



## Audit® MicroCV™ Immunoassay Linearity Set For Use With Siemens Centaur® Immunoassay Systems

Cat. No. **K806M-5**  
Contents 10 x 5 mL

Lot No. 06196A, 06196B, 06196C,  
06196D, 06196E  
06196AA, 06196BB, 06196CC,  
06196DD, 06196EE

Expires 04/22/2011

For In Vitro Diagnostic Use Only.

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### INTENDED USE

Audit® MicroCV™ Immunoassay Linearity Set for use with Siemens Centaur® Immunoassay Systems consists of two sets of five levels each of human and bovine based serum albumin. Panel #1 contains the following analytes: Cortisol, Estradiol, FSH, Ferritin, Folate, LH, Prolactin, TSH, Total T4, and Vitamin B12. Panel #2 contains hCG, Progesterone, Total T3, and Free T4. These five levels of each panel (#1 and #2) demonstrate a linear relationship to each other for their respective analytes, reagents and instruments<sup>1</sup>.

This product may also be used as unassayed quality control material for these analytes. When used for quality control purposes, it is recommended that each laboratory establish its own means and acceptable ranges and use the values provided only as guides. In addition, it may be used for proficiency testing in interlaboratory surveys and to perform CLIA directed calibration verification<sup>2</sup> for these same analytes in accordance with current CLIA-88 guidelines and regulations<sup>3</sup>.

### SUMMARY AND PRINCIPLE

As defined in the Clinical Laboratory Improvement Amendments of 1988 (CLIA) by the Centers for Medicare and Medicaid Services (CMS) and the Centers for Disease Control (CDC), each laboratory must revalidate each test method's AMR at least every six months as well as following changes in lots of analytically critical reagents or major system components<sup>1</sup>. Good laboratory practices require that stable reference materials be used to verify the accuracy and precision of testing methods and techniques. Audit® MicroCV™ Immunoassay Linearity Set for use with Siemens Centaur® Immunoassay Systems may be used as one would use human serum to verify and validate the AMR.

### WARNINGS AND PRECAUTIONS

Because this product is of human origin, it should be handled as though capable of transmitting infectious diseases. Each serum, plasma or whole blood donor unit used in the preparation of this material was tested by United States Food and Drug Administration (FDA) approved methods and found to be negative for antibodies to HIV and HCV and nonreactive for HBSAg. Because no test method can offer complete assurance that HIV, hepatitis B virus, and hepatitis C virus or other infectious agents are absent, this material should be handled as though capable of transmitting infectious diseases. This product may also contain other human source material for which there is no approved test. The FDA recommends such samples be handled at the Centers for Disease Control's Biosafety Level 2.

This product contains less than 0.1% sodium azide that may react with lead and copper plumbing to form potentially explosive metal azides. On disposal, flush with a large volume of water to prevent azide build-up.

Audit® MicroCV™ Immunoassay Linearity Set for use with Siemens Centaur® Immunoassay Systems is intended solely for in vitro diagnostic use for the purpose described on the labeling. Audit® MicroControls™, Inc. shall not be liable for any unclaimed damages arising from any other usage.

### STORAGE AND STABILITY

Audit® MicroCV™ Immunoassay Linearity Set for use with Siemens Centaur® Immunoassay Systems is stored at 2-8°C and will remain stable in the unopened vial until the expiration date. After opening, the contents should be reconstituted immediately and used according to the instrument manufacturer's instructions.

It is recommended that Audit® MicroCV™ Immunoassay Linearity Set for use with Siemens Centaur® Immunoassay Systems be used within three days after

reconstitution and stored tightly capped at 2-8°C. Leaving the vial uncapped, or prolonging its time at room temperature, will void this reconstituted stability claim. Make sure the contents of the vial are well mixed before use.

### PROCEDURE

Follow the manufacturer's instructions provided for quality control and for verifying and validating the AMR. Verify that the lot number on each vial matches the package insert. To avoid evaporation, do not leave the vial uncapped. Q.C. requirements should be performed in conformance with local, state and/or federal regulations or accreditation requirements. Calibration verification linearity material should be run<sup>4</sup>:

1. every six (6) months.
2. when a complete change of reagents for a procedure is introduced.
3. when there is major preventive maintenance or replacement of critical parts that may influence test performance.
4. when control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits.
5. when the laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

### Materials provided

Audit® MicroCV™ Immunoassay Linearity Set for use with Siemens Centaur® Immunoassay Systems, 10 x 5 mL

### INSTRUCTIONS FOR USE

1. Remove a vial from the package, reconstitute with 5ml of deionized water, and gently swirl occasionally for 10 minutes. Do not shake. Do not mix mechanically.
2. Refer to instrument or assay instruction manual for verifying and validating the AMR.
3. After sampling, replace stopper and return to original package at 2-8°C to obtain the maximum open vial stability.

### CALCULATIONS OF RESULTS

Each set of Audit® MicroCV™ Immunoassay Linearity Set for use with Siemens Centaur® Immunoassay Systems is prepared in a manner such that an equal distance exists between each consecutive level. This dilution scheme is consistent with the NCCLS recommendation<sup>2</sup> for preparing linearity sets.

