

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2057079	(X3) Date Survey Completed 01/10/2018
Name of Provider or Supplier Chandler Surgery Center	Street Address, City, State 1475 W Chandler Blvd, Chandler, 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
D2128	<p>HEMATOLOGY CFR(s): 493.851(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) scores supplied by the PT agency and interview with the facility personnel, the laboratory failed to provide evidence of remedial action for the unsatisfactory scores of 0 received under the specialty of Hematology and for the regulated analyte Prothrombin Time respectively for the 3rd event of 2017. Findings include: 1. There was no documented corrective action or remedial action presented for review pertaining to the analyte and specialty scores indicated above. 2. The unsatisfactory scores received were due to non participation in the 3rd event of 2017. 3. The technical consultant indicated that she did not realize that Prothrombin Time testing performed on the i-STAT was classified as a moderately complex test by the FDA not a waived test as it is classified for testing on some other analyzers.</p>
D5407	<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 presented for review, the laboratory failed to have the current laboratory director approve, sign and date the manual. Findings include: 1. The laboratory utilizes the manufacturer's operator manual as the laboratory's procedure manual for testing under the specialty of Hematology using the i-STAT. 2. No signature and date by the current laboratory director was evident in the manual.</p>
<p>D5447</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p> <p>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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control (QC) policy, lack of quality control documentation for testing performed under the specialty of hematology and interview with the facility personnel, the laboratory failed to perform quality control procedures each day patient testing occurred. Findings include: 1. The laboratory performs PT/INR and ACT testing on the i-STAT. 2. No QC records were presented for review for three out of three patient test results reviewed including the following: ACT testing performed on 01/29/2016 (ID #49531), and PT/INR testing performed on 03/03/2017 (ID#52089) and 12/28/2017 (ID#56202). 3. The facility personnel acknowledged that they had continued to performed QC on a monthly basis for ACT and PT/INR testing, but had not performed or documented any component of an IQCP. 5. It could not be determined at the time of the survey how may patients were tested from 01/01/2016 to the date of survey without having QC performed the same day patient testing occurred.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR 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: The Condition of Laboratory Director was found not to be met based on the failure to fulfill the laboratory director's responsibilities (See D6019, D6020 and D6031 for findings).</p>
<p>D6019</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv)</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</p>

and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:
Based on lack of documented corrective action for unsatisfactory proficiency testing (PT) results and interview with the facility personnel, the laboratory director failed to ensure that an approved corrective action plan is followed when PT results are found to be unsatisfactory. See D2128 for findings.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

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.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's Quality Control (QC) records and policies and interview with the facility personnel, the laboratory director failed to ensure that the quality control program was maintained to assure the quality of patient testing performed on the i-STAT analyzer. See D5447 for findings.

D6031

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(13)

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;

This STANDARD is not met as evidenced by:
Based on lack of signature and date of the laboratory director on the manufacturer's instructions and guidelines which the laboratory was utilizing for a procedure manual, the director failed to ensure an approved procedure manual was available for personnel (See D5407 for findings)

D6066

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(4)(ii)

Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

This STANDARD is not met as evidenced by:

Based on review of initial training documentation for testing personnel and interview with the technical consultant, the laboratory failed to have one out of two testing personnel signed off on initial training criteria prior to testing patients. Findings include: 1. There was no documented on site training for one testing personnel that was signed by either the laboratory director or technical consultant prior to testing one patient specimen for ACT. 2. The technical consultant acknowledged that there was no signed documentation referenced above.