Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0675619	02/28/2020
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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of Proficiency Testing (PT) records for 2019 and interview with the facility personnel, the laboratory failed to enroll in an HHS approved PT program for the regulated analytes, Infectious Mononucleosis (Mono) and Thyroid Stimulating Hormone (TSH), tested in the specialties of Diagnostic Immunology and Chemistry, which are included in subpart I . Findings include: 1. The laboratory uses the Sure-Vue serum Mono test kit to perform patient testing under the specialty of Diagnostic Immunology, with an approximate annual test volume of 16,733. 2. Review of the laboratory's PT records for 2019 indicated the laboratory was enrolled in 'method code# 4210, Mono Immunoserology, Sure-Vue (Waived)'. The laboratory participated in three PT events during 2019 under the waived method. 3. No other documentation was presented for review during the survey conducted on 2/28/2020 to indicate the laboratory participated in PT for the regulated analyte, Mono, using the serum method. 4. The laboratory performs TSH testing in the specialty of Chemistry. The laboratory's approximate annual test volume for the specialty of Chemistry is 1,459,019. 5. No documentation was presented for review during the survey to indicate the laboratory was enrolled in a HHS-approved PT program for the 1st and 2nd PT event of 2019 for the regulated analyte, TSH, listed in subpart I, for which the

	laboratory performs patient testing. 6. The facility personnel confirmed that the laboratory failed to enroll in PT for serum Mono during 2019 and failed to enroll in PT for TSH for the first two testing events of 2019.
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 review of Proficiency Testing (PT) records from 2018 and interview with the facility personnel, the laboratory failed to document corrective action for unsatisfactory PT scores for the regulated analyte, serum hCG Findings include: 1. The laboratory participated in PT for the regulated analyte, serum hCG, during 2018. The laboratory received a score of 0% for the 3rd testing event. 2. No corrective action documentation was presented for review during the survey to indicate the laboratory identified and corrected the error of unsatisfactory PT scores as indicated above. 3. The facility personnel confirmed that the laboratory failed to document corrective action for the unsatisfactory PT scores referenced 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 review of the manufacturer's criteria for the relative humidity requirement for the environment where the Sysmex hematology analyzer is operated, the humidity range indicated on the laboratory's log sheets and interview with the facility personnel, the laboratory failed to follow the manufacturer's instructions for the humidity levels where the Sysmex hematology analyzer is operated. Findings include: 1. The laboratory performs patient testing on the Sysmex 1000 XS hematology analyzer, with an approximate annual test volume of 559,765. 2. The manufacturer's specifications for the relative humidity (RH) are between 30% and 85% with no condensation. 3. The laboratory's temperature logs indicated an acceptable humidity range of 20% - 80%. 4. The facility personnel acknowledged that the laboratory's established humidity range was not consistent with the manufacturer's requirements.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 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. This CONDITION is not met as evidenced by: The Condition of Laboratory Director was found to be not met based on the failure to provide overall management and direction as evidenced by D6015 - ensuring that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: The laboratory director failed to ensure the laboratory was enrolled in an HHS approved proficiency testing program for the testing of the regulated analytes, serum Mono and TSH, under the sub-specialties of General Immunology and Endocrinology. See D2000 for findings.