

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2165210	(X3) Date Survey Completed 02/10/2022
Name of Provider or Supplier Campbell Health Solutions	Street Address, City, State 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
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to establish written policies and procedures for specimen processing, accessioning, and referral for eight out of eight patients. Findings include: 1. The laboratory's pre-analytic, analytic, and post-analytic policies, procedures, and patient final reports were reviewed. 2. The laboratory performed urine Toxicology testing for the doctors' patients in the facility. 3. On February 10, 2022, at 11:50 AM during a tour of the laboratory, Staff-AT stated the following: *The patients' urine specimens are collected from the doctors' offices by the testing personnel (TP) or retrieved from the laboratory's refrigerator. *To prepare for testing, the specimens are given a laboratory accession number. *The patients' accession numbers are manually entered into the toxicology analyzer and then tested. *This process was performed for eight out of eight patients' final report reviewed. 4. On February 10, 2022, at 12:20 PM during the patient look-back review, Staff-AT stated the following: *The patients' urine toxicology reports were distributed to the submitting doctors by the TP. *Later (time span varies), the TP collects the patients' final reports. If the doctor wanted the results confirmed by further testing (referred to another laboratory); they would mark "RTC" which means 'return for confirmation'. The TP completes the referring laboratory's requisition and submits the specimen(s). *If not marked 'RTC', the TP scans the final report into the doctor's electronic medical record (EMR) for the patient. *This process was performed for two</p>

	<p>out of two patients' final report reviewed 5. Review of the laboratory's policies and procedures revealed the processes described in findings #3 and #4 had not been included in their manuals. 6. On February 10, 2022, at 1:35 PM, the Staff-AT confirmed the above findings.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory director (LD) failed to employ personnel who are competent to provide technical oversight and clinical consultation responsibilities (D6004) to ensure test procedures are performed, and results recorded and reported accurately, and proficiently, affecting 5355 patients tests.</p>
<p>D6004</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b)</p> <p>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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappropriates performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director (LD) failed to ensure the employment of personnel who are competent to perform the responsibilities of technical consultant (TC) and clinical consultant (CC), affecting 5355 patients' tests. Findings: 1. The Laboratory Personnel Report (CMS-209) and the LD statement sent on 02/14/2022 were reviewed. 2. The CMS-209 received on the day of survey failed to list a TC and CC. 3. A statement signed by the LD and submitted on 02/14/2022, declares that the laboratory has been without a CC and TC since March of 2021. See D6033, D6034, D6056 and D6057. 4. 5,355 patients' tests were performed during the period of April 1, 2022 through February 10, 2022. 5. On February 10, 2022, at 1:35 PM, the Staff-AT confirmed the above findings.</p>
<p>D6033</p>	<p>TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409</p> <p>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.</p>

This CONDITION is not met as evidenced by:
REPEAT CONDITION Based on record review and interview, the laboratory failed to have a technical consultant (TC) who meets the qualification requirements and provide technical oversight (D6034) for testing performed in the subspecialty of Toxicology, affecting 5,355 patients' tests.

D6034

TECHNICAL CONSULTANT QUALIFICATIONS
CFR(s): 493.1411

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section.

This STANDARD is not met as evidenced by:
Based on record review and interview, the laboratory failed to employ a technical consultant (TC) who qualified by education and experience to provide technical consultation for the Urine Toxicology testing performed in the laboratory, affecting 5,355 patients tests. Findings: 1. The Laboratory Personnel Report (CMS-209), the LD statement sent on 02/14/2022, and quality control (QC) documents were reviewed. 2. A statement signed by the LD and submitted on 02/14/2022, declares that the laboratory has been without a TC since March of 2021. 3. The TC responsibilities are the following: *Providing technical and scientific oversight of the laboratory. *Selecting of test methodology appropriate for the clinical use of the test results; *Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered; *Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; *Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory ' s established performance specifications; *Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly; *Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; *Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. 3. Review of the QC records revealed the laboratory failed to ensure the TC responsibilities were performed in the laboratory after March 2021. 4. 5,355 patients' tests were performed during the period of April 1, 2021 through February 10, 2022. 5. On February 10, 2022, at 1:35 PM, the Staff-AT confirmed the above findings.

D6056

CLINICAL CONSULTANT
CFR(s): 493.1415

The laboratory must have a clinical consultant who meets the qualification requirements of 493.1417 of this part and provides clinical consultation in accordance with 493.1419 of this part.

This CONDITION is not met as evidenced by:
Based on record review and interview, the laboratory failed to have an employee who meets the qualification requirements and provide clinical consultation (CC) for the Urine Toxicology performed (D6057), affecting 5,355 patients' tests.

D6057

CLINICAL CONSULTANT QUALIFICATIONS
CFR(s): 493.1417

The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493.1405(b)(1), (2), or (3)(i); or (b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located.

This STANDARD is not met as evidenced by:
Based on record review and interview, the laboratory failed to employ a clinical consultant (CC) for the Urine Toxicology testing performed in the laboratory, affecting 5,355 patients' tests. Findings: 1. The Laboratory Personnel Report (CMS 209) and the LD statement sent on 02/14/2022 were reviewed. 2. The CMS-209 received on the day of survey failed to list a CC. 3. The CC responsibilities are the following: *Consultation regarding the appropriateness of the testing ordered and interpretation of test results. *Be available to provide clinical consultation to the laboratory's clients; *Be available to assist the laboratory's clients in ensuring that appropriate tests are ordered to meet the clinical expectations; *Ensure that reports of test results include pertinent information required for specific patient interpretation; and *Ensure that consultation is available and communicated to the laboratory ' s clients on matters related to the quality of the test results reported and their interpretation concerning specific patient conditions. 4. A statement signed by the LD and submitted on 02/14/2022, declares that the laboratory has been without a CC and TC since March of 2021. 5. 5,355 patients' test were performed during the period of April 1, 2021 through February 10, 2022. 6. On February 10, 2022, at 1:35 PM, the Staff-AT confirmed the above findings.