

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D2307207	(X3) Date Survey Completed 05/20/2025
Name of Provider or Supplier Harmony Health Clinic	Street Address, City, State 437 Country Club Road, Osceola, 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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory policies and procedures for hematology, a review of the hematology summary sample records, and interviews with laboratory staff, the laboratory failed to follow written procedures for Hematology IP messages of the Sysmex flags. Survey findings include: A) The laboratory policy and procedure titled, "IP Messages of the Sysmex" states the following, "It is necessary to review all flagging by the analyzer prior to reporting the patient results. 1. Check the specimen for clots or agglutination. Recollect if clots are found. 2. If not clots are detected, the specimen will be re-mixed and retested. (Limit flags =/- will only need to be repeated if the value is critical.) 3. If flag persists, at the discretion of the provider, send the sample to the reference laboratory for a manual differential." Twenty-one out of seventy-one samples had flags. The flag noted with the twenty-one sample states, "Display symbol * meaning low reliability. Indicates that the reliability of the data is low." Twenty-one samples with the flag "*". List of sample numbers with this flag: 180441559, 180632295, 180720162, 180877796, 180975768, 181145087, 181163838, 181221168, 181491572, 181572846, 181579132, 181723020, 181751562, 181755866, 181815887, 181854342, 181854805, 181855812, 181905591, 181949899, and 181963598. B) Review of the laboratory policy and procedure titled 1. Standard Relationship of patient information to patient's results states, "Patient test results are reviewed with pertinent patient data at the time the test is performed by testing personnel. B. Corrective Action 1. If apparent discrepancies are noted, repeat the test in order to verify accuracy". No repeat of the test performed</p>

on twenty-one out of seventy-one samples had flags. C) Upon request, the laboratory could not provide corrective actions and no repeated test results for the twenty-one samples with the flag "*". D) In an interview, at 3:01pm on 5/20/25, the Technical Consultant confirmed no corrective actions and no repeated test results for the twenty-one samples with the flag "*".

D5893

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(b)(c)

(b) The postanalytic 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 postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities.

This STANDARD is not met as evidenced by:

Based on review of monthly quality assessment reports and interviews with staff it was determined the laboratory failed to properly maintain quality assurance (QA) records. Survey findings follow: A. The laboratory's policies 7. Standard Quality Control Assessment states, "The laboratory monitors the effectiveness of the corrective action taken for problems identified with controls on a test method, calibration activities or error detected when reporting patient test results." B. During review of QA records for 2025, records were available for February, March, and April. QA records did not identify problems with patient results. C. In an interview, at 3:01pm on 5/20/25, the Technical Consultant confirmed no corrective actions and no repeated test results for the twenty-one samples with the flag "*" for February, March, and April.