

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0890124	(X3) Date Survey Completed 04/04/2023
Name of Provider or Supplier Seventy Second Street Medical Associates Pc	Street Address, City, State 310 East 72nd Street, New York, NY	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the personnel files for the nine testing personnel, lack of training, six-month and annual competency evaluation, SOP for competency evaluation, and an interview with general supervisor, the laboratory director failed to follow the established competency evaluation policy regarding the training, six-month and annual evaluations for the first year of employment. FINDINGS: 1. The competency evaluation policy states, "Each individual performs require a degree of skill commensurate with the individual's education, training or experience, and technical abilities. o Follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. o Maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient samples. o Adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. o Follow the laboratory's established corrective action policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance. o Be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the director. o Document all corrective actions taken when test systems deviate from the laboratory's established performance specifications." 2. Lack of training, six-month, and annual competency evaluations for the six new testing personnel hired from 1/26/2021 through 11/30/2021 for their first year of employment as well as the annual competency for the three routine testing personnel for the calendar years 2020, 2021, and 2022. 3. General supervisor</p>

confirmed on 4/4/2023 at 9:30 A.M. that the laboratory director did not perform the training, six-month, and annual competency evaluations for the six new testing personnel hired from 1/26/2021 through 11/30/2021 for their first year of employment as well as the annual competency evaluations for the three routine testing personnel in 2020, 2021, and 2022. Refer to D6029, D6053, D6054.

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 review of the Quality Assessment (QA) documentation for 2020, 2021, and 2022 and interview with the general supervisor, the laboratory failed to follow their established QA policy. FINDINGS: 1. The laboratory did not follow the QA policy section regarding personnel competency for the nine testing personnel who performed moderate complexity testing. 2. General supervisor confirmed on 4/4/2023 at 9:30 A.M. that the laboratory director did not perform the six-month and annual competency evaluations for the six new testing personnel hired from 1/26/2021 through 11/30/2021 for their first year of employment as well as the annual competency evaluations for the three routine testing personnel in 2020, 2021, and 2022. Refer to D6021, D6029, D6053 and D6054.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on the review of the Bio Fire Film Array operations manual for ambient temperature and humidity requirements, lack of laboratory room temperature and humidity documentation for 2022 through survey date, and an interview with the general supervisor, the laboratory failed to monitor the room temperature and humidity for the testing area where the two Bio Fire array analyzer were located. FINDINGS: 1. The manufacturer of the Bio Fire Film Array required an ambient temperature range of 15 - 30°C and a humidity of 20 - 80%. 2. No documentation of room temperature and humidity was available for review at the time of the survey. 3. The laboratory implemented respiratory panel patient testing on 11/7/2022 for the two BioFire Film Array analyzers (#1 S/N FA2548 and #2 (S/N FA2301). 3. General supervisor confirmed on April 4, 2023, at approximately 11:30 A.M. that the room temperature and humidity were not documented for the calendar years 11/2022 through the survey date. Refer to D6021.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on review of the laboratory procedure manual, Bio Fire Film Array operator's manual, lack of training and competency evaluation documentation, and confirmed with an interview with general supervisor, the director failed to provide overall management for all phases of moderate complexity testing. FINDINGS: The laboratory director failed to ensure that the laboratory: 1. Maintained the QA policy, refer to D6021. 2. Performed and documented the training of the six newly hired testing personnel, refer to D6029. 3. Performed and documented the six-month competency evaluations for the six newly hired testing personnel, refer to D6053. 4. Performed and documented the annual competency evaluation for the six new testing personnel and three routine testing personnel, refer to D6054.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

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. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's QA policy, QA documentation, and an interview with the general supervisor, the laboratory director failed to follow the established QA procedure for maintaining a mechanism to monitor, assess, and when detected, correct problems identified in the general laboratory system. Refer to D5209, D5291, and D5413.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

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. (e) The laboratory director must-- (e)(11) 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 review of personnel records, lack of training documentation for the six new

	<p>hired testing personnel, and interview with the general supervisor, the laboratory director failed to ensure that appropriate training was documented for the six of nine testing personnel who performed moderate complexity testing. Refer to D5209.</p>
<p>D6053</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on lack of the competency evaluation records for the six newly hired testing personnel from 1/26/2021 through 4/11/2022 and confirmed in an interview with the general supervisor, the laboratory director failed to perform the six-month competency evaluation for six of six testing personnel during the first year of patient testing. Refer to D5209.</p>
<p>D6054</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Competency Assessment policy, lack of competency evaluations records for the nine testing personnel, and confirmed with an interview with the general supervisor, the laboratory director, acting as the technical consultant, failed to assess competency for the six new testing personnel hired from 1/26/2021 through 11/30/2021 for their first year of employment as well as the annual competency evaluations for the three routine testing personnel in 2020, 2021, and 2022. Refer to D5209.</p>