From: Salazar, Alberto
Sent: Wednesday, February 02, 2011 1:59 PM
To: Amy Eichner, Ph.D.
Subject: RE: Prednisone test
Attachments: image001.jpg; image002.png

HI Amy, Thanks for being so nice and understanding! We really appreciate it! - Alberto

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From: Amy Eichner, Ph.D.
Sent: Wednesday, February 02, 2011 1:53 PM
To: Salazar, Alberto
Subject: RE: Prednisone test

Hi Alberto- You are not pestering me at all- don't worry. I understand your athlete's position and he is lucky to have someone working so hard in his interest.

Let me ask around a bit on your situation below, and see if I can come up with a way forward for you.

Kind regards,
Amy

Amy Eichner Ph.D.
Drug References Resources Manager
US Anti-Doping Agency

ATTENTION: Please notice our new address as of July 6th, 2010.

From: Salazar, Alberto
Sent: Wednesday, February 02, 2011 2:39 PM
To: Amy Eichner, Ph.D.
Subject: FW: Prednisone test

HI Amy, I haven't pestered you for a week so I thought I'd better send this. Ha Ha! Sorry, I know I'm a pain, but I'm a worrier and want to eliminate all risk. We always try to be very careful and never try to abuse the system. In the past

we've always got the TUE for Galen after he had an asthma attack, unless he wasn't competing for a month. Although we did get an answer from the IAAF via USADA last year saying that no TUE was needed if Galen was competing 8 days after his last dose, he didn't end up running so I didn't pursue it. I'm nervous now that it seems there is always a chance of a positive test? Galen is running in Dusseldorf Germany on Feb.11th, that will have been 15 days since his last dose of prednisone. I realize that should be sufficient time to clear, however I'm planning on having Galen give us a urine sample on Sunday Feb.6th which will have been ten days since his last dose. I will have it hand carried to the Mayo Clinic in Rochester and it will be tested on Monday the 7th, with the results back the next day on Tuesday. I'm forwarding to you the test details of the Glucocorticoid tests they do and was wondering if they are equal to the testing sensitivity of the WADA/IAAF testing that Galen's urine might be subject to in Dusseldorf after his race? I don't want to waste all the time and effort on getting the urine sample to the Mayo Clinic if it's not going to give us good information. The other option I have is getting it tested in Germany when Galen arrives there early next week if the German labs where we could test it are more sensitive and we could get the results by Friday. Finally, is it worth us applying for a TUE again with more information that they requested and everything in block letters, or is that going to antagonize them? Thanks for your patience with me! Sincerely, Alberto Salazar

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From: Steve Magness
Sent: Wednesday, February 02, 2011 1:15 PM
To: Salazar, Alberto
Subject: Re: Prednisone test

=Here's the link and below is the information regarding the test for glucocorticoids (prednisone): http://www.mayomedicallaboratories.com/test-catalog/print.php?unit_code=81035

Unit Code 81035: Synthetic Glucocorticoid Screen, Urine

Useful For Suggests clinical disorders or settings where the test may be helpful

Confirming the presence of the listed synthetic glucocorticoids (see "Interpretation")

Confirming the cause of secondary adrenal insufficiency

Method Name A short description of the method used to perform the test

Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS)

Stable Isotope Dilution Analysis

Reporting Name A shorter/abbreviated version of the Published Name for a test; an abbreviated test name

Synthetic Glucocorticoid Screen, U

Ordering Mnemonic An alternate Mayo code (to the Unit Code) for a test

SGSU

Aliases Lists additional common names for a test, as an aid in searching

Aerobid

AeroBid-M

Azmacort

Becloforte Inhaler

Beclomethasone Dipropionate

Beclovent Inhaler

Beconase

Betamethasone

Budesonide

Celestone

Cutivate 0.005%

Decadron

Deltasone

Depo-Medrol

Dexamethasone

Diprolene

Diprolene AF

Diprosone

Entocort EC

Flonase

Flovent

Flovent Rotadisk

Fludrocortisone

Flunisolide

Fluorometholone

Fluticasone Propionate

FML Forte Liquifilm

FML Liquifilm

FML S.O.P.

