

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 05D2096883	<b>(X3) Date Survey Completed</b> 02/25/2021
<b>Name of Provider or Supplier</b> Flow Health Laboratories, Llc	<b>Street Address, City, State</b> 8627 Washington Blvd, Culver City, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5200</b>	<p><b>GENERAL LABORATORY SYSTEMS</b> CFR(s): 493.1230</p> <p>Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on the number of deficiencies found during an onsite survey on February 25, 2021 and the severity of the cited deficiencies herein, it was determined that the Condition: General laboratory system was not met. The findings include: 1. The laboratory failed to ensure confidentiality of patient information throughout all phases of testing process that are under the laboratory's control. D5201 2. The laboratory failed to have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate. D5205 3. The laboratory failed to establish and follow written policies and procedures to assess employee and, if applicable, consultant competency as specified in the personnel requirements in subpart M. D5209 4. The laboratory failed to document all the test verification activities. D5221 5. The laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. D5291</p>
<b>D5201</b>	<p><b>CONFIDENTIALITY OF PATIENT INFORMATION</b> CFR(s): 493.1231</p>

The laboratory must ensure confidentiality of patient information throughout all phases of the total testing process that are under the laboratory's control.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's policy & procedure, random patient sample records, and interview with the laboratory general supervisor on February 25, 2021 at 11:10 am, the laboratory failed to provide documentation that shows the confidentiality of patient information throughout all phases of the total testing process. The findings include: 1. The laboratory uses slack online software system for communication and storing patient information including test requisition. According to slack software, slack can be configured for HIPAA compliance, including electronically protected health information (e-PHI). However, the laboratory could not provide any evidence with documentation showing that it had configured slack for securely storing patient information. 2. The laboratory general supervisor on February 25, 2021 at 11:10 am, affirmed that the laboratory did not have any documentation showing that it had configured slack for securely storing patient information. 3. According to the patient sample testing records reviewed, the laboratory performs 3,000 COVID-19 PCR tests, daily.

**D5205**

COMPLAINT INVESTIGATIONS  
CFR(s): 493.1233

The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's policy & procedure, random patient sample and quality control (QC) records, and interview with the laboratory general supervisor and personnel on February 25, 2021 at 11:20 am, the laboratory failed to have a system in place to ensure that it documents all complaints. The findings include: 1. The laboratory did not have any system in place to document complaints and did not inform laboratory personnel of mechanisms to anonymously report complaints about laboratory quality to outside agencies, e.g. State survey agencies. 2. The laboratory general supervisor on February 25, 2021 at 11:20 am, affirmed that the laboratory did not have any system in place to document all complaints. 3. According to the patient sample testing records reviewed, the laboratory performs 3,000 COVID-19 PCR tests, daily.

**D5209**

PERSONNEL COMPETENCY ASSESSMENT POLICIES  
CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's policy & procedure, random patient sample and quality control (QC) records, and interview with the laboratory general supervisor on February 25, 2021 at 12:15 pm, the laboratory failed to establish and follow written

policies and procedures to assess employee competency. The findings include: 1. The laboratory performs COVID-19 PCR test by using Applied Biosystem's TaqPath COVID-19 Combo Kit which FDA authorized for emergency use only. The laboratory has a total of 9 testing personnel which include 3 California licensed clinical laboratory scientist. The laboratory did not have any documentation showing that it has established and is following the written policies and procedures to assess its employee competency. The policy and procedure that must include direct observation of routine patient test performance and performance of instrument maintenance and function checks, monitoring the recording and reporting of test results, review of intermediate test results or worksheets, and assessment of test performance and problem solving skills. The failure of having a policy and procedure resulted in the laboratory's failure to evaluate competency of its all 9 testing personnel. 2. The laboratory general supervisor on February 25, 2021 at 12:15 pm, affirmed that the laboratory did not have any documentation showing that it has established and is following the written policies and procedures to assess employee competency. 3. According to the patient sample testing records reviewed, the laboratory performs 3,000 COVID-19 PCR tests, daily.

**D5221**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**  
CFR(s): 493.1236(d)

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:  
Based on Surveyor review of laboratory's policy & procedure, random patient sample, quality control (QC) and test accuracy verification records, and interview with the laboratory general supervisor on February 25, 2021 at 2:20 pm, the laboratory failed to document the annual test accuracy verification activities. The findings include: 1. The laboratory is required to verify its COVID-19 PCR test accuracy, at least twice annually. So, it used COV2-B 2020 proficiency testing (PT) sample from College of American Pathologists (CAP) to verify its test accuracy. However, it decided not to send the PT sample test result to CAP for evaluation but chose to evaluate themselves instead. The laboratory tested the PT sample on 12/16/2020. However, it did not have documentation of all the verification activities performed including review of the CAP results to compare and verify the accuracy of its own results. 2. The laboratory general supervisor on February 25, 2021 at 2:20 pm, affirmed that the laboratory did not document the verification activities. 3. According to the patient sample testing records reviewed, the laboratory performs 3,000 COVID-19 PCR tests, daily.

