

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0875212	(X3) Date Survey Completed 02/28/2018
Name of Provider or Supplier Watsonville Health Center	Street Address, City, State 1430 Freedom Blvd Ste D, Watsonville, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D3001	<p>FACILITIES CFR(s): 493.1101(a)(1)</p> <p>The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor visit of the laboratory and observation of the laboratory's layout and arrangement, lack of space necessary for conducting all phases of the testing process, and interview with the laboratory Director and testing personnel, the laboratory failed to ensure adequate space necessary for conducting all phases of the testing process. The findings include: a. The laboratory is consisted of 1 large (approximately 200 Sq. Ft.) and 1 small rooms (approximately 50 Sq. Ft.). The large room houses testing instruments, computers, 3 sinks, 1 eyewash station and a phlebotomy chair. The small room has a fume hood, a centrifuge machine and a printer, and is also used as an office for the laboratory director. The laboratory uses its work space for the blood drawing station. At a given time point, at least 3 laboratory staffs work inside the laboratory. Based on the limited space, improper work area arrangement and moderate test volume, it was determined that problems in specimen handling, examination and testing, and the reporting of test results can not be minimized. b. On February 28, 2018 at 10:30 am the laboratory Director and testing personnel affirmed that the laboratory does not have sufficient space for patient testing. c. The laboratory's testing declaration form, signed by the laboratory Director on February 23, 2018, stated that the laboratory performs 16,473 tests annually.</p>
D5201	<p>CONFIDENTIALITY OF PATIENT INFORMATION CFR(s): 493.1231</p> <p>The laboratory must ensure confidentiality of patient information throughout all phases of the total testing process that are under the laboratory's control.</p>

This STANDARD is not met as evidenced by:

Based on Surveyor observation of the laboratory's layout, control of visitor access to the laboratory areas where patient information may be easily viewed, lack of safeguards in place to ensure confidentiality of patient information and test reports, and interview with the laboratory Director and testing personnel, the laboratory failed to ensure confidentiality of patient information throughout all phases of the total testing process that are under the laboratory's control. The findings include: a. The laboratory did not have any door which is closed and locked, and it can easily be accessible by visitors; there is no control over visitor access. b. Unauthorized users are not prohibited from gaining entry into the laboratory. There is no safeguard in place to bar visitors gaining entry into the laboratory. c. On February 28, 2018 at 11:00 am the laboratory Director and testing personnel affirmed that the laboratory does not have safeguards in place to ensure confidentiality of patient information and test reports.