Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2253804	09/26/2022
Name of Provider or Supplier	**Street Address, City, State**	
Hca Florida Cape Coral Emergency	322 Sw Pine Island Rd, Cape Coral, 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 unannounced complaint survey for #2022012753 was conducted 9/14/22 through 9/26/22 at HCA Florida Cape Coral Emergency, a clinical laboratory in Cape Coral, Florida. Complaint #2022012753 was substantiated. Based on the survey findings, an Immediate Jeopardy situation was identified and HCA Florida Cape Coral Emergency was notified at 1:30 p.m., on 9/21/22. The following Conditions were not met: D3000 Facility Administration 493.1100 D5400 Analytic Systems 493.1250 D6000 Moderate Complexity Laboratory Director 493.1403 HCA Florida Cape Coral Emergency is not in compliance with Code of Federal Regulations (CFR) 42, Part 493, Laboratory Requirements. The following is a description of the noncompliance.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on observation, record review, and interview the laboratory failed to maintain required room temperature for the Strep A cartridges being stored in the temporary laboratory location that they were moved to on 08/22/2022. Findings Included: Observation of room temperature revealed the following temperatures: 09/14/22 at 11:35 AM 25.5 degrees Celsius 09/14/22 at 1:42 PM 26 degrees Celsius 09/15/22 at 5:55 PM 25.8 degrees Celsius Review of the manufacturer instructions for the Strep A Cartridges used on the Sofia analyzer state that they are to be "stored 20-25 degrees Celsius". The "Emergency Department Cape Coral Laboratory Services" has the room temperature range to be 18-24 degrees Celsius. From 08/22/2022 to 09/22/2022 the temperature was warmer than 24 degrees Celsius on 18 out of 32 days. 08/23/2022 - 25.6 degrees Celsius 08/24/2022 - 25.5 degrees Celsius 08/26/2022 - 24.9 degrees Celsius 08/29/2022 - 25.0 degrees Celsius 08/30/2022 - 24.5 degrees Celsius 09/06

	/2022 - 24.8 degrees Celsius 09/07/2022 - 24.7 degrees Celsius 09/08/2022 - 24.6 degrees Celsius 09/09/2022 - 24.8 degrees Celsius 09/10/2022 - 25.0 degrees Celsius 09/11/2022 - 24.3 degrees Celsius 09/14/2022 - 24.7 degrees Celsius 09/16/2022 - 25.6 degrees Celsius 09/18/2022 - 24.9 degrees Celsius 09/19/2022 - 25.4 degrees Celsius 09/20/2022 - 25.6 degrees Celsius 09/21/2022 - 25.6 degrees Celsius 09/22 /2022 - 24.1 degrees Celsius There was no corrective action for the temperatures being outside of the acceptable range. The Laboratory Technical Consultant revealed on 09/14/2022 at 2:00 PM that they put a fan on the floor and kept the door to the Laboratory open to try to lower the temperature, however, it was still warmer than the 24 degrees Celsius maximum temperature. An interview on 09/15/22 at 6:00 PM, the Administrative Laboratory Director confirmed that the room temperature was warmer than what the manufacturer required for storage.
