

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2035222	(X3) Date Survey Completed 02/21/2018
Name of Provider or Supplier Urgent Care Of Madison	Street Address, City, State 3751 Sullivan Street, Madison, AL	
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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the laboratory test menu, the API (American Proficiency Institute) proficiency testing (PT) records and website information, and interviews with the Practice Administrator and Testing Personnel (TP) #1, the surveyor determined the laboratory failed to enroll in an approved proficiency testing program for moderate-complexity regulated tests in 2018. The findings include: 1. During the initial tour of the laboratory on 2/21/2018 at approximately 10:00 AM, the Practice Administrator and TP #1 included on the test menu Chemistry and Endocrinology testing performed on the Seimens Dimension XPAND, and Complete Blood Counts (CBC) performed on the Medonic Hematology analyzer. 2. A review of the proficiency testing records revealed the laboratory had used API as the PT provider in 2017, however there was no documentation the 2018 PT surveys had been ordered for the moderate complexity regulated Hematology and Chemistry/Endocrinology tests. 3. A review of the PT Schedule on the API website revealed the Chemistry-Core 2018-Event #1 survey was shipped to laboratories on 1/22-1/23/2018, and results of the survey were due on 2/9/2018. (The Hematology survey will be shipped in March 2018.) 4. During an interview with the Practice Administrator and TP #1 on 2/21/2018 at 4:00 PM, the surveyor asked if the facility had ordered the 2018 PT from API or</p>

another provider (since the first API Chemistry event had already been missed). TP #1 stated he never ordered PT or any of his supplies as Management always did this. The Practice Administrator stated she was unaware that PT must be ordered for the Laboratory at the end of each calendar year, and confirmed she had not ordered the 2018 PT surveys. 5. As the interview continued at 4:10 PM, the surveyor asked if the laboratory had continued to perform Chemistry and Endocrinology patient testing in 2018. TP #1 reviewed his Dimension XPAND records and stated he had performed Chemistry/Endocrinology profiles on patients on 1/27/2018, 1/30/18, 2/3/2018, 2/6/18, 2/10/18, and 2/12/18. Thus the above noted findings were confirmed. .

D5481

CONTROL PROCEDURES

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of the Hematology quality control (QC) records, the patient log, and an interview with Testing Personnel (TP) #1, the laboratory failed to ensure at least two levels of quality control were performed and acceptable, prior to analyzing patient specimens and reporting the results on four days in November 2017. The findings include: 1. A review of the QC records for Medonic Hematology analyzer revealed no record of QC for 11/7/2017, 11/20/2017, and 11/29/2017; a further review of the QC revealed on 11/15/2017, the Normal and High QC were run, however both levels were outside acceptable ranges. 2. During an interview on 2/21/2018 at 2:45 PM, TP #1 reviewed and confirmed the above noted findings. When asked if patient CBC's (Complete Blood Counts) were performed, TP #1 reviewed the patient logs from the instrument with data as follows: A) 11/07/17: 4 patient CBC's performed B) 11/15/17: 2 patient CBC's performed C) 11/20/17: 1 patient CBC's performed D) 11/29/17: 2 patient CBC's performed [NOTE: All Hematology testing was performed on the above days by TP #2, for whom the laboratory had no documentation of education or training.] Thus the above findings were confirmed.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on a review of quality assurance documentation and interviews with Testing Personnel #1 and the Practice Administrator, the surveyor determined the laboratory failed to implement effective quality assessment reviews to identify and correct problems identified in the analytical systems. The findings include: 1. A review of quality assurance documentation revealed the laboratory routinely performed monthly quality assurance activities, however the reviews were inadequate to discover and correct problems in the following areas: A.) Review of laboratory records to ensure annual enrollment in an approved proficiency testing program for all regulated

moderate-complexity tests. (Refer to D2000.) B.) Review of Hematology data to ensure at least two levels of QC were performed and within acceptable ranges each day of patient testing. (Refer to D5481.) C.) Review of personnel records to ensure: (a) all required personnel positions are filled including a qualified Technical Consultant to provide effective technical oversight of the laboratory (refer to D6033), and (b) testing personnel provided documentation of a high school diploma or degree upon hire, and training for moderate complexity testing was documented as completed before patient testing was performed (refer to D6065 and D6066.) 2. During the exit summation on 2/21/2018 at 4:45 PM, these concerns were reviewed and discussed with Testing Personnel #1 and the Practice Administrator. .

