

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2216677	(X3) Date Survey Completed 05/14/2026
Name of Provider or Supplier Hot Clinic Inc	Street Address, City, State 16550 Ventura Blvd Ste 314, Encino, 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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy and procedure, instrument print-out, patient test results, and interview with the laboratory technical consultant on May 14, 2026, at 3:53 p.m., the laboratory testing person failed to follow the laboratory's policy & procedure in repeating the flagged test results for 1 patient out of 14 patients, reviewed. The findings include: 1. The laboratory used Micros ES60 automated CBC instrument from Horiba to measure platelet (plt). Instrument print-out showed SCH alert with an asterisk, (*) following the plt results for the sample 1019560. According to the laboratory's procedure the results should be verified by re-running the sample. However, the laboratory person reported the results without repeating the run. Therefore, the accuracy of the reported results cannot be assured and might have harmed the patient. 2. The laboratory technical consultant on May 14, 2026, at 3:53 p. m., affirmed that the laboratory testing person #1 did not follow the laboratory's procedure and repeat the test. 3. The laboratory's testing declaration form, signed by the laboratory director on 5/14/2026, stated that the laboratory performed approximately 200 plt tests, annually.</p>
D5787	<p>TEST RECORDS CFR(s): 493.1283(a)</p> <p>(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time</p>

of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory patients tests records, instrument print-out and interview with the laboratory technical consultant on May 14, 2026, at 3:20 p.m., the laboratory failed to document the identity of the testing person performing the routine chemistry and CBC tests. The findings include: 1. The laboratory had 1 licensed testing person and 2 unlicensed assistants. The assistants helped in loading the sample on the automated instrument; however, the testing person was not always present in the laboratory. It cannot be ruled out that the assistants may have performed tests since the laboratory did not document and keep any records. Therefore, the accuracy of the reported results cannot be assured and might have harmed the patient. 2. The laboratory technical consultant on May 14, 2026, at 3:20 p.m., affirmed that the laboratory did not record the identity of the person running the tests. 3. The laboratory's testing declaration form, signed by the laboratory director on 5/14/2026, stated that the laboratory performed approximately 2,400 tests, annually.

D6004

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(a)(b)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's policy and procedure, instrument print-out, patient test results and interview with the laboratory technical consultant on May 14, 2026, at 3:20 p.m., it was determined that the laboratory director failed to direct the overall operation and administration of the laboratory. The findings include: See D5401, D5787, D6014 and D6070.

D6014

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(3)(iii)

(e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's policy and procedure, instrument print-out, patient test results, and interview with the laboratory technical consultant on May 14, 2026, at 3:53 p.m., the laboratory director failed to assure that the testing personnel

were following the laboratory's procedure for repeating the flagged sample run. The findings include: See D5401.

D6070

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1425(b)(1)

(b) Each individual performing moderate complexity testing must-- (b)(1) Follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results;

This STANDARD is not met as evidenced by:
Based on Surveyor review of laboratory's policy and procedure, instrument print-out, patient test results, and interview with the laboratory technical consultant on May 14, 2026, at 3:53 p.m., it was determined that the laboratory testing person #1 failed to follow the laboratory's procedure for repeating the flagged sample run for 1 patient out of 14 patients, reviewed. The findings include: See D5401.