

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D1011922	(X3) Date Survey Completed 06/25/2019
Name of Provider or Supplier Vitaly Fishbein Md	Street Address, City, State 401 Pleasant Valley Way, West Orange, NJ	
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
D6102	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)</p> <p>The laboratory director must 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 surveyor review of Personnel Records (PR) and interview with the Office Manager (OM), the Laboratory Director failed to ensure that education records for one of one testing tersonnel were available from February 2018 to the date of a the survey. The OM confirmed on 6/25/19 at 10:00 am that the education record was not available.</p>
D6103	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)</p> <p>The laboratory director must ensure that policies and procedures are established for 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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Office Manger (OM), the Laboratory Director failed to establish a Competency</p>

Assessment (CA) procedure with the applicable elements for testing personnel who perform Allergy testing from February 2018 to the date of survey. The OM confirmed on 6/25/19 at 10:30 am that a CA procedure was not established.