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 review of the facility records and staff interview, revealed the facility administration failed to meet the requirements specified in 493.1101 through 493.1105, as evidenced by: The Laboratory failed to ensure storage conditions for blood or blood products for transfusion were monitored to prevent deterioration of the blood products. (Refer to D3021)
D3021	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(c)(1) Blood and blood products storage and distribution. If a facility stores or maintains blood or blood products for transfusion outside of a monitored refrigerator, the facility must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory failed to ensure storage conditions for blood or blood products for transfusion were monitored to prevent deterioration of the blood product was monitored continuously or every four hours 52 days out of 99 days reviewed from 06/08/2022 to 09/14/2022. Findings included: Review of the procedure titled "Storage and Disposition of Blood and Blood Components" noted refrigerator "Temperatures are continuously monitored." Review of the "Blood Bank Equipment Offline Temperature Monitoring Log" stated "Record Temperature Every (4) Hours Required." Review of the temperature log for the refrigerator where the RBC's were stored revealed the military time the temperature

was last recorded to the military time the next temperature was recorded exceeded four hours for the following: Manual monitoring of the temperature was the only method being used since 06/08/2022. On 06/08/2022 last recorded temperature was at 20:00. On 06/09/2022 next recorded temperature was at 08:00. No other temperature readings were recorded during the twelve-hour time span. On 06/09/2022 last recorded temperature was at 16:00. On 06/10/2022 next recorded temperature was at 08:00. No other temperature readings were recorded during the sixteen-hour time span. On 06/10/2022 last recorded temperature was at 16:00. On 06/11/2022 next recorded temperature was at 08:00. No other temperature readings were recorded during the sixteen-hour time span. On 06/11/2022 last recorded temperature was at 16:00. On 06/12/2022 next recorded temperature was at 08:00. No other temperature readings were recorded during the sixteen-hour time span. On 06/12/2022 last recorded temperature was at 16:00. On 06/13/2022 next recorded temperature was at 08:00. No other temperature readings were recorded during the sixteen-hour time span. On 06/13/2022 last recorded temperature was at 16:00. On 06/14/2022 next recorded temperature was at 08:00. No other temperature readings were recorded during the sixteen-hour time span. On 06/14/2022 last recorded temperature was at 16:00. On 06/15/2022 next recorded temperature was at 06:00. No other temperature readings were recorded during the fourteen-hour time span. On 06/23/2022 last recorded temperature was at 00:00. On 06/23/2022 next recorded temperature was at 08:00. No other temperature readings were recorded during the eight-hour time span. On 06/23/2022 last recorded temperature was at 20:00. On 06/24/2022 next recorded temperature was at 08:00. No other temperature readings were recorded during the twelve-hour time span. On 06/24/2022 last recorded temperature was at 16:00. On 06/25/2022 next recorded temperature was at 08:00. No other temperature readings were recorded during the sixteen-hour time span. On 06/25/2022 last recorded temperature was at 16:00. On 06/26/2022 next recorded temperature was at 08:00. No other temperature readings were recorded during the sixteen-hour time span. On 06/26/2022 last recorded temperature was at 16:00. On 06/27/2022 next recorded temperature was at 08:00. No other temperature readings were recorded during the sixteen-hour time span. On 06/27/2022 last recorded temperature was at 16:00. On 06/28/2022 next recorded temperature was at 08:00. No other temperature readings were recorded during the sixteen-hour time span. On 06/28/2022 last recorded temperature was at 16:00. On 06/29/2022 next recorded temperature was at 06:00. No other temperature readings were recorded during the fourteen-hour time span. On 07/05/2022 last recorded temperature was at 16:00. On 07/06/2022 next recorded temperature was at 08:00. No other temperature readings were recorded during the sixteen-hour time span. On 07/06/2022 last recorded temperature was at 16:00. On 07/07/2022 next recorded temperature was at 08:00. No other temperature readings were recorded during the sixteen-hour time span. On 07/14/2022 last recorded temperature was at 20:00. On 07/15/2022 next recorded temperature was at 08:00. No other temperature readings were recorded during the twelve-hour time span. On 07/15/2022 last recorded temperature was at 20:00. On 07/16/2022 next recorded temperature was at 08:00. No other temperature readings were recorded during the twelve-hour time span. On 07/16/2022 last recorded temperature was at 20:00. On 07/17/2022 next recorded temperature was at 06:00. No other temperature readings were recorded during the ten-hour time span. On 07/17/2022 last recorded temperature was at 20:00. On 07/18/2022 next recorded temperature was at 06:00. No other temperature readings were recorded during the ten-hour time span. On 07/18/2022 last recorded temperature was at 20:00. On 07/19/2022 next recorded temperature was at 06:00. No other temperature readings were recorded during the ten-hour time span. On 07/19/2022 last recorded temperature was at 20:00. On 07/20/2022 next recorded temperature was at 08:00. No other temperature readings were recorded during the