Kenalog

Liquid Pred

Medrol

Megace

Megestrol Acetate

Methylprednisolone

Mycolog-II

Nasalide

Orasone

Prednisolone

Prednisone

PULMICORT TURBUHALER

Rhinocort

Soft-SGSU

Solu-Medrol

Triamcinolone

Triamcinolone Acetonide

Vancenase

Vanceril

Specimen Required Defines the optimal specimen. This field describes the type of specimen required to perform the test and the preferred volume to complete testing. The volume allows automated processing, fastest throughput and, when indicated, repeat or reflex testing.

Container/Tube: Plastic, 13-mL urine tube

Specimen Volume: 5 mL from a random urine collection

Collection Instructions: No preservative.

Specimen Minimum Volume Defines the amount of specimen required to perform an assay once, including instrument and container dead space. Submitting the minimum specimen volume makes it impossible to repeat the test or perform confirmatory or perform reflex testing. In some situations, a minimum specimen volume may result in a QNS (quantity not sufficient) result, requiring a second specimen to be collected.

0.6 mL

Transport Temperature Provides a description of the temperatures required to transport a specimen to the laboratory. Alternate acceptable temperature(s) and unacceptable transport temperature(s) are also included. The preferred transport temperature is listed first, followed by the alternate acceptable temperature (if appropriate) and lastly, the unacceptable transport temperature(s).

Frozen\Ambient OK\Refrig OK

Reject Due To Identifies specimen types and conditions that may cause the specimen to be rejected

Specimens other than Urine

Anticoagulants other than	NA
Hemolysis	NA
Lipemia	NA
Icteric	NA

Clinical Information Discusses physiology, pathophysiology, and general clinical aspects, as they relate to a laboratory test

Synthetic glucocorticoids are widely used and have important clinical utility both as anti-inflammatory and immunosuppressive agents. The medical use of these agents, as well as their surreptitious use, can sometimes lead to a confusing clinical presentation. Patients exposed to these steroids may present with clinical features of Cushing's syndrome, but with suppressed cortisol levels and evidence of hypothalamus-pituitary-adrenal axis suppression.

Reference Values Describes reference intervals and additional information for interpretation of test results. May include intervals based on age and sex when appropriate. Intervals are Mayo-derived, unless otherwise designated. If an interpretive report is provided, the reference value field will state this.

Negative

Cutoff concentrations

Beclomethasone dipropionate: 0.10 mcg/dL

Betamethasone: 0.10 mcg/dL

Budesonide: 0.10 mcg/dL

Dexamethasone: 0.10 mcg/dL

Fludrocortisone: 0.10 mcg/dL

Flunisolide: 0.10 mcg/dL

Fluorometholone: 0.10 mcg/dL

Fluticasone propionate: 0.10 mcg/dL

Megestrol acetate: 0.10 mcg/dL

Methylprednisolone: 0.10 mcg/dL

Prednisolone: 0.10 mcg/dL

Prednisone: 0.10 mcg/dL

Triamcinolone 0.30 mcg/dL

Triamcinolone acetonide: 0.10 mcg/dL

Values for normal patients not taking these synthetic glucocorticoids should be less than the cut off concentration (detection limit).

Interpretation Provides information to assist in interpretation of the test results

This test screens for and quantitates if present, the following synthetic glucocorticoids: beclomethasone dipropionate, betamethasone, budesonide, dexamethasone, fludrocortisone, flunisolide, fluorometholone, fluticasone propionate, megestrol acetate, methylprednisolone, prednisolone, prednisone, triamcinolone, triamcinolone acetonide.

The presence of synthetic glucocorticoids in urine indicates current or recent use of these compounds. Since several of these compounds exceed the potency of endogenous cortisol by 1 or more orders of magnitude, even trace levels may be associated with Cushingoid features.

Cautions Discusses conditions that may cause diagnostic confusion, including improper specimen collection and handling, inappropriate test selection, and interfering substances

This method cannot detect all of the available synthetic steroids either available as pharmaceutical compounds or chemicals present in food. The assay confirms only the listed synthetic glucocorticoids (see "Interpretation").

