Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2258662	11/27/2024
Name of Provider or Supplier	**Street Address, City, State**	
Honorhealth Complete Care	16575 W Waddell Rd, Surprise, 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
D0000	An initial survey was performed on November 27, 2024. The facility was found to be NOT in compliance with the following CLIA conditions for specialties/subspecialties surveyed for 42 CFR: 493.803 - Successful Participation 493.1421 - Laboratory Testing Personnel - Moderate Complexity
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of Proficiency Testing (PT) reports from American Proficiency Institute (API) and PT reports sent to the State Agency for 2023 and 2024, (A) the laboratory failed to successfully participate in a PT program for the regulated analyte, Activated Partial Thromboplastin Time (APTT), for the 3rd event of 2023 and the 2nd

	event of 2024, and (B) the laboratory failed to successfully participate in a PT program for the analyte, Troponin, in the 1st and 3rd events of 2023. Findings include: A1. The laboratory's PT performance was unsatisfactory for the third event of 2023 for the regulated analyte, APTT, with a score of 40%. A2. The laboratory's PT performance was unsatisfactory for the second event of 2024 for the regulated analyte, APTT, with a score of 60%. A3. Unsatisfactory participation in the third event of 2023 and second event of 2024 for the regulated analyte, APTT, constitutes an initial unsuccessful PT performance. B1. The laboratory's PT performance was unsatisfactory for the first event of 2023 for the analyte, Troponin, with a score of 40%. B2. The laboratory's PT performance was unsatisfactory for the third event of 2023 for the analyte, Troponin, with a score of 20%. B3. Unsatisfactory participation in the first and third events of 2023 for the analyte, Troponin, constitutes an initial unsuccessful PT performance.
D2089	ROUTINE CHEMISTRY CFR(s): 493.841(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on a review of Proficiency Testing (PT) records from 2024, review of the CASPER Report 0157D for 2024, and interview with the technical consultant (TC-1), the laboratory failed to participate in the third testing event of 2024 for testing performed on the ABL90 Flex Blood Gas analyzer resulting in unsatisfactory performance and a score of 0% for the testing event, and the laboratory failed to suspend patient testing during that time period. Findings include: 1. The laboratory began patient testing on the ABL90 Flex Blood Gas analyzer in the subspecialty of Routine Chemistry in April 2024. 2. Review of the CMS CASPER 0157D (Excused Nonparticipation Report) for 2024 revealed the laboratory failed to obtain a graded PT score during the 3rd testing event of 2024 for the following analytes: pH (Blood Gas), PO2 (Blood Gas), PCO2 (Blood Gas), Chloride, Glucose, Potassium and Sodium. 3. API's PT records for the third testing event of 2024 stated "Lab Reported Test Problem" for the analytes referenced above. 4. The laboratory failed to suspend patient testing during the time frame allotted for testing and reporting proficiency testing results during the third testing event of 2024 for the analytes: pH (Blood Gas), PO2 (Blood Gas), PCO2 (Blood Gas), Chloride, Glucose, Potassium and Sodium. 5. TC-1 interviewed on 11/27/24 at 1:30 PM confirmed the laboratory participated in the third testing event of 2024 for the testing indicated above, notified the PT agency of a test problem (which excused the laboratory from receiving a graded score for PT results), and failed to suspend patient testing during that timeframe. 6. The laboratory's annual test volume under the specialty of Chemistry is 69,635.
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e)

	(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. This STANDARD is not met as evidenced by: Based on the information furnished to the State Agency by the Proficiency Testing (PT) provider, it could not be determined if the laboratory underwent training and technical assistance and if remedial action was taken to correct the PT failures for the analyte, Troponin, during the first and third events of 2023. See D2016 for findings.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the Proficiency Testing (PT) records from API for 2023, the laboratory failed to achieve satisfactory performance for the first and third events of 2023 for the analyte, Troponin, resulting in unsuccessful PT performance. See D2016 for findings.
D2128	HEMATOLOGY CFR(s): 493.851(e) (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. This STANDARD is not met as evidenced by: Based on information the Proficiency Testing (PT) provider furnishes to the State Agency, it could not be determined if the laboratory underwent training and technical assistance and if remedial action was taken to correct the PT failures for the third event of 2023 and 2nd event of 2024 for the regulated analyte, APTT. See D2016 for findings.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive

	events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on information furnished to the State Agency by the Proficiency Testing (PT) provider, the laboratory failed to achieve satisfactory performance for the third event of 2023 and the second event of 2024 for the regulated analyte, APTT, resulting in unsuccessful performance. See D2016 for findings.
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 established humidity criteria defined by the laboratory, review of the manufacturer's specifications for the i-Stat, Sysmex XN-550, Triage Meter Pro and ABL90 Flex analyzers, and interview with the technical consultant (TC-1), the laboratory failed to define criteria for the humidity of the area where the instruments are utilized. Findings include: 1. The laboratory began patient testing on 6/06/2022 in the specialties of Chemistry and Hematology, with a reported annual test volume of 137,734. 2. The manufacturer's specifications reviewed during the survey for the analyzers used by the laboratory for patient testing listed the operating relative humidity ranges as follows: Sysmex XN-550 = 20-85% relative humidity (RH) i-Stat = 10-90% RH Triage Meter Pro = 10-85% RH ABL90 Flex = 20-80% RH 3. The laboratory failed to 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, including the humidity of the room where patient testing is performed. 4. The laboratory performed patient testing on approximately 905 days from 6/06/2022 through 11/27/2024. 5. The TC-1 interviewed on 11/27/24 at 3:35 PM confirmed the laboratory failed to define the humidity criteria for the area where patient testing occurs.
D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on review of the laboratory's critical value policy, review of one out of two patient's critical test results for Blood Gas testing, and interview with the TC-1, the laboratory failed to immediately alert the individual or entity requesting the test when the test result indicates an imminently life-threatening condition, or panic or alert

	values. Findings include: 1. The laboratory performs Blood Gas testing on the ABL90 Flex analyzer. The laboratory's reported annual test volume for the specialty of Chemistry is 69,635. 2. The laboratory's established critical value policy states, "Point of Care requires that all critical values must be reported immediately to the RN, RT, EMT and/or the licensed caregiver for the patient". 3. Review of one out of two critical test results (ID#6184773) performed on 12/07/22 at 0942 indicated a critical low test result for PCO2 = 14.7 mm Hg. 4. No documented evidence was presented for review to indicate the laboratory notified the individual or entity requesting the test of the critical test value for the patient indicated above per policy. 5. The TC-1 interviewed on 11/27/24 at 3:10 PM confirmed the laboratory failed to immediately alert the individual or entity requesting the test of the critical PCO2 test result referenced above.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of personnel records and interview with the technical consultant (TC-1), the laboratory failed to have academic credentials required to qualify one of 66 testing personnel for the specialties of Chemistry and Hematology for moderate complexity testing (Refer to D6065).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the technical consultant TC-1, the laboratory failed to have documentation of academic credentials to qualify one of 66 testing personnel (TP) for moderate complexity testing. Findings include: 1. Review of the personnel records for one of 66 testing personnel for the specialties of chemistry and hematology revealed the laboratory failed to have academic credentials to qualify TP #13. 2. Interview with TC #1 on 11/27/24 at 12:30 PM confirmed the laboratory failed to have the required documentation to qualify TP #13 for moderate complexity testing. 3. The laboratory reports approximately 137,734 tests annually.