twelve-hour time span. On 07/27/2022 last recorded temperature was at 19:00. On 07/28/2022 next recorded temperature was at 06:00. No other temperature readings were recorded during the eleven-hour time span. On 07/28/2022 last recorded temperature was at 19:00. On 07/29/2022 next recorded temperature was at 06:00. No other temperature readings were recorded during the eleven-hour time span. On 07/29/2022 last recorded temperature was at 20:00. On 07/30/2022 next recorded temperature was at 08:00. No other temperature readings were recorded during the twelve-hour time span. On 07/30/2022 last recorded temperature was 20:00. On 07/31/2022 next recorded temperature was at 08:00. No other temperature readings were recorded during the twelve-hour time span. On 07/31/2022 last recorded temperature was at 20:00. On 08/01/2022 next recorded temperature was at 06:30. No other temperature readings were recorded during the ten and a half hour time span. On 08/01/2022 last recorded temperature was at 08:00. On 08/2/2022 next recorded temperature was at 06:00. No other temperature readings were recorded during the twenty-two-hour time span. On 08/02/2022 last recorded temperature was at 19:00. On 08/03/2022 next recorded temperature was at 06:00. No other temperature readings were recorded during the eleven-hour time span. On 08/10/2022 last recorded temperature was at 20:00. On 08/11/2022 next recorded temperature was at 06:00. No other temperature readings were recorded during the ten-hour time span. On 08/11/2022 last recorded temperature was at 20:00. On 08/12/2022 next recorded temperature was at 06:00. No other temperature readings were recorded during the ten-hour time span. On 08/12/2022 last recorded temperature was at 19:00. On 08/13/2022 next recorded temperature was at 00:00. No other temperature readings were recorded during the five-hour time span. On 08/13/2022 last recorded temperature was at 16:00. On 08/13/2022 next recorded temperature was at 22:00. No other temperature readings were recorded during the six-hour time span. On 08/15/2022 last recorded temperature was at 16:00. On 08/16/2022 next recorded temperature was at 06:00. No other temperature readings were recorded during the fourteen-hour time span. On 08/16/2022 last recorded temperature was at 20:00. On 08/17/2022 next recorded temperature was at 06:00. No other temperature readings were recorded during the ten-hour time span. On 08/22/2022 last recorded temperature was at 04:00. On 08/22/2022 next recorded temperature was at 20:00. No other temperature readings were recorded during the sixteen-hour time span. On 08/24/2022 last recorded temperature was at 19:00. On 08/25/2022 next recorded temperature was at 06:00. No other temperature readings were recorded during the eleven-hour time span. On 08/25/2022 last recorded temperature was at 19:00. On 08/26/2022 next recorded temperature was at 06:00. No other temperature readings were recorded during the eleven-hour time span. On 08/26/2022 last recorded temperature was at 19:00. On 08/27/2022 next recorded temperature was at 08:00. No other temperature readings were recorded during the thirteen-hour time span. On 08/27/2022 last recorded temperature was at 16:00. On 08/28/2022 next recorded temperature was at 07:00. No other temperature readings were recorded during the fifteen-hour time span. On 08/28/2022 last recorded temperature was at 07:00. On 08/28/2022 next recorded temperature was at 12:00. No other temperature readings were recorded during the five-hour time span. On 08/28/2022 last recorded temperature was at 16:00. On 08/29/2022 next recorded temperature was at 06:30. No other temperature readings were recorded during the fourteen and a half hour time span. On 08/29/2022 last recorded temperature was at 10:30. On 08/30/2022 next recorded temperature was at 06:00. No other temperature readings were recorded during the nineteen and a half hour time span. On 08/30/2022 last recorded temperature was at 18:00. On 08/31/2022 next recorded temperature was at 06:00. No other temperature readings were recorded during the twelve-hour time span. On 09/07/2022 last recorded temperature was at 16:00. On 09/08/2022 next recorded temperature was at 06:00. No other temperature readings were recorded

	during the fourteen-hour time span. On 09/08/2022 last recorded temperature was at 19:00. On 09/09/2022 next recorded temperature was at 06:00. No other temperature readings were recorded during the eleven-hour time span. On 09/09/2022 last recorded temperature was at 16:00. On 09/10/2022 next recorded temperature was at 07:00. No other temperature readings were recorded during the fifteen-hour time span. On 09/13/2022 last recorded temperature was at 16:00. On 09/14/2022 next recorded temperature was at 06:00. No other temperature readings were recorded during the fourteen-hour time span. On 09/14/2022 at 10:42 AM, the Technical Consultant stated they are monitoring the refrigerator with the RBC's every four hours. On 9/16/2022 at 5:40 PM, the Division Director of Lab Services acknowledged there were missing temperature readings.