D6004

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(a)(b)

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:
Based on a lack of documentation specifying the name and qualifications of a Technical Consultant during the on-site survey and reviews of personnel records, the surveyor determined the Laboratory Director failed to appoint and employ a qualified Technical Consultant to provide effective technical oversight of the laboratory, and further failed to ensure testing personnel provided documentation of a high school diploma or degree upon hire, and training for moderate complexity testing was documented as completed before performing patient testing (Refer to D6033, D6065 and D6066.) .

D6015

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)

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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:
Based on reviews of the laboratory test menu, the API (American Proficiency Institute) proficiency testing records and website information, and interviews with the Practice Administrator and Testing Personnel #1, the surveyor determined the Laboratory Director failed ensure the laboratory was enrolled in an approved proficiency testing program for all moderate-complexity regulated tests in 2018. (Refer to D2000.) .

D6033

TECHNICAL CONSULTANT-MODERATE COMPLEXITY

CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:

Based on a review of personnel listed on Form CMS-209 and an interview with the Practice Administrator, the surveyor determined the laboratory failed to fill the position of the Technical Consultant (TC) after the previous TC had left toward the end of 2017. The findings include: 1. During a review of personnel listed on Form CMS-209 with the Practice Administrator on 2/21/2018 at approximately 11:30 AM, the surveyor noted the facility had failed to specify a Technical Consultant (TC); the surveyor explained CLIA regulations required this position be filled. The Administrator stated they did not currently have a TC because the previous one had resigned toward the end of 2017. 2. During the exit interview with the Practice Administrator on 2/21/2018 at 4:45 PM, the TC qualifications and the requirement to have a TC were again discussed, however the facility was unable to name a TC on the day of the survey. When the Administrator asked for additional time to obtain a new TC, the surveyor agreed, stating she needed the information in the CLIA office by Friday 2/23/2018. However, as of the close of business on 2/23/2018, no additional documentation was received. Thus the above noted findings were confirmed. .

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 a review of personnel listed on Form CMS-209 and an interview with the Practice Administrator, the surveyor determined the laboratory failed to ensure two out of three testing personnel (TP) had documentation of a degree or a high school diploma before performing patient testing. The findings include: 1. A review of Form CMS-209 initially provided by the Practice Administrator revealed one testing personnel (TP #1) who performed Chemistry and Hematology testing two days a week. 2. As the survey continued, the surveyor learned two other testing personnel (#2 and #3) also performed Hematology testing on days TP #1 was off. 3. During an interview on 2/21/2018 at 3:05 PM, the Practice Administrator included the names of

TP #2 and #3 on Form CMS-209. When asked for the documentation of their level of education, the Administrator stated she did not have these records. Thus the above noted findings were confirmed. .

D6066

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(4)(ii)

Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

This STANDARD is not met as evidenced by:

Based on a review of personnel listed on Form CMS-209 and interviews with Testing Personnel (TP) #2 and the Practice Administrator, the surveyor determined the laboratory failed to ensure two out of three testing personnel (TP) had documentation of training and competency evaluations for moderate complexity testing completed before performing patient testing. The findings include: 1. A review of Form CMS-209 initially provided by the Practice Administrator revealed one testing personnel (TP #1) who performed Chemistry and Hematology testing two days a week. 2. As the survey continued, the surveyor learned two other testing personnel (#2 and #3) also performed Hematology testing on days TP #1 was off. During an interview on 2/21/2018 at 3:00 PM, TP #2 confirmed she did perform Hematology testing. When asked if she had had training to perform patient testing, she answered, "Absolutely". 3. During an interview on 2/21/2018 at 3:05 PM, the Practice Administrator included the names of TP #2 and #3 on Form CMS-209. When asked for the training documentation and competency evaluations for these testing personnel, the Administrator stated she did not have these records. Thus the above noted findings were confirmed. SURVEYOR: Laura T. Williams, BS, MT (ASCP) Licensure and Certification Surveyor