

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0097391	(X3) Date Survey Completed 06/28/2018
Name of Provider or Supplier Prohealth Physicians	Street Address, City, State 682 E Main St, Branford, CT	
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
D5477	<p>CONTROL PROCEDURES 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 record review and staff interview, the laboratory failed to check each lot number and shipment of media for its ability to support growth and, as appropriate, select or inhibit specific organisms in the subspecialty of bacteriology. Findings include: 1. Review of the quality control records for BBL Group A Select SB (SSA) on 6/28/18 revealed the laboratory failed to document the ability of the media to support growth, select or inhibit specific organisms for each lot number and shipment. Specifically, 27 of 27 shipments between 8/26/16 and 6/28/18. 2. Staff interview with the testing personnel #1 (TP1) on 6/28/18 at 9:25 AM confirmed the above findings. TP1 stated the laboratory only documented the physical condition of the media when received. 3. The laboratory performs 700 throat cultures annually in the subspecialty of bacteriology.</p>
D6015	<p>LABORATORY DIRECTOR RESPONSIBILITIES 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</p>

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. Findings include: 1. Record review of the laboratory test menu on 6/28/18 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 6/28/18 revealed no score for 2018 Event 1 for the analyte 005 Bacteriology. 3. Record review of the College of American Pathologists (CAP) proficiency testing records on 06/28/18 revealed 2018 Event 1 records were not available. 4. Record review of the CAP order form on 6/28/18 revealed the laboratory sent in the order and payment on 4/20/18. 5. Staff interview with testing personnel #1 (TP1) on 6/28/18 at 11:00 AM confirmed the above findings. TP1 stated the facility never sent in the order form/payment for 2018 enrollment and it was not noticed until April. 6. The laboratory has performed 399 throat cultures to date in 2018.

D6053

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 semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to assess and document new testing personnel competency to perform throat cultures in the subspecialty of bacteriology twice in the first year of performing patient testing. Findings include: 1. Record review of the CMS Laboratory Personnel Report 209 form on 6/28/18 revealed 2 new testing personnel since the last survey. 2. Record review of hiring records on 6/28/18 revealed the 2 new testing personnel were hired November 2016 and January 2017. 3. Record review of the testing personnel competency records on 6/28/18 revealed semiannual assessments for 2 of 2 new testing personnel were not available. 4. Staff interview with testing personnel #1 on 6/28/18 at 10:35 AM confirmed the above findings. TP1 stated competency assessment is ongoing but no documentation was available.

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 document annual competency of testing personnel to assess the knowledge and skills necessary to perform moderate complexity laboratory testing. Findings include: 1. Record review

of testing personnel competency records on 6/28/18 revealed annual competency documentation for 10 of 10 testing personnel performing throat cultures was not available for 2017. 2. Staff interview with testing personnel #1 (TP1) on 6/28/18 at 10:35 AM confirmed the above findings. TP1 stated competency assessment is ongoing but no documentation was available. 3. The laboratory performs 700 throat cultures annually in the subspecialty of bacteriology.