Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D1102844	10/22/2020
Name of Provider or Supplier	**Street Address, City, State**	
Immediate Care Of Oklahoma-Healthplex	3321 W Tecumseh Rd, Ste 125, Norman, 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 recertification survey was performed on 10/22/2020. The findings were reviewed with testing person #2 and testing person #3 at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulation: 493.1409; D6033: Technical Consultant
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (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. This STANDARD is not met as evidenced by: Based on a review of records and interview with testing person #2, the laboratory director or designee failed to sign proficiency testing attestation statements for 3 of 5 events. Findings include: (1) On 10/22/2020, the surveyor reviewed 2019 and 2020 proficiency testing records and identified the following for 3 of 5 events: (a) Second 2019 Hematology (MLE-M2) Event - The attestation statement had not been signed by the laboratory director or designee; (b) Third 2019 Hematology (MLE-M3) Event - The attestation statement had not been signed by the laboratory director or designee; (c) First 2020 Hematology (MLE-M1) Event - The attestation statement had not been

	signed by the laboratory director or designee. (2) The surveyor reviewed the findings with testing person #2 who stated on 10/22/2020 at 12:45 pm, the attestation statements had not been signed by the laboratory director or designee as shown above.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of the policy and procedure manual and interview with testing person #2, the laboratory failed to follow written procedures for CBC (Complete Blood Count) testing for 3 of 6 quality control lot numbers. Findings include: (1) On 10/22/2020 at 11:30 am, testing person #2 stated to the surveyor: (a) CBC testing was performed on the Medonic M-Series hematology analyzer; (b) The laboratory tested 3 levels (Low, Normal, High) of Boule Con-Diff Quality Control (QC) materials each day of patient testing. (2) The surveyor reviewed the written procedure titled, "NEW LOT NUMBERS FOR QC OF THE MEDONICS HEMATOLOGY ANALYZER" which stated, (a) "NEW LOT NUMBERS OF QC MATERIALS SHOULD BE OVERLAPPED WITH EXISTING LOT NUMBERS AT LEAST ONCE FOR A MINUMUM OF 5 DAYS BEFORE STARTING A NEW QC LOT NUMBER TO ENSURE PROPER REACTIVITY." (3) The surveyor reviewed records for 6 control lot numbers. There was no evidence the provided ranges were verified before the lot numbers were put into use for 3 of 6 lot numbers as follows: (a) Low control (lot #22008-21), normal control (lot #22008-22), and high control (lot #22008-23) put into use on 09/15/2020. (3) The findings were discussed with testing peson #2 who stated on 10/22/2020 at 02:45 pm the manufacturer's ranges had not been verified before the above lot numbers had been put into use.
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, manufacturer's instructions, and interview with testing person #2, the laboratory failed to ensure equipment was stored as required by the manufacturer for 1 of 3 months. Findings include: (1) On 10/22/2020 at 11:30 am, testing person #2 stated to the surveyor CBC (Complete Blood Count) was performed on the Medonic M-Series analyzer; (2) The surveyor reviewed the manufacturer's environmental requirements for the analyzer. The manufacturer required the operating environment temperature be maintained within the range of 18 - 32 degrees C

