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TECHNICAL BULLETIN
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BLOOD LEAD TEST SAFETY ALERT

The U.S. Food and Drug Administration and Centers for Disease Control and Prevention are warning laboratories and health care professionals not to use venous blood samples with Magellan Diagnostics LeadCare testing systems due to the potential for falsely low results. The CDC and FDA are assessing the potential public health risk of a negative bias associated with Magellan Diagnostics' analyzers. This safety alert applies to venous blood lead tests but does not apply to capillary blood lead tests collected by finger stick or heel stick. Physicians Laboratory began using the Magellan Diagnostics LeadCare system, which is an FDA approved test, beginning April 22, 2013 – present.

The CDC is recommending that the following be retested:

- Patients who are younger than 6 years (72 months) of age at the time of this alert (May 2017) and had a venous blood lead test result of less than 10 (ug/dL) from a test analyzed using a Magellan Diagnostics' LeadCare analyzer.
- Women who are currently pregnant or nursing and were tested in this manner using a venous sample.
  https://www.cdc.gov/nceh/lead/about/blood_lead_test_safety_alert.html

In order to obtain a list of patients from your practice that meet the above criteria, please contact Rick Noda at (402)731-4145 or rnoda@physlab.com.

The following test changes go into effect immediately:

806 Lead, Blood (Capillary)
Specimen Requirements: 1.0 mL (0.5 mL) Lavender (EDTA) Microtainer.
Patient Demographics Form for Public Health Reporting Required.
Specimen Stability: Room Temperature 24 Hours.
Performed at Physicians Laboratory

2816 Lead, Blood (Venous)
Specimen Requirements: 7 mL (0.5 mL) Royal Blue Metal Free Whole Blood (K2EDTA or Na2EDTA).
Patient Demographics Form for Public Health Reporting Required.
Specimen Stability: Room Temperature Indefinitely / Refrigerated Indefinitely.
Performed at ARUP

811 Lead Industrial Exposure Panel, Adults (Previously Named Lead/Zinc Protoporphyrin)
Specimen Requirements: 7 mL (2 mL) Royal Blue Metal Free Whole Blood (K2EDTA or Na2EDTA)
Patient Demographics Form for Public Health Reporting Required.
Specimen Stability: Room Temperature 30 Hours. Refrigerated 5 weeks.
Performed at ARUP

ESTRADIOL TESTING

There are two tests available for Estradiol testing. Test #925 is for adult premenopausal females only, and cannot detect levels lower than 20 pg/mL. For children, males, and post-menopausal females test #7439 should be ordered. For this reason, the test names will now read as follows:

#925 Estradiol, Adult Premenopausal Female
Methodology: Siemens Centaur Chemiluminescence
Performed at PLS

#7439 Estradiol, Children, Males & Postmenopausal Females
Methodology: Tandem Mass Spectrometry
Performed at PAML

24-HOUR URINE COLLECTIONS

For accurate test results on 24 hour urine collections, it is important that we receive the start and stop time of the urine collection. Please remind patients to place this information on the collection container when they are collecting the sample. Please check for this information before sending the specimen container in order to avoid testing delays or cancellations. For Copia clients, this will now be required information when ordering any 24 hour urine test.

CONVENTIONAL PAP-PAK NO LONGER MANUFACTURED

Effective immediately, the PAP-PAK is no longer being manufactured for the collection of conventional Pap smear specimens. ThinPrep and SurePath Liquid Based vials are available as a replacement and can be provided with the appropriate collection devices. Chlamydia, Gonorrhea, Trichomonas, HPV High Risk, and HPV Genotyping 16/18/45 can all be added to a Liquid Based Pap without any additional collection.

https://www.fishersci.com/shop/products/medical-packaging-pap-pak-pap-smear-collection-system-6/p-179855