

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  33D0142794	<b>(X3) Date Survey Completed</b>  03/21/2019
<b>Name of Provider or Supplier</b>  Franklin Square Pediatrics	<b>Street Address, City, State</b>  125 Franklin Avenue, Suite 203 South, Valley Stream, NY	
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>D1001</b>	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a surveyor's review of the manufacturer's packet inserts and an interview with the laboratory director, the laboratory failed to follow the manufacturer's requirements for performing external positive and negative controls for waived testing. FINDINGS: The laboratory director on March 21, 2019 at approximately 2:30 PM confirmed the surveyor's findings that: 1. Documentation for the required external control testing was not available for the Siemens Multistix and for Consult Diagnostics Multistix from January 2017 through the survey date. Approximately 500 patient specimens were tested and reported for urinalysis during this time frame. 2. Documentation for the required external control testing was not available for Cholestech LDX from January 2017 through November 2017. The laboratory director stated that the Cholestech LDX was discontinued in December 2017. Approximately 100 patient specimens were tested and reported for Cholestech LDX from January through November 2017. 3. Documentation for the required external control testing was not available for the OSOM Genzyme Rapid Strep A for the calendar year 2018. Approximately 100 patient specimens were tested and reported for Rapid Strep A in calendar year 2018. THIS IS A REPEATED DEFICIENCY FROM THE SURVEYS CONDUCTED ON NOVEMBER 7, 2014 AND OCTOBER 31, 2016.</p>
<b>D2000</b>	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p>

Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.

This CONDITION is not met as evidenced by:

Based on lack of proficiency testing (PT) records and confirmed in an interview with the laboratory director at the time of the survey, the laboratory failed to enroll in an approved PT program for the bacteriology testing/throat cultures for the calendar year 2019.

**D3037**

**RETENTION REQUIREMENTS**

CFR(s): 493.1105(a)(4)

Proficiency testing records. Retain all proficiency testing records for at least 2 years.

This STANDARD is not met as evidenced by:

Based on the lack of American Proficiency Institute (API) Proficiency Testing (PT) records for calendar years 2017 and 2018 and confirmed in an interview with the laboratory director, the laboratory failed to retain API PT records and documentation to include signed attestation forms, test result forms, PT resulted samples print-outs and a signed PT summary reports for all three events in 2017 and all three events in 2018.

**D5211**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**

CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:

Based on lack of PT records and an interview with the laboratory director, the laboratory failed to evaluate, perform and document remedial action for the PT scores of less than 100% for the followings: 2017 third event: Red Blood Cells (RBC) = 80% 2018 first event: Bacteriology = 80%

**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's review of the laboratory's Quality Assessment (QA) policies and procedures and confirmed in an interview with the laboratory director, at the time of this survey, the laboratory failed to follow their established QA policy and perform a QA review for the 2017 and 2018 calendar years.

**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 a surveyor's review of laboratory's temperature records and interview with the laboratory director, the laboratory failed to follow the laboratory's temperature policy for laboratory testing. FINDINGS: 1. The laboratory's temperature policy requires the refrigerator, freezer, room, humidity and the incubator temperature to be monitored on each day of testing. 2. On March 21, 2019 at approximately 2:30 PM the laboratory director confirmed surveyor's findings that the documentation of temperature records for the laboratory's refrigerator, freezer, room, humidity and the incubator were not available for review for May 2017, June 2017, August 2017, September 2017, and from January through August 2018. 3. Approximately 400 patient samples were tested and reported during the above time frames. THIS IS A REPEATED DEFICIENCY FROM THE SURVEY CONDUCTED ON OCTOBER 31, 2016.

**D5471**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(e)(1)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on surveyor's review of the bacteriology Quality Control (QC) documentation and an interview with the laboratory director, the laboratory failed to check each new batch, lot number and shipment of 0.04 bacitracin disc for positive and negative reactivity from December 2017 through August 2018. FINDINGS: 1. On March 21, 2019 at approximately 3:00 PM the laboratory director confirmed surveyor's findings that the laboratory failed to check each new batch, lot number and shipment of the bacitracin disc for positive and negative reactivity in April, May, and July 2017 and from December 2017 through August 2018. 2. The laboratory failed to record the lot number/expiration date for the shipment of bacitracin disc received in the lab from

	<p>December 2017 through August 2018. 3. Approximately 200 patients specimens were tested and reported for throat culture during this time period.</p>
<p><b>D5477</b></p>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(e)(4)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on a surveyor's review of records and confirmed in an interview with the laboratory director at the time of this survey, the laboratory failed to perform bacteriology QC as required in April, May, and July 2017 and from December 2017 through August 2018. The laboratory failed to: 1. Perform and document the sterility for the Selective Strep Agar (SSA) Media; 2. Document the physical characteristics of the SSA Media for any deterioration; 3. Check each new batch, lot number and shipment of SSA Media for positive and negative reactivity. Approximately 200 patient specimens were tested and reported for throat culture during the above time period.</p>
<p><b>D6000</b></p>	<p><b>MODERATE COMPLEXITY LABORATORY DIRECTOR</b> CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor findings and interview with the laboratory director, the laboratory director failed to provide overall management of the laboratory. The laboratory director failed to ensure that the laboratory: 1. Maintained the plan of correction from the surveys conducted on 11/7/2014 and 10/31/16; 2. successfully participate in PT. Refer to D6015 3. maintained the laboratory's QC program for bacteriology, refer to D6020. 4. maintained the laboratory's established QA program for all phases of laboratory testing, refer to D6021. THIS IS A REPEATED DEFICIENCY FROM THE SURVEY CONDUCTED ON OCTOBER 31, 2016.</p>
<p><b>D6015</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)</p> <p>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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.</p>

	<p>This STANDARD is not met as evidenced by:  Based on the surveyor's review of laboratory records and an interview with the laboratory director, the laboratory failed to enroll in Proficiency Testing (PT) for bacteriology for the first event 2019. FINDINGS: The laboratory director confirmed on March 21, 2019 at approximately 3:00 PM that the laboratory failed to enroll in a PT program for throat cultures for the first event of 2019.</p>
<p><b>D6020</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b>  CFR(s): 493.1407(e)(5)</p> <p>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 the quality control program is established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by:  Based on the surveyor's review of Quality Control (QC) records and confirmed, during this onsite survey with the laboratory director, the laboratory director failed to ensure that the QC program for bacteriology testing was maintained to assure quality of laboratory services. Refer to: D1001, D5413, D5471, D5471 THIS IS A REPEATED DEFICIENCY FROM THE SURVEY CONDUCTED ON OCTOBER 31, 2016.</p>
<p><b>D6021</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b>  CFR(s): 493.1407(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:  Based on a review of the laboratory Quality Assessment (QA) policy, and interview with the laboratory director, the laboratory director failed to follow their QA procedure for having an on going mechanism to monitor, assess and when indicated correct problems identified in the general laboratory system for bacteriology in calendar year 2017 and up to survey date. Refer to D3037, D5211, D5291</p>