Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0675619	02/08/2018
Name of Provider or Supplier	**Street Address, City, State**	
Honorhealth Medical Group Saguaro	18404 N Tatum Boulevard #101, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records for 2017 for testing performed in the specialty of Chemistry and interview with the technical consultant, the laboratory director failed to sign the PT attestation statement. Findings include: 1. The PT attestation statement presented for review for the first testing event of 2017 lacked the director's signature. 2. The technical consultant confirmed that the PT attestation statement indicated above was not signed by the laboratory director.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) 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. This STANDARD is not met as evidenced by: Based on lack of Quality Assessment (QA) policies for review, review of Proficiency Testing (PT) records and interview with the facility personnel, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated correct problems identified in the general laboratory systems including, but not limited to, proficiency testing performance and employee

	competency. Findings include: 1. No QA documentation was presented for review during the survey to indicate the laboratory had established written policies and procedures for an ongong mechanism to monitor, assess, and when indicated correct problems identified with employee training and competency. See D6029, D6053 and D6054 for specific findings. 2. No documentation was presented for review during the survey to indicate that the corrective action taken as part of the laboratory's QA process was effective at monitoring and correcting errors associated with unsatisfactory PT scores. See D5293 for specific findings. 3. The facility personnel confirmed that the laboratory's QA processes at the time of the survey were not effective at identifying and correcting problems associated with employee competency and proficiency testing performance.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (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. This STANDARD is not met as evidenced by: Based on review of the laboratory's Proficiency Testing (PT) results, Quality Assessment (QA) records and interview with the facility personnel, it was determined that the laboratory failed to document corrective actions taken to resolve problems associated with unsatisfactory Proficiency Testing (PT) scores. Findings include: 1. The laboratory participates in PT as a means to verify accuracy for microscopic urinalysis testing and received an unsatisfactory score of 50% for the 1st testing event of 2017. 2. It is the practice of the laboratory to complete a "PT Exception Investigation Worksheet" for any unsatisfactory PT scores. 3. The PT Exception Investigation Worksheet presented for review during the survey for Q1 Chem, Urine Microscopic indicated that the error was due to technician interpretation and the corrective action documented on the form stated, "proper training with various sediments, including pictures as well". 4. No retraining documentation was presented for review during the survey to indicate the laboratory performed the corrective action documented on the PT Exception Investigation Worksheet. 5. The facility personnel confirmed that the laboratory did not perform the corrective action documented on the form for the unsatisfactory PT score indicated above.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by:

	Based on lack of room temperature records for review and interview with the facilty personnel, the laboratory failed to monitor and document the temperature of the room where blood collection tubes are stored prior to patient use. Findings include: 1. The laboratory performs patient testing under the specialties of Diagnostic Immunology, Chemistry and Hematology, with an approximate annual test volume of 2,996,898. 2. No documentation was presented for review to indicate the laboratory monitored and documented the temperature of the room where blood collection tubes are stored. The blood collection tubes have a manufacturer's storage requirement of 4 to 25 degrees Celsius. 3. The facility personnel confirmed that the laboratory did not monitor and document the room temperature as indicated above.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on lack of training documentation and interview with the facility personnel, the laboratory director failed to ensure that prior to testing patients' specimens, all personnel have the appropriate training for the type and complexity of services offered, and have demostrated that they can perform all testing operations reliably to provide and report accurate results. Findings include: A1. No documentation of initial training was presented for review for two out of two testing personnel hired in November 2016 and August 2017. A2. The facility personnel confirmed that the testing personnel indicated above did not have documentation of initial training prior to testing patient specimens. B1. No documentation of initial training was presented for review for five out of five testing personnel who perform KOH testing. The laboratory resumed KOH testing on 01/24/2017 but failed to provide and document training for this test. B2. The facility personnel confirmed that the five testing personnel indicated above did not have documented training for KOH 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 facility personnel, the technical consultant failed to evaluate and document the performance of two testing personnel at least semiannually during the first year the individuals tested patient specimens. Findings include: 1. No semiannual competency evaluation documentation was presented for review for two out of two testing

	personnel who began patient testing in November 2016 and May 2017, respectively. 2. The facility personnel confirmed that the laboratory did not have documentation of a semiannual competency evaluation for the two testing personnel indicated above. **This is a repeat deficiency from the previous survey conducted on February 24, 2016.
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 competency evaluation documentation for review and interview with the facility personnel, the technical consultant failed to evaluate and document the performance of individuals responsible for moderate complexity testing at least annually. Findings include: 1. No 2016 annual competency evaluation documentation was presented for review for one out of one testing personnel. 2. The facility personnel confirmed that the laboratory failed to provide documentation of an annual competency evaluation from 2016 for the testing personnel indicated above.