	(Centigrade); (3) The surveyor then reviewed laboratory's temperature records from May 2020 through July 2020 and identified temperature readings were not documented for 1 of 3 month as follows: (a) June 2020 - Days 9 and 21 (4) The surveyor reviewed the records with testing person #2 who stated on 10/22/2020 at 03: 05 pm temperatures of the laboratory had not be documented as indicated above.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with testing person #2, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures for 3 of 3 months. Findings include: (1) On 10/22 /2020 at 11:30 am, testing person #2 stated to the surveyor that CBC (Complete Blood Count) testing was performed on the Medonic M-Series analyzer; (2) The surveyor reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance logs. The requirements for daily maintenance were as follows: (a) Check Reagent Levels (b) Check Printer Paper (c) Background Count (d) Quality Control (e) Clean Probe(s) w/alcohol (3) The surveyor then reviewed maintenance records for 3 months (May 2020 through July 2020). There was no evidence the daily maintenance had been performed: (a) Between 05/05/2020 and 05/07/2020 (b) Between 05/09/2020 and 05/11/2020 (c) Between 05/25/2020 and 05/27/2020 (d) Between 06/09/2020 and 06/11/2020 (e) Between 06/16/2020 and 06/18/2020 (f) Between 07/04/2020 and 07 /06/2020 (g) Between 07/08/2020 and 07/11/2020 (h) Between 07/12/2020 and 07/14 /2020 (i) Between 07/17/2020 and 07/19/2020 (j) Between 07/21/2020 and 07/23 /2020 (k) Between 07/25/2020 and 07/27/2020 (l) Between 07/27/2020 and 07/29 /2020 (4) The surveyor reviewed the records with testing person #2, who stated on 10 /22/2020 at 03:00 pm the daily maintenance had not been performed as required.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of records and interview with testing person #2, the laboratory failed to ensure reference intervals were determined as appropriate for the laboratory's patient population. Findings include: (1) On 10/22/2020 at 11:30 am, testing person #2 stated to the surveyor CBC (Complete Blood Count) testing was performed using the Medonic M-Series analyzer; (2) The surveyor reviewed two patient CBC reports - the first report was for an adult female patient with the testing performed on 07/15 /2020 at 04:03 pm; the second report was for an adult male patient with the testing performed on 10/05/2020 at 07:31 pm. Both reports included the same reference intervals for the CBC parameters of RBC (Red Blood Cell), Hemoglobin, and Hematocrit which were: (a) RBC - 3.50 - 5.50 10^12/l (b) Hemoglobin - 11.5 -16.5 g

	/dL (c) Hematocrit - 35.0 - 55.0 % (3) The surveyor reviewed the findings with testing person #2, who stated on 10/22/2020 at 03:15 pm the patient reports did not include gender specific reference ranges. NOTE: Routinely, female reference intervals for the analytes RBC, Hemoglobin, and Hematocrit are lower than male reference intervals.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records and interview with testing person #2, the technical consultant failed to provide technical oversight in accordance with 493.1413 of this subpart. Findings include: (1) The technical consultant failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications. Refer to D6035; (2) The technical consultant failed to ensure that persons performing moderate complexity testing had been evaluated semiannually during the first year of testing. Refer to D6053.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing

	tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on a review of records and interview with testing person #2 and testing person #3, the laboratory failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications for 4 of 4 competency evaluations performed. Findings include: (1) On 10/22/2020, the surveyor reviewed records for 4 persons performing moderate complexity testing in 2019 and 2020. The records showed the evaluation for 4 of 4 persons had been performed by an individual who did not meet the regulatory qualification requirements of the technical consultant: (a) Testing Person #1 - The 05/28/2020 evaluation had been performed by testing person #3 (this person had earned a high school diploma); (b) Testing Person #2 - The 08/02/2020 evaluation had been performed by testing person #3; (c) Testing Person #3 - The 05/15/2020 evaluation had been performed by testing person #2 (this person had earned a bachelor of science in Sociology); (d) Testing Person #4 - The 07/03/2019 and 06/22/2020 evaluations had been performed by testing person #2. (2) The surveyor explained to testing person #2 and testing person #3 that all components of the competency evaluations must be performed by a person who qualifies as a technical consultant (an individual with a minimum of a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution, and at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service). Testing person #2 stated to the surveyor on 10/22/2020 at 11:10 am, the evaluations had been performed by individuals who did not meet the regulatory qualifications of a technical consultant.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of records and interview with the testing person #2, the technical consultant failed to ensure persons performing moderate complexity testing had been evaluated semiannually during the first year of testing for 2 of 2 testing persons. Findings include: (1) On 10/22/2020, the surveyor reviewed personnel records. The following was identified: (a) Testing Person #1 - The initial training for this person was completed on 03/23/2019. There was no evidence that a semiannual evaluation had been performed (due 9/2019); (b) Testing Person #3 - The initial training for this person was completed on 03/21/2019. There was no evidence that a semiannual evaluation had been performed (due 09/2019); (2) The surveyor reviewed the records with testing person #3 who stated on 10/22/2020 at 11:05 am there were no records to prove the above persons had been evaluated semiannually.