

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  07D0697008	<b>(X3) Date Survey Completed</b>  09/03/2019
<b>Name of Provider or Supplier</b>  Prohealth Physicians Pc	<b>Street Address, City, State</b>  141 Willard Ave, Newington, 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>D2000</b>	<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 record review and staff interview the laboratory failed to enroll in proficiency testing (PT) for all specialties in which testing is performed. Findings include: 1. Record review of the laboratory test menu on 9/3/19 revealed the laboratory performs moderate complexity throat cultures in the subspecialty of bacteriology. 2. Record review of the Centers for Medicare and Medicaid Services (CMS) CASPER Report 0155D on 9/3/19 revealed no score for 2018 Events 1 and 2 for the analyte 005 Bacteriology. 3. Record review of the laboratory's College of American Pathologists (CAP) proficiency testing records on 9/3/19 revealed the laboratory did not have PT records for 2018 events 1 and 2. 4. Staff interview with the laboratory director (LD) on 9/3/19 at 10:30 AM confirmed the above findings. The LD stated he/she took over the position and thought the laboratory was enrolled. The LD also stated when he/she found out the laboratory was not enrolled, PT Events 1 and 2 had already been missed.</p>
<b>D2006</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p>

The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, testing personnel (TP) did not test proficiency testing (PT) samples in the same manner as patient samples. Findings include: 1. Record review of the laboratory's PT records for throat culture and urine culture from the College of American Pathologists (CAP) on 9/3/19 revealed the laboratory director (LD) reviewed all the plates read by TP for 2018 Event 3 before the due date. 2. Staff interview with the LD on 9/3/19 at 11:00 AM confirmed the above findings. The LD stated he/she does not routinely review patient test results. This is a repeat deficiency.

**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 record review and staff interview, the laboratory failed to have a policy in place to assess the competency of all laboratory personnel. Findings include: 1. Review of the laboratory's competency records on 9/3/19 revealed: a. The laboratory did not have policy in place to assess the competency of the technical consultant (TC) or clinical consultant based on their CLIA responsibilities. b. The laboratory failed to assess the competency of the TC and the CC. 2. Staff interview with the laboratory director (LD) on 9/3/19 at 9:10 AM confirmed the laboratory did not have a policy in place to assess the competency of the above laboratory personnel and they were not assessed. The LD stated he/she was unaware that this is a regulatory requirement.

**D5391**

**PREANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to establish written quality assessment policies and procedures in the specialty of microbiology to assess preanalytic systems. Findings include: 1. Record review of the laboratory procedure manual on 9/3/19 revealed the laboratory failed to provide evidence of quality assessment policies to monitor, assess and if necessary correct problems involving

	<p>preanalytic systems. 2. Staff interview with the laboratory director on 9/3/19 at 11:00 AM confirmed the above finding.</p>
<p><b>D5791</b></p>	<p><b>ANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1289(a)(c)</p> <p>(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to establish written quality assessment policies and procedures in the specialty of microbiology to assess problems in analytic systems. Findings include: 1. Record review of the laboratory procedure manual on 9/3/19 revealed the manual did not contain a quality assessment policy to monitor, assess and if necessary correct situations involving analytic systems. 2. Staff interview with the laboratory director on 9/3/19 at 11:00 AM confirmed the above finding.</p>
<p><b>D5891</b></p>	<p><b>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1299(a)</p> <p>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 postanalytic systems specified in 493.1291.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to establish written quality assessment policies and procedures in the specialty of microbiology to assess postanalytic systems. Findings include: 1. Record review of the laboratory procedure manual on 9/3/19 revealed the laboratory failed to provide evidence of a quality assessment policies to monitor, assess and if necessary correct situations involving postanalytic systems. 2. Staff interview with the laboratory director on 9/3/19 at 11:00 AM confirmed the above finding.</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 observation, record review and staff interview, the laboratory director (LD) failed to provide overall management and direction in accordance with 493.1407. The cumulative effect of this lack of oversight resulted in the laboratory director's inability to ensure accuracy and reliability of patient test results in the specialty of microbiology. 1. The LD failed to ensure the competency of all laboratory personnel and failed to ensure all testing personnel (TP) are evaluated on all test</p>

platforms and test complexities annually to ensure competency to perform and report accurate test results in the specialty of microbiology. Refer to D6014 and D6029. 2. The LD failed to ensure the laboratory was enrolled in a proficiency testing (PT) program for all regulated analytes. Refer to D6015. 3. The LD failed to ensure PT samples are tested as required. Refer to D6016. 4. The LD failed to ensure quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. Refer to D6021.

