PeaceHealth Laboratories

Laboratory Developed Tests (LDT):

Clinical diagnostic tests without The U.S. Food and Drug Administration (FDA) approval must meet the performance specifications according to the Clinical Laboratory Improvement Amendment of 1988 (CLIA). PeaceHealth Laboratories follows regulations pertaining to the identification of non-FDA approved test methods available from our laboratories. For laboratory developed tests not using a research use only kit (RUO), and for FDA approved, cleared or 510(k) exempt assays with alterations:

> This test was developed and its performance characteristics determined by PeaceHealth Laboratories. The U. S. Food and Drug Administration has not approved or cleared this test however, FDA clearance or approval is not required for clinical use. The laboratory is regulated under CLIA as qualified to perform high-complexity testing. This test is used for clinical purposes. It should not be regarded as investigational or for research.