Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0912551	10/26/2021
Name of Provider or Supplier	**Street Address, City, State**	
Belleville Health Care Pc	265 Main Street Suite B, Belleville, MI	

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
D3027	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(1) Test requisitions and authorizations. Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director (LD) and Testing Personnel (TP) #1, the laboratory failed to retain test requisitions for at least 2 years for 14 (patient #1 - #14) of 14 patient results reviewed. Findings include: 1. Record review for 14 of 14 patient test results reviewed revealed a lack of documentation of the requesting test requisitions. 2. We queried, testing personnel #1 stated that the requisitions are shredded once the testing is completed and results turned out. 3. A phone interview on 10/19/2021 at approximately 11:47 am, the LD confirmed the laboratory did not retain test requisitions for 2 years.
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, lack of documentation, and interview with the Laboratory Director (LD), the laboratory failed to monitor and document the refrigerator temperature each day of operation for 6 (May to October in 2021) of 13 months of operation. Findings include: 1. A record review of the laboratory's temperature monitoring logs revealed for 6 of 13 months of operation the refrigerator that stores the urine specimens for the toxicology testing, lack of documentation of the temperatures from May 18 to October 19, 2021. 2. A phone interview on 10/19/2021 at approximately 11:47 am, the LD confirmed the laboratory did not document the refrigerator temperature each day of operation.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: . Based on observation and interview with the Laboratory Directory (LD), the laboratory stored expired calibration material in the laboratory refrigerator for 9 (February to October) of 9 months observed. Findings include: 1. An observation by the surveyor on 10/19/2021 at 9:45 am during a tour of the laboratory revealed the following expired calibration material stored in the refrigerator: a. DRI Tetrahydrocannabinol (THC) Urine Calibrator 50 ng/ml material - lot 73758925 expired 2/28/2021 and lot 73995868 expired 9/30/2021 b. DRI Multi-Drug Urine Calibrator 2 - lot 73955420 expired 5/31/2021 and lot 74013950 expired 7/31/2021 c. DRI Drugs of Abuse Low Calibrator - lot 73861352 expired 7/31/2021 2. A phone interview on 10/19/2021 with the LD at approximately 11:47 am confirmed calibration materials had exceeded the expiration date. ***Repeat Deficiency from 11 /25/2019 survey ***
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: . A. Based on record review, lack of documentation, and interview with the Laboratory Director (LD), the laboratory failed to perform and document the monthly eyewash maintenance for 2 months (September and October) of 12 months reviewed. Findings include: 1. A record review of the "Eye wash Monthly Log" revealed a lack of documentation for the following 2 months (September and October) of 12 months reviewed: a. September 2021 - lack of documentation b. October 2021 - lack of documentation 2. A phone interview on 10/19/2021 at approximately 11:47 am, the LD confirmed the eyewash monthly maintenance was not performed and documented. B. Based on record review, lack of documentation, and interview with the Laboratory Director (LD), the laboratory failed to perform and document the monthly Indiko Plus maintenance for 4 (June, July, September, and October 2021) of 12 months reviewed. Findings include: 1. Record review revealed for 4 (June, July, September, and October

	2021) of 12 months reviewed, the lack of documentation of the monthly maintenance for decontaminating all the reservoirs and tubing on the Indiko Plus toxicology analyzer. 2. A phone interview on 10/19/2021 at approximately 11:47 am, the LD confirmed the monthly maintenance was not performed and documented.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director (LD), the laboratory failed to document corrective action for improper temperature of refrigerator #2 that stores the toxicology reagents and calibration material for 12 days (July 24, 27, and 30; August 5, 10, and 24; September 1, 8, 16, and 29; October 12 and 14) of 12 days in 12 months reviewed. Findings include: 1. A record review of the "Refrigerator Temperature Log #2" revealed for 12 of 12 days in 12 months, the following temperature readings were above the "acceptable range 2 - 8 degrees C" and no corrective action was documented as follows: a. July 24, 2021 - temperature 9 b. July 27, 2021 - temperature 9 c. July 30, 2021 - temperature 9 d. August 5, 2021 - temperature 9 e. August 10, 2021 - temperature 10 f. August 24, 2021 - temperature 9 g. September 1, 2021 - temperature 9 h. September 8, 2021 - temperature 9 i. September 16, 2021 - temperature 9 j. September 29, 2021 - temperature 9 k. October 12, 2021 - temperature 9 l. October 14, 2021 - temperature 9 2. A phone interview on 10/19/2021 at approximately 11:47 am the LD confirmed that no corrective action was documented for the refrigerator temperatures out of the stated range.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director (LD), the laboratory failed to include the correct name of the laboratory where the toxicology testing was performed on the patient "Test Results" form for 11 (December 2020 to October 2021) of 11 months reviewed. Findings include: 1. A record review for 11 of 11 months of patient test results revealed for 14 patients the name of the testing facility (Well-Health Medical Associates) does not match the name on the CLIA Certificate (Belleville Health Care PC). 2. A phone interview on 10/19/2021 at approximately 11:47 am with the LD, he confirmed the testing facility name on the patient's final test report does not match the CLIA Certificate.

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 record review and interview with the Laboratory Director (LD), the laboratory failed to provide accurate reference intervals on the toxicology "Test Results" form for 11 (December 2020 - October 2021) of 11 months reviewed. Findings include; 1. A record review for 11 of 11 months of patient toxicology test results revealed the reference range of 0-0 for the qualitative toxicology testing. 2. During the phone interview on 10/19/2021 at approximately 11:47 am, the LD confirmed the reference range of 0-0 did not reflect the qualitative testing of a negative result.