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NOTICE DATE: September 25, 2013

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EFFECTIVE DATE: September 25, 2013

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## U-M offers new early detection test for prostate cancer Mi-Prostate Score test improves on PSA for predicting cancer

### NEW TEST

#### MiPS (Mi-Prostate Score)

Order Code: MIPS  
Fee Code: 10385, QA001  
CPT: 81479-TC x2, 81479-26 (CMS G0452)

Effective September 25, 2013, the MLabs Michigan Center for Translational Pathology (MCTP) Laboratory is now offering the Mi-Prostate Score, or MiPS test to provide a personalized prostate cancer risk assessment for patients with elevated Serum PSA for estimating prostate cancer risk in patients without a previous negative biopsy.

More than 1 million men will undergo a prostate biopsy this year, but only about one-fifth of those biopsies will result in a cancer diagnosis. The reason is that the traditional prostate cancer screening test – a blood test to measure prostate specific antigen, or PSA – does not give doctors a complete picture. Now, the University of Michigan Health System has begun offering a new urine test called Mi-Prostate Score to improve on PSA screening for prostate cancer. The test incorporates three specific markers that could indicate cancer and studies have shown that the combination is far more accurate than PSA alone.

“Many more men have elevated PSA than actually have cancer but it can be difficult to determine this without biopsy. We need new tools to help patients and doctors make better decisions about what to do if serum PSA is elevated. **Mi-Prostate Score** helps with this,” says Scott Tomlins, M.D., Ph.D., assistant professor of pathology and urology at the University of Michigan.

Mi-Prostate Score was developed from a discovery in the lab of a genetic anomaly that occurs in about half of all prostate cancers, an instance of two genes changing places and fusing together. This gene fusion, *T2:ERG*, is believed to cause prostate cancer. Studies in prostate tissues show that the gene fusion almost always indicates cancer.

The new urine test looks for the *T2:ERG* fusion as well as another marker, *PCA3*. This is combined with serum PSA measure to produce a risk assessment for prostate cancer. The test also predicts risk for having an aggressive tumor, helping doctors and patients make decisions about whether to wait and monitor test levels or pursue immediate biopsy.

**The combined MiPS test is now available only from the University of Michigan MLabs to provide patient specific prostate cancer risk assessment.**

Note that the MiPS test is performed using the same Gen-Probe Progenisa urine transfer tubes as the PCA3 assay. For questions regarding How to Send a Specimen, please call **MLabs at 800-862-7284**. You may also visit us at [www.mlabs.umich.edu](http://www.mlabs.umich.edu).



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**EFFECTIVE DATE:** September 9, 2013

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**REFERENCE RANGE CHANGE**

**Glucose, Serum, 1 Hour Postprandial**

Order Code: GLU1P

Please note that after discussion with the UMHS Endocrinology Department, the Glucose 1 Hour Postprandial interpretation changed as follows:

Reference Range: 1 Hr Postprandial: 50 gm load: <135 mg/dL, 100 gm load: <190 mg/dL.

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**EFFECTIVE DATE:** October 7, 2013

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**METHODOLOGY CHANGE**

**Fluconazole, Serum**

Order Code: MMLR

Reference Laboratory: Mayo FLUCO (82522)

Effective October 7, 2013, the test methodology for Mayo Medical Laboratories Fluconazole assay will change from High-Performance Liquid Chromatography (HPLC) to Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS). This change will result in greater specificity and remove interference issues. It will also allow for a reduction in the specimen volume requirement and the acceptability of serum gel collection. There will be no change in reference values or CPT code.

Collection Instructions: Collect specimen in a red top or SST tube. Centrifuge and aliquot 1 mL of serum into a plastic vial within 2 hours of collection; refrigerate.

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**EFFECTIVE DATE:** October 23, 2013

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**REFERENCE RANGE CHANGE**

**Carbon Monoxide, Blood**

Order Code: CO2B

Fee Code: 32069

LOINC: 20563-3

Reference Laboratory: Mayo COHBB (8649)

The reference range for Mayo Medical Laboratories Carbon Monoxide, Blood, assay will change as follows effective October 23, 2013:

Reference Range: Normal Concentration: Non-smokers: 0 – 2%; Smokers: <or= 9%. Toxic Concentration: >or= 20%.

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**EFFECTIVE DATE:** October 29, 2013

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**NEW TEST**

**Fecal Occult Blood, Immunoassay (IFOB)**

Order Code: IFOB  
Fee Code: pending

Effective October 29, 2013, the MLabs Chemical Pathology Laboratory will begin offering Fecal Occult Blood testing by Immunoassay (IFOB). An OCS (OC Sampling Bottle) available from MLabs will be required for specimen collection. No other collection containers will be acceptable.

The test system is intended for the qualitative detection of fecal occult blood in feces. It is recommended for use in routine physical exams, monitor for bleeding in patients and screening for colorectal cancer or other GI disorders that can cause gastrointestinal bleeding (e.g., diverticulitis, polyps, and Crohn's disease). No dietary restrictions are necessary for the patient due to the detection of human hemoglobin in this assay.

Collection Instructions: Follow directions contained in the sample kit. Collect feces from the sample collection paper or specimen caught in a clean cup or collected during routine physical exams during the visit (i.e., DRE). Contamination from toilet water should be avoided.

1. Fill in the patient demographic information on the sampling bottle. Open the green cap by turning to the left and pulling upwards.
2. Randomly scrape the surface of the fecal sample with the sample probe. Cover the grooved portion of the sample probe completely with stool sample.
3. Close the sampling bottle by inserting the sample probe and screwing cap on tightly to the right. DO NOT reopen. Return the sample device as directed by the physician or in the laboratory mailer provided.

The inoculated sample may be stored at room temperature for up to 15 days or can be refrigerated at 2-8 degrees C for up to 30 days.

Reference Range: Negative