Once each vial of the total set is tested, raw data may be entered via the AUDITOR™ QC Program at [www.auditmicro.com](http://www.auditmicro.com). An on-line graph showing actual values versus predicted values for each analyte is then available to print, along with slope and intercept data. Call (866) 25-AUDIT for more information.

### LIMITATIONS OF THE PROCEDURE

Make sure that each vial is brought to room temperature before testing. If the contents of any of the vials become frozen, discard all vials and request a replacement set, as the results will not be valid.

<sup>1</sup>Dilution schemes are based on guidelines provided by The National Committee for Clinical Laboratory Standards (NCCLS) in approved guideline EP6-A, "Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach, Approved Guideline", April 2003.

<sup>2</sup>Federal Register 42 CFR Part 493, Department of Health and Human Services, January 24, 2003; p.3691.

<sup>3</sup>Federal Register 42 CFR Part 493, Department of Health and Human Services, January 24, 2003; §493.2.

<sup>4</sup>Federal Register 42 CFR Part 493, Department of Health and Human Services, January 24, 2003; §493.1255, (b) (1) (ii).

**LINEARITY FACTOR**

Each lot of product is manufactured such that a linear relationship exists among levels. The analyte concentrations in this insert were derived from multiple replicate analyses. Actual results obtained may vary depending on instrumentation, methodology and assay temperature. Results may also be dependent on the accuracy of the instrument/reagent system calibration. The degree of acceptable non-linearity is an individual judgment based on methodology, clinical significance and medical decision levels of the test analyte. The material and information presented here in no manner constitutes an overruling of any federal, state or other regulatory body's regulations and/or guidelines.

**ORDERING INFORMATION**

Product Number	Product Description	Product Packaging
K806M-5	Audit® MicroCV™ Immunoassay Linearity Set for use with Siemens Centaur® Immunoassay Systems	10 x 5mL

**Panel 1 - Centaur®**

	UNITS	A	B	C	D	E
Cortisol - old	ug/dL	0.895	26.2	45.0	62.1	75.7
Cortisol - new	ug/dL	0.648	22.4	41.0	61.4	75.9
Estradiol – E26III	pg/mL	58.2	308	633	867	989
FSH	mIU/mL	2.25	40.4	80.8	124	168
Ferritin	ng/mL	3.27	286	604	965	1278
Folate	ng/mL	0.106	4.46	8.91	15.4	22.9
LH	mIU/mL	0.399	49.3	96.5	159	194
Prolactin	ng/mL	1.38	40.6	82.3	134	195
TSH	µIU/mL	0.055	36.1	73.7	118	*
TSH3	µIU/mL	0.052	34.25	70.43	110.3	149.3
TSH3 Ultra	µIU/mL	0.045	35.93	73.08	112.8	153.3
Total T4	ug/dL	0	4.77	11.1	16.9	23.7
Vitamin B12	pg/mL	84.3	584	1117	1604	1986

**Panel 1 – Centaur CP®**

	UNITS	A	B	C	D	E
Cortisol - old	ug/dL	0.789	27.6	54.0	74.6	*
Cortisol - new	ug/dL	0.658	23.9	46.0	67.1	81.9
Estradiol – E26III	pg/mL	68.2	382	668	883	1006
FSH	mIU/mL	0.662	37.6	81.4	123	179
Ferritin	ng/mL	1.26	272	642	1031	1401
LH	mIU/mL	0.2814	43.4	85.7	134	172
Prolactin	ng/mL	1.38	39.4	88.7	148	209
TSH	µIU/mL	0.048	36.5	83.5	127	173
TSH3	µIU/mL	0.043	34.53	71.83	108.0	144.8
TSH3 Ultra	µIU/mL	0.051	40.15	81.70	120.8	159.0
Total T4	ug/dL	0	5.23	12.4	18.6	23.7
Vitamin B12	pg/mL	102	588	1082	1420	1734

**Panel 2 - Centaur®**

	UNITS	A	B	C	D	E
hCG	mIU/mL	6.85	236	471	675	912
Progesterone - old	ng/mL	2.46	20.0	37.2	53.3	67.9
Progesterone - new	ng/mL	1.6	16.7	32.2	46.8	59.7
Total T3	ng/mL	0.84	2.37	3.77	5.21	8.00
Free T4	ng/dL	0.369	3.94	7.61	11.6	17.4

**Panel 2 – Centaur CP®**

	UNITS	A	B	C	D	E
hCG	mIU/mL	4.61	229	445	650	878
Progesterone - old	ng/mL	2.54	19.2	33.9	43.7	52.5
Progesterone - new	ng/mL	1.94	17.5	35.3	50.5	67.4
Total T3	ng/mL	0.690	1.94	3.31	4.50	6.76
Free T4	ng/dL	0.063	3.92	7.08	10.6	14.2

\*These results are beyond the analytical measurement range (AMR) of the method. If a dilution of Level E is necessary to achieve a value within the AMR, please contact AUDIT MicroControls Technical Support Department at (866) 252-8348 for more information.

\*\*Testosterone and Free T3 are not available in this lot. Please contact Siemens to purchase MCM materials for these two analytes.