

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0706848	(X3) Date Survey Completed 10/31/2018
Name of Provider or Supplier Mark Adelman Md Pa	Street Address, City, State 9980 Central Park Blvd N Ste 322, Boca Raton, FL	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with Testing Personnel (TP) # A, the laboratory failed to perform the annual competency assessment on 2 out of 2 testing personnel since at least 2017. Findings include: Review of employee documentation found no competency evaluations on testing person #A and #B for the years 2017 to 2018. During an interview on 10/31/2018 at 10:30 AM, with the TP#A, she confirmed that there were no competencies performed on the employees listed above for the years of reference.</p>
D5293	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of quality assurance policy and laboratory records from 2016 to 2018 and interview with Testing Personnel (TP) #A revealed that the laboratory failed to document the quality assurance (QA) activity during the years 2016, 2017 and 2018.</p>

	<p>Findings include: Review of quality control records revealed that there was no documentation of the QA activity during the years 2016 to 2018. During an interview on 10/31/2018 at 10:30 AM, with the TP#A, she confirmed that there were no records of QA activity for the years of reference.</p>
<p>D5537</p>	<p>ROUTINE CHEMISTRY CFR(s): 493.1267(b)(d)</p> <p>For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Quality control (QC) records for the IRMA True Point Arterial Blood Gas (ABG) analyzer and interview with Testing personnel (TP) # A, the laboratory failed to perform external quality control once in a month as per their Individualized Quality Control Plan (IQCP) for pH, pO₂ and pCo₂ tests for 1 out of 26 months reviewed. Findings include: Review of QC documentation for ABG testing showed that no external controls tested on July 2018 as per their IQCP, during this month 41 patients were tested. During and Interview on 10/31/2018 at 11.30 am, the TP#A confirmed that the laboratory failed to test external controls on July 2018.</p>
<p>D6021</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on review of quality assurance policy and laboratory records from 2016 to 2018 and interview with Testing Personnel (TP) #A revealed that the laboratory director failed to document the quality assurance (QA) activity during the years 2016, 2017 and 2018. Findings include: Review of quality control records revealed that there was no documentation of the QA activity during the years 2016 to 2018. During an interview on 10/31/2018 at 10:30 AM, with the TP#A, she confirmed that there were no records of QA activity for the years of reference. Refer to 5293</p>