Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2063217	(X3) Date Survey Completed 04/20/2023
Name of Provider or Supplier Mt Auburn Urgent Care	**Street Address, City, State** 2230 Auburn Ave, Cincinnati, OH	

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	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 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. This CONDITION is not met as evidenced by: Based on record review and an interview with the Laboratory Owner (LO), the laboratory failed to enroll in a proficiency testing (PT) program for the specialty of Microbiology. This deficient practice had the potential to affect 106 patients tested from 05/16/2022 through 10/11/2022. Findings Include: 1. The laboratory failed to enroll in a PT program for Sexually Transmitted Infections (STI) testing in urine specimens. (Refer to D2001)
D2001	ENROLLMENT CFR(s): 493.801(a)(1)(2)(i) The laboratory must-- (1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart. (2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS;

	This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Owner (LO), the laboratory failed to enroll in a proficiency testing (PT) program for Sexually Transmitted Infections (STI) testing in urine specimens. This deficient practice had the potential to affect 106 patients tested under the specialty of Microbiology from 05/16/2022 through 10/11/2022. Findings Include: 1. The Laboratory Director's summary of the laboratory's 2022 alternative PT activities was reviewed on 04/11/2023 and showed only one previously tested patient urine specimen for STI identification sent to a third party laboratory. 2. Further review of the Laboratory Director's summary found the following statements: "...There were significant discrepancies between the two results. The results from the in-house testing showed a positive for presence of the following: BVAB-2 L. Iners T. Vaginalis C. Albacian The third-party testing did not correlate with these findings, and in fact showed a positive result for the following: Enterococcus faecalis Staphylococcus epidermidis" 3. Review of the laboratory's "Proficiency Testing" policy and procedure, approved via signature and date by the Laboratory Director on 10/18/2021, and provided for the inspection via electronic mail (email) on 04/20/2023 at 9:29 AM, found the following statement: "It is the responsibility of Mount Auburn Technical Supervisor to ensure that proficiency testing takes place according to schedule within adherence to COLA/CAP regulations, and that the results are reported to the Regulatory Compliance Officer." 4. The LO confirmed the laboratory was not enrolled with an HHS approved PT provider for STI identification regulated testing and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 04/11/2023 at 11:42 AM.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on record review and an interview with the Laboratory Owner (LO), the laboratory failed to successfully participate in a Proficiency Testing (PT) program for the SARS-CoV-2 liquid (molecular) testing performed under the subspecialty of Virology. This deficient practice had the potential to affect 447 patients tested from 10

	/28/2021 through 10/11/2022. Findings Include: 1. The laboratory failed to achieve a PT score of 80% (percent) for the SARS-CoV-2 liquid (molecular) test in the first PT event in 2022 in the subspecialty of Virology. (Refer to D2061)
D2061	VIROLOGY CFR(s): 493.831(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Owner (LO), the laboratory failed to to attain an overall Virology proficiency testing (PT) event score of at least 80%. This deficient practice had the potential to affect 447 patients tested from 10/28/2021 through 10/11/2022. Findings Include: 1. The laboratory's 2022 American Proficiency Institute (API) PT records were reviewed on 04/11/2023 and revealed an overall Virology test score for SARS-CoV-2 liquid (molecular) of 50% for the first PT event of 2022. 2. The LO confirmed the laboratory did not attain an overall API Virology PT event score for SARS-CoV-2 liquid (molecular) of at least 80% for the first PT testing event in 2022. The interview occurred on 04/11/2023 at 11:35 AM.
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 an interview with the Laboratory Owner (LO), the laboratory failed to establish and follow written policies and procedures to assess the competency of the Technical Supervisor (TS) and General Supervisor (GS) based on the responsibilities of the position and at a frequency determined by the laboratory, and Testing Personnel (TP) as specified in the personnel requirements in subpart M for the high complexity testing procedures performed in the specialty of Microbiology. This deficient practice had the potential to affect 553 patient tests performed between 10/28/2021 through 04/11/2023. Findings Include: 1. Review of the laboratory's Form CMS-209 on 04/11/2023, and approved by the Laboratory Director on 03/23/2023, revealed one individual listed and qualified by the Laboratory Director to function as a TS, and one individual to function as both the GS and TP. 2. Review of the laboratory's "Personnel Training and Competency" policy and procedure manual, provided on 04/11/2023 at 4:33 PM via electronic mail (email) found the following statements: "The employee must have distinct documentation of competency to satisfy all 6 methods of assessment for each assigned instrumentation and/or methodology at both the 6 month and annual review periods. Additional competency reviews are required for General and Technical Laboratory Supervisors at the 6-month and Annual intervals. These reviews are related to supervisory-specific functions and should be treated as a distinct review with separate supporting documentation requirements." 3. The Inspector requested from the LO the laboratory's

