

510(k) SUMMARY: eSensor® Thrombophilia Risk Test on XT-8 System

Preparation Date: March 24, 2010

Submitted By:

Osmetech Molecular Diagnostics
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K093974

Contacts:

Robert Dicheck, Vice President - Quality & Regulatory Affairs (Official Correspondent)
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Proprietary Names and Classifications:

For the assay:

eSensor® FII-FV-MTHFR Genotyping Test (Kit)
eSensor® Thrombophilia Risk Test (Kit)
eSensor® FII-FV Genotyping Test (Kit)
eSensor® FII Genotyping Test (Kit)
eSensor® FV Genotyping Test (Kit)
eSensor® MTHFR Genotyping Test (Kit)

Regulation: 21CFR 864.7280

Panel: Hematology (81)

Classification: II

Product Codes: NPR, NPQ, OMM

For the instrument:

eSensor® XT-8 Instrument (System)

Regulation: 21CFR 862.2570

Panel: Clinical Chemistry (75)

Classification: II

Product Code: NSU - Instrument for Clinical Multiplex Test Systems

Common name:

For the assays:

FII, Factor II, coagulation factor II, prothrombin, G20210A
FV, Factor V, coagulation factor V, G1691A
MTHFR, methylenetetrahydrofolate reductase
Thrombosis Risk Genotyping Test
Thrombophilia Risk Test

For the instrument.

Instrument for Clinical Multiplex Test Systems

Intended uses:

This submission includes five separate product configurations, which were evaluated with the same data set.

1) The eSensor® Thrombophilia Risk Test is an *in vitro* diagnostic for the detection and genotyping of Factor II

(Prothrombin) G20210A, Factor V (Factor V Leiden) G1691A and MTHFR (human 5, 10 methylenetetrahydrofolate reductase gene) C677T and A1298C mutations in patients with suspected thrombophilia from isolated genomic DNA obtained from whole blood samples. The test is intended to be used on the eSensor® XT-8 System.

2) The eSensor® FII-FV Genotyping Test is an *in vitro* diagnostic for detection and genotyping of Factor II (Prothrombin) G20210A and Factor V (Factor V Leiden) G1691A mutations in patients with suspected thrombophilia from isolated genomic DNA obtained from whole blood samples. The test is intended to be used on the eSensor® XT-8 System.

3) The eSensor® FV Genotyping Test is an *in vitro* diagnostic for the detection and genotyping of a single point mutation (G to A at position 1691; also known as Factor V Leiden) of the human Factor V gene (FV; Coagulation Factor V gene) in patients with suspected thrombophilia from isolated genomic DNA obtained from whole blood samples. The test is intended to be used on the eSensor® XT-8 System.

4) The eSensor® FII Genotyping Test is an *in vitro* diagnostic for the detection and genotyping of a single point mutation (G to A at position 20210 of the human Factor II gene (FII; prothrombin gene) in patients with suspected thrombophilia, from isolated genomic DNA obtained from whole blood samples. The test is intended to be used on the eSensor® XT-8 System.

5) The eSensor® MTHFR Genotyping Test is an *in vitro* diagnostic for the detection and genotyping of point mutations (C to T at position 677) and (A to C at position 1298) of the human 5, 10 methylenetetrahydrofolate reductase gene (MTHFR) in patients with suspected thrombophilia, from isolated genomic DNA obtained from whole blood samples. The test is intended to be used on the eSensor® XT-8 System.

Special conditions for use statement(s):

For Prescription Use Only

The eSensor® Thrombophilia Risk Tests are *in vitro* diagnostic devices intended for genotyping either a single or multiple mutations or polymorphisms in an amplified DNA sample utilizing electrochemical detection technology, for use on the eSensor® XT-8 Instrument.

Predicate devices:

Verigene® F5 Nucleic Acid Test, Verigene® F2 Nucleic Acid Test, Verigene® MTHFR Nucleic Acid Test, K070597

eSensor® XT-8 Instrument, K073720 and K090901

Device Description:

The eSensor® Thrombophilia Risk Tests on the eSensor® XT-8 System are *in vitro* diagnostic devices for performing hybridization and genotyping of multiple mutations and/or polymorphisms in an amplified DNA sample. A single-use, disposable test cartridge is used to perform hybridization and genotyping. The cartridge contains an EEPROM chip which transmits the cartridge lot number, expiration date and protocol identity to the XT-8 instrument.

