Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0023780	03/17/2021
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	A recertification survey was conducted from March 15, 2021 to March 17, 2021. Melbourne Medical Laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories. The following Condition was cited: D5300 Preanalytic Systems 493.1240
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, the laboratory failed to report moderately complex Corona Virus Disease 2019 (COVID 19) antibody tests run on the Advia Centaur chemistry analyzer. The total volume of COVID 19 antibody tests was 1,307. Findings Included: Review of validations performed on the Advia Centaur chemistry analyzer revealed COVID 19 antibody test was validated on 08/27/20. There had been 1,307 patients tested since 08/27/20. On 03/17/21 at 10:00 AM, Testing Person A revealed he faxed the COVID 19 antibody tests to another section per the laboratory policy. On 03/17/21 at 10:10 AM, the Office Manager responsible for faxing COVID 19 results to the Department of Health (DOH) revealed via phone that she did not fax the antibody results to DOH, only the antigen results. On 03/16/21 at 5:00 PM, Testing Person A acknowledged the laboratory did not have a policy for reporting

	COVID 19 results to the DOH. On 03/17/21 at 2:00 PM, the Manager acknowledged the laboratory did not have documentation to show that COVID 19 antibody results were reported to the DOH.
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. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to retain Quality Control records for at least two years. Findings: Review of the "Quality Assurance Program for Melbourne Medical Laboratory" signed and dated by the Laboratory Director on 02 /02/2021 read, "All quality control records must be documented and maintained for all analytes performed in our facility. These records must be kept for a minimum of two years." Review of the lot to lot comparison for hematology controls showed the laboratory failed to retain the documentation of the comparisons from 03/15/19 to 10 /26/20. On 03/16/2021 at 3:35 PM, Testing Personnel B stated the lab did not print the records and she was unable to retrieve the documentation from the hematology instrument.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to follow the Quality Assessment (QA) procedure for monitoring, assessing and correcting identified problems. Findings: 1. Review of the Monthly QA Checklists showed the checklist was not completed for 11/2019 and 12/2019. The checklist was completed but not signed by the Laboratory Director for the months of 03/2019, and 01/2020 to 01/2021. On 03/15/2021 at 4:50 PM, Testing Personnel B stated two months of QAs were missing and the Laboratory Director had not signed all the QAs. 2. Review of "Laboratory Quarterly Quality Assurance Review" last signed by the Laboratory Director on 02/02/21 revealed that "Every three months the Medical Director and Laboratory Manager will meet to discuss the overall functionality of the lab. A quarterly report detailing the information reviewed in the meeting will be signed and dated by the Medical Director and Laboratory Manager." Review of Quality Assurance documents found quarterly reviews for 01/15/19, 04/18/19, and 08/08/19. No other quarterly reviews were provided. On 03/16/2021 at 3:50 PM, Testing Person A stated the quarterly report had not been documented since 08/08/2019.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240

	Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory's Quality Assessment program failed to monitor and evaluate the overall quality of the preanalytic system and correct identified problems. Findings: Cross Reference D5311: Based on observation, record review, and interview, the laboratory's procedure on Quality Assurance failed to include the rejection of patient specimens collected in expired tubes. Cross Reference D5391: Based on observation, record review, and interview, the laboratory failed to have an effective Quality Assurance (QA) plan that identified issues during the pre-analytic phase of testing from 06/30/2019 to 03/15/2021.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory's procedure on Quality Assurance failed to include the rejection of patient specimens collected in expired tubes. Findings: During a tour of the laboratory's in-house blood drawing station on 03/15/2021 at 12:45 PM, the following expired tubes where found: 218 expired EDTA (Ethylenediaminetetraacetic acid) tubes: 15 expired on 06/30/2019 42 expired on 08/31/2020 32 expired on 09/30/2020 57 expired on 10/31/2020 43 expired on 11/30/2020 29 expired on 01/31/2021 51 expired Sodium Citrate tubes: 6 expired on 07/31/2020 1 expired on 11/30/2020 30 expired on 01/31/2021 14 expired on 02/28 /2021 53 expired Sodium Fluoride Potassium Oxalate tubes: 2 expired on 05/31/2020 3 expired on 07/31/2020 1 expired on 10/31/2020 20 expired on 12/31/2020 5 expired on 01/31/2021 22 expired on 02/28/2021 87 expired PPT (Plasma Preparation tubes): 16 expired on 06/30/2020 38 expired on 12/31/2020 33 expired on 01/31/2021 171 expired SST (Serum Separation tubes): 27 expired on 07/31/2020 103 expired on 10 /31/2020 20 expired on 12/31/2020 21 expired on 02/28/2021 23 expired Serum Separator Clot Activator tubes: 4 expired on 06/30/2020 6 expired on 07/31/2020 13 expired on 03/08/2021 6 expired Para-Pak-C&S vials (culture and sensitivity vials for stool collection): 2 expired on 12/2020 4 expired on 01/2020 9 expired Total Fix stool collection vials: 9 expired on 03/2020 - 9 Observations in the patient specimen refrigerator on 03/15/2020 at 2:00 PM, revealed 9 Patients that had expired tubes. The laboratory reported laboratory test results for CBC with Differential (Diff), Vitamin B-12, Folate, Ferretin and Iron Package on Patient #2 drawn on 03/03/2021 at 12:10 PM. The laboratory reported laboratory test results for CBC with Diff, Sediment (Sed) Rate, Comprehensive Metabolic Panel (CMP), and Vitamin D 25 Hydroxy on Patient

