

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  03D2025037	<b>(X3) Date Survey Completed</b>  11/29/2023
<b>Name of Provider or Supplier</b>  Sante Chandler, Llc	<b>Street Address, City, State</b>  825 S 94th St, Chandler, 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>D5301</b>	<p>TEST REQUEST CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</p> <p>This STANDARD is not met as evidenced by: Based on lack of test requisition documentation for review and interview with the technical consultant (TC-1), the laboratory failed to have a written or electronic request for patient testing for one out of five patient records reviewed during the survey. Findings include: 1. The laboratory began using the i-Stat analyzer for patient testing in December 2022. 2. No written or electronic request for testing was presented for review for one out of five patient records reviewed during the survey (patient ID: 010364, tested on 12/19/22 at 2:06 PM). 3. The TC-1 interviewed on 11/29/23 at 11:10 AM confirmed the laboratory failed to have an electronic or written test requisition for testing for the patient indicated above. 4. The laboratory's annual reported test volume in the specialties of Chemistry and Hematology is 216.</p>
<b>D5407</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and interview with the Technical Consultant (TC-1), the laboratory failed to have the current laboratory director approve, sign and date test procedures before use. Findings include: 1. The current laboratory director indicated in the CLIA Federal Database and assigned on</p>

the CMS-209, Laboratory Personnel Form presented for review during the survey has been listed as the laboratory director since 06/07/22. 2. The laboratory began patient testing on 12/19/22 in the specialties of Hematology and Chemistry with an annual test volume of 216. 3. The policy and procedure manual presented for review during the survey conducted on 11/29/23 was not approved, signed and dated by the current laboratory director before use. 4. The TC-1 interviewed on 11/29/23 at 10:55 AM confirmed that the policy and procedure manual indicated above was not approved, signed and dated by the current laboratory director prior to performing patient testing.

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

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.

This STANDARD is not met as evidenced by:  
Based on lack of performance evaluation documentation and interview with the technical consultant (TC-1), the technical consultant failed to evaluate and document the performance of one testing personnel, at least semiannually during the first year the individual tested patient specimens. Findings include: 1. No documentation of semiannual competency evaluation was presented for review during the survey conducted on 11/29/2023 for one out of one testing personnel who underwent initial training on 01/20/2022. 2. The TC-1 interviewed on 11/29/23 at 10:10 AM confirmed that the technical consultant failed to perform and document a semiannual competency evaluation for the testing personnel indicated above. 3. The laboratory uses the i-Stat analyzer to perform patient testing in the specialties of Chemistry and Hematology with a reported annual test volume of 216.

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

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.

This STANDARD is not met as evidenced by:  
Based on lack of performance evaluation documentation and interview with the technical consultant (TC-1), the technical consultant failed to evaluate and document the performance of one individual responsible for moderate complexity testing at least annually. Findings include: 1. No documentation of annual competency evaluation was presented for review for one out of one testing personnel who underwent initial training for i-Stat testing on 1/20/22. 2. The TC-1 interviewed on 11/29/23 at 10:10 AM confirmed the technical consultant failed to evaluate and document the performance of one out of one testing personnel at least annually. 3. The laboratory uses the i-Stat analyzer to perform patient testing with a reported annual test volume of 216.