

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D2337408	(X3) Date Survey Completed 09/02/2026
Name of Provider or Supplier Harmony Health Clinic	Street Address, City, State 15111 Hwy 165, Scott, AR	
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) (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 upon a review of the American Proficiency Testing Institute (API) proficiency test attestation records for 2 events in 2026, lack of documentation, and interviews with laboratory staff, the laboratory failed to secure the required signatures to attest to the routine integration of proficiency test samples in the patient workload on 2 of the 2 events reviewed. Survey findings follow: A) Review of the attestation forms for API Hematology/Coagulation 2026 1st proficiency test event revealed that it was not signed by the lab director or designee or the testing personnel. B) Review of the attestation forms for API Hematology/Coagulation 2026 2nd proficiency test event revealed that it was not signed by the lab director or designee. C) In an interview, at 9:46 a.m.on 9/2/26, the laboratory staff member (#2 on the form CMS 209) confirmed the API proficiency testing attestation forms identified above were not signed by the required personnel.
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) (c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory.

	This STANDARD is not met as evidenced by: Based upon observation made during a tour of the laboratory, review of the laboratory policy and procedure manual, lack of documentation, review of patient result reports, and interview with laboratory staff, the laboratory failed to have written procedures or manufacturer's instruction for use (IFU) for respiratory disease panels performed on the Biomerieux Biofire analyzer. Findings follow: A) During an initial tour of the laboratory on 9/2/26 at 08:45 a.m., two Biomerieux Biofire analyzer units were observed on the laboratory testing bench. B) Review of the laboratory's policy and procedure manual revealed that there was no written procedure or manufacturer's IFU for the performance of respiratory disease panels on the Biofire analyzer. C) Upon request, the laboratory could not produce a written procedure or manufacturer's IFU for the Biofire analyzer. D) Review of patient result records for May 2026 revealed that respiratory disease panels were performed and reported on patients. E) In an interview on 9/2/26 at 09:54 a.m., the laboratory staff member (#2 on the form CMS 209) confirmed that there was no written procedure or manufacturer's IFU for respiratory panels performed on the Biomerieux Biofire analyzers.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 upon manufacturer's package insert, observation, lack of documentation, and interview with laboratory staff, the laboratory failed to change the expiration date on Afinion Hemoglobin A1C test cartridges when placed into room temperature storage . Findings follow: A) Review of the manufacturer's package insert for Afinion A1C Hemoglobin cartridges revealed that the expiration date for the cartridges is to be changed to 90 days when stored at room temperature. B) During a tour of the laboratory on 9/2/26 at 01:15 p.m., ten Afinion A1C Hemoglobin cartridges, lot # 10236501, expiration date 2028-01-08 with a storage temperature requirement of 2 degrees centigrade (C) to 8 degrees C, were observed in the laboratory testing area at room temperature with no change in expiration date or date when the cartridges were placed in the room temperature environment. C) In an interview on 9/2/26 at 01:15 p.m., the laboratory staff member (number 2 on the form CMS 209) confirmed that the expiration date of the cartridges identified above had not been amended and could not state the date that the cartridges were placed into room temperature.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