The analysis process for each sample consists of three steps: 1) Genomic DNA isolated from whole blood obtained using EDTA as anti-coagulant is combined with PCR Mix and Taq polymerase enzyme and is subjected to amplification of target sequences by PCR using a thermal cycler. 2) Amplified DNA is treated with exonuclease enzyme to generate single-stranded target DNA. 3) Single-stranded, amplified target DNA is mixed with hybridization and genotyping reagents and transferred to an eSensor® Test cartridge, and the cartridge is inserted in the eSensor® XT-8 Instrument. The instrument controls the circulation of the sample inside the cartridge to allow hybridization at a controlled temperature and then detects and genotypes the sample by voltammetry.

Genotyping of the test panel polymorphisms is achieved by a sandwich assay principle: 1) Each pair of electrodes contains a different synthetic oligonucleotide capture probe which is complementary to one of the target DNA

fragments. 2) The hybridization reagents contain pairs of ferrocene-labeled synthetic oligonucleotide signal probes; one member of each pair is complementary to the major allele sequence of the target polymorphism, while the second member of the pair is complementary to the minor allele sequence. Each member of the probe pair has a ferrocene label with a different oxidation potential for each allele. 3) Single-stranded, amplified target DNA hybridizes to its specific capture probe, and in turn hybridizes to the allele-specific, ferrocene-labeled signal probe. 4) Each electrode of the array is analyzed by voltammetry; the target polymorphism is determined by the location of the electrode containing the capture probe, and the genotype is identified by the ratio of signals from the allele-specific ferrocene labels. The array also includes positive and negative controls to confirm the hybridization reaction and detect non-specific signals.

Upon completion of the test, the EEPROM chip on the cartridge contains information that prevents its re-use with a new sample. The eSensor® XT-8 instrument analyzes the results and provides a report of the test results

Comparison to technological features of the predicate devices:

The following is a comparison of the Osmetech Molecular Diagnostics eSensor® Thrombophilia Risk Test on the XT-8 System to the predicates

Characteristic	The Verigene F5 Nucleic Acid Test, The Verigene F2 Nucleic Acid Test, The Verigene MTHFR Nucleic Acid Test (Predicate: K070597)	eSensor® Thrombophilia Risk Test
Test type	Qualitative genetic test for single nucleotide polymorphism detection	Same as predicate
Sample Type	Genomic DNA obtained from a human whole blood sample	Same as predicate
Target of detection	Single-nucleotide polymorphism	Same as predicate
DNA extraction	Performed off-line	Same as predicate
Genes	Factor V Leiden, Factor II, Prothrombin, MTHFR	Same as predicate
Number of Loci genotyped	3(FV, FII and MTHFR C677T	4 (FV, FII and MTHFR C677T and A1298C)
Genotyping reaction location	Test cartridge	Same as predicate
Genotyping principle	Sandwich hybridization test	Same as predicate
Instrument operating system	The Verigene System consists of two instruments, the Verigene Processor and the Verigene Reader.	eSensor® Instrument Model XT-8 (K073720 and K090901) is a single instrument with Processor and Reader
Assay results	Assay signal results are interpreted by a software program and are assigned a result that is presented to the end-user in a report format	Same as predicate

Performance Characteristics:

Site to Site, Operator to Operator, Day to Day, Run to Run and sample to sample reproducibility

The reproducibility study was performed over 5 non consecutive days at 3 different sites (2 external sites and 1 internal site). Each site performed the testing twice each day, using two different operators and the same testing materials. Each site had a separate XT-8 instrument. 5 gDNA samples containing a combination of samples which include hetero and homozygotes for FV, MTHFR C677T and A1298C, as well as FII heterozygotes were run in duplicate each day by each operator in order to assess intra-assay reproducibility

Summary of Inter-laboratory, Inter-operator, Reproducibility Results

Site	Operator	Samples Tested	First pass Correct calls	First pass no- calls	Miscalls	Final Correct calls	% Agreement
Site A	1	50	50	0	0	50	100%
	2	50	50	0	0	50	100%
Site B	1	50	50	0	0	50	100%
	2	50	49	1	0	50	100%
Site C	1	50	49	*1	0	50	100%
	2	50	50	0	0	50	100%
All	All	300	298	2	0	300	100%

*This no-call was due to MTHFR-A1298C low signal. FII, FV and MTHFR-C677T were correctly called.