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 with the Technical Consultant, the laboratory failed to maintain documentation of background counts being performed on the Sysmex XP-300 Complete Blood Count (CBC) Hematology Analyzer since installed on 03/24/2022. Findings Included: Review of the "Daily Operating Procedures" of the Sysmex XP-300 revealed to "Record the background check on a daily checklist or keep a copy of the printout for documentation. Compare the results to the acceptable background limits." Review of CBC maintenance records revealed no documentation of the daily background check. Interview on 09/15/2022 at 5:00 PM the Technical Consultant confirmed that the only documentation of background check were on the Hematology analyzer and that he was not sure how long or how many was stored. He could not pull up any background counts beyond the current day.
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 the Laboratory failed to have a request for patient testing from an authorized person for 2 out of 13 Patients. Findings Included: Review of Patient #4's chart revealed that a CBC (Complete Blood Count) was analyzed and reported without a request for testing. Review of Patient #5's chart revealed that an ABG was analyzed and reported without a request for testing. Interview on 09/14/2022 at 3:00 PM, the Vice President of Quality and Patient Safety Administration confirmed that there was not a request for the tests.
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 policies and procedures signed and approved by the Laboratory Director and be specific to their laboratory (See D5407), failed to have acceptable room temperatures for the testing performed (See D5413), failed to perform complete verification studies prior to patient testing (See D5421), failed to perform all required maintenance (See D5429), failed to do quality control daily when there was no IQCP (Individualized Quality Control Plan) (See D5445), reporting patient results when 2 levels of control were not performed (See D5447), and failed to have corrective action when refrigerator temperatures were not recorded (See D5781).
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 failed to have a policy on the Sysmex XP-300 Hematology analyzer since it was delivered on 03/24/2022. Findings Included: Review of Policies and Procedures revealed that the Laboratory did not have a policy for testing on the Sysmex XP-300 Hematology Analyzer besides the manufacturer's instructions. Interview on 09/15/2022 at 4:00 PM the Division Director of Lab Services stated that he thought the policies were covered by the sister Hospital and confirmed there was no other policy for the Sysmex XP-300.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the

	current laboratory director before use. This STANDARD is not met as evidenced by: Based on record review and interview the Laboratory failed to have policies signed by the current Laboratory Director prior to use for all policies reviewed since the Laboratory opened on 03/10/2022. Findings Included: Interview on 09/16/2022 at 12: 00 PM the Division Director of Lab Services for IRL (Integrated Regional Laboratories) stated verification studies started on 03/10/2022, the Hematology analyzer was delivered on 03/24/2022, and the grand opening of the Laboratory (go live date) was 04/22/2022. The Laboratory also had a Laboratory Director change that was effective 09/06/2022. The "Siemens ePOC Blood Analysis System" policy was signed by the original Laboratory Director on 11/2021 and was not signed by the new Laboratory Director. The "Citrate Activated Partial Thromboplastin Time Testing (APTT) on Hemochron Signature Elite" was not signed by either Laboratory Director. The "Citrate Prothrombin Time with INR (PT/INR) on Hemochron Signature Elite" was not signed by either Laboratory Director. The "MetLac 12 Panel on Piccolo Xpress" was not signed by either Laboratory Director. The "TOX Drug Screen on Quidel Triage MeterPro" was not signed by either Laboratory Director. The "Cardiac Panel (Troponin I) on Quidel Triage MeterPro" was not signed by either Laboratory Director. The "Emergency Issue Units" was signed by original Laboratory Director 10 /2021. This policy is for the sister Hospital and references wristband number, a surgery center, and a specific printer name that is not applicable to this Laboratory. The Laboratory does perform emergency issue of blood units. Interview on 09/15 /2022 at 4:00 PM the Division Director of Lab Services stated that he thought the policies were covered by the sister Hospital and confirmed that all of the policies do not translate to the stand alone Emergency Room Laboratory. He also confirmed that the new Laboratory Director did not sign off on the policies when she became Laboratory Director on 09/06/2022.
