specimen type	Level	Total CV (%)	Level	Total CV (%)
Serum	77	1.5	74	2.1
Serum	294	1.4	293	1.5
Urine	48	1.5		
Urine	277	1.4		

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

Specimen type: Site	Comparison System (X)	N	Regression Equation	Syx	R	Sample Range
Serum: MSK	DAX	155	Y=0.98X-3.0	3.4	0.996	41-323
Plasma(y), Serum(x)	ADVIA 1650	48	Y=0.99X+2.9	2.21	0.999	60-381
Urine: MSK	CX3	87	Y=1.06X-1.2	4.8	0.989	0-249

Interfering Substances

Analyte	Interfering Substance	Interfering Sub. Conc. (mg/dL)	Analyte conc.	Effect	
				conc.	%
GLU-OX	Bilirubin	10	91.9	-3.5	-3.8
GLU-OX	Bilirubin	25	91.9	-13.6	-14.8
GLU-OX	Hemoglobin	500	86.7	6.1	7.0
GLU-OX	Lipids (Trig)	900	187.0	-5.8	-3.1

Analytical Range

Serum/Plasma: 0 - 750 mg/dL
 Urine: 0 - 750 mg/dL

Expected Values

Serum: 74 - 106 mg/dL
 Urine: <0.5 g/day

13. HDL

SUMMARY OF SAFETY AND EFFECTIVENESS

High Density Lipoprotein Method for the Bayer ADVIA 1650 (mg/dL)

Intended Use

This *in vitro* diagnostic assay is intended to measure HDL Cholesterol in human serum and plasma on an ADVIA® 1650 Chemistry System. Such measurements are used in the risk assessment of coronary artery disease.

Imprecision

Advia 1650			RA-XT	
Specimen type	Level	Total CV (%)	Level	Between Day CV (%)
Serum	28	3.8	15.5	5.1
Serum	53	3.2	52.3	1.9

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

Specimen type: Site	Comparison System (X)	N	Regression Equation	Syx	R	Sample Range
Serum: MSK	RA-XT	121	$Y=1.03X+3.91$	2.5	0.987	12-94
Plasma(y), Serum(x)	ADVIA 1650	79	$Y=1.09X-1.9$	4.50	0.960	26-98

Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	Analyte conc.	Effect	
			conc.	%
Bilirubin	25	29.7	-0.4	-1.3
Hemoglobin	500	29.2	-5.6	-19.2

Analytical Range

10-135 mg/dL

Expected Values (years: mg/dL)

Male, Ages 30 – 50: 27.8 to 52.89 mg/dL

Female, Ages 30 – 50: 33.9 to 86.87 mg/dL

14. IPHOS

SUMMARY OF SAFETY AND EFFECTIVENESS

Inorganic Phosphorus Method for the Bayer ADVIA 1650 (mg/dL)

Intended Use

This *in vitro* diagnostic assay is intended to measure inorganic phosphorus concentration in human serum, plasma and urine on the ADVIA® 1650 system. Such measurements are used in the diagnosis and treatment of kidney diseases, parathyroid gland disorders, and Vitamin D imbalance.

Imprecision

Advia 1650			Technicon DAX=Serum	
Specimen type	Level	Total CV (%)	Level	Total CV (%)
Serum	3.0	1.7	3.2	3.0
Serum	5.7	2.6	6.7	2.3
Serum	7.7	2.0	9.4	2.1
Urine	32.0	1.6		
Urine	170.6	0.7		

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

Specimen type: Site	Comparison System (X)	N	Regression Equation	Syx	R	Sample Range
Serum: MSK	DAX	154	$Y=0.93X+0.20$	0.18	0.978	1.1-7.3
Serum: ARI	CX7	152	$Y=1.01X+0.30$	0.25	0.983	1.4-10.0
Plasma(y), Serum(x)	ADVIA 1650	50	$Y=0.98X-0.23$	0.11	0.975	2.0-4.1
Urine: MSK	Cobas Fara	92	$Y=1.02X-0.2$	1.3	0.998	5-87

Interfering Substances

Analyte	Interfering Substance	Interfering Sub. Conc. (mg/dL)	Analyte conc.	Effect	
				conc.	%
IPHOS	Bilirubin	25	3.4	0.0	-0.6
IPHOS	Hemoglobin	500	2.7	0.9	33.3
IPHOS	Lipids (Trig)	500	3.4	-0.2	-5.9

Analytical Range

Serum/Plasma: 0 - 20 mg/dL
 Urine: 5 - 100 mg/dL

Expected Values

Serum: 2.7 - 4.5 mg/dL
 Urine: 0.4 - 1.3 g/d

15. IRON

SUMMARY OF SAFETY AND EFFECTIVENESS

Iron Method for the Bayer ADVIA 1650 (µg/dL)

Intended Use

This *in vitro* diagnostic method is intended to measure iron concentration in human serum and plasma on an ADVIA® 1650 Chemistry System. Measurements are used in the diagnosis and treatment of iron deficiency anemias and hemochromatosis.

