

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D2160761	(X3) Date Survey Completed 05/31/2022
Name of Provider or Supplier Laboratory For Dna-Guided Medicine	Street Address, City, State 10 Jefferson St, Unit C3, Hartford, CT	
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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on record review, lack of documentation and staff interview, the laboratory failed to enroll in an approved Proficiency Testing (PT) program for Bacteriology in 2021 and timely for 2022. Findings include: 1. Record review on 5/31/2022 on the 'BD Max CT/GC/TV Assay' procedure revealed: a. The molecular assay detects the analytes Chlamydia trachomatis (CT), Neisseria gonorrhoea (GC) and Trichomonas vaginalis (TV). b. The procedure was signed and approved by the laboratory director on 12/18/2020. 2. Record review on 5/31/2022 of two patient test requisitions and reports revealed the following: a. Patient A urine specimen was collected on 2/10/2021 with orders for CT, GC and TV testing. b. Patient B urine specimen was collected on 2/11/2021 with orders for CT, GC and TV testing. c. Results for CT, GC and TV were reported on Patients A and B on 2/11/2021. 3. Record review on 5/31/2022 of the laboratory's 2021 Proficiency Binder revealed the lack of documentation of proficiency testing results for CT, GC and any correspondence with any PT program regarding testing. 4. Record review on 5/31/2022 of the laboratory's 2022 Proficiency binder revealed the following: a. An order confirmation form dated 2/4/2022 for the American Proficiency Institute (API) program with the following information: i. Catalog # 311-22 Chlamydia/GC (molecular) with shipment dates 6/13</p>

/2022 and 9/19/2022. ii. Catalog # 362-22 Trichomonas vaginalis with shipment dates 2/7/2022, 6/13/2022 and 9/19/2022. iii. Catalog # 386-22 SARS-CoV-2 Swab (molecular) with shipment dates 6/13/2022 and 9/19/2022. b. Lack of documentation of Event 1 results for CT/GC. 5. Record review on 5/31/2022 of the API web address, <https://api-pt.com/catalog.aspx> of the 2022 Catalog of Programs revealed: a. Microbiology enrollment requirements state 'regulated tests are in bold type'. b. page 76: Chlamydia/GC (molecular) program 311 includes the analytes CT and GC with shipment dates of February 7th, June 13th, and September 19th. c. Both CT and GC are in bold type. 6. Staff interview on 5/31/2022 at 1:00 PM with the technical supervisor (TS) confirmed the laboratory had not enrolled in proficiency testing in 2021 but had contacted API and was told API could not supply testing for 2021 for CT, GC. TS confirmed the laboratory enrolled in February 2022 for the above testing and had not performed Event 1 for CT/GC.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:
Based on record review, lack of documentation and staff interview, the laboratory failed to enroll in an approved Proficiency Testing (PT) program or verify the accuracy for the analyte Trichomonas vaginalis in the subspecialty of parasitology in 2021. Findings include: 1. Record review on 5/31/2022 on the 'BD Max CT/GC/TV Assay' procedure revealed: a. The molecular assay detects the analytes Chlamydia trachomatis (CT), Neisseria gonorrhoea (GC) and Trichomonas vaginalis (TV). b. The procedure was signed and approved by the laboratory director on 12/18/2020. 2. Record review on 5/31/2022 of two patient test requisitions and reports revealed the following: a. Patient A urine specimen was collected on 2/10/2021 with orders for CT, GC and TV testing. b. Patient B urine specimen was collected on 2/11/2021 with orders for CT, GC and TV testing. c. Results for CT, GC and TV were reported on Patients A and B on 2/11/2021. 3. Record review on 5/31/2022 of the laboratory's 2021 Proficiency Binder revealed the lack of documentation of the following: a. Proficiency testing results for TV. b. Any correspondence with any PT program regarding testing. c. Twice annual verification for accuracy for the TV analyte in 2021. 4. Staff interview on 5/31/2022 at 1:00 PM with the technical supervisor (TS) confirmed the laboratory had not enrolled in proficiency testing in 2021 but had contacted American Proficiency Institute (API) and was told API could not supply testing for 2021 for TV. The TS further commented that the laboratory did not verify the accuracy of the TV analyte by an alternate method.

