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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>45D1000448 | <b>(X3) Date Survey Completed</b><br>01/15/2020 |
| <b>Name of Provider or Supplier</b><br>Ob/Gyn Of Houston, Llp  | <b>Street Address, City, State</b><br>6410 Fannin # 200, Houston, TX   |   |
| 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>   |
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| <b>D0000</b>              | The laboratory was found out of compliance with the CLIA regulations. The conditions not met were: D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director; The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit.   |
| <b>D5311</b>              | <p><b>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL</b><br/>CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on observations, review of the manufacturer's instructions, laboratory policies, and confirmed in interview, the laboratory failed to follow the laboratory policy and ensure testing for the BD Affirm VPIII microbial identification test were performed within 72 hours per the manufacturer's instructions. Findings were: 1. Observations on 1/15/2020 at 1000 hours in the laboratory revealed the laboratory used the BD Affirm VPIII Ambient Temperature Transport System (ATTS) for specimen collection for the BD Affirm VPIII microbial identification test. 2. Review of the package insert for the BD Affirm VPIII microbial identification test (670160JAA (03) 2017-08) under specimen collection and transportation revealed "Specimen collection is a critical step...When using the BD Affirm VPIII Ambient Temperature Transport System (ATTS): The total time between sample collection and proceeding with sample preparation should be no longer than 72 h when the specimen is stored at ambient</p> |

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|                     | <p>conditions (15 to 30 C). The system has also been qualified for transport use at refrigerated conditions (2 to 8 C)." 3. Review of the laboratory procedure BD Affirm VPIII microbial identification test under Specimen Collection, Storage, and Transportation revealed "label the sample collection tube with the patient identification information. Include the time the sample was collected." 4. Observations on 1/15/2020 at 1000 hours in the laboratory revealed 5 of 5 patient specimens with no documentation of the date and time of collection for each specimen. 23076 25551 33010 13237 7916 5. An interview with the office manager on 1/15/2020 at 1140 hours in her office confirmed the above findings. She acknowledged that without the date and time of collection, she was unable to document that the testing were performed within 72 hours per the manufacturer's instructions.</p> |
| <p><b>D5391</b></p> | <p><b>PREANALYTIC SYSTEMS QUALITY ASSESSMENT</b><br/>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:<br/>Based on review of quality assessment reports and interview, the laboratory failed to monitor, assess and correct problems identified in preanalytical systems. Refer to D5311</p>  |
| <p><b>D5400</b></p> | <p><b>ANALYTIC SYSTEMS</b><br/>CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by:<br/>Based on review of laboratory policies, review of quality control records, review of patient final reports, and confirmed in interview, the laboratory failed to monitor and evaluate the overall quality of its analytic systems. Refer to D5413, D5415, D5445</p>                                      |
| <p><b>D5413</b></p> | <p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b><br/>CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p>   |

This STANDARD is not met as evidenced by:  
 Based on review of the manufacturer's instructions, laboratory records, and confirmed in interview, the laboratory failed to document acceptable environmental and instrument conditions for testing with the BD Affirm VPIII Microbial Identification Test per the manufacturer's instructions. Findings were: 1. Review of the package insert for the BD Affirm VPIII microbial identification test (670160JAA (03) 2017-08) under procedure revealed "Verify that the BD MicroProbe Lysis Block is at 85 5 C, and that reagents are at 22-28 C and well mixed." 2. Review of the laboratory patient test records from 09/2019 to 1/2020 revealed no documentation of the lysis block temperature or processing temperature for all 189 patients tested from 09/2019 to 1/2020. Refer to patient alias list. 3. An interview with the office manager on 1/15 /2020 at 1120 hours confirmed the above findings. She acknowledged that the testing person should document the environmental and instrument conditions for each day of patient testing.

**D5415**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
 CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:  
 Based on review of the manufacturer's instructions, observations, and confirmed in interview, the laboratory failed to document the open expiration date for the BD Affirm VPIII test kits stored at room temperature. Findings were: 1. Review of the package insert for the BD Affirm VPIII microbial identification test (670160JAA (03) 2017-08) under storage of reagents revealed "The BD Affirm VPIII test kit is stable until the expiration date indicated on the kit box when stored at 2 to 8 C. Alternatively, store at room temperature (up to 30 C) no more than 3 months." 2. Observations on 1/15/2020 at 1050 hours revealed the following reagent lot numbers of BD Affirm VPIII microbial identification reagent kits stored under the BD Max instrument stored at room temperature. lot 9239410, exp 6/30/2020, labeled with "12 /17/19" lot 9179153, exp 5/12/2020, labeled with "11/4" 3. Review of the above reagents revealed no open expiration date. 4. An interview with the office manager on 1/15/2020 at 1115 hours in her office confirmed the above findings.

**D5445**

**CONTROL PROCEDURES**  
 CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
 Based on review of the laboratory quality control logs, patient test records, and confirmed in interview, the laboratory failed to document the quality control for the BD Affirm VPIII microbial identification per the laboratory INDIVIDUALIZED QUALITY CONTROL PLAN (IQCP). a) new lot numbers b) monthly Findings were:  
 1. Review of the laboratory INDIVIDUALIZED QUALITY CONTROL PLAN (IQCP) records revealed "specimen based quality control samples can be performed in conjunction with the reagent evaluation procedure as long as each new lot and received date of Probe Analysis Cards (PAC) reagent are evaluated prior to use and at least every 31 days. a) new lot numbers 2. Review of the laboratory reagent log revealed the laboratory opened BD Affirm VPIII microbial identification reagent lot 8222964 on 10/11/19. Note: No documentation of the date received was available for the above reagent lot. 3. Observations on 1/15/2020 at 1050 hours revealed the following reagent lot numbers of BD Affirm VPIII microbial identification stored at room temperature. lot 9239410, exp 6/30/2020, labeled with "12/17/19" lot 9179153, exp 5/12/2020, labeled with "11/4" 4. Review of the QC log from 2018-2019 revealed no documentation of the required QC for the new lot of 8222964 opened on 10/11/19. Furthermore, no documentation was available for QC performed for the lot numbers observed in the laboratory lot 9239410, exp 6/30/2020, lot 9179153, exp 5/12/2020. b) monthly 5. Review of the QC log from 2018-2019 revealed no documentation of the required monthly QC for 3 of 12 months: (11/4/19, 12/5/19, or 1/6/2020). 6. Review of the CMS116 revealed the laboratory performed 3000 BD Affirm testing annually. 7. An interview with the laboratory manager on 1/15/2020 at 1120 hours in her office confirmed the above findings.

**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 review of the laboratory records and staff interview, it was revealed the laboratory director failed to provide overall management and direction for the laboratory. The findings were: 1. The laboratory director failed to ensure pre-analytic and analytic systems provided quality results (see D6007). 2. The laboratory director failed to ensure a quality control program was developed and followed to provide quality laboratory services (see D6020).

**D6007**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
 CFR(s): 493.1407(e)(1)

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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's records and staff interview, it was revealed the laboratory director failed to ensure pre-analytic and analytic systems provided quality results. Refer to D5311, D5413, D5415

**D6020**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(5)

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 the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's records, and staff interview, it was revealed the laboratory director failed to ensure a quality control program was developed and followed to provide quality laboratory services. Refer D5445