Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D1066648	04/13/2018
Name of Provider or Supplier	**Street Address, City, State**	
Baltimore Health Care Pc	3350 Wilkens Avenue #307, Baltimore, MD	

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 review of laboratory records, interview with the office manager, and the testing person, the laboratory did not enrolled in CMS approved proficiency testing program for performing urine drug screens. Findings: On the day of the initial survey March 30, 2018 the laboratory was not enrolled in an approved proficiency testing program (PT) and the laboratory did not have written procedures for performing PT. The office manager stated that she was unsure if PT enrollment was performed. The laboratory did not have documentation of enrollment until April 13, 2018 that showed the laboratory submitted paperwork on April 4, 2018 for PT enrollment. The laboratory began patient testing in October 2017.
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 review of laboratory records, interview with the laboratory manager, and the testing person, the laboratory did not have policies and procedures for performing urine drug screens collection and processing. Findings: 1. The laboratory did not have written step by step instructions for the collection of urine specimens when performing drug screens. 2. The laboratory did not have written instructions for specimen labeling containers once urine specimens were collected. 3. The laboratory did not have written instructions for urine specimen processing after the collection of the patient specimen and stating how much specimen is needed to perform the test. 4. The testing person stated that she labels the urine specimen cuvettes with the patient name and line the cuvettes up on the analyzer before adding 2 ml's of specimen. 5. The laboratory did not have written instructions for urine specimen storage when testing can not be performed. 6. The laboratory did not have written instructions when urine specimens did not meet the laboratory's criteria of acceptability and needed recollection. 7. The "Quality Assurance/ Quality Management Plan" states that specimen preparation, storage, and stability are described in individual procedures for each test. This plan was made available at survey closing on April 13, 2018. 8. The "Quality Control Policy" states that the laboratory will provide instructions for collection, labeling, preservation, transportation of specimens. This plan was made available at survey closing on April 13, 2018. 9. The testing person and the laboratory manager confirmed that written step by step instruction for the collection and processing of urine dug screens was not available.
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 review of laboratory records, interview with the laboratory manager, and the testing person, the laboratory did not have a written procedure manual for performing urine drug screen testing reviewed and signed by the laboratory director. Findings: 1. On the day of the survey the laboratory did not have a written procedure manual that was approved by the laboratory director with step by step instructions for the daily operations of running the laboratory including performing urine drug screens, patient normal values, and patient critical values. 2. The testing person had a packet of procedures for daily start up of the analyzer, loading patient specimens on the analyzer, quality control, calibration of the analyzer, and maintenance procedures. 3. The testing person stated that she was not aware of a laboratory standard operation procedure manual. She was given a packet of procedures she follows for performing patient testing. 4. The testing person packets of procedures were not reviewed and signed by the laboratory director as being a part of the standard operation procedures. 5. The "Quality Assurance/Quality Management Plan" states that all polices and

	procedures have been authorized by the laboratory director prior to implementation and personnel has reviewed and read the policies. This plan was made available at survey closing on April 13, 2018.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of laboratory records, interview with the office manager, and the testing person, the laboratory did not have written step by step instructions for all areas of laboratory testing for the overall acceptability of performing urine drug screen testing. Findings: 1. The laboratory did not have procedures for documenting the name of the person performing patient testing. 2. The testing person stated that she was the only testing person right now. Review of patient testing from January and April 2018 did not show the name nor initials of the person performing the urine drug screen. The testing person stated that she was the only person performing patient testing since October 2017. 3. The laboratory did not have step by step procedures for retrieving previous performed QC form the laboratory computer database. The testing person stated that she sends QC to the laboratory director for review and he emails back. The testing person was unable to open the emails to show that QC was reviewed by the laboratory director prior to performing patient testing. 4. The laboratory did not have procedures for the storage of QC , calibration reagents, and the stability of the reagents. On the day of the survey the laboratory did not know the temperature range of QC and calibrators reagents were stored and the length of time reagents can be stored once opened. The "Quality Assurance/ Quality Management Plan" states that QC reagents storage and stability are described in individual procedures for each test. The "Quality Control Policy" states that reagents and materials will be labeled for identity monitored for proper storage and expiration. Both plans were made available at survey closing on April 13, 2018. 5. The laboratory did not have procedures for monitoring the refrigerator and room temperatures each day of patient testing and the acceptable range. On the day of the survey the laboratory was not documenting refrigerator and room temperatures. The testing person stated that she documents temperatures but was unable to open the previous temperature logs from October 2017 in the electronic record. 6. The laboratory did not have step by step procedures for

