Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2104727	05/16/2019
Name of Provider or Supplier	**Street Address, City, State**	
Prestige Emergency Room Llc	2810 N Loop 1604 W, Suite 110, San Antonio, TX	

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	The laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCIES: D5200 - 42 C.F.R. 493.1220 Condition: Lab General Systems D5400 - 42 C.F.R. 493.1250 Condition: Analytic Systems D6000 - 42 C.F.R. 493.1403 Condition: Laboratory Director; moderate complexity D6033 - 42 C.F.R. 493.1409 Condition: Technical Consultant; moderate complexity Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representative was given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's proficiency testing records, and staff interview, it was revealed the laboratory failed to retain the instrument printouts for 2 of 17 events. The findings were: 1. A review of the laboratory's American Proficiency Institute's proficiency testing records from 2017 (Hematology events 1, 2, and 3, Chemistry events 2 and 3), 2018 (Hematology events 1, 2, and 3, Chemistry events 1, 2, and 3, and Immunology events 1, 2, and 3) and 2019 (Hematology event 1, Chemistry event 1, and Immunology event 1) revealed the laboratory failed to retain the instrument printouts for the following events: 2017 Hematology event 3 2018 Immunology event 1 2. The laboratory was asked to provide documentation of the instrument printouts. No documentation was provided. 3. An interview with the technical consultant on 05/16/2019 at 1015 hours in exam room 2 - after his review of the records - confirmed the findings. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 04/14/2017
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 review of the laboratory's quality control records, and staff interview, it was revealed the laboratory failed to retain quality control printouts for CKMB testing performed on the PathFast analyzer from June 2018 to September 2018. The findings were: 1. A review of the laboratory's Creatine Kinase MB quality control records from 2018 and 2019 revealed the laboratory failed to retain the instrument printouts from June 2018 to September 2018. 2. The laboratory was asked to provide documentation of the instrument printouts. No documentation was provided. 3. An interview with the technical consultant on 05/16/2019 at 1200 hours outside the laboratory revealed that he did not know where the records were and that they may have been misplaced. This confirmed the findings.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's records, and staff interview, it was revealed the laboratory failed to provide overal quality in laboratory general systems. The findings were: 1. The laboratory failed to ensure there was documentation of performing a competency assessment on the technical consultant (refer to D5209). 2. The laboratory failed to ensure there was documentation of the review of 1 of 6 events (refer to D5211). 3. The laboratory failed to ensure there was documentation of

	evaluating proficiency testing results which were not scored by the proficiency testing agency (refer to D5213). 4. The laboratory failed to ensure there was documentation of performing corrective actions for an unacceptable proficiency testing score (refer to D5221). 5. The laboratory failed to ensure there was a quality assessment plan which could identify and correct problems in laboratory general systems (refer to D5291)
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of performing a competency assessment on the technical consultant. The findings were: 1. A review of the laboratory's submitted Form CMS 209 (signed by the laboratory director on 05/16/2019) revealed the laboratory identified 1 technical consultant. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of a competency assessment of the technical consultant. The technical consultant had been employed by the laboratory since September 2017. 3. The laboratory was asked to provide a competency assessment. No documentation was provided. 4. An interview with the technical consultant on 05 /16/2019 at 1055 hours in exam room 2 revealed he thought a competency assessment had been performed, however he was unable to provide it for review. This confirmed the findings.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's chemistry proficiency testing results from 2017, 2018, and 2019, and staff interview, revealed the laboratory failed to have documentation of the review of 1 of 6 events. The findings were: 1. A review of the laboratory's American Proficiency Institute's chemistry proficiency testing results from 2017 (events 2 and 3), 2018 (events 1, 2, and 3) and 2019 (event 1) revealed the laboratory failed to have documentation of the review of 1 of 6 events. The event without documentation of review was: 2017 event 3 2. The laboratory was asked to provide documentation of the review of the event. No documentation was provided. 3. An interview with the technical consultant on 05 /16/2019 at 1015 hours in exam room number 2 - after his review of the records - confirmed the findings.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without

	analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's proficiency testing records from 2017, 2018 and 2019, and staff interview, it was revealed the laboratory failed to have documentation of evaluating proficiency testing results which were not scored by the proficiency testing agency. The findings were: 1. A review of the laboratory's American Proficiency Institute's proficiency testing records from 2017 (Hematology events 1, 2, and 3, Chemistry events 2 and 3), 2018 (Hematology events 1, 2, and 3, Chemistry events 1, 2, and 3, and Immunology events 1, 2, and 3) and 2019 (Hematology event 1, Chemistry event 1, and Immunology event 1) revealed the laboratory failed to have documentation of evaluating the following proficiency testing results: a) 2017 chemistry event 2 D-dimer samples: CM-06 CM-08 CM-10 b) 2017 chemistry event 3 D-dimer samples: CM-11 CM-14 CM-15 c) 2018 chemistry event 1 D-dimer samples: CM-02 CM-03 CM-05 d) 2018 chemistry event 2 D-dimer samples: CM-06 CM-08 CM-09 e) 2018 chemistry event 3 D-dimer samples: CM-11 CM-13 CM-15 f) 2019 chemistry event 1 D-dimer samples: CM-01 CM-03 CM-04 CM-05 g) 2017 hematology event 2 Monocytes samples: HEM-07 HEM-10 2. The laboratory was asked to provide documentation of evaluating the identified results not scored by the proficiency testing agency. No documentation was provided. 3. An interview with the technical consultant on 05/16 /2019 at 1015 hours in exam room 2 - after his review of the records - confirmed the findings.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's chemistry proficiency results from 2017, 2018, and 2019, and staff interview, it was revealed the laboratory failed to have documentation performing corrective actions for unacceptable results. The findings were: 1. A review of the laboratory's American Proficiency Institute's chemistry proficiency results from 2017 (events 2 and 3), 2018 (events 1, 2, and 3) and 2019 (event 1) revealed the laboratory failed to have documentation of acceptable corrective actions for unacceptable results of 1 of 6 events. For 2017 event 3, the laboratory scored 40% for the analyte of PCO2. The laboratory's documented corrective action was: "PCO2 specimen improperly prepared. Spoke with tech, may have left out (open) too long." 2. The laboratory was asked to provide documentation of performing additional corrective actions to rule out instrument issues, etc. No documentation was provided. 3. An interview with the technical consultant on 05/16/2019 at 1015 hours in exam room 2 - after his review of the records- confirmed the findings.
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 review of the laboratory's records, and staff interview, it was revealed the laboratory's quality assessment plan failed to identify and correct problems in laboratory general systems. The findings were: 1. The laboratory's quality assessment plan failed to ensure the laboratory had documentation of performing a competency assessment on the technical consultant (refer to D5209). 2. The laboratory's quality assessment plan failed to ensure the laboratory had documentation of the review of 1 of 6 events (refer to D5211). 3. The laboratory's quality assessment plan failed to ensure the laboratory had documentation of evaluating proficiency testing results which were not scored by the proficiency testing agency (refer to D5213). 4. The laboratory's quality assessment plan failed to ensure the laboratory had documentation of performing corrective actions for an unacceptable proficiency testing score (refer to D5221). NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 04/14/2017
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 review of the laboratory's records, and staff interview, it was revealed the laboratory failed to provide overal quality in analytic systems. The findings were: 1. The laboratory failed to have documentation of following manufacturer's instructions (refer to D5411). 2. The laboratory failed to ensure expired linearity material was not available for use (refer to D5417). 3. The laboratory failed to have documentation of performing required maintenance (refer to D5429). 4. The laboratory failed to have documentation of performing calibration verifications every six months (refer to 5439). 5. The laboratory failed to have documentation of monitor quality control over time (refer to D5441). 6. The laboratory failed to follow its IQCP Plan (refer to D5445). 7. The laboratory failed to have documentation of establishing its own quality control means and ranges (refer to D5469). 8. The laboratory failed to have documentation of performing corrective actions after quality control failure (refer to D5783). 9. The laboratory failed to have a quality assessment plan which could identify and correct problems in analytic systems (refer to D5791).