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 observation, record review, and interview the laboratory failed to maintain required room temperature for the Triage Meter Pro cartridges being stored in the temporary laboratory location that they were moved to on 08/22/2022. Findings Included: Observation of room temperature revealed the following temperatures: 09/14 /22 at 11:35 AM 25.5 degrees Celsius 09/14/22 at 1:42 PM 26 degrees Celsius 09/15 /22 at 5:55 PM 25.8 degrees Celsius Review of the manufacturers' instructions for the D-dimer and Troponin tests on the Triage Meter Pro stated under "Warnings and Precautions" that "Optimal results will be achieved by performing testing at temperatures between 20 to 24 degrees Celsius". Under "Storage and Handling Requirements" it states "Before using refrigerated Test Devices, all individual foil

	pouches to reach operating temperature (20 - 24 degrees Celsius)." The "Emergency Department Cape Coral Laboratory Services" has the room temperature range to be 18-24 degrees Celsius. From 08/22/2022 to 09/22/2022 the temperature was warmer than 24 degrees Celsius on 18 out of 32 days. 08/23/2022 - 25.6 degrees Celsius 08/24 /2022 - 25.5 degrees Celsius 08/26/2022 - 24.9 degrees Celsius 08/29/2022 - 25.0 degrees Celsius 08/30/2022 - 24.5 degrees Celsius 09/06/2022 - 24.8 degrees Celsius 09/07/2022 - 24.7 degrees Celsius 09/08/2022 - 24.6 degrees Celsius 09/09/2022 - 24.8 degrees Celsius 09/10/2022 - 25.0 degrees Celsius 09/11/2022 - 24.3 degrees Celsius 09/14/2022 - 24.7 degrees Celsius 09/16/2022 - 25.6 degrees Celsius 09/18 /2022 - 24.9 degrees Celsius 09/19/2022 - 25.4 degrees Celsius 09/20/2022 - 25.6 degrees Celsius 09/21/2022 - 25.6 degrees Celsius 09/22/2022 - 24.1 degrees Celsius There was no corrective action for the temperatures being outside of the acceptable range. The Laboratory Technical Consultant revealed on 09/14/2022 at 2:00 PM that they put a fan on the floor and kept the door to the Laboratory open to try to lower the temperature, however, it was still warmer than the 24 degrees Celsius maximum temperature. An interview on 09/15/22 at 6:00 PM, the Administrative Laboratory Director confirmed that the room temperature was warmer than what the manufacturer required for storage.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i) (B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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 the Laboratory failed to perform verification studies for 4 out of 5 analyzers prior to performing patient testing. Findings Included: Review of Verification Studies revealed the following: Epoc: The "Validation studies" (signed by the Laboratory Director on 04/01/2022) revealed that the 2 instruments were not validated at this Laboratory and only validated for arterial specimens. There were 46 patients ran. Sysmex XP 300: The instrument was moved on 08/22/22. The manufacturer stated that "at a minimum a calibration verification and QC (Quality Control) needs to be performed after a move". The Laboratory did not perform calibration verification as required by the manufacturer. There were 311 patients ran since the move on 08/22/22. Hemochron Signature Elite: There was no documentation of a verification study being performed on this loaner instrument when it was received. When the instrument was moved to the temporary location, there was no verification study performed for the PT/INR testing. There was no documentation of when the loaner instrument came into the Laboratory and when the old instrument was removed. There were 165 patients ran. Triage Meter: During the verification study on the Triage meter for Troponin when moved on 08/22/22, the Laboratory was running and reporting patient results during the verification study process. There was no verification studies done for D-dimer. There were 185 patients ran for Troponin and 28 patients ran for D-Dimer. Interview on 09/16/2022 at 6:00 PM the Administrative Laboratory Director confirmed that the verification studies were not complete.