	trouble shooting when temperatures were out of range. 7. The laboratory did not have step by step instructions for sending urine drug screens out for reference laboratory testing and confirmation procedures when the urine screen tested positive for one or more of the specified drugs. 8. The "Quality Control Policy" states that the laboratory will provide instructions for collection, labeling, preservation, and transportation of specimens. This procedure was made available at survey closing on April 13, 2018 9. The laboratory did not have step by step safety procedures for laboratory personnel to follow in the event of an emergency such as chemical spills, fires, urine exposure, or electrical hazard. The "Quality Assurance/ Quality Management Plan" states that the laboratory reduces personnel exposure to blood borne pathogens through engineering and work practice. This procedure was made available at survey closing on April 13, 2018 10. The laboratory did not have material safety data sheets available for the laboratory reagents used when performing urine drug screens to inform personnel of the steps to take in the event of an emergency. The "Quality Assurance/ Quality Management Plan" states that all personnel receive annual training in hazardous waste procedures. This procedure was made available at survey closing on April 13, 2018. 11. The laboratory did not have any hazardous waste training documents available showing the initial training performed on laboratory personnel nor the procedures performed.
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 observation of the laboratory on March 30, 2018 at about 10:30 AM, interview with the laboratory manager, and the testing person, the laboratory did not document the refrigerator and room temperature each day of patient testing when performing urine drug screens. Findings: The laboratory did not have procedures for monitoring the refrigerator and room temperatures each day of patient testing and the acceptable range. On the day of the survey the laboratory was not documenting refrigerator and room temperatures. The testing person stated that she documents temperatures but was unable to open the previous temperature logs from October 2017 in the electronic record.
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 review of maintenance records, interview with the laboratory manager, and

	the testing person, the laboratory director did not review and sign maintenance records. Findings: 1. The laboratory director did not review and sign the analyzer daily cleaning and inspection log form November 2017 to March 2018. 2. The laboratory director did not review and sign the monthly cleaning, replacement log, and recommended replacement schedule from November 2017 to March 2018. 3. The testing person stated that she was unaware that the laboratory director needed to review and sign maintenance logs.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of laboratory records, interview with the laboratory manager, and the testing person, the laboratory did not have written procedures for performing calibration verification procedures nor did the laboratory document corrective action procedures when calibration verification failed to meet the laboratory's criteria of acceptability. Findings: 1. The laboratory did not have written step by step instructions for testing personnel to follow for performing calibration verification on the toxicology analyzer. 2. The laboratory did not have instructions for how to perform calibration verification, when to perform calibration verification, storage of verification material, and the amount of reagent to use for testing. 3. The laboratory did not document corrective action procedures on 3/1/18 when calibration verification precision failed and was out of range. 4. The testing person stated that she called the manufacturer and they walked her through steps to make corrections. 5. The testing person did not document corrective action procedures and the laboratory director was not informed of the error. 6. The testing person stated that she was not informed of the steps to follow for documentation of corrective action procedures. 7. The "Quality Control Policy" states that recalibrating may be needed, consult test procedure manual, notify the director, and document on the corrective action log. The policy was made available on the survey closing date of April 13, 2018.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the

	reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of laboratory documents, interview with the laboratory manager, and the testing person, the laboratory did not document corrective action procedures when calibration procedures did not met the laboratory's criteria of acceptability. Findings: 1. The laboratory failed calibration procedures for the cocaine analyte on 3/29/2018 and corrective action procedures were not documented. 2. The laboratory failed calibration procedures for the ethanol analyte on 3/2/2018 and corrective action procedures were not documented. 3. The laboratory failed calibration procedures for the MC5425 analyte on 6/6/2017 and corrective actions were not documented. 4. The "Quality Control Policy" states that recalibration may be needed, consult test procedure manual, notify the director, and document on the corrective action log. The policy was made available on the survey closing date of April 13, 2018.
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 review of laboratory records, interview with the office manager, and the testing person, the laboratory director failed to enrolled in CMS approved proficiency testing program for performing urine drug screens. Findings: Refer to D2000 On the day of the initial survey March 30, 2018 the laboratory was not enrolled in an approved proficiency testing program (PT) and the laboratory did not have written procedures for performing PT. The office manager stated that she was unsure if PT enrollment was performed. The laboratory did not have documentation of enrollment until April 13, 2018 that showed the laboratory submitted paperwork on April 4, 2018 for PT enrollment. The laboratory began patient testing in October 2017.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of laboratory records, interview with the laboratory manager, and the testing person, the laboratory director failed to establish and maintain the quality

