

Medical Center, Navicent Health
MEDICAL LABORATORIES COMMUNIQUE'
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CHEMISTRY

Total T4 (TT4) Assay: Effective Aug 14, 2017 the reference range for TT4 assay will be adjusted from 4.87-11.72 to 5.34-12.19 microg/dL. This revision is due to a modification in the manufacturer's reagents. Total T4 is a function of free T4 and bound T4 which is predominately bound to Thyroxine Binding Globulin (TBG). Current recommendation for thyroid function screening is to begin with a TSH level. If the TSH is abnormal or falls into the subclinical range, the recommended follow-up test is free-T4; these are offered standalone or as a reflex panel. These two tests (TSH and free-T4) have been improved upon over the years and are currently the focus for the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) for standardization and harmonization. These tests now are superior to Total T4 in clinical sensitivity of thyroid dysfunction and should be used first. There is still some utility in TT4 and total T3 measurements for long-term monitoring of select patients.

Cancer Antigen19-9 (CA19-9): Effective Aug 14, 2017 we will once again be running CA19-9 assays in-house. Earlier this year we began sending CA19-9 tests out due to an interaction with biotin supplements in the Beckman test. We will now be running the Abbott test, which correlates with the previous method. For the next 12 months, we will re baseline each patient with the new method while reporting the old method result in a comment.

TOXICOLOGY

Heroin Urine Drug Screen: Effective Oct 1, 2017 we will be able to screen urine samples for the presence of a heroin metabolite 6-acetyl morphine (6-AM). Heroin (3,6-diacetylmorphine) itself is not active at the opioid receptor and it must first be metabolized to 6-AM. 6-AM is then metabolized to morphine, conjugated and excreted. The new assay will be automatically added to any opiate positive sample in the medical drug testing profiles to aid in determining if the opiate positive is due to heroin use. It will also be added to the Drug Screen Urine Comprehensive and the Pain Management Urine Medical Drug Screen. This is a screening test and should only be used to determine medical decisions. Positive screening results should be confirmed using a definitive method. Codeine, Morphine, Hydrocodone, and Hydromorphone can cause a positive in the opiate screen (depending on concentration).

MICROBIOLOGY

Herpes Simplex Testing: Effective: Oct 1, 2017 we will be running a molecular assay for the qualitative detection and differentiation of Herpes simplex type 1 and 2 in house. It will be offered 24/7 and results will be available same day. This test replaces the traditional Herpes Culture which was unable to differentiate the types of herpes and took 2 days from specimen receipt to results. This test is performed from swab specimens of cutaneous and mucocutaneous lesions from various body sites. Once the specimen is collected, it should immediately be placed in viral transport media obtained from Microbiology Department of the Laboratory

SPECIAL CHEMISTRY

Serum Anti-Nuclear Antibodies: Effective: Aug 28, 2017 we will be moving our Anti-Nuclear Antibody (ANA) screen and reflex antigen specific panel testing to the Biorad Bioplex2200. We are changing platforms from one run daily, to a random-access instrument that will be run continually Monday-Friday 8am-5pm. Measurement of antinuclear antibodies (ANAs) in serum is the most commonly performed screening test for patients suspected of having a connective tissue disease. Some of the antigens in the Profile will be different with this change. Instead of testing for antibodies to Histones we will be testing for antibodies to Chromatin, the DNA-Histone structure that is more biologically relevant. With a positive screen the autoantibody specificity can distinguish which connective tissue disease is present. The specific antigens that we will interrogate inhouse are:

- dsDNA antibodies
- Chromatin antibodies (will replace Histone antibodies)
- Scl 70 antibodies (topoisomerase 1)
- Jo 1 antibodies (histidyl tRNA synthetase)
- SSA/Ro and SSB/La antibodies
- RNP antibodies
- Sm antibodies
- SmRNP antibodies-**new test**
- Ribosome P antibodies-**new test**
- Centromere antibodies

We recommend that in most situations the **Serum ANA with reflex** panel be ordered along with the Cyclic citrullinated peptide (CCP), antibody and Rheumatoid Factor (RF). The strength of the ANA pan positive along with the specificity of the various antigens can aid in the distinction between the various connective tissue conditions.

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Test Information Guide – New Tests

Total T4 (TT4):

Alternate name: N/A
Specimen: Serum, gel tube
Minimum Volume: 1.0 mL
Stability: 6 days at 2-8°C
Available: 24/7
Turnaround Time: 2 – 4 hr depending on # of test on run
 CPTs: 84436
Normal Ranges: 6.63 – 10.79 microg/dL 1-8 yr
 5.95 – 9.78 microg/dL 9- 11 yr
 5.57 – 9.09 microg/dL 12- 14 yr
 5.34 – 12.19 microg/dL ≥15 yr

Heroin Urine Drug Screen:

Alternate name: 6AM
Specimen: Urine, random
Minimum Volume: 0.2mL
Stability: 2-8°C for 5 days
Available: 24/7
Turnaround Time: 1-4 hours
 CPTs: 80307
Normal Ranges: Negative

Herpes Simplex Virus Type1/2 Molecular Detection

Alternate name: Herpes Simplex Virus (HSV) Type1/2 DNA Amplification, HSV Type1/2 DNA Amplification
Specimen: Cutaneous and Mucotaneous lesions in viral transport media
Minimum Volume: NA
Stability: 2-8°C for 7 days
 CPT: 87529 (x2)
Available: 24/7
Turnaround Time: 2-4 hours
Normal Range: Negative
Interpretative guide: Negative results do not preclude infection. This test does not distinguish between viable and nonviable organisms.

Cancer Antigen 19-9

Alternate name: CA19-9
Specimen: Serum, gel tube
Minimum Volume: 1.0 mL
Stability: 7 days at 2-8°C
Available: 24/7
Turnaround Time: 2 -4 hr depending on # of tests on run
 CPTs: 86301
Normal Ranges: ≤37 U/mL

Serum Anti-Nuclear Antibody

Alternate name: Screen ANA, Screen ANA with reflex
Specimen: Serum, gel tube
Minimum Volume: 0.5 mL
Stability: 2-8°C for 7 days
Available: Monday-Friday 8am-7pm
Turnaround Time: next business day
 CPTs: 86038
Normal Ranges: Negative
Interpretative guide:

ANA Screen:

Positive >1.0 AI
 Negative <1.0 AI

dsDNA

Negative: ≤ 4 IU/mL
 Positive: ≥ 10 IU/mL
 Indeterminate: 5 - 9 IU/mL

For Chromatin, Ribosomal P, SS-A, SS-B, Sm, SmRNP, RNP, Scl-70, Jo-1, and Centromere B

Positive >1.0 AI
 Negative <1.0 AI

Based on the positive results from the panel the conditions below may be more probable. Those conditions will be listed in the interpretation.

- Systemic Lupus Erythematosus (SLE)
- Sjögren's Syndrome
- Scleroderma (Systemic Sclerosis)
- Mixed Connective Tissue Disease (MCTD)
- Polymyositis

