

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 39D2070065	<b>(X3) Date Survey Completed</b> 02/22/2018
<b>Name of Provider or Supplier</b> Allegheny Vein & Vascular	<b>Street Address, City, State</b> 900 Chestnut Street Suite A, Bradford, PA	
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>D6032</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(14)</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)(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.</p> <p>This STANDARD is not met as evidenced by: Based on, the review of the laboratory's personnel records and interview with Testing Personnel (TP) #2, the Laboratory Director (LD) failed to specify, in writing the duties and responsibilities of each person involved in patient testing. Findings include: 1. On the date of survey 02/22/2018, the laboratory could not provide documentation of responsibilities of each person involved in patient testing. 2. On the CLIA 209 Laboratory Personnel Report Form, their are: -1 of individual qualified as the LD, clinical consultant, technical consultant and testing personnel. -3 of 3 individual qualified as TP. 2. TP #2 confirmed the findings above on 02/22/2018 around 12:30 PM.</p>
<b>D6046</b>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform</p>

test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of competency assessment records and interview with Testing personnel (TP) #2. The Technical consultant (TC) (Laboratory Director) failed to evaluate the competency of all TP as required from 2016 and 2017. Findings Include: 1. At the date of survey, 02/22/2018, competency assessment records reviewed, revealed that testing personnel #2 who was not listed as the TC lead the competency training, and 3 of 3 testing personnel documents were not signed by the designated TC (laboratory director) on the CMS 209 laboratory personnel form. 2. TP #2 confirmed the findings above on 02/22/2018 around 12:45 PM.

**D6051**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:

Based on, the review of proficiency testing records and interview with Testing personnel (TP) #1 and #2, the Technical Consultant failed to evaluate the assessment of 2 of 3 testing personnel through external proficiency testing samples or internal blind testing samples from 2016 to the date of survey. Findings Include: 1. On the date of survey, 02/22/2018, review of proficiency testing attestation forms, revealed 1 of 3 testing personnel performed in the American Proficiency Institute (API) proficiency testing for Event 1, 2 and 3 for 2016 and 2017. 2. TP#2 confirmed the finds above on 02/22/2018 around 01:00 PM