| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 03D2114951 | 09/26/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Southwest Kidney Institute, Plc | 2538 E University Dr, Ste 110, Phoenix, AZ | |

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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| **D2009** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of proficiency testing (PT) attestation statements for the first and second event of 2019 and interview with the laboratory director, the laboratory failed to have the director or a qualified designee sign the attestation statements for the 1st event of PT performed under the specialty of Chemistry and the 2nd event of PT performed under the specialty of Hematology. Findings include: 1. The PT attestation statements noted above did not have the signature either of the director or an individual that would qualify as a designee; a technical consultant meeting the qualifications under CLIA regulation 493.1409. 2. The laboratory director acknowledged that the individual that signed the attestation statements indicated above did not qualify as a designee. |
| **D5291** | GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1239(a)<br><br>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 general laboratory systems requirements specified at 493.1231 through 493.1236.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of quality assessment (QA) policies and interview with the facility |

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| | personnel, the laboratory failed to perform and document quality assessment activities as indicated in laboratory policy. Findings include: 1. The laboratory's QA policy at the time of the survey included a monthly review of laboratory records including Quality Control, Proficiency Testing, Problems, Maintenance logs and temperature logs. 2. No monthly QA documentation was presented for review to indicate the laboratory performed and documented QA activities as indicated above from September 2017 through December 2018 and from April 2019 through the date of the survey conducted on September 26, 2019. 3. The facility personnel confirmed that the laboratory could not locate documentation of QA activities stated above. |
| **D5293** | GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1239(b)(c)<br><br>(b) The general laboratory 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 general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of proficiency (PT) scores reported to HHS and the State Agency for the analytes tested under the sub-specialty of routine chemistry for the first event of 2019, review of remedial PT routine chemistry scores graded by the PT program on May 30, 2019 and interview with the laboratory director, the laboratory failed to provide a documented explanation and corrective action as to why the laboratory did not participate in the PT provider's scheduled PT event for routine chemistry for the first event of 2019. Findings include: 1. No documentation was presented for review pertaining to the participation in the PT provider's scheduled PT for the first event of 2019 for routine chemistry. 2. No documented explanation and corrective action was presented for review pertaining to the non-participation in the PT event indicated above. 3. No documented analysis of the graded and non-graded remedial PT was presented for review. 4. The laboratory director acknowledged that documentation pertaining the remedial PT performance and scheduled PT non-performance was not available for review. |
| **D5429** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of maintenance log sheets for the Abacus5 and AU680 instruments used to test patient samples, and interview with the laboratory director, the laboratory failed to document the weekly and monthly maintenance for the Abacus5 for November 2018, and July 2019, and the monthly maintenance for the AU680 for July 2019. Findings include: 1. The laboratory did not document weekly and monthly maintenance for the whole month of November 2018 and for weeks three, four in July 2019 and the month of July 2019. Weekly maintenance includes Hardcleaning with Hypoclean CC. Monthly maintenance includes Check Tubing for Leaks and Shear |

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| | Valve Cleaning. 2. The laboratory did not document the monthly maintenance for the AU680 for July 2019. The monthly maintenance includes Clean Sample Probe, Reagent Probe and HbA1c Wash Wells, Clean the Mix Bar Wash Cells, Clean the Wash Nozzle Unit and Check the Tube Mounting Joints, Clean the DI Water Tank, DI Filter and Sample Probe Filter. 3. The laboratory director acknowledged that the maintenance items listed above were not documented. |
| **D5439** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(b)<br><br>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of calibration verification documentation for the Beckman Coulter AU680 chemistry analyzer and interview with the laboratory director, the laboratory failed to perform and document calibration verification procedures as required. Findings include: 1. The laboratory uses a Beckman Coulter AU680 analyzer to conduct patient testing in the specialty of Chemistry, with an approximate annual test volume of 184,304. 2. No documentation was presented for review for 2018 and 2019 to indicate the laboratory performed a calibration verification at least once every six months, including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results. The laboratory provided documentation of a calibration verification performed on 10/25/2018, but no other documentation was presented for review. 3. The laboratory director confirmed that the laboratory was missing one calibration verification from 2018 and missed the calibration verification event that should have occurred in March 2019, according to the laboratory's calibration verification schedule. |
| **D5801** | TEST REPORT<br>CFR(s): 493.1291(a)<br><br>The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from |