	competency assessment documentation for the TS, GS and TP based on the responsibilities of the position. The LO confirmed the laboratory did not follow the policy and procedure for the assessment of the TS, GS and TP, and did not assess competency for the TS and GS based on the responsibilities of the position and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 04/11/2023 at 11:30 AM.
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 and an interview with the Laboratory Owner (LO), the laboratory failed to perform test accuracy verification (TAV) twice annually for Sexually Transmitted Infections (STI) testing in urine specimens not included in subpart I. This deficient practice had the potential to affect 106 patients tested under the specialty of Microbiology from 05/16/2022 through 10/11/2022. Findings Include: 1. The Laboratory Director's summary of the 2022 alternative PT activities was reviewed on 04/11/2023 and showed only one previously tested patient urine specimen sent to a third party laboratory. 2. Review of the laboratory's "Proficiency Testing" policy and procedure, approved via signature and date by the Laboratory Director on 10/18/2021 and provided for the inspection via electronic mail (email) on 04/20/2023 at 9:29 AM, found the following statement: "1. At least twice a year in periodic intervals, external split-sample testing will be performed on at least five specimens per sample matrix for all analytes (genes) tested where possible. 2. Some assays, particularly in genetic testing, have analytes for which no approves proficiency program is available, and an external laboratory is not available for an exchange program. In these cases, Mount Auburn will perform internal blinded proficiency testing through aliquot splitting. a. A panel of a minimum 10 patients samples with a variety of results for the analytes to be covered will be selected by the Compliance Officer." 3. The inspector requested the 2022 TAV documentation of Sexually Transmitted Infections (STI) testing in urine specimens not included in subpart I from the LO. 4. The LO confirmed the laboratory did not, at least twice a year, in periodic intervals, conduct external split-sample testing on at least five specimens per sample matrix for all analytes (genes) tested, per the laboratory's own policy and procedure, and was unable to provide the requested information. The interview occurred on 04/11/2022 at 11:42 AM.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Owner (LO), the laboratory failed to establish and follow written policies and procedures, and document all assessment activities of an ongoing mechanism to monitor, assess, and

	correct problems identified in the post analytic systems. This deficient practice had the potential to affect 553 patients tested in the specialty of Microbiology from 10/28 /2021 through 04/11/2023. Findings Include: 1. The 2022 monthly "Quality Assessment Monitoring Logs" provided via electronic mail (email) on 03/24/2023 was reviewed on 04/11/2023 and found the "Proficiency Testing Results Reviewed" column had not been checked for February, May, June, July, August, October, November, and December. 2. Further review of the 2022 monthly "Quality Assessment Monitoring Logs" on 04/11/2023 found a Laboratory Director approval signature of 03/23/2023 on all logs. 3. Review of the laboratory's policy and procedure titled "Quality Assurance Monitoring" provided on 04/19/2023 at 8:03 AM found the following statement: "The quarterly Quality Assessment Review will consist of the following parameters: 12. The previous quarter's Quality Assessment Review Form will be inspected to ensure all corrective action has been completed. Effectiveness of the corrective actions will be assessed and noted. Any corrective actions from the previous quarter's Quality Assessment Review not completed by the date of the current Quality Assessment Review will be documented and brought to the immediate attention of the Lab Director." 4. On 04/11/2023 at 12:05 PM the inspector requested documentation of the previous quarter's quality assessment review and any corrective actions assessed and noted from the LO. The LO was unable to provide the requested information.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Owner (LO), the Laboratory Director failed to ensure verification procedures used were adequate to determine the accuracy, precision, and other pertinent performance characteristics of the newly implemented Viia 7 Applied Biosystems instrument test system for Sexually Transmitted Infections (STI) testing in urine specimens. This deficient practice had the potential to affect 106 patients tested under the specialty of Microbiology from 05/16/2022 through 10/11/2022. Findings Include: 1. The laboratory's Viia 7 Applied Biosystems validation plan titled "DETERMINATION OF THE Women's Health/STI pathogens to include Virus/Bacteria/ABR, USING REAL-TIME REVERSE TRANSCRIPTASE QUANTITATIVE POLYMERASE CHAIN REACTION (RT-QPCR)" provided on 03/27/2023 at 9:32 AM via electronic mail (email) was reviewed on 04/11/2023 and did not find any indication of data review or evaluation of accuracy, precision, and other pertinent performance characteristics acceptability prior to patient testing on 05/16/2022 by the Laboratory Director. 2. On 04/11/2023 at 11:55 AM, during a telephone interview the LO stated "the initial validation of the STI panels was conducted in February 2022 by DNA Healthcare Solutions." 3. The inspector requested the Laboratory Director reviewed and approved validation plan for the Viia 7 Applied Biosystems instrument test system used for Sexually Transmitted Infections (STI) testing in urine specimens which were implemented on 02/17/2022 from the LO. 4. On 04/19/2023 at 8:03 AM via email the LO provided a second Viia 7 Applied Biosystems validation plan titled "DETERMINATION OF THE Women's Health/STI pathogens to include Virus /Bacteria/ABR, USING REAL-TIME REVERSE TRANSCRIPTASE

	QUANTITATIVE POLYMERASE CHAIN REACTION (RT-QPCR)" with no indication of data review or the approval of the evaluation of accuracy, precision, and other pertinent performance characteristics acceptability prior to patient testing on 05 /16/2022 by the Laboratory Director.