Genomic DNA Extraction Reproducibility

A total of 6 whole blood samples of different genotypes were extracted by three commonly used extraction methods and tested using the eSensor® Thrombophilia Risk Test. The data were evaluated after first-pass results. There were zero no-call or miscalls. All samples gave 100% correct calls when compared with DNA sequencing. There was no impact of extraction method observed in this study. The following table summarizes the results of extraction reproducibility study.

Extraction Method	# Samples Tested	First pass correct calls	First pass No Calls	Miscalls	Final correct calls	Final Agreement %
A	6	6	0	0	6	100%
B	6	6	0	0	6	100%
C	6	6	0	0	6	100%
Total	18	18	0	0	18	100%

Lot to Lot Reproducibility

A total of 5 genomic DNA samples, containing positive calls for FII, FV, and MTHFR C677T and A1298C, were tested in duplicates using three different kit lots of the eSensor® Thrombophilia Risk Test. The data were evaluated after first-pass results and following an additional run for a single no-call. All samples gave 100% correct calls when compared with DNA sequencing. There was a single first-pass no-call, but no impact of kit lot observed in this study. The following table summarizes the results of lot to lot reproducibility study.

LOT	Samples Tested	First pass correct calls	First pass		Final		Final correct calls	Final % Agreement
			No Calls	Mis-Calls	No Calls	Mis-Calls		
1	20	20	0	0	0	0	20	100%
2	20	19	1	0	0	0	20	100%
3	20	20	0	0	0	0	20	100%
Total	60	59	*1	0	0	0	60	100%

*The single no-call was due to FII low signal. FV, MTHFR-C677T and MTHFR-A1298C were correctly called.

Method Comparison

In a method comparison study, a total of 219 gDNA samples extracted from whole blood with A260-280 ratios of 1.0-2.9 were genotyped using the eSensor® Thrombophilia Risk Test and DNA sequencing. All samples gave 100% agreement with DNA sequencing.

FV Mutation

Results by DNA Sequencing	First Pass Results							Final Results						
	eSensor® Results			1st Pass No-calls	Miscalls	% Agreement	95% LCB	eSensor® Results			Final No-calls	Miscalls	% Agreement	95% LCB
	WT	HET	MUT					WT	HET	MUT				
WT	181	0	0	1	0	99.45%	97.42%	182	0	0	0	0	100.00%	98.37%
HET	0	27	0	1	0	96.43%	84.15%	0	28	0	0	0	100.00%	89.85%
MUT	0	0	9	0	0	100.00%	71.69%	0	0	9	0	0	100.00%	71.69%

FII Mutation

Results by DNA Sequencing	First Pass Results							Final Results						
	eSensor® Results			1st Pass No-calls	Miscalls	% Agreement	95% LCB	eSensor® Results			Final No-calls	Miscalls	% Agreement	95% LCB
	WT	HET	MUT					WT	HET	MUT				
WT	183	0	0	1	0	99.46%	97.45%	184	0	0	0	0	100.00%	98.39%
HET	0	27	0	0	0	100.00%	89.50%	0	27	0	0	0	100.00%	89.50%
MUT	0	0	6	2	0	75.00%	40.03%	0	0	8	0	0	100.00%	68.77%

MTHFR (C677T) Mutation

Results by DNA Sequencing	First Pass Results							Final Results						
	eSensor® Results			1st Pass No-calls	Miscalls	% Agreement	95% LCB	eSensor® Results			Final No-calls	Miscalls	% Agreement	95% LCB
	WT	HET	MUT					WT	HET	MUT				
WT	68	0	0	0	0	100.00%	95.69%	68	0	0	0	0	100.00%	95.69%
HET	0	118	0	2	0	98.33%	94.85%	0	120	0	0	0	100.00%	97.53%
MUT	0	0	31	0	0	100.00%	90.79%	0	0	31	0	0	100.00%	90.79%

