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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 39D0679659 | (X3) Date Survey Completed 09/13/2022 |
| Name of Provider or Supplier Shady Grove Fertility Pittsburgh | Street Address, City, State 6400 Brooktree Court, Suite 100, Wexford, PA | |
| 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 |
|---------------------------|--|
| 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 review of laboratory procedure manuals, review of competency assessment records, and interview with the Technical consultant (TC)#2, the laboratory failed to establish a competency assessment procedure to assess the competency of 4 of 4 Testing Personnel (TP) who perform endocrinology test from 02/19/2020 to the day of survey Findings Include: 1. On the day of survey, 09/13/2022 at 03:23 pm., the laboratory could not provide a written procedure that includes the six points of CLIA to assess the competency of 4 of 4 TP (CMS 209 personnel #2, #3,#4 and #5) for the following endocrinology testing from 02/9/2020 to 09/13/2022. - TSH (Thyroid Stimulating Hormone) - FSH (Follicle-Stimulating Hormone) - LH (Luteinizing Hormone) - Estradiol (E2), - Progesterone, - HCG (Human Chorionic Gonadotropin), - Prolactin . 2. The TC#2 confirmed the findings above on 09/13/2022 at 05:45 pm.</p> |
| D5215 | <p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> |

This STANDARD is not met as evidenced by:
Based on review of the College of American Pathologist (CAP) proficiency testing (PT) records and interview with the Technical consultant (TC)#2, the laboratory failed to verify the accuracy for 3 of 3 Prolactin and 2 of 3 Progesterone PT results event A of 2022 . Findings Include: 1. On the day of survey, 09/13/2022 at 03:33 pm, review of 2022 CAP proficiency testing records revealed, the laboratory did not verify the accuracy for the following PT results for CAP Sex hormones Event A 2022: - 3 of 3 Prolactin PT results were not graded by the proficiency testing agency due to non consensus (Y-01, Y-02, Y-03). - 2 of 3 Progesterone PT results were not graded due to outside method/instrument reportable range (Y-02, Y-03). 2. The TC #2 confirmed the findings above on 09/13/2022 around 05:45 pm.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:
Based on lack of documentation and interview with the Technical consultant (TC)#2, the laboratory failed to verify twice annually the accuracy for Semen Analysis in 2021 and 2022. Findings include: 1. The laboratory's Alternative Proficiency Assessment Methods for Semen Analysis procedure (page 3) under interval states: " Internal PT samples will be shipped two times per year, each sample set should contain two specimens for each test. Each Sample should be evaluated based on test menu (concentration, motility, viability, morphology and DNA fragmentation) in each testing site." 2. On the day of survey, 09/13/2022 at 05:30 pm., The laboratory could not provide documentation of verification of accuracy performed for Semen Analysis (Motility and Viability) from 01/01/2021 to 09/13/2022. 3. Review of the CMS 116 revealed the laboratory's annual test volume for semen analysis is 107 patient testing. 4. The TC#2 confirmed the findings above on 09/13/2022 at 05:45 pm.