Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0023780	09/23/2025
Name of Provider or Supplier	**Street Address, City, State**	
Melbourne Medical Laboratory	95 Bulldog Blvd Ste 103, Melbourne, FL	

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	An announced CLIA recertification survey was conducted at Melbourne Medical Laboratory on April 28, 2025 - September 23, 2025. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Condition was cited: D6108 - 493.1447 Condition: Laboratory Technical Supervisor
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to provide a clean eye washing station for safety incidents. Finding included: 1. On 4/29/2025 at 5: 26 PM, the eye wash station had brown debris in the sink. When the eye wash station was turned on brown liquid came out of the water head. The shower had brown stains around the head as well. 2. Review of laboratory safety read, "Use the eyewash or the shower located near the employee bathroom if any employee was splashed or spilled with any chemicals or samples." 3. On 4/28/2025 at 5:45 PM, the Laboratory Technologist confirmed the eyewash station was not cleaned for emergency use.
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 interview, review of quality control records, and patient test reports, the laboratory failed to use non-expired reagents on the Horiba ABX Pentra XL 80 Hematology Analyzer on 03/06/2024, 05/06/2024, 05/07/2024, 05/09/2024, 07/10 /2024, 07/12/2024, 07/15/2024, 07/18/2024, and 07/19/2024. Findings Included: 1. Review of the Quality Control List showed hematology controls for lot numbers PX445L, PX445N, and PX445H expired on 03/05/2024, and showed the controls were run on 03/06/2024. Review of Quality Control List showed the first day the hematology controls for lot number PX446L, PX446N, and PX446H were on 03/07 /2024. Review of the Report by date: 03/06/2024 showed nine Patients' samples were tested. A comparison of the Report by date and the Patients test reports confirmed the results from 03/06/2024 were reported. 2. Review of Quality Control List showed the hematology controls for lot number PX446L, PX446N, and PX446H expired on 05/05 /2024, and showed the controls were run on 05/06/2024, 05/07/2024, and 05/09/2024. Review of Quality Control List showed the first day the hematology controls for lot number PX447L, PX447N, and PX447H were on 05/13/2025. Review of the Report by date: 05/06/2024 showed 22 Patient samples were tested. Review of the Report by date: 05/07/2024 showed 21 Patient samples were tested. Review of the Report by date: 05/09/2024 showed 25 Patient samples were tested. A comparison of the Report by date and the Patient test reports confirmed the results from 05/06/2024, 05/07 /2024, and 05/09/2024 were reported. 3. Review of the Quality Control List showed hematology controls for lot number PX447L, PX447N, and PX447H expired on 07/05 /2024, and showed the controls were run on 07/08/2024, 07/10/2024, 07/12/2024, 07 /15/2024, 07/18/2024, and 07/19/2024. Review of Quality Control List showed the first day the hematology controls for lot number PX4478, PX448N, and PX448H were on 07/22/2024. Review of the Report by date: 07/08/2024 showed 20 patient samples were tested. Review of the Report by date: 07/09/2024 showed five patient samples were tested. Review of the Report by date: 07/10/2024 showed seven Patient samples were tested. Review of the Report by date: 07/12/2024 showed one Patient sample was tested. Review of the Report by date: 07/15/2024 showed six Patient samples were tested. Review of the Report by date: 07/18/2024 showed seven Patient samples were tested. Review of the Report by date: 07/19/2024 showed one Patient's sample was tested. A comparison of the Report by date and the Patient's test reports confirmed the results from 07/08/2024, 07/10/2024, 07/12/2024, 07/15/2024, 07/18 /2024, and 07/19/2024 were reported. 4. During an interview on 04/29/2025 at 3:45 PM, Testing Personnel A confirmed Patient test results from the hematology analyzer were reported out when the controls were expired.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) (d)(3)(i) Each quantitative procedure, include two control materials of different concentrations; This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to have 2 levels of Vitamin D chemistry controls pass on 05/23/20253 and 5/24/2023 before running Patient specimens. Findings Included: Review of Advia QC Review revealed the following: 1. Vitamin D level 1 control failed on 05/23/2023 at 10:39 AM, with no rerun. 2. Vitamin D level 2 control failed on 05/23/2023 at 10:39 AM, with no rerun. 3. No Vitamin D level 1 and Vitamin D level 2 controls were run on 05/24/2023. Review of Patient reports revealed the following: 1. Patient #1 specimen was received

