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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 44D0710170 | (X3) Date Survey Completed 04/12/2023 |
| Name of Provider or Supplier Covenant Medical Group Central Lab | Street Address, City, State 6600 Nightingale Ln, Lower Level, Knoxville, TN | |
| 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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| D5775 | <p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.</p> <p>This STANDARD is not met as evidenced by: Citation #1 Based on observation of the Laboratory's two Beckman DxH instruments, lack of documentation of twice a year comparison evaluations for 2022 and upon interview with the Laboratory Manager, determined the laboratory failed to perform and document twice a year evaluations between the two Beckman DxH instruments for performance of Complete Blood Cell Counts (CBCs) in 2022. The findings include: 1. Observation of the Laboratory's Beckman DxH 1 (S#BF12138) and DxH 2 (S#BF12137) instruments in use for performing CBCs in the laboratory for patient testing. 2. Lack of documentation for twice a year comparison evaluations between the two DxH instruments in 2022. 3. Interview at approximately 1:00 p.m. on April 12, 2023 with the Laboratory Manager confirmed the laboratory failed to perform and document twice a year evaluations between the two Beckman DxH instruments for performance of CBCs in 2022. Citation #2 Based on observation of the Laboratory's two Stago instruments, lack of documentation of twice a year comparison evaluations for 2022 and upon interview with the Laboratory Manager, determined the laboratory failed to perform and document twice a year evaluations between the two Stago instruments for performance of Prothrombin time (PT) and Partial thrombolastin time (PTT) analytes in 2022. The findings include: 1. Observation of the Laboratory's Stago 1 (S#7300) and Stago 2 (S#7272) instruments in use for performing PT and PTT in the laboratory for patient testing. 2. Lack of documentation for twice a year comparison evaluations between the two Stago instruments in 2022. 3. Interview at</p> |

approximately 1:00 p.m. on April 12, 2023 with the Laboratory Manager confirmed the laboratory failed to perform and document twice a year comparison evaluations between the two Stago instruments for performance of PT and PTT in 2022. Citation #3 Based on observation of the Laboratory's Aution Max and Aution Eleven instruments, lack of documentation of twice a year comparison evaluations for 2022 and upon interview with the Laboratory Manager, determined the laboratory failed to perform and document twice a year evaluations between the two Aution instruments for performance of Urinalysis in 2022. The findings include: 1. Observation of the Laboratory's Aution Max and Aution Eleven in use for performing Urinalysis in the laboratory for patient testing. 2. Lack of documentation for twice a year comparison evaluations between the two Aution instruments in 2022. 3. Interview at approximately 1:00 p.m. on April 12, 2023 with the Laboratory Manager confirmed the laboratory failed to perform and document twice a year comparison evaluations between the two Aution instruments for Urinalysis in 2022. Citation #4 Based on observation of the Laboratory's Aution Max/Iris IQ and urine microscope, lack of documentation of twice a year comparison evaluations for 2022 and upon interview with the Laboratory Manager, determined the laboratory failed to perform and document twice a year evaluations between the two methodologies for performance of urine microscopy in 2022. The findings include: 1. Observation of the Laboratory's Aution Max/Iris IQ and urine microscope in use for performing urine microscopy in the laboratory for patient testing. 2. Lack of documentation for twice a year comparison evaluations between the two methodologies for urine microscopy in 2022. 3. Interview at approximately 1:00 p.m. on April 12, 2023 with the Laboratory Manager confirmed the laboratory failed to perform and document twice a year comparison evaluations between the two methodologies for urine microscopy in 2022.

D6103

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(13)

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.

This STANDARD is not met as evidenced by:
Based on review of competency assessments for the technical consultants and interview with the Laboratory Manager, determined the Laboratory Director failed to evaluate four of four technical consultants listed on the Centers for Medicare and Medicaid Form 209(CMS 209) in 2022. The findings include: 1. Review of 2022 competency assessments revealed no documentation of competency assessment for four of four technical consultants in 2022. 2. Interview at approximately 1:00 p.m. on April 12, 2023 with the Laboratory Manager confirmed the Laboratory Director failed to evaluate four of four technical consultants in 2022.