Imprecision

Advia 1650			Technicon DAX	
Specimen type	Level	Total CV (%)	Level	Total CV (%)
Serum	64	3.1	81	5.5
Serum	175	2.6	194	3.2
Serum	295	2.2	322	3.1

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

Specimen type	Comparison System (X)	N	Regression Equation	Syx	R	Sample Range
Serum – MSK	DAX	40	Y=0.88X + 4.5	4.8	0.997	6 - 253
Plasma(y), Serum(x)	ADVIA 1650	57	Y=0.96X+15.5	6.9	0.978	40 - 186

Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	Analyte conc.	Effect	
			conc.	%
Bilirubin	25	111.6	1.9	1.7
Hemoglobin	500	N/A	N/A	N/A
Lipids (Trig)	500	107.9	-11.1	-10.3

Analytical Range

0 to 1000 µg/dL

Expected Values

Males: 65 to 175 µg/dL

Females: 50 to 170 µg/dL

16. Mg

SUMMARY OF SAFETY AND EFFECTIVENESS

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

Intended Use

This *in vitro* diagnostic assay is intended to measure magnesium concentration in human serum, plasma and urine on an ADVIA® 1650 Chemistry System. Such measurements are used in the diagnosis and treatment of hypermagnesemia and monitoring of patients receiving prolonged magnesium-free intravenous therapy.

Imprecision

Advia 1650			Technicon DAX= Serum	
Specimen type	Level	Total CV (%)	Level	Total CV (%)
Serum	1.9	2.3	2.4	5.6
Serum	3.4	2.0	3.9	3.6
Urine	8.7	11.9		

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

Specimen type	Comparison System (X)	N	Regression Equation	Syx	R	Sample Range
Serum – TRYTN	DAX	193	$Y=0.91X + 0.10$	0.131	0.973	0.9 – 5.3
Serum – BERLIN	HITACHI	112	$Y=0.95X + 0.25$	0.124	0.916	1.5 – 3.1
Plasma(y), Serum(x)	ADVIA 1650	51	$Y=0.97X + 0.02$	0.032	0.963	1.6 – 2.1
Urine – BERLIN	HITACHI	97	$Y=0.99X + 0.31$	0.253	0.997	1.4 – 15.0

Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	Analyte conc.	Effect	
			conc.	%
Bilirubin	25	2.6	0.4	14.0
Hemoglobin	500	2.7	0.2	7.4
Lipids (Trig)	500	1.8	1.0	55.6

Analytical Range

Serum/Plasma: 1.6 to 6 mg/dL
 Urine: 1.6 to 25 mg/dL

Expected Values (values in Tietz converted to mg/dL)

Serum/Plasma: 1.6 – 2.6 mg/dL
 Urine: 7.3 – 12.2 mg/d

17. K

SUMMARY OF SAFETY AND EFFECTIVENESS**Potassium Method for the Bayer ADVIA 1650 (mmol/L)****Intended Use**

This *in vitro* diagnostic assay is intended to measure potassium concentration in human serum, plasma and urine on an ADVIA® 1650 Chemistry System. Such measurements are used mainly to monitor electrolyte balance in the diagnosis and treatment of primary aldosteronism, metabolic alkalosis, diarrhea, severe vomiting, diuretic administration, diabetic ketoacidosis, and other diseases.

