

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2240178	(X3) Date Survey Completed 04/27/2023
Name of Provider or Supplier Immediate Care Of Oklahoma, Llc	Street Address, City, State 5700 Se 74th, Ste 100 A, Oklahoma City, OK	
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
D0000	The initial survey was performed on 04/27/2023. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the general supervisor at the conclusion of the survey.
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the general supervisor, the laboratory failed to ensure proficiency testing records had been maintained; and failed to ensure proficiency testing attestation statements had been signed by the laboratory director and/or testing person for six of eight events reviewed. Findings include: (1) A review of 2022 and 2023 proficiency testing records identified the following for six of eight events: (a) IDR (Infectious Disease, Respiratory Panel)-A 2022 (i) The attestation statement had not been signed by the laboratory director and testing person; (ii) A copy of the results submitted to the proficiency testing program had not been maintained. (b) First Microbiology Event 2022 (i) The attestation statement had not been signed by the laboratory director; (ii) A copy of the results submitted to the proficiency testing program had not been maintained. (c) IDR-B 2022 (i) The</p>

attestation statement had not been maintained. (d) IDR-C 2022 (i) The attestation statement had not been maintained. (e) Second Microbiology Event 2022 (i) The attestation statement had not been signed by the laboratory director. (f) IDR-A 2023 (i) The attestation statement had not been signed by the laboratory director and testing person; (ii) A copy of the results submitted to the proficiency testing program had not been maintained. (g) First Microbiology Event 2023 (i) The attestation statement had not been signed by the laboratory director and testing person. (2) The findings were reviewed with the general supervisor who stated on 04/27/2023 at 12:40 pm, the attestation statements had not been signed and records not maintained as stated above.

D5215

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the general supervisor, the laboratory failed to evaluate the accuracy of testing when proficiency results had not been graded by the proficiency program for three of six proficiency testing events reviewed. Findings include: (1) A review of 2022 and 2023 proficiency testing records for 2022 and 2023 and identified the following had not been graded by the proficiency testing program, with no evidence the laboratory performed a self-evaluation of the results for three of six events: (a) IDR (Infectious Disease, Respiratory Panel)-A 2022 (i) Parainfluenza Subtype - Five of five results had not been graded by the proficiency testing program. Under "Your Grade" it stated "See Note [26]" which indicated an Educational Challenge. (b) IDR-A 2023 (i) Coronavirus Strain - Five of five results had not been graded by the proficiency testing program. Under "Your Grade" it stated "See Note [26]" which indicated an Educational Challenge. (c) First 2023 Microbiology Event (i) Enterobacter cloacae - One of five results had not been graded by the proficiency testing program. Under "Expected Results" it stated, "See Data Summary"; (ii) Candida tropicalis - One of five results had not been graded by the proficiency testing program. Under "Expected Results" it stated, "See Data Summary"; (iii) Resistance Gene: dfrA - Three of five results had not been graded by the proficiency testing program. Under "Expected Results" it stated, "See Data Summary"; (iv) Resistance Gene: mecA - Four of five results had not been graded by the proficiency testing program. Under "Expected Results" it stated, "See Data Summary"; (v) Resistance Gene qnr - Three of five results had not been graded by the proficiency testing program. Under "Expected Results" it stated, "See Data Summary"; (vi) Resistance Gene sul - Three of five results had not been graded by the proficiency testing program. Under "Expected Results" it stated, "See Data Summary". (2) The records were reviewed with the general supervisor who stated on 04/27/2023 at 12:40 pm, the laboratory had not evaluated the results that were not graded by the proficiency testing program.

D5317

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL
CFR(s): 493.1242(d)

If the laboratory accepts a referral specimen, written instructions must be available to

the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section.

This STANDARD is not met as evidenced by:

Based on interview with the general supervisor, the laboratory failed to provide written instructions to clients collecting and referring testing for UTI (Urinary Tract Infection) Pathogens, Wound Pathogens, Vaginitis with STI (Sexually Transmitted Infections) pathogens, Respiratory Bacterial Pathogens, and Respiratory Viral Pathogens for two of two test systems. Findings include: (1) On 04/27/2023 at 10:30 am, the general supervisor stated the following: (a) The laboratory began performing testing for UTI (Urinary Tract Infection) Pathogens, Wound Pathogens, Vaginitis with STI (Sexually Transmitted Infections) pathogens, and Respiratory Bacterial and Viral Pathogens using the Bio-Rad CFX Opus 96 Real Time PCR (Polymerase Chain Reaction) analyzer denoted by the laboratory as "Machine 1" on 01/03/2022; (b) The laboratory began performing testing for UTI (Urinary Tract Infection) Pathogens, Wound Pathogens, and Vaginitis with STI (Sexually Transmitted Infections) using the Bio-Rad CFX 96 Real Time C1000 Touch Thermal Cycler analyzer denoted by the laboratory as "Machine 2" in July 2022 (the exact date could not be determined); (c) Specimens were transported to the laboratory from seven different sister locations. (3) Interview with the general supervisor on 04/27/2023 at 01:40 pm confirmed the laboratory did not provide written instructions (i.e., client service manual) to the clients to explain the laboratory's specimen handling and transport requirements.

