



July 3, 2007

Esoterix Coagulation Service Update: Effective July 15th

Esoterix is committed to keeping our clients informed of changes, updates, and enhancements to our testing services as they occur. A complete listing of service changes is included with this letter and has been posted to our website at www.esoterix.com in the test menu section. All changes go into effect on July 15, 2007.

For additional information, please call us at (800) 444-9111. We value you as a customer and thank you for choosing Esoterix.

Assay Changes (Effective July 15, 2007)

Test Code/Test Name	Tests Included	CPT Code	Specimen Requirement	Comments
300250 - Aspirincheck	11-Dehydro Thromboxane B2/Creatinine Ratio RUO*	83520 ,82570	9 mL urine with specific preservative.	Discontinued Test Code. Replaced with 300353 AspirinWorks, see below.
300353 - AspirinWorks	AspirinWorks™ results	83520, 82570	9mL urine; add Chlorstat tablet within 4 hours. Stable refrigerated for 24 hours. Freeze sample within 24 hours; ship frozen on dry ice for overnight delivery.	reported in pg 11dhTxB2/mg creatinine; Change to FDA approved kit. See attached sample report for interpretive comments. <u>*** Please note updated test contains both 83520 and 82570 for CPT code reporting.</u>

Patient: PROFILE 300353 A
Patient ID:
Gender / Age / DOB: / /
Referring Physician:
Accession No.: 43T0016160

Coagulation In-House Account
3176 South Peoria Court
Aurora, CO 80014
National Account No.: 999944

Date/Time Reported: Jun. 26, 2007 8:43AM CT
Specimen:

Date/Time Collected: Not Given
Date Received: Jun. 25, 2007

Test	Result	Unit	Flag	Reference Range
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AspirinWorks

AspirinWorks(TM) Results	1499	pg 11dhTxB2 /mg creat		
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AspirinWorks Interpretation

Result <=1500 pg 11dhTxB2 per mg creatinine: If the patient is on aspirin therapy a urinary level below 1500 pg 11dhTxB2/mg creatinine is in a range consistent with a healthy population responsive to aspirin. If the patient is not on aspirin, the patient may have taken aspirin or another aspirin-like platelet suppressing agent.

Patient: PROFILE 300353 A

Patient ID:

Accession No.: 43T0016160

Test	Result	Unit	Flag	Reference Range
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AspirinWorks (continued)

Aspirinworks(TM) Report

Aspirinworks(TM) is an enzyme-linked immunoassay that measures urinary levels of 11-dehydro thromboxane B2 (11dhTxB2), a stable metabolite of thromboxane A2 (TXA2). Results are reported as pg urinary 11dhTxB2 per mg urinary creatinine in order to normalize results for the concentration of the urine sample tested.

Aspirin serves as an antithrombotic agent through its suppression of platelet TXA2. In a typical response to aspirin, urinary levels of 11dhTxB2 are reduced compared to levels in the same population not on aspirin therapy. Not all individuals on aspirin therapy show the expected reduction in urinary levels of 11dhTxB2, while some individuals not on aspirin have lower than expected values. The basis for these findings may be multi-factorial (see below).

Interpretation of Aspirinworks(TM) in Aspirin therapy

The manufacturer recommended cut-off value of 1500 pg urinary 11dhTxB2 per mg urinary creatinine was based on the evaluation of 166 apparently healthy adults before and/or after receiving controlled doses of aspirin (81 mg to 325 mg). Values below the 1500 pg/mg cutoff value distinguished those on aspirin therapy with 95% agreement.

Individuals on aspirin therapy may have urinary 11dhTxB2 values above the 1500 pg 11dhTxB2 per mg creatinine cut-off for a variety of reasons including but not limited to, non-compliance to daily aspirin therapy, inadequate aspirin dose, increased platelet turnover, increased platelet activation, drug interactions (NSAID, heparin), the presence of certain COX polymorphisms and up-regulation of COX 2 activity in monocytes/macrophages. One limitation of this assay is that urinary 11dhTxB2 concentrations reflect in vivo thromboxane production from both platelet and extra-platelet sources. There is no clinical evidence that modifying a patient's aspirin therapy according to their level of urinary 11-dhTxB2 improves patient outcomes.

Platelet Inhibition in the Absence of Aspirin

Many common over the counter medications such as Alka Seltzer(TM), Bufferin(TM) and Kaopectate(TM) contain aspirin or salicylate compounds. A variety of prescription compounds may also contain aspirin or salicylate components including Darvon(TM). Non-steroidal anti-inflammatory drugs such as Motrin(TM), Naprosyn(TM) and Alleve(TM) may also temporarily reduce platelet function. Red wine, purple grape juice, a diet rich in fish, fish oils or herbal preparations such as garlic, St John's Wort or ginkgo biloba may reduce platelet function and result in decreased urinary 11dhTxB2.

References:

Eur Heart J. 2006;27:647-654.

Circulation. 2002;105:1650-1655.

Thromb Haem. 1997;78:1434-1437.

Thrombosis Research 2007; doi:10.1016/j.thrombres.2006.08.014

AspirinWorks(TM) Test Kit package insert. Corgenix, Inc. 11575 Main St, Suite 400, Broomfield, CO. 80020.2007

Patient: PROFILE 300353 B
Patient ID:
Gender / Age / DOB: F / 29 Y /
Referring Physician:
Accession No.: 43T0016161

Coagulation In-House Account
3176 South Peoria Court
Aurora, CO 80014
National Account No.: 999944

Date/Time Reported: Jun. 26, 2007 8:44AM CT
Specimen:

Date/Time Collected: Not Given
Date Received: Jun. 25, 2007

Test	Result	Unit	Flag	Reference Range
AspirinWorks				
AspirinWorks(TM) Results	1501	pg 11dhTxB2 /mg creat		

AspirinWorks Interpretation

Result >1500 pg 11dhTxB2 per mg creatinine: If the patient is on aspirin therapy a urinary level above 1500 pg 11dhTxB2/mg creatinine suggests an inadequate response to aspirin. This result is in the range of response that would be expected in an individual not on aspirin therapy.

Patient: PROFILE 300353 B

Patient ID:

Accession No.: 43T0016161

Test	Result	Unit	Flag	Reference Range
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AspirinWorks (continued)

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Thrombosis Research 2007; doi:10.1016/j.thrombres.2006.08.014

AspirinWorks(TM) Test Kit package insert. Corgenix, Inc. 11575 Main St, Suite 400, Broomfield, CO. 80020.2007