K974721

Summary of Safety and Effectiveness

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Unconjugated Estriol Method for the Bayer Immuno 1™ System

Listed below is a comparison of the performance of the Bayer Immuno 1™ Unconjugated Estriol method and a similar device granted clearance of substantial equivalence (Diagnostic Products Corporation Coat-a-Count Free Estriol RIA method). The information below was extracted from the Bayer Immuno 1 Unconjugated Estriol method sheet and the DPC Free Estriol RIA Package Insert.

Intended Use

This *in vitro* diagnostic method is intended to quantitatively measure unconjugated estriol in human serum on the Bayer Immuno 1 System. Measurements of unconjugated estriol are used to evaluate fetal well-being by monitoring the level of the hormone derived from fetal-placental circulation.

uEstriol Method:	**Bayer Immuno 1™**		**DPC Coat-a-Count®**	
Part Number:	Reagents T01-3987-51 Calibrators T03-3986-01		kit(s) TKEF1 (100) TKEF5 (500)	
Expected Values:	< 2.0 to 42.0 ng/mL		graphical	
Precision (within-run):	mean	% CV	mean	% CV
(n = 20 over 10 days)	0.41	3.6%	0.74	9.1
	3.60	3.2%	2.9	5.5
	6.49	1.5%	7.9	3.8
	11.37	2.3%	12.2	3.8
Precision (total):			(inter-assay only presented)	
(n = 20 over 10 days)	0.41	4.9%	0.74	21.2
	3.60	3.4%	2.90	9.3
	6.49	2.3%	7.90	9.9
	11.37	2.7%	12.20	8.0

Regression Equation: **y = 0.87x + 0.62**

where:

y	=	Immuno 1 uE_3 Assay
x	=	DPC Coat-a-Count Free Estriol RIA
n	=	249
r	=	0.98
Sy.x	=	1.23
range	=	0 to 30 ng/mL

Specificity: Cross Reactants Spiked into Normal Human Serum Pools

Compound	DPC Free Estriol % Crossreactivity	Bayer Immuno 1 uE3 % Crossreactivity
Estriol-3-sulfate	0.46%	1.70%
Estriol-3-(β-D-glucuronide)	0.26%	1.60%
Estriol-16-α-(β-D-glucuronide)	0.66%	0.05%
Estriol-17-β-(β-D-glucuronide)	not detected	0.08%
Estradiol	0.13%	0.44%
Estrone	0.05%	0.06%
Estrone-β-D-glucuronide	not detected	0.07%
Estrone-3-sulfate	not detected	0.06%
16-Epiestriol	0.26%	0.30%
17-Epiestriol	0.10%	1.00%
Cortisol	not detected	not detected
11-deoxycortisol	not detected	not detected
5α-Dihydroxytestosterone	not detected	not detected
Testosterone	0.003%	not detected
16a-Hydroxyestrone	not reported	7.60%

Gabriel J. Muraca, Jr.

12/11/97
Date

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Gabriel Muraca, Jr.
Manager Regulatory Affairs
Bayer Corporation
511 Benedict Avenue
Tarrytown, New York 10591-5097

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Re: K974721
Unconjugated Estriol Assay for the Bayer Immuno 1™ System
Regulatory Class: I
Product Code: CGI
Dated: December 18, 1997
Received: December 18, 1997

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 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/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): k974721

Device Name: **Bayer Immuno 1™ System**
Unconjugated Estriol

Indications For Use:

This *in vitro* diagnostic method is intended to quantitatively measure unconjugated estriol (uE_3) in human serum on the Bayer Immuno 1™ system. Measurements of uE_3 are used in evaluating fetal well-being by monitoring the level of the hormone derived from fetal-placental circulation.

This diagnostic method is not intended for use on any other system.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number k974721

(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)