

New eGFR Calculation

Saint Luke's laboratories will change to the newest eGFR calculation which will exclude a race modifier.

The glomerular filtration rate (GFR) is a measure of kidney function used to prognosticate CKD, determine dosage of clinical therapies, and referral for transplant. GFR cannot be measured directly and an "estimated" GFR is calculated from serum creatinine, age, gender, and race to account for differences in muscle mass.

However, current literature reflects that a race coefficient may be more harmful than beneficial. The race coefficient, developed in 1999, attempts to correct for more lean body mass among black individuals. In 2021, the National Kidney Foundation and American Society of Nephrology released a joint statement denouncing the use of race modifiers in calculating eGFR. The clinical impact of overestimated GFR includes limited access to specialized nephrology care and exclusion from kidney transplantation.

Chloride and Alkaline Phosphatase Reference Interval

The chloride and alkaline phosphatase reference intervals will be updated to reflect an internal study of 4000 healthy controls to better reflect our local patient population.

Quantiferon Transition to T-Spot

According to World Health Organization data, one third of the world's population is infected with tuberculosis. In 2020, there were 1.5 million tuberculosis-related deaths worldwide. In recent years, *Mycobacterium tuberculosis* (MTB) has become more deadly due to emergence of strains that are resistant to most or all TB drugs. Interferon-Gamma Release Assays (IGRAs) are blood tests used in conjunction with other modalities for diagnosis of MTB infection. The two commercially available IGRA tests, Quantiferon and T-spot, are based on the same principle of measuring interferon-gamma produced by memory T cells following stimulation by the MTB antigens ESAT-6 and CFP-10.

Saint Luke's Laboratory has performed the Quantiferon test in-house since March 2013. Within the next few months, this testing will transition to T-spot & will be performed by a reference laboratory. As with Quantiferon, T-spot does not differentiate between active and latent MTB infection. Likewise, positive results may occur due to previous or current infection with other mycobacterial organisms, including *M. kansasii*, *M. szulgai*, and *M. marinum*. Both ESAT-6 and CFP-10 are absent from TB vaccine (BCG) strains, excluding previous vaccination as a cause of false-positives.

An advantage of T-spot vs. Quantiferon is elimination of the need for multiple special collection tubes with complex handling requirements. Further information will follow on specimen collection requirements. T-spot results are reported as positive, negative, or borderline.

C. difficile Toxin Deleted from GI Panel

The BioFire GI panel, available through Saint Luke's Microbiology, detects the most common enteric pathogens including viruses, bacteria, and parasites by PCR. Overall sensitivity of the panel is 98.5% and specificity is 99.2%, which is superior to culture and enzyme immunoassay test methods. Effective mid-May, the GI panel will no longer include results for *C. difficile*. The EPIC test name will change to GI Pathogen Panel without *C. diff*. When indicated, individual *C. difficile* PCR should be ordered.

Indications for utilization of GI panel and *C. difficile* PCR testing are built into the Epic order with decision tree. Providers should follow these recommendations when considering GI panel testing. When testing for *C. difficile* is indicated, providers should order the individual *C. difficile* PCR. The C DIFF EIA test will be performed as a reflex test whenever the C DIFF PCR test is positive.

New Lyme Disease Reflex

Lyme disease is caused by infection with *Borrelia burgdorferi*, transmitted by Ixodes ticks. Total Lyme cases, including both confirmed and probable infections, were 34,945 for 2019 according to CDC data. Both Missouri and Kansas are considered low incidence states for Lyme disease, with 17 and 35 reported cases in 2019, respectively. The highest incidence state was Pennsylvania, with 8,998 reported cases.

The clinical diagnosis of Lyme disease is supported by serologic testing. A two-tier test method, with confirmatory testing by western blot following reactive Lyme antibody immunoassay, has been in place since 1995. In 2019, test criteria were reviewed & updated by FDA & CDC to include an alternative confirmatory process. The current guideline allows for confirmatory testing by a second immunoassay, instead of western immunoblot. Confirmatory Lyme antibody immunoassays cleared by FDA have demonstrated equivalent or superior performance to western blot.

Lyme disease serology is available through Saint Luke's Regional Laboratory and forwarded to LabCorp. Effective immediately, LabCorp has replaced Lyme Total Antibody reflex testing by western blot with separate Lyme IgM and IgG immunoassays.

Annual Notice to Physicians for Laboratory Testing

Saint Luke's Regional Laboratories (SLRL) works to ensure compliance with all guidelines governing the submission of Medicare claims for laboratory services including, but not limited to, medical necessity and Advance Beneficiary Notice (ABN) use.

Medicare will only pay for tests that meet the Medicare definition of medical necessity. The Office of the Inspector General (OIG) wants to ensure that physicians order only medically necessary tests & that physicians know that the OIG may impose civil penalties on those who order otherwise. The OIG does recognize that a physician must be able to order any tests, including screening tests they believe appropriate for the treatment of their patients. Medicare

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may deny payment for a test that the physician believes appropriate, but which does not meet the Medicare definition of medical necessity. In this case, the orders should be accompanied by a properly executed ABN.

SLRL offers only Medicare defined Organ and Disease related panels. The individual components of these panels & the corresponding CPT/HCPCS codes and additional detailed information can be found in the on-line [Lab Test Directory](#). Customized panels should not be used. The Medicare Limitation Amount for each CPT/HCPCS code can be found in the Medicare National Limitation Amount reference supplied to physician's offices by Medicare.

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