

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D2164374	(X3) Date Survey Completed 03/30/2023
Name of Provider or Supplier Women's Health Group, Pa East, The	Street Address, City, State 8315 Positano Dr, Manhattan, KS	
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
D5411	<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 the review of the IQCP for serum human chorionic gonadotropin (hCG) using Consult hCG combo test kit, package insert for Consult hCG combo test cassette, serum hCG quality control (QC) records, and interview with testing personnel (TP) #1, the laboratory failed to perform QC for serum hCG as required by the manufacturer's instructions for 5 of 15 months from 9/18/21 to 3/30/23. Findings: 1. Review of the IQCP for serum human chorionic gonadotropin (hCG) using Consult hCG combo test kit required QC to be performed monthly. 2. Review of the package insert for Consult hCG combo test cassette, serum hCG revealed the manufacturer required serum QC testing to follow federal, state and local guidelines. CMS has defined monthly as a time period not to exceed 31 days. 3. Review of QC records from 9/18/21 to 3/30/23, revealed QC test interval exceeded 31 days for 5 of 15 months from 1/1/22 to 3/30/23. a. QC for 10/21 was performed 44 days after the last acceptable QC: 9/15/21 to 10/28/21. Sixteen patient results were reported. b. QC for 1/22 was performed 44 days after the last acceptable QC: 12/7/21 to 1/20/22. Fifteen patient results were reported. c. QC for 4/22 was performed 49 days after the last acceptable QC: 3/7/22 to 4/25/22. Four patient results were reported. d. QC for 8/22 was performed 57 days after the last acceptable QC: 7/5/22 to 8/31/22. Fifteen patient results were reported. e. QC for 10/22 was performed 54 days after the last acceptable QC: 8/31/22 to 10/24/22. Thirteen patient results were reported. 4. Interview with</p>

TP#1 on 3/30/23 at 10:15 a.m. confirmed, the laboratory failed to perform QC for serum hCG as required by the manufacturer's instructions for 5 of 15 months from 9/18/21 to 3/30/23.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on review of CMS form 209, competencies, and interview with TP #1, the technical consultant (TC) failed to evaluate and document competency at least semiannually during the first year the individual tests patient specimens for 1 of 4 new testing personnel (TP). Findings: 1. Review of the site's CMS for 209 for personnel revealed 4 new testing personnel since last survey that had worked at the site for more than 6 months. 2. Review of personnel competency records revealed no semiannual competency was performed by the TC during 2022 for TP#2. 3. Interview with the TP #1 on 3/30/23 at 9:10 a.m. confirmed, the technical consultant failed to evaluate and document competency at least semiannually during the first year the individual tests patient specimens for 1 of 4 new TP.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:
Based on review of the current CMS-209, lack of documentation and interview, the technical consultant (TC) failed to document the annual competency for 1 of 7 testing personnel (TP). Findings: 1. The CMS-209 document listed 7 persons as active testing personnel whom had been testing for more than 1 year. 2. No annual competency document performed by the TC on TP #2 (due 2/23) was made available at the time of survey. 3. Interview with TP #1 on 3/30/23 at 9:10 a.m. confirmed, the technical consultant failed to document the annual competency for 1 of 7 TP.