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Customer Testing Report

Generated On: 12/18/2024 Report Status: FINAL

Performing Laboratory:

US Specialty Labs LP | 15150 Avenue of Science, Suite 100 San Diego, CA 92128 CLIA# 05D2130115 | Laboratory Director: Robert Veve, M.D Ordering Physician: Kulbersh Health Screening Services | Phone: 866-781-4007

Patient Information here.

Panel / Test	Result	Normal Reference Range
25-(OH) Vitamin D	27.50 ng/mL	25-100 ng/mL
Collected: Sep 17, 2024 Reported: Dec 18, 2024		
Folate	5.0 ng/mL	>4 ng/mL
Collected: Sep 17, 2024		
Reported: Dec 18, 2024		
Vitamin B12	245.0 pg/mL	180-914 pg/mL
Collected: Sep 17, 2024		
Reported: Dec 18, 2024		

Testing Methods

Alanine Aminotransferase (ALT)

INSTRUMENT: Au680 from Beckman Coulter The Alanine Aminotransferase (ALT) assay utilizes colorimetry, turbidimetry, latex agglutination, or homogeneous EIA. This assay is intended to be used as an aid in the diagnosis of elevated or decreased ALT levels.

Anti-Mullerian Hormone (AMH)

INSTRUMENT: DXI 800 from Beckman Coulter The Anti-Mullerian Hormone (AMH) assay utilizes enzyme immunoassays (utilizing paramagnetic particle solid phase and chemiluminescent detection). This assay is intended to be used as an aid in the diagnosis of elevated or decreased AMH levels.

Aspartate Aminotransferase (AST)

INSTRUMENT: Au680 from Beckman Coulter The Aspartate Aminotransferase (AST) assay utilizes colorimetry, turbidimetry, latex agglutination, or homogeneous EIA. This assay is intended to be used as an aid in the diagnosis of elevated or decreased AST levels.

Blood Urea Nitrogen (BUN)

INSTRUMENT: Au680 from Beckman Coulter The Blood Urea Nitrogen (BUN) assay utilizes colorimetry, turbidimetry, latex agglutination, or homogeneous EIA. This assay is intended to be used as an aid in the diagnosis of elevated or decreased BUN levels.



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Total Cholesterol

INSTRUMENT: Au680 from Beckman Coulter The Total Cholesterol assay utilizes colorimetry, turbidimetry, latex agglutination, or homogeneous EIA. This assay is intended to be used as an aid in the diagnosis of elevated or decreased total cholesterol levels.

Cortisol

INSTRUMENT: Beckman Coulter Access II This cortisol test uses uses enzyme-mediated chemiluminescence. his assay is intended to be used as an aid in the diagnosis of elevated or decreased cortisol levels.

Creatinine

INSTRUMENT: Au680 from Beckman Coulter The Creatinine assay utilizes colorimetry, turbidimetry, latex agglutination, or homogeneous EIA. This assay is intended to be used as an aid in the diagnosis of elevated or decreased creatinine levels.

DHEA-S

INSTRUMENT: DXI 800 from Beckman Coulter The DHEA-S assay utilizes enzyme immunoassays (utilizing paramagnetic particle solid phase and chemiluminescent detection). This assay is intended to be used as an aid in the diagnosis of elevated or decreased DHEA-S levels.

Estradiol (Sensitive)

INSTRUMENT: DXI 800 from Beckman Coulter The Estradiol assay uses enzyme immunoassays (utilizing paramagnetic particle solid phase and chemiluminescent detection) for determination of estradiol. The estradiol assay is intended to be used as an aid in the diagnosis of elevated or decreased estradiol levels.

FIT - Human Hemoglobin (hHb)

This test is performed by the FDA 510(k) cleared OC-Auto Diana using OC-Sensor DIANA iFOB test kit (K092330 510(k)). This test is an immunochemical assay and intended for the qualitative detection of human hemoglobin (hHb) in the stool. A negative result does not mean that colorectal cancer or colon polyps are not present. If a patient collected samples during the menstrual period or is experiencing active bleeding from hemorrhoids, a test result is most likely to yield a false positive result. In such a case, a recollection is highly recommended.

Follicle-Stimulating Hormone (FSH)

INSTRUMENT: DXI 800 from Beckman Coulter The Follicle-Stimulating Hormone (FSH) assay uses enzyme immunoassays (utilizing paramagnetic particle solid phase and chemiluminescent detection) for determination of FSH. The FSH assay is intended to be used as an aid in the diagnosis of elevated or decreased FSH levels.

Free Thyroxine (FT4)

INSTRUMENT: DXI 800 from Beckman Coulter The Free Thyroxine (FT4) assay uses enzyme immunoassays (utilizing paramagnetic particle solid phase and chemiluminescent detection) for determination of FT4. This assay is intended to be used as an aid in the diagnosis of elevated or decreased FT4 levels.

