Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2165210	05/22/2025
Name of Provider or Supplier	**Street Address, City, State**	
Campbell Health Solutions	16650 S Harlem Ave, Tinley Park, IL	

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
D5022	TOXICOLOGY CFR(s): 493.1213 If the laboratory provides services in the subspecialty of Toxicology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on direct observation, review of laboratory policies and procedures, laboratory records, patient test reports, manufacturer's package insert, lack of documentation, and interviews with the technical consultant (TC) and testing personnel (TP) #1; the laboratory failed to follow written policies and procedures to assess TC competency for one of one TC (See D5209), failed to perform calibration verifications every six months for nine of nine applicable urine toxicology analytes performed on the Indiko Plus analyzer (See D5439), failed to perform corrective actions for out of range humidity readings for 41 of 67 testing dates reviewed (See D5781), failed to maintain a record system that included accurate date and time of specimen receipt into the laboratory and accurate date and time of all specimen testing (See D5787), failed to include the address of the laboratory that performed the urine toxicology testing on three of five patient test reports reviewed (See D5805), and failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems in patient reporting for five of five patient urine toxicology testing dates reviewed from 2023 through the date of survey, 05/22/2025 (See D5891).
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 laboratory policies and procedures, laboratory records, lack of documentation, and interview with the technical consultant (TC); the laboratory failed to follow written policies and procedures to assess TC competency for one of one TC in the subspecialty of urine toxicology. Findings include: 1. Review of laboratory policies and procedure revealed the procedure titled, "Competency Assessment", which stated the following: i. Under "Technical Consultant": "The following parameters will be reviewed to assess competency of Technical Consultant: 1. Is the TC/TS [Technical Supervisor] available to provide consultation to the laboratory? 2. Does the TC/TS select test methods that are appropriate for the laboratory's patient population? 3. Does the TC/TS assure that performance specifications are established or verified for necessary tests? 4. Does the TC/TS ensure that the laboratory is enrolled and participating in an approved HHS [Health and Human Services] approved proficiency testing [PT] program for each test requiring PT? 5. How well does the laboratory perform PT? Are the appropriate staff reviews conducted when PT results are received from the provider? 6. Does the TC/TS ensure that a Quality Control (QC) program is in effect and is adequate for the laboratory's testing performance? 7. Does the TC/TS resolve technical problems and insure remedial actions are taken whenever there is a test system failure? 8. Does the TC/TS ensure that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly? 9. Does the TC/TS identify training needs and assure that each individual performing tests receives regular in-service training and education appropriate for the tests they are performing? 10. Does the TC/TS evaluate the competency of the testing personnel and assure that all staff members maintain their competency to perform tests accurately, report results promptly, accurately and proficiently? 11. Does the TC/TS use the following techniques, as well as any additional techniques determined by the laboratory to be appropriate for evaluating the competency of the testing personnel?" ii. Under "How often should it be done?": "Evaluating and documenting competency of testing personnel (TP) [and the] technical consultant ....will be done at least semiannually during the first year (initial, 6 month and annual). Thereafter, competency assessment for TP [and] TC ....must be performed at least annually." 2. Review of laboratory competency assessment records revealed the laboratory failed to assess TC competency for one of one TC. 3. Interview with the TC on 05/22/2025, at 09:55 am, confirmed the laboratory failed to follow written policies and procedures to assess TC competency for one of one TC in the subspecialty of urine toxicology.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (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 policies and procedures, laboratory records, lack of documentation, and interviews with the technical consultant (TC) and testing personnel (TP) #1; the laboratory failed to perform calibration verifications every six months for nine of nine applicable urine toxicology analytes performed on the Indiko Plus analyzer from 2023 through the date of survey, 05/22/2025. Findings include: 1. Review of laboratory policies and procedures revealed the policy titled, "Quality Assessment Plan", which stated, under "Calibration and Calibration Verification", "We perform calibration and calibration verification procedures following the manufacturer's instructions at least every six months ...." 2. Review of laboratory calibration records revealed the following urine toxicology analytes performed on the Indiko Plus analyzer (Serial Number: 864000092388) contained only two-point calibrations and therefore require calibration verification every six months: a. 6-Acetylmorphine [Heroin] b. Amphetamine c. Benzodiazepine d. Cocaine e. Methadone Metabolite f. Hydrocodone g. Opiate h. Oxycodone i. Creatinine 3. Review of laboratory records revealed a lack of calibration verification documentation for nine of nine applicable urine toxicology analytes from 2023 through the date of survey, 05/22/2025. 4. Interviews with the TC and TP #1 on 05/22/2025, at 09:23 am, confirmed the laboratory failed to perform calibration verifications every six months for nine of nine applicable urine toxicology analytes performed on the Indiko Plus analyzer from 2023 through the date of survey, 05/22/2025.
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 direct observation, review of manufacturer's package inserts, laboratory policies and procedures, laboratory records, lack of documentation, and interviews with the technical consultant and testing personnel (TP) #1; the laboratory failed to perform corrective actions for out of range humidity readings for 41 of 67 testing dates reviewed, affecting patients in the subspecialty of toxicology from 2023 through the date of survey, 05/22/2025. Findings include: 1. Upon a tour of the laboratory on 05/22/2025, at 08:54 am, surveyors observed urine toxicology testing performed on the Indiko Plus analyzer (Serial Number: 864000092388). 2. Review of manufacturer's package insert for the Indiko Plus analyzer revealed the following