MTHFR (A1298C) Mutation

Results by DNA Sequencing	First Pass Results							Final Results						
	eSensor® Results			1st Pass No-calls	Miscalls	% Agreement	95% LCB	eSensor® Results			Final No-calls	Miscalls	% Agreement	95% LCB
	WT	HET	MUT					WT	HET	MUT				
WT	69	0	0	0	0	100.00%	95.75%	69	0	0	0	0	100.00%	95.75%
HET	0	117	0	3	0	97.50%	93.67%	0	120	0	0	0	100.00%	97.53%
MUT	0	0	30	0	0	100.00%	90.50%	0	0	30	0	0	100.00%	90.50%

Other Characteristics of the eSensor® Thrombophilia Risk Tests:

Characteristic	Result									
Limit of detection	<p>Two genomic DNA samples of different genotypes were extracted from whole blood stored in EDTA and serially diluted and tested 20 times each at input amounts of 0.1, 1, 10, 100, and 500 ng/PCR. using the eSensor® Thrombophilia Risk Test. Up to two additional run were performed for tests that gave a first pass no call result..</p> <p>All samples and replicates from 10ng-500ng input amount and above were called correctly with 100% agreement and 97.53% (95% LCB). At the limit of detection (1ng input amount), 39/40 replicates were correctly called which translates to 98% agreement 88.68% (95% LCB). The single no-call at the LOD was a positive cartridge control failure and not due to the input gDNA amount.</p> <p>The lower detection limit was determined to be 1ng of purified DNA per reaction and the upper detection limit was determined to be 500 ng of purified DNA per reaction. The recommended range of DNA input amounts for the eSensor® Thrombophilia Risk Test is from 10 to 500 ng.</p>									
Interfering substances	<p>Test performance was not affected by addition of the following substances to two whole blood samples of different genotypes prior to extraction</p> <ul style="list-style-type: none"> ● Heparin (3,000 U/L) ● Cholesterol (250 mg/dL) ● Bilirubin (30 mg /dL whole blood). ● Hemoglobin (~20g /dL whole blood). ● EDTA (at a concentration equivalent to 5-fold higher than that provided by a standard EDTA blood collection tube) 									
Interfering mutations and polymorphisms	<p>The following interfering mutations were tested in 40 replicates alongside a Wild-Type control gDNA sample, with no effect observed on, multiplex amplification of target gene sequences, or genotyping of FII-FV-MTHFR panel mutations by the eSensor® Thrombophilia Risk Test:</p> <table border="1" data-bbox="727 842 1260 1089"> <thead> <tr> <th>Non-Panel Mutation or Polymorphism</th> <th>Panel Mutation</th> </tr> </thead> <tbody> <tr> <td>1692A>C</td> <td rowspan="3">FV-1691G>A</td> </tr> <tr> <td>1689G>A</td> </tr> <tr> <td>1696A>G</td> </tr> <tr> <td>20207A>C</td> <td rowspan="2">FII-20210G>A</td> </tr> <tr> <td>20209C>T</td> </tr> </tbody> </table>	Non-Panel Mutation or Polymorphism	Panel Mutation	1692A>C	FV-1691G>A	1689G>A	1696A>G	20207A>C	FII-20210G>A	20209C>T
Non-Panel Mutation or Polymorphism	Panel Mutation									
1692A>C	FV-1691G>A									
1689G>A										
1696A>G										
20207A>C	FII-20210G>A									
20209C>T										

Kit Stability:

eSensor® Thrombophilia Risk Test kit components should be stored under the appropriate conditions until the expiration date printed on the label:

- PCR Box containing FII-FV-MTHFR PCR Mix and Taq Polymerase: Store at -20°C in a designated pre-PCR area.
- Cartridges: Store at 10° to 25°C
- Genotyping Box containing Exonuclease, FII-FV-MTHFR Signal Buffer, XT-Buffer 1 and XT-Buffer 2: Store at -20°C in a designated post-PCR area.