	on 05/23/2024 and reported on 05/24/2023 for Vitamin D 25 Hydroxy. 2. Patient #2 specimen was received on 05/23/2024 and reported on 05/24/2023 for Vitamin D 25 Hydroxy. Review of Quality Control policy revealed no policy for how vitamin D controls should be performed. On 04/28/2025 at 5:45 PM, the Technologist confirmed failure to have 2 levels of Vitamin D chemistry controls pass on 05/23/20253 and 05 /24/2023 before running Patient specimens.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b) (1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on interview, observation, review of the controls containers and temperature logs, the laboratory failed to identify and document corrective actions for temperatures out of range for the freezer for 88 of 154 days of operation of the laboratory between 08/05/2024 to 04/28/2025. Findings Included: 1. A tour of the laboratory on 04/28/2025 at 11:50 AM, revealed Bio-Rad Liquichek Immunology Controls and Bio-Rad Liquid Assayed Level 1, and Bio-Rad Liquid Assayed Level 3 stored in Freezer B. 2. Review of the control containers indicated the controls need to be stored at -20 to -70 degrees Celsius (C). 3. Review of the Temperature Log for Freezer B showed the temperatures were above -20 degrees C with no correction action documented for following 88 days: 08/05/2024 recorded -17 degrees C 08/06 /2024 recorded -11 degrees C 08/07/2024 recorded -19 degrees C 08/08/2024 recorded -17 degrees C 08/09/2024 recorded -19 degrees C 08/12/2024 recorded -15 degrees C 08/13/2024 recorded -18 degrees C 08/15/2024 recorded -18 degrees C 08 /16/2024 recorded -18 degrees C 08/19/2024 recorded -19 degrees C 08/20/2024 recorded -19 degrees C 08/21/2024 recorded -19 degrees C 08/23/2024 recorded -15 degrees C 08/27/2024 recorded -19 degrees C 08/28/2024 recorded -19 degrees C 10 /16/2024 recorded -18 degrees C 10/18/2024 recorded -18 degrees C 10/23/2024 recorded -19 degrees C 10/25/2024 recorded -18 degrees C 11/13/2024 recorded -18 degrees C 11/14/2024 recorded -13 degrees C 11/15/2024 recorded -18 degrees C 11 /22/2024 recorded -19 degrees C 11/26/2024 recorded -18 degrees C 12/05/2024 recorded -19 degrees C 12/19/2024 recorded -18 degrees C 12/23/2024 recorded -19 degrees C 12/24/2024 recorded -19 degrees C 01/03/2025 recorded -19 degrees C 01 /05/2025 recorded -19 degrees C 01/08/2025 recorded -17 degrees C 01/09/2025 recorded -17 degrees C 01/20/2025 recorded -19 degrees C 01/21/2025 recorded -12 degrees C 01/24/2025 recorded -19 degrees C 02/04/2025 recorded -16 degrees C 02 /12/2025 recorded -11 degrees C 02/14/2025 recorded -17 degrees C 02/17/2025 recorded -13 degrees C 02/18/2025 recorded -16 degrees C 02/19/2025 recorded -17 degrees C 02/20/2025 recorded -17 degrees C 02/21/2025 recorded -17 degrees C 02 /24/2025 recorded -17 degrees C 02/25/2025 recorded -17 degrees C 02/26/2025 recorded -17 degrees C 02/27/2025 recorded -16 degrees C 02/28/2025 recorded -16 degrees C 03/03/2025 recorded -15 degrees C 03/04/2025 recorded -18 degrees C 03

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D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on interview and review of the procedure manual and personnel record, the Technical Supervisor failed to have 2 levels of Vitamin D chemistry controls pass on 05/23/20253 and 05/24/2023 before running patients (See D6117); and the Technical Supervisor failed to document the high complexity Hematology training and the initial competency evaluation of one (A) of two Testing Personnel (A, B) from 10/14/2024 to 04/28/2025 (See D6120).
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on record review and interview, the Technical Supervisor failed to have 2 levels of Vitamin D chemistry controls pass on 05/23/20253 and 5/24/2023 before running Patient specimens. Findings Included: Review of Advia QC Review revealed the following: 1. Vitamin D level 1 control failed on 05/23/2023 at 10:39 AM, with no rerun. 2. Vitamin D level 2 control failed on 05/23/2023 at 10:39 AM, with no rerun. 3. No Vitamin D level 1 and Vitamin D level 2 controls were run on 05/24/2023.

	Review of Patient reports revealed the following: 1. Patient #1 specimen was received on 05/23/2024 and reported on 05/24/2023 for Vitamin D 25 Hydroxy. 2. Patient #2 specimen was received on 05/23/2024 and reported on 05/24/2023 for Vitamin D 25 Hydroxy. Review of Quality Control policy revealed no policy for how vitamin D controls should be performed. On 04/28/2025 at 5:45 PM, the Technologist confirmed failure to have 2 levels of Vitamin D chemistry controls pass on 05/23/20253 and 05 /24/2023 before running Patient specimens.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (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; (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the procedure manual and personnel record, and interview, the Technical Supervisor failed to document the high complexity Hematology training and the initial competency evaluation for one (A) of two Testing Personnel (A, B) from October 14, 2024 to April 28, 2025. This is a repeat deficiency from the 04/18 /2017 recertification survey. Findings Included: 1. Review of the procedure manual section Test Methods, Instrumentation, Reagents, Materials and Supplies noted, "Supervisors will train employees on all test methods in the laboratory within the scope of the employees training and licensure." 2. Review of the personnel records for Testing Personnel A showed there was no documentation that indicated Testing Personnel A had received any training for high complexity Hematology testing and no documentation of Testing Personnel A initial competency evaluation. 3. During an interview on 04/29/2025 at 11:45 AM, Testing Personnel A stated she started on October 14, 2024 as a high complexity testing personnel, and she received no training on the Horiba ABX Pentra XL 80 Hematology Analyzer. 4. During an interview on 04 /29/2025 at 12:03 PM, Testing Personnel A stated an initial competency evaluation on herself was not completed.