

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D1100344	(X3) Date Survey Completed 10/16/2019
Name of Provider or Supplier Confidential Care	Street Address, City, State 1650 45th St Suite 2a, Munster, IN	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on document review and interview, the laboratory failed to follow written policies and procedures to assess the competency of one of one Testing Personnel (SP1) and one of one General Supervisor (SP1). Findings included: 1. Review of "Laboratory Personnel Report (CLIA)" Form (CMS-209), signed by the laboratory director on 10-11-2019, indicated SP1 was the laboratory's only Testing Person. SP1 was also the laboratory's only General Supervisor and only Technical Supervisor. 2. Review of policies and procedures indicated the following: a. A policy/procedure titled: "Leadership Responsibilities," reference number 7009, approved by the Laboratory Director on 1-17-2019, read: "Responsibilities of the Clinical Laboratory Director shall include...Determining the competency and qualifications of each staff member and which procedures/tests staff may perform..." b. A policy/procedure titled: "Laboratory Staff Competency," reference number 9002, approved by the Laboratory Director on 1-17-2019, indicated SP1 "shall assess staff competence." The policy /procedure read: "Competencies (sic) assessments shall include the following...Direct observations of routine patient test performance...Direct observation of performance of instrument maintenance function checks and calibration..." 3. Review of competency documentation for SP1, hire date May, 2015, indicated the following: a. A document titled: "Technologist/Scientist Competency Assessment LC-MS/MS - System" indicated an annual competency assessment was performed on SP1 on 6-10-2019. For each item on the competency assessment check sheet, a check mark was placed in the column titled: "Pass." There was no date or initials placed in the column titled: "Assessor initials/date." On the last page of the assessment, SP1 signed the</p>

assessment form in the box titled: "Employee Signature," and dated the form "6/10/19." The Laboratory Director signed the last page of the assessment form in the box titled; "Assessor Signature," and dated the form "9/8/2019." b. A document titled: "Technologist/Scientist Competency Assessment LC-MS/MS - System," indicated an annual competency assessment was performed on SP1 on 7-17-2018. For each item on the competency assessment check sheet, a check mark was placed in the column titled: "Pass." SP1's initials and "7/17/18" was placed in the column titled: "Assessor initials/date" for each item on the check sheet. On the last page of the assessment, SP1 signed the assessment form in the box titled: "Employee Signature," and dated the form "6/7/2018." The Laboratory Director signed the last page of the assessment form in the box titled: "Assessor Signature," and dated the form "7/28/2018." c. A document titled: "Competency Assessment," for the position of "General Supervisor," indicated SP1 had a competency assessment performed for the Liquid Chromatography Mass Spectrometry (LC-MS) on 7-1-2019 and a competency assessment performed on the Siemen's Viva E analyzer on 6-28-2019. SP1's name was printed on the last page of the competency assessment form in the box titled: "Reviewer's Name" and SP1's signature was in the box titled: "Reviewer's Signature." The Laboratory Director's signature was not on the competency form. d. A document titled: "Competency Assessment," for the position of "General Supervisor," indicate SP1 had a competency assessment performed for the LCMS on 7-12-2018 and a competency assessment performed on the Siemen's Viva E analyzer on 7-5-2018. SP1's name was printed on the last page of the competency assessment form in the box titled: "Reviewer's Name" and SP1's signature was in the box titled: "Reviewer's Signature." The Laboratory Director's signature was not on the competency form. 4. Review of patient records indicated the following: a. SP1 performed patient testing on the LCMS for patients #1 through #10 on 8-14-2019. b. SP1 performed patient testing on the Siemen's Viva E analyzer for patients #1 through #10 on 8-15-2019. 5. In interview on 10-16-2019 at 1:45 PM, SP1 indicated they were the only testing personnel, general supervisor, and technical supervisor. On the same date at 3:02 PM, SP1 indicated they performed their own competency assessment and marked "Pass" on the "Technologist/Scientist Competency Assessment LC-MS/MS - System," check sheet to indicate they knew how to perform the test. SP1 indicated the Laboratory Director did not directly observe them performing patient testing, analyzer maintenance, function checks, and calibration as part of the competency assessment. SP1 further indicated the Laboratory Director counter signed the "Technologist /Scientist Competency Assessment LC-MS/MS - System," check sheet on the next date the Laboratory Director was at the laboratory, but did not perform the competency assessment. SP1 also indicated the Laboratory Director did not perform the competency assessment on the Siemen's Viva E analyzer.