

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0960256	(X3) Date Survey Completed 12/27/2023
Name of Provider or Supplier Ford Bio Medical Laboratory	Street Address, City, State 5601 Schaefer Road Suite 200, Dearborn, MI	
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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Owner, the laboratory failed to retain its molecular amplification original cycle threshold (Ct) values for its quality control, patient testing, and wipe tests for 5 (August 2023 to December 2023) of 5 months since the laboratory began testing using these methods. Findings include: 1. A review of the laboratory's patient testing and quality control documentation for its molecular testing panels revealed the laboratory had manually transcribed "+" on the plate maps indicating when wells on the 96-well plates had positive amplification. 2. A review of the laboratory's "LOD Vaginitis" policy revealed a section stating, "After consulting with the Streamline Scientific and re-evaluating the data, the limit of detection (LOD) was determined for the Vaginitis assays to be 36.00 Ct." 3. The surveyor requested the original cycle threshold (Ct) values for the laboratory's quality control, patient testing, and wipe tests on 12/20/23 at 2:08 pm, 12/26/23 at 2:01 pm, and 12/27/23 at 12:32 pm and the records were not made available. 4. An interview on 12/27/23 at 12:45 pm with the Owner confirmed the Ct values for the laboratory's quality control, patient testing, and wipe tests were not available.</p>
D5400	<p>ANALYTIC SYSTEMS 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</p>

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.

This CONDITION is not met as evidenced by:

. Based on record review, observation, and interviews, the laboratory failed to ensure reagents and collection tubes had not exceeded expiration dates (refer to D5417), failed to establish performance specifications for its Sexually Transmitted Infection (STI) and Chlamydia and Gonorrhea (CT/NG) molecular assay panels (refer to D5423), failed to perform control procedures at least every date of patient testing for its Urinary Tract Infection (UTI), Vaginitis, Sexually Transmitted Infection (STI), and Chlamydia and Gonorrhea molecular-based panels (refer to D5445), and failed to perform corrective action when the negative control for its molecular vaginitis panel failed (refer to D5781).

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 observation, record review, and interview with the Owner, the laboratory failed to label reagents to include the expiration dates for 27 reagent bottles available for use. Findings include: 1. The surveyor observed the following reagents without labels indicating the expiration dates on 12/19/23 at 9:18 am: a. QIAGEN Buffer ATL Tissue Lysis Buffer 200 mL b. QIAGEN Buffer AVE Elution Buffer 125 mL c. Aliquots bottles labeled with the following: i. "AL 3/22/22" ii. "100% ETH 3/22/22" iii. "AW2 3/22/22" iv. "AVE" v. "AW1" vi. "100% Ethanol" vii. "AVE" viii. "AL cRNA" ix. "AW2" d. Five green-top conical tubes with clear liquid e. QIAGEN Buffer AE Elution Buffer 128 mL f. QIAGEN Buffer AVE Elution Buffer 125 mL g. QIAGEN Proteinase K Solution 6.0 mL h. Two bottles labeled "DI Water 11/5/23" connected to the Thunderbolt analyzer. i. One green top conical tube labeled "MeOH 11/27" j. Two QIAGEN Nuclease-Free Water 50 mL bottles k. One brown glass bottle labeled with "10% 2-propanol/water 11/25" l. One bottle labeled with "ANA Wash Buffer Prepared 10/07/23" 2. A review of the laboratory's "Reagent Management Policy" revealed a lack of protocol for labeling reagents. 3. An interview on 12/19/23 at 9:25 am with the Owner confirmed the reagent bottles listed above did not indicate the expiration dates.

D5417

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

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

. Based on observation, record review, and interview with the Owner, the laboratory failed to ensure reagents and collection tubes had not exceeded expiration dates for 26 reagents and collection tubes available for use. Findings include: 1. The surveyor observed the following reagents that had exceeded expiration dates on 12/19/23 at 9:18 am: a. QIAGEN Buffer ATL Tissue Lysis Buffer 50 mL expired 7/27/21. b. QIAGEN Buffer ATL Tissue Lysis Buffer 50 mL expired 8/24/21. c. QIAGEN Buffer ATL Tissue Lysis Buffer 50 mL expired 11/24/22. d. Sixteen green-top lithium heparin blood collection tubes expired 9/30/23. e. Astral Diagnostics Gram Stain Safranin expired 7/26/19. f. Astral Diagnostics Gram Stain Crystal Violet expired 5/16/19. g. Astral Diagnostics Wright-Giemsa Stain expired 9/1/17. h. Astral Diagnostics Gram Stain Decolorizer expired 6/21/19. i. Astral Diagnostics Deionized water reagent grade expired 8/23/19. j. Astral Diagnostics Stain Iodine concentrate expired 3/8/19. k. ANA Wash Buffer expired 12/7/23. 2. A review of the laboratory's "Reagent Management Policy" revealed a section stating, "Use all kits, reagents, controls, standards, etc., prior to the specified expiration date." 3. An interview on 12/19/23 at 9:33 am with the owner confirmed the reagents listed above had exceeded their expiration dates.

