

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0958535	(X3) Date Survey Completed 03/28/2018
Name of Provider or Supplier Baymeadows Healthcare	Street Address, City, State 10058 Baymeadows Rd, Jacksonville, 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
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 record review and staff interview, the laboratory failed to enroll in a proficiency testing program for the requested addition of specialty of Bacteriology. The findings include: The review of proficiency testing records for the requested addition of Neisseria Gonorrhoeae testing and Chlamydia testing on the GeneXpert instrument showed the laboratory had not established means to verify accuracy of its testing procedures by enrolling in a proficiency testing program. The interview on 3/28 /18 at 12:00pm confirmed the laboratory had not enrolled in proficiency testing because they thought the analytes were waived.</p>
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Based on record review and laboratory staff interview, the laboratory did not test proficiency test samples the same number of times it tests patient samples for 3 of 9 testing events reviewed for 2017. The findings include: A review of the laboratory's American Proficiency Institute (API) records showed the following: 1. The 2017 1st event for Hematology samples HEM-01, HEM-02, HEM-03, HEM-04, HEM-05 were</p>

tested multiple times. HEM-01: 3/16/18 at 10:37, 10:40, 11:25, and 11:27 HEM-02: 3/16/18 at 10:44, 10:46, 11:29, and 11:31 HEM-03: 3/16/18 at 10:49, 10:51, 11:33, and 11:35 HEM-04: 3/16/18 at 10:54, 10:56, 11:37, and 11:39 HEM-05: 3/16/18 at 10:58, 11:01, 11:40, and 11:43 The tests performed were: White Cell Count, Red Cell Count, Hemoglobin, Hematocrit, Platelet Count, Mean corpuscular volume (MCV), Red cell distribution width (RDW), Neutrophils, Lymphocytes, Monocytes, Eosinophils, and Basophils. 2. The 2017 1st event for Chemistry samples CH-1, CH-2, CH-3, CH-4, CH-5 were tested multiple dates and times. CH-1: 1/24/17 at 12:50 and 1/26/17 at 11:51 CH-2: 1/24/17 at 12:56 and 1/26/17 at 12:08 CH-3: 1/25/17 at 12:59 and 1/26/17 at 12:09 CH-4: 1/24/17 at 13:01 and 1/26/17 at 12:10 CH-5: 1/24/17 at 13:03 and 1/26/17 at 12:10 3. The 2017 3rd event for Chemistry Samples CH-11, CH-12, CH-13, CH-14, CH-15 were tested multiple dates and times. CH-11: 8/29/17 at 17:23 and 8/30/17 at 10:54 CH-12: 8/29/17 at 17:27 and 8/30/17 at 10:57 CH-13: 8/29/17 at 17:30 and 8/30/17 at 10:58 CH-14: 8/29/17 at 17:32 and 8/30/17 at 11:00 CH-15: 8/29/17 at 17:34 and 8/30/17 at 11:01 The tests performed were: Calcium, Albumin, Alkaline phosphatase, Aspartate transaminase, Direct bilirubin, Magnesium, Total bilirubin, Amylase, Glucose, Alanine transaminase, Total protein, Blood urea nitrogen, Creatinine, Gamma-glutamyl transferase, Creatine kinase, Uric acid, Potassium, Sodium, Chloride, Carbon dioxide, Triglycerides, Cholesterol, Thyroxine, Free Thyroxine, Thyroid Stimulating Hormone, and Free T3. The interview on 3/28/18 at 9:40am with the testing person confirmed samples were not tested the same number of times patient samples are tested.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES
CFR(s): 493.1235

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.

This STANDARD is not met as evidenced by:
Based on record review and interview with staff, the laboratory had not performed annual competency assessments on staff. The finding include: On 3/28/18, the laboratory lead testing person was asked to provide copies of the competency assessment for the testing personnel. The testing person acknowledged at 12:30pm that he was not able to provide the requested records.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals

(normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on review laboratory procedures and staff interview it was determined that the laboratory failed to have written procedures for four additional laboratory processes (Neisseria Gonorrhoeae, Chlamydia, Influenza A and B, and Streptococcus, group A). The findings include: The review of the procedure manual on 3/28/18 showed the laboratory did not have a written procedure that described how patient testing was to be performed, quality control requirements, calibration and calibration verification, corrective action when failures occur, proficiency testing requirements, and how results are entered into patient's test records for the requested addition of testing on the GeneXpert instrument. The 3/28/18 interview with the testing person at 12:00pm confirmed the procedure manual had not been updated to show the addition of Neisseria Gonorrhoeae, Chlamydia, Influenza A & B, and Streptococcus A testing.

D5481

CONTROL PROCEDURES

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review and interview with laboratory staff, the laboratory failed to have quality controls (QC) in acceptable range prior to reporting patient results for 1 of 28 days in February 2018. The findings include: The review of the laboratory QC records on 3/28/18 showed on 2/19/18 "BrimmunoPL1" had a result of "no value" at 8:27pm for the analyte Vitamin B12. Four patients were tested for Vitamin B12 between 9:31pm and 10:55pm. The QC records show a repeat of "BrimmunoPL1" for Vitamin B12 at 11:58pm and the value is in range. The interview on 3/28/18 at 11:47am with the testing person confirmed he had missed repeating the QC before performing patient testing.