

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0896693	(X3) Date Survey Completed 02/14/2019
Name of Provider or Supplier Compunet Clinical Laboratories Llc	Street Address, City, State 3120 Governor'S Place Blvd, Kettering, OH	
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 record review, and an interview with Technical Supervisor (TS), the laboratory failed to follow their written policy and procedure to assess competency of the TS and General Supervisor (GS), as specified in the personnel requirements in subpart M, for two out of two Competency Assessments for 2017 and 2018. Findings Include: 1. Review of the laboratory's "Technical Employee Competency Assessment" policy and procedure found the following statement: "... personnel acting as clinical consultants, technical consultants, technical supervisors and/or general supervisors are required to have a competency assessment based on their federal regulatory responsibilities." 2. Review of the laboratory's CMS-209 Personnel Report form found one person serving as both TS and GS. Furthermore, the CMS-209 Personnel report form, approved and signed by the lab director on 2/6/19, indicated that the TS and GS did not perform Testing Personnel (TP) duties. 3. Review of the laboratory's Competency Assessment documentation found the lab failed to assess the TS and GS for competency based on the federal regulatory responsibilities, using only the competency assessment form for TPs. 4. An interview with the TS, on 12/14/19 at 10:30 am, confirmed that the competency assessments forms used for the TS and GS were for TPs.</p>
D5807	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>Pertinent "reference intervals" or "normal" values, as determined by the laboratory</p>

performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:

Based on record review and an interview, the laboratory failed to report the correct reference interval for the lymphocyte percentage, for fifteen out of fifteen patients, as determined by the laboratory and approved by the Laboratory Director. Findings Include: 1. Review of the laboratory's established reference ranges listed the lymphocyte percentage reference range: "18-47%" 2. Review of fifteen of the laboratory's patient test reports from 2018, found the following reported reference interval for the lymphocyte percentage: "14-51%" 3. An interview with Technical Supervisor, on 2/14/19 at 11:10 am, confirmed that the lab failed to report the correct reference interval for the lymphocyte percentage on the fifteen out of fifteen reviewed patient test reports.

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for 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; (8) 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.

This STANDARD is not met as evidenced by:

Based on record review and an interview with Technical Supervisor (TS), the TS failed to evaluate the competency of testing personnel, in fifteen out of twenty competency assessments in 2017 and 2018, to assure that the staff maintain their competency to perform test procedures and report test results promptly, accurately, and proficiently. Findings Include: 1. Review of the laboratory's "Technical Employee Competency Assessment" policy and procedure found the following statement: "The following include the minimum qualifications for assessors: High complexity testing: Section director (technical supervisor) or individual meeting general supervisor qualification." 2. Review of the laboratory's delegation form for competency assessment found the following statement, signed by the TS on 1/22/18 and 1/2/19: "... have completed competency training and will train all technical staff along with sign off on initial, 6 month and yearly competency training." 3. Review of the laboratory's competency documentation from 2017 and 2018 found that the TS failed to perform the assessment for fifteen out of twenty Testing Personnel (TP) competency assessments. TP #4 assessed for competency by the manager from another site and TP #3 for 2017 and 2018; TP #7 assessed for competency by the phlebotomy supervisor for 2017 and 2018; TP #5 assessed for competency by TP #3 twice in 2018; TP #6 assessed for competency by TP #3 and the phlebotomy supervisor 3 times in 2018. 4. An interview with the TS, on 2/14/19 at 10:45 am, confirmed that 15 out of 20 competency assessments were conducted by individuals not listed on the CMS-209 as a TS or General Supervisor (GS).