D5423

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Owner, the laboratory failed to establish performance specifications for its Sexually Transmitted Infection (STI) and Chlamydia and Gonorrhea (CT/NG) molecular assay panels for 3 (October 2023 to December 2023) of 3 months since the laboratory started patient testing. Findings include: 1. A review of the laboratory's establishment of performance specification documentation revealed a lack of documentation for the Laboratory-Developed Sexually Transmitted Infection (STI) and Chlamydia and Gonorrhea (CT/NG) molecular assay panels. 2. A review of patient testing records revealed testing for the Sexually Transmitted Infection (STI) and Chlamydia and Gonorrhea (CT/NG) molecular assay panels began on 10/12/23. A total of 58 patients were tested using the CT/NG panel and a total of 30 patients were tested using the STI panel. 3. A review of the laboratory's "Sexually Transmitted Microbiota Simplicity Panel 96-well" manufacturer's instructions revealed a section titled "The Following is Included in the Kit" stating, "96-well PCR plate pre-loaded with the Sexually Transmitted Microbiota Simplicity Panel assays and positive control. Negative control assay is plated but negative control is user supplied" showing the laboratory uses manufacturer pre-loaded plates. 4. A review of the laboratory's "CT/NG Microbiota Simplicity Panel 96-Well" manufacturer's instructions revealed a section titled "The Following is Included

in the Kit" stating, "96-well PCR Plate pre-loaded with CT/NG Simplicity Panel assays and positive control. Negative control assay is plated but negative control is user supplied" showing the laboratory uses manufacturer pre-loaded plates. 5. An interview on 12/20/23 at 12:46 pm with Testing Personnel #1 revealed the laboratory had not established performance specifications for its Sexually Transmitted Infection (STI) and Chlamydia and Gonorrhea (CT/NG) molecular assay panels prior to performing and reporting patient testing.

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 record review and interview with the Owner, the laboratory failed to perform control procedures at least every date of patient testing for its Urinary Tract Infection (UTI), Vaginitis, Sexually Transmitted Infection (STI), and Chlamydia and Gonorrhea molecular-based panels for 158 of 214 total patients tested using these panels. Findings include: 1. A review of the laboratory's "Quality Control of RT-PCR Molecular Testing Reagents" revealed a section stating, "The positive control templates used for quality control testing should amplify within the reportable range. the quality control test verifies that the positive control templates amplify for each analyte undergoing quality control testing, unless otherwise indicated by vendor. The negative control template used for quality control testing is composed of molecular grade water. The negative control template is to show that the RT-PCR reagents do not have non-specific amplification before the Ct cutoff of each assay." and "The above controls are performed on any new lots prior to use for any clinical specimens, and on a weekly basis thereafter." 2. The surveyor requested the laboratory's Individualized Quality Control Plan on 12/20/23 at 9:39 am and it was not made available. 3. A review of the laboratory's patient plate maps and quality control logs revealed 158 patients had testing performed using the molecular-based panels without control procedures performed for the following panels on the following dates: a. UTI Panel i.08/08/2023, 3 patients. ii. 08/10/2023, 1 patient. iii. 09/14/2023, 1 patient. iv. 09/27/2023, 3 patients. v. 10/16/2023, 2 patients. vi. 10/20/2023, 1 patients. vii. 11/01/2023, 2 patients. viii. 11/02/2023, 1 patient. ix. 11/06/2023, 1 patient. x. 12/05/2023, 1 patient. xi. 12/09/2023, 1 patient. b. Vaginitis Panel i. 08/04/2023, 1 patient. ii. 08/07/2023, 3 patients. iii. 08/10/2023, 1 patient. iv. 08/23/2023, 1 patient. v. 09/07/2023, 2 patients. vi.09/19/2023, 1 patient. vii. 09/29/2023, 3 patients. viii. 10/03/2023, 2 patients. ix. 10/04/2023, 2 patients. x. 10/13/2023, 4 patients. xi. 10/17/2023, 2 patients. xii. 10/18/2023, 3 patients. xiii. 10/23/2023, 1 patient. xiv. 10/25/2023, 1 patient. xv. 11/02/2023, 4 patients. xvi. 11/06/2023, 1 patient. xvii. 11/08/2023, 3 patients. xviii. 11/10/2023, 3 patients. xix. 11/11/2023, 3 patients. xx. 11/13/2023, 3 patients. xxi. 11/16/2023, 2 patients. xxii. 11/20/2023, 3 patients. xxiii. 11/30/2023, 6 patients. xxiv. 12/01/2023, 2 patients. xxv. 12/02/2023, 2 patients. xxvi. 12/03/2023, 1 patient. xxvii. 12/06/2023, 3 patients. xxviii. 12/07/2023, 3 patients. xxix. 12/12/2023,