In-process stability has been established for the following components, working reagents and samples:

- Cartridges can be stored for up to 30 days after opening the foil pouches. If stored, cartridges should be kept in their original foil pouch at room temperature in a dry place with the zip-loc closure sealed.
- Reagents can be thawed up to 5 times.
- Whole blood stored in EDTA can be stored for up to 4 weeks after collection prior to extraction of gDNA for use in the eSensor® Thrombophilia Risk Tests.
- PCR product can be stored at 4°C or -20°C for up to 7 days.
- Exonuclease-digested PCR product can be stored store at 4°C or -20°C for up to 7 days.
- After combining the exonuclease-digested PCR with hybridization reagents, the hybridization reaction can be loaded on the cartridge and held at ambient temperature for up to 8 hours before initiating hybridization of the cartridge on the XT-8 instrument.

Conclusion:

The above internal and clinical test results support the safety and effectiveness of the eSensor® Thrombophilia Risk Tests on the eSensor® XT-8 System, and demonstrate substantial equivalence to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center-WO66-G609
Silver Spring, MD 20993-0002

Osmetech Molecular Diagnostics
c/o Mr. Robert S. Dicheck
VP, Quality & Regulatory Affairs
757 South Raymond Avenue
Pasadena, CA 91105

APR 22 2010

Re: k093974

Trade/Device Name: eSensor® Thrombophilia Risk Test
eSensor® FII-FV Genotyping Test
eSensor® FII Genotyping Test
eSensor® FV Genotyping Test
eSensor® MTHFR Genotyping Test
Regulation Number: 21 CFR §864.7280
Regulation Name: Factor V Leiden DNA Mutation Detection Systems
Regulatory Class: Class II
Product Code: NPQ, NPR, OMM, NSU
Dated: April 1, 2010
Received: April 5, 2010

Dear Mr. Dicheck:

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 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) that do not require approval of a premarket approval application (PMA). 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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 – Mr. Robert S. Dicheck

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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



for

Maria M. Chan, Ph.D
Director

Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k)-Number (if known): k093974

Device Name: eSensor® Thrombophilia Risk Test

Indications for Use:

The eSensor® Thrombophilia Risk Test is an *in vitro* diagnostic for the detection and genotyping of Factor II (Prothrombin) G20210A, Factor V (Factor V Leiden) G1691A and MTHFR (human 5, 10 methylenetetrahydrofolate reductase gene) C677T and A1298C mutations in patients with suspected thrombophilia from isolated genomic DNA obtained from whole blood samples. The test is intended to be used on the eSensor® XT-8 System.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Keena Philip

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k093974

Indications for Use Form

510(k) Number (if known): K093974

Device Name: eSensor® FV Genotyping Test

Indications for Use:

The eSensor® FV Genotyping Test is an *in vitro* diagnostic for the detection and genotyping of a single point mutation (G to A at position 1691; also known as Factor V Leiden) of the human Factor V gene (FV; Coagulation Factor V gene) in patients with suspected thrombophilia from isolated genomic DNA obtained from whole blood samples. The test is intended to be used on the eSensor® XT-8 System.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Deena Philip

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K093974

Indications for Use Form

510(k) Number (if known): K093974

Device Name: eSensor® FII Genotyping Test

Indications for Use:

The eSensor® FII Genotyping Test is an *in vitro* diagnostic for the detection and genotyping of a single point mutation (G to A at position 20210 of the human Factor II gene (FII; prothrombin gene) in patients with suspected thrombophilia, from isolated genomic DNA obtained from whole blood samples. The test is intended to be used on the eSensor® XT-8 System.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Leena Philip

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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Indications for Use Form

510(k) Number (if known): K093974

Device Name: eSensor® FII-FV Genotyping Test

Indications for Use:

The eSensor® FII-FV Genotyping Test is an *in vitro* diagnostic for detection and genotyping of Factor II (Prothrombin) G20210A and Factor V (Factor V Leiden) G1691A mutations in patients with suspected thrombophilia from isolated genomic DNA obtained from whole blood samples. The test is intended to be used on the eSensor® XT-8 System.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Leena Philip

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Indications for Use Form

510(k) Number (if known): K093974

Device Name: eSensor® MTHFR Genotyping Test

Indications for Use:

The eSensor® MTHFR Genotyping Test is an *in vitro* diagnostic for the detection and genotyping of point mutations (C to T at position 677) and (A to C at position 1298) of the human 5, 10 methylenetetrahydrofolate reductase gene (MTHFR) in patients with suspected thrombophilia, from isolated genomic DNA obtained from whole blood samples. The test is intended to be used on the eSensor® XT-8 System.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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