Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0726652	02/15/2022
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
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: . Based on record review and interview with the Technical Consultant (TC), the laboratory failed to report all SARS-CoV-2 test results every day of patient testing for 15 (November 2020 to February 2022) of 15 months the laboratory has been testing for SARS-CoV-2. Findings include: 1. The surveyor observed the laboratory's BD Veritor Plus SARS-CoV-2 Antigen test system on 2/15/22 at 9:46 am. 2. A review of the laboratory's test records revealed only positive patients tested using the BD Veritor Plus SARS-CoV-2 Antigen test system had been reported to the health department. 3. An interview on 2/15/22 at 1:27 pm with the TC confirmed the laboratory started testing in November 2020 and had not been reporting negative results to the health department.
D3029	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(2) Test procedures. Retain a copy of each test procedure for at least 2 years after a procedure has been discontinued. Each test procedure must include the dates of initial

	use and discontinuance. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant (TC), the laboratory failed to include a date of discontinuance on 1 (Establishing Quality Control Ranges) of 2 policies regarding new lots of quality control materials for Complete Blood Count (CBC) testing. Findings include: 1. A review of the laboratory's "Establishing Quality Control Ranges" policy revealed a section titled "Procedure for Establishing Q.C. Ranges" stating, "1. Begin parallel one month prior to expiration of current Q.C. lot or when inventory is down to a one-month supply. 2. Begin running new lot as unknown patient samples. a. Enter results in new reference file of Q.C. Update File of each test. b. The mean, S.D, and CV are automatically or manually calculated. 3. Obtain a minimum of 30 values for unassayed controls and 10 values for assayed controls. a. Update new reference file b. This program erases current reference file and replaces it with the new reference file. 4. Make the necessary changes to lot number description in abbreviation file, as well as changing QC Log ranges to reflect new Q.C. ranges." 2. A review of the laboratory's quality control lot documentation revealed the laboratory performs testing on the new lot once prior to putting it into use. 3. An interview on 2/15/22 at 1:27 pm with the TC confirmed the laboratory tests the new lot of quality control once before putting it into use and the policy listed above was discontinued. 4. A review of the laboratory's "Establishing Quality Control Ranges" policy revealed it did not indicate the date it was discontinued.
D3033	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(i) In addition, the laboratory must retain 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 observation, record review, and interview with the Technical Consultant (TC), the laboratory failed to retain the Beckman Coulter AcT Diff 2 test system performance specifications verified by the laboratory for the current test system in use. Findings include: 1. The surveyor observed a Beckman Coulter AcT Diff 2 Complete Blood Count (CBC) analyzer during a tour of the laboratory on 2/15/22 at 9: 41 am. 2. A review of the laboratory's records revealed a lack of documentation of the Beckman Coulter AcT Diff 2 verification of performance specifications performed by the laboratory. 3. An interview on 2/15/22 at 1:27 pm with the TC confirmed the Beckman Coulter AcT Diff 2 verification of performance specification documentation was not available.
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by:

	. Based on record review and interview with Testing Personnel #1 (TP1), the laboratory failed to have a documented request for patient testing from an authorized person for 5 (Patients 22040000, 212230001, 210350005, 201160002, and Patient 3) of 12 patient test records reviewed. Findings include: 1. A review of patient testing logs revealed the following patients received testing: a. Patient 22040000 had a Complete Blood Count (CBC) performed on 11/29/21. b. Patient 212230001 had a CBC performed on 08/11/21. c. Patient 210350005 had a CBC performed on 02/04 /21. d. Patient 201160002 had a CBC performed on 04/25/20. e. Patient 3 had a throat culture performed on 06/08/21. 2. An interview on 2/15/22 at 11:50 am with TP1 confirmed the patients listed above did not have test request for the testing performed.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #1 (TP1), the laboratory failed to check each batch of Group A Selective Strep Agar (SSA media) for sterility for 18 of 18 lots and shipments of media used by the laboratory from March 2020 to February 2022. Findings include: 1. A review of the laboratory's "Strep Group A Culture Screen Manual" revealed a lack of procedure for ensuring sterility of new lots of SSA media. 2. A review of the laboratory's "Lot/Shipment QC for SSA Media Taxo A Discs" documentation revealed a lack of documentation of sterility testing for the following lots and shipments of SSA media: a. Lot 498472 opened on 1/10/22. b. Lot 497724 opened on 1/17/22. c. Lot 498472 opened on 2/7 /22. d. Lot 492208 opened on 9/14/21. e. Lot 494289 opened on 11/30/21. f. Lot 487940 opened on 8/10/21. g. Lot 487940 opened on 8/16/21. h. Lot 491108 opened on 9/13/21. i. Lot 136790 opened on 5/10/21. j. Lot 136916 opened on 5/24/21 k. Lot 484080 opened on 6/7/21. l. Lot 484919 opened on 6/22/21. m. Lot 462530P opened on 6/15/20. n. Lot 464789P opened on 9/16/20. o. Lot 470364P opened on 10/9/20. p. Lot 475951 opened on 1/13/21. q. Lot 457580P opened on 3/24/20. r. Lot 456107P opened on 3/26/20. 3. An interview on 2/15/22 at 12:47 pm with TP1 confirmed the laboratory did not check each lot or shipment of media for sterility prior to use.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

	This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #1 (TP1), the laboratory failed to ensure test reports were sent to the final report destination for 1 (Patient 201160002) of 12 patient test records reviewed. Findings include: 1. A review of the patient testing logs revealed Patient 201160002 had Complete Blood Count (CBC) testing performed on 04/25/20. 2. The surveyor requested the test report for the patient listed above on 2/15/22 at 11:29 am and it was not made available. 3. An interview on 2/15/22 at 11:29 am with TP1 confirmed the test report for the patient listed above was not available.