Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0898696	08/20/2026
Name of Provider or Supplier	**Street Address, City, State**	
Archer Crosley Md	412 Lindberg Avenue, Mcallen, TX	

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	The Archer Crosley MD laboratory was found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, CLIA requirements for laboratories as a result of an announced validation survey on August 20, 2026 and recertification is recommended. Standard level deficiencies were cited.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: Based on review of the laboratory's records and interview, the laboratory failed to retain the lot number, expiration date and open date of the Medonic M series Pack with Diluent and Lyse used on the Medonic M series used to test the Complete Blood Count (CBC) for 21 of 24 months reviewed from September 2024 - August 2026. Findings follow. A. Review of the reagent log on the Medonic M analyzer for the Medonic M series Pack with the Diluent and Lyse only showed records from 05/11 /2026 to present. B. Interview with testing personnel #1 (as listed on the CMS Form 209) on August 20, 2026 at 1130 hours in the laboratory confirmed they did not periodically print the reagent log from the analyzer so all that they had was what could be recovered on the analyzer.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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.

This STANDARD is not met as evidenced by:
Based on review of the manufacturer's instructions, laboratory policy and procedure, test reports, pre-survey paperwork, and interview, the laboratory failed to provide an updated policy and procedure for handling flagged Complete Blood Count (CBC) indices using the Medonic M series analyzer for nine out of nine test reports reviewed from April 2026 - May 2026. Findings follow. A. Review of the Medonic M-series User Manual, (no revision date), under Section 9: Parameter and System Information Messages at the chart for WBC Differential Abnormalities stated, "Indicator BD Message WBC DIFF: High interference between populations. Description The calculated populations for LYM, MID, GRAN overlap too much. Often in pathological samples with granulocytosis or lymphocytosis a blood smear is recommended. Action Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results. Indicator OM Message WBC DIFF: Only one WBC population found: Slide review advised. Description There was only one mode in the WBC distribution between the LYM-L and GRAN-H settings. Often in pathological samples with granulocytosis or lymphocytosis a blood smear is recommended. Action Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results. Indicator TM Message WBC DIFF: Too many WBC population found: Slide review advised. Description There were more than two modes in the WBC distribution between LYM-L and GRAN-H settings. Action Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results." B. Review of the laboratory's policy and procedure titled Policy for Handling Flagged CBC Differentials, approved 09/04 /2013, stated, "It will be the policy of this laboratory to rerun flagged CBC results. If the second run still shows flags, then the lab will evaluate flagged differentials according [to] the procedures in the unit's operator manual. See that the sample requirements are met, that the unit is in good working order, and that the testing procedure is correctly followed. Sometimes the flags will disappear when the sample is allowed to equilibrate at room temperature for 15 to 20 minutes, or by re-drawing the patient. If the flags disappear, then report that result. If the flags persist, then report and have the clinician review the patient's results in totality and review the patient clinically. The lab will then perform whatever follow-up action the clinician requests." C. Review of randomly selected reports showing flags from the data logs printed from the analyzer showed nine out of nine reports were reported that included flags on the WBC differential as listed by Date of Service, ID number, and flags: 1. 04 /30/2026, 19288, LYM % BD MID % BD GRAN % BD LYM BD MID BD GRAN BD 2. 5/11/2026, 20276, LYM % BD MID % BD GRAN % BD LYM BD MID BD GRAN BD 3. 05/11/2026, 18579, LYM % OM MID % OM GRAN % OM LYM OM MID OM GRAN OM 4. 05/12/2026, 22006, LYM % OM MID % OM GRAN % OM LYM OM MID OM GRAN OM 5. 05/14/2026, 22035, LYM % OM MID % OM GRAN % OM LYM OM MID OM GRAN OM 6. 05/15/2026, 22138, LYM % OM MID % OM GRAN % OM LYM OM MID OM GRAN OM 7. 05/15/2026, 22193, LYM % BD MID % BD GRAN % BD LYM BD MID BD GRAN BD 8. 05/26/2026, 21638, LYM % OM MID % OM GRAN % OM LYM OM MID OM GRAN OM 9. 05/28/2026, 22042, LYM % TM MID % TM GRAN % TM LYM TM MID TM GRAN TM D. Review of the presurvey paperwork titled CMS Form 116 showed an estimated annual test volume of 8,000 for the CBC. E. Interview with the technical consultant on August 20, 2026 at 1210 hours in the breakroom acknowledged the laboratory's policy and procedure needed to be updated and that the flagged results

	should not be reported. KEY: WBC = White Blood Cell Count WBC DIFF = White Blood Cell Differential LYM = Lymphocytes MID = Monocytes/Mid GRAN = Granulocytes