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 a review of records and interview with the general supervisor, the laboratory failed to ensure the room temperature was maintained as defined by the laboratory in the IQCP (Individualized Quality Control Plan) for two of two laboratory developed test systems for three of five months reviewed. Findings include: (1) On 04/27/2023 at 10:30 am, the general supervisor stated the following: (a) The laboratory began performing testing for UTI (Urinary Tract Infection) Pathogens, Wound Pathogens, Vaginitis with STI (Sexually Transmitted Infections) Pathogens, and Respiratory Bacterial and Viral Pathogens using the Bio-Rad CFX Opus 96 Real Time PCR (Polymerase Chain Reaction) analyzer denoted by the laboratory as "Machine 1" on 01/03/2022; (b) The laboratory began performing testing for UTI (Urinary Tract Infection) Pathogens, Wound Pathogens, and Vaginitis with STI (Sexually Transmitted Infections) using the Bio-Rad CFX 96 Real Time C1000 Touch Thermal Cycler analyzer denoted by the laboratory as "Machine 2" in July 2022 (the exact date could not be determined). (2) A review of the establishment studies (sample stability studies) and IQCP developed for the above test systems defined the acceptable room temperature storage of samples for the above testing as 18-27 degrees C (Centigrade);

(3) A review of laboratory temperature records for January 2022, February 2022, July 2022, February 2023, and March 2023 identified documented temperatures less than 18 degrees C for three of five months as follows: (a) January 2022 - Five of 20 temperatures were documented as less than 18 degrees C; (b) February 2022 - One of 19 temperatures were documented as less than 18 degrees C; (c) February 2023 - Three of 20 temperatures were documented as less than 18 degrees C. (4) The records were reviewed with the general supervisor who stated on 04/27/2023 at 01:40 pm the laboratory temperature had not been maintained as required.

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 a review of records and interview with the general supervisor, the laboratory failed to ensure the performance specification data had been evaluated prior to implementing the new testing for one of two new analyzers introduced into the laboratory. Findings include: (1) On 04/27/2023 at 10:30 am, the general supervisor stated the laboratory began performing testing for UTI (Urinary Tract Infection) Pathogens, Wound Pathogens, and Vaginitis with STI (Sexually Transmitted Infections) using the Bio-Rad CFX 96 Real Time PCR (Polymerase Chain Reaction) analyzer denoted by the laboratory as "Machine 2" in July 2022; (2) A review of the establishment studies for the test system identified the data had not been signed and dated as approved by the laboratory until 11/10/2022; (3) The records were reviewed with the general supervisor who stated on 04/27/2023 at 02:30 pm, the establishment studies had not been signed and dated as approved by the laboratory prior to putting the test system into use for 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 a review of records and interview with the general supervisor, the laboratory failed to perform QC (Quality Control) as stated in the IQCP (Individualized Quality Control Plan) for three of four months reviewed. Findings include: (1) On 04/27/2023 at 10:30 am, the general supervisor stated the following: (a) The laboratory began performing testing for UTI (Urinary Tract Infection) Pathogens, Wound Pathogens, Vaginitis with STI (Sexually Transmitted Infections) Pathogens, and Respiratory Bacterial and Viral Pathogens using the Bio-Rad CFX Opus 96 Real Time PCR (Polymerase Chain Reaction) analyzer denoted by the laboratory as "Machine 1" on 01/03/2022; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) A review of the QCP (Quality Control Plan) identified positive and negative QC (Quality Control) materials were to be tested on a weekly basis; (3) A review of QC records for August 2022, December 2022, February 2023, and March 2023 identified QC had not been performed weekly during three of four months for two of four tests as follows: (a) Vaginitis with STI Pathogens (i) Vaginitis Pathogens QC had not been performed between: (aa) 08/05/2022 and 08/29/2022 (bb) 02/09/2022 and 02/20/2023 (cc) 03/01/2023 and 03/23/2023 (ii) STI Pathogens QC had not been performed between: (aa) 03/01/2023 and 03/23/2023 (b) Respiratory Bacterial and Viral Pathogens (i) QC had not been performed between: (aa) 03/03/2023 and 03/14/2023 (4) The records were reviewed with the general supervisor who stated on 04/27/2023 at 03:45 pm, QC had not been performed as stated above.

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 a review of records and interview with the general supervisor, the laboratory failed to have a system that twice a year evaluated and defined the relationship between test results for UTI (Urinary Tract Infection) Pathogens, Wound Pathogens, and Vaginitis with STI (Sexually Transmitted Infections) pathogens, performed using two different analyzers during the review period of July 2022 through the current date. Findings include: (1) On 04/27/2023 at 10:30 am, the general supervisor stated the following: (a) The laboratory began performing testing for UTI (Urinary Tract Infection) Pathogens, Wound Pathogens, and Vaginitis with STI (Sexually Transmitted Infections) Pathogens using the Bio-Rad CFX Opus 96 Real Time PCR (Polymerase Chain Reaction) analyzer denoted by the laboratory as "Machine 1" on 01/03/2022; (b) The laboratory began performing testing for UTI (Urinary Tract Infection) Pathogens, Wound Pathogens, and Vaginitis with STI (Sexually Transmitted Infections) Pathogens using the Bio-Rad CFX 96 Real Time C1000 Touch Thermal Cycler analyzer denoted by the laboratory as "Machine 2" in July 2022 (the exact date could not be determined). (2) A review of records from July 2022 through the current date identified no evidence the relationship between the testing performed using the two analyzers had been evaluated during the review period; (3) The findings were reviewed with the general supervisor who stated on 04/27/2023 at 02:50 pm, the relationship between the testing performed on the two analyzers had not been evaluated at least twice annually during the review period.