

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  07D0644520	<b>(X3) Date Survey Completed</b>  08/06/2018
<b>Name of Provider or Supplier</b>  Starling Physicians Pllc	<b>Street Address, City, State</b>  1 Lake St, New Britain, CT	
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>D2010</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to test proficiency testing (PT) samples in the same manner as routine patient samples. Findings include: 1. Record review on 8/6/18 of PT raw data submitted to the American Association of Bioanalysts (ABB) for evaluation revealed PT samples were tested multiple times and /or by multiple testing personnel (TP) as indicated below: A. Non-Chemistry: The following Complete Blood Count-PT samples were repeated. a) Q3-2016: Samples 1, 3, 4 and 5 b) Q1-2016: Samples 1 through 5 c) Q1-2017: Samples 1 through 5 d) Q2-2017: Samples 1, 3 and 4 e) Q3-2017: Samples 1 through 5 f) Q1-2018: Samples 1 and 4 B. Non-Chemistry: The following Urine sediment photographs were tested by multiple TP. a) Q2-2017: Images 1 through 4 tested by 4 TP. b) Q1-2018: Images 1 through 4 tested by 4 TP. C. Non-Chemistry: The following Rapid Plasma Reagin (RPR) and Infectious Mononucleosis (IM) PT samples were repeated. a) Q3-2017: Samples 1 through 5 for IM b) Q3-2017: Samples 1 through 5 for RPR 2. Record review of the laboratory's policy for routine patient sample testing on 8/6/18 revealed patient samples are tested only one time unless flagged as critical value, which will be repeated. 3. Staff interview with the technical supervisor on 8/6/18 at 11:30 AM confirmed the above findings.</p>
<b>D5209</b>	<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,</p>

consultant competency.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory competency policies and procedures failed to include requirements to assess the competency of the general supervisor (GS) and clinical consultant (CC) based on the regulatory responsibilities and failed to perform said competency. Findings include: 1. Record review of the laboratory's personnel assessment policy on 8/6/18 revealed the CC assessment was not included. 2. Record review on 8/6/18 of competency documentation for 2016 and 2017 revealed assessment based on regulatory responsibilities for the GS and CC was not available. 3. Staff interview with the laboratory technical supervisor on 8/6/18 at 10:00 AM confirmed the above findings.

**D5405**

**PROCEDURE MANUAL**

CFR(s): 493.1251(c)

Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory.

This STANDARD is not met as evidenced by:

Based on record review and staff interview the laboratory failed to provide a complete standard operating procedure (SOP) manual in the specialties of chemistry, hematology and microbiology. Findings include: 1. Record review of the laboratory's SOP manuals on 8/6/18 revealed: a) Laboratory specific SOP indicating step-by-step procedures in the pre-analytic, analytic and post-analytic phases of testing was not available. b) Operator manuals provided by the instrument manufacturers in lieu of laboratory specific SOP were in use. c) Information of the laboratory's calibrator and control materials and acceptable limits was not included. d) Information for maintenance frequency, specimen requirements, stability limits and storage was not included. 2. Staff interview with the technical supervisor on 8/6/18 at 2:30 PM confirmed the SOP manuals are incomplete in the specialties of chemistry, hematology and microbiology. 3. The laboratory performs 618,635 tests annually.

**D5407**

**PROCEDURE MANUAL**

CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to ensure an approved laboratory procedure was in place prior to performing potassium hydroxide (KOH) testing. Findings include: 1. Record review of the 'Procedure for KOH' on 8/6/18 revealed the procedure was not signed and approved by the laboratory director. 2. Staff interview with the laboratory manager on 8/6/18 at 11:20 AM confirmed the above findings.

**D5433**

**MAINTENANCE AND FUNCTION CHECKS**

CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to establish policies and procedures for maintenance and function checks on microscopes in the specialty of microbiology. Findings include: 1. Record review of the dermatology procedure manual on 8/6/18 revealed a microscope maintenance procedure was not available. 2. Record review of the 2016, 2017 and 2018 microscope maintenance on 8/6/18 revealed the following: a) 4 of 4 microscopes are utilized in the dermatology department. b) Function check documentation for the above microscopes was not available. c) Preventative maintenance records for the above microscopes was not available. 3. Staff interview with testing personnel #1 on 8/6/18 at 11:10 AM confirmed the above findings.

**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 record review and staff interview, the laboratory director failed to ensure new testing personnel (TP) received appropriate training to perform moderate complexity testing prior to reporting patient test results. Findings include: 1. Record review of 2016 and 2017 TP files on 8/6/18 revealed the training documentation for 2 of 2 new TP was not available. 2. Staff interview with the laboratory manager on 8/6/18 at 10:00 AM confirmed the above findings. 3. The laboratory performs approximately 421,828 chemistry, 191,679 hematology, 7,510 diagnostic immunology and 5,128 microbiology tests annually.

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(9)

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.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to evaluate the competency of testing personnel (TP) to perform moderate complexity testing annually. Findings include: 1. Record review of the 2017 TP competency records on 8/6/18 revealed documentation for 1 of 5 TP performing testing in hematology and chemistry was not available. 2. Staff interview with the technical supervisor on 8/6/18 at 10:00 AM confirmed the above findings. 3. Record review of the 2016 and 2017 competency records on 8/6/18 revealed documentation for 4 of 4 TP that perform potassium hydroxide (KOH) preparations was not available. 4. Staff interview with the laboratory manager on 8/6/18 at 11:20 AM confirmed the above findings. 3. Laboratory performs 626,145 moderate complexity tests annually.