Imprecision

Advia 1650

Specimen type	Level	Total CV (%)
Serum	3.0	3.0
Serum	6.4	2.7
Urine	28.5	6.1
Urine	102.9	4.8

Technicon DAX=Serum

Level	Total CV (%)
3.4	1.6
7.5	1.7

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

Specimen type	Comparison System (X)	N	Regression Equation	Syx	R	Sample Range
Serum – MSK	DAX	156	Y=1.09X – 0.2	0.08	0.995	2.2 – 8.1
Plasma(y), Serum(x)	ADVIA 1650	49	Y=0.92X-0.01	0.16	0.890	3.4 – 4.8
Urine – MSK	CX3	99	Y=1.01X – 0.2	1.2	0.999	7 – 116

Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	Analyte conc.	Effect	
			conc.	%
Bilirubin	25	3.3	0.0	0.3
Hemoglobin	500	N/A	N/A	N/A
Lipids (Trig)	500	3.3	0.2	6.1

Analytical Range

Serum/Plasma: 1 to 10 mmol/L
Urine: 3 to 300 mmol/L

Expected Values

Serum: 3.5 – 5.1 mmol/L
Plasma Males: 3.5 – 4.5 mmol/L
Plasma Females: 3.4 – 4.4 mmol/L
Urine: 25 – 125 mmol/d (varies with diet)

18. Na

SUMMARY OF SAFETY AND EFFECTIVENESS

Sodium Method for the Bayer ADVIA 1650 (mmol/L)

Intended Use

This *in vitro* diagnostic assay is intended to measure sodium concentration in human serum, plasma and urine on an ADVIA® 1650 Chemistry System. Such measurements are used mainly in the diagnosis and treatment of gross changes in water and salt balance, aldosteronism, diabetes insipidus, adrenal hypertension, Addison's disease, dehydration, inappropriate antidiuretic hormone secretion, diabetic acidosis, severe diarrhea, or other diseases involving electrolyte imbalance.

Imprecision

Advia 1650

Specimen type	Level	Total CV (%)
Serum	119	1.7
Serum	143	1.8
Urine	63	1.9
Urine	208	2.0

Technicon DAX=Serum

Level	Total CV (%)
115	0.9
141	0.9
166	1.2

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

Specimen type	Comparison System (X)	N	Regression Equation	Syx	R	Sample Range
Serum – MSK	DAX	156	Y=1.02X – 0.2	1.08	0.970	121 – 154
Plasma(y), Serum(x)	ADVIA 1650	69	Y=0.92X+11.6	1.45	0.964	139 - 156
Urine – MSK	CX3	97	Y=0.95X + 6.2	3	0.997	20 – 202

Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	Analyte conc.	Effect	
			conc.	%
Bilirubin	25	122.8	0.0	0.0
Hemoglobin	500	128.7	2.3	1.8
Lipids (Trig)	500	117.3	3.1	2.6

Analytical Range

Serum/Plasma: 100 to 200 mmol/L

Urine: 10 to 400 mmol/L

Expected Values

Serum/Plasma: 136 – 145 mEq/L

Urine: 40 – 220 mmol/d

19. TBILI

SUMMARY OF SAFETY AND EFFECTIVENESS

Total Bilirubin Method for the Bayer ADVIA 1650 (mg/dL)

Intended Use

This *in vitro* diagnostic assay is intended to measure total bilirubin concentration in human serum and plasma on an ADVIA® 1650 Chemistry System. Such measurements are used in the diagnosis and treatment of hemolytic, biliary, and liver disorders, including hepatitis and cirrhosis.

Imprecision

Advia 1650

Specimen type	Level	Total CV (%)
Serum	1.0	7.6
Serum	5.0	4.1
Serum	7.7	2.2

Technicon DAX

Level	Total CV (%)
0.7	**
5.1	2.3
12.5	2.2

**Value not significant when level approaches zero.

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

Specimen type	Comparison System (X)	N	Regression Equation	Syx	R	Sample Range
Serum – MSK	DAX	156	$Y=1.10X + 0.08$	0.194	0.999	0.1 – 29.5
Serum/Plasma	ADVIA 1650	51	$Y=0.94X + 0.16$	0.071	0.954	0.3 – 1.4

Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	Analyte conc.	Effect	
			conc.	%
Hemoglobin	200	0.9	-0.5	-61.6
Hemoglobin	500	0.9	-1.1	-122.1
Lipids (Trig)	500	0.9	0.5	55.6

Analytical Range

0 to 30 mg/dL

Expected Values

0.3 to 1.2 mg/dL

20. UA

SUMMARY OF SAFETY AND EFFECTIVENESS

Uric Acid Method for the Bayer ADVIA 1650 (mg/dL)

Intended Use

This *in vitro* diagnostic assay is intended to measure uric acid concentration in human serum, plasma and urine on an ADVIA® 1650 Chemistry System. Such measurements are used in the diagnosis and treatment of renal failure, gout, and eclampsia.

