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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 19D2072678 | (X3) Date Survey Completed 03/10/2020 |
| Name of Provider or Supplier Akrivis Laboratories, Llc | Street Address, City, State 1402 South Magnolia Street, Suite H, Hammond, LA | |
| 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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| D0000 | A Certification Survey was performed on March 10, 2020 at Akrivis Laboratories, LLC, CLIA ID # 19D2072678. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited. |
| 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 interview with personnel, the laboratory failed to ensure written policies and procedures to assess competency for the General Supervisor were complete. Findings: 1. Review of the laboratory's "Employee Competency" policy revealed the following" Competency assessment is performed by the following individuals: Technical Supervisor: The TC/TS performs the competency of the GS and the TP." 2. Review of personnel records for the General Supervisor revealed Technical Supervisor 1 performed the competency assessment for her duties as General Supervisor, not the Laboratory Director. 3. In interview on March 10, 2020, Technical Supervisor 1 confirmed the Laboratory Director did not perform the competency assessment for the General Supervisor.</p> |
| D5417 | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> |

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| | <p>This STANDARD is not met as evidenced by: Based on observation and interview with personnel, the laboratory failed to ensure reagents did not exceed expiration dates. Findings: 1. Observation by surveyor during laboratory tour on March 10, 2020 revealed the following expired items: Located in Freezer 2: a) Cerilliant Propoxyphene D5, Lot #201191602, Expiration date: Jan 2020, Quantity: one (1) vial b) Cerilliant P904 Propoxyphene D5, Lot # FE01191602, Expiration date: Jan 2020, Quantity: one (1) vial 2. In interview on March 10, 2020 at 9:18 am, the General Supervisor confirmed the identified items were expired.</p> |
| <p>D6087</p> | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii)</p> <p>The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed test methods as required. Refer to D5417.</p> |
| <p>D6103</p> | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)</p> <p>The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure complete policies and procedures were established for assessing personnel competency. Refer to D5209.</p> |
| <p>D6112</p> | <p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451</p> <p>The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with personnel, the Technical Supervisors failed to provide technical and scientific oversight for the laboratory. Refer to D5417.</p> |