

### **333.040 Medical laboratories not subject to law.**

This chapter applies to all medical laboratories within the State of Kentucky, except:

- (1) Medical laboratories operated by the United States government;
- (2) Medical laboratories operated by a licensed physician, or a group of licensed physicians, solely and exclusively in connection with the diagnosis and treatment of their own patients; if any referred work is received or performed by such medical laboratories, all provisions of this chapter shall apply;
- (3) Medical laboratories operated by hospitals licensed by the secretary for health and family services;
- (4) Medical laboratories operated and maintained exclusively for research purposes, involving no patient or public health service whatsoever; and
- (5) Medical laboratories operated by facilities holding a permit pursuant to KRS 315.035 and holding a valid certification issued pursuant to the Clinical Laboratory Improvement Act of 1988 (CLIA), as amended, solely and exclusively in connection with assisting a patient with the use of CLIA-waived tests available from the facility's stock or inventory, and in connection with testing and treatment of patients covered under collaborative care agreements established under KRS 315.010 and other applicable laws. If any referred work is received or performed by these medical laboratories, all provisions of this chapter shall apply.

**Effective:** June 20, 2005

**History:** Amended 2005 Ky. Acts ch. 99, sec. 603, effective June 20, 2005. -- Amended 1998 Ky. Acts ch. 426, sec. 554, effective July 15, 1998; and ch. 531, sec. 2, effective July 15, 1998. -- Amended 1978 Ky. Acts ch. 298, sec. 1, effective June 17, 1978; and ch. 384, sec. 108, effective June 17, 1978. -- Amended 1974 Ky. Acts ch. 74, Art. VI, sec. 107(1). -- Created 1968 Ky. Acts ch. 180, sec. 4.