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| | the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.<br><br>This STANDARD is not met as evidenced by:<br>**Based on review of patient test reports and interview with the laboratory director, the laboratory failed to have a system in place to ensure that test results are accurately and reliably transmitted from the laboratory's information system (LIS) to the final report destination in the patient's electronic medical record (EMR). Findings include: 1. It is the practice of the laboratory to electronically transmit patient test results from the instruments to the LIS and from the LIS to the EMR. The laboratory performs testing on the Beckman Coulter AU680 chemistry analyzer, Abacus 5 hematology analyzer and the Access 2 analyzer used for endocrinology testing. The laboratory's approximate annual test volume is 288,396. 2. During the previous survey conducted on 8/30/2017 the laboratory was issued a Standard Deficiency [493.1291(a)] for failing to have a system in place to ensure the accuracy and timely reporting of patient test results that are electronically transmitted from the Merge LIS system to the Athena EMR system. As a result of the deficiency, the laboratory's Plan of Correction indicated a policy was implemented stating that the lab would perform audits twice a year and a successful audit of transmitted results was performed on 9/29/17. 3. No documentation was presented for review from 2018 through the date of the survey conducted on September 26, 2019 to indicate the laboratory followed their policy indicated in the Plan of Correction referenced above and performed a biannual audit of electronically transmitted test results. 4. The laboratory director confirmed that the laboratory did not have record of biannual audits of electronically transmitted test results from 2018 and 2019 through the date of the survey. **This is a repeat deficiency from the previous survey conducted on 8/30/2017. |
| **D5891** | POSTANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1299(a)<br><br>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 postanalytic systems specified in 493.1291.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of Quality Assessment (QA) documentation, review of patient test reports and interview with the laboratory director, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems. Findings include: 1. It is the practice of the laboratory to electronically transmit patient test results from the instruments to the LIS and from the LIS to the EMR. The laboratory performs testing on the Beckman Coulter AU680 chemistry analyzer, Abacus 5 hematology analyzer and the Access 2 analyzer used for endocrinology testing. The laboratory's approximate annual test volume is 288,396. 2. During the previous survey conducted on 8/30/2017 the laboratory was issued a Standard Deficiency [493.1291 (a)] for failing to have a system in place to ensure the accuracy and timely reporting of patient test results that are electronically transmitted from the Merge LIS system to |

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| | the Athena EMR system. As a result of the deficiency, the laboratory's Plan of Correction indicated a policy was implemented stating that the lab would perform audits twice a year and a successful audit of transmitted results was performed on 9/29 /17. 4. No documentation was presented for review during the survey conducted on 9 /26/2019 to indicate the laboratory established a policy or procedure regarding the laboratory's audit process for electronically transmitted test results as stated in the Plan of Correction from the previous survey. The laboratory's Plan of Correction from the previous survey stated that "Quality Management Policy 3002 was updated to include semiannual audits of results transmitted electronically". 5. The laboratory director acknowledged that the policy number indicated by the laboratory on the previous deficiency statement was incorrect, however no written policy or procedure was presented for review as evidence during the survey. |
| **D6021** | 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 quality assessment programs are established and maintained to assure the quality of laboratory services provided.<br><br>This STANDARD is not met as evidenced by:<br>Based on repeat deficiencies and review of quality assessment policies and forms, the laboratory director failed to ensure that the quality assessment program is maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. See D5291, D5293, D5801 and D5891 for findings. |