	#3 drawn on 03/02/3021 at 2:13 PM. The laboratory reported laboratory test results for Lipid Profile and CMP on Patient #4 drawn on 03/10/2021 at 7:35 AM. The laboratory reported laboratory test results for CBC with Diff, and CMP on Patient #6 drawn on 03/11/2021 at 9:48 AM. The laboratory reported laboratory test results for Urinalysis, Lipid Profile, Thyroxine Total, Thyroid Stimulating Hormone (TSH), Triiodothyronine (T3), and CMP on Patient #7 drawn on 03/10/2021 at 8:21 AM. The laboratory reported laboratory test results for Lipid Profile, TSH, Free Thyroxine, T3, and CMP on Patient #8 drawn on 03/10/2021 at 13:35. The laboratory had extra tubes of blood on Patient #1 drawn on 03/03/2021 at 5:20 PM, Patient #5 drawn on 03/10 /2021 at 8:14 AM, and Patient #9 drawn on 03/10/2021 at 12:06 PM, whose blood tests were tested at other laboratories. Review of the "Quality Assurance Program for Melbourne Medical Laboratory" signed and dated by the Laboratory Director on 02/02 /2021, section E read, "Specimens may be rejected for the following..." It failed to include specimens collected in expired tube. According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification, signed and dated by the Laboratory Director on 03/08/21, the laboratory had a Total Estimated Annual Test Volume of 186,258 tests. On 03/15/2021 at 2:00 PM, Testing Personnel A and Testing Personnel B stated the laboratory had tubes that were expired and tests results were reported from expired tubes. On 03/16/2021 at 3:30 PM, Testing Personnel B stated that rejection of expired tubes was not included in the list of reasons for rejecting samples.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on record review, observation, and interview, the laboratory failed to have an effective Quality Assurance (QA) plan that identified issues during the pre-analytic phase of testing from 06/30/2019 to 03/15/2021. Findings: Review of the "Quality Assurance Program for Melbourne Medical Laboratory" signed and dated by the Laboratory Director on 02/02/2021, section E read, "Specimens may be rejected for the following..." It failed to include specimens collected in expired tube." Review of the laboratory's Monthly QA Checklist from 06/30/2019 to 03/15/2021 read, no problems with the "optimum integrity of a specimen from time of collection through the testing process." The laboratory's QA program failed to identify issues with expired blood collection tubes. During a tour of the laboratory's in-house blood drawing station on 03/15/2021 at 12:45 PM, the following expired tubes were found: 218 expired EDTA (Ethylenediaminetetraacetic acid) tubes, 51 expired Sodium Citrate tubes, 53 expired Sodium Fluoride Potassium Oxalate tubes, 87 expired Plasma Preparation tubes, 6 expired Para-Pak-C&S vials (culture and sensitivity vials for stool collection), and 9 expired Total Fix stool collection vials. Observations in the patient specimen refrigerator on 03/15/2020 at 2:00 PM, revealed 9 Patients (#1, #2, #3, #4, #5, #6, #7, #8, #9) that had expired tubes and 6 patients (#2, #3, #4, #6, #7, #8) with test results reported by the laboratory. According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification, signed and dated by the Laboratory Director on 03/08/21, the laboratory had a Total Estimated Annual Test Volume of 186,258 tests. On 03/15/2021 at 2:00 PM, Testing Personnel A and Testing Personnel B stated the laboratory had tubes that were expired and tests results

