

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0233859	(X3) Date Survey Completed 09/05/2018
Name of Provider or Supplier Pro Lab, Llc	Street Address, City, State 10401teays Valley Road Ste 1b, Scott Depot, WV	
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
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with Laboratory Manager (LM), the laboratory did not participate successfully in the 1st event 2017 Chemistry Core Findings include: 1. The Chemistry Core proficiency testing first event of 2017 which includes all routine chemistry analytes performed by the laboratory received a zero score for non-participation. 2. Refer to details outlined in D2089 of this report which supports this mandatory deficiency of non-participation for the Chemistry core 1st event 2017 3. On Sept 5, 2018 at 2PM, the LM did agree that the laboratory did not submit the testing scores by the due date. However, they did do an internal evaluation.</p>

D2089

ROUTINE CHEMISTRY

CFR(s): 493.841(c)

Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:

Based on review of Chemistry proficiency testing (PT), the laboratory failed to participate in the Routine Chemistry proficiency testing event for 2017. Findings include: 1. The American Proficiency testing institute (API) PT score report showed the laboratory received a zero score for all routine chemistry analytes for the 1st event 2017. 2. Laboratory proficiency testing evaluation for the Chemistry 1st event 2017 showed documentation stating " I was very late in submitting results for this survey" 3. The PT score report showed the laboratory received a score of zero because no results were received by the due date. 4. There was no director or testing personnel signature on the attestation statement.

D2094

ROUTINE CHEMISTRY

CFR(s): 493.841(e)

(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

This STANDARD is not met as evidenced by:

Based on review of chemistry proficiency testing records and interview with Laboratory Manager (LM) and Testing Personnel #2, the laboratory did not document evaluation of unacceptable analytes scores (less than 100% score). Findings include: 1. The Chemistry Core PT survey 2nd event of 2017 had a LDL Cholesterol score of 80% with no documentation of evaluation. 2. The Chemistry Core PT survey 1st event of 2017 had a Phosphorus score of 80% with no documentation of evaluation. 3. The Chemistry core PT survey 2nd event of 2018 had a LDL Cholesterol score of 80% with no documentation of evaluation. 4. On 9/5/18 at approximately 2PM, the LM and TP2 stated they thought 80% scores were successful and the unacceptable analyte did not need an evaluation.

D5213

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(b)(1)

The laboratory must verify the accuracy of any analyte or subspecialty without

analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.

This STANDARD is not met as evidenced by:

Based on review of Hematology Proficiency Testing records and interview with Laboratory Manager (LM), the laboratory did not evaluate all results that are not scored by the Proficiency testing Program. Findings include: 1. The 2017/2018 Hematology/ Coagulation Proficiency Testing events had no evaluation for a non-graded blood cell ID. 2. On September 5, 2018 at approximately 2:30PM, the LM did not know the Differential PT cell ID for the non-graded scores were not documented.

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 review of laboratory procedure manual and interview with the LM, the current laboratory director had not signed and dated the laboratory procedure manual. Findings include: 1. The Dunbar Medical Associates Procedure Manual cover sheet was signed by the former laboratory director in 2011. It was not signed by the current laboratory director. 2. On 9/5/18 at approximately 1:30 PM, the LM agreed that the procedure manual was not signed by the current laboratory director.

D5437

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based on record review, interview with LM and direct observation, the laboratory did not ensure that temperature thermometers were calibrated. Findings include: 1. The laboratory was monitoring refrigerator temperatures to maintain the integrity of reagents. Certificate of Calibration documentation for the Fisher Scientific Refrigerator thermometer had a calibration due date of 5/19/18. 2 The laboratory was monitoring humidity and room temperature daily. The Control Company thermometer which monitored room temperature and humidity had a calibration due date of 10/7 /13. 3. The LM stated she did not realize that thermometer calibrations expired.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

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.

This STANDARD is not met as evidenced by:

Based on review of Quality Assessment records and interview with Laboratory Manager (LM), the laboratory director did not ensure the Quality Assessment program had been reviewed consistently by the Laboratory Director or qualified staff. Findings include: 1. The 2017 and 2018 QA Checklists review were recorded monthly but the evidence of director review and/or technical consultant review was inconsistent. 2. For 2017 and 2018, approximately 1/3 of QA Checklists were reviewed by the Laboratory Manager (LM) only who did not meet the qualifications for Technical consultant. Some months the QA checklists were signed by TP2 who did qualify for the technical consultant. But, the responsibility was not delegated in writing by the director or assigned as part of TP2 job description. 3. On 9/5/18 at approximately 11:30 AM, the LM agreed there was inconsistency of director review due to the transition of the retiring director to the new director.

D6032

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(14)

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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of personnel records and interview with Laboratory manager (LM) , the laboratory director did not specify in writing all duties and responsibilities of personnel who are performing technical consultant duties. Findings include: 1. Testing personnel #2 (TP2) was fulfilling the functions as the technical consultant as evidenced by the signature on the Monthly QA checklist and Personnel Competency Assessment for Testing Personnel (TP1/LM). 2. The functional job description of TP2 did not specify the duties and responsibilities of the technical consultant or the delegation of duties by the laboratory director. The functional job description described testing personnel duties only. 3. On 9/5/18 at approximately 9:30 AM, the LM stated TP2 functional job description did not contain technical consultant duties. TP2 was reviewing and signing documents for competency and QA because TP2 met the qualification of the Technical consultant. This practice began after the 2016 CLIA survey at the Direction of the previous laboratory surveyor. However, TP2 functional

job description was not updated to include TC duties or had the duties delegated in writing by the laboratory director