**D6014**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(3)(iii)

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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:  
Based on record review and staff interview, the laboratory director failed to ensure all testing personnel (TP) are evaluated on all test platforms and test complexities annually to ensure competency to perform and report accurate test results in the specialty of microbiology. Refer to D6054.

**D6015**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)

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.

This STANDARD is not met as evidenced by:  
Based on record review and staff interview, the laboratory failed to enroll in a proficiency program for the subspecialty of bacteriology. Refer to D2000.

**D6016**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(i)

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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

	<p>Based on record review and staff interview, testing personnel (TP) did not test proficiency testing (PT) samples in the same manner as patient samples. Refer to D2006.</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 record review and staff interview, the laboratory failed to establish a quality assurance program to monitor and correct problems in preanalytical, analytical and post analytical laboratory testing. Refer to D5391, D5791 and D 5891.</p>
<p><b>D6029</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(11)</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)(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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director failed to ensure all testing personnel are evaluated on all test platforms and test complexities annually to ensure competency to perform and report accurate test results in the specialty of microbiology. Refer to D6054.</p>
<p><b>D6054</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> 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 record review and staff interview, the technical consultant (TC) failed to evaluate all testing personnel (TP) on all test platforms and test complexities annually to ensure competency to perform and report accurate test results in the specialty of microbiology. Findings include: 1. Record review on 9/3/19 of the laboratory's 2017, 2018 and 2019 competency records revealed: a. The laboratory failed to evaluate 1 of</p>

7 TP in 2017 and 1 of 5 TP in 2018 for any moderate complexity testing. b. The laboratory failed to evaluate 7 of 7 TP in 2017 and 5 of 5 TP in 2018 for mycology testing with dermatophyte test media. c. The laboratory failed to evaluate TP for high complexity testing. 2. Record review on 9/3/19 of the laboratory's 2017 CMS 209 form revealed the laboratory employed 7 moderate complexity TP in 2017. 3. Record review on 9/3/19 of the laboratory's 2019 CMS 209 form revealed the laboratory employed 5 moderate complexity TP in 2018. 4. Record review on 9/3/19 of the laboratory's 2018 Event 3, and 2019 Event 1 College of American Pathologists (CAP) proficiency testing (PT) records revealed the laboratory reported the organism gram stain characteristics in addition to the colony count. This changes the test complexity to high complexity. 5. Record review on 9/3/19 of a final patient test report revealed the laboratory reported the organism gram stain characteristics in addition to the colony count. 6. Staff interview with LD who is also the TC on 9/3/19 at 10:00 AM confirmed the above findings. The LD stated the gram stain characteristics can be determined according to the media the organism grows on and he/she was unaware that reporting more than the colony count constituted a change in complexity from moderate to high. The LD further stated he/she was not sure how to do the evaluation if the LD is also a TP.

**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 record review and staff interview, the laboratory director (LD) failed to provide overall management and direction in accordance with 493.1445. 1. The LD failed to meet the qualifications to direct and oversee high complexity testing in the specialty of microbiology. Refer to D6078

**D6078**

**LABORATORY DIRECTOR QUALIFICATIONS**

CFR(s): 493.1443

The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical

laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to employ a laboratory director (LD) who meets the qualifications to direct and oversee high complexity testing in the specialty of microbiology. Findings include: 1. Record review of the LD qualifications on 9/3/19 revealed the LD is a doctor of medicine, but failed to have at least 2 years of experience directing or supervising high complexity testing. 2. Record review on 9/3/19 of the laboratory's 2018 Event 3, and 2019 Event 1 College of American Pathologists (CAP) proficiency testing (PT) records revealed the laboratory reported the organism gram stain characteristics in addition to the colony count. 3. Record review on 9/3/19 of a final patient test report revealed the laboratory reported the organism gram stain characteristics in addition to the colony count. 4. Staff interview with LD on 9/3/19 at 10:00 AM confirmed the laboratory was performing high complexity testing in the specialty of microbiology. The LD stated the gram stain characteristics can be determined according to the media the organism grows on. The LD further stated he/she was unaware that reporting more than the colony count constituted a change in complexity from moderate to high.