

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 28D2096855	(X3) Date Survey Completed 09/15/2023
Name of Provider or Supplier American Family Care - Omaha	Street Address, City, State 4004 North 132nd Street, Suite 101, Omaha, NE	
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
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 surveyor review of maintenance records (Refer to D5429) and review of quality control records (Refer to D5445, D5449) the laboratory failed to monitor and evaluate the overall quality of testing.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor record review of hematology preventative maintenance logs, interview with the technical consultant, the laboratory failed to ensure staff performed the monthly-required preventative maintenance for the hematology analyzer for five of eight months of patient testing reviewed. Findings are: 1. Review of hematology preventative maintenance logs from January 2023 - August 2023 showed the laboratory did not perform the monthly-required hematology maintenance for</p>

February 2023, April 2023, June 2023, July 2023, and August 2023 as required by the manufacturer. 2. Interview with the technical consultant on 9/15/2023 at 10:40 AM confirmed the laboratory failed to ensure staff performed the monthly-required preventative maintenance on the hematology analyzer for February 2023, April 2023, June 2023, July 2023, and August 2023. Based on surveyor record review of microbiology Cepheid instrument preventative maintenance logs, lack of documentation of microbiology Cepheid instrument preventative maintenance logs, and interview with the technical consultant, the laboratory failed to ensure staff performed preventative maintenance on the microbiology Cepheid instrument for four of eight months of patient testing reviewed. Findings are: 1. Review of 2023 microbiology Cepheid instrument preventative maintenance logs revealed the laboratory did not have the microbiology Cepheid instrument preventative maintenance logs from May 2023 - August 2023. 2. Interview with the technical consultant on 9/15/2023 at 10:45 AM confirmed the laboratory failed to ensure staff performed the required preventative maintenance on the microbiology Cepheid instrument from May 2023 - August 2023.

D5445

CONTROL PROCEDURES
CFR(s): 493.1256(d)(1)(2)(g)

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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on surveyor review of the laboratory's Individualized Quality Control Plan (IQCP) for COVID, Flu, and RSV testing, review of quality control records for COVID, Flu, and RSV, review of patient testing performed for COVID, Flu, and RSV, and interview with the technical consultant the laboratory failed to follow the IQCP for one out of four months reviewed of patient testing. Findings are: 1. The laboratory's IQCP for COVID, Flu, and RSV testing indicates the laboratory must run quality control every 30 days or when the laboratory receives a new lot or new shipment. 2. Review of quality control records revealed quality control last performed on 8/1/2023. 3. Review of patient testing records revealed 94 patients tested from 8/2 /2023 - 9/15/2023 for COVID, Flu, and RSV. 4. Interview with the technical consultant on 9/15/2023 at 11:55 AM confirmed the laboratory failed to run quality control every 30 days, following the IQCP.

D5449

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(ii)(g)

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.

This STANDARD is not met as evidenced by:
Based on surveyor review of quality control records, patient testing records, and an interview with the technical consultant the laboratory failed to perform quality control each day of patient testing for trichomonos and chlamydia/gonorrhea from January 2023 - June 2023. Findings are: 1. Review of quality control records from 1/3/2023 - 5/23/2023 for trichomonas revealed quality control testing was only performed on 1/3/2023, 4/3/2023, and 4/26/2023. 2. Review of patient testing records for trichomonas revealed 99 patients tested from 1/3/2023 - 5/23/2023. 3. Review of quality control records from 1/1/2023 - 6/5/2023 for chlamydia/gonorrhea revealed quality control testing was only performed on 1/24/2023 and 4/3/2023. 4. Review of patient testing records from chlamydia/gonorrhea revealed 116 patients tested from 1/1/2023 - 6/5/2023. 5. Interview with the technical consultant on 9/15/2023 at 11:50 AM confirmed the laboratory had not performed quality control each day of patient testing.

D6063

LABORATORY TESTING PERSONNEL
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:
Based on lack of documentation the laboratory failed to have proof of education on testing personnel #4 and #11, as listed on the CMS-209, performing moderate complexity testing. Refer to D6065.

D6065

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:
Based on lack of documentation and interview with the technical consultant and clinic owner the laboratory failed to have proof of education on two out of seven testing personnel listed on the CMS-209. Findings are: 1. No proof of education documentation for testing personnel #4 and testing personnel #7, as listed on the CMS-209, performing moderate complexity testing was presented at time of survey. 2. Interview on 9/18/2023 at 12:00 PM with the technical consultant and clinic owner confirmed no documentation was available.