Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0951411	06/24/2019
Name of Provider or Supplier	**Street Address, City, State**	
Doctors Urgent Care Llc	51342 National Road East, St Clairsville, OH	

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
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: Based upon a review of manufacturer's instructions, test logs, and an interview with Testing Personnel (TP), the laboratory failed to document the time in which specimens were collected. This deficient practice had the potential to affect all patients tested under the specialty of chemistry. Findings were as follows: 1. The manufacturer Qualigen, states under its testing procedure for the Fast Pack ip system, document 65000160 Rev. 007 (06/15) "Sample should be centrifuged and serum separated from the clot within 3 hours from time of collection. Plasma should be separated within 3 hours from time of collection. If not tested within 24 hours, samples should be frozen at -20C or colder for up to 2 months." 2. Review of the laboratory document titled "Doctors Urgent Care, Specimen Requirements", effective date 09/14/1998 found the following requirements: Test Longevity Refrigerator CBC 8 hours 24 hours Sed Rate 2 hours 24 hours Chemistry 8 hours 72 hours *(refer to insert for specific analyte) PT/PTT 2 hours 8 hours Urine 1 hour 8 hours 3. Review of the laboratory's test log titled, "Immunoassay Daily Log"did not contain a section time of specimen collection. 4. Review of the laboratory's test log titled, "Interoffice Labs" used for CBC specimens sent out did not contain a section for time of specimen collection. 4. The surveyor requested documentation of specimen collection times for routine chemistry testing from TP#1. TP#1 verified specimen collection times were not recorded. The interview occurred 06/24/2019 at 11:30 AM. C; degrees Celsius
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the

	laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of proficiency test records and the laboratory procedure manual, the Laboratory Director (LD), failed to follow the written procedure manual for proficiency testing and did not review and sign the results section. This deficient practice had the potential to affect all patients tested under the specialty of chemistry. Findings include: 1. Review of the approved laboratory procedure manual titled, "Quality Assessment Manual", approved and signed by the LD on 05/15/2019 found the following statement under section 8 subsection K: "The results are reviewed and signed by the medical director and laboratory supervisor. The laboratory director must ensure all proficiency testing reports received are reviewed by appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action." 2. Review of the 05/23/2019 urinalysis, 06/11/2019 vitamin D, 06 /13/2019 testosterone and PSA self evaluation proficiency test records did not find any LD review signatures and dates. 3. The surveyor requested documentation of the LD review of the 05/23/2019 urinalysis, 06/11/2019 vitamin D, 06/13/2019 testosterone and PSA proficiency testing results from Test Personnel #1. Testing Personnel #1 verified the LD did not review and sign any proficiency test results. The interview occurred 06/24/2019 at 10:50AM.
D5893	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c) (b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on policy review, record review, and an interview with Testing Personnel (TP), the Laboratory Director (LD) failed to ensure a post analytic quality assessment program was maintained to assure the quality of laboratory services provided and to identify failures in laboratory quality. This deficient practice had the potential to affect all patients tested under the specialty of chemistry. Findings Include: 1. Review of the laboratory's policy and procedure manual titled, "Quality Assessment Manual", signed and dated by the LD on 05/15 2019, revealed a "Quality Assessment" procedure which contained the following statements: "Monthly Quality Assessment Our QA program is assessed monthly to evaluate and monitor the overall quality of our testing process. In this way, the effectiveness of our policies and procedures may be evaluated. As necessary, our policies will be reviewed based on the results of the monthly evaluations and revisions will be communicated to the lab staff." 2. Further review of the quality assessment documents revealed a blank "Quality Assurance Assessment" checklist. 3. The surveyor requested completed Quality Assurance Assessment checklists to review. TP#1 verified the were no Quality Assurance Assessment checklists completed and there was no documentation available for any quality assessment performed in the laboratory. The interview occurred 06/24/2019 at 11:50 AM.

D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and an interview with Testing Personnel (TP), the Laboratory Director failed to ensure policies and procedures were established for monitoring individuals who conduct preanalytical, analytical, and post analytical phases of chemistry testing procedures to assure they are competent, and maintain their competency to process specimens, perform test procedures, and report test results promptly and proficiently. This deficient practice had the potential to affect all patients tested under the specialty of chemistry. Findings Include: 1. Review of the laboratory's policies and procedures, provided on the date of the inspection, did not find any instructions for the assessment of competency of the TP performing moderately complex testing procedures. 2. The Surveyor requested the laboratory's competency assessment policy and procedure from TP#1. TP#1 confirmed the laboratory did not have a competency assessment policy and procedure established and was unable to provide the requested documentation on the date of the inspection. The interviews occurred on 06/24/2019 at 10:30 AM.