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 weekly maintenance 2 out of 4 months reviewed and monthly maintenance for 1 out of 4 months reviewed in 2022 on the Sysmex XP-300 Hematology Analyzer. Findings Included: Review of the "XP-300 Maintenance Log" revealed the weekly maintenance of "Clean SRV Tray". In August 2022 there was no weekly maintenance performed the 3rd week and in July 2022 there was no weekly maintenance documented the 3rd or 4th week. Review of the "XP-300 Maintenance Log" revealed that maintenance of "Clean RBC and WBC Transducer and Clean Waste Chamber" must be performed monthly. There was no monthly maintenance documented in June 2022. An interview on 09/16/2022 at 2:00 PM, the Administrative Laboratory Director confirmed that the maintenance was not documented.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview the Laboratory failed to develop an IQCP (Individualized Quality Control Plan) when the frequency of QC (quality control) was reduced for the Triage Meter Pro and the Epoc since testing began on 04/22/2022. Findings Included: Review of QC records from 04/22/2022 to 09/15/2022 for the Triage Meter Pro Troponin and D-dimer testing revealed that liquid QC was done monthly. There was no IQCP. Review of QC records from 04/22/2022 to 09/15/2022 for the Epoc blood gas testing revealed that liquid QC was done monthly. There was no IQCP. Interview on 09/15/2022 at 5:00 PM the Technical Consultant confirmed that QC was only done monthly and that there was no IQCP developed for either instrument.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different

	concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to run two levels of controls on each day of testing for 4 of 31 days in August 2022 on the Piccolo Xpress Chemistry Analyzer and 11 out of 30 days in June 2022 on the Sysmex XP-300 Hematology Analyzer. Findings Included: The laboratory was using the Piccolo Xpress Chemistry Analyzer to run the MetLac 12 Panel. The MetLac 12 Panel tests for Albumin, Calcium, Chloride, Creatinine, Glucose, Lactate, Magnesium, Phosphorus, Potassium, Sodium, Total Carbon Dioxide, and Blood Urea Nitrogen (BUN). Review of the procedure titled "MetLac 12 Panel on Piccolo Xpress" noted the external controls (level 1 and 2) must be tested each day of patient testing. Review of the computerized data of the tests performed on the Piccolo Xpress Chemistry Analyzer showed that one level of controls was run on the following days: 08/02/22 - 2 patients tested 08/12/22 - 2 patients tested 08/26/22 - 3 patients tested 08/30/22 - 1 patient tested On 09/15/2022 at 5:30 PM, the Division Director of Lab Services confirmed that two levels of controls were not run on the above mentioned dates. The laboratory was using the Sysmex XP-300 Hematology Analyzer for CBC (Complete Blood Count) testing. Review of quality control results revealed no controls performed on the following days: 06/09/22 - 13 patients tested 06/10/22 - 13 patients tested 06/11/22 - 5 patients tested 06/12/22 - 7 patients tested 06/13/22 - 8 patients tested 06/14/22 - 5 patients tested 06/24/22 - 6 patients tested 06/25/22 - 10 patients tested 06/26/22 - 6 patients tested 06/27/22 - 11 patients tested 06/28/22 - 16 patients tested On 09/14/2022 at 4:25 PM, the Technical Consultant confirmed that controls were not ran on the CBC analyzer on the aforementioned 11 days and Patients were tested and results reported.
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 record review and interview, the Laboratory failed to document corrective action for 43 of 48 times when the temperature of the refrigerator where the Red Blood Cells (RBC) were stored was not monitored continuously or every four hours from 06/09/2022 to 09/14/2022. Findings included: Review of the "Blood Bank Equipment Offline Temperature Monitoring Log" stated "Record Temperature Every (4) Hours Required." Review of the temperature log for the refrigerator where the RBC's were stored revealed the military time the temperature was last recorded to the military time the next temperature was recorded exceeded four hours. Review of the temperature log for the "Describe Problem and Corrective Action" column showed six times the problem was no lab staff and for thirty-seven times nothing was

	documented. On 9/16/2022 at 5:40 PM, the Division Director of Lab Services confirmed there were missing temperature readings and the lack of corrective actions.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on observation, record review, and interview the Laboratory Director failed to provide oversight over the laboratory (See D6007), failed to implement a Quality Assurance program (See D6021), failed to have a Quality Assurance program to identify and correct problems (See D6022), and failed to have competency evaluation (See D6030).
