

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2153680	(X3) Date Survey Completed 12/11/2018
Name of Provider or Supplier Premier Urgent Care	Street Address, City, State 1301 E 47th St, Chicago, IL	
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 the surveyor's review of the laboratory's manuals, records, and an interview with the technical consultant (TC) and staff; the laboratory failed to enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS for each of the specialties and subspecialties for which it seeks certification. Findings: 1. The laboratory is currently performing tests in the specialties and subspecialties of Hematology, Routine Chemistry, and Microbiology. 2. The proficiency policy in the laboratory manual does not indicate the PT program the laboratory has selected to join/enroll. 3. No documentation was presented as evidence that the laboratory had enrolled in an HHS approved PT program. 4. On an Initial survey conducted on 12/11/2018 at 4::30 PM, the TC and staff confirmed that they had not selected and enrolled in a proficiency testing program.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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,</p>

consultant competency.

This STANDARD is not met as evidenced by:

Based on the surveyor's review of the Laboratory Personnel Report (CMS 209), the policies, procedures, records, and an interview with the technical consultant (TC) and staff; the laboratory failed to establish written policies and procedures that meet the personnel requirements in subpart M to assess employees performing Bacteriology, Routine Chemistry and Hematology, affecting 3 out of 3 testing personnel (TP).

Findings: 1. The CMS 209 lists 3 TP performing the following tests in the laboratory: Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (NG) test, using the cepheid system; routine blood Chemistry analysis and Cellular Blood Count (CBC) analysis. 2. The employee records show that 3 out of 3 TP have been trained to performed all the tests listed in Findings#1. 3 The laboratory's manual and competency procedure does not include the following competency evaluation processes as required for each test system or procedure used for patient testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; b). Monitoring the recording and reporting of test results (for example, recording patients and their results in the labs' test log and EMR system); c). If applicable, review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; d). Direct observation of performance of instrument maintenance and function checks; e). Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and f). Assessment of problem solving skills; and g). Evaluating and documenting the performance of individuals responsible for moderately complex testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually. 4. On an Initial survey conducted on December 11, 2018 at 4:30 PM, the TC and staff confirmed the above.

D5311

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL

CFR(s): 493.1242(a)

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.

This STANDARD is not met as evidenced by:

Based on the surveyor's review of the laboratory's manuals, volume worksheet, and an interview with the technical consultant (TC) and staff; the laboratory failed to establish written policies and procedures for its specimen submission, handling and referral of each patient's specimen, affecting 76 patients. Findings: 1. The laboratory's manual failed to include the following required written pre-analytic procedures: (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. 2. The laboratory documents on the "Laboratory Non-waived CLIA Test Volume Worksheet" that the laboratory has performed tests on 76 patients. 3. On an Initial

	<p>survey conducted on 12/11/2018 at 4:30 PM, the TC and staff confirmed the above findings.</p>
D5391	<p>PREANALYTIC SYSTEMS QUALITY ASSESSMENT 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: Based on the surveyor's review of the laboratory's manuals, volume worksheet, and an interview with the technical consultant (TC) and staff; the laboratory failed to establish written policies and procedures to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242, affecting 76 patients. Findings: 1. The laboratory's manual failed to include written policies and step-by-step procedures to assess the practices/issues related to test requests, specimen submission, handling and referrals of patients' samples. 2. The laboratory documents on the "Laboratory Non-waived CLIA Test Volume Worksheet" that the laboratory has performed tests on 76 patients. 3. On an Initial survey conducted on 12/11/2018 at 4:30 PM, the TC and staff confirmed the above findings.</p>
D5891	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's manuals, records, volume worksheet, and an interview with the technical consultant (TC) and staff; the laboratory failed to establish written policies and procedures to monitor, assess, and when indicated, correct problems identified in the post-analytic systems specified in 493.1291, affecting 76 patients. Findings: 1. Review of the patients' test results and final reports reveal that all test results are manually entered into the patients' chart in the laboratory's electronic medical record (EMR) system. 2. The laboratory's manual does not include written policies and step-by-step procedures that accomplishes the following: a). The monitoring and evaluating of the accuracy and completeness of the laboratory's test results manually entered into the patients' EMR chart b). The laboratory's turn-around times and procedures for notification of test results e.g., routine tests, STATS, abnormal or panic values; and c). If applicable, a mechanism to periodically verify the accuracy of: its calculated data; its results sent to interfaced systems; and patient specific data. 3. The laboratory documents on the "Laboratory Non-waived CLIA Test Volume Worksheet" that the laboratory has performed tests on 76 patients. 4. On an Initial survey conducted on 12/11/2018 at 4:30 PM, the TC and staff confirmed the above findings.</p>
D6000	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p>

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 the surveyor's review of the laboratory's manuals, records, volume worksheet, the Laboratory Personnel Report (CMS 209), and an interview with the technical consultant (TC) and staff; the laboratory director (LD) failed to provides overall management and direction in accordance with 493.1407 of this subpart, affecting 76 patients and 3 testing personnel (TP). Findings: 1. The LD failed to ensure that the laboratory is enrolled in an HHS approved proficiency testing program. See D6015. 2. The LD failed to ensure that the approved procedure manual which is available to all personnel include all aspect of the testing process, prior to testing patients. See D6031.

D6015

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)

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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:

Based on the surveyor's review of the laboratory's manuals, records, and an interview with the technical consultant (TC) and staff; the laboratory director (LD) failed to ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. Findings: 1. The laboratory is currently performing tests in the specialties and subspecialties of Hematology, Routine Chemistry, and Microbiology. No documentation has been presented as evidence the laboratory had enrolled in an HHS approved PT program for the tests performed, prior to testing patients. See D2000. 2. On an Initial survey conducted on 12/11/2018 at 4::30 PM, the TC and staff confirmed that they had not selected and enrolled in a proficiency testing program.

D6031

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(13)

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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:

Based on the surveyor's review of the laboratory's manuals, volume worksheet, the

Laboratory Personnel Report (CMS 209), and an interview with the technical consultant (TC) and staff; the laboratory director (LD) failed to ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process, affecting 76 patients and 3 testing personnel (TP). Findings: 1. The LD failed to ensure that the laboratory's manuals include the following required written policies and step-by-step procedures for: (1) Record retention. (2) Confidentiality of Patient Information - ensuring confidentiality of patient information throughout all phases of the total testing process that are under the laboratory's control. (3) Specimen identification and integrity - ensuring positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. (4) Complaint investigations - must have a system in place to ensure that it documents all complaints and problems reported to the laboratory and investigate them. (5) Pre-analytic processes - See D5391 (6) Specimen processing. - See D5311 and (7) Post-analytic process - See D5891. 2. The laboratory documents on the "Laboratory Non-waived CLIA Test Volume Worksheet" that the laboratory has performed tests on 76 patients. 3. The CMS 209 shows that 3 TP have been trained to perform the tests in the laboratory. 4. On an Initial survey conducted on 12/11/2018 at 4:30 PM, the TC and staff confirmed the above findings.