

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0678176	(X3) Date Survey Completed 01/18/2019
Name of Provider or Supplier Center For Women's Health	Street Address, City, State 4840 College Blvd, Overland Park, 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
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 procedures and interview with the laboratory supervisor on January 18, 2019 at 10:30 AM confirmed the laboratory failed to establish a written procedure to assess employee competency.</p>
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of manufacturer's insert, observation of Eldoncard RhD, quality control and interview the laboratory failed to meet condition: Analytic systems. The laboratory failed to follow manufacturer's insert (refer to D5411); failed to label Eldoncard RhD with open date or expiration date (refer to D5415) and failed to perform quality control each day of patient testing (refer to D5449).</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 review of Eldoncard RhD manufacturer's insert and interview with the laboratory supervisor the laboratory failed to follow the manufacturer's requirements for storage and stability. Findings: 1. Review of the Eldoncard manufacturer's insert revealed "An EldonBag can be opened for removal of cards at least 50 times during the six months period." No documentation for amount of times EldonBag has been opened could be provided. 2. Interview with the laboratory supervisor on January 18, 2019 at 10:30 AM confirmed the laboratory failed to follow the manufacturer's guidelines for storage and stability of Eldoncards for Rh testing.</p>
<p>D5415</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on observation of Eldoncard RhD cards lot # 18411 in use and interview with the laboratory supervisor the laboratory failed to label Eldoncard RhD cards in use with an expiration date. Findings: 1. Observation of Eldoncard RhD card package states "expires 6 months after first opening". 2. Observation of Eldoncard RhD card package showed no open date or expiration date on package. 3. Interview with the laboratory supervisor on January 18, 2019 at 10:30 AM confirmed the laboratory failed to label Eldoncard RhD cards in use with open date or expiration date.</p>
<p>D5449</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of Eldoncard RhD quality control (QC) and interview with the laboratory supervisor on January 18, 2019 at 10:30 AM the laboratory failed to perform a positive and negative control for Eldoncard RhD each day of patient testing.</p>

D6018

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(iii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on review of proficiency testing (PT) for 2017 and 2018 and interview with the laboratory supervisor the laboratory director failed to ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance. Findings: 1. Review of PT for 2017 showed no review by appropriate staff of 1st event 2017, 2nd event 2017 and 3rd event 2017 to evaluate the laboratory's performance. 2. Review of PT for 2018 showed no review by appropriate staff of 1st event 2018 and 2nd event 2018 to evaluate the laboratory's performance. 3. Interview with the laboratory supervisor on January 18, 2019 at 10:30 AM confirmed the laboratory director failed to ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance.

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 competencies and interview with the laboratory supervisor the technical consultant failed to evaluate and document semi-annual competency for two of four testing personnel. Findings: 1. Review of competencies showed no semi-annual competency completed for testing personnel #1 and #4. 2. Interview with the laboratory supervisor on January 18, 2019 at 10:30 AM confirmed the technical consultant failed to evaluate and document semi-annual competency for testing personnel #1 and #4.

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 competencies and interview with the laboratory supervisor the technical consultant failed to evaluate and document annual competency for one of four testing personnel in 2017 and 2018. Findings: 1. Review of competencies showed

no annual competency for testing personnel #4 in 2017 and 2018. 2. Interview with the laboratory supervisor on January 18, 2019 at 10:30 AM confirmed the technical consultant failed to evaluate and document annual competency in 2017 and 2018 for testing personnel #1.