To All Medical Laboratory Users:

This edition of the Lab Med Update has the following articles:

IF YOU HAVE AN ARTICLE(S) YOU WOULD LIKE TO SHARE CONTACT:

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UNIVERSITY of VIRGINIA HEALTH SYSTEM

MEDICAL LABORATORIES

Laboratory Medicine Update
December 2020

Urine Osmomality

All results are now being reported with the validated reference interval of 150-1150mOsm/kg. The result can vary with diet and hydration.

Flow Cytometry Analysis

There are 13 orderable tests in Epic for Flow Cytometry depending on the patient history, diagnosis, evaluation, and monitoring status required for treatment. Clarification for what is performed for three of the orderable tests is listed below.

- LAB3925 Flow Cytometry T, B, Natural Killer Cell Screen (TBNK): Test includes percentage and absolute count for CD3, CD4, CD8, CD19 and CD16+CD56, as well as CD4:CD8, helper to suppressor ratio. Percentages are reported as a percentage of lymphocytes and are reported to the nearest whole number. This assay is not designed to detect leukemia/lymphoma. No pathologist consultation is provided.

- LAB6106 FLOW ANTI-CD20 PANEL: Test includes percentage for CD19 and CD20 as a percentage of lymphocytes. Reference ranges are not provided. Percentages are reported to the nearest whole number. This assay is not designed to detect leukemia/lymphoma. No pathologist consultation provided.

- LAB2554 Flow Cytometry Immunophenotyping (CD0): Markers tested determined by sample type, patient history, and pathologist's discretion. Results include pathology consultation report. This assay was designed to detect leukemia/lymphoma. This testing does not provide verified minimal residual disease (MRD) analysis.

Anti-Fungal Drug Testing

The Toxicology Laboratory has validated the following anti-fungal drugs and will perform testing in-house beginning on December 1, 2020. The sendout tests will be discontinued. The three drugs are orderable in Epic and require a red top tube (no gel separator).

- **Itraconazole**: includes the metabolite hydroxyintraconazole. Reference Range for Itraconazole: (Trough) Localized infection >0.5 ug/mL; Systemic infection >1.0 ug/mL. There is no therapeutic range established for hydroxyintraconazole; activity and serum concentration are similar to parent drug
- **Posaconazole**: Reference range >0.7 ug/mL.
- **Voriconazole**: Reference range 1.0 – 5.5 ug/mL

Genomics Lab Tumor Percent Limitation

Results of testing performed on FFPE tissue should be interpreted in context of clinical findings, tumor sampling, and other laboratory data. For all FFPE assays, our methods are valid if the % tumor cells in the sample is 20% or more of the section identified by pathology review. If the % tumor cells is <20%, we will still attempt to do the assay but, a negative result should be interpreted with caution due to the potential for decreased analytical sensitivity. If results obtained do not match other clinical or laboratory findings please contact the laboratory. Misinterpretation of results may occur if the information provided is inaccurate or incomplete.

Fragile X Testing

The Genomics Laboratory has validated a new diagnostic assay of Fragile X Syndrome (FXS). The FXS is a trinucleotide repeat disease caused predominantly by the expansion of CGG sequences in the 5' untranslated region of the Fragile X Mental Retardation 1 (FMR1) gene on the X chromosome at Xq27.3. The number of (CGG)n repeat is associated with a constellation of disorders that can affect patients both young and old. The Asuragen amplideX PCR/CE FMR1 assay use a three-primer CGG Repeat Primed (RP) PCR from purified genomic DNA and fragment sizing on an Applied Biosystems Genetic Analyzer. The size of the PCR products are converted to the number of CGG repeats using size and mobility conversion factors. This assay provides accurate sizing of alleles up to 200 CGG repeats, identification of full mutation alleles >200 CGG repeats and a characteristic product peak profile that resolves zygosity in female samples.