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 record review and staff interview the laboratory failed to provide complete procedures in the subspecialty of bacteriology, parasitology and virology. Findings include: 1. Record review of laboratory's BD Max System 'CT/GC/TV' and 'SARS-CoV-2' assay procedures and 'Lyra SARS-CoV-2' assay on 5/31/2022 revealed the lack of documentation of the following procedures: a. Step by step performance of the procedure including a repeat test procedure. b. Instrument maintenance procedures. c. Quality control procedure including type, identity, number, frequency and acceptability criteria. d. Corrective action for control result failures. e. Reportable ranges and normal value. f. Procedure when the system becomes inoperable. g. Procedure for entering patient results into the laboratory information system including the protocol for the required public health reportable laboratory findings. 2. Staff interview on 5/31/2022 at 11:00 AM with the technical supervisor confirmed the BD Max System procedures and Lyra SARS-CoV-2 procedure are incomplete and need updating. 3. The laboratory performs 1500 tests in the specialty of microbiology annually.

D5413

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

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.

This STANDARD is not met as evidenced by:

Based on record review, surveyor observation and staff interview, the laboratory failed to provide evidence of monitoring and documenting heating block temperature requirements per manufacturer's instructions in the subspecialty of virology. Findings include: 1. Record review on 05/31/2022 of the temperature maintenance logs for the years of 2021 and 2022 revealed lack of documentation of the heating block temperature. 2. Record review on 05/31/2022 of the 'Lyra Direct SARS-COV-2 Assay Procedure Manual' revealed an acceptable dry heating block temperature of 95 degrees Celsius +/- 1 degree Celsius. 3. Surveyor observation on 05/31/2022 at 2:30 PM of the extraction room revealed a 'myBlock Mini Dry Bath' heating block without an external thermometer. 4. Staff interview on 05/31/2022 at 2:30 PM with the technical supervisor confirmed the above findings and was unaware that daily

documentation of heating block temperature is a manufacturer requirement for a successful lysing of cellular components. 5. The laboratory performs 1500 tests annually in the subspecialty of microbiology annually.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to verify the accuracy of the test performance for the 'BD Max CT/GC/TV Assay' procedure prior to reporting patient test results in the subspecialties of bacteriology and parasitology. Findings include: 1. Record review on 5/31/2022 of the laboratory's 'BD Max CT/GC/TV Assay' procedure validation data/summary revealed the following: a. The assay detects the analytes Chlamydia trachomatis (CT), Neisseria gonorrhoea (GC) and Trichomonas vaginalis (TV) from urine or vaginal/endocervical specimens. b. 27 samples were tested to confirm test performance characteristics. c. Samples utilized for test comparison to determine accuracy of test results were received from an unknown reference laboratory. d. Lack of documentation of the reference laboratory results to determine correlation that the results obtained by the laboratory were correct. e. Lack of documentation of validation for multiple specimen types. f. Validation results were reviewed and approved by the laboratory director on 12/18/2020. 2. Staff interview on 5/31/2022 at 11:00 AM with the technical supervisor (TS) confirmed the above. The TS commented the reference laboratory was in Massachusetts but could not recall the reference laboratory name and where the documentation of test results for comparison may be. 3. The laboratory performs approximately 200 BD Max GC/CT/TV assays annually in the specialty of microbiology.

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 staff interview, the laboratory failed to establish the required performance specifications of precision, analytical sensitivity/specificity, interfering substances, and reportable/reference ranges prior to patient testing on new instrumentation in the subspecialties of routine chemistry and specialty of hematology. Findings include: 1. Record review on 05/31/2022 of the QuantStudio 7 Pro validation summary labeled 'Laboratory for DNA Guided Medicine Intra Laboratory Test Result Comparison for Samples Run on AutoGenomics Infiniti Platform vs Quantstudio Platform' revealed the following: a. Accuracy for CYP2C9, CYP2C19, CYP2D6, VKORC1 genetic mutations was tested on 10 samples. b. Lack of documentation for precision, analytical sensitivity/specificity, interfering substances, and reportable/reference ranges for the above genetic mutations. c. Approved and signed by the laboratory director (LD) on November 11, 2021. 2. Record review on 05/31/2022 of the validation raw data plate layout runs on the QuantStudio 7 Pro from September 2021 through November 2021 revealed current patient samples being run concurrently and reported with the validation samples prior validation approval by the LD. 3. Staff interview on 05/31/2022 at 12:30 PM with the technical supervisor confirmed the above findings and stated, "He had to start patient testing on the QuantStudio for PGX immediately due to the discontinuation of AutoGenomics Infiniti Platform support". 4. The laboratory performs approximately 200 tests for CYP2C9, CYP2C19, CYP2D6 annually in the subspecialty of routine chemistry and approximately 100 tests for VKORC1 in the specialty of hematology.