

## 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. The Health Care Financing Administration (now the Centers for Medicare & Medicaid Services) Office of General Counsel (OGC) determined in August, 1997, that LBA was subject to all CLIA requirements. Therefore, any facility performing this procedure must be certified by CLIA and must obtain the correct certificate. Failure to comply with any of the CLIA requirements will result in enforcement actions and/or sanctions being taken.

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. Therefore, any facility performing this test must meet all CLIA requirements for high complexity testing: Patient Test Management; Proficiency Testing; Quality Control; Personnel, and Quality Assurance. **Therefore any facility performing LBA must hold a valid registration certificate, Certificate of Compliance, or Certificate of Accreditation. LBA is not a Provider-Performed Microscopic Procedure (PPMP) test. LBA is also a non-covered Medicare service.** [CLIA Regulations](#) (CDC Website)

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. [NOTE: In some cases, a powder has been developed that when sprinkled on the blood will form 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.

LBA is also known as Hemaview, Free Radical Blood Screening, etc.

### **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. A portion of the test is legitimate: pH.
- 2. Thromboelastograph:** This is a valid test which has been categorized by the CDC as moderate and 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 one 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.

**4. Cytotoxic Testing (Food Allergy Testing):** Cytotoxic testing involves taking about 10 ccs of blood from a patient. The white blood cells (WBCs/leukocytes) are mixed with plasma and sterile water and placed on microscopic slides, after each slide has been coated with the dried extract of a particular food. 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. Also called Brian's Test or Leukocyte Antigen Testing.

To obtain further information on LBA and other alternative laboratory testing, please contact your State Survey Agency or CMS Regional Office.