



KAREN L. SMITH, MD, MPH
Director and State Public Health Officer

State of California—Health and Human Services Agency
California Department of Public Health



EDMUND G. BROWN JR.
Governor

June 25, 2018

Heidi Bauer, MD, MS, MPH
Chief, STD Control Branch
California Department of Public Health
Division of Communicable Disease Control
850 Marina Bay Parkway
Building P, 2nd Floor
Richmond, CA 94804

Dear Dr. Bauer:

Pursuant to Health and Safety Code section 101160, Laboratory Field Services (LFS) in the California Department of Public Health (CDPH) retains authority over the public health laboratory program. Furthermore, Title 17 of the California Code of Regulations section 1079(e) specifically prohibits a person from performing any test or making any examination in a certified public health laboratory unless that person is a public health microbiologist or is approved by CDPH to perform specified procedures.

LFS is electing to exercise this authority to approve unlicensed personnel to administer CLIA-waived syphilis rapid screening tests (RSTs) under the umbrella authority of a public health laboratory if the following requirements are met:

- The CLIA-waived RSTs for syphilis shall be approved as waived tests and be used according to the manufacturer's instructions.
- Blood collection is performed by skin puncture only.
- Testing is performed onsite and reported directly to the person requesting the test.
- Disease intervention staff performing RSTs for syphilis shall complete a minimum of 20 hours of basic phlebotomy didactic training as outlined in Title 17 of the California Code of Regulations section 1035.1(e)(1).

You have specifically inquired about the minimum 20-hour basic phlebotomy didactic training requirement. It is the view of LFS that the 20-hour basic phlebotomy didactic training requirement is necessary to ensure that laboratory personnel standards, including standards for unlicensed personnel, are sustained in order to provide accurate, reliable, and necessary test results. This view is consistent with legislative findings and declarations expressed in Business and Professions Code section 1223(a).

Furthermore, the training requirement is consistent with existing training standards and requirements for certified and licensed medical professionals, such as emergency medical technicians and licensed paramedics identified in Business and Professions Code section 1241(b)(8), HIV counselors performing waived HIV tests pursuant to Health and Safety Code section 120917, and Limited Phlebotomy Technicians pursuant to Title 17 of the California Code of Regulations 1034(a)(1)(A). It is the position of LFS that the 20-hour basic phlebotomy didactic training requirement, which can easily be accomplished via online courses, ensures that all unlicensed field staff working in a public health laboratory environment maintain infection control techniques for the safety of themselves and patients when administering the CLIA-waived syphilis RSTs.

Sincerely,

A handwritten signature in blue ink that reads "Paul Kimsey". The signature is written in a cursive style with a large, stylized initial "P".

Paul Kimsey, PhD
Director, Office of the State Public Health Laboratory

cc: Robert J. Thomas
Chief, Laboratory Field Services