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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 31D0903505 | (X3) Date Survey Completed 09/19/2019 |
| Name of Provider or Supplier Kathleen M Thomsen Md Mph | Street Address, City, State 252 West Delaware Avenue, Pennington, NJ | |
| 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 surveyor review of the Competency Assessment (CA) records and interview with the Testing Personnel (TP), the laboratory failed to use the required elements applicable to Bacteriology and Mycology testing for assessing the competency of TP in the calendar years 2018 and 2019. The TP #1 listed on the CMS form 209 confirmed on 9/19/19 at 1:00 pm the laboratory did not use the required elements. Note: This was cited on the previous survey performed on 9/20/19.</p> |
| D5401 | <p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual, observation of the microscope and interview with the Testing Personnel (TP), the laboratory failed to follow Microscope Maintenance Procedure (MMP) in the calendar year 2017 and 2018. The finding includes: 1. The PM stated to perform preventive maintenance of microscope annually but there was no evidence of maintenance performed since 3/1/16. 2. The TP</p> |

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| | <p>#1 listed on CMS form 209 confirmed on 9/19/19 at 1:00 pm that the laboratory did not follow MMP.</p> |
| <p>D5411</p> | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Manufacturer Package Inserts (MPI), lack of a Temperature Log (TL) and interview with Testing Personnel (TP), the laboratory failed to follow the MPI for the Gram Stain Set and Biggy Agar to monitor and document Room Temperature (RT) where Microbiology and Mycology tests were performed from 9/20/17 to the date of survey. The TP #1 listed on CMS form 209 confirmed on 9/19/19 at 1:20 pm that the laboratory did not follow the MPI.</p> |
| <p>D5477</p> | <p>CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor review of the Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to check each new lot number and shipment of Biggy Agar media for its ability to select or inhibit growth from 9/20/17 to the date of the survey. The TP #1 listed on CMS form 209 confirmed on 9/19/19 at 1:40 pm the laboratory did not perform the above QC. Note: This was cited on the previous survey performed on 9/20/19.</p> |