Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0726652	03/09/2026
Name of Provider or Supplier	**Street Address, City, State**	
Robert Levy, Md	2845 Monroe, Dearborn, MI	

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
D3033	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(i) (a)(3)(i) Records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years. This STANDARD is not met as evidenced by: . Based on record review and interview with the technical consultant, the laboratory failed to retain its verification of performance specifications precision data for its Sysmex XP-300 for 23 (April 2024 to March 2026) of 23 months since the test system has been used for patient testing. Findings include: 1. A review of the laboratory's Sysmex XP-300 hematology analyzer's verification of performance specifications revealed it was implemented in April 2024 and the data used to verify precision was not present. 2. The surveyor requested the precision data on 3/9/26 at 3:16 pm and it was not made available. 3. An interview on 3/9/26 at 3:23 pm with the technical consultant confirmed the above findings.
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 record review and interview with the technical consultant, the laboratory failed to follow its test procedure for solving instrumentation errors on the Sysmex

	XP-300 hematology analyzer for two (Patients #7 and #8) of 10 patient test records reviewed. Findings include: 1. A review of the laboratory's "XP-300 Instructions for use" revealed a section stating, "When TROUGH Discriminatory (T1) or (T2) cannot be set or when frequency for a set discriminator position is higher than the range, it is flagged as WBC histogram error" and "T2: High TROUGH discriminator, that distinguishes mixed cells and neutrophils, cannot be determined." 2. A review of the laboratory's "XP-300 CLSI Procedure" included a table for how the laboratory is to address any flags, codes, or messaged. In the section for "T2", it stated, "Check tube for clot, if no visible clots present, rerun sample, if flag repeats, send to Reference lab for manual slide review. If visible clots are observed, the specimen is unacceptable and CBC results cannot be resulted. The specimen should be rejected." 3. A review of 10 patient test reports revealed the following patients had hematology testing reported with unresolved errors: a. Patient #7 had a Complete Blood Count with Differential (CBC with diff) ordered on 08/12/2025. The test report included a "T2" error and had incomplete differential results. b. Patient #8 had a CBC with diff ordered 11/12/2025. The test report included a "T2" error and had incomplete differential results. 4. An interview on 3/9/26 at 2:55 pm with the technical consultant confirmed the laboratory's procedure was not followed.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: . Based on record review and interview with the technical consultant, the laboratory failed to verify reference intervals as part of the performance specifications for the Sysmex XP-300 hematology analyzer for 23 (April 2024 to March 2026) of 23 months since the test system has been used for patient testing. Findings include: 1. A review of the laboratory's Sysmex XP-300 hematology analyzer's verification of performance specifications revealed it was implemented in April 2024 and the data used to verify reference intervals was not present. 2. An interview on 3/9/26 at 3:13 pm with the technical consultant confirmed the laboratory had not verified its reference intervals.