	control (QC) programwhen performing toxicology testing. Findings: Refer to D5403 1. The laboratory director failed to have step by step written procedures for retrieving previous performed QC form the laboratory computer database. The testing person stated that she sends QC to the laboratory director for review and he emails back. The testing person was unable to open the emails to show that QC was reviewed by the laboratory prior to performing patient testing. 2. The laboratory director failed to have procedures for the storage of QC, calibration reagents, and the stability of the reagents. On the day of the survey the laboratory did not know the temperature range of QC and calibrators reagents were stored and the length of time reagents can be stored once opened. The "Quality Assurance/ Quality Management Plan" states that QC reagents storage and stability are described in individual procedures for each test. The "Quality Control Policy" states that reagents and materials will be labeled for identity monitored for proper storage and expiration. Both plans were made available at survey closing on April 13, 2018. 3. The laboratory director failed to perform the review of the Levy Jennings graphs. The "Quality Control Policy" states that QC and Levy Jennings will be reviewed monthly by the laboratory director and documented. This plan was made available at survey closing on April 13, 2018.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of laboratory records, interview with the laboratory manager, and the testing person, the laboratory director (LD) failed to establish and maintain quality assurance (QA) programs for performing toxicology testing. Findings: 1. The laboratory director failed to maintain and document QA procedures for the preanalytic, analytic, and postanalytic phases of performing laboratory testing. 2. The "Quality Assurance/ Quality Management Plan" states that the preanalytic indicators include patient identification, accuracy of orders, specimen identification/labeling, and specimen acceptability/rejection. This plan was made available at survey closing on April 13, 2018 and the laboratory director did not have written procedures for performing and documenting the preanalytic indicators. 3. The "Quality Assurance/ Quality Management Plan" states that the analytic indicators include specimen type and stability, calibration/calibration verification, quality control, and proficiency testing. The review of temperature records, maintenance records, corrective action procedures, training, and competency was not included in the plan indicators for review and documentation by the laboratory director. This plan was made available at survey closing on April 13, 2018 and the laboratory director did not have written procedures for performing and documenting the analytic indicators. 4. The "Quality Assurance/ Quality Management Plan" states that the postanalytic indicators include critical values, corrected/revised reports, report review by the LD/TP, and quality control reports/peer review. This plan was made available at survey closing on April 13, 2018 and the laboratory director did not have written procedures for performing and documenting the postanalytic indicators. 5. The "Quality Assurance/ Quality Management Plan" states that an internal audit is performed to ensure the adequacy of

	standard operating procedures. This plan was made available at survey closing on April 13, 2018
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on review of laboratory documents, interview with the laboratory manager, and the testing person, the laboratory director failed to ensure that corrective action procedures were documented when calibration procedures did not met the laboratory's criteria of acceptability. Findings: Refer to D5781 The laboratory director failed to ensure that corrective action procedures performed when calibration failed.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on review of laboratory records, interview with the laboratory manager, and the testing person, the laboratory director failed to establish written training and competency procedures for performing preanalytic, analytic, and postanalytic phase of toxicology testing. Findings: 1. The laboratory failed to have written step by step instructions for performing and documenting training and competency when testing urine drug screens. 2. The laboratory begin patient testing in October 2017. 3. The testing person stated that she begin working at the facility in May, 2017 and was trained by the company that manufactured the analyzer on May 5, 2017. 4. The laboratory manager stated that she did not know they needed written training and competency procedures for performing in house patient testing. 5. The testing person stated that she has documentation of the manufacturers training but was unable to locate on the day of the survey.
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 review of laboratory records, interview with the laboratory manager, and the testing person, the laboratory director failed to have a written procedure manual for performing urine drug screen testing reviewed and signed by the laboratory director. Findings: Refer to D5401 The laboratory director failed to have step by step written instructions that were approved and documented for laboratory staff to follow when performing toxicology testing.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: The laboratory director failed to have the duties and responsibilities for personnel involved with performing laboratory toxicology testing. Findings: 1. The laboratory director did not have the duties for the laboratory director, clinical consultant, technical consultant, nor the testing person. 2. The "Quality Assurance/ Quality Management Plan" states that duties and responsibilities are found in the job description for each position. 3. The laboratory manager stated that all job descriptions were at human resources.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on review of laboratory records, interview with the laboratory manager, and the testing person, the laboratory director acting as the technical consultant failed to ensure that calibration verification procedures meet the laboratory's criteria of

	acceptability. Findings: D5437 1. The technical consultant failed to ensure that corrective action procedures were documented on 3/1/18 when calibration verification precision failed and was out of range. 4. The testing person stated that she called the manufacturer and they walked her through steps to make corrections. 5. The testing person did not document corrective action procedures and the laboratory director was not informed of the error. 6. The testing person stated that she was not informed of the steps to follow for documentation of corrective action procedures. 7. The "Quality Control Policy" states that recalibrating may be needed, consult test procedure manual, notify the director, and document on the corrective action log. The policy was made available on the survey closing date of April 13, 2018.
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 review of laboratory documents, interview with the laboratory manager, and the testing person, the laboratory director acting as the technical consultant failed to complete semiannual competency procedures for the testing person performing toxicology testing. Findings: Refer to D6030 1. The laboratory begin testing patient urine drug screens in October 2017. 2. The testing person stated that she begin working at the facility in May, 2017 and was trained by the company that manufactured the analyzer on May 5, 2017. 3. The testing person stated she did not have any competency procedures performed after the initial training performed by the company On May 5, 2017.