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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 36D2026993 | (X3) Date Survey Completed 11/13/2018 |
| Name of Provider or Supplier Kettering Health Huber Heights | Street Address, City, State 8701 Old Troy Pike, Huber Heights, 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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| 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, the laboratory failed to follow written policies and procedures to assess and document the competency of the Technical Consultants based on the responsibilities of the position. All patients tested at this laboratory have the potential to be affected. Findings Include: 1. Review of policies and procedures, on 11/13/18 at 9:04 am, found no mention of assessing the competency of the Technical Consultants based on the responsibility of that position. 2. Review of the laboratory's competency documentation, on 11/13/18 at 9:12 am, found no completed competency assessment for the Technical Consultants based on responsibilities of that position. 3. An interview with Technical Consultant #2, on 11/13/18 at 9:37 am, confirmed that no competency assessment was performed for the Technical Consultants based on responsibilities of that position.</p> |
| D5807 | <p>TEST REPORT CFR(s): 493.1291(d)</p> <p>Pertinent "reference intervals" or "normal" values, as determined by the laboratory 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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview, the laboratory failed to report the correct</p> |

reference interval for the partial pressure of oxygen (P02), for three out of three 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 P02 reference range: "P02 80-100 mmHg" 2. Review of three of the laboratory's patient test reports from 2018, found the following reported reference interval: Patient #1: "P02 45.8 mmHg (75-100 mmHg)" Patient #2: "P02 40.2 mmHg (75-100 mmHg)" Patient #3: "P02 50.3 mmHg (75-100 mmHg)." 3. An interview with Technical Consultant (TC) #2, on 11/13/18 at 10:14 am, confirmed that the lab failed to report the correct reference interval for the P02 on patient test report.