

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D0997516	(X3) Date Survey Completed 08/05/2019
Name of Provider or Supplier John A Murphy Md Pc	Street Address, City, State 2450 Ne Maryrose Pl, Ste 220, Bend, OR	
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
D2003	<p>ENROLLMENT CFR(s): 493.801(a)(2)(ii)</p> <p>For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1)</p> <p>This STANDARD is not met as evidenced by: Based on review of Proficiency Testing records and discussions with the staff the laboratory failed to establish and maintain accuracy of the BD Affirm VPIII test system. Findings include: 1. The laboratory was not enrolled in a Proficiency Testing program for the BD Affirm VPIII test system or did not have an established written plan to verify and maintain accuracy of the testing procedure biannually for the BD Affirm VPIII test system. 2. The laboratory director and lead testing personnel confirmed these findings on 08/05/2019 at 15:00 PM.</p>
D5447	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of Quality control records and discussions with the staff the laboratory failed to perform 2 level of controls each day of patient testing for the BD Affirm VPIII test system. Findings include: 1. Review of quality control(QC) records</p>

	<p>showed the trivalent positive and negative quality control for the BD Affirm VPIII were performed on 03/22/2019 and 08/01/2019. 2. The laboratory testing personnel stated that " the trivalent positive and negative controls were done everytime they open a new kit of BD Affirm VPIII as recommended by the manufacturer's package insert". 3. The laboratory did not have an Individualized Quality Control Plan (IQCP) developed for the BD Affirm VPIII, that would allow them follow manufacture's package inserts recommendation for QC frequency. 4. The laboratory director and lead testing personnel confirmed these findings 08/05/2019 @ 15:00PM.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR 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 review of personnel, training and competency records the laboratory director failed to provide overall management and direction of the laboratory. Refer to D6029 and D6030.</p>
<p>D6029</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES 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 review of personnel and training records and discussions with the staff the Laboratory Director failed to ensure that prior to patient testing the laboratory testing personnels have the proper education and training documentations. Findings include. 1. 3 out of 3 testing personnel performing the BD Affirm VPIII moderately complex test system did not have copies of diploma or transcript of records at the time of survey. 2. 1 out of 3 testing personnel hired 06/25/2019 did not have her initial training record at the time of survey. 3. The laboratory director and the lead testing personnel confirmed these findings on 08/05/2019 at 15:00 PM.</p>
<p>D6030</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</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)(12) Ensure that policies and procedures are established for</p>

monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on review of competency records, laboratory policies and procedures the Laboratory Director who also served as the Technical Consultant failed to assess and provide documentation of competencies for the testing personnels. Findings include:

1. Review of laboratory's policy and procedure revealed that the laboratory did not have a written policy to make sure that testing personnel were assessed competency prior to performing patient testing for the moderate complex BD Affirm VPIII test system usually within six months and annually thereafter.
- 2.. 3 out of 3 testing pesonnel, hire dates 11/2017, 02/2019 and 06/25/2019 that were performing moderately complex BD Affirm VPIII test system did not have any of their competency assessment documentations at the time of survey.
3. The laboratory director and the lead testing personnel confirmed these findings on 08/05/2019 at 15:00PM.