JUN 30 1999

Attachment 5

K991576

## 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 |

Gabriel J. Muraca, Jr.

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

4/29/99
Date

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. | Effect % |
|---|---|---|---|---|
| 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. | Effect % |
|---|---|---|---|---|
| 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. | Effect % |
|---|---|---|---|---|
| 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. | Effect % |
|---|---|---|---|---|
| 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

| Specimen type | Level | Total CV (%) |
|---|---|---|
| Serum | 5.9 | 2.7 |
| Serum | 10.8 | 2.9 |
| Serum | 12.0 | 3.5 |
| Urine | 6.2 | 2.4 |
| Urine | 21.2 | 2.5 |

Technicon DAX = Serum

| Level | Total CV (%) |
|---|---|
| 7.7 | 2.3 |
| 10.3 | 1.6 |
| 12.5 | 1.5 |

Dupont Dimension=Urine

| Level | Between Day CV (%) |
|---|---|
| 8.8 | 0.6 |
| 14.5 | 2.6 |

**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. | Effect % |
|---|---|---|---|---|
| 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

| Specimen type | Level | Total CV (%) |
|---|---|---|
| Serum | 88.4 | 1.6 |
| Serum | 111.8 | 2.0 |
| Urine | 86.8 | 1.7 |
| Urine | 290.4 | 3.8 |

Beckman CX7=Serum,Urine

| Level | Total CV (%) |
|---|---|
| 80 | 1.3 |
| 118.8 | 1.1 |
| 89.4 | 3.4 |
| 250 | 1.5 |

Technicon DAX=Serum

| Level | Total CV (%) |
|---|---|
| 97 | 1.5 |
| 112 | 1.8 |

### 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. | Effect % |
|---|---|---|---|---|
| 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. | Effect % |
|---|---|---|---|---|
| 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

| Specimen type | Level | Total CV % |
|---|---|---|
| Serum | 1.8 | 3.8 |
| Serum | 8.4 | 3.7 |
| Urine | 84.6 | 2.9 |
| Urine | 209.3 | 4.0 |

Technicon DAX=Serum

| 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: 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. | Effect % |
|---|---|---|---|---|
| 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. | Effect % |
|---|---|---|---|---|
| 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

| Specimen type | Level | Total CV (%) |
|---|---|---|
| Serum | 0.3 | 4.6 |
| Serum | 1.6 | 4.4 |

Technicon DAX

| Level | Total CV (%) |
|---|---|
| 0.2 | ** |
| 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. | Effect % |
|---|---|---|---|---|
| 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

| Specimen type | Level | Total CV |
|---|---|---|
| Serum | 77 | 2.4 |
| Serum | 279 | 3.3 |
| Urine | 42 | 3.5 |
| Urine | 285 | 3.6 |

Technicon DAX=Serum

| Level | Total CV (%) |
|---|---|
| 71 | 4.2 |
| 262 | 2.1 |
| 367 | 1.7 |

**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. | Effect % |
|---|---|---|---|---|---|
| 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

| Specimen type | Level | Total CV (%) |
|---|---|---|
| Serum | 77 | 1.5 |
| Serum | 294 | 1.4 |
| Urine | 48 | 1.5 |
| Urine | 277 | 1.4 |

Technicon DAX=Serum

| Level | Total CV (%) |
|---|---|
| 74 | 2.1 |
| 293 | 1.5 |

**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. | Effect % |
|---|---|---|---|---|---|
| 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

| Specimen type | Level | Total CV (%) |
|---|---|---|
| Serum | 28 | 3.8 |
| Serum | 53 | 3.2 |

RA-XT

| Level | Between Day CV (%) |
|---|---|
| 15.5 | 5.1 |
| 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. | Effect % |
|---|---|---|---|---|
| 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

| Specimen type | Level | Total CV (%) |
|---|---|---|
| Serum | 3.0 | 1.7 |
| Serum | 5.7 | 2.6 |
| Serum | 7.7 | 2.0 |
| Urine | 32.0 | 1.6 |
| Urine | 170.6 | 0.7 |

Technicon DAX=Serum

| Level | Total CV (%) |
|---|---|
| 3.2 | 3.0 |
| 6.7 | 2.3 |
| 9.4 | 2.1 |

**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. | Effect % |
|---|---|---|---|---|---|
| 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

| Specimen type | Level | Total CV (%) |
|---|---|---|
| Serum | 64 | 3.1 |
| Serum | 175 | 2.6 |
| Serum | 295 | 2.2 |

Technicon DAX

| Level | Total CV (%) |
|---|---|
| 81 | 5.5 |
| 194 | 3.2 |
| 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. | Effect % |
|---|---|---|---|---|
| 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

| Specimen type | Level | Total CV (%) |
|---|---|---|
| Serum | 1.9 | 2.3 |
| Serum | 3.4 | 2.0 |
| Urine | 8.7 | 11.9 |

Technicon DAX= Serum

| Level | Total CV (%) |
|---|---|
| 2.4 | 5.6 |
| 3.9 | 3.6 |

**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. | Effect % |
|---|---|---|---|---|
| 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. | Effect % |
|---|---|---|---|---|
| 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. | Effect % |
|---|---|---|---|---|
| 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

| Specimen type | Level | Total CV (%) |
|---|---|---|
| Serum | 3.9 | 1.9 |
| Serum | 8.6 | 1.6 |
| Serum | 10.0 | 2.3 |
| Urine | 12.4 | 2.3 |
| Urine | 23.9 | 5.2 |

Technicon DAX=Serum

| Level | Total CV (%) |
|---|---|
| 5.2 | 3.0 |
| 8.5 | 2.7 |
| 10.0 | 2.6 |

Beckman CX7=Urine

| Level | Total CV (%) |
|---|---|
| 12 | 3 |
| 24 | 3 |

**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. | Effect % |
|---|---|---|---|---|
| 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

| Specimen type | Level | Total CV |
|---|---|---|
| Serum | 18 | 2.4 |
| Serum | 50 | 2.2 |
| Serum | 86 | 1.7 |
| Urine | 461 | 4.6 |
| Urine | 618 | 2.3 |

Technicon DAX=Serum

| Level | Total CV (%) |
|---|---|
| 21 | 3.5 |
| 59 | 1.8 |
| 102 | 1.7 |

Beckman CX3=Urine

| Level | Total CV (%) |
|---|---|
| 460 | 7.5 |
| 620 | 7.5 |

**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. | Effect % |
|---|---|---|---|---|
| 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

JUN 30 1999

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Gabriel J. Muraca, Jr.
Manager Regulatory Affairs
Bayer Corporation
Business Diagnostic Division
511 Benedict Avenue
Tarrytown, New York 10591-5097

Re: K991576
Trade Name: Bayer ADVIA® 1650 Chemistry System
Regulatory Class: II
Product Code: CIX, CJK, KHM, CIT, CIC, CGX, JFY, CGS, CIG, CFR, CGA, LBS, CDQ
Regulatory Class: I
Product Code: CEO, JIY, CFO, KNK
Dated: April 29, 1999
Received: May 6, 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.

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,

Steven Gutman

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): K991576

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 electrylyte 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 K991576

(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)