Free triiodothyronine (Free T3)

INSTRUMENT: DXI 800 from Beckman Coulter TheFree triiodothyronine (Free T3) assay uses enzyme immunoassays (utilizing paramagnetic particle solid phase and chemiluminescent detection) for determination of FT3. This assay is intended to be used as an aid in the diagnosis of elevated or decreased FT3 levels.

HDL Cholesterol

INSTRUMENT: Au680 from Beckman Coulter The HDL assay utilizes colorimetry, turbidimetry, latex agglutination, or homogeneous EIA. This assay is intended to be used as an aid in the diagnosis of elevated or decreased HDL levels.

Hematocrit

Instrument: ysmex XN-1000 Methodology: Fluorescent flow cytometry using a semi-conductor laser and hydrodynamic focusing in dedicated channels. This assay is intended to be used as a screening aid in the diagnosis of elevated or decreased hematocrit levels.

Hemoglobin A1C

INSTRUMENT: Au680 from Beckman Coulter The Hemoglobin A1C assay utilizes colorimetry, turbidimetry, latex agglutination, or homogeneous EIA. This assay is intended to be used as an aid in the diagnosis of elevated or decreased HbA1c levels.

High-Sensitivity CRP

INSTRUMENT: Au680 from Beckman Coulter The HSCRP assay utilizes colorimetry, turbidimetry, latex agglutination, or homogeneous



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EIA. This assay is intended to be used as an aid in the diagnosis of elevated or decreased HSCRP levels.

LDL Cholesterol

INSTRUMENT: Au680 from Beckman Coulter The HSCRP assay utilizes colorimetry, turbidimetry, latex agglutination, or homogeneous EIA. This assay is intended to be used as an aid in the diagnosis of elevated or decreased HSCRP levels.

Luteinizing Hormone (LH)

INSTRUMENT: DXI 800 from Beckman Coulter The Luteinizing Hormone (LH)assay uses enzyme immunoassays (utilizing paramagnetic particle solid phase and chemiluminescent detection) for determination of LH. This assay is intended to be used as an aid in the diagnosis of elevated or decreased LH levels.

Progesterone

INSTRUMENT: 8060 LC-MSMS from Shimadzu. The progesterone assay is a Liquid Chromatography Tandem Mass Spectrometry (LC-MS/MS) assay for the quantitative determination of progesterone. The Progesterone assay is intended to be used as an aid in the diagnosis of elevated or decreased progesterone levels.

Prolactin (PRL)

INSTRUMENT: DXI 800 from Beckman Coulter The Prolactin (PRL) assay is an enzyme immunoassays (utilizing paramagnetic particle solid phase and chemiluminescent detection) for the quantitative determination of prolactin. This assay is intended to be used as an aid in the diagnosis of elevated or decreased PRL levels.

Prostate-Specific Antigen (PSA)

INSTRUMENT: DXI 800 from Beckman Coulter The Prostate-Specific Antigen (PSA) assay is an enzyme immunoassays (utilizing paramagnetic particle solid phase and chemiluminescent detection) for the quantitative determination of PSA. This assay is intended to be used as an aid in the diagnosis of elevated or decreased PSA levels.

Free Testosterone (male)

INSTRUMENT: DXI 800 from Beckman Coulter The Free Testosterone assay is an enzyme immunoassays (utilizing paramagnetic particle solid phase and chemiluminescent detection) for the quantitative determination of free testosterone. This assay is intended to be used as an aid in the diagnosis of elevated or decreased free testosterone levels.

Total Testosterone (female)

INSTRUMENT: 8060 LC-MSMS from Shimadzu. The Female Total Testosterone assay is a Liquid Chromatography Tandem Mass Spectrometry (LC-MS/MS) assay for the quantitative determination of Total Testosterone. The Total Testosterone assay is intended to be used as an aid in the diagnosis of elevated or decreased testosterone levels.

Total Testosterone (male)

INSTRUMENT: DXI 800 from Beckman Coulter The Total Testosterone assay is an enzyme immunoassays (utilizing paramagnetic particle solid phase and chemiluminescent detection) for the quantitative determination of total testosterone. This assay is intended to be used as an aid in the diagnosis of elevated or decreased total testosterone levels.

Thyroid Stimulating Hormone (TSH)

INSTRUMENT: DXI 800 from Beckman Coulter The Thyroid Stimulating Hormone (TSH) assay is an enzyme immunoassays (utilizing paramagnetic particle solid phase and chemiluminescent detection) for the quantitative determination of TSH. This assay is intended to be used as an aid in the diagnosis of elevated or decreased TSH levels.

Thyroperoxidase Antibody (TPOAb)

INSTRUMENT: DXI 800 from Beckman Coulter The Thyroperoxidase Antibody (TPOAb) assay is an enzyme immunoassays (utilizing paramagnetic particle solid phase and chemiluminescent detection) for the quantitative determination of TPOAb. This assay is intended to be used as an aid in the diagnosis of elevated or decreased TPOAb levels.

