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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 36D0685582 | (X3) Date Survey Completed 04/09/2018 |
| Name of Provider or Supplier Public Health-Dayton & Montgomery | Street Address, City, State 117 South Main Street, Dayton, 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 |
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| D5891 | <p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview with Testing Personnel (TP), the laboratory failed to establish and follow written policies and procedures and document all assessment activities of the ongoing mechanism to monitor, assess, and correct problems identified in the postanalytic systems. Findings Include: 1. Review of the laboratory's "Dayton & Montgomery County Policy and Procedures" manual provided on the date of inspection found no mention of general laboratory post analytic quality assessment. 2. The Surveyor requested the laboratory's post analytic quality assessment policy and procedure to include the general laboratory systems and 2016, 2017 and 2018 post analytic general laboratory systems quality assessment documentation from TP#2. TP#2 confirmed the laboratory did not have any post analytic quality assessment policy and procedures established, did not document any post analytic quality assessment activities, and was unable to provide the requested documentation. The interview occurred on 04/09/2018 at 12:00 PM.</p> |
| D6046 | <p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(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.</p> |

This STANDARD is not met as evidenced by:

Based on review of the laboratory's standard operating guidelines, competency assessment documentation, and an interview with the Technical Consultant (TC), the TC failed to evaluate and document the competency, and assure Testing Personnel (TP) maintained their competency to perform moderately complex testing procedures and report test results promptly, accurately, and proficiently. Findings Include: 1. Review of the laboratories standard operating guidelines titled "Public Health-Dayton & Montgomery County "Multiple Divisions" Standard Operating Guidelines for PHDMC Laboratory Competency Assessment" revealed the following statement: "Procedure: 2. Testing is to be performed under the following circumstances: D. Annually for all testing staff 3. The Technical Consultant will be responsible for directly observing Competency Assessment of personnel who perform moderate complexity testing." 2. Review of the laboratory's competency assessment documentation for TP#2 and TP#3, found no 2016 records for TP#2 and TP#3 and no 2017 records for TP#3 as required. 3. The TC confirmed that the laboratory did not assess the competency of TP#2 and TP#3, as required, and was unable to provide the requested documentation on the date of the inspection. The interviews occurred on 04/09/2018 at 11:06 AM.