Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2103356	05/26/2021
Name of Provider or Supplier	**Street Address, City, State**	
Haven Health Sky Harbor	1880 E Van Buren St, 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
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: Based on lack of test requisition documentation for review and interview with the facility personnel, the laboratory failed to have a written or electronic request for patient testing for two out of four patient records reviewed during the survey. Findings include: 1. The laboratory performs Arterial Blood Gas (ABG) testing and routine chemistry testing under the specialty of Chemistry, with an approximate annual test volume of 2,075. 2. No written or electronic request for ABG testing was presented for review for two of four patient records reviewed during the survey, patient# 315124 tested on 5/12/19 at 07:18 AM and patient# 315079 tested on 3/15/20 at 12:54 PM. 3. The laboratory's established policy reviewed during the survey conducted on May 26, 2021 titled, "Blood Gas-CG4+ or CG8+" stated, "A physician/provider must order a Blood Gas/CG4+ or CG8+ test and document it in the patient's records." 4. The facility personnel confirmed that the laboratory did not have an electronic or written test requisition for testing that was performed on the patients indicated above.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) 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. This STANDARD is not met as evidenced by: Based on lack of calibration verification documentation for blood gas testing and interview with the testing personnel, the laboratory failed to perform and document calibration verification procedures as required. Findings include: 1. The laboratory performs Arterial Blood Gas (ABG) testing on the I-Stat analyzer, with an approximate annual test volume of 2,075. 2. Review of the laboratory's established policy titled, "Calibration & Calibration Verification" during the survey conducted on May 26, 2021 stated, "Calibration verification is required every six months for Blood Gas cartridges." 3. No documentation was presented for review to indicate the laboratory performed a calibration verification for ABG testing at least once every six months during 2019, 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 performed a calibration verification on 11/08/18. A calibration verfiication was not performed again until 5/29/20. 4. The facility personnel acknowledged that a calibration verification was not performed every 6 months on the I-stat analyzer as required for ABG testing.
D5801	TEST REPORT CFR(s): 493.1291(a) 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 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. This STANDARD is not met as evidenced by: Based on review of patient test results in the laboratory's Electronic Medical Record (EMR), review of patient test records and interview with the facility personnel, the laboratory failed to ensure that test results are accurately and reliably sent from the point of data entry to the final report destination. Findings include: 1. The laboratory performs Arterial Blood Gas (ABG) testing on the I-Stat analyzer in the specialties of Chemistry and Hematology, with an approximate annual test volume of 2,075. 2. The laboratory utilizes an EMR, Point Click Care, as the final report destination for results

	of laboratory testing. 3. The laboratory's established policy titled, "Blood Gas-CG4+ or CG8+" reviewed during the survey conducted on 5/26/21 stated, "Reports will be scanned into the patient's EHR." 4. Review of ABG test results for patient (MR# 315757) performed on 9/12/20 at 07:12 AM revealed the ABG test results were missing from the EMR. 5. The facility personnel confirmed the ABG test results indicated above were not reliably sent to the EMR.