

CLIA: SPECIAL ALERT

LIVE BLOOD CELL ANALYSIS (LBA) UNDER CLIA

[Alternative - Non-Traditional Laboratory Testing]

Live Blood Cell Analysis (LBA) is a test which is used for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or assessment of the health of human beings. LBA is also known as Hemaview, Free Radical Blood Screening, or Nutritional Blood Analysis. LBA is not a Provider-Performed Microscopic Procedure (PPMP) test. It is also a non-covered Medicare service.

In January 1996, the Centers for Disease Control (CDC), determined that the LBA test procedure automatically defaulted to high complexity because it had not been categorized by CDC. In addition, the Centers for Medicare & Medicaid Services (previously the Health Care Financing Administration) Office of General Counsel (OGC) determined in August 1997, that LBA was subject to all CLIA requirements for high complexity testing¹ (i.e. patient test management, proficiency testing, quality control, personnel and quality assurance). Therefore, any facility performing this procedure must be certified by CLIA and hold a valid registration certificate, Certificate of Compliance, or Certificate of Accreditation. Failure to comply with any of the CLIA requirements will result in enforcement actions and/or sanctions being taken.

LBA is performed by placing a drop of blood from the patient's fingertip on a microscope slide under a glass coverslip to keep it from drying. In some cases, a powder has been developed that, when sprinkled on the blood, forms a type of "coverslip". The slide is then viewed at high magnification with a dark-field microscope that forwards the image to a television monitor. The results are then used for prescribing nutritional supplements.

Other examples of Alternative Testing (Non-Traditional Laboratory Testing) that are subject to CLIA:

- 1. Biological Terrain Assessment (BTA):** BTA is a computerized analysis of blood, urine, and saliva specimens used to recommend nutritional programs, vitamin and mineral supplements, homeopathic products, and/or herbs. Analysis is determined through pH determinations which are the portion of the test that is legitimate.
- 2. Thromboelastograph:** This is a valid test which has been categorized by the CDC as either moderate or high complexity, depending on whether the instrument prints the test results. The test is performed by a perfusionist in the operating room or sometimes in blood gas laboratories.
- 3. Dental sensitivity testing:** This test determines whether a person is sensitive to materials in fillings. If sensitive, all fillings can be removed and replaced. All reviewing agencies could not determine whether the method was valid.

¹ www.cms.gov/CLIA/

4. Cytotoxic Testing (Food Allergy Testing); also called Brian's Test or Leukocyte Antigen Testing: Cytotoxic testing involves taking about 10 cc of blood from a patient. Microscopic slides are coated with the dried extract of a particular food. White blood cells (WBCs/leukocytes) are then mixed with plasma and sterile water and placed on the coated microscopic slides. The reaction of the cells to the extracts is then examined under a microscope. If the cells collapse, disintegrate, or change shape, the patient is supposedly allergic to that particular food. This evidence of food allergy is then used to explain a variety of symptoms. To correct this condition, the clinic offers a personalized diet program which includes vitamin and mineral supplements.

To obtain further information on LBA and other alternative laboratory testing, please contact your State or Regional Survey Agency. Contact information for these agencies can be found on the CLIA website at: http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/State_Agency_and_Regional_Office_CLIA_Contacts.html

Questions can also be sent to: LabExcellence@cms.hhs.gov