Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 34D2083112	**(X3) Date Survey Completed** 08/15/2022
Name of Provider or Supplier Pathways To Life, Inc	**Street Address, City, State** 1015 Conference Drive, Greenville, NC	
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
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 review of 2019 American Association of Bioanalysts (AAB) and 2020, 2021, and 2022 American Proficiency Institute (API) proficiency testing (PT) records and interview with general supervisor (GS) 8/15/22, the laboratory failed to retain all records for at least two years from the date of the PT event. Findings: 1. Review of 2019 AAB PT records revealed the laboratory failed to retain graded results for 1 of 3 test events (Q2). During interview at approximately 2:20 p.m., the GS stated that when she first started working here, she was unable to access the AAB account set up by the previous TP. She stated she had to create a new account, so she should be able to print the 2019 Q2 graded results. 2. Review of 2020, 2021, and 2022 API PT records revealed the laboratory failed to retain the report form used to record PT results or documentation of online reporting for 5 of 5 test events (2020 1st and 2nd, 2021 1st and 2nd, and 2022 1st).
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)

	Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of laboratory procedure, review of laboratory records, review of quality assessment (QA) documentation and interview with GS 8/15/22, the laboratory failed to retain calibration records for the toxicology testing performed on the Diatron Pictus 500 for a period of approximately 2 years, 8/9/19 through 9/29/21. Findings: Review of laboratory procedure "Calibration and Calibration Verification (Linearity)" revealed "Calibrations will be documented in the designated log book.". Review of laboratory records revealed no documentation of calibration performance for a period of approximately 2 years, 8/9/19 through 9/29/21. Review of QA documentation revealed "Laboratory Quality Assessment Review" forms completed by the GS. The forms stated review of calibration data was performed and results were acceptable. They also indicated calibration documentation would be printed at a later time. There was no documentation the calibration records were printed. For example: a. QA review form for January, February and March 2019 states "Calibrations reviewed in analyzer software; most calibrations were printed & in calibration book. Verified calibrations were done on analyzer computer.". b. QA review form for October, November and December 2019 states "Calibrations reviewed on analyzer computer; will be printed @ later date.". c. QA review form for January, February and March 2020 states "Calibrations from 2020 were not printed due to calibrations only held for 20 runs on analyzer. Reviewed calibration on analyzer 4/20/20 - all ok.". d. QA review form for October, November and December 2020 states "Calibrations reviewed on analyzer; all ok cals performed @ least monthly when QC & patient samples processed - will print later.". e. QA review form for July, August and September 2021 states "Calibration records reviewed on analyzer; will print later - all ok...". Interview with GS at approximately 12:30 p.m. confirmed calibration documentation was not printed and retained from 8/9/19 through 9/29/21. She stated the analyzer only goes back 20 calibrations. She also stated she discovered the flash drive was missing in August of 2021 so she was unable to retrieve or print calibrations previously performed and she notified admin of this problem on August 19, 2021.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and review of personnel records 8/15/22, the laboratory failed to ensure procedures were followed for evaluation of testing personnel (TP) competency. Findings: Review of the laboratory's "Personnel Competency Assessment" procedure states "... Six months and annually Laboratory staff who conducts the pre-analytical, analytical, and post-analytical phases of testing will be monitored as it applies to their specific duties, at six months and annually, to assure that they are competent to perform test procedures, and/or