	were reported from expired tubes. On 03/16/2021 at 3:30 PM, Testing Personnel B stated that rejection of expired tubes was not included in the list of reasons for rejecting samples.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to have an effective Quality Assurance (QA) plan that identified issues during the analytic phase of testing from 03/15/2019 to 03/15/2021. Findings Cross Reference D5403: Based on record review and interview, the laboratory procedure manual failed to include the rejection of patient specimens collected in expired blood collection tubes. Cross Reference D5413: Based on record review and interview with Testing Person A, the laboratory failed to have refrigerator temperatures within the manufacturers' instructions for 2 (July 2019 and December 2019) out of 5 months (February 2021, May 2020, September 2020, July 2019, and December 2019) reviewed. Cross Reference D5415: Based on observation, record review, and interview, the laboratory failed to label the quality control vials currently in use with the open date and expiration date. Cross Reference D5417: Based on observation and interview, the laboratory used Microalbumin controls that were expired since 01/31/21 and the laboratory failedto ensure blood tubes were not used past their expiration date since 06 /30/19. Cross Reference D5429: Based on record review and interview, the laboratory failed to perform maintenance per the manufacturers' instructions for at least 2 (2019-2021) out of 2 years reviewed. Cross Reference D5439: Based on record review and interview, the laboratory failed to provide documentation of the performance of the calibration on the Horiba ABX Pentra XL80 hematology instrument at least once every 6 months. This is a repeat deficiency from recertification survey on 11/28/2018.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values.

	(12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory procedure manual failed to include the rejection of patient specimens collected in expired blood collection tubes. Findings: Review of the "Quality Assurance Program for Melbourne Medical Laboratory" signed and dated by the Laboratory Director on 02/02/2021, section E read, "Specimens may be rejected for the following..." It failed to include specimens collected in expired tube. According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification, signed and dated by the Laboratory Director on 03/08/21, the laboratory had a Total Estimated Annual Test Volume of 186,258 tests. On 03/16/2021 at 3:30 PM, Testing Personnel B stated that rejection of expired tubes was not included in the list of reasons for rejecting samples.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on record review and interview with Testing Person A, the laboratory failed to have refrigerator temperatures within the manufacturers' instructions for 2 (July 2019 and December 2019) out of 5 months (February 2021, May 2020, September 2020, July 2019, and December 2019) reviewed. Findings Included: Review of daily refrigerator temperatures revealed the following days the temperature was not between 2-8 degrees Celsius (C) (required temperature range per the manufacturer of the reagents, controls, and calibrators stored in the refrigerator): refrigerator D- 07/07 /19 (1 degree C), 07/18/19 (1 degree C), 07/19/19 (1 degree C), 07/24/19 (1 degree C), 07/29/19 (1 degree C), and 12/05/19 (1 degree C); refrigerator A- 07/03/19 (1 degree C), 07/10/19 (1 degree C), 07/11/19 (1 degree C), 07/22/19 (1 degree C), and 12/10/19 (1 degree C); refrigerator B- 07/09/19 (1 degree C) and 12/03/19 (1 degree C). On 03/15/21 at 4:30 PM, Testing Person A acknowledged the refrigerator temperatures were out range as per manufacturers' requirement and did not have any corrective action.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper

