Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0530411	06/28/2021
Name of Provider or Supplier	**Street Address, City, State**	
Honorhealth Tempe Medical Center	1500 S Mill Ave, Tempe, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on lack of employee competency policies and procedures for review and interview with the facility personnel, the laboratory failed to establish policies and procedures to assess the competency of Technical Consultants, Technical Supervisors and General Supervisors. Findings include: 1. The CMS-209, Laboratory Personnel form submitted for review during the survey conducted on June 28, 2021 listed 15 Technical Supervisors, 4 Technical Consultants and 22 General Supervisors. 2. No documentation was presented for review to indicate the laboratory established policies and procedures to assess the competency of the Technical Supervisors, Technical Consultants and General Supervisors. 3. The facility personnel confirmed that the laboratory did not have policies established to assess the competency of the laboratory personnel indicated above.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) 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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The

	laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of Quality Control (QC) documentation and interview with the facility personnel, the laboratory failed to perform and document control procedures using the number and frequency as required for testing performed in the specialty of Diagnostic Immunology. Findings include: 1. The laboratory performs Mono testing on patient specimens using the Cardinal Health Mono II Rapid Test kit under the specialty of Diagnostic Immunology, with an annual approximate test volume of 46. 2. On the date of the survey, June 28, 2021, review of the manufacturer's package insert for the test kit indicated above stated, "For external QC testing, use the controls provided in the kit....Quality Control requirements should be established in accordance with local, state and federal regulations or accreditation requirements. Minimally, Cardinal Health recommends that positive and negative external controls be run with each new lot and with each new untrained operator." Each mono kit includes 1 Mono Positive control and 1 Mono Negative control. 3. One patient test report (specimen ID# 0624: S00002S) for mono testing performed on 06/24/21 was reviewed during the survey. 4. The laboratory log used to track QC performance for the mono test kit indicated that external QC (positive and negative, lot# 16201240) was last performed by the laboratory on 06/01/21. 5. No other QC documentation was provided for review during the survey for the Mono II Rapid test, to indicate the laboratory performed two levels of control material of different concentrations each day of patient testing (including patient testing that occurred on 06/24/21, see #3 above) as required since January 1, 2016. The laboratory had not established an Individualized Quality Control Plan (IQCP) for this test. 6. Approximately 3 patients were tested using the mono test kit in June 2021, to the date of the survey. 7. The facility personnel confirmed that the laboratory did not perform and document external controls each day of patient testing as required since January 1, 2016.
D5543	HEMATOLOGY CFR(s): 493.1269(a)(d) (a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of laboratory test records for Body Fluid testing and interview with the facility personnel, the laboratory failed to perform at least one control material each day of patient testing. Findings include: 1. The laboratory performs body fluid counts using a hemacytometer. The laboratory's 'Cell Count Control Log Sheet' used to document the body fluid controls states, "One level of Control every 8 hours of patient testing. Count and record each side of the counting chambers - results should match within 10%. The 2 levels should be alternated equally." 2. Patient test report (0609:BF00005S) for a Cerebrospinal Fluid (CSF) analysis performed by the laboratory on 06/09/21 was reviewed during the survey conducted on June 28, 2021. 3. No cell count Quality Control (QC) documentation was presented for review to indicate the laboratory performed one level of control material every 8 hours of

	patient testing on 06/09/21. 4. The facility personnel confirmed that the laboratory failed to perform and document one level of control material every 8 hours of patient testing on 6/09/21, as indicated in laboratory policy.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on lack of quality control records and review of control procedures, the laboratory director failed to ensure that quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. See D5445 and D5543 for findings.