Imprecision

Advia 1650			Technicon DAX=Serum		Beckman CX7=Urine	
Specimen type	Level	Total CV (%)	Level	Total CV (%)	Level	Total CV (%)
Serum	3.9	1.9	5.2	3.0	12	3
Serum	8.6	1.6	8.5	2.7	24	3
Serum	10.0	2.3	10.0	2.6		
Urine	12.4	2.3				
Urine	23.9	5.2				

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

Specimen type	Comparison System (X)	N	Regression Equation	Syx	R	Sample Range
Serum – MSK	DAX	154	$Y=1.05X + 0.48$	0.27	0.994	0.2 – 18.0
Plasma(y), Serum(x)	ADVIA 1650	61	$Y=1.03X + 0.02$	0.063	0.999	2.4 – 8.9
Urine – ARI	CX7	30	$Y=1.03X - 0.5$	3.06	0.989	8 – 91

Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	Analyte conc.	Effect	
			conc.	%
Bilirubin	25	4.5	-0.2	-4.2
Hemoglobin	500	6.2	0.2	3.2
Lipids (Trig)	500	4.3	-0.4	-9.3

Analytical Range

Serum/Plasma: 0 to 20 mg/dL
 Urine: 0 to 180 mg/dL

Expected Values

Males/Serum: 3.5 to 7.2 mg/dL
 Females/Serum: 2.6 to 6.0 mg/dL
 Urine: 250 to 750 mg/dL

21. UN

SUMMARY OF SAFETY AND EFFECTIVENESS

Urea Nitrogen Method for the Bayer ADVIA 1650 (mg/dL)

Intended Use

This *in vitro* diagnostic assay is intended to measure urea nitrogen (an end product of nitrogen metabolism) concentration in human serum, plasma and urine on a **ADVIA® 1650** Chemistry system. Such measurements are used in the diagnosis and treatment of kidney disease, urinary tract obstruction, and acute or chronic renal failure.

Imprecision

Advia 1650			Technicon DAX=Serum		Beckman CX3=Urine	
Specimen type	Level	Total CV	Level	Total CV (%)	Level	Total CV (%)
Serum	18	2.4	21	3.5	460	7.5
Serum	50	2.2	59	1.8	620	7.5
Serum	86	1.7	102	1.7		
Urine	461	4.6				
Urine	618	2.3				

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

Specimen type	Comparison System (X)	N	Regression Equation	Syx	R	Sample Range
Serum – MSK	DAX	34	$Y=1.12X - 0.8$	1.01	0.997	8 – 64
Plasma(y), Serum(x)	ADVIA 1650	54	$Y=1.0X - 0.2$	0.22	0.997	7 – 22
Urine – MSK	CX3	79	$Y=1.03X + 24.8$	34.8	0.990	67 – 988

Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	Analyte conc.	Effect	
			conc.	%
Bilirubin	25	16.3	-0.2	-1.2
Hemoglobin	500	20.2	-0.6	-3.0
Lipids (Trig)	500	15.8	0.7	4.4

Analytical Range

Serum/Plasma: 5 to 150 mg/dL
 Urine: 35 to 1000 mg/dL

Expected Values

6 to 20 mg/dL



DEPARTMENT OF HEALTH & HUMAN SERVICES

MAY 21 1999

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Gabriel J. Muraca, Jr.
Manager Regulatory Affairs
BAYER CORPORATION
511 Benedict Avenue
Tarrytown, NY 10591-5097

Re: K990346

Trade Name: Bayer ADVIA® 1650 Chemistry System
Regulatory Class: II
Product Code: JGS, CEM, CGZ, JJE
Dated: April 21, 1999
Received: April 28, 1999

Dear Mr. Muraca:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

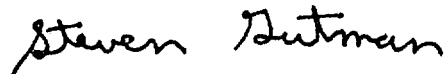
Page 2

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D, M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K990346

Device Name: **Bayer ADVIA® 1650 Chemistry System**

Indications For Use:

The ADVIA 1650 Chemistry System is an automated, clinical chemistry analyzer that can run tests on human serum, plasma, or urine in random access, batch, and STAT modes at a throughput rate of 1200 photometric tests per hour and 450 electrolyte tests per hour. The photometric analyzer performs clinical chemistry and immuno-turbidimetric methods. The electrolyte portion of the analyzer measures the sodium, potassium, and chloride concentrations in serum, plasma or urine samples based on a potentiometric procedure that uses ion-selective electrodes. The ADVIA 1650 is intended for use in conjunction with certain reagents to measure a variety of analytes contained in human fluids.

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K990346

(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)