Lack of detection does not preclude use of synthetic glucocorticoid because adrenal suppression may persist for some time after the exogenous steroid is discontinued.

Clinical Reference Provides recommendations for further in-depth reading of a clinical nature

1. Cave A, Arlett P, Lee E: Inhaled and nasal corticosteroids: factors affecting the risks of systemic adverse effects. Pharmacol Ther 1999 Sep;83(3):153-179

2. Bijlsma JW, van Everdingen AA, Huisman M, et al: Glucocorticoids in rheumatoid arthritis: effects on erosions and bone. Ann NY Acad Sci 2002 Jun;966:82-90

3. Sandborn WJ: Steroid-dependent Crohn's disease. Can J Gastroenterol 2000 Sep;14 Suppl C:17C-22C

4. Benvenuti S, Brandi ML: Corticosteroid-induced osteoporosis: pathogenesis and prevention. Clin Exp Rheumatol 2000 Jul-Aug;18(4 Suppl 20):S64-S66

5. Loke TK, Sousa AR, Corrigan CJ, Lee TH: Glucocorticoid-resistant asthma. Curr Allergy Asthma Rep 2002 Mar;2(2):144-150

Method Description Describes how the test is performed and provides a method-specific reference

The synthetic glucocorticoids are extracted from 0.5 mL of urine using an acetonitrile protein precipitation followed by methylene chloride liquid extraction of the solvent. Cortisol-9,11,12,12-d, and triamcinolone-d1 acetonide-d6 are added to each sample before the liquid extraction and serve as the internal standards. Then, 17 uL of the reconstituted sample extract is injected into a high-performance liquid chromatography (HPLC) system and analyzed by tandem mass spectrometry (LC-MS/MS). The mass spectrometer has an electrospray interface and is operated in the multiple-reaction monitoring positive mode. The calibration utilizes a 4-point standard curve over a concentration range of 0 mcg/dL to 25 mcg/dL. (McWhinney BC, Ward G, Hickman PE: Improved HPLC method for simultaneous analysis of cortisol, 11-deoxycortisol, prednisolone, methylprednisolone, and dexamethasone in

serum and urine. Clin Chem 1996;42:979-981; Savu S, Silvestro L, Haag A, Sorgel F: A confirmatory HPLC-MS/MS method for ten synthetic corticosteroids in bovine urines. J Mass Spectrom 1996 December;31 [12]:1351-1363)

Day(s) and Time(s) Test Performed Outlines the days and times the test is performed. This field reflects the day and time the sample must be in the testing laboratory to begin the testing process and includes any specimen preparation and processing time required before the test is performed. Some tests are listed as continuously performed, which means assays are performed several times during the day.

Monday, Thursday; 11 a.m.

Analytic Time Defines the amount of time it takes the laboratory to setup and perform the test. This is defined in number of days. The shortest interval of time expressed is "same day/1 day," which means the results may be available the same day that the sample is received in the testing laboratory. One day means results are available 1 day after the sample is received in the laboratory.

2 days

Maximum Laboratory Time Defines the maximum time from specimen receipt at Mayo Medical Laboratories until the release of the test result

4 days

Specimen Retention Time Outlines the length of time after testing that a specimen is kept in the laboratory before it is discarded

2 weeks

Performing Laboratory Location The location of the laboratory that performs the test

Rochester

Test Classification Provides information regarding the medical device classification for laboratory test kits and reagents. Tests may be classified as cleared or approved by the US Food and Drug Administration (FDA) and used per manufacturer's instructions, or as products that do not undergo full FDA review and approval, and are then labeled as an Analyte Specific Reagent (ASR), Investigation Use Only (IUO) product, or a Research Use Only (RUO) product.

This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

CPT Code Information Provides guidance in determining the appropriate Current Procedural Terminology (CPT) code(s) information for each unit code or profile. The listed CPT codes reflect Mayo Medical Laboratories interpretation of CPT coding requirements. It is the responsibility of each laboratory to determine correct CPT codes to use for billing.

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