Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2142914	(X3) Date Survey Completed 01/15/2019
Name of Provider or Supplier Steward Urgent And Primary Care Center	**Street Address, City, State** 5360 South 2700 West, Taylorsville, UT	

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
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 laboratory proficiency testing (PT) record review, method verification record review, lack of documentation, and interview with staff, the laboratory failed to verify the accuracy of 2 of 2 nonregulated analytes tested on the Triage analyzer (Troponin and Myoglobin) at least twice annually in 2018. The laboratory began patient testing in June of 2018 and tests approximately 5 Troponin and Myoglobin samples per month. Finding include: 1. PT records document initial PT enrollment for Troponin and Myogblobin in 2019. 2. Test method verification records document initial method verification studies (accuracy verification) done on the Triage on 03/13 /2018. 3. The laboratory lacked documentation of enrollment in PT in 2018 or a second verification of accuracy by another method for Troponin and Myoglobin testing in 2018. 4. Staff stated on 01/15/2019 at approximately 11:00 a.m. they contacted their PT provider too late in 2018 to get PT samples for 2018 and confirmed they had not verified the accuracy of testing a second time by another method in 2018.
D5425	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(3) The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section. This STANDARD is not met as evidenced by:

	Based on Individualized Quality Control Plan (IQCP) review, lack of documentation, and interview with staff, the IQCP plan risk assessment failed to include laboratory acquired quality control (QC) data to support the laboratory's quality control plan (QCP) for reduced frequency of external QC, from each day of testing, to each new cartridge lot and shipment, and at least monthly, for 3 of 3 non-waived tests performed on the Triage analyzer (Creatine Kinase MB isoenzyme {CKMB}, Troponin, and Myoglobin). The laboratory performed approximately 5 moderately complex tests per month on the Triage. Findings include: 1. The laboratory QCP included with their IQCP stated external QC should be performed with each lot number and at least monthly. 2. The laboratory lacked documentation of QC performance to support the QCP for reduce QC performance frequency for non-waived testing performed on the Triage. 3. The technical consultant confirmed on 01 /15/2019 at approximately 12:00 p.m. the laboratory failed to perform QC each day of testing until they could document the test system was stable for up to a one month interval.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on test report review and interview with staff, the laboratory test report failed to include the address of the laboratory where testing was performed for 7 of 7 complete blood count (CBC) test reports reviewed from 07/02/2018-01/10/2019. The laboratory began patient testing in 06/2018 and performs approximately 1 CBC per day. Findings include: 1. CBC test reports reviewed from 07/02/2018, 07/24/2018, 08/04/2018, 09 /20/2018, 12/17/2018, 01/03/2019, and 01/10/2019 failed to include the address of the laboratory. 2. Staff confirmed on 01/15/2019 at approximately 1:00 p.m. CBC reports scanned into the electronic medical record failed to include the address of the testing location.
D6041	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3) (b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered; This STANDARD is not met as evidenced by: Based on laboratory test record review, proficiency testing (PT) record review, lack of documentation, and interview with staff, the technical consultant failed to enroll in an approved PT testing program for complete blood count (CBC) testing on the Sysmex and CK MB testing on Triage analyzers in 2018. The laboratory began testing in June

	of 2018 and performs approximately 1 CBC per day and 5 Creatine Kinase MB isoenzyme (CKMB) tests per month. Findings include: 1. Laboratory records document the laboratory began patient testing on CMS regulated analytes on the Sysmex and Triage analyzers in June of 2018. 2. PT records document initial PT enrollment on January 2019. 3. The laboratory lacked documentation of PT enrollment for 2018 for CBC and CKMB. 4. Staff stated on 01/15/2019 at approximately 11:00 a.m. they contacted their PT provider too late in 2018 to get PT samples for 2018.
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: The laboratory failed to ensure 2 of 5 testing personnel performing moderately complex testing met the qualification requirements. (See 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 personnel training and competency record review, laboratory personnel records review, and interview with staff, the laboratory lacked documentation that 2 of 5 testing personnel met the educational benchmark to perform moderately complex testing. The laboratory performs approximately 200 moderately complex tests a month. Findings include: 1. Competency records document 5 testing personnel were trained to perform moderately complex complete blood count testing on the Sysmex XN450 and CK MB, Troponin, and Myoglobin testing on the Triage. 2. Laboratory personnel records failed to include documentation 2 of the 5 testing personnel (employees 3 and 4) met the minimum requirements to perform moderately complex testing. 3. Staff confirmed on 01/15/2019 at approximately 12:00 p.m. all 5 employees performed moderate complex testing and they failed to have the required documents for employees 3 and 4.