	use. This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to label the quality control vials currently in use with the open date and expiration date. Findings Included: Examination of the Horiba Difftrol whole blood hematology controls for the Horiba ABX Pentra XL80 instrument on 03/15/2021 at 12:25 PM, showed the quality control vials for level 1, 2 and 3 did not have the opened expiration date for the vials currently being used. Review of the product information sheet for the controls noted, "ABX Difftrol is stable for 16 sampling events over a maximum of 16 days after a vial has been opened, provided it is properly handled and promptly refrigerated after each use." On 03/16/2021 at 3:16 PM, Testing Personnel A stated the opened expiration date were not listed on the control vials.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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 observation and interview, the laboratory used Microalbumin controls that were expired since 01/31/21 and the laboratory failed to ensure blood tubes were not used past their expiration date since 06/30/19. . Findings: 1. A tour of the laboratory on 03/15/21 at 11:00 AM, revealed Microalbumin controls level 1 and level 2 that expired on 01/31/21. On 03/15/21 at 12:00 PM, Testing Person B acknowledged the expired controls were being used and no other controls were available for Urine Microalbumin testing. 2. Observations in the patient specimen refrigerator on 03/15 /2020 at 2:00 PM, revealed 9 Patients that had expired tubes. The laboratory reported laboratory test results for CBC with Differential (Diff), Vitamin B-12, Folate, Ferretin and Iron Package on Patient #2 drawn on 03/03/2021 at 12:10 PM. The laboratory reported laboratory test results for CBC with Diff, Sediment (Sed) Rate, Comprehensive Metabolic Panel (CMP), and Vitamin D 25 Hydroxy on Patient #3 drawn on 03/02/3021 at 2:13 PM. The laboratory reported laboratory test results for Lipid Profile and CMP on Patient #4 drawn on 03/10/2021 at 7:35 AM. The laboratory reported laboratory test results for CBC with Diff, and CMP on Patient #6 drawn on 03/11/2021 at 9:48 AM. The laboratory reported laboratory test results for Urinalysis, Lipid Profile, Thyroxine Total, Thyroid Stimulating Hormone (TSH), Triiodothyronine (T3), and CMP on Patient #7 drawn on 03/10/2021 at 8:21 AM. The laboratory reported laboratory test results for Lipid Profile, TSH, Free Thyroxine, T3, and CMP on Patient #8 drawn on 03/10/2021 at 13:35. The laboratory had extra tubes of blood on Patient #1 drawn on 03/03/2021 at 5:20 PM, Patient #5 drawn on 03/10 /2021 at 8:14 AM, and Patient #9 drawn on 03/10/2021 at 12:06 PM, whose blood tests were tested at other laboratories. The Clinical Laboratory Improvement Amendment (CLIA) Application for Certification signed and dated by the Laboratory Director on 03/08/2021 listed the Total Estimated Annual Test Volume was 186,258 tests. On 03/15/2021 at 2:00 PM, Testing Personnel A and Testing Personnel B stated the laboratory had tubes that were expired and tests results were reported from expired tubes.

D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to perform maintenance per the manufacturers' instructions for at least 2 (2019-2021) out of 2 years reviewed. Findings Included: During a tour of the laboratory on 03/15/21 at 11:00 AM, two microscopes were observed. One microscope had preventative maintenance (PM) last performed on 09/13/2019 and was due in 09/2020. The second microscope last had a PM on 08/06/2012 and was due on 06/2013. Interview on 03/16/21 at 9:30 AM Testing Person #A confirmed that the PMs on the microscopes were not done. During the tour on 03/15/21 at 11:00 AM a timer was observed. The calibration on the timer was last done on 10/2001 and was due 10/2003. Interview on 03/15/21 at 11:00 AM Testing Person #B confirmed that no calibrations had been done on the timer. The laboratory has a distilled water system that feeds both of the chemistry analyzers. During the tour on 03/15/2021 at 11:00 AM a alarm on the screen indicated that the UV (ultraviolet) light failed. Interview on 03/15/21 at 3:00 PM Testing Person #A confirmed what the code meant. He also stated that he just makes sure that there is a reading of >15 on the monitor, and was not sure how long the UV light fail alarm had been on. Review of the pipettes revealed calibrations performed 02/10/21. Interview on 03/15/21 at 4:36 PM Testing Person #B confirmed that no calibrations were done in 2020 or 2019. Review of 2019-2021 maintenance records on the Advia 1800 Chemistry analyzer revealed that every 2 months it is required to clean dilution tray, clean and replenish cuvettes, and cuvette conditioner bottle. This was only done on 06 /01/2020 in the last 2 years. Every 3 months it is required to wash the ISE electrode lines and every 4 months it is required to clean the ancillary reagent bottle filters, replace reaction & dilution cuvettes, and clean the pure water bottle filter. There was no documentation of the 3 month or 4 month maintenance being performed. Review of February 21, September 20, May 20, December 19, and June 19 on the Advia Centaur XP chemistry analyzer revealed the weekly maintenance of cleaning water bottle reservoir & manifold, prime water from reservoir to manifolds, and check water trap was not documented any of the 5 months reviewed. Review of February 21, September 20, May 20, December 19, and June 19 on the ABX Pentra XL 80 reveal weekly maintenance of concentrated cleaning not documented September 2020 and June 2019. Interview on 03/17/21 at 1:00 PM the Testing Person #A confirmed that if it was not documented in the maintenance book then it was not there. Review of centrifuge maintenance revealed that it is to be done quarterly. It had not been performed since the 3rd quarter in 2019. Testing Person #A confirmed that it had not been done on 03/15/21 at 10:40 AM. Review of policy and procedure (last reviewed by the laboratory director on 02/02/2021) revealed that "All routine maintenance on all instruments will be performed according to manufacturer's specifications unless otherwise documented. All maintenance must be documented on log and signed. Any preventative maintenance operations performed on an instrument by a service representative must be documented and kept in the maintenance log."
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)

	Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to perform calibration on the Horiba ABX Pentra XL80 hematology instrument at least once every 6 months. This is a repeat deficiency from recertification survey on 11/28/2018. Findings Included: Review of the laboratory's quality control documents showed the laboratory performed calibrations on the Horiba ABX Pentra XL80 hematology instrument on 07 /25/2019 and 01/11/2021. No other documentation of calibration on the hematology instrument was available for review. On 03/16/20 at 3:27 PM, Testing Personnel A stated there were no other calibrations performed on the instrument.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to provide overall management and direction of the laboratory. Findings: Cross Reference D6082: Based on record review and interview, the Laboratory Director failed to ensure testing systems used in the laboratory provided quality laboratory services for all aspects of testing performance, including analytic and postanalytic phases of testing from 03/15/2019 to 03/15/2021.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic

	phases of testing. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure testing systems used in the laboratory provided quality laboratory services for all aspects of testing performance, including preanalytic and analytic phases of testing from 03/15 /2019 to 03/15/2021. Findings: Based on observation, record review, and interview, the laboratory's procedure on Quality Assurance failed to include the rejection of patient specimens collected in expired tubes. (See D5311) The Laboratory Director failed to ensure the laboratory had an effective Quality Assurance (QA) plan that identified issues during the pre-analytic phase of testing from 06/30/2019 to 03/15 /2021. (See D5391) The Laboratory Director failed to ensure the laboratory procedure manual included the rejection of patient specimens collected in expired blood collection tubes. (See D5403) The Laboratory Director failed to ensure the laboratory's refrigerator temperatures were within range according to manufacturers' instructions for 2 (July 2019 and December 2019) out of 5 months (February 2021, May 2020, September 2020, July 2019, and December 2019) reviewed. (See D5313) The Laboratory Director failed to ensure the laboratory labeled the quality control vials currently in use with the open date and expiration date. (See D5415) The Laboratory Director failed to ensure the laboratory did not use Microalbumin controls that were expired since 01/31/21. (See D5417) The Laboratory Director failed to ensure the laboratory performed maintenance per the manufacturers' instructions for at least 2 (2019-2021) out of 2 years reviewed. (See D5429) The Laboratory Director failed to ensure the laboratory performed calibrations on the Horiba ABX Pentra XL80 hematology instrument at least once every 6 months. This is a repeat deficiency from recertification survey on 11/28/2018. (See D5439)
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to sign the Proficiency Testing Performance Evaluation for 3 (2020 1st, 2nd, 3rd) of 6 events (2019 1st, 2nd, 3rd, and 2020 1st, 2nd, 3rd) for the specialty of Hematology. Findings: Review of the American Proficiency Institute Proficiency Testing (PT) records showed the Laboratory Director had not signed the evaluation forms for the 1st, 2nd and 3rd events in 2020 for hematology. On 03/15/2021 at 4:50 PM, Testing Personnel A stated the Laboratory Director had not signed the evaluations.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

	This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure the laboratory followed and identified failures in their Quality Assessment (QA) policy. Findings: The Laboratory Director failed to follow and identify failures in the Quality Assessment (QA) procedures for monitoring, assessing and correcting identified problems. (See D5291)
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for 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; (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 record review and staff interview, the Technical Supervisor failed to evaluate competency evaluations on 2 of 2 (A, B) Testing Personnel and failed to evaluate the initial training on 1(A) of 2 (A, B) Testing Personnel. Findings: Review of the Quality Assurance Program for Melbourne Medical Laboratory signed and dated by the Laboratory Director on 02/02/2021 read, "Annually, a performance review will be conducted by the supervisor on each technical personnel. The laboratory supervisor will witness the tech running patient samples on each analyzer. The supervisor will fill out a competency checklist and make suggestions for technical improvements." Review of the Laboratory Personnel Report signed by the Laboratory Director on 3/8/2021 showed the Laboratory Director was the Technical Supervisor. Review of the Technologist Competency Assessment form for Testing Personnel A showed the 12/31/2020 competency was signed by Testing Personnel B and the 07/16 /2019 competency was signed by a former Testing Personnel. Review of the Medical Technologist Competency Assessment form and the Med Tech Training Checklist for Testing Personnel B showed they were signed by Testing Personnel A on 12/30/2020. On 03/15/21 at 4:07 PM, the Manager stated they failed to document the initial training for Testing Personnel B in 2016.