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

	This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the PathFast analyzer, review of the laboratory's calibration records, and staff interview, it was revealed the laboratory failed to have documentation of following the manufacturer's instructions for performing quality control testing validate the calibration. The findings were: 1. A review of the manufacturer's instructions for the PathFast analyzer (2015 LSI Medience Corporation) under the section titled "Validity check of calibration" revealed: "Validity of the calibration is confirmed by within-range QC assay results." 2. A review of the laboratory's calibrations records from October 2018 to May 2019 identified the laboratory calibrated assays performed on the PathFast analyzer without documentation of performing quality control afterwards to validate the calibrations. a) CKMB Calibration Date 08/14/2018 09/27/2018 10/10/2018 11/07/2019 12/02/2018 12/30/2018 01/27/2019 02/24/2019 03/17/2019 04/13/2019 05/10/2019 b) Troponin Calibration Date 08/14/2018 08/29/2018 09/26/2018 10/24/2018 11/21/2018 11/30 /2018 12/28/2018 01/25/2019 02/21/2019 03/29/2019 04/23/2019 c) BNP Calibration Date 08/06/2018 09/03/2018 10/01/2018 10/28/2018 11/25/2018 12/23/2018 01/19 /2019 02/16/2019 03/16/2019 04/13/2019 05/16/2019 d) D-dimer Calibration Date 08 /22/2018 09/19/2018 10/17/2018 10/28/2018 11/25/2018 12/23/2018 01/12/2019 02/09 /2019 04/06/2019 05/03/2019 e) C-reactive Protein Calibration Date 08/14/2018 08/29 /2018 09/26/2018 10/24/2018 11/11/2018 12/09/2018 01/06/2019 02/02/2019 02/24 /2019 03/23/2019 04/02/2019 3. The laboratory was asked to provide documentation of validating the calibrations performed on the identified days by performing quality control testing. No documentation was provided. 4. An interview with testing personnel number 2 (as listed on Form CMS 209) on 05/16/2019 at 1400 hours in exam room 2 revealed the laboratory performed quality control testing every 7 days following its IQCP. He stated that if the calibration was performed on a day that did not correspond with the 7-day schedule, the laboratory did not performed quality control testing to validate the calibration. This confirmed the findings.
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 surveyor observation of linearity material stored in the laboratory's refrigerator, and staff interview, it was revealed the laboratory failed to ensure that expired linearity material was not available for use. The findings were: 1. Surveyor observation of linearity material stored in the laboratory's refrigerator on 05/16/2019 at 1430 hours revealed the following expired reagents: a) Audit MicroControls BNP (extended) Lot: 06576 expiration: 2017-12-28 b) Audit MicroControls hs-CRP Lot: 06600 expiration: 2018-10-24 2. An interview with the technical consultant on 05/16 /2019 at 1430 hours in the laboratory - after his review of the reagents - confirmed they were expired. This confirmed the findings.
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 review of the manufacturer's instructions for the Medonic M-series hematology analyzer, review of the manufacturer's instructions for the PathFast analyzer, review of the manufacturer's instructions for the Abbot i-STAT analyzer, review of the laboratory's maintenance records from June 2017 to April 2019, and staff interview, revealed the laboratory failed to have documentation of performing required maintenance. The findings were: 1. A review of the manufacturer's instructions for the Medonic M-series hematology analyzer from June 2017 to April 2019 revealed the following maintenance was required to be performed: a) Monthly - clean Aspiration probes - clot prevention cleaning b) Biannually - 6 month cleaning 2. A review of the laboratory's maintenance records for the Medonic M-series hematology analyzer from June 2017 to April 2019 revealed the laboratory failed to have documentation of performing the following maintenance: November 2017 Monthly December 2017 Monthly Biannually January 2018 Monthly February 2018 Monthly April 2018 Monthly May 2018 Monthly June 2018 Monthly July 2018 Monthly August 2018 Monthly September 2018 Monthly October 2018 Monthly November 2018 Biannually January 2019 Monthly February 2019 Monthly March 2019 Monthly April 2019 Monthly 3. A review of the manufacturer's instructions for the PathFast analyzer revealed the manufacturer required the following maintenance to be performed: a) Monthly - clean outside of instrument - clean piercing nozzle edges - clean tip holder 4. A review of the laboratory PathFast maintenance records from January 2018 to April 2019 revealed the laboratory failed to have documentation of performing monthly maintenance for the following months: April 2018 May 2018 June 2018 July 2018 August 2018 September 2018 October 2018 November 2018 December 2018 January 2019 February 2019 March 2019 April 2019 5. A review of the manufacturer's instructions for the Abbott i-STAT analyzer revealed the manufacturer required the following maintenance: a) 6 month - Cal Verification - Thermal Probe Check - CLEW Update 6. A review of the laboratory's i-STAT maintenance records from June 2017 to April 2019 revealed the laboratory failed to have documentation of performing the Thermal Probe Check during the entire period of 23 months. 7. The laboratory was asked to provide documentation of performing the identified maintenance. No documentation was provided. 8. An interview with the technical consultant on 05/16/2018 at 1145 hours by the front desk - after his review of the records - confirmed the findings.
