

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2173822	(X3) Date Survey Completed 12/14/2021
Name of Provider or Supplier Premier Ankle And Foot Specialists Pc	Street Address, City, State 2410 South Queen Street, York, PA	
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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <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.</p> <p>This CONDITION is not met as evidenced by: Based on review of the laboratory records and interview with the laboratory's testing personnel, the laboratory failed to enroll in a proficiency testing (PT) program approved by HHS, for Bacteriology and Mycology tests in 2020 and 2021. Refer to Dtag: D6088</p>
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 lack of documentation and interview with Testing Personnel (TP) #1, the laboratory failed to follow their policy to assess the competency of 1 of 2 General Supervisor (GS) from 1/14/2019 to the day of survey. Findings include: 1. On</p>

the day of survey, 12/14/2021, the TP#1 could not provide a competency assessment records for 1 of 2 GS (CMS 209 Employee #4). 2. The TP#2 confirmed the finding above on 05/05/2021 around 12:20 p.m.

D6088

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)

The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:

Based on review of the laboratory records and interview with the laboratory's testing personnel, the laboratory director failed to ensure that the laboratory was enrolled in a proficiency testing (PT) program that is approved by HHS, for Bacteriology and Mycology testing performed from January 29, 2020 to the day of survey. Finding include: 1. On the day of survey 12/14/2021 at 08:40 a.m. review of the laboratory records revealed that the laboratory was not enrolled in an approved PT program for bacterial and fungal identification from 01/29/2020 to 12/14/2021. 2. No documented proof of PT enrollment was available at the time of inspection. Interview with the laboratory's testing personnel at the time of inspection confirmed that the laboratory did not enroll in an approved PT program for the Bacterial and fungal identification 3. According to the laboratory's annual volume (on CMS 116 form) a total of 10,000 patients were tested annually from 2020 through the day of survey. 4. The Testing Personnel confirmed the findings above on 12/14/2021 at 12:00 p.m.

D6121

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(8)(i)

The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.

This STANDARD is not met as evidenced by:

Based on review of competency assessment records and interview with the testing personnel (TP), the technical supervisor (TS) failed to perform direct observation of routine patient testing, specimen handling and processing for 1 of 2 testing personnel (TP) who performed bacterial and fungal identification by polymerase chain reaction (PCR) from 12/14/2019 to the day of survey. Findings Include: 1. On the day of survey, 12/14/2021 at 11:00 a.m., review of 1 of 2 TP competency assessment records indicated "direct observation through zoom" on 12/15/2020 and 12/09/2021. 2. Interview with the testing personnel revealed that the TS have not being on site to perform direct observations neither was there a zoom observation as stated on the competency assessment form. 3. The testing personnel confirmed the findings above on 12/14/2021 around 11:15 a.m. * Please note: Virtual observations are unacceptable.

D6122

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(8)(ii)

The procedures for evaluation of the competency of the staff must include, but are not limited to monitoring the recording and reporting of test results.

This STANDARD is not met as evidenced by:

Based on review of competency assessment records and interview with the testing personnel (TP), the technical supervisor (TS) failed to perform direct observation of performance of instrument maintenance and function checks for 1 of 2 testing personnel (TP) who performed bacterial and fungal identification by polymerase chain reaction (PCR) in the Thermofisher QuantStudios analyzer from 12/14/2019 to the day of survey. Findings Include: 1. 1. On the day of survey, 12/14/2021 at 11:00 a.m., review of 1 of 2 TP competency assessment records indicated "direct observation through zoom" on 12/15/2020 and 12/09/2021. 2. Interview with the testing personnel revealed that the TS have not being on site to perform direct observations neither was there a zoom observation as stated on the competency assessment form. 3. The testing personnel confirmed the findings above on 12/14/2021 around 11:15 a.m. * Please note: Virtual observations are unacceptable.