| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 19D1010157 | 07/12/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Doctors Urgent Care | 971 Robert Boulevard, Slidell, LA | |

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 |
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| **D0000** | A Certification Survey was conducted on July 12, 2018 at Doctors Urgent Care-CLIA ID # 19D1010157. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard deficiencies were cited. |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with personnel, the laboratory failed to have a complete policy and procedure manual. Findings: 1. Review of the laboratory's policy and procedure manual revealed the following written procedure was not included: a) Quality Control (QC) to include but not limited to: detailed procedure for performance |

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| | of new lot establishment of means and acceptable ranges 2. In interview on July 12, 2018 at 1:31 pm, Personnel 3 confirmed the laboratory's current QC procedure did not include detailed instructions for establishment of means and acceptable ranges. |
| **D5411** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, record review, and interview with personnel, the laboratory failed to perform and document visual inspections on blood culture bottles before use per manufacturer's requirements. Findings: 1. Observation by surveyor during laboratory on July 12, 2018 revealed the laboratory receives BD BACTEC and Thermo Scientific VersaTREK REDOX culture bottles. 2. Further observation revealed the laboratory utilized the following BD BACTEC and Thermo Scientific VersaTREK REDOX culture bottles: BD BACTEC Plus Aerobic/F Culture Vials Lot # 8086999 BD BACTEC Lytic/10 Anaerobic Culture Vials Lot # 8086522 and Lot # 7297501 Thermo Scientific VersaTREK REDOX 2 EZ Draw 40 mL Lot # 262871 Thermo Scientific VersaTREK REDOX 1 EZ Draw 40 mL with Stir Bar Lot # 255567 3. Review of the manufacturer package inserts revealed the following: a) BD BACTEC: "Prior to use, each vial should be examined for evidence of damage, contamination or deterioration. Vials displaying evidence of damage or contamination such as leakage, cloudiness, discoloration (darkening), bulging or depressed septum should not be used." b) Thermo Scientific VersaTREK REDOX: "Visually inspect all bottles for contamination, cracks, or other signs of deterioration. Do not use bottles that appear turbid or damaged." 4. In interview on July 12, 2018 at 9:48 am, Personnel 3 stated the laboratory receives blood culture bottles from the reference laboratories that perform the testing. Personnel 3 further stated the laboratory performs the collection and bottles are inspected prior to use. Personnel 3 stated the laboratory does not document visual inspection of the culture bottles. |
| **D5445** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(1)(2)(g)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, record review, and interview with personnel, the laboratory failed to have a complete Individualized Quality Control Plan (IQCP) to support the reduction in frequency of external quality control (QC) for D-dimer testing. Findings: |

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| | 1. Observation by surveyor during laboratory tour on July 12, 2018 revealed the laboratory utilized the Alere Triage MeterPro for D-dimer testing. 2. Review of the laboratory's IQCP for D-dimer revealed the laboratory performed two (2) levels of external quality control once per day for ten (10) consecutive days, then again at Day 20 and Day 30. 3. Review of the laboratory's Quality Control Plan revealed the laboratory reduced the frequency of external QC testing to every thirty (30) days, new lot/shipment of reagents. 4. In interview on July 12, 2018 at 3:20 pm, Personnel 6 stated the laboratory is open everyday from 9:00 am to 6:00 pm. 5. Further review of the laboratory's QC data revealed the laboratory did not include two levels of quality control each 8 hours of operation, as required by CFR 493.1269. The laboratory did not include documentation of QC performance every 8 hours for 30 days. The Quality Control Plan did not indicate if QC performance was within or exceeded an eight (8) hour period of patient test performance. 6. In interview on July 12, 2018 at 3:20 pm, Personnel 3 stated the laboratory performed QC once per day for IQCP. 7. Review of the laboratory's Task 1 and 3 forms revealed the laboratory performs four hundred eighty five (485) D-dimer tests annually. |
| **D6014** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(3)(iii)<br><br>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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required. Refer to D5411. |
| **D6020** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that the quality control was maintained to assure quality laboratory services were provided. Refer to D5445. |
| **D6030** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(12)<br><br>The laboratory director is responsible for the overall operation and administration of |

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| | 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;<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures were established for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Findings: 1. The Technical Consultant failed to evaluate and document the performance of individuals at least semi-annually during the first year for one (1) of three (3) testing personnel reviewed. Refer to D6053. 2. The Technical Consultant failed to evaluate and document personnel competency annually for one (1) of three (3) testing personnel reviewed. Refer to D6054. |
| **D6031** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(13)<br><br>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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Refer to D5403. |
| **D6053** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(9)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with personnel, the Technical Consultant failed to evaluate and document the performance of individuals at least semi-annually during the first year for one (1) of three (3) testing personnel reviewed. Findings: 1. Review of the laboratory's "Laboratory Quality Assurance" policy under "Competency" section revealed "The competency of testing personnel is done on the following schedule: Initially before testing is allowed, again at 6 months, yearly thereafter." 2. In interview on July 12, 2018 at 2:51 pm, Personnel 6 stated Personnel 5 was hired |

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| | February 7, 2017, but is no longer employed effective May 3, 2018. 3. Review of personnel records for Personnel 5 revealed no documentation of performance of semi-annual competency evaluation. 4. In further interview on July 12, 2018 at 2:51 pm, Personnel 6 stated the laboratory could not find the documentation of semi-annual competency for Personnel 5. |
| **D6054** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(9)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with personnel, the Technical Consultant failed to evaluate and document personnel competency annually for one (1) of three (3) testing personnel reviewed. Findings: 1. Review of the laboratory's "Laboratory Quality Assurance" policy under "Competency" section revealed "The competency of testing personnel is done on the following schedule: Initially before testing is allowed, again at 6 months, yearly thereafter." 2. In interview on July 12, 2018 at 2:51 pm, Personnel 6 stated Personnel 5 was hired February 7, 2017, but is no longer employed effective May 3, 2018. 3. Review of personnel records for Personnel 5 revealed no documentation of performance of annual competency evaluation. 4. In further interview on July 12, 2018 at 2:51 pm, Personnel 6 stated the laboratory could not find the documentation of annual competency for Personnel 5. |