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 review of the laboratory's calibration verification records for testing performed on the PathFast analyzer and the i-STAT analyzer, and staff interview, it was revealed the laboratory failed to have documentation of performing calibration verification every six months. The findings were: 1. A review of the laboratory's PathFast calibration verification records from November 2017 to April 2019 revealed the laboratory documented calibration verification being performed on the following analytes: a) CKMB 11/09/2017 08/05/2018 (9 months later) 02/06/2019 (6 months later) b) Troponin 11/09/2017 08/05/2018 (9 months later) 02/06/2019 (6 months later) c) BNP 11/2/2017 08/06/2018 (9 months later) 02/05/2019 (6 months later) d) D-dimer 11/02/2017 07/16/2018 (8 months later) 02/05/2019 (7 months later) e) hs-CRP 11/09/2017 07/19/2018 (8 months later) 02/05/2019 (7 months later) 2. A review of the laboratory's i-STAT calibration verification records from 2018 to 2019 revealed the laboratory failed to have documentation of performing calibration verification for the analyte beta HCG throughout the entire period 3. Each of the identified analytes utilized 2 calibrators and 2 levels of quality control, thus calibration verification was required every six months. 4. The laboratory was asked to provide documentation of performing calibration verification every six months as required. No documentation was provided. 5. An interview with the technical consultant on 05/16/2019 at 1315 hours in exam room 2 - after his review of the records- confirmed the findings.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records from 2018 and 2019, and staff interview, it was revealed the laboratory failed to have documentation of monitoring quality control results over time to detect shifts and trends. The findings were: 1. A review of the laboratory's quality control records from 2018 and 2019 revealed the laboratory failed to have documentation of monitoring quality control

	values over time for the following analytes: a) PathFast - CKMB - Troponin - BNP - D-dimer - hs CRP b) Frend - TSH 2. The laboratory was asked to provide documentation of monitoring quality control values for the identified analytes to detect shifts and trends. No documentation was provided. 3. An interview with the technical consultant on 05/16/2019 at 1410 hours in exam room 2 revealed the laboratory did not monitor quality control values over time for the identified analytes. This confirmed the findings. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 04/14/2017
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 review of the laboratory's IQCP for testing performed on the PathFast analyzer, review of the laboratory's quality control records, and staff interview, it was revealed the laboratory failed to have documentation of following their IQCP. The findings were: 1. A review of the laboratory's IQCP for analytes tested on the PathFast analyzer revealed quality control testing was to be performed every 7 days, with each new shipment and with each new lot for the following tests: CKMB Troponin BNP D-dimer hs-CRP 2. A review of the laboratory's quality control records from August 2018 to April 2019 revealed the following days where the laboratory performed calibration on a new lot or new shipment without documentation of performing quality control testing: a) CKMB 09/17/2018 10/10/2018 12/02/2018 02/24/2019 b) Troponin 11/30/2018 02/21/2019 c) BNP 09/03/2018 10/28/2018 d) D-dimer 10/28 /2018 01/12/2019 03/09/2019 e) hs-CRP 11/11/2018 02/29/2019 3. The laboratory was asked to provide documentation of performing quality control testing on the identified days following its IQCP for each analyte. No documentation was provided. 4. An interview with testing personnel number 2 (as listed on Form CMS 209) on 05 /16/2019 at 1400 hours in exam room 2 revealed the laboratory performed quality control testing every 7 days following its IQCP. He stated that if the calibration on a new lot was performed on a day that did not correspond with the 7-day schedule, the laboratory did not performed quality control testing. This confirmed the findings.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the

	methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the BioRad Liquichek D-dimer Control, review of the manufacturer's instructions for the BioRad Liquichek Cardiac Markers Plus Controls, review of the Cliniqa Liquid QC Immunoassay Control, and staff interview, it was revealed the laboratory failed to have documentation of establishing its own means and ranges. The findings were: 1. A review of the manufacturer's instructions for the BioRad Liquichek D-dimer Control (2018-06, 5872-00) under the section titled "Assignment of Values" revealed:"It is recommended that each laboratory establish its own means and acceptable ranges and use those provided only as guides." 2. A review of the manufacturer's instructions for the BioRad Liquichek Cardiac Markers Plus Controls (2018-05, 16000202-00) under the section titled "Assignment of Values" revealed: "It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides." 3. A review of the manufacturer's instructions for the Cliniqa Liquid QC Immunoassay Control (32928_06 1/18/13) under the section titled "Assignment of Values" revealed: "The expected Range of the Mean is provided to assist the laboratory until it has established its own mean and standard deviation." 4. A review of the laboratory's quality control records from 2019 revealed the laboratory utilized the following control lots: a) Liquichek D-dimer Lot: 16970 b) Liquichek Cardiac Markers Lot: 23690 c) Cliniqa Liquid QC Lot: 170609B 5. The laboratory was asked to provide documentation of establishing the means and/or ranges as required by the manufacturer. No documentation was provided. 6. An interview with the technical consultant on 05/16/2019 at 1330 hours in the laboratory revealed the facility used the means and ranges provided by the manufacturer and did not establish their own. This confirmed the findings. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 04/14/2017
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's CKMB quality control records from 2019, review of the patient test records, and staff interview, it was revealed the laboratory failed to have documentation of performing corrective actions for patient samples tested prior to a quality control failure. The findings were: 1. A review of the laboratory's CKMB quality control records from 2019 revealed the laboratory had a quality control failure on 03/17/2019. To resolve the failure, the instrument was calibrated and quality

	control was retested. The retested quality control material was successful. Because calibration was required to resolve the quality control failure, remediation of patient samples tested since the previous successful quality control testing was required. 2. The previous successful quality control testing was performed on 03/10/2019. 3. A review of patient test records from 03/10/2019 to 03/16/2019 identified the following patient results which required remediation: Test Date Account number 03/10 8373 03 /11 8388 03/11 8391 03/12 8416 03/13 8458 03/14 8469 03/14 8476 03/14 8486 4. The laboratory was asked to provide documentation of performing corrective actions. No documentation was provided. 5. An interview with the technical consultant on 05 /16/2019 at 1310 hours in the laboratory revealed patients had not be remediated. This confirmed the findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's records, and staff interview, it was revealed the laboratory's quality assessment plan failed to identify and correct problems in analytic analytic systems. The findings were: 1. The laboratory's quality assessment plan failed to ensure the laboratory followed manufacturer's instructions (refer to D5411). 2. The laboratory's quality assessment plan failed to ensure expired reagents were not available for use (refer to D5417). 3. laboratory's quality assessment plan failed to ensure the laboratory performed required maintenance (refer to D5429). 4. The laboratory's quality assessment plan failed to ensure calibration verifications were performed every six months (refer to D5439). 5. The laboratory's quality assessment plan failed to ensure the laboratory monitored quality control over time (refer to D5441). 6. The laboratory's quality assessment plan failed to ensure the laboratory followed its IQCP Plan (refer to D5445). 7. The laboratory's quality assessment plan failed to ensure the laboratory established its own quality control means and ranges (refer to D5469). 8. The laboratory's quality assessment plan failed to ensure the laboratory performed corrective actions after quality control failure (refer to D5783). NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 04/14/2017
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 review of the laboratory's records and staff interview, it was revealed the laboratory director failed to provide overall management for the laboratory. The findings were: 1. The laboratory director failed to ensure proficiency testing results were reviewed (refer to D6018). 2. The laboratory director failed to ensure corrective

	actions were performed (refer to D6019). 3. The laboratory director failed to ensure a quality control plan was established and followed (refer to D6020). 4. The laboratory director failed to ensure a quality assessment plan was established and followed (refer to D6021). 5. The laboratory director failed to ensure testing personnel had documentation of training (refer to D6029).
