

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D1000448	<b>(X3) Date Survey Completed</b>  02/10/2022
<b>Name of Provider or Supplier</b>  Ob/Gyn Of Houston, Llp	<b>Street Address, City, State</b>  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>
<b>D0000</b>	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. .
<b>D5445</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(1)(2)(g)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: I. Based on review of the laboratory IQCP (INDIVIDUALIZED QUALITY CONTROL PLAN), quality control and patient test records from 2020 and 2021, and confirmed in interview, the laboratory failed to document quality control in the frequency established by the quality control plan for one of twelve months reviewed for the Vaginal Panel (bacterial vaginosis, Candida species associated with vulvovaginal candidiasis, and Trichomonas vaginalis) PCR testing on the BD MAX. Findings included: 1. Review of the laboratory Quality Control Plan for the IQCP for the BD Max revealed the laboratory will perform external controls with every new lot# /shipment, and every 30 days. 2. Review of the quality control records for the Vaginal Panel for the BD Max from January 2021 to December 2021 revealed the laboratory performed quality control beyond 30 days for one of twelve months reviewed. 5/5/21 6 /8/21 Elapsed time of 33 days 3. Random review of patient testing from 6/6/21 and 6/7</p>

/21 included the following five patients: Patient ID 28217, 156321, 34565, 28679, 19927. 4. An interview with the technical consultant on 2/10/22 at 1220 hours via phone confirmed the above findings. II. Based on review of the laboratory IQCP (INDIVIDUALIZED QUALITY CONTROL PLAN), quality control and patient test records from 2020 and 2021, and confirmed in interview, the laboratory failed to document quality control in the frequency established by the quality control plan for twelve of twelve months reviewed for the Candida species, Gardnerella vaginalis and Trichomonas vaginalis DNA testing on the BD Affirm. Findings included: 1. Review of the laboratory Quality Control Plan for the IQCP for the BD Affirm revealed the laboratory will perform external controls with every new lot#/shipment, and every 30 days. 2. Review of the laboratory records revealed the laboratory used two BD MicroProbe Processors: SN 503004 and SN A564012. 3. Review of the quality control records from January 2021 to December 2021 revealed the laboratory performed quality control for the Candida species, Gardnerella vaginalis and Trichomonas vaginalis DNA testing on the BD Affirm beyond the 30 days per the quality control plan for twelve of twelve months reviewed. SN 503004 1/20/21 - 3/2/21; elapsed time 41 days 3/2/21 - 4/5/21; elapsed time 33 days 4/5/21 - 5/11/21; elapsed time 36 days 5/11/21 - 6/18/21; elapsed time 37 days 6/18/21 - 8/19/21; elapsed time 60 days 8/19/21 - 9/27/21; elapsed time 38 days 9/27/21 - 11/29/21; elapsed time 32 days 11/29/21 - 1/12/22; elapsed time 44 days SN A564012 1/8/21 - 2/19/21; elapsed time 40 days 3/3/21 - 5/5/21; elapsed time 60 days 5/5/21 - 6/11/21; elapsed time 36 days 6/11/21 - 7/19/21; elapsed time 38 days 7/19/21 - 8/27/21; elapsed time 48 days 8/27/21 - 10/27/21; elapsed time 60 days 10/27/21 - 12/29/21; elapsed time 62 days 4. Review of the laboratory annual test volume for the BD Affirm revealed the laboratory performed 5000 tests annually. 5. An interview with the technical consultant on 2/10/22 at 1220 hours via phone confirmed the above findings.

**D5775**

**COMPARISON OF TEST RESULTS**  
CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory and patient test records from 2020 and 2021, and confirmed in interview, the laboratory failed to document twice annually the comparison studies for 3 of 3 tests (Candida species, Gardnerella vaginalis and Trichomonas vaginalis ) analyzed on 2 of 2 BD MicroProbe Processors and the BD Max. Findings included: 1. Review of the laboratory records from 2020 and 2021 revealed the laboratory performed Candida species, Gardnerella vaginalis and Trichomonas vaginalis patient testing using both BD MicroProbe Processors: SN 503004 and SN A564012 and the BD Max. 2. Review of the laboratory records from 2020 and 2021 revealed no documentation of the twice annually comparison of Candida species, Gardnerella vaginalis and Trichomonas vaginalis on both the BD MicroProbe processors and BD Max for 2020 and 2021. 3. Review of the laboratory CMS116 signed by the laboratory director on 2/9/22 revealed the laboratory performed 15000 microbiology tests annually. 4. An interview with the technical consultant on 2/10/22 at 1220 hours via phone confirmed the above findings.

**D5791**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**

CFR(s): 493.1289(a)(c)

(a) 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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's records, and staff interview, the laboratory quality assessment failed to detect, monitor, and correct failures in the analytic systems. Refer to D5445 -I, II; and D5775