	report test results promptly and proficiently. The Competency Assessment form will be used to document the competency of the staff member. Any staff member found not to be competent in any area will be retrained in that specific area. ..." Review of the Competency Assessment form revealed the following methods of evaluation: "Direct observation of test performance", "Monitor test result recording & reporting", "Review of worksheets, QC, & Temp/hum records", "Instrument maintenance", "Assessment of test performance (PT/blind samples) records", "Assessment of problem-solving skills records". Review of personnel records revealed TP #1 (who also serves as general supervisor) was trained October-November 2018. Review of personnel records for TP #1 revealed technical competency evaluations performed 5 /30/19, 12/23/19, 12/28/20, and 12/23/21. The competency evaluations did not include documentation that the following required methods were utilized by the laboratory director to evaluate TP #1's competency: Direct observation of test performance, Assessment of test performance using proficiency samples or blind samples, and Assessment of problem solving skills.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of 2019 AAB and 2020, 2021, and 2022 API PT records and interview with the GS 8/15/22, the laboratory failed to review and evaluate all PT results received. 1. Review of 2019 AAB and 2020, 2021, and 2022 API PT records revealed the laboratory failed to document review and evaluation of graded results for 1 of 8 test events (2019 AAB Q3). There was no documentation of corrective action for the unacceptable creatinine result, and the results had not been signed and dated by the laboratory director. During interview at approximately 2:25 p.m., the GS stated the results were reviewed, but she was unsure why the results had not been signed.
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 the laboratory's policies and procedures and interview with the GS 8/15/22, the laboratory's procedure manual was not complete and current for the testing performed. Findings: 1. Review of the laboratory's procedure manual revealed the laboratory did not have a written procedure for reporting patient urine toxicology test results in the electronic medical records system. During interview at approximately 12:15 p.m., the GS stated she does not enter results in patient charts. She stated she gives the results to front desk personnel and they upload them into patient charts. 2. Review of the laboratory's procedure manual revealed the laboratory did not have a written procedure for interpreting urine toxicology test results (positive /negative, present/absent, etc.).
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 review of laboratory procedures, review of performance verification records and interview with GS 8/15/22, the laboratory failed to verify specimen stability before testing patient samples in November of 2018, a period of approximately 3 years and 8 months. The laboratory also failed to verify performance specifications for the Diatron Pictus 500 toxicology analyzer when the laboratory moved to a new location in May of 2020, a period of approximately 2 years and 3 months. 1. The laboratory failed to verify specimen stability before testing patient samples. Findings: Review of laboratory procedure "Specimen Collection and Processing-Pictus 500" revealed "Use fresh urine specimens for the test. If the test can't be analyzed immediately, it may be stored in the refrigerator (2-8 degrees Celcius (C)) for up to 7 days....An aliquot of the sample will be frozen (-20 degrees C) for 30 days just in case there is a discrepancy between the screening results and the confirmation results.". Review of performance verification records revealed no documentation of specimen stability verifications. Interview with GS at approximately 10:00 a.m. confirmed the laboratory had no documentation of specimen stability verifications. She stated she thought it was completed but it might have been lost when the laboratory moved. She also stated that samples are ran once a week and sometimes once a month and the samples are frozen until testing can take place. 2. The laboratory failed to verify performance specifications for the Diatron Pictus 500 analyzer when it was moved to a new location in May of 2020. Findings: Review of performance verification records revealed no documentation of a performance verification for the Diatron Pictus 500 analyzer when it was moved to a new location in May of 2020. Interview with GS at approximately 10:00 a.m. confirmed the laboratory had no documentation of a

	performance verification when the Diatron Pictus was moved to the new location. She stated she was told by service that all she had to do was run controls and calibrators which she did. GS was unable to produce the records indicating this was performed.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of laboratory test list, review of patient test report, review of laboratory procedure, review of calibration records and review of calibration verification records 8/15/22, the laboratory failed to perform calibration verifications using the criteria established by the laboratory for potential of hydrogen (PH) and creatinine (CREA) at least every 6 months since testing began in October of 2018, a period of approximately 3 years and 10 months. Findings: Review of laboratory test list and random patient test report, "Patient Id 100163", revealed the laboratory performs and reports quantitative test results for PH and CREA. Review of calibration records revealed the laboratory performs a two-point calibration for PH and CREA at least once a month. Review of laboratory procedure "Calibration and Calibration Verification (Linearity)" revealed "Calibration Verifications will be performed every 6 months when less than 3 calibrators are used to calibrate the analyte...The following calibration verification materials will be used for the following analytes...Urine Creatinine: Thermo Scientific DRI* Creatinine Detect* 2.0 milligrams per deciliter (mg/dL) Calibrator,...20 mg/dL Calibrator,...7.5 mg/dL Control and...23.0 mg/dL Control....pH...ph-Detect* 3.0 Calibrator...11.0 Calibrator...3.6 Control and ...11.5 Control.". Review of calibration verification records revealed every 6 months, 3 random quality control (QC) results were chosen from 2 levels of previously ran QC results. The results were averaged for each level and a "zero" value, which was not tested on the analyzer, was used as a third level to document the performance of a calibration verification for PH and CREA.