Triglycerides

INSTRUMENT: Au680 from Beckman Coulter The Triglycerides assay is an Enzymatic GPO-POD (without glycerol and sample blanks). This assay is intended to be used as an aid in the diagnosis of elevated or decreased triglycerides levels.

Vitamin D

INSTRUMENT: DXI 800 from Beckman Coulter

The Vitamin D assay is an enzyme immunoassays (utilizing paramagnetic particle solid phase and chemiluminescent detection) for the



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quantitative determination of vitamin D. This assay is intended to be used as an aid in the diagnosis of elevated or decreased vitamin D levels.

About your test results

Laboratory tests performed by myLAB Box clinical laboratory affiliates on at-home self-collection kits deliver highly accurate results that are as good as testing done in a doctor's office or clinical laboratory.

Positive means the test detected levels of the agent being tested for, and/or a value above the normal reference range. Positive results are sometimes reported as "detected."

Negative means the test did not detected levels of the agent being tested for, and/or a value below the normal reference range. Negative results are sometimes reported as "not detected."

Retesting may sometimes be required or recommended. Positive test results for syphilis and hepatitis C infection require repeat testing by a different method to confirm the diagnosis. This confirmatory test should be performed at your primary care physician or local health department.

Any unexpected positive or negative test results should be repeated. A false-negative result may occur if there is a problem with the sample that is collected or if a person is taking antibiotics at the time of testing. In addition, a false-negative result is possible if testing is performed too soon after exposure during the "window period." This is the time between when a person is exposed to a sexually-transmitted infection (STI) and when the infection shows up on a test. If the sample that is tested does not have enough antibodies or organisms to detect an infection, the test result will be negative. For these reasons, repeat testing is recommended within 1-3 months after getting a negative test result following a high-risk exposure.

Understanding results that are not positive or negative

myLAB Box clinical laboratory affiliates use the most sensitive and specific testing methods available to analyze test samples. In some cases, however, testing might not provide clear or valid results.

Preliminary Detection: This analyte has been detected during preliminary testing. The performing lab is unable to confirm the detection due to insufficient testing material. Please submit a new specimen for confirmation testing.

Equivocal means the test result is neither positive nor negative. This can mean that the test result was too close to the validated cut-off for the assay. This may happen if there is a problem with the sample that is collected or if a person is taking antibiotics or other medicines at the time of testing. An equivocal result may also be due to a slightly increased "false positive" signal or having too low a concentration of the infectious organism or antibody to be accurately detected by this test. An equivocal result does not imply a positive result or conclusive identification of any infectious organism or antibody. Please consult with your medical provider to determine if retesting or confirmatory testing is needed. To retest with the convenience of the myLAB Box at-home self-collection kit, enjoy a courtesy discount with code MYLABBOX1025 for 25% off your test.

Indeterminate means the results of repeat testing are not conclusive. This may happen if there is a problem with the sample that is collected or if a person is taking antibiotics or other medicines at the time of testing. An indeterminate result may also be due to a slightly increased "false positive" signal or having too low a concentration of the infectious organism or antibody to be accurately detected by this test. An indeterminate result does not imply a positive result or conclusive identification of any infectious organism or antibody. Please consult with your medical provider to determine if retesting or confirmatory testing is needed. To retest with the convenience of the myLAB Box at-home self-collection kit, enjoy a courtesy discount with code MYLABBOX1025 for 25% off your test.

Invalid means repeat testing has failed to provide a result. This may happen if the substance being analyzed (e.g., a protein, chemical substance, or DNA) is at too low a concentration to be accurately detected by this test. An invalid result may also be due to a problem with the sample that is collected, interfering substances such as medications, or an excessive amount of foreign matter in the sample (e.g., fecal matter, blood, or food debris). Retesting with a new sample is recommended. To retest with the convenience of the myLAB Box at-home self-collection kit, enjoy a courtesy discount with code MYLABBOX1025 for 25% off your test.

Disclaimer

Tests used in myLAB Box kits have been developed by myLAB Box clinical laboratory affiliates, who determine precise performance characteristics for each test. These performance characteristics help ensure the consistency and accuracy of test results. Tests have not been approved by the US Food and Drug Administration (FDA), although individual components of some tests performed in the



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laboratory are FDA-cleared. The FDA has determined that such clearance or approval is not necessary for laboratory-developed tests such as those offered by my LAB Box. These tests are used for clinical purposes and should not be regarded as investigational or for research. myLAB Box clinical laboratory affiliates follow the rigorous accreditation guidelines of the College of American Pathologists (CAP) and are certified by the Clinical Laboratory Improvement Act (CLIA) of 1988 as qualified to perform high-complexity clinical testing.