	system specifications under, "Environmental Conditions", "humidity 40 - 80%". 3. Review of laboratory policies and procedures revealed the policy titled, "Quality Assessment Plan", which stated, under "Corrective Actions", "We have policies and procedures to follow when laboratory systems do not meet our performance specifications, such as when ....improper storage temperatures occur ...." 4. Review of laboratory records revealed the log titled, "Temperature and Humidity Log", which indicated the acceptable range of humidity to be "40 - 80%". 5. Review of laboratory records revealed 41 of 67 testing dates reviewed were below the minimum 40% humidity for acceptable analyzer performance with no corrective action documented. Date: Humidity: 06/08/2023 37% 06/13/2023 39% 06/14/2023 37% 06/15/2023 37% 06/20/2023 37% 04/02/2024 32% 04/04/2024 34% 04/05/2024 35% 04/16/2024 32% 04/18/2024 34% 04/19/2024 35% 04/23/2024 35% 04/25/2024 34% 04/26/2024 35% 10/16/2024 36% 10/17/2024 35% 10/22/2024 35% 10/25/2024 34% 10/29/2024 37% 10/31/2024 36% 11/01/2024 34% 11/02/2024 37% 11/09/2024 38% 11/13/2024 35% 11/14/2024 38% 11/21/2024 37% 11/22/2024 38% 11/28/2024 33% 11/29/2024 35% 03/04/2025 36% 03/06/2025 34% 03/07/2025 34% 03/11/2025 35% 03/13/2025 32% 03/14/2025 30% 03/18/2025 30% 03/20/2025 35% 03/21/2025 34% 03/25/2025 34% 03/27/2025 33% 03/28/2025 32% 6. Interviews with the TC and TP #1 on 05/22 /2025, at 12:47 pm, confirmed the laboratory failed to perform corrective actions for out of range humidity readings for 41 of 67 dates reviewed from 2023 through the date of survey, 05/22/2025.
D5787	TEST RECORDS CFR(s): 493.1283(a) (a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, and interviews with the technical consultant (TC) and testing personnel (TP) #1; the laboratory failed to maintain a record system that included accurate date and time of specimen receipt into the laboratory and accurate date and time of all specimen testing for three of five urine toxicology patients reviewed from 2023 through the date of survey, 05/22/2025. Findings include: 1. Review of laboratory policies and procedures revealed the policy titled, "Quality Assessment Plan", which stated, under "Test Records", "We maintain test records that demonstrate positive identification of the specimen and include the date and time of specimen receipt into the laboratory ....and the records and dates of all specimen testing ...." 2. Review of laboratory policies and procedures revealed the procedure titled, "Post Analytic Procedure", which stated, under "Recording Patient Test Results", "Test reports should include: ..... -date and time the specimen was collected -date and time the specimen was tested" 3. Review of patient test reports revealed the laboratory failed to maintain a record system that included accurate date and time of specimen receipt into the laboratory and accurate date and time of all specimen testing for three of five urine toxicology patients reviewed. a. Medical Record Number (MRN): 5747066 Collection Date and Time: 04 /09/2024 - 03:03 pm Reported Date and Time: 04/09/2024 - 03:03 pm b. MRN: 6498578 Collection Date and Time: 10/24/2024 - 03:11 pm Reported Date and Time:

