

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2141562	(X3) Date Survey Completed 04/11/2018
Name of Provider or Supplier Healthgains	Street Address, City, State 2920 Ne 207th St Suite 901, Aventura, 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
D5391	<p>PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242.</p> <p>This STANDARD is not met as evidenced by: Based on the observation, record review and interview with the testing person it was determined that laboratory failed to have the same collection date on laboratory computer printed log and the send out requisition form. Findings included: Observation on April 11, 2018 revealed that laboratory computer printed log had a date of 4/10/18, while the Lab Corp send out requisition form had the collection date as 4/11/18 for patient #2. During the interview on April 11, 2018 at 11:30AM, testing person confirmed that laboratory computer printed log had a blood collection date of 4/10/18, while the Lab Corp send out requisition form had the collection date as 4/11/18. Also, there was no documentation for corrective action for if there were any errors.</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the director of operations, laboratory failed to sign and date the procedure manual for testosterone testing. Findings included: Record review on April 11 at 11:45 AM showed that the laboratory director</p>

did not sign and date the policy and procedure manual. During an interview at 12:00PM, the director of the operations confirmed that the laboratory director had not signed and dated the policy and procedure manual for testosterone testing.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

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.

This CONDITION is not met as evidenced by:
Based on record review, the laboratory did not have a director at the time of the initial laboratory inspection for endocrinology specialty. The findings include: During the initial laboratory inspection for endocrinology specialty on May 11, 2018 at 12:00PM, the laboratory did not have a laboratory Director as evidenced by Lack of Director signature on required forms AHCA-3170, Form CMS-209, and Form CMS-116. During an interview on 4/11/18 at 12:00 PM, the director of operations was asked about the Lab Director however, no explanation was provided and forms AHCA-3170, Form CMS-209, and Form CMS-116 did not contain the Laboratory director signature.