

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  03D2114951	<b>(X3) Date Survey Completed</b>  07/17/2024
<b>Name of Provider or Supplier</b>  Southwest Kidney Institute, Plc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	Based on the on-site survey performed on 7/17/24, the laboratory was found to be out of compliance based on the following <b>CONDITION LEVEL DEFICIENCIES</b> : D2016 - 42 C.F.R. 493.803 Condition: Successful Participation D6000 - 42 C.F.R. 493.1403 Condition: Laboratory Director, moderate complexity D6063 - 42 C.F.R. 493.1421 Condition: Laboratory Testing Personnel
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This <b>CONDITION</b> is not met as evidenced by: Based on review of the Certification and Survey Enhanced Reporting (CASPER) 155 report and American Proficiency Institute's (API) proficiency testing records, the laboratory failed to successfully participate in two of three consecutive testing events</p>

	<p>in the subspecialty of Routine Chemistry for the regulated analyte, Total Bilirubin, in 2022 resulting in an initial unsuccessful performance. Refer to D2096. 1. The laboratory's PT performance was unsatisfactory for the second event of 2022 as indicated below: - Total Bilirubin - 40% 2. The laboratory's PT performance was unsatisfactory for the third event of 2022 as indicated below: - Total Bilirubin - 20%</p>
<p><b>D2096</b></p>	<p><b>ROUTINE CHEMISTRY</b> CFR(s): 493.841(f)</p> <p>Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Certification and Survey Enhanced Reporting (CASPER) 155 report and American Proficiency Institute's (API) proficiency testing records, the laboratory failed to achieve satisfactory performance (80% or greater) for two of three consecutive testing events in the subspecialty of Routine Chemistry for the regulated analyte, Total Bilirubin. Findings include: 1. A review of the CASPER 155 report revealed the following unsatisfactory scores: 2022 event 2, Total Bilirubin - 40% 2022 event 3, Total Bilirubin - 20% 2. A review of the proficiency testing scores from API confirmed the above findings.</p>
<p><b>D6000</b></p>	<p><b>MODERATE COMPLEXITY LABORATORY DIRECTOR</b> CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the Certification and Survey Enhanced Reporting (CASPER) 155 report and American Proficiency Institute's (API) proficiency testing records, the laboratory director failed to provide overall management and direction of the laboratory services. Refer to D6016.</p>
<p><b>D6016</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(i)</p> <p>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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Certification and Survey Enhanced Reporting (CASPER) 155 report and the American Proficiency Institute's (API) proficiency testing records from the second and third events of 2022, the laboratory director failed to ensure</p>

	<p>successful participation in an HHS approved proficiency testing program. Refer to D2096.</p>
<p><b>D6063</b></p>	<p><b>LABORATORY TESTING PERSONNEL</b> CFR(s): 493.1421</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of personnel records and interview with the facility personnel, the laboratory failed to provide documentation of academic credentials to qualify one out of three testing personnel for moderate complexity testing. Refer to D6065</p>
<p><b>D6065</b></p>	<p><b>TESTING PERSONNEL QUALIFICATIONS</b> CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p> <p>(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</p> <p>This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the technical consultant (TC-1), the laboratory failed to provide documentation of academic credentials to qualify one out of three testing personnel (TP-1) for moderate complexity testing. Findings include: 1. The laboratory performs 413,760 patient tests annually under the specialties of Chemistry and Hematology. 2. Review of the personnel records for one out of three testing personnel showed the laboratory failed to have academic credentials to qualify TP-1. 3. No documentation was presented for review during the survey to indicate the laboratory had the diploma and corresponding transcripts of the testing personnel indicated above evaluated by a foreign transcript evaluation agency to ensure the equivalent education requirements. 4. Interview with TC-1 on 7/17/24 at 9:00 AM confirmed the laboratory failed to provide the required documentation to qualify TP-1 for moderate complexity testing.</p>