**D5291**

**GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1239(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:  
Based on Surveyor review of laboratory's policy & procedure, random patient sample and quality assessment records, and interview with the laboratory general supervisor on February 25, 2021 at 2:30 pm, the laboratory failed to establish and follow written

policies and procedures for general laboratory systems quality assessment. The findings include: 1. The laboratory did not have any written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems. The lack of quality assessment policy and procedure, and failure to monitor and assess the quality of its general laboratory systems resulted laboratory not performing competency assessment of its employees, no documentation of annual test accuracy verification activities and complaints, and potential breach of patient confidentiality. 2. The laboratory general supervisor on February 25, 2021 at 2:30 pm, affirmed that the laboratory did not have written policies and procedures for general laboratory systems quality assessment. 3. According to the patient sample testing records reviewed, the laboratory performs 3,000 COVID-19 PCR tests, daily.

**D5805**

**TEST REPORT**  
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:  
Based on Surveyor review of laboratory's policy & procedure, random patient sample and quality control (QC) records, and interview with the laboratory general supervisor on February 25, 2021 at 2:50 pm, the laboratory failed to include the name and address of the laboratory location where the test was performed. The findings include: 1. The laboratory was previously located at 8885 Venice Blvd, Ste 105, Los Angeles, CA 90034, and moved to a new location, 8627 Washington Blvd, Culver City, CA 90232 effective February 8, 2021. However, the laboratory used another laboratory's name and address, Signal Diagnostics, CLIA # 05D2081405, 8885 Venice Blvd, Los Angeles, CA 90034 on all its patient test report. 2. The laboratory general supervisor on February 25, 2021 at 2:50 pm, affirmed that the laboratory failed to include the name and address of the laboratory location on its test report at where the test was performed. 3. According to the patient sample testing records reviewed, the laboratory performs 3,000 COVID-19 PCR tests, daily.

**D6076**

**LABORATORY DIRECTOR**  
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:  
Based on Surveyor review of laboratory's policy & procedure, random patient sample, quality control (QC), quality assessment and employee competency assessment records, and interview with the laboratory general supervisor during an onsite survey

of the laboratory on February 25, 2021, and the severity and the number of deficiencies found and cited herein, it was determined that the laboratory director failed to provide effective direction over the operation of the laboratory, hence the Condition: Laboratories performing high complexity testing; laboratory director was not met. The laboratory director's failure to provide direction over the laboratory operation has a consequence of potential erroneous test result reporting and patient harm. The findings include: 1. The laboratory director failed to assure compliance with the applicable regulations. D6079 2. The laboratory director failed to ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; D6094 3. The laboratory director failed to ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results; D6102 4. The laboratory director failed to ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills D6103 5. The laboratory director failed to specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. D6107

**D6079**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
 CFR(s): 493.1445(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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reappoints 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 & procedure, random patient sample, quality control (QC) and annual verification of test accuracy records, and interview with the laboratory general supervisor and personnel on February 25, 2021 at 2:50 pm, the laboratory director failed to assure laboratory's compliance with the applicable regulations. The findings include: See D5201, D5205, D5209, D5221, D5291, D5805 and D6120

**D6094**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
 CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:  
Based on Surveyor review of laboratory's policy & procedure, random patient sample, quality control (QC) and personnel competency assessment records, and interview with the laboratory general supervisor on February 25, 2021 at 2:30 pm, the laboratory director failed to ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. The findings include: See D5291.

**D6102**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:  
Based on Surveyor review of laboratory's policy and procedure, and personnel training & competency assessment records, and interview with the laboratory general supervisor on February 25, 2021 at 12:15 pm, the laboratory director failed to ensure that all personnel received the appropriate training. The findings include: See D5209 and D6120.

**D6103**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:  
Based on Surveyor review of laboratory's policy and procedure, and personnel training & competency assessment records, and interview with the laboratory general supervisor on February 25, 2021 at 12:15 pm, the laboratory director failed to ensure that all personnel competency assessment has been performed according to the established policy and procedure. The findings include: See D5209.

**D6107**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of

the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:  
Based on Surveyor review of laboratory's policy and procedure, test accuracy verification and personnel training & competency assessment records, and interview with the laboratory general supervisor on February 25, 2021 at 12:15 pm, the laboratory director failed to specify in writing the responsibilities and duties of all laboratory personnel. The findings include: 1. The laboratory did not have any document showing that the lab director has specified in writing the responsibilities and duties of any laboratory personnel. 2. The laboratory general supervisor on February 25, 2021 at 12:15 pm, affirmed that the laboratory did not have any documentation showing that the laboratory director had specified in writing the responsibilities and duties of all laboratory personnel.

**D6120**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:  
Based on Surveyor review of laboratory's policy and procedure, and personnel training & competency assessment records, and interview with the laboratory general supervisor on February 25, 2021 at 12:15 pm, the laboratory technical supervisor failed to evaluate the competency of all 9 testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The findings include: 1. The laboratory employs a total of 9 testing persons who does COVID-19 PCR testing and reporting. The employees work during day or night shift. Among 9 testing persons, 3 are California licensed clinical laboratory scientists. However, the laboratory did not have any documentation showing that the laboratory technical supervisor had evaluated the competency of any of the laboratory testing personnel doing COVID-19 PCR testing. The outcome of a non-competent staff performing and reporting COVID-19 PCR test rendering erroneous test result, consequences misdiagnosis and potential harm to the patients. 2. The laboratory general supervisor on February 25, 2021 at 12:15 pm, affirmed that the laboratory did not have any documentation showing that the laboratory technical supervisor had evaluated the competency of any laboratory personnel doing COVID-19 PCR testing. 3. According to the patient sample testing records reviewed, the laboratory performs 3,000 COVID-19 PCR tests, daily.