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (E) The laboratory director must-- (E)(1) 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 observation, record review, and interview the Laboratory Director failed ensure storage conditions for blood or blood products for transfusion were monitored to prevent deterioration of the blood products (See D3021) and failed failed to have policies and procedures signed and approved by the Laboratory Director and be specific to their laboratory (See D5407), failed to have acceptable room temperatures for the testing performed (See D5413), failed to perform complete verification studies prior to patient testing (See D5421), failed to perform all required maintenance (See D5429), failed to do quality control daily when there was no IQCP (Individualized Quality Control Plan) (See D5445), reporting patient results when 2 levels of control were not performed (See D5447), and failed to have corrective action when refrigerator temperatures were not recorded (See D5781) since the Laboratory started patient testing on 04/22/2022.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and

	maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on record review and interview the Laboratory Director failed to ensure that quality assessment programs were maintained to ensure quality of the laboratory services provided since beginning patient testing on 04/22/2022. Findings Included: Review of the Quality Assurance (QA) policy signed by the original Laboratory Director on 10/2021 and not signed by the new Laboratory Director revealed that the Laboratory will "monitor temperature each day and document any corrective actions, validate all test procedures, run controls according to manufactures' recommended intervals, and run controls as defined for any method implemented with an Individual Quality Control Program (IQCP)". There was no QA documentation. The policy had test specialties that are not performed at the laboratory. Interview on 09/16/2022 at 6: 00 PM the Technical Consultant confirmed that there was no QA documentation.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based of record review and interview, the Laboratory Director failed to ensure the Quality Assurance program identified and corrected the problem of not recording temperature of the refrigerator, where the Red Blood Cells (RBC) were stored, either continuously or every four hours from 06/09/2022 to 09/14/2022. Review of the laboratory's procedure titled "Continuous Quality Improvement Plan" stated one of the goals of the laboratory included "Improve the identification, communication and correction of errors." The laboratory failed to correct the problem of not recording the temperature of the refrigerator continuously or every 4 hours where RBC's were stored (See D3021). Review of the "Blood Bank Equipment Offline Temperature Monitoring Log" stated "Record Temperature Every (4) Hours Required." Review of the bottom of the temperature log was a line for the "Date/Signature Supervisor Review." Review of the following pages of the temperature logs showed there was no supervisor that signed off or initialed the review where the recording of the temperature exceeded four hours for the following pages listed according to the first date and time recorded on the page: 08/16/2022 at 12:00 08/24/2022 at 19:00 08/31 /2022 at 06:00 09/09/2022 at 16:00 Review of the following pages of the temperature logs showed there was one supervisor that signed off or initialed the review where the recording of the temperature exceeded four hours for the following pages listed according to the first date and time recorded on the page: 06/26/2022 at 04:00 07/19 /2022 at 08:00 07/28/2022 at 06:00 08/07/2022 at 16:00 08/12/2022 at 08:00 08/21 /2022 at 00:00 09/04/2022 at 16:00 Review of the following pages of the temperature logs showed there were two supervisors who signed off or initialed the review where the recording of the temperature exceeded four hours for the following pages listed according to the first date and time recorded on the page: 06/09/2022 at 00:00 06/13 /2022 at 04:00 06/21/2022 at 20:00 07/09/2022 at 00:00 07/13/2022 at 12:00 07/23

	/2022 at 16:00 On 9/16/2022 at 5:40 PM, the Division Director of Lab Services confirmed there were missing temperature readings.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on record review and interview the Laboratory Director failed to have competency evaluations for 3 out of 3 Testing Personnel (the Technical Consultant who is also a Testing Person #A, Testing Person #B, and Testing Person #C) since the Laboratory opened on 04/22/2022. Findings Included: Review of competency evaluations revealed the Technical Consultant who is also a Testing Person did not have a competency for either position. Testing Person #B had an initial competency done 04/30/2022 for the Epoc signed off by a Staff member who did not qualify as a Laboratory Director or Technical Consultant. Testing Person #C only had initial training on they Sysmex XP-300, ID Now-Covid, Urinalysis, the emergency release of blood dated for 07/17/2022, no competency. There was also a Testing Person #D who tested patients on 08/22/2022 who is the Division Director of Lab Services for IRL (Integrated Regional Laboratories) who did not have any competencies. Interview on 09/16/2022 at 5:00 PM the Administrative Laboratory Director confirmed that there were no other competencies.