

**Introduced by Senator Galgiani**

February 19, 2016

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An act to amend Section 1246.5 of the Business and Professions Code, relating to clinical laboratories.

**LEGISLATIVE COUNSEL'S DIGEST**

SB 1418, as introduced, Galgiani. Clinical laboratory testing.

Existing law provides for the regulation and licensure of clinical laboratories and clinical laboratory personnel by the State Department of Public Health and makes a violation of a provision under this law a misdemeanor. Existing law authorizes a person to request, and a licensed clinical laboratory or public health laboratory to perform, pregnancy, glucose level, cholesterol, occult blood, and other specified tests. Existing law authorizes a registered clinical laboratory to perform these tests, as specified.

Existing law authorizes the results of the test to be provided directly to the person requesting the test if the test is on or for his or her own body. Existing law requires that those test results be provided in a manner that presents clear information and that identifies results indicating the need for referral to a physician.

This bill would make technical, nonsubstantive changes to these provisions.

Vote: majority. Appropriation: no. Fiscal committee: no.  
State-mandated local program: no.

*The people of the State of California do enact as follows:*

- 1 SECTION 1. Section 1246.5 of the Business and Professions
- 2 Code is amended to read:

1 1246.5. (a) Notwithstanding any other provision of law, any  
2 law, a person may request, and any a licensed clinical laboratory  
3 or public health laboratory may perform, the laboratory tests  
4 specified in this section. A registered clinical laboratory may  
5 perform the laboratory tests specified in this section if the test is  
6 subject to a certificate of waiver under ~~CLIA~~ *the federal Clinical*  
7 *Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a)*  
8 *(CLIA)* and the laboratory has registered with the department under  
9 paragraph (2) of subdivision (a) of Section 1265. A program for  
10 nondiagnostic general health assessment that includes a laboratory  
11 test specified in this section shall comply with the provisions of  
12 Section 1244. The results from any test may be provided directly  
13 to the person requesting the test if the test is on or for his or her  
14 own body. These test results shall be provided in a manner that  
15 presents clear information and that identifies results indicating the  
16 need for referral to a physician and surgeon.

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18 (b) (1) *The tests that may be conducted pursuant to this section*  
19 *are: pregnancy, glucose level, cholesterol, occult blood, and any*  
20 *other test for which there is a test for a particular analyte approved*  
21 *by the federal Food and Drug Administration for sale to the public*  
22 *without a prescription in the form of an over-the-counter test kit.*  
23 *A test approved only as an over-the-counter collection device may*  
24 *not be conducted pursuant to this section. all of the following:*

25 (A) *Pregnancy.*

26 (B) *Glucose level.*

27 (C) *Cholesterol.*

28 (D) *Occult blood.*

29 (E) *Any other test for which there is a test for a particular*  
30 *analyte approved by the federal Food and Drug Administration*  
31 *for sale to the public without a prescription in the form of an*  
32 *over-the-counter test kit.*

33 (2) *A test approved only as an over-the-counter collection device*  
34 *may not be conducted pursuant to this section.*