1 patient. c. STI Panel i. 10/14/2023, 2 patients. ii. 10/19/2023, 2 patients. iii. 10/26/2023, 2 patients. iv. 10/27/2023, 4 patients. v. 11/02/2023, 1 patient. vi. 11/03/2023, 1 patient. vii. 12/01/2023, 3 patients. viii. 12/02/2023, 2 patients. d. Chlamydia and Gonorrhea Panel i. 10/12/2023, 2 patients. ii. 10/13/2023, 2 patients. iii. 10/16/2023, 2 patients. iv. 10/18/2023, 2 patients. v. 10/19/2023, 4 patients. vi. 10/21/2023, 2 patients. vii. 10/25/2023, 4 patients. viii. 10/24/2023, 2 patients. ix. 10/26/2023, 4 patients. x. 10/28/2023, 2 patients. xi. 10/31/2023, 2 patients. xii. 11/03/2023, 4 patients. xiii. 11/06/2023, 2 patients. xiv. 11/08/2023, 4 patients. xv. 11/10/2023, 2 patients. xvi. 11/17/2023, 4 patients. xvii. 11/18/2023, 2 patients. xviii. 12/01/2023, 4 patients. xix. 12/05/2023, 4 patients. xx. 12/07/2023, 2 patients. xxi. 12/11/2023, 2 patients. 4. An interview on 12/20/23 at 9:39 am with the Owner confirmed the laboratory had been performing external quality controls weekly and had not established an Individualized Quality Control Plan for the molecular-based panels listed above.

D5781

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
. Based on record review and interview with Testing Personnel #1, the laboratory failed to perform corrective action when the negative control for its molecular vaginitis panel failed for 1 of 92 patients reviewed. Findings include: 1. A review of the laboratory's "Vaginitis Plate Maps" revealed one patient tested on 10/23/23 had a positive result for the negative control. 2. A review of the laboratory's "Quality Control of RT-PCR Molecular Testing Reagents" revealed a section stating, "The negative control template used for quality control testing is composed of molecular grade water. The negative control template is to show that the RT-PCR reagents do not have non-specific amplification before the Ct cutoff of each assay. If an assay amplifies using the negative control template before the cutoff for that assay, then it has failed quality control testing and requires further review by the Supervisor or designee." 3. A review of the laboratory's "Vaginal Microbiota Simplicity Panel 96-well" procedure revealed a section stating, "Any failure of the positive or negative control should require a repeat run. If the control failure continues, it is recommended to have the qPCR instrument and the sample extraction workflow evaluated to ensure they are functioning properly." 4. The surveyor requested the laboratory's raw data from this run on 12/26/23 at 2:21 pm and 12/27/23 at 12:32 pm and it was not made available. 5. An interview on 12/27/23 at 12:45 pm with Testing Personnel #1 revealed no corrective action was performed for the patient tested on 10/23/23 with the failed negative control.

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

. Based on record review and interviews, the Laboratory Director failed to ensure performance specifications were established for its Sexually Transmitted Infection (STI) and Chlamydia and Gonorrhea (CT/NG) molecular assay panels (refer to D6085), failed to ensure controls were performed at least each date of patient testing for its Urinary Tract Infection (UTI), Vaginitis, Sexually Transmitted Infection (STI), and Chlamydia and Gonorrhea molecular-based panels (refer to D6093), and failed to ensure patient test results were not reported when the negative control for its molecular vaginitis panel failed (refer to D6097).

D6085

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(3)

The laboratory director must ensure that the test methodologies selected have the capability of providing the quality of results required for patient care.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Owner, the Laboratory Director failed to ensure performance specifications were established for its Sexually Transmitted Infection (STI) and Chlamydia and Gonorrhea (CT/NG) molecular assay panels. Refer to D5423.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Owner, the Laboratory Director failed to ensure controls were performed at least each date of patient testing for its Urinary Tract Infection (UTI), Vaginitis, Sexually Transmitted Infection (STI), and Chlamydia and Gonorrhea molecular-based panels. Refer to D5445.

D6097

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(7)

The laboratory director must ensure that patient test results are reported only when the system is functioning properly.

This STANDARD is not met as evidenced by:

. Based on record review and interview with Testing Personnel #1, the Laboratory Director failed to ensure patient test results were not reported when the negative control for its molecular vaginitis panel failed. Refer to D5781.