	This STANDARD is not met as evidenced by: Based on observation and interview with laboratory staff, the laboratory had supplies available for use after their expiration date. Findings follow: A) During a tour of the laboratory on 9/2/26 at 1:10 pm, two (of two) containers of "Bactalert FA Plus", lot 004103448 expiration date 2026-05-14) were observed in the laboratory available for use beyond the expiration date. B) During a tour of the laboratory on 9/2/26 at 1:10 pm, two (of two) containers of "Bactalert FN Plus", lot 00403692 expiration date 2026-05-25) were observed in the laboratory available for use beyond the expiration date. C) During a tour of the laboratory on 9/2/26 at 1:10 pm, four (of four) BD 6.0 ml Trace Element blood collection tubes containers of "lot 5076224 expiration date 2026-03-31) were observed in the laboratory available for use beyond the expiration date. D) In an interview on 09/2/26 at 01:15 pm the testing personnel # 2 (as identified on the CMS-209 form) confirmed that the items, identified above, had exceeded their expiration date and were available for use in the laboratory.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: . Through a review of the new instrument validation documentation dated 3/3/26 for the Sysmex XN330 Hematology analyzer, lack of documentation, as well as interviews with staff, the Laboratory the laboratory director failed to approve validation procedures to ensure they are adequate to determine the accuracy, precision, and other pertinent performance characteristics as evidenced by: A) A review of the validation documentation for the Sysmex XN 330 Hematology analyzer dated 3/3/26, revealed the validation procedures were not approved and signed by the Laboratory Director. B) In an interview on 9/2/26 at 10:30 a.m., laboratory staff member #2 (as listed on CMS form 209) confirmed the validation procedures for the Sysmex XN 330 Hematology Analyzer were not approved or signed by the Laboratory Director.
D6033	TECHNICAL CONSULTANT-MODERATE COMPLEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based upon review of the CMS 209 form, review of personnel records, lack of documentation, and review of official transcripts provided by laboratory staff, the laboratory failed to employ a qualified technical consultant in a laboratory performing moderately complex testing as evidenced in: D6034: The laboratory failed to appoint a technical consultant meeting the required qualifications of technical consultant for a laboratory performing moderately complex testing.
D6034	TECHNICAL CONSULTANT QUALIFICATIONS

CFR(s): 493.1411

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section.

This STANDARD is not met as evidenced by:

Based upon a review of the CMS 209 form, review of the statement of delegation of authority, review of personnel records, lack of documentation, and interview with laboratory staff, the laboratory failed to employ a qualified technical consultant. Finding follow: A) Review of the CMS 209 form revealed that the laboratory staff member (number 2 on the form CMS 209) was designated as the technical consultant. B) Review of the statement of delegation of authority signed by the laboratory director revealed the the laboratory staff member (number 2 on the form CMS 209) was authorized to perform the duties of the technical consultant. C) Review of the personnel records for the laboratory staff member (#2 on the form CMS 209) revealed a diploma awarding a bachelor's degree in healthcare administration from Southern New Hampshire University and a certificate in laboratory science from Concorde Career College neither of which individually or taken together documented the required qualifications of a technical consultant. D) When requested to provide documentation of the required academic qualifications of a technical consultant via email on 9/3/26, the laboratory staff member (#2 on the form CMS 209) provided a transcript from Southern New Hampshire University which documented ten semester hours in chemistry and biology in combination. E) On 9/3/26 via email the staff member (#2 on the form CMS 209) was provided with a copy of the required qualifications of a technical consultant but did not offer documentation of additional academic qualifications.

D6045

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(7)

(b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;

This STANDARD is not met as evidenced by:

Based upon review of American Proficiency Testing Institute (API) proficiency testing (PT) results, laboratory review of PT results, lack of documentation, and interview, the laboratory failed to document the training of testing personnel. Findings follow: A) Review of API Hematology Coagulation 2026 Event 1st event results revealed a score of 80% for hemoglobin and 80% for hematocrit with a note that samples were not mixed adequately by the testing personnel. B) Review of API Hematology Coagulation 2026 Event 2nd event results revealed a score of 0% for all analytes with a note that stated the testing personnel failed to perform the testing. C) Review of the CMS 209 form revealed that no testing personnel were submitted on the form. D) In an interview on 9/2/26 at 10:15 a.m. the laboratory staff member (# 2 on the form CMS 209) stated that the testing personnel referred to in the API Hematology/Coagulation events, identified above, was no longer employed and left

employment "around the end of July or the first of August". E) When asked for the training documents for the testing personnel identified above during an interview on 9/2/26 at 10:15 a.m. the laboratory staff member (#2 on the form CMS 209) stated "I don't think I still have them".