	10/24/2024 - 03:11 pm c. MRN: 8094287 Collection Date and Time: 03/18/2025 - 02: 37 pm Reported Date and Time: 03/18/2025 - 02:37 pm 4. Interviews with the TC and TP #1 on 05/22/2025, at 12:47 pm, confirmed the laboratory failed to maintain a record system that included accurate date and time of specimen receipt into the laboratory and accurate date and time of all specimen testing for three of five urine toxicology patients reviewed from 2023 through the date of survey, 05/22/2025.
D5805	TEST REPORT CFR(s): 493.1291(c) (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 review of laboratory policies and procedures, patient test reports, lack of documentation, and interviews with the technical consultant (TC) and testing personnel (TP) #1; the laboratory failed to include the address of the laboratory that performed the urine toxicology testing on three of five patient test reports reviewed. Findings include: 1. Review of laboratory policies and procedures revealed the policy titled, "Quality Assessment Plan", which stated, under "Test Reports and Reference Lab Reports", "We verify that reports have all essential information, including: positive patient identification, name and address of the testing lab, report date, units of measurement or interpretation of results, reference intervals." 2. Review of laboratory policies and procedures revealed the procedure titled, "Post Analytic Procedure", which stated, under "Recording Patient Test Results", "Test reports should include: - name and address of the testing site" 3. Review of three of five urine toxicology patients test reports revealed the laboratory failed to indicate the address of the performing laboratory on the final reports. Date: Medical Record #: 04/09/2024 5747066 10/24/2024 6498578 03/18/2025 8094287 4. Interviews with the TC and TP #1 on 05/22/2025, at 11:17 am, confirmed the laboratory failed to include the address of the laboratory that performed the urine toxicology testing on three of five patient test reports reviewed.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, lack of documentation, and interview the technical consultant; the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems in patient reporting for five of five patient urine toxicology testing

	dates reviewed from 2023 through the date of survey, 05/22/2025. Findings include: 1. Review of laboratory policies and procedures revealed the policy titled, "Quality Assessment Plan", which stated, under "Test Reports and Reference Lab Reports", "Test reports from our laboratory are reviewed for accuracy and turnaround times. This review includes: accurate transcription or transferal of results and the accuracy of results from calculated data." 2. Review of laboratory records revealed the monthly quality assurance reviewed failed to monitor test reports for accuracy in transcription /transferal of results and the accuracy of results of calculated interpretations from 2023 through the date of survey, 05/22/2025. 3. Interview with the TC on 05/22/2025, at 11:16 am, confirmed the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems in patient reporting for five of five patient urine toxicology testing dates reviewed.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on direct observation, review of laboratory policies and procedures, laboratory records, patient test reports, manufacturer's package inserts, lack of documentation, and interviews with the technical consultant (TC) and testing personnel (TP) #1; the laboratory director failed to ensure that quality assessment programs are maintained to assure the quality of laboratory services (See D6020), failed to ensure calibration verifications were performed every six months for nine of nine applicable urine toxicology analytes performed on the Indiko Plus analyzer (See D6023), failed to ensure corrective action are taken and documented whenever deviations from established performance characteristics are identified (See D6024), and failed to ensure reports of test results include pertinent information required for interpretation (See D6026).
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, lack of documentation, and interview the technical consultant; the laboratory director failed to ensure the quality assurance program was established and maintained to assure accuracy in transcription/transferal of results and the accuracy of results of calculated interpretations from 2023 through the date of survey, 05/22/2025 (See D5891).
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical

	performance for each test system; This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, lack of documentation, and interviews with the technical consultant (TC) and testing personnel (TP) #1; the laboratory director failed to ensure calibration verifications were performed every six months for nine of nine applicable urine toxicology analytes performed on the Indiko Plus analyzer (See D5439).
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratorys established performance specifications are identified, and that patient test results are reported only when the system is functioning properly; This STANDARD is not met as evidenced by: Based on direct observation, review of manufacturer's package inserts, laboratory policies and procedures, laboratory records, lack of documentation, and interviews with the technical consultant and testing personnel (TP) #1; the laboratory director failed to ensure corrective actions were performed for out of range humidity readings for 41 of 67 testing dates reviewed, affecting patients in the subspecialty of toxicology from 2023 through the date of survey, 05/22/2025 (See D5781).
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) (e)(8) Ensure that reports of test results include pertinent information required for interpretation; This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, lack of documentation, and interviews with the technical consultant (TC) and testing personnel (TP) #1; the laboratory director failed to maintain a record system that included accurate date and time of specimen receipt into the laboratory and accurate date and time of all specimen testing for three of five urine toxicology patients reviewed (See D5787) and failed to ensure final patient laboratory reports included the address of the laboratory that performed the urine toxicology testing on three of five patient test reports reviewed from 2023 through the date of survey, 05/22/2025 (See D5805).