

## MEMORANDUM

**TO:** All Regional Medical Laboratory Clients  
**FROM:** Patti Loykasek, Manager of Immunology and Molecular Pathology  
Gerald C. Miller, Ph.D., Chief of Immunology and Microbiology  
**DATE:** February 15, 2018  
**SUBJECT:** **Changing Normal Range and Methodology of Performing and Reporting of CH50**

Regional Medical Laboratory is pleased to announce the implementation of a **new methodology for the evaluation of Human Hemolytic Complement (CH50)**. This assay is an FDA approved quantitative IVD assay that will improve testing reliability, workflow and turnaround time (TAT). The methodology utilizes liposomes, encapsulating glucose-6-phosphate dehydrogenase (G6PDH) to mimic an invading microorganism. The patient's serum sample provides the complement for the lysis of the liposome which releases G6PDH and reacts with glucose-6-phosphate and NAD. The change in absorbance is measured and is proportional to the complement activity in the sample. The results are compared to a calibration curve which gives a value for the patient's sample. Complement activity has been correlated with the active stage of Systemic Lupus Erythematosus, Rheumatoid Arthritis, some forms of nephritis and inherited deficiencies of the classical complement system.

The new normal range will be **41.68-95.06 U/mL**.

This new methodology requires a change in specimen collection.

- **Collection Device:**
  - Collect specimen in a **red top no gel with clot activator tube**
- **Special Handling:**
  - **Clot** for **one hour** at room temperature.
  - **Separate** the serum from cells ASAP or **no longer than 2 hours** after collection.
  - Transfer at least **1 ml of serum** to an RML transport tube.
  - The **minimum** specimen is **0.3 ml**.
- **Transport Temperature and Stability:**
  - It is **critical to freeze** the complement specimen **immediately** after the transfer of specimen to a transport tube.
  - Stable for 2 weeks frozen
- **Reasons for Rejection:**
  - Use of serum separator tube
  - Clotting at 2-8° C
  - Exposure to repeated freeze/thaw cycles. The specimen must arrive in the laboratory frozen.
  - Samples containing high levels of lipid, hemoglobin or bilirubin cause interference and should be avoided.

### General Information

- **Test Name:** **Complement, total (CH50)**
- **Test Number:** **5569251**
- **Mnemonic:** **CH50**
- **LOINC Code:** **4532-8**
- **CPT Test Code:** **86162**
- **Performed:** **Monday - Friday**
- **Expected TAT:** **5-7 days, batched**

Direct all questions or concerns to Patti Loykasek, Manager of Immunology, or Gerald C. Miller, Ph.D., Chief of Immunology and Microbiology, at 918-744-2553.