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that 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 review of the laboratory's proficiency testing records and staff interview, it was revealed the laboratory director failed to ensure proficiency testing results were reviewed (refer to D5211).
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records and staff interview it was revealed the laboratory director failed to ensure an appropriate corrective action plan was followed for a proficiency testing failure (refer to D5221).
D6020	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 program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records and staff interview, it was revealed the laboratory director failed to ensure a quality control plan was established

	and maintained to assure quality. The findings were: 1. The laboratory director failed to ensure the laboratory monitored quality control testing over time (refer to D5441). 2. The laboratory director failed to ensure the laboratory followed its IQCP (refer to D5445). 3. The laboratory director failed to ensure the laboratory established its own means and/or ranges (refer to D5469). NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 04/14/2017
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 review of the laboratory's records and staff interview, it was revealed the laboratory director failed to ensure quality assessment plans could identify and correct problems. The findings were: 1. The laboratory director failed to ensure the quality assessment plan identified and corrected problems in laboratory general systems (refer to D5297). 2. The laboratory director failed to ensure the quality assessment plan identified and corrected problems in analytic systems (refer to D5791). NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 04/14/2017
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records and staff interview, it was revealed the laboratory director failed to ensure testing personnel had documentation of training prior to performing patient testing (refer to D6066). NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 04/14/2017
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

	This CONDITION is not met as evidenced by: Based on review of the laboratory's records and staff interview, it was revealed the technical consultant failed to provide oversight. The findings were: 1. The technical consultant failed to ensure a quality control plan was established and followed (refer to D6042). 2. The technical consultant failed to perform competency assessments as required (refer to D6053 and D6054).
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (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 review of the laboratory's quality control records and staff interview, it was revealed the technical consultant failed to ensure a quality control plan was established and maintained to assure quality. The findings were: 1. The technical consultant failed to ensure the laboratory monitored quality control testing over time (refer to D5441). 2. The technical consultaant failed to ensure the laboratory followed its IQCP (refer to D5445). 3. The technical consultant failed to ensure the laboratory established its own means and/or ranges (refer to D5469).
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records, and staff interview, it was revealed the technical consultant failed to perform competency assessments semiannually during the first year for 1 of 1 testing personnel. The findings were: 1. A review of the laboratory's personnel records revealed the following hire date: a) testing personnel number 7 - 12/06/2017 Thus, two competency assessment were required by 12/06/2018 2. The laboratory was asked to provide documentation of the required competency assessments. No documentation was provided. 3. An interview with the technical consultant on 05/16/2019 at 1130 hours by the front desk - after his review of the records- confirmed the findings.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records and staff interview, it was revealed the technical consultant failed to document annual competency assessment for 5 of 5 testing personnel in 2017 and 2018. The findings were: 1. A review of the laboratory's personnel records revealed 5 testing personnel required competency assessment be performed in 2017 and 2018. They were (as listed on Form CMS 209) Testing personnel number 1 Testing personnel number 2 Testing personnel number 3 Testing personnel number 4 Testing personnel number 5 2. The laboratory was asked to provide documentation of the technical consultant performing competency assessments in 2017 and 2018 for the identified personnel. The laboratory provided training documentation filled out each year by testing personnel number two who did not meet the qualifications as a technical consultant. No documentation of competency assessment performed by the technical consultant were provided. 3. An interview with the technical consultant on 05/15/2019 at 1130 hours at the front desk - after his review of the records - confirmed the findings.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records and staff interview, it was revealed the laboratory failed to have documentation of training for 2 of 7 testing personnel. The findings were: 1. A review of the laboratory's submitted Form CMS 209 (signed by the laboratory director on 05/16/2019 revealed the laboratory identified 7 testing personnel. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of training for 2 of 7 testing personnel on the PathFast analyzer and the Frend analyzer. They were (as listed on Form CMS 209): Testing personnel number 6 Testing personnel number 7 3. The laboratory was asked to provide documentation of training on the identified analyzers. No documentation was provided. 4. An interview with the technical consultant on 05/16/2019 at 1130 hours by the front desk - after his review of the records - confirmed the findings. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 04/14/2017